Legal Studies Research Paper No. 2013-12

DOES REGULATION CHILL DEMOCRATIC DELIBERATION? THE CASE OF GMOS

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Breakthroughs in science and technology pose a challenge to the U.S. legal system: either regulate under pre-existing laws using a business-as-usual approach, or pass new laws to deal with new relationships and conflicts created by these breakthroughs. How does the legal process determine when to regulate and when to legislate? Does that process adequately ensure deliberative democratic debate and implementation of democratic consensus? Does it adequately protect urgent interests in the meantime? Currently, this determination is ongoing with regard to new scientific developments such as climate change science, and new technological developments such as hydraulic fracturing of unconventional natural gas shales. To examine this type of legislation/regulation decision, this Article focuses on an older example: the creation of the regulatory structure for genetically-modified organisms ("GMOs") in the 1980s and 1990s. The evidence explored in this case study suggests that deliberative asymmetries between the political branches, not public consensus behind a regulatory solution, led to both the creation and the persistence of a regulatory framework for GMOs under existing laws. The Article raises questions for contemporary regulation/legislation debates and lays a foundation for discussion of potential legal reforms.

I. INTRODUCTION

Breakthroughs in science or technology often raise the question of whether new law is needed, or whether regulation under old law is sufficient. Frequently, the public debates and Congress wait while agencies regulate by analogy under pre-existing statutes. Does it matter? Can Congress simply undo through legislation any early

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agency rulemaking based on existing statutes if the public demands it? In other words, does the present structure of government afford the citizenry a constitutionally adequate opportunity to reach democratic consensus on whether new science and technology require new laws?

This challenge is often presented with urgency. Representatives of the new industry are eager to employ the new science to improve the world and to beat the competition to the market. Skeptics credibly challenge that the infant technology has not yet resolved or even identified all potential new risks and urge precautionary regulation in the meantime. The urgency of these interests often leads federal agencies to regulate based on their authority under statutes that pre-dated the new technology. In some respects, such interpretation of existing statutory authority is the *sina qua non* of agency power; Congress drafts laws broadly so the laws may be applied to emerging situations. But inevitably some scientific or technological developments will be game-changers—breakthroughs that so defy analogy to previous circumstances that pre-existing laws cannot be said to represent a real democratic consensus on the best legal framework for the new relationships and conflicts created.

Which technologies are game-changers? That question is, and must be, subject to debate, and a citizen's opinion of the appropriateness of agency action without new statutory authority may turn on the answer. If the lawmaking process provides an adequate mechanism for democratic deliberation and for implementation of any consensus that new law is needed, then regulation that merely protects interests in the interim is unproblematic from a separation of powers perspective. If, however, the existence of regulation under old law somehow curtails or interferes with the democratic process of arriving at or implementing democratic consensus, such regulatory action would undermine the democratic values that separation of powers was intended to protect. On the other hand, to tie the hands of regulators or to put a freeze on industry while the citizenry engages in the often-extended process of arriving at democratic consensus could jeopardize important social goals including environmental and human health protection, industry competitiveness, and advancement of knowledge.

The dilemma is hardly new. From steam engines to stem cells, U.S. law has long been engaged in adapting to newly-emerging science and technology. Recently, the Obama Administration has aggressively pursued agency action to protect what the President and his Cabinet view as threats to human and environmental health from developments like hydraulic fracturing of unconventional shale gas

and large-scale industrial emissions of greenhouse gases.[1] Legal scholars and political scientists have widely discussed the relative agility of the executive branch in policy-setting, in contrast to the collective action problems of the legislative branch.[2] This agility may be viewed as an advantage with regard to new science and technology, which often raise urgent concerns ranging from environmental protection to business competitiveness. But the noted agility of the regulatory process may have adverse democratic consequences if regulatory action happens before public consensus can form about proper legal controls. The danger is greater in the case of path-breaking new science and technology than in the typical instance of federal regulation under old statutes. Such path-breaking technologies and advances in science do not immediately enter the public consciousness or become familiar subjects of relationships and disputes for the average citizen. This Article aims to explore a critical question raised by these cases of path-breaking technology and scientific knowledge that strain analogy under pre-existing statutes: does creating a regulatory framework under pre-existing statutes at the early stage of public awareness of the technology have a "chilling effect" on public deliberation about whether new legislation is necessary or desirable?

Opponents of hydraulic fracturing and supporters of greenhouse gas ("GHG") controls may favor aggressive administrative action now, but the democratic consequences of this executive branch policy-

1. *See, e.g.*, Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act, 74 Fed. Reg. 66,496 (Dec. 15, 2009) (concluding that motor vehicle emissions of six greenhouse gases endanger public health and welfare); Light-Duty Vehicle Greenhouse Gas Emissions Standards and Corporate Average Fuel Economy Standards; Final Rule, 75 Fed. Reg. 25,324 (May 7, 2010) (setting greenhouse gas emissions standards for cars and light trucks under Clean Air Act); Letter from EPA Asst. Admin. Steven A. Owners to Deborah Goldberg, Earthjustice (Nov. 23, 2011), *available at* http://www.epa.gov/oppt/chemtest/pubs/EPA-Letter-to-Earthjustice-on-TSCA-Petition.pdf (partially granting Earthjustice request for rulemaking regarding disclosure of hydraulic fracturing fluid content).

2. *See, e.g.*, Terry M. Moe & William G. Howell, *The Presidential Power of Unilateral Action*, 15 J.L. ECON. & ORG. 132 (1999) (suggesting constitutional ambiguity as basis of presidential power to make law unilaterally); Aaron J. Saiger, *Obama's "Czars" for Domestic Policy and the Law of the White House Staff*, 79 FORDHAM L. REV. 2577 (2011) (examining the consolidation of administrative power in the White House and the ability of policymaking "czars" to operate outside the formal structure of the Administrative Procedures Act); Keith E. Whittington & Daniel P. Carpenter, *Executive Power in American Institutional Development*, 1 PERSP. ON POL. 495 (2003) (rejecting narrative of legislative dominance through case studies of executive political leadership, policy innovation, and shaping of policy agenda). *But see* Kevin M. Stack, *The President's Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263 (2006) (offering criticism of the presidential power theory by arguing that powers granted to executive officers do not extend to the President for deference purposes absent an express grant of such power to the President by Congress).

making advantage may seem less appealing when considered in other contexts. A review of the legislative and regulatory actions regarding genetically-modified organisms ("GMOs") in the 1980s[3] —and the consequences of those actions for deliberative democracy about the technology in the decades since—may shed a more cautionary light on the aggressive pursuit of regulatory action to deal with emerging science and technology. This Article studies the case of regulation of GMOs to evaluate one historical choice to regulate in the short term to protect critical interests while a debate over the need for new legislation was beginning. In the 1980s, the Reagan and Bush (I) Administrations directed various federal agencies to regulate under existing laws, and Congress introduced but failed to pass legislation specific to the newly marketable technology.[4] Twenty-five years later, concerns about GMOs and GMO regulation persist, and scientists have begun to identify unintended environmental and health consequences related to the use of GMOs.[5] Still, the regulatory framework remains largely unchanged since its birth in the mid-1980s.

Although a vocal group of opponents to GMOs has generated public protests, court cases, and regulatory reviews,[6] research shows that most Americans have engaged in few or no discussions about GMOs.[7] After a flurry of investigation in the 1980s, Congress has shown little interest in modifying the agencies' existing statutory authority. And recent events in biotech regulation reveal gaps in agency authority under the old statutes,[8] raising the question whether a sufficient mechanism exists to spark congressional review and public deliberation to address such gaps as they emerge. This Article examines the give-and-take between the agencies, the public, the courts, and Congress in an effort to gauge the level of democratic participation (or even acquiescence) in the creation and persistence of the choice to regulate biotechnology under laws that predate the technology.

This case study is intended to lay a foundation for future studies of the legislation/regulation dynamic with regard to now-emerging

3. The terms "genetically modified organism" or "GMO" actually describe products that have been genetically modified by any method, including traditional breeding methods as well as modern biotechnology. According to conventional practice, however, this article uses the term "GMO" interchangeably with "genetically-engineered organism" to refer to products altered by means of biotechnology.

4. *See infra* notes 102-153 and accompanying text.

5. *See infra* notes 193-232 and accompanying text.

6. *See infra* notes 233-243 and accompanying text.

7. *See infra* notes 175-185 and accompanying text.

8. *See infra* notes 19-22, 139-153 and accompanying text.

scientific and technological developments like climate change science and hydraulic fracturing of unconventional shales. From these case studies, both contemporary and retrospective, conclusions and recommendations may be drawn about necessary adjustments to the legislation/regulation decision-making process. Any such adjustments should aim to ensure robust democratic participation and implementation of democratic consensus, while also protecting urgent interests such as market participation and health and environmental protection in the face of emerging science and technology. Part II sets up the stakes of the debate by reviewing an important but little-noticed event in biotechnology regulation in 2011. Part III places the GMO case study in context of the debate over administrative legitimacy and deliberative democracy. Part IV examines in detail the choice between regulation and legislation of GMOs in the 1980s. Part V examines developments in the GMO debate between the mid-1980s and today, asking whether the persistence of the regulatory framework reflects democratic consensus around that approach. Finally, Part VI reflects on the lessons learned and questions drawn from this history, and suggests approaches to examination of contemporary legislation/regulation dilemmas and potential political reforms.

II. ON BIOLISTICS, BLUEGRASS, AND GAPS IN THE GMO FRAMEWORK

The stakes of the regulation-versus-legislation debate for deliberative democracy may be illustrated by a contemporary example. This example raises questions about how effectively a regulatory solution to emerging technology—a solution based on legislation that was drafted and passed before contemplation of the new developments—can be adapted to fit that new technology. Where the new technology and the relationships or conflicts created by it are difficult to analogize to more familiar situations, a further question arises whether the existence of an imperfect-fit regulatory structure has any impact on the potential for democratic development of a more tailored regime based on new legislation. In other words, does early regulation under existing statutes have a chilling effect on the deliberative process that might eventually result in new legislation specific to the emerging technology?

In September 2010, Scotts Miracle-Gro Co. ("Scotts") wrote to federal regulators about its new strain of Kentucky bluegrass, which had been modified by biotechnology to be resistant to the herbicide Roundup. Rather than using bacteria or viruses to insert the new genes, as the first generation of biotechnology products had done,

Scotts's product was created through the use of biolistics,[9] or a "gene gun," that shoots microparticles of heavy metals coated with DNA and RNA into cells to transfer the genetic traits.[10] Scotts sought assurances that its product was not subject to the federal laws and regulations that govern new varieties of biotech plants.[11]

The statute Congress utilized to delegate to the United States Department of Agriculture's ("USDA") Animal and Plant Health Inspection Service ("APHIS") the authority to regulate plants with genetic modifications was the Federal Plant Pest Act of 1957,[12] which was later consolidated with other plant protection laws by the Plant Protection Act of 2000[13] ("PPA"). Under this statute, APHIS exercises jurisdiction over "plant pests," defined as anything that could injure, damage, or cause disease in plants, including bacteria and viruses.[14] Consistent with the policy recommendations of the executive branch,[15] APHIS interpreted its jurisdiction over plant pests to extend to the bacteria and viruses used to transfer new genetic traits into plants.[16] Since the bacteria or virus remained in the genetically modified organisms ("GMOs"), the PPA gave APHIS regulatory oversight over most GMO plants at that time and for many years afterward.[17]

On the Friday before the Fourth of July weekend in 2011, APHIS sent a letter to Scotts confirming that APHIS had no authority under federal law to regulate Scotts's new herbicide-resistant Kentucky

9. *See* Letter from Dr. Richard Shank, Senior Vice President, The Scotts Miracle-Gro Company, to Tom Vilsack, Secretary, United States Department of Agriculture (Sept. 13, 2010), *available at* http://www.aphis.usda.gov/brs/aphisdocs/scotts_kbg.pdf ("Transformation of Kentucky bluegrass is stably integrated using purified trait DNA transferred by biolistics.").

10. *See* Paul Voosen, *Biotech: In Major Shift, USDA Clears Way for Modified Bluegrass*, GREENWIRE (July 6, 2011) www.eenews.net/public/Greenwire/2011/07/06/3.

11. *See* Letter from Dr. Richard Shank to Tom Vilsack, *supra* note 10.

12. *See* Pub. L. No. 85-36, 71 Stat. 31 (1957) (codified at 7 U.S.C. §§ 150aa-150jj), *reorganized by* Plant Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 438 (codified as amended in scattered sections of 7 U.S.C.).

13. Pub. L. No. 106-224, 114 Stat. 438 (codified as amended in scattered sections of 7 U.S.C.).

14. 7 U.S.C. § 7702 (2012). The Plant Protection 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." *Id.*

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

16. *See* Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests, 52 Fed. Reg. 22,892, 22,908 (June 16, 1987) [hereinafter Introduction of Plant Pests].

17. *Id.*

bluegrass.[18] The USDA determined that Scotts's herbicide-resistant bluegrass did not fall within the terms of APHIS's regulatory jurisdiction over GMOs under the PPA because the new traits were transferred by the gene gun instead of by microbes. Based on that letter, Scotts was free to develop, produce and sell its genetically-modified Kentucky bluegrass with no oversight from regulators.

Is the public aware that a new class of biotech plants is not subject to federal controls? The USDA opinion letter acknowledging the gap in authority was published late on a Friday before a holiday weekend. Media coverage of the decision was not extensive.[19] Anecdotally, during a presentation to agricultural law professors in January 2012, not one member of the audience had heard about the Kentucky bluegrass decision.[20] If even agricultural law experts are unaware of gaps in legislative authority that leave a new generation of biotechnology products unregulated, are such legislative gaps receiving sufficient attention by the public and by Congress? Did the regulatory structure created under the pre-existing laws include a mechanism for requesting additional legislative authority when such gaps became apparent? Has Congress been alerted to those gaps? Do citizens have adequate opportunity to debate and arrive at consensus on whether new law may be needed or appropriate? Does the existence of an imperfect regulatory structure based on pre-existing statutes chill debate over the potential creation of a legislative solution that would fill the gaps?

18. Letter from Michael C. Gregoire, Deputy Adm'r, Animal & Plant Health Inspection Serv., to Dr. Richard Shank, Senior Vice President, The Scotts Miracle-Gro Co. (July 1, 2011), *available at* http://www.aphis.usda.gov/brs/aphisdocs/scotts_kbg_resp.pdf.

19. *See* Jerry Hagstrom, *USDA Rules on GE Bluegrass*, AGWEEK, July 19, 2011 at 36; Robert Johnson, *This Genetically Modified Grass May Lead To a New Generation of Superweed*, BUS. INSIDER, July 12, 2011; Andrew Pollack, *U.S.D.A. Ruling on Bluegrass Stirs Cries of Lax Regulation*, N.Y. TIMES, July 7, 2011, at B2; *U.S. Won't Regulate Modified Grass*, CALGARY HERALD, July 4, 2011, at B3; Paul Voosen, *How Unwitting Kiwis, and Their Petunias, Punched Through U.S. Biotech Regs*, N.Y. TIMES, July 15, 2011; Voosen, *supra* note 10. Several news sources noted the low profile that the USDA gave the announcement. *See* Hagstrom, *supra* (describing "little noticed July 1 news release"); Johnson, *supra* (describing how a "significant" USDA announcement "slipped" to the public "when most people were looking to the long weekend rather than the news"); Voosen, *supra* (noting decision released "on the Friday before the Fourth of July weekend"). Several news sources noted the low profile that USDA gave the announcement. *See* Hagstrom, *supra* (describing "little noticed July 1 news release"); Johnson, *supra* (describing how a "significant" USDA announcement "slipped" to the public "when most people were looking to the long weekend rather than the news"); Voosen, *supra* note 10 (noting decision released "on the Friday before the Fourth of July weekend").

20. Alison Peck, Address at a Meeting of the Section on Agricultural Law, Association of American Law Schools (Jan. 7, 2012).

APHIS's decision that it lacked authority to regulate a new class of biotechnology products was described by news accounts as a "major shift"[21] that "punched through U.S. biotech regs."[22] More accurately, the "shift" was consistent with existing biotech laws and regulations. Rather than changing the law, the USDA's decision shone light on a place where no law existed at all. By basing GMO regulation on the PPA's grant of authority to USDA to regulate plant pests, the executive branch left a gap in the regulatory framework for any new biotechnology that did not rely on bacteria or viral vectors.

In a 1986 statement entitled the Coordinated Framework for Regulation of Biotechnology ("1986 Coordinated Framework"), the White House Office of Science and Technology Policy ("OSTP") divided regulatory authority for agricultural biotechnology among three federal agencies: the USDA, which regulates the testing and commercialization of new agricultural biotech products; the Food and Drug Administration ("FDA"), which regulates the introduction and marketing of foods created through the use of genetic engineering; and the Environmental Protection Agency ("EPA"), which regulates genetically-altered microorganisms and pesticide properties of genetically-engineered plant varieties.[23] Each of these agencies regulates under statutes that pre-date commercial agricultural biotechnology. The FDA's authority is based primarily on the Federal Food, Drug and Cosmetic Act,[24] a 1938 act that includes authorization for the FDA to ensure food safety through regulation of food additives and misbranding.[25] The USDA's authority stems primarily from a law that dates back to the Federal Plant Pest Act of 1957, reorganized in the PPA, which gave the USDA jurisdiction over bacteria and viruses.[26] The EPA derives its authority from the relatively modern pesticide and toxics control laws of the 1970s, including the Federal Insecticide, Fungicide and Rodenticide Act[27] ("FIFRA") and the Toxic

21. Voosen, *supra* note 10.

22. Voosen, *supra* note 10. Even among agricultural law experts, few heard about the decision. When the author presented this development to a group of agricultural law scholars in January 2012, no member of the audience had heard of the events. Peck, *supra* note 21.

23. *See* 1986 Coordinated Framework, *supra* note 15, at 23,302; *see also* Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (Dec. 31, 1984) [hereinafter Proposed Coordinated Framework].

24. Ch. 675, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-399f (2012)).

25. *See* 21 U.S.C. §§ 321(s) (defining "food additive"), 321(n) (defining "misbranding"), 331 (prohibiting introduction of adulterated or misbranded foods), 371-72 (providing for regulatory and enforcement authority by FDA).

26. *See generally* 7 U.S.C. §§ 7701-7786 (2012).

27. Ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y

Substances Control Act[28] ("TSCA").[29]

This tripartite regulatory structure resulted from White House policy directives during the 1980s and early 1990s, at the advent of commercialization of biotech products.[30] In the 1986 Coordinated Framework, the OSTP acknowledged concerns over whether pre-existing laws were adequate to address the new technology, and whether review mechanisms for new products were sufficient.[31] The OSTP acknowledged that the Reagan Administration believed it had the responsibility to respond to these questions.[32] The OSTP concluded that, for the most part, existing laws "would address regulatory needs adequately."[33] The OSTP directed the FDA, the USDA, and the EPA to establish oversight mechanisms for the new biotech products based on the existing statutes. In part, its decision was justified based on the urgency of the issue and the relative speed of the regulatory process. The OSTP concluded, "The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation."[34]

The 1986 Coordinated Framework was buttressed by a 1992 "Final Statement on Scope" published by the OSTP.[35] The Final Statement on Scope reiterated the division of regulatory authority announced in the 1986 Coordinated Framework and "sets forth the proper basis for agencies' exercise of oversight authority within the

(2012)). Congress originally enacted FIFRA in 1947; the act was rewritten in 1972. *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*, U.S. ENVTL. PROTECTION AGENCY, http://www.epa.gov/oecaagct/lfra.html (last updated June 27, 2012).

28. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended in scattered sections of 15 U.S.C. (2012)).

29. *See* Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313 (June 26, 1986) (providing the EPA policy statement for exercising authority under FIFRA and TSCA).

30. 1986 Coordinated Framework, *supra* note 16, at 23,302; Proposed Coordinated Framework, *supra* note 24, at 50,856.

31. *See* 1986 Coordinated Framework, *supra* note 16, at 23,302 ("The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques.").

32. *Id.*

33. *Id.* at 23,303.

34. *Id.*

35. *See* Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6,753, 6,756 (Feb. 27, 1992) [hereinafter 1992 Final Statement on Scope]; *see also* Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 31,118 (July 31, 1990) [hereinafter Proposed Statement of Scope].

scope of discretion afforded by statute."[36] The Final Statement on Scope articulated principles to guide agency discretion, such as the statement that "federal agencies shall exercise oversight of planned introductions of biotechnology products into the environment only upon evidence that the risk posed by the introduction is unreasonable"; that is, where the value of the risk-reduction measure outweighs the cost of the measure.[37]

Based on the direction of the OSTP in the 1986 Coordinated Framework and the Final Statement on Scope, the FDA, the EPA, and the USDA proceeded to articulate policy statements and regulations in the late 1980s and into the 1990s.[38] These policies and regulations, with some more recent amendments,[39] still control biotechnology oversight today.

III. SEPARATION OF POWERS: BROAD DELEGATION OR NO DELEGATION?

The question of whether and how agencies may regulate emerging science and technology sheds important light on the broader debate over the scope of executive regulatory power. Before the proliferation of the administrative state, the lawmaking function was simply presumed to reside in the legislature, and early justifications of agency action relied primarily on the analogy of a "transmission belt,"[40] shuttling authority from the legislature making the laws to the agencies enforcing them.[41] Later justifications focused instead on the

36. 1992 Final Statement on Scope, *supra* note 35, at 6,753.

37. *Id.* at 6,756.

38. *See, e.g.*, Introduction to Plant Pests, *supra* note 17; Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (Nov. 6, 1992) [hereinafter USDA – Genetically Engineered Organisms and Products]; Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter FDA – Statement of Policy]; Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994) [EPA – Proposed Policy].

39. *See, e.g.*, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4,706 (Jan. 18, 2001); Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms, 62 Fed. Reg. 23,945 (May 2, 1997).

40. *See* Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669, 1675 (1975); *see also* Steven P. Crowley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 99 (1998).

41. *See* Emily Hammond Meazell, *Presidential Control, Expertise, and the Deference Dilemma*, 61 DUKE L.J. 1763, 1771-74 (2012) (arguing that when disputes arise between executive and independent agencies, courts should give deference to those actions that are more closely aligned with statutory language and congressional intent); *see also* Mark Fenster, *The Birth of a "Logical System": Thurman Arnold and the Making of Modern Administrative Law*, 84 OR. L. REV. 69, 76 (2005) (analyzing the role of judicial

technical expertise of agencies to fill in the details of the laws,[42] and then on the rights given to allow a broad array of interest groups to influence agency decision-making.[43] Eventually another theory emerged, the presidential control model, in which the power of agencies was justified by agencies' relationships with the President and the electoral accountability of that office.[44] In 2001, then visiting professor at Harvard Law School Elena Kagan announced, "We live today in an era of presidential administration,"[45] and the presidential or political control theory is now widely viewed as the dominant theory of agency legitimacy.[46] The Obama Administration has taken a proactive role in setting policy through agency action since the stalemate in Congress after the 2010 elections, brandishing the slogan "We Can't Wait."[47]

While a more attenuated link between legislative action and regulatory power may be tolerated under these new theories that seek

review in both limiting and legitimizing the administrative state as it shifts from a model of broad agency discretion to a reliance on technical expertise). *See generally*, Harold H. Bruff, *Presidential Power Meets Bureaucratic Expertise*, 12 U. PA. J. CONST. L. 461 (2010).

42. *See* Fenster, *supra* note 42, at 76 (analyzing the role of judicial review in both limiting and legitimizing the administrative state as it shifts from a model of broad agency discretion to a reliance on technical expertise); Meazell, *supra* note 42, at 1771-74.

43. *See, e.g.*, MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 31-85 (1965); Steven P. Crowley, *Public Interested Regulation*, 28 FLA. ST. U. L. REV. 7, 9 (2000) (discussing the various divisions of interest group theory while advocating a neopluralist model); Reuel E.Schiller, *Enlarging the Administrative Polity: Administrative Law and the Changing Definition of Pluralism, 1945-1970*, 53 VAND. L. REV. 1389, 1396-98 (2000) (chronicling the rise and fall of interest group pluralism and the shifting role of the judiciary in controlling the administrative state).

44. *See* Lisa Shultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 485-92 (2003); William P. Marshall, *Eleven Reasons Why Presidential Power Inevitably Expands and Why It Matters*, 88 B.U. L. REV. 505, 515 (2008); Meazell, *supra* note 42, at 1774-77; *see also* Jeffery E. Shuren, *The Modern Regulatory State: A Response to Changing Circumstances*, 38 HARV. J. ON LEGIS. 291, 295 (2001). *But see* Mariano-Florentino Cuellar, *Auditing Executive Discretion*, 82 NOTRE DAME L. REV. 227, 230-32 (2006) (arguing that inadequate oversight of executive agencies could be cured by the creation of an auditing agency).

45. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2246 (2001).

46. *See* Glen Staszewski, *Political Reasons, Deliberative Democracy, and Administrative Law*, 97 IOWA L. REV. 849, 851 (2012); Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 485-92 (2003); *see also* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984) (holding that agencies could "properly rely upon the incumbent administration's views of wise policy to inform its judgments").

47. Charlie Savage, *Shift on Executive Power Lets Obama Bypass Rivals*, N.Y. TIMES, April 23, 2012, at A1.

to explain and defend the modern administrative state, most scholars nevertheless assume some continued connection, however permissive, between congressional delegation and agency action. Even the most expansive theories of agency legitimacy must somehow explain how the constitutional separation of powers between legislature and executive is preserved.[48]

On the question of legitimacy of agency action, the easiest cases occur at the margins: when an executive action would directly contradict a statute, agency action is almost certainly unlawful;[49] when Congress has given clear authority to agencies to regulate a certain subject matter, agency action is obviously permitted.[50] But emerging science and technology present the fuzzy cases. When the subject matter is arguably a "game-changer"— creating conflicts and relationships that citizens have not yet had an opportunity to debate— it may be thought that existing statutes can be read broadly by agencies to apply to the new technology. At the same time, where no public debate has occurred about potentially game-changing technologies, it may reasonably be argued that no legislative delegation can have occurred at all. When it comes to potentially game-changing technological and scientific developments, how new is too new? When it comes to broad readings of existing authority, how far is too far?

Major scientific and technological breakthroughs paint democratic participation concerns in sharp relief because of their very

48. *See, e.g.*, Kagan, *supra* note 45, at 2250-51 (emphasis added) (noting inconsistency between view of President-agency relationship as constrained by Congress, and, alternatively, "Clinton's use of what I call directive authority—his commands to executive branch officials to take specified actions *within their statutorily delegated discretion*"); Savage, *supra* note 48 (describing the Obama Administration's focus on regulatory actions that do not require legislation and abandonment of proposals criticized as inconsistent with statutes).

49. For example, the Obama Administration backed off an early attempt to change the repayment timing for federal student loans after challenges that it had no authority to alter the congressionally-designated rule. *See* Savage, *supra* note 48. It is important to emphasize that the unlawfulness of such action is only "almost" certain. Courts have upheld agency actions that directly conflict with statutory requirements, if strict textual application of the statute would produce results apparently inconsistent with congressional intent. *See* Coal. for Responsible Regulation, Inc. v. EPA, 684 F.3d 102 (D.C. Cir. 2012) (upholding EPA decision in conjunction with Endangerment Finding to set greenhouse gas regulation threshold at higher level than described by Clean Air Act); *cf.* Clinton v. City of New York, 524 U.S. 417, 429 (1998) (applying the absurdity doctrine to support judicial interpretation of statute); Pub. Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 454-55 (1989). *But see* John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2390 (2003) (criticizing the absurdity doctrine as inconsistent with strict textualist trend of modern Supreme Court jurisprudence).

50. *See* Stack, *supra* note 2.

novelty.[51] One of the key substantive characteristics of deliberative democracy, as articulated by Joshua Cohen and others,[52] is that its institutions move beyond mere expression of "pre-political preferences"[53] of the majority. Instead, through the requirement that policies be justified with reference to the common good on terms that all reasonable people could accept, deliberative democracy is intended to shape the views of all citizens, even of those whose pre-political preferences might otherwise have constituted a majority. This occurs in two ways. First, "the practice of presenting reasons will contribute to the formation of a commitment to the deliberative resolution of political questions."[54]By participating in the process of deliberative democracy, citizens become more likely to internalize its ideal of justifying preferences based on the common good. This commitment will lead to a greater likelihood of advancing arguments with genuine reference to that ideal, rather than merely cloaking pre-political preferences in language likely to be accepted within that system. Second, it may alter the actual content of a citizen's views—from pre-political preferences to those more readily acceptable by reference to the common good. "Assuming a commitment to deliberative justification, the discovery that I can offer no persuasive reasons on behalf of a proposal of mine may transform the preferences that motivate the proposal."[55] In other words, a commitment to deliberation may affect both (1) which of his preferences a citizen decides to advance in the political process, and on what basis; and (2) the content of the preferences that a citizen actually holds to after deliberation.[56]

51. While administrative law scholars have argued for ever increasing expansion of the power of the executive branch to act without direct mandate from Congress, political scientists and constitutional scholars have been devising and advocating mechanisms to promote greater accountability of the political process to the people. *See generally* Joseph Bessette, *Deliberative Democracy: The Majority Principle in Republican Government*, *in* HOW DEMOCRATIC IS THE AMERICAN CONSTITUTION? (Robert Dahl ed., 2d ed. 2003); AMY GUTMANN & DENNIS THOMPSON, DEMOCRACY AND DISAGREEMENT (1998); Joshua Cohen, *Deliberation and Democratic Legitimacy, in* DELIBERATIVE DEMOCRACY: ESSAYS ON REASON AND POLITICS 67 (James Bohman & William Rehg eds., 1997); *see also* Michael R. Harris, *Environmental Deliberative Democracy and the Search for Administrative Legitimacy: A Legal Positivism Approach*, 44 U. MICH. J.L. REFORM 343 (2011) (offering a legal positivist approach to improving democratic involvement in the environmental regulatory process).

52. *See generally* Bessette, *supra* note 51; Cohen, *supra* note 51.

53. This term is not used by Cohen, but may be found in other descriptions of the theory. *See, e.g.*, Staszewski, *supra* note 46, at 852.

54. Cohen, *supra* note 51, at 76.

55. *Id.*

56. Cohen, *supra* note 51, at 72-73. *But see* Lynn M. Sanders, *Against Deliberation*, 25 POL. THEORY 347, 349 (1997) (arguing that the views of uninvolved citizens are due the respect that a free flow of values and ideas requires).

Emerging science and technology raise an unusual dilemma from a standpoint of deliberative democracy. Cohen's term presumes that citizens possess, at some "pre-political" stage, a certain amount of information, such as facts about the activity to be subject to law, knowledge of the policy options available, and information about the likely impacts of a given policy. With new science and technology, however, most citizens have not yet had enough information or opportunity to form even "pre-political preferences" about the issues raised by the new developments.[57] Until citizens have had a meaningful opportunity to understand and form opinions about new developments, decisions can only be made by the small minority who have such knowledge and experience.

IV. DEMOCRATIC PROCESS IN THE CREATION OF THE GMO REGULATORY FRAMEWORK

Testifying before Congress in 1985 about genetically modified organism ("GMO") technology, Dr. Frank Young, the Commissioner of the FDA, emphasized the need for public participation in the establishment of legal controls over the technology at the advent of its commercialization. Quoting geneticist Tracy Sonneborn, Dr. Young told Congress that the following statement was "particularly applicable . . . today":[58]

> The human problems raised by these new possibilities are not fundamentally different from the problems Huxley put forceably before the public. They are the problems of morals, ethics, religions and politics. . . . How they will be used obviously will not be decided by scientists alone. Nor should this be decided alone by professional politicians or theologians or by philosophers or by moralists. It must be decided on an enlightened and broadly based public opinion.[59]

Was the GMO regulatory structure established in the 1980s in fact "decided on an enlightened and broadly based public opinion"? Or did the 1986 Coordinated Framework, 1992 Final Statement on Scope,

57. Most citizens do have pre-political preferences with regard to general issues implicated by new science and technology, such as belief in science for defining limits of legal controls, or trust in federal and state regulators. *See infra* notes 60-80 and accompanying text (surveys discussing general science awareness and attitudes toward technology regulation). Nevertheless, those opinions are general and may not control a citizen's response to a particular new technology. *See* discussion *infra* notes 70-80 and accompanying text.

58. *Biotechnology Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 98th Cong. 16 (1984) [hereinafter *Hearing on Biotechnology Regulation*].

59. *Id.*

and subsequent federal agency regulations and policies impede democratic deliberation on GMOs? There is no way to prove what would have happened in a parallel universe in which no regulatory framework was created under pre-existing laws. It is possible, however, to approach this question by analyzing the way the GMO regulatory framework was created, and its reception since then.

First, how much did the public know or understand about biotechnology at the advent of its commercialization? Did the public want the new technology to be controlled, and did it trust federal regulators to exercise those controls? Second, how much opportunity did the public have to participate in the creation of the biotechnology control framework—either through executive channels that ultimately held sway, or through the alternative legislative process that might have held sway? Taken together, the answers to these questions may shed some light on the level of democratic consensus involved in the initial choice to regulate rather than legislate.

A. HOW MUCH DID THE PUBLIC KNOW ABOUT BIOTECHNOLOGY IN THE 1980S?

In 1987, the former congressional Office of Technology Assessment ("OTA") issued a report on its survey of public perceptions about biotechnology.[60] This survey considered public awareness of and attitudes about science and technology in general, and about the new biotechnology in particular. The survey suggests two things: first, the level of public awareness and understanding of biotechnology was relatively low in the mid-1980s when the 1986 Coordinated Framework was announced, and second, Americans did feel that strict regulation of the new industry was important, but did not have strong trust in federal agencies.

In its survey, the OTA classified respondents as "science observant" if they described themselves as having a very good understanding of science, being very interested in science, or being very concerned about science policy.[61] The OTA found that slightly less than half (forty-seven percent) of the U.S. population could be classified as "science observant."[62] The OTA survey determined that

60. *See generally* OFFICE OF TECH. ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY (May 1987), *available at* http://www.fas.org/ota/reports/8721.pdf.

61. *Id.* at 20.

62. *Id.* This included 16% who rated their basic understanding of science and technology as "very good"; 23% who described themselves as "very interested" in science and technology; and 22% who report that they are "very concerned" about science policy. *Id.* at 13, 14, 19. Some respondents were included in more than one of the categories.

the science observant, however, were not much more likely than the norm to have voted in recent congressional or local elections, campaigned for a candidate, or written to a public official.[63]

Public awareness of biotechnology in particular was not high. The OTA survey found that thirty-five percent of respondents had heard "a lot" (six percent) or "a fair amount" (twenty-nine percent) about genetic engineering.[64] In contrast, sixty-three percent had heard "almost nothing" (twenty-four percent) or "relatively little" (thirty-nine percent) about it.[65] Despite this substantial rate of unfamiliarity with the subject, OTA reported that "more than half of American adults (fifty-six percent) can provide a meaningful—if not necessarily strictly accurate—explanation of genetic engineering."[66]

Support for advancement of the technology was clear: a majority of respondents supported equal or increased government support for biotechnology research,[67] and most supported small-scale field tests.[68] When asked about large-scale environmental releases (short of commercial release), however, respondents were more skeptical: fifty-three percent said firms should not be able to make such releases, even "if the risks of environmental danger are judged to be very small."[69]

Most Americans did not have fully-formed opinions about biotechnology. As late as 1994, one study, based on a survey of New Jersey residents, noted that "many respondents had not thought a great deal about the issues surrounding biotechnology."[70] Interviewers and interview monitors noted that "[m]any respondents were quite introspective, carefully considering their answers, as if they were really thinking about the issues for the first time."[71] The study authors concluded that "most citizens seem to be in the initial stages of making up their minds about this new technology" and had not formed an opinion that the technology was universally morally

63. *Id.* at 21.

64. *Id.* at 45. The OTA describes this level of awareness as "moderate." *Id.*

65. *Id.*

66. *Id.* at 47. The survey offered a variety of potential responses for respondents to select. The most common response chosen, after the response of "Don't know," was, "Altering/manipulating genes" (20%). *Id.* at 46. Other options provided by the survey, such as "Producing improved/superior organisms" and "Altering gene to produce desired/specific result," were chosen by three to six percent of respondents. *Id.*

67. *Id.* at 83.

68. *Id.* at 84.

69. *Id.* at 87-88.

70. WILLIAM K. HALLMAN & JENNIFER METCALFE, PUBLIC PERCEPTIONS OF AGRICULTURAL BIOTECHNOLOGY: A SURVEY OF NEW JERSEY RESIDENTS 35 (1994), *available at* http://ageconsearch.umn.edu/bitstream/18170/1/pa94ha01.pdf.

71. *Id.* at 35.

acceptable or unacceptable.[72]

Public opinion about regulation was also ambivalent. As a general matter, Americans were about evenly split on the need for technology regulation generally.[73] With regard to biotechnology, however, Americans did favor regulation. OTA found that seventy-seven percent of the public agreed with the statement that "'the potential danger from genetically altered cells and microbes is so great that strict regulations are necessary.'"[74] Forty-three percent of respondents "strongly agree[d]" with the statement.[75]

Whom did the public want to do the regulating? Survey respondents reported relatively low trust in federal agencies. When asked whether they would believe statements about the risk of a biotech product from various groups, respondents were more inclined to believe university scientists, public health officials, and environmental groups than federal agencies.[76] Similarly, respondents were asked to imagine a case in which a federal agency said a genetically altered organism did not pose a significant risk, but a national environmental group said it did.[77] Respondents were far more likely to believe the environmental group (sixty-three percent) than the federal agency (twenty-six percent).[78] When asked who should be in charge of determining whether large-scale releases should be permitted, a plurality of respondents (thirty-seven percent) chose "government agency."[79] Another five percent, however, did not choose from among the options suggested by the survey ("company that developed the product; external scientific body; government agency;

72. *Id.* at 36.

73. A majority (54%) of respondents to the OTA survey disagreed with the statement, "Unless technological development is restrained, the overall safety of our society will be jeopardized significantly in the next 20 years." OFFICE OF TECH. ASSESSMENT, *supra* note 61, at 30 tbl.16. College graduates were the most likely to disagree with the statement (74% to 23%). *Id.* The percentage of the public favoring increased control over technology, however, had increased from 28% in 1972 to 43% in the mid-1980s. *Id.* at 31.

74. *Id.* at 81.

75. *Id.*

76. *Id.* at 89-90. Respondents were asked to indicate whether they would "definitely believe," would be "inclined to believe," would be "inclined not to believe," would "definitely not believe," or were "not sure." *Id.* University officials received significantly higher credibility ratings (nineteen percent would "definitely believe," sixty-seven percent would be "inclined to believe") than federal agencies (nine percent "definitely believe," sixty percent would be "inclined to believe"). *Id.* at 90. Although the OTA tabular material on page 90 does not identify how many would "definitely believe" federal agencies, the accompanying text indicates that a total of sixty-nine percent were *at least* "inclined to believe."

77. *Id.*

78. *Id.*

79. *Id.* at 88-89.

industrial trade association") but instead chose "other group" and wrote in choices such as "Public/voters/taxpayers/community."[80] The results of the OTA survey suggest that a majority of Americans in the 1980s thought biotech should be regulated, but may not have confidently entrusted the creation of the regulatory scheme to federal agencies.

B. DID THE PUBLIC SUPPORT THE REGULATORY FRAMEWORK?

The regulatory process itself includes opportunities for citizen participation, and the sufficiency of these procedures for democratic legitimacy has been the focus of scholarly debate since the early days of the administrative state.[81] Some concerns raised by critics of the administrative state are apparent in the creation of the GMO regulatory framework, casting doubt on any suggestion that immediate regulation of GMOs under pre-existing statutes reflected any considered public preference at the time, express or implied.

First, these policies occurred in a different era of regulatory action—the pre-Internet era. Agency comments can now be submitted electronically, and voter signatures can similarly be obtained through the Internet. For example, the USDA's Animal and Plant Health Inspection Service received more than 66,000 comments on its 2008 proposal to revise its regulations regarding the importation, interstate movement and environmental release of certain GMOs.[82] In contrast, executive documents opened for public comment in the 1980s received far less direct public input. The 1984 proposed Coordinated Framework, for example, was opened for comment on December 31, 1984, requesting comments addressed directly to the relevant agencies or to the OSTP.[83] In a 1985 notice, the OSTP reported that it had received seventy-nine comments to the OSTP, thirty-four to the FDA, sixty-eight to the EPA, and fifty to the USDA.[84] Similarly, early

80. *Id*. at 89, 108. The survey question asked, "'Who should be responsible for deciding whether or not commercial firms should be permitted to apply genetically altered organisms on a large-scale basis— the company that developed the product, an external scientific body, a government agency, an industrial trade association, or other group"? The survey gave respondents the options of choosing one of the enumerated entities, or choosing "other group" and specifying their answers. *Id*. at 108.

81. *See supra* notes 58-79 and accompanying text.

82. Email from Richard S. Coker, Regulatory & Envtl. Analysis Branch, Biotechnology Regulatory Servs., USDA, to author (Aug. 18, 2009) (on file with author) (referring to comments received on Proposed Rule; Importation, Interstate Movement and Release Into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008, (Oct. 9, 2008)).

83. Proposed Coordinated Framework, *supra* note 23, at 50856.

84. *See* Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,174 (Nov.

regulations defining the USDA's oversight procedures under the PPA received fewer than two hundred comments.[85] In the 1986 Coordinated Framework, OSTP invited comments but announced that the policy would be effective immediately.[86] The Biotechnology Science Coordinating Council, an interagency coordinating group created by the OSTP to address scientific issues related to biotechnology, scheduled its first public hearing for July 9, 1986—two weeks after publication of the final 1986 Coordinated Framework document.[87]

However, the number of comments on proposed regulations may be moot. Political scientists have generally concluded that public comments on proposed regulations make little difference in the final outcome of regulations.[88] But more recent research has suggested that public input at the rule development stage—before any proposed regulation is issued—does have substantial impact on the outcome of regulations.[89] One study of commenter influence after Advanced Notice of Proposed Rulemakings showed significant influence: when most commenters wanted less regulation, the proposed rules moved toward less regulation almost seventy percent of the time.[90] When early commenters wanted to see more regulation, the rules followed suit approximately fifty-percent of the time.[91] Moreover, organized interest groups such as businesses appear to dominate public input on rule development, just as they do in the less influential notice and

14, 1985) [hereinafter OSTP – Coordinated Framework].

85. *See* Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044, 17,044 (Mar. 31, 1993) (to be codified at 7 C.F.R. pt. 340) (reporting eighty-four comments received on proposed rule); Introduction of Organisms and Products, *supra* note 16, at 22,892 (reporting the final rule and that184 comments had been received on the proposed rule, including comments received at public hearing).

86. *See* 1986 Coordinated Framework, *supra* note 15, at 23,302.

87. *See The Biotechnology Science Coordination Act of 1986: Hearings Before the Subcomm. on Natural Resources, Agriculture Research and Environment and the Subcomm. on Science, Research and Technology of the H. Comm. on Science and Technology*, 99th Cong. 36 (1986) [hereinafter *Hearing on 1986 Act*], *available at* http://babel.hathitrust.org/cgi/pt?id=mdp.39015013107316;view=1up;seq=3 (statement of David T. Kingsbury, Chairman, Biotechnology Science Coordinating Committee).

88. *See, e.g.*, Marissa Martino Golden, *Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard?*, 8 J. PUB. ADMIN. RES. & THEORY 245 (1998); William F. West, *Formal Procedures, Informal Procedures, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis*, 64 PUB. ADMIN. REV. 66 (2004). *But see* Susan Webb Yackee, *Assessing Inter-Institutional Attention to and Influence on Government Regulations*, 36 BRIT. J. POL. SCI. 723 (2006) (finding evidence of commenter influence during notice and comment period).

89. *See* Keith Naughton et al., *Understanding Commenter Influence During Agency Rule Development*, 28 J. POL'Y ANALYSIS & MGMT. 258 (2009).

90. *Id.* at 272.

91. *Id.*

comment phase.[92] Anecdotal reports suggest cooperation between the White House and the biotechnology industry during the development of the 1986 Coordinated Framework outside the formal notice and comment process.[93]

Important aspects of the regulatory framework were established entirely outside the notice-and-comment rulemaking procedures of the Administrative Procedure Act[94] ("APA"). For example, in 1992 FDA issued a policy statement that new biotech foods would not need to be submitted for food additive review and were not required to be specially labeled.[95] In a lawsuit by consumer groups challenging the FDA's labeling policy, a federal district court rejected a claim that the policy statement should have been promulgated through notice-and-comment rulemaking.[96] A policy statement may avoid APA rulemaking requirements, the court observed, if it does not impose any new rights or obligations, or restrain policymakers from exercising discretion.[97] The court held that the policy statement left the agency with discretion, and thus did not have the "force and effect of law" that triggers APA rulemaking procedure.[98] The court focused on the fact that the policy statement announced merely a presumption, not a rule, that biotech foods would be "generally recognized as safe" ("GRAS") under the Federal Food, Drug, and Cosmetic Act[99] ("FDCA"). [100] The court did not consider whether the food labeling interpretation of the FDCA might trigger notice and comment, however, even though the FDA's interpretation of the misbranding section of the FDCA was not

92. *Id*. This data led the study authors to conclude that "overall influence of interest groups during the regulatory policymaking process is, in all likelihood, underestimated in studies that do not take into account the politics of the rule development stage." *Id.*

93. For example, a biotechnology industry association representative testified to Congress that he had received a draft copy of EPA's guidelines for the final Coordinated Framework. *See Hearing on 1986 Act*, *supra* note 87, at 79 (statements of Richard Godown, Executive Director, Industrial Biotechnology Association, and Dr. Alan Goldhammer). . As of the date of the hearing, the Domestic Policy Council was still reviewing the draft Coordinated Framework and was unable to testify as to the "precise wording" of the final version. *See id.* at 16-18. The industry representative also testified that he and a witness from OSTP had exchanged drafts of their testimony prior to the hearing. *See id.* at 80.

94. Ch. 324, 60 Stat. 237 (1946) (codified as amended in scattered sections of 5 U.S.C.)

95. *See* FDA – Statement of Policy, *supra* note 38, at 22,984.

96. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 172-73 (D.D.C. 2000).

97. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 172.

98. *Id.*

99. Ch. 675, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-399f (2012)).

100. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179.

similarly stated as a presumption. FDA has since relied on that interpretation to deny consumers' claims that they have a right to receive information about whether foods contain GMO ingredients.[101]

C. DID THE PUBLIC REJECT NEW LEGISLATION?

At around the same time the White House was preparing the 1986 Coordinated Framework and agencies were announcing initial policy statements and proposed regulations, numerous congressional committees convened hearings to consider whether new legislation was needed for the new technology.[102] In a 1984 hearing on the adequacy of the legislative structure to regulate new biotechnology, the subcommittee chairman took notice of the Reagan Administration's ongoing review of agency authority under existing statutes, as well as the differences between the role of agencies and the role of Congress when faced with new technology:

> The administration must begin by working within the authority it has. We in the Congress are aware that the existing legislation was not drafted with biotechnology in mind – either to promote its development or to protect against its associated risks. Thus, even the most appropriate and intelligent operation of current programs may not suffice, and

101. In its substantive analysis of the FDA's GRAS presumption and labeling provisions under the arbitrary and capricious standard, the court also granted *Chevron* deference to the FDA's interpretation of the FDCA. *See id*. at 178 (citing Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984)). This standard of review is of questionable viability with regard to policy statements because of the United States Supreme Court's decision in *U.S. v. Mead*, 533 U.S. 218 (2001) (stating congressional delegations to agencies not intended to have the force and effect of law are entitled only to deference proportional to their power to persuade). It is unclear whether this lower level of deference, however, would have affected the outcome of the court's ruling, which was sympathetic to the FDA's reading of the FDCA.

102. *See, e.g.*, *Federal Oversight of Biotechnology: Hearing Before the Subcomm. on Hazardous Wastes and Toxic Substances, Senate Comm. On Environment and Public Works*, 100th Cong. 441 (1987); *Releasing Genetically Engineered Organisms Into the Environment: Hearing Before the Subcomm. on Toxic Substances and Environmental Oversight of the Senate Comm. On Environment and Public Works*, 99th Cong. 740 (1986); *Hearing on 1986 Act*, *supra* note 87, at 89; *Biotechnology Development: Hearings Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 99th Cong. 53 (1985); *Planned Releases of Genetically-Altered Organisms: The Status of Government Research and Regulation: Hearing Before the Subcomm. On Investigations and Oversight of the House Comm. On Science and Technology*, 99th Cong. 72 (1985) [hereinafter *Hearing on Planned Releases*]; *Biotechnology Regulation: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. On Energy and Commerce*, 98th Cong. 193 (1984); *Hearing on Biotechnology Regulation*, *supra* note 58, at xx; *Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Natural Resources, Agriculture Research and the Environment and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong. 36 (1983) [hereinafter *Hearing on Environmental Implications*].

> may bring special problems that cannot be properly addressed.[103]

In 1985, Representative Don Fuqua of Florida, chairman of the House Committee on Science and Technology, introduced a bill to define the regulatory structure for biotechnology products.[104] The Biotechnology Science Coordination Act of 1986 ("H.R. 4452") would have amended the TSCA to provide for a three-level regulatory review of field testing and commercial use of biotech products by the USDA and the EPA. A companion bill was introduced in the Senate by Senators Dave Durenberger of Minnesota and Max Baucus of Montana.[105] Although H.R. 4452 was the subject of several hearings, it was not brought to a vote by the ninety-ninth Congress.[106] The Omnibus Biotechnology Act of 1990,[107] the final legislative attempt to alter the 1986 Coordinated Framework, was not reported out of committee.[108]

Throughout a series of hearings beginning in the ninety-eighth Congress in 1983, legislators repeatedly expressed concern about the need to inform or to reassure the public of the safety of the new technology.[109] Subcommittee members cited various reasons for public

103. *Hearing on Biotechnology Regulation*, *supra* note 58, at 2.

104. H.R. 4452, 99th Cong. (1986).

105. S. 1967, 99th Cong. (1985).

106. *See Bill Summary & Status: 99th Congress (1985-1986): H.R. 4452*, LIBR. CONGRESS THOMAS, http://thomas.loc.gov/home/LegislativeData.php?&n=BSS&c=99 (select "Fuqua, Don [D-FL-2]" in the "Choose House Members" field; select the subheading "—Department Operations, Research, and Foreign Agriculture" under "Agriculture" in the "Choose House Committee" field; then click the "Search" button; then follow "H.R.4452" hyperlink) (last visited Sep. 28, 2012).

107. 15 U.S.C. § 2601-2697 (2012).

108. H.R. 5232, 101st Cong. (1990); *see* Adam D. Sheingate, *Promotion v. Precaution: The Evolution of Biotechnology Policy in the United States*, 36 BRIT. J. POL. SCI. 243, 251-52 (2006); *see also* Mary Ellen Jones, Politically Corrected Science: Early Negotiation of U.S. Agricultural Biotechnology Policy 317-24 (Nov. 19, 1999) (unpublished Ph.D. dissertation, Virginia Polytechnic Institute and State University) (on file with Virginia Tech's Digital Library and Archives, Virginia Polytechnic Institute and State University), *available at* http://scholar.lib.vt.edu/theses/available/etd-120199-091346/unrestricted/MEJ-etd-modified.pdf.

109. *See, e.g.*, *Hearing on 1986 Act*, *supra* note 87, at 14 (statement of Rep. Claudine Schneider) ("I think that the proposal for public hearings and public participation is of utmost importance because we are on the edge of a new and emerging era . . . ."); *Hearing on Biotechnology Regulation*, *supra* note 58, at 78 (statement of Rep. John Dingell) ("On regulating biotechnology, one of our major problems is the high level of uncertainty that now exists, or at leas the high level of lack of public confidence in scientific uncertainty."); *Hearing on Biotechnology Regulation*, *supra* note 58, at 78 (statement of Bernadine Healy Bulkley, Deputy Director, Office of Science and Technology Policy) (stating NIH RAC guidelines provided "an opportunity for the public to air its concerns and to have them addressed directly by a group of scientific experts," that NIH press "played a vital role in educating the public," and that congressional hearings aid in "airing public concerns").

concern. Some members focused on past disasters arising from introduction of non-native species into ecosystems, such as kudzu and gypsy moths.[110] Other members cited unanticipated and catastrophic failures of other technologies, such as the nuclear accidents and the Bhopal gas leak tragedy.[111]

In a 1986 hearing on a proposed bill to regulate biotechnology, the subcommittee chairman emphasized that one purpose of the bill was to instill confidence in the public that the testing of biotechnology and the resulting products were safe.[112] The need for public assurance also motivated one of the first hearings held on biotechnology, designed to consider the potential consequences of general release of genetically modified organisms ("GMOs") into the environment and the need for legislation.[113] Ecologists testified that biotechnology products might interact with other organisms in the environment, and that scientists have no reliable models for predicting the probability or scope of risk from the introduction of non-native species.[114]

During this period, legislators devoted substantial attention to assessing whether the existing statutes identified by the Reagan Administration gave agencies sufficient authority to regulate biotechnology. Members of Congress expressed different (and equivocal) views on the question. Representative John Dingell, chairman of the House Committee on Energy and Commerce, in particular expressed doubts about the scope of existing authority.[115]

110. *See, e.g., Hearing on Environmental Implications*, *supra* note 102, at ____. Negative impacts on ecosystems have, in fact, begun to occur in recent years. In some cases, the cause has been excessive use of herbicides like Roundup, which many agricultural products were genetically engineered to resist, rather than from the genetically-engineered traits themselves. *See* William Neuman & Andrew Pollack, *Farmers Cope With Round-Up Resistant Weeds*, N.Y. TIMES, May 4, 2010, at B1; *GMOs Breed 'Superweeds,' Study Says*, PESTICIDE & TOXIC CHEMICAL NEWS, Jan. 25, 2010, at 6. In other cases, scientists have discovered genetically-engineered strains of plants growing widely in the wild, potentially competing with native, non-modified counterparts. *See* Andrew Pollack, *Canola, Pushed by Genetics, Moves Into Uncharted Territories*, N.Y. TIMES, Aug. 9, 2010; Geoffrey Brumfiel, *Genetically Modified Canola 'Escapes' Farm Fields*, NPR (Aug. 6, 2010), http://www.npr.org/templates/story/story.php?storyId=129010499.

111. *See Hearing on Biotechnology Regulation*, *supra* note 58, at 6-7.

112. *Hearing on 1986 Act*, *supra* note 87, at 3-4 (statement of Rep. Fuqua). "[I]t is hoped that this visible and public process – and I have to underline that, Mr. Chairman – of testing biotechnology products will instill the confidence in the general public that the testing is controlled and safe and that the eventual commercial products can be safely used." *Id.* at 9-10. "I think the public would have much greater confidence in what we're attempting to do if there was some type of uniform guidelines." *Id.*

113. *Hearing on Environmental Implications*, *supra* note 102, at 2 (statement of Rep. Albert Gore Jr.).

114. *See id.* at 5-16 (statement of Dr. Martin Alexander, Cornell University); *id.* at 18-28 (statement of Dr. Frances Sharples, Oak Ridge National Laboratory).

115. *See Hearing on Biotechnology Regulation*, *supra* note 58, at 72-73, 83

Referring to statutes including the Federal Insecticide, Fungicide, and Rodenticide Act[116] ("FIFRA"), the Toxic Substances Control Act[117] ("TSCA"), and the Federal Food, Drug, and Cosmetics Act[118] ("FDCA"), Dingell noted that "a lot of these statutes are somewhat old . . . We never considered recombinant DNA and any of the techniques which would be used in exploiting that particular discovery."[119] Dingell analogized the regulation of biotechnology under existing statutes to the well-documented error that "generals always fight the war they are in with the last war's techniques and equipment."[120] Dingell said that the FDCA was probably written with sufficient breadth to cover the new technology, but "I am not sure Congress had the same wisdom in other statutes."[121]

In particular, a great deal of congressional attention focused on whether the TSCA, which gave the EPA jurisdiction over chemicals, was sufficiently broad to encompass biotechnology.[122] The TSCA gives the EPA authority to regulate any "significant new use" of a "chemical substance."[123] The EPA defined living organisms as "chemical substance[s],"[124] and microorganisms created through biotechnology met the definition of "new"; therefore biotechnology was subject to Pre-Market Notification requirements.[125]

(statement of Rep. Dingell).

116. Ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (2012)).

117. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended in scattered sections of 15 U.S.C. (2012)).

118. Ch. 675, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-399f (2012)).

119. *Hearing on Biotechnology Regulation*, *supra* note 58, at 72-73.

120. *Id.* at 83.

121. *Id.* at 73.

122. *See, e.g.*, *Issues in the Federal Regulation of Biotechnology: From Research to Release, Report of Subcomm. on Investigations and Oversight of the H. Comm. on Science and Technology*, 99th Cong., 58-62 (1986) [hereinafter *Issues in the Federal Regulation of Biotechnology*]; *Hearing on 1986 Act*, *supra* note 87, at 3 (statement of Rep. Fuqua); *Hearing on Environmental Implications*, *supra* note 102, at 32-33 (statement of Rep. Gore). The EPA has relied on TSCA to review new intergeneric microorganisms. *See Biotechnology Program Under the Toxic Substances Control Act (TSCA)*, ENVTL. PROTECTION AGENCY, http://www.epa.gov/biotech_rule/pubs/fs-001.htm (last visited Oct. 3, 2012).

123. 15 U.S.C. § 2602(2)(A) (2012) (defining "chemical substance"); *see also Issues in the Federal Regulation of Biotechnology*, *supra* note 122, at 58.

124. *See* Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,886 (Dec. 31, 1984).

125. *See* 15 U.S.C. § 2604(a); Statement of Policy: Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,325 (June 26, 1986) (determining that microorganisms were subject to TSCA "and that through deliberate human intervention contain genetic material from dissimilar source organisms, are 'new' and therefore subject to [premarket

In the 1983 hearing, Congress received testimony on the scope of existing environmental regulations from Geoffrey M. Karny, an analyst for the Office of Technology Assessment, the former science advisory body to Congress.[126] Karny testified that, in his view, the EPA's authority to regulate "chemical substances" under the TSCA should be read to include living organisms.[127] However, even under this broad reading of the statutory language, Karny noted that the TSCA was primarily a notice-based statute, and might not give EPA sufficient regulatory authority to require toxicological data or safety studies to ensure against any substantial environmental risks from biotechnology.[128] Karny suggested that FIFRA might be a more effective tool for the EPA because its premarket registration procedure required safety data.[129] He concluded, "[W]ith the exception of FIFRA there is no federal law that clearly covers the deliberate release of genetically modified organisms into the environment."[130]

In a 1986 hearing on the 1986 Coordinated Framework, the subcommittee chairman questioned a microbiologist on whether the TSCA could be read to allow the EPA's definition of inter-generic microorganisms as "significant new uses" of existing chemical substances. The witness conceded that the definition "grates on the nerves of some scientists."[131] The witnesses responded that such a "strain[ed]" construction was necessary because the statute pre-dated biotechnology:

> So it bothers us a little in the sense that that's not the way you would define it if you were starting from scratch. . . . But in view of the fact that these people are working with an existing statute and with TSCA, I think that they've done the best that could be done.[132]

While some members of Congress expressly questioned the EPA's authority under the TSCA, other testimony suggests that other members of Congress believed that agency authority under some existing statutes was adequate. In a 1984 letter to the President's lead science advisor at the Office of Science and Technology Policy ("OSTP")

notification] requirements of TSCA").

126. *Hearing on Environmental Implications*, *supra* note 102, at 30-53.

127. *See id.* at 32-33. Representative Gore noted that the United States Supreme Court had interpreted the federal utility patent law, 35 U.S.C. § 101, to extend to living organisms. *Id.* at 32 (referring to Diamond v. Chakrabarty, 447 U.S. 303 (1980)).

128. *Hearing on Environmental Implications*, *supra* note 102, at 33.

129. *Hearing on Environmental Implications*, *supra* note 102, at 34.

130. *Hearing on Environmental Implications*, *supra* note 102, at 35.

131. *See Issues in the Federal Regulation of Biotechnology*, *supra* note 122, at 59 (statement of Dr. Monica Riley, American Society for Microbiology).

132. *Id.* at 58-59.

and chair of the Cabinet Council Working Group on Biotechnology, House committee and subcommittee chairs advised that "[w]e believe that existing legislation is probably adequate to provide for appropriate federal review of both research and commercialization of biotechnology."[133]

In a hearing on the 1986 House bill, the committee chairman, Representative Donald Fuqua, was asked whether the bill was necessary to give agencies sufficient authority to regulate genetically engineered products intended for release into the environment. Although Representative Fuqua initially deferred the question to counsel,[134] he later responded, "I don't think we're really extending any authority that they do not currently have or is not currently on law."[135] Instead, the bill was intended to coordinate agency procedures to streamline industry applications and ensure public confidence in the system.[136]

In the hearings, Congress heard testimony from representatives of federal agencies and science advisors within the Reagan Administration regarding their sense of the adequacy of existing legislation. The deputy director of the OSTP, Bernadine Healy Bulkley, described the work and recommendations of an inter-agency working group that began work in April 1984. That work included evaluating the scope of existing regulatory authority; developing policy statements by the EPA, the FDA and the USDA; and creating an inter-agency scientific review mechanism.[137] Finally, the working group recommended creation of "an ongoing coordinated mechanism to address the broader issues within the regulatory process."[138] The purpose of this body was to monitor changes in biotechnology and "to serve as a means of identifying potential gaps in regulation in a timely fashion, making appropriate recommendations for either administrative or legal action."[139]

When asked whether the working group had identified any gaps in current regulatory authority, Bulkley responded, "I think it is very important to stress that we shouldn't be dogmatic about that, and that

133. *See Hearing on Biotechnology Regulation*, *supra* note 58, at 69-70 (reprinting letter from Reps. John D. Dingell, Henry A. Waxman, George E. Brown Jr., and Albert Gore, Jr., to George A Keyworth II, Science Advisor to the President, Office of Science and Technology Policy, May 24, 1984).

134. *See Hearing on 1986 Act*, *supra* note 87, at 9.

135. *Id.*

136. *Id.*

137. *See Hearing on Biotechnology Regulation*, *supra* note 58, at 12 (statement of Bernadine Healy Bulkley).

138. *Id.* at 13.

139. *Id.*

it is important to have a dynamic mechanism in place which can monitor this, and point to areas that could be gaps."[140] In response to a request from a subcommittee member to submit a full answer on that subject for the record, Bulkley submitted the following testimony:

> Although at the present time no gaps in statutory authority to protect the public health and safety have been identified, it is important for the Federal Government to have in place a mechanism to monitor the research, development and commercialization of products processes [sic] in an emerging field such as biotechnology for situations in which new legislation is warranted. . . . When such a need becomes apparent, the administration will recommend appropriate action by Congress.[141]

Federal agency representatives also testified that existing legislation appeared adequate, and that the agencies would monitor the technology and request additional authority if necessary. For example, a witness from the USDA, Karen Darling, testified that the USDA had begun to regulate biotechnology under the Federal Plant Pest Act,[142] the Plant Quarantine Act,[143] and the Virus-Serum-Toxin Act.[144] According to Darling, "[w]e are, however, constantly reevaluating our regulatory position as the state of the art of biotechnology changes. . . . If processes or products are shown to require additional measures, the USDA will amend its regulations or request additional authority."[145] Similarly, the FDA Commissioner, Dr. Frank Young, testified that existing authority was sufficient, and that "if there was an identifiable loophole" in the FDA's statutory authority, "we must bring that to the attention of both the administration and Congress."[146]

One of the justifications given by agency representatives for pursuing a regulatory solution was the expediency of such an approach. Bulkley of OSTP testified that "one of our major concerns in designing [the 1986 Coordinated Framework] is something that we

140. *Id.* at 80.

141. *Id.* at 81-82.

142. Pub. L. No. 85-36, 71 Stat. 31 (1957) (codified as amended at 7 U.S.C. §§ 150aa-150jj), *reorganized by* Plant Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 438 (2000) (codified as amended in scattered sections of 7 U.S.C.).

143. Ch. 308, 37 Stat. 315 (1912) (codified as amended at 7 U.S.C. §§ 151-165, 167) (repealed 2000).

144. Ch. 145, 37 Stat. 832 (1913) (codified at 21 U.S.C. §§ 151-158 (2012)); *see Hearing on Biotechnology Regulation*, *supra* note 58, at 37 (statement of Karen Darling, Deputy Assistant Secretary, Marketing and Inspection Services, USDA).

145. *Hearing on Biotechnology Regulation*, *supra* note 58, at 38 (statement of Karen Darling, Deputy Assistant Secretary, Marketing and Inspection Services, USDA).

146. *Id.* at 88 (statement of Dr. Frank E. Young, Commissioner, FDA).

think would be operational almost immediately."[147] She testified that alternative approaches could have taken up to two years to implement.[148]

Despite the assurance that federal agencies would monitor the technology and request additional authority when necessary, one member of Congress expressed concern that putting in place an immediate regulatory solution might have the effect of deflecting public attention away from the issue. Representative Walgren raised this question to ecologists in discussing the limited development of risk assessment models for biotechnology, despite the attention paid to risk from laboratory testing at the Asilomar Conference in the 1970s.[149] Representative Walgren asked, "Was there an adequate response in the scientific community to develop risk assessment in that context, or did we just become comfortable with the ways that were proposed to deal with handling that research and, therefore, forget about the problem?"[150]

As late as 1990, legislation was introduced in the House that would have overhauled regulation of biotechnology, but the bill was never reported out of committee.[151] Some Capitol Hill staffers with responsibility for biotechnology during that era attributed the waning of congressional interest in part to the existence and apparent viability of the 1986 Coordinated Framework.[152] As one commentator noted, "The [1986] Coordinated Framework, although unable to bring the controversy to full closure because it never addressed the underlying social and political issues, nevertheless had averted the immediate crisis of public clamor for safety by designating a means of oversight of rDNA research and products in the private sector."[153]

D. REGULATION VERSUS LEGISLATION: COMPARING THE APPROACHES

How would the congressional proposal have differed from the

147. *Id.* at 94 (statement of Bernadine Healy Bulkley).

148. *Id.*

149. *See Hearing on Environmental Implications*, *supra* note 102, at 55 (statement of Rep. Walgren). The Asilomar conference resulted in the creation of a federal advisory committee, the Recombinant-DNA Advisory Committee of the National Institute of Health ("RAC-NIH"). *See* SHELDON KRIMSKY, BIOTECHNICS AND SOCIETY 183 (1991); s*ee generally* DONALD S. FREDRICKSON, THE RECOMBINANT DNA CONTROVERSY (2001) (providing a memoir of Asilomar conference and creation of NIH guidelines for recombinant-DNA research).

150. *Id.*

151. Omnibus Biotechnology Act of 1990, H.R. 5232, 101st Cong. (1990).

152. *See* Sheingate, *supra* note 108, at 252 (citing interviews with former House and Senate staff).

153. Jones, *supra* note 108, at 323.

regulatory solution actually implemented? Most significantly, the Biotechnology Science Coordination Act of 1986[154] ("H.R. 4452") would have created a permitting structure for all biotechnology products. Under H.R. 4452, before testing or general release into the environment, all "genetically-engineered organisms" would have been subject to permitting authority of the EPA or the USDA. The bill would have given the EPA authority by amending the Toxic Substances Control Act[155] ("TSCA") to require a permit for any "genetically-engineered organism," defined by the bill as "a bacterium, virus, fungus, plant cell, plant tissue, animal cell, or animal tissue which has been deliberately altered to contain genetic material derived from more than one taxonomic genus, and which is not expressly regulated under section 401 of [this Act][156] or under any other Federal law."[157] The approach of H.R. 4452 to create a regulatory structure for all "genetically-engineered organisms" would have departed substantially from the approach of the Final Statement on Scope and the 1986 Coordinated Framework. The 1986 Coordinated Framework instead established a policy that any decision to regulate should be based on the characteristics of the final product, not the mere fact that the product was created through the use of biotechnology.[158]

The bill also would have resulted in a legislatively-created Biotechnology Science Coordinating Committee ("BSCC") under the Office of Science and Technology Policy ("OSTP").[159] The primary purposes of the legislatively-created BSCC would have been to coordinate information and promote uniformity and cooperation

154. H.R. 4452, 99th Cong. (1986).

155. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended in scattered sections of 15 U.S.C. (2012)).

156. Section 401 of the H.R. 4452 proposed to create the USDA's regulatory authority over genetically-engineered organisms.

157. H.R. 4452, 99th Cong. § 301(b).

158. The Final Statement on Scope, by its own description, "describes a risk-based scientifically sound approach to the oversight of planned introductions of biotechnology products into the environment that focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created." 1992 Final Statement on Scope, *supra* note 35, at 6,753. Similarly, the 1986 Coordinated Framework "takes into account" the recommendations of an Ad Hoc Group of Gorvernment Experts convened by the Organization for Economic Cooperation and Development ("OECD"). The OECD group's recommendations stated, "There is no scientific basis for specific legislation for the implementation of rDNA technology and applications. Member countries should examine their existing oversight and review mechanisms to ensure that adequate review and control may be applied while avoiding any undue burdens that may hamper technological developments in this field." 1986 Coordinated Framework, *supra* note 15, at 23,308.

159. H.R. 4452, 99th Cong. §§ 101-104.

among federal agencies with regard to biotechnology science.[160] The legislatively-created BSCC would have required that meetings be open and that summaries of proceedings be available to the public, with exceptions for protecting confidential business or commercial information.[161] Such meetings would have been announced in the Federal Register at least a week in advance.[162] The BSCC would have made recommendations for scientific research to a Biotechnology Science Review Program ("BSRP"), housed within the OSTP.[163] The BSRP would have been charged with identifying research needs, developing a biotechnology research agenda, and coordinating the use of public and private resources for biotechnology science review and regulation.[164]

In the hearing on the bill, a biotechnology industry witness testified to Congress that the legislatively-created BSCC would be undesirable because it would be difficult to modify or terminate if circumstances required.[165] The BSCC created by the Reagan Administration, in contrast, was created for a duration of two years, renewable based on review of the "continuing need" for the body.[166] The BSCC Charter did not provide for specific democratic accountability for the decision to terminate the BSCC; nor did the Charter specify alternative means of performing the information, coordination, and public participation functions of the BSCC in the event it was not continued.[167] Nonetheless, the acting director of the OSTP described the work of the Domestic Policy Working Group and the Administration's BSCC, and he testified that the regulatory structure established by the executive under existing statutes was sufficient.[168] The acting director also testified that the BSRP proposed by the bill would be "an inappropriate and duplicative role for

160. *Id.* at § 102.

161. *Id.* at § 104(b)-(c).

162. *Id.* at §104(a).

163. *Id.* at § 201.

164. *Id.* at § 201(a).

165. *See Hearing on 1986 Act*, *supra* note 87, at 84 (statement of Richard Godown, Executive Director, Industrial Biotechnology Association) ("[I]f it is created statutorily – it is kind of like building a brick wall – it is a little difficult to get it down when it is no longer needed, and it is especially difficult to modify it.").

166. Charter of the Biotechnology Science Coordinating Committee, *in Issues in the Federal Regulation of Biotechnology, supra* note 122, at 108, 110 (Appendix D).

167. *See generally* Charter of the Biotechnology Science Coordinating Committee, *in Issues in the Federal Regulation of Biotechnology, supra* note 122, at 108;); *see also* Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,175-76 (1985).

168. *See Hearing on 1986 Act*, *supra* note 87, at 29-30 (statement of Richard G. Johnson, Acting Director, OSTP).

OSTP."[169]

The Administration's BSCC was charged with monitoring changes in biotechnology science and identifying potential gaps in regulations, and making recommendations for additional regulatory or legislative action.[170] The BSCC was dissolved after its members failed to reach agreement on the scope of organisms that would be subject to, and exempt from, regulation.[171] Its materials were forwarded to the President's Council on Competitiveness, led by then-Vice President Dan Quayle to promote U.S. industry.[172] The Council on Competitiveness used the BSCC's materials in finalizing the Final Statement on Scope in 1992.[173]

In the 1980s, two parallel conversations were taking place. In the regulatory conversation, emphasis was placed on streamlining regulation, securing competitive advantage for the U.S. biotechnology industry, and utilizing existing agency authority immediately and exclusively. This regulatory conversation claimed that there was "[n]o scientific basis" for new legislation based on the biotechnology process itself. The regulatory apparatus moved with characteristic speed: a review and framework of existing regulation with application to biotechnology was proposed in 1984 and finalized in 1986, and the identified federal agencies developed their initial policy statements within a few years afterward.[174] In contrast, in the legislative conversation, emphasis was placed on protecting the environment; reassuring the public of safety through risk assessment and disclosure; and legislatively filling arguable gaps in agency authority. This conversation claimed that the question of whether new legislation was needed was ultimately a political, not a scientific, one. The process moved deliberately: Numerous hearings were convened by various legislative committees during the mid-1980s, and legislation was introduced, but never brought to a vote, in the House and Senate.

While these two conversations were occurring, the 1986 Coordinated Framework laid the foundation of the regulatory

169. *Id.* at 30.

170. *See Hearing on Biotechnology Regulation*, *supra* note 58, at 13 (statement of Bernadine Healy Bulkley).

171. *See* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 739-40 (2003); *see also* Proposed Statement of Scope, *supra* note 35, at 31,119-20.

172. *See* Proposed Statement of Scope, *supra* note 35, at 31,119-20.

173. *See id.*; *see also* 1992 Final Statement on Scope, *supra* note 35, at 6,754; Proposed Statement of Scope, *supra* note 35, at 31,119-20.

174. *See* Introduction of Organisms and Products, *supra* note 16; USDA – Genetically Engineered Organisms and Products, *supra* note 39; FDA – Statement of Policy, *supra* note 38; EPA – Proposed Policy, *supra* note 38.

apparatus in 1984 and 1986; the frame was erected by the proceeding agency policy statements and rulemakings in the late 80s and early 90s; and the apparatus was secured by the time of the Final Statement on Scope in 1990 and 1992. Did this rapid regulatory action have deliberative consequences, or a "chilling" effect on further public action? Or could the apparatus have been razed if the public consensus arrived at through these two conversations had eventually shifted in favor of new and unique legislative controls on the biotechnology industry? Does the persistence of the framework signal agreement with it by the majority of citizens? Consideration of the political and deliberative history on the biotech debate since the publication of the Final Statement on Scope offers some insights into these questions.

V. DOES THE PERSISTENCE OF THE REGULATORY FRAMEWORK INDICATE DEMOCRATIC CONSENSUS AROUND A REGULATORY SOLUTION?

The relative agility of executive action does not necessarily pose a constitutional dilemma as long as the regulatory framework does not substantially chill democratic deliberation. If deliberation does continue without chilling, and if the law is responsive enough to change as necessary to reflect any new consensus at which the polity ultimately arrives, then prompt regulatory action may be an effective precautionary mechanism while the lengthy process of public debate on new technology proceeds.

In the case of genetically modified organisms ("GMOs"), even if the regulatory framework was put in place before the public had achieved consensus on whether and how to legally control the technology, the 1986 Coordinated Framework and its progeny have now persisted for a quarter-century. During a generation of public debate, Congress has not passed any new legislation substantially altering the legislative authority for GMO regulation. Does that persistence imply public agreement with, or at least acquiescence in, the GMO regulatory framework under pre-existing legislation?

A. PRESENT LEVEL OF PUBLIC KNOWLEDGE OF AND SATISFACTION WITH BIOTECHNOLOGY REGULATION

Research has shown that public debate about biotechnology in the United States has been far from widespread, particularly among those who are more skeptical of the technology. In 2005, researchers surveyed Canadian and American adults to determine the effect of informal personal networks on discussion, awareness and perceptions of genetically-modified foods. Such informal personal networks, along with news media, are the two leading sources of information about new

or unknown risks for most people.[175] Remarkably, of 1,200 American adults surveyed in 2006, fifty-three percent said they had *never* had a conversation about genetically-modified foods.[176] Another nineteen percent of Americans said they had discussed genetically-modified foods "once or twice."[177] Only six percent of Americans said they had discussed the issue "frequently."[178]

Surveys of Americans conducted between 2001 and 2006 for the Pew Initiative on Food and Biotechnology confirm that most of the public had not talked about the technology.[179] While the study reported that consumers relied most on friends and loved ones for information about biotechnology,[180] fifty-four percent of respondents in 2001 said they had heard "not too much" or nothing at all about genetically modified foods sold in grocery stores, and the number of unaware consumers had increased by 2006.[181]

This lack of discussion correlates closely with a low level of information about biotechnology. In the 2005 survey of Americans and Canadians, a majority of respondents said they had "heard of" biotechnology, but only ten percent said they were "very familiar" with it.[182] About as many—nine percent—of Americans were "not at all familiar" with it.[183] Although the prevalence of genetically modified ("GM") foods in supermarkets meant that nearly all Americans had consumed GM foods by the mid-2000s, only twenty-six percent of

175. Roger E. Kasperson et al., *The Social Amplification of Risk: A Conceptual Framework*, 8 RISK ANALYSIS 177, 184 (1988).

176. William K. Hallman, *Predicting Approval and Discussion of Genetically Modified Foods in Canada and the United States*, *in* FIRST IMPRESSIONS: UNDERSTANDING PUBLIC VIEWS ON EMERGING TECHNOLOGIES 20, 29 (Edna F. Einseidel ed., 2005).

177. *Id.*

178. *Id.* In the United States, respondents with more positive reactions to the word "biotechnology" were more likely to have discussed the issue, whereas Canadian respondents with more pessimistic views on the issue were more likely to have discussed it. *Id.* at 33. Both Americans and Canadians were more likely to have discussed the issue if they perceived risk associated with the technology, but the correlation among U.S. respondents was less than half of that among Canadian respondents. *Id.* at 34. Americans were more likely to have discussed biotechnology if they found GMO research morally acceptable, while Canadians were more likely to have discussed it if they found GMO research morally unacceptable. *Id.*

179. Memorandum from The Mellman Group, Inc. to The Pew Initiative on Food and Biotechnology (Nov. 16, 2006) [hereinafter Pew Initiative] (on file with author), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf.

180. *Id.* at 1, 6.

181. *Id.* at 2.

182. *See* William K. Hallman, *GM Foods in Hindsight*, *in* EMERGING TECHNOLOGIES: FROM HINDSIGHT TO FORESIGHT 13, 14 (Edna F. Einsiedel ed., 2008).

183. *Id.*

respondents during that time period believed they had, while sixty percent believed they had not.[184] According to the authors of one study, "[W]hile the battle over biotechnology has raged between experts, most of the shots have passed over the heads of the non-combatants."[185]

Because of the lack of awareness of biotechnology among most consumers, public attitudes about the level of biotechnology regulation are difficult to isolate.[186] Among survey respondents who claimed to be familiar with biotechnology regulation in the early to mid-2000s, however, forty-one percent said there was too little regulation, nineteen percent said the amount of regulation was about right, and sixteen percent said there was too much.[187] Mandatory regulation of GM foods as a category, such as that contemplated by the proposed Biotechnology Science Coordination Act of 1986[188] ("H.R. 4452"), might improve consumer confidence somewhat, though perhaps not dramatically. In the Pew Initiative surveys, interviewers informed survey respondents that "currently the Food and Drug Administration ('FDA') reviews data regarding the safety of genetically modified foods that are voluntarily submitted by food companies."[189] When asked about their views if the FDA were mandated to regulate all GM foods before they entered the market, forty-one percent said they would be more willing to eat them, fourteen percent would be less willing, while thirty-five percent said it would make no difference.[190]

Confusion about the regulatory process itself is suggested by another survey result: on one hand, only fourteen percent of respondents trusted "government regulators" for information about biotechnology, ranking eighth out of eleven options.[191] At the same time, twenty-nine percent said they trusted "the Food and Drug Administration, or FDA" for such information, the fourth most selected option.[192]

184. Pew Initiative, *supra* note 179, at 2.

185. William K. Hallman & Jennifer Metcalfe, *Public Perceptions of Agricultural Biotechnology: A Survey of New Jersey Residents* 36 (1994), *available at* http://ageconsearch.umn.edu/bitstream/18170/1/pa94ha01.pdf.

186. *Cf.* Pew Initiative, *supra* note 179, at 6.

187. *Id.* at 5.

188. H.R. 4452, 99th Cong. (1986).

189. Pew Initiative, *supra* note 179, at 6.

190. *Id.*

191. *Id.* at 6-7.

192. *Id.* Topping the list were "friends and family" (37%), "farmers," (33%), and "scientists and academics" (32%). At the bottom were "government regulators" (14%), "food manufacturers" (14%), "biotechnology companies" (11%) and (ignominiously capitalized by the study authors), "The News Media" (9%). *Id.*

B. MOUNTING EVIDENCE OF ENVIRONMENTAL AND HEALTH IMPACTS OF GMOS

Even though few Americans in the 2000s were aware of or discussing genetically modified organisms ("GMOs"), evidence has begun to mount sustaining some of the concerns about the environmental and human health impacts of GMOs. This evidence directly challenges some of the assumptions upon which the regulatory framework was based. In 1992 under the Bush (I) Administration, the Office of Science and Technology Policy ("OSTP") based its Final Statement on Scope on the conclusion of the National Research Council ("NRC") that "crops modified by molecular and cellular methods [i.e., biotechnology] should pose risks no different from those modified by classical methods for similar traits."[193] Based on that conclusion and conclusions that biotechnology was no different in any material way from traditional plant breeding,[194] the OSTP's Final Statement on Scope announced a policy that products created through biotechnology would not necessarily be subject to any different regulatory oversight than organisms modified through traditional methods.[195]

Two decades after the publication of the Final Statement on Scope, the conclusion that GMOs pose no unique risks has been increasingly called into question. While research is still ongoing, several significant environmental impacts related to herbicide-tolerant crops have been identified. In the past decade, farmers have reported the appearance of several herbicide-resistant weeds, a phenomenon related to genetically-modified seeds.[196] The weeds have developed resistance to the herbicide glyphosate, an extremely popular and effective herbicide sold by Monsanto Corporation under the brand name "Roundup."[197] To enable farmers to spray Roundup on fields without killing crops, Monsanto also sells corn, soybean, and cotton

193. Final Statement on Scope, *supra* note 35, at 6,755.

194. The Final Statement on Scope also cited the NRC's conclusions that "[t]he same physical and biological laws govern the response of" GMOs and organisms modified by classical methods; "[i]nformation about the process used to produce a [genetically-modified] organism is . . . not a useful criterion" for determining whether a product requires oversight; "no conceptual distinction exists" between GMOs and products modified by classical techniques; and "[i]n many respects molecular methods resemble the classical methods for modifying particular strains of microorganisms," but can be "even more useful than the classical methods." *Id.*

195. *Id.* at 6,756.

196. *See* Neuman & Pollack, *supra* note 110, at B1; *GMOs Breed 'Superweeds,' Study Says*, *supra* note 110, at 6.

197. Neuman & Pollack, *supra* note 110, at B1.

seeds that have been genetically modified to tolerate Roundup.[198] Monsanto's "Roundup-Ready" seeds were also heralded as an environmental advantage because they allowed farmers to plant without tilling the soil, a method that controls weeds but also causes soil erosion and runoff of soil, pesticides and herbicides.[199]

In the past decade, however, the easy combination of Roundup-Ready seed and Roundup herbicide has begun to backfire. In 2000, the first Roundup-resistant weed appeared in a Delaware soybean field.[200] Since then, ten resistant weed species in twenty-two states have appeared, primarily in soybean, corn, and cotton fields.[201] The appearance of glyphosate-resistant weeds has sent production agriculture scrambling to outdated herbicides and more labor-intensive strategies to control weeds. The president of the Arkansas Association of Conservation Districts told *The New York Times*, "[Glyphosate-resistant weed growth] is the single largest threat to production agriculture that we have ever seen."[202] The chairman of the Georgia Cotton Commission was quoted as saying, "If we don't whip this thing, it's going to be like the boll weevil did to cotton. . . . It will take it away."[203]

A spokesperson for Monsanto has stated the problem is "a serious issue, but it's manageable."[204] The company acknowledged, however, that it underestimated the pace of the herbicide-resistant weed growth and failed to educate farmers about the need to diversify herbicide use to avoid resistance.[205] Monsanto, which has already lost substantial market share to Chinese-produced glyphosate, faces a further economic threat as farmers who cannot rely on Roundup for weed control cease buying Roundup-Ready seed.[206]

Other researchers have reported the discovery of GM plants crossing with non-modified strains of the plant in the wild. In 2010, researchers from several major U.S. universities and the EPA reported

198. *Id.*
199. *Id.*
200. *Id.*
201. *Id.* The problem has been more extreme in the South, but by 2010 had spread as far north as Missouri, home of the St. Louis-area-based Monsanto. *See* Georgina Gustin, *Roundup's Potency Slips, Foils Farmers; Resistant Weeds Are Spreading North, Adding Costs, Workload*, ST. LOUIS POST-DISPATCH, July 25, 2010, at A1. One herbicide-tolerant crop, pigweed, can grow up to three inches a day and reach heights of seven feet, and is so hardy that it can damage harvesting equipment. Neuman & Pollack, *supra* note 110, at B1.
202. Neuman & Pollack, *supra* note 110, at B1.
203. *Id.*
204. *Id.*
205. Gustin, *supra* note 201, at A1.
206. *Id.*

that eighty-six percent of canola plants collected from alongside roadways in North Dakota tested positive for glyphosate resistance.[207] The authors stated that at least two of the samples tested positive for multiple transgenic traits, which have not been released commercially.[208] According to one of the study's co-authors, "this finding suggests that feral populations are reproducing and have become established outside of cultivation."[209] Monsanto claimed that these findings merely reflected the fact that ninety percent of canola crops are now genetically modified.[210] While researchers generally agreed that the GM canola plants were not likely to out-compete other wild plants,[211] the findings raised concerns regarding the potential for "coexistence" of GM and non-GM varieties of the same plant.[212]

Other researchers have recently begun to establish links between GMO plants and harm to human and animal health. In one study, researchers in Quebec, Canada, found that pregnant and non-pregnant women showed lingering effects of exposure to herbicides closely related to GM plants. Further, the study found that the effects were transferrable through the placenta to fetuses.[213] Monsanto has responded that "the authors do not report or allege adverse effects in this paper—all of the women in this study were healthy and all of the infants were normal."[214]

207. *See* Andrew Pollack, *Canola, Pushed by Genetics, Moves Into Uncharted Territories*, N.Y. TIMES, Aug. 9, 2010, at D3; Brumfiel, *supra* note 110.

208. *GM Canola Spread Widely Outside N.D. Farms: Study*, CBC NEWS (Aug. 6, 2010), http://www.cbc.ca/news/world/story/2010/08/06/gm-canola-wild-north-dakota.html.

209. *Id.* (quoting Cynthia Sagers, associate professor of biological sciences at the University of Arkansas).

210. *See* Pollack, *supra* note 19 at D3.

211. *See* Brumfiel, *supra* note 110.

212. *See* Pollack, *supra* note 19 at D3; Brumfiel, *supra* note 110.

213. *See* Aziz Aris & Samuel Leblanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, 31 REPRODUCTIVE TOXICOLOGY 528, 532 (2011) (online ahead of press), available at http://somloquesembrem.files.wordpress.com/2010/07/arisleblanc2011.pdf. In the study, the researchers tested both pregnant and non-pregnant women for the presence of glyphosate and gluphosinate, another common herbicide for which herbicide-tolerant GM seed varieties have been developed. *Id.* at 529. The study reported that one metabolite of the gluphosinate herbicide was detected in 100% of the maternal and umbilical cord blood samples, and in 67% of the non-pregnant women's blood samples. *Id.* at 531 tbl.3. Another metabolite of gluphosinate was detected in 93% of maternal blood samples, 80% of fetal blood samples, and 69% of non-pregnant women's blood samples. *Id.* at 532. The study noted that, while the human health dangers of GM seed themselves is uncertain, health risks may come from increased exposure to herbicides associated with GM foods. *Id.* at 1.

214. MONSANTO CO., MONSANTO VIEWPOINTS 1 (2011), *available at* http://www.monsanto.com/newsviews/Documents/Aris_LeBlanc_reproductive_toxicology.pdf (last visited Mar. 14, 2012).

Other research has suggested a link between herbicide-tolerant GM plants, increased use of herbicides, and animal or human health. In 2009, French researchers reported that rats fed three different varieties of GM corn for three months showed significant disturbances in liver and kidney function.[215] The rats were fed glyphosate-tolerant (Roundup-Ready) maize and two varieties of maize engineered with *Bacillus thuringiensis* (*Bt*) toxins, a bacteria-derived insecticide.[216] The study authors concluded that "our data strongly suggests that these GM maize varieties induce a state of hepatorenal toxicity."[217] The authors noted that the effects might be the result of the consumption of glyphosate and *Bt* toxin residues associated with the feed,[218] "although unintended metabolic effects due to mutagenic properties of the GM transformation process cannot be excluded."[219]

In January 2011, just before the USDA's decision to deregulate Roundup-Ready alfalfa, a well-known plant pathologist sent a confidential letter to Department of Agriculture Secretary Vilsack, warning Vilsack of a newly discovered plant pathogen associated with the overuse of glyphosate.[220] In the letter, which was leaked to the public,[221] Dr. Don Huber, professor emeritus at Purdue University, reported the discovery of a previously-unknown organism "that appears to significantly impact the health of plants, animals, and probably human beings."[222] The organism, found in high concentrations in Roundup-Ready soybeans and corn, had been confirmed in a wide variety of livestock that had experienced spontaneous abortions and infertility, and had also been linked to two pervasive plant diseases driving down soy and corn crop yields.[223] In the letter, Huber explained the decision to inform the USDA of the danger before finalizing the research:

> We are informing the USDA of our findings at this early stage, specifically due to your pending decision regarding

215. Joël Spiroux de Vendômois et al., *A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health*, 5 INT'L J. BIOLOGICAL SCI. 706, 717 (2009).

216. *Id.* at 707.

217. *Id.* at 717.

218. *Id.* at 707, 717.

219. *Id.* at 717.

220. Letter from Col. (Ret.) Don M. Huber, Emeritus Professor, Purdue Univ., to Thomas Vilsack, Sec'y, USDA (Jan. 16, 2011) (on file with author), *available at* http://farmandranchfreedom.org/letter-dr-huber-roundup-animal-miscarriage-infertility/.

221. *See* Letter from Col. (Ret.) Don M. Huber, Emeritus Professor, Purdue Univ., to European Comm'n (Mar. 2011), *available at* http://farmandranchfreedom.org/letter-european-commision-dr-huber-gmo-roundup/.

222. Letter from Huber to Vilsack, *supra* note 220.

223. *Id.*

> approval of [Roundup-Ready] alfalfa. Naturally, if either the [Roundup-Ready] gene or Roundup itself is a promoter or co-factor of this pathogen, then such approval could be a calamity. Based on the current evidence, the only reasonable action at this time would be to delay deregulation at least until sufficient data has exonerated the [Roundup-Ready] system, if it does.[224]

In the letter, Huber described the threat as "unique and of a high risk status."[225] Huber requested access to the USDA data, urged a moratorium on deregulation of Roundup-Ready crops, and asked the USDA to devote resources to additional research.[226]

Monsanto has publicly dismissed the research.[227] In a letter on its website responding to Huber's claims, Monsanto claimed that "[i]ndependent field studies and lab tests by multiple U.S. universities and by Monsanto prior to, and in response to, these allegations do not corroborate [Huber's] claims."[228] Other scientists have also expressed skepticism, particularly due to the lack of research offered in support of the claims made in the letter.[229] The USDA acknowledged that it received the letter from Huber, delivered by a third party.[230] A USDA spokesperson was quoted as saying it did not investigate the matter because "'we do not respond to third-party letters.'"[231] The USDA approved deregulation of Roundup-Ready alfalfa on January 27, 2011.[232]

C. GMO REGULATION REFORM ACTIVISM AND ITS IMPACTS

Since the late 1990s, some citizens have staged campaigns to press

224. *Id.*

225. *Id.*

226. *Id.*; *see also* Letter from Huber to European Comm'n, *supra* note 221 ("I feel I would be totally irresponsible to ignore my own research and the vast amount of published research now available that support the concerns we are seeing in production agriculture, without bringing it to the attention of the Secretary of Agriculture with a request for him to initiate the much needed independent research.").

227. *See* P.J. Huffstutter, *As Soybeans Die, A Theory Blooms; But Experts Pan Letter Asserting Link Between Disease, Gene-Modified Crops*, CHICAGO TRIBUNE, Apr. 15, 2011, at 21.

228. *Statement About alleged Plant Pathogen Potentially Associated with Roundup Ready Crops*, MONSANTO CO. (Feb. 22, 2011), http://www.monsanto.com/newsviews/Pages/huber-pathogen-roundup-ready-crops.aspx.

229. *See* Huffstutter, *supra* note 227.

230. *See* Michael J. Crumb, *Scientists Question Claims in Biotech Letter*, LEWISTON MORNING TRIBUNE (IDAHO), Apr. 4, 2011.

231. *Id.*

232. *See* Record of Decision, Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status, Jan. 27, 2011, http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_rod.pdf.

for greater regulation of GMOs. Strategies have included public protests, petitions to regulatory agencies, and lawsuits. In 1996, a group called Mothers For Natural Law ("MFNL") launched a public awareness campaign against GMOs, and in 1998 and 1999 received 500,000 signatures on a petition calling for labeling of GMO products.[233] MFNL has allied with the Organic Consumers Association ("OCA"), an organization formed in 1998 to "promot[e] the views and interests of the nation's estimated 50 million organic and socially responsible consumers." [234]On its website, OCA calls for a "global moratorium on genetically engineered foods and crops."[235] Organizations that have actively campaigned for greater regulation of GMOs or genetically-engineered foods include the Center for Food Safety, a legal and policy advocacy group;[236] the Union of Concerned Scientists, an alliance of scientists that produces technical reports and advocacy on scientific matters of public interest;[237] and internationally-focused environmental interest groups such as Greenpeace.[238] In addition, the Pew Charitable Trusts sponsored the Pew Initiative on Food and Biotechnology to spotlight policy issues and serve as a credible source of information and ideas.[239]

Like the MFNL petition, much anti-GMO activism has focused on the issue of labeling of genetically-engineered foods. OCA currently sponsors a grassroots initiative aimed at requiring such labeling. The project, called "Millions Against Monsanto," organized a march from New York to Washington, D.C. in October 2011.[240] Marchers asked

233. For a good discussion of this campaign and other early anti-GMO activism efforts, see Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. Rev. 733, 753-54 (2003); *see also* MOTHERS FOR NATURAL LAW, http://www.safe-food.org/ (website of Mothers for Natural Law).

234. *See About the OCA: Who We Are and What We're Doing*, ORGANIC CONSUMERS ASSOCIATION, http://www.organicconsumers.org/aboutus.cfm (last visited Mar. 14, 2013).

235. *Id.*

236. The Center for Food Safety is a non-profit advocacy organization "working to protect human health and the environment by curbing the use of harmful food production technologies by promoting organic and other forms of sustainable agriculture." *See About the Center for Food Safety*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/about-us (last visited Apr. 16, 2013). Strategies include legal actions, scientific and policy reports, educational materials, market pressure, and grassroots campaigns. *Id.*

237. *See About Us*, UNION OF CONCERNED SCIENTISTS, http://www.ucsusa.org/about/ (last visited Mar. 14, 2013).

238. *See Sustainable Agriculture: No to GMOs*, GREENPEACE, http://www.greenpeace.org/usa/en/campaigns/genetic-engineering/ (last visited Mar. 14 2013).

239. *See Agricultural Biotechnology*, PEW CHARITABLE TR., http://www.pewtrusts.org/our_work_detail.aspx?id=442 (last visited Mar. 21, 2013).

240. *See* Jenna Telesca, *Natural Food Industry Brings Attention to GMOs*,

passersby to send comments to the FDA through the "Just Label It" campaign, another grassroots campaign sponsored by a variety of natural food organizations and businesses such as Organic Valley and Stonyfield Farms.[241] The Just Label It campaign joined in a petition to request that the agency require labeling of GMO foods.[242] The petition to the FDA was filed by the aforementioned advocacy organization, the Center for Food Safety, in October 2011.[243]

Surveys indicate that consumers strongly support labeling. A survey conducted for Just Label It in February 2012 indicated that ninety-one percent of U.S. general election voters favored labeling GMO foods, with eighty-one percent strongly supporting such measures.[244] Even after being read arguments for and against labeling, eighty-nine percent continued to support labeling measures, with seventy-seven percent strongly in favor.[245]

These results do not necessarily indicate a sharp increase in awareness of GMOs, however, because the report does not indicate what level of knowledge, if any, respondents had about GMOs before completing the survey. Moreover, surveys indicating overwhelming support for GMO labeling are called into question by the failure of California's Proposition 37 in November 2012. The measure, which would have made California the first state to require labeling of GM foods, was defeated fifty-three percent to forty-seven percent.[246] Early surveys had indicated sixty percent support for the measure,[247] a substantial majority but considerably less than the ninety-one percent suggested by the Just Label It survey. Opponents of the measure

SUPERMARKET NEWS (Oct. 17, 2011), http://supermarketnews.com/speciality/natural-food-industry-brings-attention-gmos.

241. *See id.*; *see also Partners*, JUST LABEL IT!, http://justlabelit.org/partners/ (last visited Mar. 14, 2013); *Genetic Engineering in Agriculture*, UNION CONCERNED SCIENTISTS, http://www.ucsusa.org/food_and_agriculture/our-failing-food-system/genetic-engineering/ (last visited Mar. 14, 2013).

242. *See* CTR. FOR FOOD SAFETY, CITIZEN PETITION BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATION (2011), *available at* http://www.centerforfoodsafety.org/files/ge-labeling-petition-10-11-2011-final1_21309.pdf; *see also Record-Breaking One Million Public Comments Demand FDA Label Genetically Engineered Foods*, CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/issues/307/factory-farms/press-releases/700/record-breaking-one-million-public-comments-demand-fda-label-genetically-engineered-foods (last visited Mar. 14, 2013) [hereinafter *Labeling Petition*].

243. *Labeling Petition*, *supra* note 242.

244. *See* THE MELLMAN GROUP, INC., VOTES OVERWHELMINGLY SUPPORT A LABELING REQUIREMENT FOR GE FOODS 1 (2012), *available at* http://justlabelit.org/wp-content/uploads/2012/01/Mellman-Survey-Results.pdf.

245. *Id.* at 3.

246. *See* Andrew Pollack, *After the Loss, the Fight to Label Modified Food Continues*, N.Y. TIMES, Nov. 8, 2012, at B4.

247. *Id.*

outspent supporters by five to one, with Monsanto, the largest producer of genetically-modified seeds, contributing $8.1 million to the opposition campaign, nearly as much as the $9.2 million raised in total by supporters.[248]

In the 2011 petition to the FDA filed by the Center for Food Safety, petitioners urged the FDA to reconsider their 1992 policy statement on labeling of genetically engineered foods.[249] In its 1992 Statement of Policy: Foods Derived from New Plant Varieties ("FDA – Policy Statement"), FDA established the policy that genetically-engineered foods could be marketed without special labeling.[250] In the FDA – Policy Statement, FDA stated that it had no information to show that genetically-engineered foods "differ from other foods in any meaningful or uniform way, or that, as a class, foods develop by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding."[251] The FDA interpreted section 201(n) of the Federal Food, Drug, and Cosmetics Act[252] ("FDCA") as not requiring labeling of genetically-engineered foods without evidence of health risks or other "meaningful" changes in the food product.[253]

The FDA underscored the policy from the FDA – Policy Statement in a 2001 statement of guidance for industry on voluntary labeling of foods ("2001 Statement of Guidance"). In the 2001 Statement of Guidance, the FDA advised that voluntary labeling of a food that was not bioengineered could itself be misleading if it "implies that the labeled food is superior to foods that are not so labeled."[254] Emphasizing its policy from the FDA – Policy Statement, the FDA supported this policy by noting that the FDA has "concluded that the use, or absence of use, of bioengineering in the production of a food" or ingredient does not, in and of itself, mean that there is a material

248. *Id.*

249. *See* CTR. FOR FOOD SAFETY, *supra* note 242, at 2-3.

250. FDA – Statement of Policy, *supra* note 38, at 22,984. The FDCA provided that foods shall be deemed misbranded if their labeling "fails to reveal facts . . . *material* with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual." 21 U.S.C. § 321(n) (2012).

251. FDA – Statement of Policy, *supra* note 38, at 22,991.

252. Ch. 675, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301-399f (2012)).

253. FDA – Statement of Policy, *supra* note 38, at 22,991. It is important to realize that section 201(n) of the FDCA translates to 21 U.S.C. § 321.

254. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance, 66 Fed. Reg. 4,839, 4,840 (2001).

difference in the food.[255] Therefore, a label statement that expresses or implies that a food is superior (e.g., safe or of higher quality) because it is not bioengineered would be misleading.[256] The FDA gave no specific guidance as to what might be considered an implication of "higher quality," but only noted that it would consider the entire label to determine whether a statement was misleading.[257]

The Center for Food Safety's 2011 labeling petition urged the FDA to treat genetically-engineered foods as misbranded under the FDCA unless the foods contained a label with the words "GENETICALLY ENGINEERED." Petitioners argued that the lack of such label "fails to reveal facts . . . material" to consumers within the meaning of the statute. The petition echoed arguments rejected by a federal district court in 2001. In *Alliance for Bio-Integrity v. Shalala*,[258] plaintiffs challenged the FDA's 1992 decision not to require labeling of GMOs.[259] Plaintiffs argued that the information was "material" under the FDCA because consumers sought to rely on the information in making purchasing decisions.[260] The district court held that the question of materiality under the FDCA was a "factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact."[261] The court deferred to the FDA's reading of Section 201(n) and its determination that changes from genetic modification were not "material" unless they led to "unique risks to consumer health or uniform changes to food derived through rDNA technology."[262]

More than a decade after *Alliance for Bio-Integrity*, the Center for Food Safety's 2011 labeling petition renewed the argument about the meaning of "material" in section 201(n) of the FDCA. First, the petition argued that, under section 201(n), the "material" standard is merely exemplary, not exhaustive, of factors that may cause a label to be false or misleading.[263] Failure to label products as genetically engineered is misleading, the petitioners argued, because recent scientific studies of GMOs reveal differences from foods not created

255. *Id.*
256. *Id.*
257. *Id.*
258. 116 F. Supp. 2d 166 (D.D.C. 2001).
259. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 171 (D.D.C. 2001).
260. *Alliance for Bio-Integrity*, 116 F. Supp. at 178.
261. *Id.* at 179.
262. *Id.* at 178-79.
263. *See Labeling Petition*, *supra* note 242, at 9-10 (citing the section 201(n) requirement).

through genetic engineering.[264] Further, the petition argued that consumers are misled by failure to label a product that lacks a proven safety record differently from products whose safety has been proven over many generations—an argument that would apply to all GMO products and foods derived from them because of their relative novelty.[265] The petition pointed out that FDA uses a "voluntary consultation" process for new genetically engineered foods and does not conduct safety testing.[266]

Another argument offered in the petition for requiring mandatory labeling is that consumer demand illustrates numerous non-organoleptic reasons why consumers may choose not to purchase genetically-modified foods, such as potential health impacts, unknown risks, and environmental impacts.[267] The petition noted that the FDA did consider consumer interest in such properties as a factor when it decided to require labeling of irradiated foods.[268] The petition tacitly suggested that the court in *Alliance for Bio-Integrity* misconstrued this argument by holding that consumer demand for information, by itself, did not make information "material" under section 201(n) of the FDCA.[269]

The labeling campaign has been one of the most visible, but not the only, grassroots effort for greater regulation of GMOs. For example, the Center for Food Safety has also been active in filing lawsuits challenging the USDA's deregulation of certain GMO plants, including Roundup-Ready alfalfa, sugar beets, and freeze-tolerant eucalyptus.[270] This litigation strategy has met with some success: in

264. *See Labeling Petition*, *supra* note 242, at 10. For example, the petition noted that the United States Court of Appeals for the Sixth Circuit in a 2010 case recognized that record evidence demonstrated a compositional difference in milk from cows treated with the genetically engineered hormone rbST, and milk from untreated cows, a finding that contradicted FDA's position. *Id.* at 11 (citing Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 636-37 (6th Cir. 2010)). The court in that case noted that the compositional difference in milk from treated and non-treated cows need not be proven definitively; it is sufficient, for purposes of labeling, that the absence of rBST in milk from untreated cows can be demonstrated, while such absence cannot be verified in the milk of treated cows. *Int'l Dairy Foods Ass'n*, 622 F.3d at 637.

265. *Labeling Petition*, *supra* note 242, at 10.

266. *Id.* at 11.

267. *Id.* at 12.

268. *Id.* at 14.

269. *Id.* at 13.

270. *See, e.g.*, Ctr. for Biological Diversity v. Animal & Plant Health Inspection Serv., No. 10-14175-CIV, 2011 WL 4737405 (S.D. Fla. Oct. 6, 2011) (providing an example of an unsuccessful challenge to an environmental assessment approving freeze-tolerant eucalyptus field tests); Complaint, Ctr. for Food Safety v. Vilsack, No. CV11 1310 EDL (N.D. Calif. Mar. 18, 2011) (challenging deregulation of alfalfa after an environmental impact statement under the National Environmental Policy Act); Ctr.for Food Safety v. Vilsack, No. C 08-00484 JSW, 2009 WL 3047227 (N.D. Calif. Sep. 21,

the alfalfa litigation, a U.S. district court ordered that the USDA had to consider the impacts of GMO contamination of non-GMO crops as a "significant effect on the human environment" under the National Environmental Policy Act[271] ("NEPA").[272] Although the remedies portion of the decision was reversed and remanded by the United States Supreme Court, the application of NEPA review to GMO deregulation decisions was not appealed.[273]

The Union of Concerned Scientists ("UCS"), an alliance of citizens and scientists that offers technical analysis and advocacy on a range of scientific issues of public concern, has actively promoted a more precautionary approach to GMO development and regulation.[274] According to the UCS website, its official position on GMOs is that "the technology has potential benefits, but we are critics of its commercial application and regulation to date."[275] UCS advocates, among other measures, a more rigorous and conservative regulatory approach to approval of GMO-based products, and support for food labeling laws.

Despite these efforts, most Americans, at least as of the mid-2000s, had *never* had a conversation about biotechnology.[276] Even if more recent activities succeeded where earlier efforts failed and placed the issue within the public attention of the majority of Americans, public awareness and debate for most citizens on those issues is, at best, nascent— more than a quarter-century after the creation of the regulatory framework. If surveys showed that the majority of Americans were aware of biotechnology, were in favor of its development, and were unconcerned about risk, GMO activists could fairly be viewed as another vocal minority in a pluralist democracy. In an era of rising public concern about the health and safety of America's food system, however, the lack of impact of GMO grassroots activities on overall public awareness of GMOs is notable.[277]

2009) (providing an example of a successful challenge to deregulation of glyphosate-resistant sugar beets based on an environmental assessment under the National Environmental Policy Act); Geertson Seed Farms v. Johanns, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007) (providing an example of a successful challenge to deregulation of glyphosate-resistant alfalfa after an environmental assessment); Int'l Ctr. for Tech. Assessment v. Johanns, 472 F. Supp. 2d 8 (D. Mass. 2007) (challenging, with success, the USDA's categorical exclusion from the National Environmental Policy Act analysis of open-air field tests of glyphosate-resistant creeping bentgrass and Kentucky bluegrass).

271. Pub. L. No. 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. §§ 4321-4347 (2012)).

272. *See Geertson Seed Farms*, 2007 WL 518624, at *19.

273. *See* Monsanto v. Geertson Seed Farms, __ U.S. __, 130 S. Ct. 2743, 2749 (2010).

274. *Genetic Engineering in Agriculture*, *supra* note 241.

275. *Id.*

276. *See* Hallman, *supra* note 176, at 29.

277. In the 2000s, public awareness of the food system was raised to unprecedented

D. CONGRESSIONAL ACTION TO REVISE PLANT BIOTECHNOLOGY LEGISLATION

Grassroots efforts to encourage labeling of genetically-engineered foods and other regulation of GMOs have not been mirrored by significant action in Congress to revise or even reconsider the 1980s regulatory framework. Since H.R. 4452 failed to unseat the 1986 Coordinated Framework in the 1980s, Congress has taken relatively little action to modify the legislative authority on which the established regulatory structure is based.

The one issue to receive some recent attention from Congress is the issue of labeling of GMOs under the FDCA. On April 24, 2013, the Genetically Engineered Food Right-to-Know Act ("GE Food Right-to-Know Act") was introduced in both the House and, for the first time since 2000, in the Senate.[278] The bills, introduced by Senator Barbara Boxer and Representative Pete DeFazio, were co-sponsored by nine Senators and twenty-two Representatives.[279] Both the House and Senate versions of the GE Food Right-to-Know Act begin with legislative findings that "the process of genetic engineering results in material changes to food derived from those organisms," and that the FDA "requires the labeling of more than 3,000 ingredients, additives, and processes."[280] The bills would amend the FDCA to provide that the genetic engineering is a "material" fact that must be on food labels.

levels through the success of mainstream books and movies. Michael Pollan's 2006 investigation of the modern food system, *The Omnivore's Dilemma*, reportedly sold more than 250,000 copies in 2008 alone. *See* Wesley Longhofer et al., *A Fresh Look at Sociology Bestsellers*, AM. SOC. ASS'N: CONTEXTS, http://contexts.org/articles/spring-2010/a-fresh-look-at-sociology-bestsellers/ (last visited Apr. 16, 2013). By comparison, the top-selling book written by a professional sociologist in 2008 sold 10,000 copies. *Id.* The 2009 movie *Food Inc.*, a critique of corporate agriculture that focused extensively on corporate ownership of plant biotechnology patents, grossed almost $4.5 million dollars at the box office and ranked 31st among all-time top-grossing documentaries. *See Food Inc.*, NUMBERS: BOX OFF. DATA, MOVIE STARS, IDLE SPECULATION, http://www.the-numbers.com/movies/2009/0FOIN.php (last visited Apr. 16, 2013); *Genres: Documentary*, BOX OFFICE MOJO, http://www.boxofficemojo.com/genres/chart/?id=documentary.htm (last visited Apr. 16, 2013).

278. *See* S. 809, 113th Cong., 159 CONG. REC. 2960 (2013), *available at* http://www.centerforfoodsafety.org/files/labbill2013_26678.pdf (introducing S. 809 to require labeling of genetically engineered foods); H.R. 1699, 113th Cong.,159 CONG. REC. 2297 (2013), *available at* http://www.centerforfoodsafety.org/files/defazi_021_xml_34551.pdf (introducing H. 1699 to require labeling of genetically engineered foods); *see also Federal Legislation Introduced to Require the Labeling of Genetically Engineered Foods*, CTR. FOR FOOD SAFETY (Apr. 24, 2013), http://www.centerforfoodsafety.org/press-releases/2116/federal-legislation-introduced-to-require-the-labeling-of-genetically-engineered-foods.

279. *See* S. 809; H.R. 1699.

280. *See* S. 809; H.R. 1699.

Senator Boxer and Representative DeFazio had written to FDA Commissioner Margaret Hamburg in March 2012, joined by more than fifty members of the House and Senate in support of the Center for Food Safety's 2011 petition.[281] In the letter, the bicameral group of legislators noted the poor fit between the FDCA, written long before biotechnology was contemplated, and regulation of genetically-engineered food. The letter stated that the FDA's current interpretation of the FDCA "uses 19th century concepts to regulate 21st century food technologies."[282] The letter criticized the FDA's interpretation of the "material" standard of section 201(n) in the FDCA as limited only to organoleptic properties, arguing that "novel food technologies" like genetic engineering on a commercial scale had "so far slipped underneath FDA's limited threshold for materiality" because molecular changes cannot necessarily be detected by the senses.[283]

The GE Food Right-to-Know Act, if passed, would undermine one of the basic assumptions of the 1986 Coordinated Framework: that GMO foods are no different than their conventional counterparts and should not be regulated on the basis of the process used to create them.[284] Previous versions of the bill, however, have received little attention from the House or the Senate. The GE Food Right-to-Know Act was first introduced in Congress by the most notable congressional opponent to the assumptions of the 1986 Coordinated Framework, Representative Dennis Kucinich of Ohio. For over a decade, Representative Kucinich repeatedly introduced three bills that would have altered the governing legislation. One bill, called the Genetically Engineered Right to Know Act,[285] ("GE Right to Know Act") would

281. Letter from Barbra Boxer, U.S. Senator, and Peter Defazio, U.S. Congressman, to Margaret Hamburg, Commisioner, FDA (Mar. 12, 2012) (on file with author), *available at* http://boxer.senate.gov/en/press/releases/031212.cfm. The letter was led by Senator Barbara Boxer and Representative Peter DeFazio. *See* Letter from Barbara Boxer, U.S. Senator, Peter DeFazio, U.S. Congressman, Michael Taylor, Deputy Comm'r for Food, FDA, to Margaret Hamburg, Comm'r, FDA (Feb. 2011) (on file with author), *available at* http://www.nationalorganiccoalition.org/GMO/Final%20Boxer-DeFazio%20GE%20Labeling%20Letter%202%202%2012.pdf. The letter to Commissioner Hamburg was joined by nine Senators and 44 Representatives. All signatories were Democrats.

282. Letter from Barbra Boxer and Peter Defazio to Margaret Hamburg, *supra* note 281.

283. *Id.*

284. *See* 1986 Coordinated Framework, *supra* note 15, at 23,308 (noting no scientific basis for regulating GMO products distinctly from other products); *see also* Final Statement on Scope, *supra* note 35, at 6,753 (focusing regulatory activity on characteristics of product, not process used to create it).

285. *See* H.R. 3553, 112th Cong. (2011); H.R. 5577, 111th Cong. (2010); H.R. 6636, 110th Cong. (2008); H.R. 5269, 19th Cong. (2006); H.R. 2916, 108th Cong. (2003); H.R.

have amended the FDCA and two other statutes[286] to treat as misbranded any genetically-engineered food, unless the food label included the words "GENETICALLY ENGINEERED" and the statement, "THIS PRODUCT CONTAINS A GENETICALLY ENGINEERED MATERIAL, OR WAS PRODUCED WITH A GENETICALLY ENGINEERED MATERIAL."[287] In its findings, the bill addresses the controversy over FDA's interpretation of the term "material":

> The Congress finds as follows:
>
> (1)The process of genetically engineering foods results in the material change of such foods.
>
> (2)The Congress has previously required that all foods bear labels that reveal material facts to consumers.
>
> (3)Federal agencies have failed to uphold Congressional intent by allowing genetically engineered foods to be marketed, sold and otherwise used without labeling that reveals material facts to the public.[288]

The GE Right to Know Act had fifty-eight co-sponsors when it was introduced in 1999.[289] The number of cosponsors dwindled to just eleven in the 110th Congress[290] and nineteen in the 111th Congress,[291] but rebounded to thirty-one after the bill was re-introduced in the 112th Congress in 2011.[292]

Two other Kucinch-led bills, the Genetically Engineered Food Safety Act ("GE Food Safety Act") and the Genetically Engineered Technology Farmer Protection Act ("GE Technology Farmer Protection Act") were re-introduced frequently between 1999 and 2011.[293] The

4814, 107th Cong. (2002); H.R. 3377, 106th Cong. (1999).

286. The other modified statutes are the Federal Meat Inspection Act, ch. 2907, 34 Stat. 1260 (1907) (codified as amended at 21 U.S.C. §§ 601-683 (2012)), and the Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (1957) (codified as amended at 21 U.S.C. §§ 451-472 (2012)). To date, no genetically-engineered meat or poultry products have been approved for marketing.

287. H.R. 5577, 111th Cong. § 3 (2010).

288. *Id.* at § 2.

289. *See Bill Summary & Status: 106th Congress (1999-2000): H.R. 3377: Cosponsors*, LIBR. CONGRESS THOMAS, http://thomas.loc.gov/cgi-bin/bdquery/z?d106:HR03377:@@@P.

290. *See Bill Summary & Status: 110th Congress (2007-2008): H.R. 6636: Cosponsors*, LIBR. CONGRESS THOMAS, http://thomas.loc.gov/cgi-bin/bdquery/z?d110:HR06636:@@@P.

291. *See Bill Summary & Status: 111th Congress (2009-2010): H.R. 5577: Cosponsors*, LIBR. CONGRESS THOMAS, http://thomas.loc.gov/cgi-bin/bdquery/z?d111:hr5577:@@@P.

292. *See Bill Summary & Status: 112th Congress (2011-2012): H.R. 3553: Cosponsors*, LIBR. CONGRESS THOMAS, http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR03553:@@@P.

293. *See* Genetically Engineered Safety Act, H.R. 3554, 112th Cong. (2011); H.R.

first bill, the GE Food Safety Act, would have amended the FDCA to require that the FDA treat genetically-engineered material in foods as "food additives."[294] The bill expressly rejected the presumption previously announced by the FDA that genetically-engineered foods would be presumed to be "generally recognized as safe" ("GRAS") and therefore not subject to food additive review.[295] The second bill, the GE Technology Farmer Protection Act, creates new legal protections for farmers and workers related to biotechnology patents, such as mandatory product disclosure requirements;[296] prohibitions on certain limitations in technology licenses,[297] protections against cross-pollination of non-GMO crops;[298] and liability rules for injuries from environmental releases.[299] The bill would also have amended the Federal Insecticide, Fungicide, and Rodenticide Act[300] ("FIFRA") to require the EPA to review and possibly limit the use of certain plant-incorporated pesticides that may encourage pests to develop resistance to the pesticide.[301]

These bills would have substantially changed the legal controls on GMOs, and revamped much of the legislative authority for the FDA, the EPA, and the USDA regulation based on the 1986 Coordinated Framework. The bills generated relatively little legislative momentum. The GE Technology Farmer Protection Act attracted no more than eight cosponsors.[302] None of the bills was ever reported out of committee. The only committee to hold hearings on the state of biotechnology regulation in the 2000s was the Domestic Policy

5578, 111th Cong. (2010); H.R. 6635, 110th Cong. (2008); H.R. 5268, 109th Cong. (2006); H.R. 2917, 108th Cong. (2003); H.R. 4813, 107th Cong. (2002); H.R. 3883, 106th Cong. (2000); Genetically Engineered Farmer Protection Act, H.R. 3555, 112th Cong. (2011); H.R. 5579, 111th Cong. (2010); H.R. 6637, 110th Cong. (2008).

294. *See* H.R. 3554, 112th Cong. § 203.

295. *See id.* at § 202 ("Given the consensus among the scientific community that genetic engineering can potentially introduce hazards, such as allergens or toxins, genetically engineered foods need to be evaluated on a case-by-case basis and cannot be presumed to be generally recognized as safe."). In its 1992 statement of policy, the FDA had announced that foods genetically engineered to contain "substance[s] . . . already present at generally comparable or greater levels in currently consumed foods" would be presumed to be GRAS. FDA – Statement of Policy, *supra* note 38, at 22,990. This presumption was more lenient than previous FDA policy for conventional food ingredients, in which the burden remained on the manufacturer to show that any altered ingredient remains GRAS. *See* Marden, note 234, at 748-49.

296. *See* H.R. 3554, 112th Cong. § 102.

297. *Id.* at § 103.

298. *Id.* at § 105.

299. *Id.* at § 203.

300. Ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 136-136y (2012)).

301. H.R. 3555, 112th Cong. § 106.

302. *See* H.R. 3555, 111th Cong. (2011).

Subcommittee of the House Oversight and Government Reform Committee, a committee chaired by Kucinich. In July and September 2010, the Subcommittee held hearings on the effects of glyphosate-resistant plants on production agriculture.[303] The subject of the hearings, "Are 'Superweeds' an Outgrowth of USDA Biotech Policy?", clearly focused on the exercise of regulatory oversight under the existing regulatory framework. Representative Kucinich, the chief congressional champion of stricter regulation of biotechnology, was defeated in the 2012 Ohio legislative primaries.[304]

A congressional caucus intended to study and provide public information about biotechnology has been largely inactive and provided little publicly-accessible information. A bipartisan group of Senators and Representatives announced the creation of the Congressional Biotechnology Caucus in July 1991.[305] The Caucus was "revived" nine years later by a coalition of sixty-five members of Congress "dedicated to fostering a greater understanding of biotechnology issues."[306] The Caucus was listed in a fall 2012 congressional directory,[307] but maintains no website nor currently publicizes other activities.[308]

E. PRESIDENTIAL ELECTIONS AS PUBLIC CONSENT TO THE REGULATORY FRAMEWORK

The presidential control model posits that Presidential elections offer sufficient democratic process to legitimatize agency action. This

303. Are "Superweeds" an Outgrowth of USDA Biotech Policy?: Hearing on Before the Subcomm. On Domestic Policy, H. Comm. on Oversight and Government Reform, 111th Cong. 158, 160 (2010).

304. *See* Paul Kane, *Kucinich Loses to Colleague in Primary Vote for Redistricted Ohio Seat*, WASH. POST, Mar. 7, 2012, at A5. The article attributed Kucinich's loss to a weak Democratic voter turnout in a "new Republican-drawn congressional map" and to a cultural turn against colorful personalities in Congress. *Id.*

305. *See* "The Pink Sheet," *Congressional Biotech Caucus Will Look at Patent Law*, ELSEVIER BUS. INTELLIGENCE, http://www.elsevierbi.com/publications/the-pink-sheet/53/028/congressional-biotech-caucus-will-look-at-patent-law (last visited Apr. 16, 2013).

306. *See Dooley Announces Revival of Biotechnology Caucus*, CAL DOOLEY (July 20, 2000), http://web.archive.org/web/20031224223203/http://www.dooley.house.gov/issues2.cfm?id=1569.

307. *See* Leadership Directories, *112th Congress, 2nd Session*, CONGRESSIONAL YELLOW BOOK, Fall 2012, at 992.

308. Inquiries to staff members listed in the directory about the activities of the Caucus produced no additional information about Caucus activities. *See* e-mail from John Goldberg, House Comm. on Agric., to Creg Ryan Hupp (Feb. 27, 2013) (on file with author) (advising author's assistant to consult organization lists for most recent registration of Congressional Biotechnology Caucus). Inquiries to other staff members identified in the Congressional Yellow Book received no response.

theory has been developed as a defense of the democratic legitimacy of administrative action as a whole, and not of any one particular decision.[309] Critics of the theory have challenged the assumption that presidential elections can reasonably reflect majority will, because most of the electorate knows little about specific agency actions and in any event, voters could not express opinions on those myriad actions through one vote with one alternative.[310]

The regulatory history of genetically modified organisms ("GMOs") confirms the notion that, at best, the presidential control model can offer a justification for administrative action in general; it would be difficult to argue that any of the seven presidential elections since the 1986 Coordinated Framework represented a voter mandate for or against biotechnology. Since most Americans still were not aware of biotechnology in 2006, earlier elections could not have represented any majority opinion on the subject. And the pendulum swing from pro-industry administrations (during which federal regulations and policies were proposed) to a more environmentally precautionary one (during which additional federal regulations and policies were proposed) and then back, and then back once again, sends conflicted messages about the validity of Presidential elections as indicators of public attitude on the persistence of GMO regulatory policy.

Perhaps the failure of GMO policy to become a major presidential campaign issue in itself sends a message about democratic opinion. Could decades of citizen passivity on the GMO issue indicate that the public prefers to defer to federal regulators on issues of science that most laypersons do not understand? While this conclusion is tempting, surveys on public attitudes about GMOs suggest the answer may not be so simple. For example, in a 2005 survey on science governance (including biotechnology), fifty-four percent of Americans were classified as "scientific elitists"—that is, they answered that decisions about technology should be left to experts and should be based on scientific evidence of risks and benefits.[311] However, another

309. *See, e.g.*, Bressman, *supra* note 44, at 490-91 ("The presidential control model seeks to ensure that administrative policy decisions reflect the preferences of the one person who speaks for the entire nation. . . . [T]he result represents majority will. If it does not, then the next election cycle, at least in theory, will ensure that it does.").

310. *See* Staszewski, *supra* note 46, at 867-69; Glen Staszewski, *Reason-Giving and Accountability*, 93 MINN. L. REV. 1253, 1266-71 (2009).

311. *See* George Gaskell et al., *Social Values and the Governance of Science*, 310 SCIENCE 1908 (2005); *see also* George Gaskell et al., *Supporting Online Material*, SCIENCE, 2, 9 (Jan. 12, 2006) [hereinafter *Supporting Online Material*], http://www.sciencemag.org/content/suppl/2006/01/12/310.5756.1908.DC1/Gaskell.SOM.REV.pdf.

forty-six percent of Americans preferred that decisions about technology be made on a different basis: twenty-two percent were classified as "moral elitists," meaning that they answered that decisions should be based on expert opinions of moral and ethical issues, rather than science.[312] Another fourteen percent were "moral democrats," who answered that decisions about technology should be made by average citizens based on moral and ethical issues, and eleven percent were "scientific democrats," who believed that decisions should be made by average citizens based on scientific evidence of risks and benefits.[313]

Moreover, trust in scientists does not always equate to trust in federal regulators. When asked in a 1987 government survey whether they would believe statements about the risk of a biotech product from various groups, survey respondents were more inclined to believe university scientists, public health officials, and environmental groups than federal agencies.[314] Similarly, respondents were asked to imagine a case in which a federal agency said a genetically altered organism did not pose a significant risk, but a national environmental group said it did.[315] Respondents were far more likely to believe the environmental group (sixty-three percent) than the federal agency (twenty-six percent).[316]

This data suggests two things that cast doubt on the assumption that public silence represents democratic approval for the 1986 Coordinated Framework. First, a slight majority of Americans prefer that decisions be made by scientific experts, but not necessarily by federal regulators. Second, nearly half of Americans do not favor decision-making by scientific experts at all, but prefer that decisions about new technology be based on expert or public citizen opinions about moral and ethical values related to that technology, or by public opinion about scientific risks and benefits.[317]

VI. DID THE CREATION OF THE 1986 COORDINATED FRAMEWORK HAVE A CHILLING EFFECT ON

312. Gaskell et al., *supra* note 311; *Supporting Online Material*, *supra* note 311, at 2, 9.

313. *Id.*

314. OFFICE OF TECH. ASSESSMENT, *supra* note 60, at 89-90. In the survey, 86% of respondents said they were at least "inclined to believe" statements about risk from university scientists, compared to 82% for public health officials, 71% percent for environmental groups, and 69% for federal agencies. *Id.* at 89-90.

315. *Id.* at 90.

316. *Id.*

317. *See* Gaskell et al., *supra* note 311; *Supporting Online Material*, *supra* note 311, at 2, 9.

DEMOCRATIC DELIBERATION?

For a quarter-century, the 1986 Coordinated Framework has guided the creation of a regulatory framework for legal controls on biotechnology that continues today. These regulations, based on authority under statutes written before the technology was imagined, were implemented at the same time as a brief early period of congressional interest in the topic. This congressional interest has not been approached since. The executive branch interpreted the scope of its regulatory authority and argued against Congress creating new oversight legislation. Federal agencies elaborated policies through policy statements and guidance documents that determined what information the public would receive about the new technology. In some cases, these policy statements were not subject to notice and comment but were still granted deference by courts. While a vocal group of citizens has challenged biotech regulatory policy since the late 1990s, those challenges have not translated into legislative change to the federal agencies' statutory authority, substantial reinterpretation of that authority by the agencies themselves, or strong familiarity with biotechnology by the average American.

Did the creation of a regulatory scheme under existing statutes interfere with public debate over the legal controls for biotechnology? Did the pre-emptive strike by the Executive branch undermine congressional attempts to develop momentum to pass new legislation specific to the technology? Did the quick regulatory solution, allowing the new products to come to market, deflect public attention away from the debate? Before commercialization was a fact of economic life, did the public have a meaningful opportunity to understand the new technology, to engage in democratic deliberation about whether and how to control the technology, and to discuss whether such controls should be based on existing statutes or new ones?

No retrospective case study can prove what might have been. Still, the history of biotechnology development and public awareness of that technology raises doubts as to whether the public has had an opportunity to engage in meaningful democratic deliberation about biotech controls. As of 2006, most Americans had never had a conversation about biotechnology.[318] Congressional leaders abandoned the effort by 1990 because of the existence, by that time, of the 1986 Coordinated Framework.[319] Even as studies have begun to document serious harms to the environment and potential harms to human health related to the widespread planting of herbicide-

318. *See supra* notes 175-185 and accompanying text.
319. *See supra* notes 22-39 and accompanying text.

resistant biotech crops,[320] Congress has taken little action to review the regulatory structure, and the chief proponent of such oversight in the House was defeated in the 2012 primaries.[321] Surveys do not support an inference that the public is simply content to defer to regulators on controls of new technology. Nearly half of Americans do not believe such decisions should be made by scientific elites at all, and more Americans said they would trust university scientists, public health officials, and environmental groups than federal regulators.[322]

What might have happened if federal agencies did not have the institutional advantage of being able to move much more quickly than legislatures? Once the most involved actors—industry and regulators—were satisfied that biotechnology products would be brought to market and a framework existed for the exercise of regulatory authority, the impetus for public attention and deliberation to the new technology could only have been weakened. Not until over a decade later, in the late 1990s, did any significant grassroots concern over GMO controls begin. And a number of years of such grassroots organizing still failed to bring the issue to the attention of most Americans.

The creation of the GMO regulatory structure is water under the bridge. Substantial changes in the legislative authority of federal agencies to regulate GMOs will depend on further grassroots activism, strong new proponents in Congress, and, in all likelihood, growing evidence of environmental and human health harms. Unfortunately, it may also require a crisis of even greater magnitude than the widespread crop losses attributable in recent years to glyphosate-resistant weeds.[323] As early as 1987, then-Senator Al Gore lamented,

> In Congress, each proposal designed to bring regulatory order to biotechnology has met vigorous opposition from the industry and the Administration. Without a crisis to focus attention on biotechnology, it is difficult to argue for making regulatory reform in this area a priority, especially when compared to the needs to reform other major environmental laws such as Superfund and the Clean Air Act.[324]

But this history of legislative and regulatory dynamics in the GMO context offers a pertinent lesson for technologies emerging for commercial use today. The Clean Air Act itself is now the focus of a

320. *See supra* notes 193-232 and accompanying text.
321. *See supra* notes 245-248, 281-308 and accompanying text.
322. *See supra* notes 60-80 and accompanying text.
323. *See supra* notes 194-232 and accompanying text.
324. Al Gore, *Planning a New Biotechnology Policy*, 5 HARV. J.L. & TECH. 19, 26-27 (1987).

tug-of-war between the Obama Administration, Congress, and the federal courts over the scope of executive power to regulate greenhouse gas emissions under that legislation, written decades before climate change was a national policy issue. A similar debate has surged over the Obama Administration and the EPA's use of regulatory authority under the Clean Water Act to regulate hydraulic fracturing of unconventional gas shales.

In this current round of expansive regulatory interpretation of statutes that pre-dated controversial new technologies and scientific developments, the ideological battle lines are reversed. Instead of a pro-industry administration eager to facilitate products coming to market, the charge is being led by a pro-conservation administration eager to institute precautionary measures to prevent major environmental harms. Judgments about the democratic legitimacy of the current regulatory effort, however, should not be clouded by one's opinion of the ideologies or priorities of the acting administration. If the GMO case study raises concerns about executive action that precedes, and possibly preempts, public deliberation about newly-emerging science or technology, those concerns should apply all such agency action, regardless of the ideological appeal of the short-term goal such action serves. If the result seems to be an unsatisfying compromise of urgent protections to facilitate long-term engagement, then perhaps new mechanisms for balancing legislative power and agency authority in the short term should be explored.