

THE NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD: A STATUTE IN NEED OF A DO-OVER

By Julie K. Smith

This paper examines law, science, and policy issues behind the 2016 federal genetically modified organism (GMO) food labeling law. It argues in favor of the FDA's approach of regulating GMOs based on product characteristics rather than on the process by which they were created. Because GMO labeling addresses subjective personal preferences rather than objective concerns, it should be voluntary rather than mandatory.

For thousands of years, humans have genetically modified plants and animals to improve characteristics like flavor, nutrient content, production yield, shelf life, and pest resistance. Older agricultural methods modified DNA indirectly, but genetic engineering can now be used to modify DNA directly, resulting in more efficient improvements in the characteristics of our foods. Most consumers have only a minimal understanding of genetics and genetic engineering and many express reservations about modifying foods in the laboratory. Although scientists have concluded that genetic engineering does not in itself cause health or environmental problems, a majority of Americans say that all GMO foods should be labeled.

When Vermont and other states enacted GMO food labeling laws, Congress feared a patchwork of conflicting local laws and quickly passed a federal mandatory GMO labeling statute. The federal statute has strong preemption clauses that nullify most state GMO labeling laws. But the new law's scope is arguably narrow and ambiguous, and even labeling proponents deem it unacceptable. The new GOP administration's focus on reducing federal regulation may provide an opportunity to revisit and revise or repeal the federal GMO labeling statute. In the bigger picture, scientists need to better educate both legislators and citizens about complex technical fields like genetics in order to facilitate better-informed policy choices.

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I. INTRODUCTION

Two surprising events occurred in 2016. First, in July, President Obama signed the National Bioengineered Food Disclosure Standard,¹ a statute that provides for mandatory labeling of foods containing ingredients from genetically modified organisms (“GMOs”). The mandatory labeling provision was surprising in light of a 600-page National Academies Report that had been released in May.² That report found no substantiated evidence of GMO food safety or environmental issues and recommended that GMO regulation be product-based rather than process-based.³ The statute was also surprising because the House of Representatives had previously passed a very different federal GMO labeling law⁴ that provided for voluntary rather than mandatory GMO labeling.⁵ Second, in November 2016, Donald Trump was elected President of the United States despite nearly all polls predicting a win for Hillary Clinton. These two unexpected events are now intersecting, as President Trump’s hostility toward federal regulations threatens to derail the rulemaking needed to implement the new GMO labeling statute. Derailment would be a good thing.

This paper examines law, science, and policy behind the new federal GMO labeling statute, and explores the following questions: (1) Is mandatory GMO labeling a good idea? (2) How did voluntary GMO labeling legislation morph into a mandatory labeling statute? (3) Just what does the new GMO labeling statute require, and what ambiguities will need to be interpreted through rulemaking and the courts? (4) Isn’t there a disconnect between a mandatory GMO labeling statute and the scientific conclusions and recommendations from the National Academies? (5) What are the policy reasons, including public opinion, behind the GMO labeling statute, and are those adequately addressed by the statute? (6) How can scientists better explain complex topics, such as genetics and genetic engineering, so that lawmakers

1. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified at 7 U.S.C. § 1639).

2. NAT’L ACADS. OF SCI., ENG’G, & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016), <https://www.nap.edu/catalog/23395>.

3. Product-based regulations (the current approach in the United States) consider the composition, characteristics, and risk profiles of individual GMOs. Process-based regulations (the current approach in the European Union) focus on the fact that all GMOs were made using methods of genetic engineering. So while both U.S. and EU regulators evaluate human health, environmental health, and nutritional content of GMOs, the EU requires all GMOs to be approved by a central authority whereas the U.S. requires approval by specific agencies only when there are articulable health, environmental, or nutritional concerns. See Katharine Gostek, *Genetically Modified Organisms: How the United States’ and the European Union’s Regulations Affect the Economy*, 24 MICH. ST. INT’L L. REV. 761, 765–66 (2015); Jessica Lau, *Same Science, Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe*, HARV. U.: SCI. IN THE NEWS (Aug. 9, 2015), <http://sitn.hms.harvard.edu/flash/2015/same-science-different-policies/>; see also discussion *infra* Part III.

4. Safe and Accurate Food Labeling Act of 2015, H.R. 1599, 114th Cong. §§ 101–304 (2015).

5. H.R. 1599 § 291; see discussion *infra* Section IV.B.

and the general public can make informed decisions in these areas?

This paper concludes that mandatory GMO labeling is unjustified and is associated with unacceptable economic and noneconomic costs. Moreover, there are serious defects in the new federal GMO labeling statute. The statute is ambiguous, not science-based, fails to consider state-of-the-art genetic engineering methodology, and does not even satisfy the demands of labeling proponents. The statute is in need of a do-over, and Donald Trump's efforts to reduce federal regulation may provide an opportunity to return to a more rational, voluntary labeling scheme.

Part II of this paper provides background information on GMO foods and public opinion about GMO labeling. Part III examines the science of GMOs and the scientific approach to GMO regulation. Part IV discusses state and federal GMO labeling laws, particularly the federal statute enacted in 2016. While preemption of state legislation is an important feature, the federal statute's labeling mandate is not science-based, and the statute's scope is so limited that even pro-labeling advocates are left unsatisfied. Part V recommends a return to a voluntary GMO labeling standard, considers whether the new GOP administration offers an opportunity to revise or repeal the federal GMO labeling law, and briefly considers the need to improve the science literacy of both legislators and the public.

II. BACKGROUND ON GMOs AND PUBLIC OPINION ON GMO LABELING

A. *What Is a GMO? What Foods Contain GMOs?*

Any attempt to regulate GMOs, and foods made from GMOs, is complicated by the fact that there is no single satisfactory GMO definition. Intuitively, the term encompasses modification of the genetic material—DNA.⁶ But farmers and scientists have been modifying the DNA of plants and animals for millennia, selecting new and improved characteristics through the use of cross-breeding, radiation and chemically-induced mutagenesis, hybridization, tissue culture, and (more recently) genetic engineering.⁷ Most current GMO definitions attempt to encompass the use of genetic engineering⁸ while excluding more traditional forms of genetic modification.⁹ But genetic

6. DAVID T. SUZUKI ET AL., AN INTRODUCTION TO GENETIC ANALYSIS 2 (4th ed. 1989) (“The science of genetics attempts to understand the properties of the genetic material, *deoxyribonucleic acid*, best known by its abbreviation DNA.”).

7. NAT'L RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS 23–28 (2004), <https://www.nap.edu/catalog/10977> (summarizing techniques “other than genetic engineering” that have been used to genetically modify plants and noting that “[m]odification to produce desired traits in plants, animals, and microbes used for food began about 10,000 years ago.”).

8. Genetic engineering is also referred to as recombinant DNA technology, bioengineering, or biotechnology.

9. See, e.g., Vermont Consumer Protection Rule 121, 06-031 VT. CODE R. § CP 121.01(6) (2015) (effective July 1, 2016), <http://www.ago.vermont.gov/assets/files/PressReleases/Consumer>

engineering itself includes a vast universe of methods and resulting genetic modifications.¹⁰ This diversity of methods and products, added to politicization of the term “GMO,” makes it nearly impossible for any definition to precisely capture all of the things that people think of as GMOs while excluding products of traditional agricultural husbandry.¹¹ Working GMO definitions typically include the following elements: (a) changing DNA to alter the characteristics of an organism (b) by using genetic engineering, recombinant DNA, bioengineering, or biotechnology techniques (c) in a way that could not occur in nature or through conventional breeding.¹²

Some GMO opponents apply far more expansive definitions.¹³ This lack

/Final%20Rule%20CP%20121.pdf (“The term ‘genetic engineering’ does not encompass a change of genetic material through the application of traditional breeding techniques, conjugation, fermentation, traditional hybridization, in vitro fertilization, or tissue culture.”).

10. See discussion *infra* Part III.

11. See Nathanael Johnson, *It’s Practically Impossible to Define “GMOs”*, GRIST (Dec. 21, 2015), <http://grist.org/food/mind-bomb-its-practically-impossible-to-define-gmos/>; Giovanni Tagliabue, Letter to the Editor, *The Nonsensical GMO Pseudo-category and a Precautionary Rabbit Hole*, 33 NATURE BIOTECHNOLOGY 907, 907 (2015) (“The term genetically modified organisms (GMOs) is a useless and imprecise category used to pigeonhole products . . . It is theoretically and practically impossible to precisely specify a supposed common denominator for all these products; . . . GMOs are not a thing per se—they are simply an ill-labeled group of things . . . produced in certain ways, each of which has a unique profile of risks and benefits.”).

12. E.g., *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG. (May 2014), http://www.who.int/foodsafety/areas_work/food-technology/Frequently_asked_questions_on_gm_foods.pdf?ua=1 (“Genetically modified organisms (GMOs) can be defined as organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called ‘modern biotechnology’ or ‘gene technology’, sometimes also ‘recombinant DNA technology’ or ‘genetic engineering’. It allows selected individual genes to be transferred from one organism into another, also between non-related species.”); see also Julia M. Diaz & Judith L. Fridovich-Keil, *Genetically Modified Organism (GMO)*, ENCYCLOPÆDIA BRITANNICA (Nov. 28, 2016), <https://www.britannica.com/science/genetically-modified-organism> (“[An] organism whose genome has been engineered in the laboratory in order to favour the expression of desired physiological traits or the production of desired biological products . . . [R]ecombinant genetic technologies are employed to produce organisms whose genomes have been precisely altered at the molecular level, usually by the inclusion of genes from unrelated species of organisms that code for traits that would not be obtained easily through conventional selective breeding.”); *What is GMO?*, NON-GMO PROJECT, <https://www.nongmoproject.org/gmo-facts/what-is-gmo/> (last visited Apr. 25, 2017) (“A GMO, or genetically modified organism, is a plant, animal, microorganism or other organism whose genetic makeup has been modified using recombinant DNA methods (also called gene splicing), gene modification or transgenic technology. This relatively new science creates unstable combinations of plant, animal, bacterial and viral genes that do not occur in nature or through traditional crossbreeding methods.”).

13. See, e.g., Initial Brief of Appellant at 12, *Reilly v. Chipotle Mexican Grill, Inc.*, No. 16-17461-EE (11th Cir. Jan. 31, 2017) (asserting that meat and dairy from animals that consume GMOs are also GMOs); ariadne, Comment to *Bakewell Cream Baking Powder Customer Reviews*, KING ARTHUR FLOUR (Nov. 29, 2016), <http://www.kingarthurfLOUR.com/shop/items/bakewell-cream-baking-powder-8-oz#customer-reviews> (asserting that baking powder containing corn starch from GMO corn is also a GMO).

of definitional clarity confounds regulators and citizens alike and is probably one reason that many GMO commentators do not even try to define the subject matter they are expounding upon. They may simply be relying on the old standard “I know it when I see it” definitional approach.¹⁴

Definitional ambiguities aside, the first commercial GMO food was the Flavr Savr tomato,¹⁵ a fruit engineered to ripen more slowly that was approved by the FDA in 1994. Fast-forward to 2017 when, according to the U.S. Department of Agriculture, about ninety percent of the soybeans, cotton, and corn grown in the U.S. are GMO varieties.¹⁶ For the most part these are GMO commodity crops genetically engineered to enhance farming practice, e.g., to be more tolerant of herbicides used to control weeds, to be more resistant to insect damage, or to be both herbicide-tolerant and insect-resistant.¹⁷ They are used to produce corn starch, corn syrup, and soybean and cottonseed oils that are used in most processed foods.¹⁸ Other GMO crops in the U.S. include potato, squash, papaya, canola, alfalfa, and sugar beet.¹⁹ Recently approved GMO foods, such as apples²⁰ and mushrooms²¹ that do not turn brown when cut, aim to appeal directly to consumers. GMOs in the future may include organic crops that have been “rewilded” through the reintroduction of genes from wild relatives²² and corn engineered to prevent contamination by aflatoxin.²³ The first GMO meat, from a salmon that grows twice as fast as

14. *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring) (invoking an “I know it when I see it” standard to famously explain the difficulty of intelligibly defining hardcore pornography).

15. Warren E. Leary, *F.D.A. Approves Altered Tomato That Will Remain Fresh Longer*, N.Y. TIMES (May 19, 1994), <http://www.nytimes.com/1994/05/19/us/fda-approves-altered-tomato-that-will-remain-fresh-longer.html>.

16. *Adoption of Genetically Engineered Crops in the U.S.*, U.S. DEP'T OF AGRIC., ECON. RES. SERV., (July 12, 2017), <https://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/> (follow “CSV (comma separated values) format of all data” hyperlink).

17. *Id.*

18. David Johnson & Siobhan O'Connor, *These Charts Show Every Genetically Modified Food People Already Eat in the U.S.*, TIME (Apr. 30, 2015), <http://time.com/3840073/gmo-food-charts/>; *Which Genetically Engineered Foods Are Approved in the U.S.?*, GENETIC LITERACY PROJECT, <http://gmo.geneticliteracyproject.org/FAQ/which-genetically-engineered-foods-are-approved-in-the-us/> (last visited Oct. 9, 2017).

19. *Id.*

20. Andrew Pollack, *Gene-Altered Apples Get U.S. Approval*, N.Y. TIMES (Feb. 13, 2015), https://www.nytimes.com/2015/02/14/business/gmo-apples-are-approved-for-growing-in-us.html?_r=0.

21. Emily Waltz, *Gene-Edited CRISPR Mushroom Escapes US Regulation*, 532 NATURE 293, 293 (2016), <http://www.foroeuropa.it/documenti/rivista/nature2016.pdf>.

22. Martin Marchman Andersen et al., *Feasibility of New Breeding Techniques for Organic Farming*, 20 TRENDS PLANT SCI. 426, 426 (2015), <http://linkinghub.elsevier.com/retrieve/pii/S1360138515001120>.

23. Dhiraj Thakare et al., *Aflatoxin-free Transgenic Maize Using Host-induced Gene Silencing*, 3 SCI. ADVANCES e1602382 (2017), <http://advances.sciencemag.org/content/advances/3/3/e1602382.full.pdf>.

non-engineered fish, was approved in 2015.²⁴

Many people and organizations oppose GMOs and GMO ingredients in the food supply, and many believe that GMO ingredients should be explicitly labeled.²⁵ These preferences raise questions about which foods to label, how to label them, and whether labeling should be voluntary or mandatory.²⁶

B. Public Opinion on GMO Labeling

Organizations that object to GMOs in the food supply, including Consumers Union and Just Label It, claim that around ninety percent of consumers support mandatory GMO labeling.²⁷ But a Rutgers survey on GMO labeling casts doubt upon those claims.²⁸ The Rutgers group found that consumer responses about GMO labeling depended heavily on the structure of the question being asked. When asked what additional information they would like to see on food labels, a majority said no additional information was needed and only seven percent mentioned GMOs.²⁹ When presented with a list of potential new labeling categories, fifty-nine percent stated that GMO ingredients should be labeled.³⁰ When asked directly whether GMO ingredients should be labeled, seventy-three percent responded yes.³¹ Public understanding about GMOs was low, with fifty-four percent of respondents

24. Heidi Ledford, *Salmon is First Transgenic Animal to Win US Approval for Food*, NATURE (Nov. 19, 2015), <http://www.nature.com/news/salmon-is-first-transgenic-animal-to-win-us-approval-for-food-1.18838>.

25. See discussion *infra* Section II.B.

26. In principle, foods can be labeled as either containing GMOs or not containing GMOs. In practice, mandatory labeling schemes generally require foods to disclose that they do contain GMOs and voluntary labeling schemes typically permit foods to represent that they do not contain GMOs. Compare VT. STAT. ANN. tit. 9, § 3043(b) (2016) (requiring under Vermont statute that foods be labeled "partially produced with genetic engineering," "may be produced with genetic engineering," or "produced with genetic engineering."), with NON-GMO PROJECT, <https://www.nongmoproject.org/> (last visited Apr. 27, 2017) ("Non-GMO Project Verified is North America's MOST TRUSTED SEAL for GMO avoidance."). But see U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DERIVED FROM GENETICALLY ENGINEERED PLANTS (Nov. 2015), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm> (providing guidance about voluntary statements that foods either are or are not derived from genetically-engineered plants).

27. *New Poll: Nearly Nine in 10 Americans Want Labels on GMO Food*, JUST LABEL IT (Dec. 2, 2015), <http://www.justlabelit.org/press-room/new-poll-nearly-nine-in-10-americans-want-labels-on-gmo-food/>; *GMO Foods: What You Need to Know*, CONSUMER REP. (Feb. 26, 2015, 3:20 PM), <http://www.consumerreports.org/cro/magazine/2015/02/gmo-foods-what-you-need-to-know/index.htm>.

28. See William K. Hallman et al., *Public Perceptions of Labeling Genetically Modified Foods 5* (Rutgers Sch. Env. Sci., Working Paper 2013–01, 2013), http://humeco.rutgers.edu/documents_pdf/news/gmlabelingperceptions.pdf.

29. *Id.* at 3–4.

30. *Id.* at 4. The other potential labeling categories were hormones, pesticides, antibiotics, U.S. origin, and allergens. *Id.* For each category, approximately sixty percent of respondents agreed that such information should be required on labels. *Id.*

31. *Id.*

stating that they knew little or nothing about GMO foods, and twenty-five percent saying they had never heard of GMO foods.³²

Surveys by McFadden and Lusk reinforce the proposition that many consumers that favor GMO labeling have little knowledge, and harbor many misconceptions, about basic genetics, DNA, and GMOs.³³ In those surveys, eighty-four percent of respondents favored mandatory GMO labeling, but a similar number (eighty percent) would require labeling of any foods containing DNA.³⁴ A third of the respondents thought that non-GMO tomatoes have no genes and that vegetables have no DNA.³⁵ Commentators seeking to explain why consumers have such strong feelings about things they do not understand have hypothesized that, when faced with complex issues that would take considerable effort to understand, the public tends to rely on intuition, biases, and heuristics to form malleable and manipulable beliefs, even strong beliefs that are contradicted by evidence.³⁶

C. Arguments for and Against GMO Labeling

It must be noted that a substantial (though not complete) overlap exists between those who advocate for GMO labels and those who oppose GMOs entirely. Many GMO opponents view labeling as a means to stigmatize GMOs and thereby limit their sale and consumption.³⁷ Setting aside caveats about the accuracy of public opinion surveys and limited levels of public understanding about genetic engineering,³⁸ people do cite both objective and subjective reasons for requiring labels on GMO foods.³⁹ Objective reasons include

32. *Id.* at 3.

33. See Brandon R. McFadden & Jason L. Lusk, *What Consumers Don't Know About Genetically Modified Food, and How That Affects Beliefs*, 30 FASEB J. 3091 (2016).

34. *Id.* at 3094. (commenting that labeling foods that contain DNA would be “an absurd policy that would apply to the majority of foods in a grocery store.”)

35. *Id.* at 3093. These beliefs are factually incorrect. *E.g.*, Suzuki, *supra* note 6 (explaining that the cells of all organisms from bacteria to humans contain DNA subdivided into chromosomes with functional regions called genes).

36. Stefaan Blancke et al., *Fatal Attraction: The Intuitive Appeal of GMO Opposition*, 20 TRENDS PLANT SCI. 414, 415 (2015); see also McFadden & Lusk, *supra* note 33, at 3091; Amos Tversky & Daniel Kahneman, *Judgment Under Uncertainty: Heuristics and Biases*, 185 SCI. 1124, 1131 (1974). Thoughts about overcoming intuition and heuristics through innovative education are discussed briefly in Section V.C.2 below.

37. Bruce Chassy & Jon Entine, *Why We Oppose GMO Labeling: Science and the Law*, HUFFINGTON POST: BLOG (Dec. 27, 2015, 6:38 PM), http://www.huffingtonpost.com/jon-entine/gmo-labeling-science-and-_b_8871680.html (collecting quotes from organizations that promote GMO labeling as a means to discredit GMOs).

38. Even those opinions formed through sub-conscious reflex, intuition, and heuristics tend to be explained and justified, a phenomenon known as motivated reasoning, typically through the overly enthusiastic adoption of arguments that have been put forth by activists, organizations, acquaintances, and the press. Blancke, *supra* note 36, at 417.

39. See, e.g., Claire Marris, *Public Views on GMOs: Deconstructing the Myths*, 2 EMBO REP. 545, 546 (2001); Deniza Gertsberg, *6 Reasons to Avoid GMOs*, GMO J. (Sept. 27, 2010), <http://gmo-journal.com/2010/09/27/6-reasons-to-avoid-gmos/>; Gary Null, *44 Reasons to Ban or Label GMOs*, GREENMEDINFO (Nov. 6, 2015, 10:15 AM), <http://www.greenmedinfo.com/>

concerns about adverse health effects and harms to the environment.⁴⁰ Subjective reasons include beliefs about the “unnaturalness”⁴¹ of GMOs or the morality of “playing God” through genetic engineering, concerns about corporate greed harming small farmers,⁴² invocation of stronger or weaker versions of the precautionary principle,⁴³ or the simple assertion of a naked “right to know.”⁴⁴

Those who oppose mandatory labeling view labels as (a) costly to farmers, the food supply chain, and consumers; (b) confusing, uninformative, unscientific, and misleading in that they falsely imply danger; and (c) stigmatizing such that they hinder progress and acceptance of research and development that could help solve the world’s hunger problems.⁴⁵

While deeply-held subjective beliefs are difficult to challenge, a close look at the science behind GMOs clearly demonstrates that they do not, as a class, require labeling for objective health or environmental reasons.

blog/44-reasons-ban-or-label-gmos; Julie Wilson, *Top 10 Reasons GMOs Should Be Labeled*, NAT. NEWS (Mar. 23, 2015), http://www.naturalnews.com/049091_GMOs_labeling_food_industry.html.

40. See, e.g., Michelle Schoffro Cook, *Top 20 Frankenfoods to Avoid*, CARE2 (Sept. 12, 2013), <http://www.care2.com/greenliving/top-20-frankenfoods-to-avoid.html> (“While agribusinesses continue to claim they are safe, increasing amounts of research demonstrate that GM foods are harmful to human health, damage ecosystems, cause financial calamity for many farmers, and release trans genes that could randomly transfer to other life forms in the environment with the potential for disastrous consequences. A growing body of research links genetically-modified food consumption with sterility, allergies, infant mortality, organ defects, childhood illnesses, and cancer.”).

41. A common heuristic exploited by anti-GMO activists is that GMOs are unnatural, and unnatural is bad, so GMOs are bad. See, e.g., Cook, *supra* note 40 (including a colorful photo of a syringe sticking out of a tomato).

42. Some labeling proponents/GMO opponents seem motivated largely by animosity toward the Monsanto Company. See, e.g., Kelly L. Derricks, *March Against Monsanto*, MARCH AGAINST MONSANTO (June 26, 2014), <https://www.march-against-monsanto.com/home/>; *Millions Against Monsanto*, ORGANIC CONSUMERS ASS’N, <https://www.organicconsumers.org/campaigns/millions-against-monsanto> (last visited Apr. 26, 2017).

43. *Wingspread Conference on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK (Jan. 26, 1998), <http://sehn.org/wingspread-conference-on-the-precautionary-principle/>. An influential articulation of the precautionary principle comes from the 1998 Wingspread Conference: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.” *Id.*

44. E.g., Arthur Caplan, *GMO Foods Should be Labeled, but Not for Safety: Bioethicist*, NBC NEWS (Sept. 8, 2015, 4:06 PM), <http://www.nbcnews.com/health/health-news/why-gmo-foods-should-be-labeled-n423451> (arguing that people have a right to know what is in their foods even when there are no safety or other objective concerns).

45. E.g., *Labels for GMO Foods Are a Bad Idea*, SCI. AM. (Sept. 1, 2013), <https://www.scientificamerican.com/article/labels-for-gmo-foods-are-a-bad-idea/>; Chassy & Entine, *supra* note 37.

III. A SCIENCE-BASED APPROACH TO LABELING & OTHER GMO REGULATIONS

The Pew Research Center, in collaboration with the American Association for the Advancement of Science, reports that scientists and the general public express very different opinions about current science-related topics like climate change, nuclear power, vaccines, evolution, and GMOs.⁴⁶ One of the largest opinion gaps relates to GMO safety, with eighty-eight percent of scientists but only thirty-seven percent of the public saying that GMOs are safe to eat.⁴⁷ As discussed in Section II.B above, these strong public opinions about GMOs must be viewed with the caveat that most people do not really understand what GMOs are.⁴⁸

Looking at GMOs through a scientist's lens, we see that genetic engineering is merely a toolbox of diverse methods for making changes to an organism's DNA, just as evolution⁴⁹ and traditional breeding⁵⁰ are toolboxes of diverse methods for making changes to an organism's DNA. Organisms produced through genetic engineering do not intrinsically raise more health or environmental concerns than organisms produced through evolution or traditional breeding.⁵¹

Genetic engineering is a process, not a thing. It includes everything from the use of plant virus vectors to introduce entirely new genes into an organism⁵² to the use of gene editing⁵³ to make small and very precise changes

46. PEW RESEARCH CTR., PUBLIC AND SCIENTISTS' VIEWS ON SCIENCE AND SOCIETY 37 (2015), http://assets.pewresearch.org/wp-content/uploads/sites/14/2015/01/PI_ScienceandSociety_Report_012915.pdf.

47. *Id.* at 39.

48. See Hallman, *supra* note 28, at 3 (showing the low level of public understanding about GMOs); Erin Brodwin, *Jimmy Kimmel Asks Anti-GMO People What GMOs Are — and Hilariously, They Have No Idea*, BUS. INSIDER (Oct. 10, 2014, 1:18 PM), <http://www.businessinsider.com/jimmy-kimmel-what-is-a-gmo-2014-10>. The paradox was hilariously demonstrated by Jimmy Kimmel using a completely non-scientific survey outside a farmer's market. Almost all of those questioned enthusiastically stated they avoid eating GMOs, but most could not explain why or describe what GMOs are. *Id.*

49. Evolution is the accumulation and natural selection of randomly-arising mutations in a population over time.

50. Traditional breeding includes cross-breeding, hybridization, mutagenesis, tissue culture, and natural or artificial selection in the laboratory or field.

51. See discussion *infra* Section III.C.

52. E.g., Ramasamy Manikandan et al., *Transgenic Rice Plants Expressing Synthetic cry2AX1 Gene Exhibits Resistance to Rice Leaffolder (Cnaphalocrosis medinalis)*, 3 BIOTECH 6:10 (2016), <http://link.springer.com/10.1007/s13205-015-0315-4> (showing insect-resistant rice created by agrobacterium-mediated transfer of a chimeric crystal protein gene from *Bacillus thuringiensis*).

53. See, e.g., Luisa Bortesi & Rainer Fischer, *The CRISPR/Cas9 System for Plant Genome Editing and Beyond*, 33 BIOTECHNOLOGY ADVANCES 41 (2015). For a discussion on the uses of CRISPR-Cas9 gene editing techniques to rapidly modify sequences within an organism's DNA in a precise and predictable manner, see Elizabeth Pennisi, *The CRISPR Craze*, 341 SCI. 833 (2013). The fact that gene editing is a recombinant DNA technique, yet it "can create a plant that in ALL aspects is identical to one that is not considered to be a GMO" is already confounding

to a native gene within the organism.⁵⁴ GMOs may include an almost infinite universe of large or small genetic changes. While knowledge that an organism has been genetically modified provides some limited information about how it was produced, a GMO label doesn't disclose anything about the type(s) of modification, the organism's resulting characteristics, or the risk of resulting health or environmental concerns.

The science-based approach to GMOs regulates them as individual products based on their specific characteristics rather than as a class based on the type of methods used to create them.⁵⁵ This is the approach applied by most scientists and science-based organizations, including the Food and Drug Administration, to the issue of GMO labeling.

A. Food and Drug Administration (FDA) Position

The FDA regulates the safety and labeling of foods under the Food, Drug, and Cosmetic Act (FDCA),⁵⁶ which prohibits the introduction of misbranded food into interstate commerce.⁵⁷ A food is misbranded if its labeling is "false or misleading in any particular,"⁵⁸ and labeling is misleading if it fails to reveal material facts.⁵⁹ In 1992, the FDA issued its seminal policy statement on the legal regulation of GMO foods.⁶⁰ That policy statement, which has been

regulators. *GMO FAQ: How Are Governments Regulating CRISPR and New Breeding Technologies (NBTs)?*, GENETIC LITERACY PROJECT, <https://gmo.geneticliteracyproject.org/FAQ/how-are-governments-regulating-crispr-and-new-breeding-technologies-nbts/> (last visited May 3, 2017). The FDA has announced that it is maintaining a product-focused, science-based regulatory policy with respect to genome-edited products. See Robert M. Califf & Ritu Nalubola, *FDA's Science-based Approach to Genome Edited Products*, FDA VOICE (Jan. 18, 2017), <https://blogs.fda.gov/fdavoices/index.php/2017/01/fdas-science-based-approach-to-genome-edited-products/>.

54. See, e.g., Waltz, *supra* note 21, at 293 (showing that browning-resistant mushroom was created using the gene-editing tool CRISPR–Cas9 to delete a few base pairs, without adding any exogenous DNA, from one of the mushroom's own polyphenol oxidase genes).

55. This science-based approach was cogently articulated more than twenty-seven years ago in a report by the National Research Council: "Information about the process used to produce a genetically modified organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight. . . . The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods." NAT. RES. COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 14–15 (1989), <http://public.eblib.com/choice/publicfullrecord.aspx?p=3377243>.

56. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

57. *Id.* § 331(a).

58. *Id.* § 343(a)(1).

59. *Id.* § 321(n). The term "material facts" is not defined, and the FDA's interpretation of that term was challenged in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178 (D.D.C. 2000).

60. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>. Note that the FDA uses the term "genetically engineered (GE)," rather than genetically modified, to describe organisms made using

resolutely reaffirmed on many occasions,⁶¹ reflects the FDA's informed judgement that: (a) the regulatory status of a food depends on its objective characteristics rather than the methods by which it was developed,⁶² (b) foods derived via genetic engineering do not as a class differ in any meaningful or uniform way from, or raise different or greater safety concerns than, foods produced by traditional plant breeding,⁶³ (c) the fact that a food was derived by genetic engineering is not generally material information that would require labeling under the FDCA,⁶⁴ and (d) if a food derived by genetic engineering *is* materially different from its traditional counterpart, the material differences must be disclosed on the food's label.⁶⁵ In *Alliance for Bio-Integrity v. Shalala*⁶⁶ a federal court held that the FDA's position was entitled to *Chevron* deference.⁶⁷ The court upheld the FDA's conclusion that the process of genetic modification is not a material fact that warrants special labeling for genetically engineered foods as a class.⁶⁸ The court also deferred to the FDA's interpretation that the FDCA does not require or even authorize special labeling for genetically engineered foods "solely because of consumer demand."⁶⁹ Nevertheless, in November 2015 the FDA, acknowledging that many consumers want to know the GMO status of foods and that some manufacturers are interested in providing such information, produced a nonbinding guidance document on the voluntary labeling of GMO foods.⁷⁰

recombinant DNA technology.

61. *E.g.*, *Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Commerce*, 113th Cong. 2 (2014) (statement of Michael M. Landa, Director, Center for Food Safety and Applied Nutrition, U.S. Food & Drug Admin.), <http://docs.house.gov/meetings/IF/IF14/20141210/102797/HHRG-113-IF14-Wstate-LandaM-20141210.pdf> ("This 1992 statement and its scientific underpinnings still reflect FDA's current thinking about foods derived from GE plants and, based on our evaluations, we are confident that the GE foods in the U.S. marketplace today are as safe as their conventional counterparts.").

62. Statement of Policy: Foods Derived from New Plant Varieties, *supra* note 60.

63. *Id.* at 22991.

64. *Id.*

65. *Id.* ("Thus, consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."). The FDA has, in fact, required additional labeling on GMO foods when it found material compositional differences. *Labeling of Foods Derived from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/IngredientsPackaging/Labeling/GEPlants/ucm346858.html> (last updated Jan. 18, 2017) (noting that the FDA required labels specifying compositional differences of GMO-derived canola and soybean oils).

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

67. *Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) (holding that courts should defer to reasonable interpretations of statutes by the agencies charged with implementing them).

68. *Shalala*, 116 F. Supp. 2d at 179.

69. *Id.*

70. U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DERIVED FROM GENETICALLY ENGINEERED PLANTS (Nov. 2015), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>.

The overriding general principle of the guidance was that any label stating that a food is or is not derived from genetically-engineered plants must be truthful and not misleading.⁷¹

B. Other Scientists and Scientific Organizations: a Broad Scientific Consensus

Looking beyond the FDA, there is a broad scientific consensus on the health, environmental safety, and promise of GMO foods.⁷² Against this background, both the American Medical Association (AMA)⁷³ and American Association for the Advancement of Science (AAAS)⁷⁴ have issued strong statements opposing the labeling of GMO foods. Some scientists feel so strongly that “non-GMO” food labels are misleading and harmful that they avoid purchasing and consuming foods that contain such labels.⁷⁵

71. *Id.* The FDA similarly provided draft guidance on voluntary labeling indicating whether food has or has not been derived from genetically engineered salmon. U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOOD HAS OR HAS NOT BEEN DERIVED FROM GENETICALLY ENGINEERED ATLANTIC SALMON (Nov. 2015), <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>.

72. *See, e.g.*, Joel Achenbach, *107 Nobel Laureates Sign Letter Blasting Greenpeace over GMOs*, WASH. POST (June 30, 2016), <https://www.washingtonpost.com/news/speaking-of-science/wp/2016/06/29/more-than-100-nobel-laureates-take-on-greenpeace-over-gmo-stance/> (noting that Nobel laureates signed a letter urging Greenpeace to end opposition to GMOs, especially golden rice that could reduce blindness and death of children in the developing world, in view of scientific consensus on health and environmental safety and potential benefits of GMOs); Jon Entine, *Activists Claim That Without Long-Term Studies, GMOs Cannot Be Considered Safe: What Does Science Say?*, GENETIC LITERACY PROJECT (May 19, 2017), <https://geneticliteracyproject.org/2017/05/19/activists-claim-without-long-term-studies-gmos-cannot-considered-safe-science-say/>; Daniel Norero, *More Than 280 Organizations and Scientific Institutions Support the Safety of GM Crops*, SÍ QUIERO TRANSGÉNICOS (June 19, 2017), <http://www.siquierotransgenicos.cl/2015/06/13/more-than-240-organizations-and-scientific-institutions-support-the-safety-of-gm-crops/>; *The International Scientific Consensus on Genetically Engineered Food Safety*, CREDIBLE HULK BLOG (Nov. 22, 2015), <http://www.crediblehulk.org/index.php/2015/11/22/the-international-scientific-consensus-on-genetically-engineered-food-safety/> (collected research on GMO safety and the collected positions of worldwide scientific and health organizations).

73. *See* AM. MED. ASS'N, COUNCIL ON SCI. & PUB. HEALTH, LABELING OF BIOENGINEERED FOODS 7 (2012), <https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council%20Reports/council-on-science-public-health/a12-csaph2-bioengineeredfoods.pdf> (“Despite strong consumer interest in mandatory labeling of bioengineered foods, the FDA’s science-based labeling policies do not support special labeling without evidence of material differences between bioengineered foods and their traditional counterparts. The Council supports this science-based approach . . .”).

74. *See* AM. ASS'N FOR THE ADVANCEMENT OF SCI., STATEMENT BY THE AAAS BOARD OF DIRECTORS ON LABELING OF GENETICALLY MODIFIED FOODS (2012), https://www.aaas.org/sites/default/files/AAAS_GM_statement.pdf (“Legally mandating such a label can only serve to mislead and falsely alarm consumers.”).

75. *See, e.g.*, Layla Katirae et al., *We’re Scientists. We’re Moms. And We Avoid Non-GMO Products*, LAYLA KATIRAE BLOG (Nov. 4, 2016), <https://medium.com/@BioChicaGMO/were-scientists-we-re-moms-and-we-avoid-non-gmo-products-33bc0aa351a3> (showing scientist-moms

Despite a broad scientific consensus on GMOs and the scientific approach to GMO regulation, the National Academies of Sciences, Engineering, and Medicine convened a committee of experts from diverse disciplines to reexamine all available evidence regarding benefits and negative effects of genetically engineered crops. In 2016, that committee produced a 607 page report detailing its findings.⁷⁶

C. The National Academies 2016 Report (NAS Report)

The NAS Committee took a fresh look at the primary GMO literature, rather than relying on reviews and summaries, and also considered over 700 comments and documents submitted by individuals and organizations.⁷⁷ As a result, the report reflects broad input and diverse expertise, experience, and perspective.⁷⁸

The NAS Report acknowledges the definitional difficulties surrounding GMOs⁷⁹ and employs the term “genetically engineered” to mean “introduction or change of DNA, RNA, or proteins by human manipulation to effect a change in an organism’s genome or epigenome.”⁸⁰

The NAS Report embraces the science-based approach to GMO regulation, recommending a tiered approach that is based on novelty, potential hazard, and exposure of products rather than on the process by which they were made.⁸¹ Regarding GMO experience to date,⁸² the NAS Committee

taking action on view that non-GMO labels can mislead consumers and are often inconsistent with healthy diet and sustainability values).

76. NAT'L ACADS. OF SCI., ENG'G, & MED., GENETICALLY ENGINEERED CROPS: EXPERIENCES AND PROSPECTS (2016), <https://www.nap.edu/catalog/23395> [hereinafter NAS Report].

77. *Id.* at xiii–xiv.

78. The methodology of the report furthers the stated mission of the joint National Academies “to provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions.” *Id.* at iii.

79. *Id.* at 7 (“The committee conducted its work at a time during which the genetic-engineering approaches that had been in use when national and regional regulatory systems were first developed were being replaced with newer approaches that did not fit easily into most regulatory systems or even into some older definitions of the term ‘genetically engineered.’”); *Id.* at 509 (“[A]ny attempt by regulators to define the scope of a regulatory system through the definition of specified technologies will be rapidly outmoded by new approaches.”).

80. *Id.* at 579. Like most scientists, the NAS Committee took the position that “genetically modified” encompasses alterations by both genetic engineering and non-genetic engineering methods.

81. *Id.* at 514. The same product characteristics approach would therefore be applied to both GMO and non-GMO foods. *See Id.* at 3 (“Emerging technologies have blurred the distinction between genetic engineering and conventional plant breeding to the point where regulatory systems based on process are technically difficult to defend.”).

82. *Id.* at 97. The majority of GMOs in production from the 1990s to 2015 had been modified to express insect-resistance, herbicide-resistance, or both. *Id.* Future GMOs will express more diverse and consumer-friendly traits. *See, e.g.,* Caitlin Dewey, *The Apple that Never Browns Wants to Change Your Mind About Genetically Modified Foods*, WASH. POST: WONKBLOG (Jan. 23, 2017), <https://www.washingtonpost.com/news/wonk/wp/2017/01/23/the-apple-that-never->

examined evidence accumulated over the past two decades relating to the health and environmental effects of GMOs.

The NAS Committee re-analyzed original data from studies claiming that genetically engineered foods have an adverse effect on human health. These studies included animal testing, compositional (nutrient and chemical) analysis, allergenicity testing, and epidemiological data for claimed associations between GMOs and cancer, kidney disease, obesity, gastrointestinal tract diseases, celiac disease, food allergies, and autism.⁸³ The NAS Committee found no substantiated proof of adverse health effects from currently commercialized GMOs and concluded that GMO foods do not present a higher risk to human health than their non-GMO counterparts.⁸⁴

The NAS Committee also considered claims that genetically engineered foods have an adverse effect on the environment, examining data on arthropod diversity, butterflies and bees, crop and weed biodiversity, population losses at the landscape and ecosystem levels, use of fertilizers and herbicides and resulting runoff, changing practices of monoculture and crop rotation, and dispersal of genes into weeds or adjacent unmanaged environments.⁸⁵ The NAS Committee found no evidence of a causal relationship between GMOs and adverse agronomic or environmental problems.⁸⁶ There was some evidence of associated problems such as insect and weed resistance, and possibly the loss of monarch butterfly habitats, but those were caused primarily by poor agricultural practices like the overuse of herbicides and insecticides and the failure to set aside refuges of non-GMO varieties,⁸⁷ rather than by the use of GMOs per se.

Beyond finding no evidence for negative effects of GMOs on health or the environment, the NAS Report describes the promise of current and future GMOs with traits that benefit human health and/or the environment. Examples include foods with improved nutritional content⁸⁸ or reduced toxins,⁸⁹ and crops with increased yields and stress tolerance.⁹⁰

While the NAS Report concludes that GMOs have not produced negative

browns-wants-to-change-your-mind-about-genetically-modified-foods/ (describing how future GMOs may include convenience and other consumer-friendly factors, “potentially opening the market to pink pineapples, antioxidant-enriched tomatoes, and other food currently in development.”).

83. NAT’L ACADS. OF SCI., ENG’G, & MED., *supra* note 76 at 171–225.

84. *Id.* at 225.

85. *Id.* at 97–155.

86. *Id.* at 154–55.

87. *Id.*

88. *Id.* at 226–27 (showing that GMO golden rice produces beta-carotene that can alleviate the vitamin A deficiency that causes blindness and death in malnourished children).

89. *Id.* at 229–30 (showing that GMO potatoes with lower asparagine content produce lower levels of the human carcinogen acrylamide when cooked at high temperatures).

90. *Id.* at 411 (showing that beneficial traits that can be developed through genetic engineering include heat-, cold-, drought-, or salt-tolerance, improved water use and nutrient uptake, introduction or improvements in nitrogen fixation, and quality standardization).

health or environmental effects, and that future GMO regulation should focus on the characteristics of products rather than the processes used to make them, the report stops short of making recommendations about GMO labeling.⁹¹ It concludes that labeling is a legislative policy choice that may require consideration of factors like multiple (GMO, organic, and non-GMO/non-organic) co-existing supply chains, constraints on trade, and consumer preference.⁹²

Some scientists have criticized the NAS Report for not going far enough to dispel concerns about negative health and environmental effects of GMOs. Giddings and Miller, for example, argue that the NAS Report fails to convey the longstanding and broad consensus in the scientific community about GMOs,⁹³ that it inappropriately imports public opinion into scientific questions,⁹⁴ that it is likely to confuse non-expert readers,⁹⁵ and that it fails to provide adequate direction to policymakers.⁹⁶ So while its conclusions are reassuring, the overall tone, methodology, and policy ramifications of the NAS Report are the subject of continuing debate in the Correspondence Section (reader feedback) of *Nature Biotechnology*.⁹⁷

Although science unambiguously tells us that GMOs as a class do not harm health or the environment, many people continue to demand GMO labeling for reasons of personal preference, or because they don't understand the issue, or often by merely reciting the mantra of a naked "right to know." The law has responded by enacting GMO labeling legislation at both the state and federal levels.⁹⁸

91. *Id.* at 501.

92. *Id.* at 296–310.

93. L. Val Giddings & Henry Miller, Letter to the Editor, *US National Academies Report Misses the Mark*, 34 *NATURE BIOTECHNOLOGY* 1226, 1227 (2016).

94. *Id.* ("Science is not democratic. The citizenry do not get to vote on whether a whale is a mammal or a fish, the temperature at which water boils, or whether the number 'pi' should be rounded off.").

95. *Id.* ("This is particularly unfortunate, given the continuing circulation of anti-genetic-engineering tropes in the general media.").

96. *Id.* (lamenting the report's "singular failure to provide direction to policymakers on how to build on the 25 years of evidence that has put to rest many of the initial hypothetical concerns focused on transgenic technology").

97. Fred Gould et al., Letter to the Editor, *Elevating the Conversation About GE Crops*, 35 *NATURE BIOTECHNOLOGY* 302, 302–04 (2017) (responding to criticism by authors of the NAS Report); Paul Vincelli et al., Letter to the Editor, *National Academies Report Has Broad Support*, 35 *NATURE BIOTECHNOLOGY* 304, 304–06 (2017) (responding to criticism by scientists who participated in a forum on the NAS Report); L. Val Giddings & Henry Miller, Reply to Letters to the Editor, 35 *NATURE BIOTECHNOLOGY* 306, 306–08 (2017) (replying to and elaborating on the criticisms of the NAS Report).

98. Some commentators contend that mandatory GMO labeling is a form of compelled commercial speech that violates the First Amendment. Jonathan H. Adler, *Compelled Commercial Speech and the Consumer Right to Know*, 58 *ARIZ. L. REV.* 421, 458–63 (2016); *Contra* George A. Kimbrell & Aurora L. Paulsen, *The Constitutionality of State-Mandated Labeling for Genetically Engineered Foods*, 39 *VT. L. REV.* 341, 388–90 (2014). This interesting issue will eventually be addressed in the courts and is not discussed further in this paper.

IV. THE LEGISLATIVE RESPONSE

A. State GMO Labeling Laws and Federal Preemption

GMO labeling laws have been proposed, through legislation or ballot initiative, in at least thirty states.⁹⁹ The labeling laws failed in six states, including Washington, Oregon, and California,¹⁰⁰ but were passed in Vermont, Connecticut, and Maine.¹⁰¹ The Connecticut and Maine laws were conditioned on the passage of similar legislation in additional states.¹⁰² Vermont became the first and only state to require labeling of GMO foods after it passed House Bill 112 in May 2014. The Vermont law¹⁰³ became effective on July 1, 2016,¹⁰⁴ and required labeling of all foods “entirely or partially produced with genetic engineering” and offered for sale in Vermont.¹⁰⁵ Commentators predicted that Vermont’s law would become a de facto national standard, since it is impractical to create a single-state food supply chain.¹⁰⁶ Some food producers announced plans to label GMO foods nationwide,¹⁰⁷ but a few “down to earth” Vermont retailers found that it was cheaper and easier to simply label all foods as GMOs, whether they were or not.¹⁰⁸ In less than one month, Congress stepped in and the Vermont labeling law (and pending bills in other states) was preempted by federal legislation.¹⁰⁹

B. Dueling Federal Approaches: Voluntary or Mandatory GMO Labeling?

Concerned that a patchwork of conflicting state and local GMO labeling

99. Glenn S. Kerner & Nilda M. Isidro, *The Ongoing Battle over GMO Labeling*, FOR DEF., Apr. 2016, at 36, 40, <https://www.goodwinlaw.com/-/media/files/publications/attorney-articles/2016/ftd1604kernerisidro.pdf>.

100. *Id.* at 41.

101. *Id.* at 40 (noting that other states also passed labeling laws, including a labeling law in Alaska that was limited to GMO salmon).

102. Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN ST. L. REV. 789, 803–04 (2013).

103. *Labeling of Food Produced with Genetic Engineering*, VT. STAT. ANN. tit. 9, §§ 3041–48 (2014).

104. Stephanie Strom, *G.M.O.s in Food? Vermonters Will Know*, N.Y. TIMES (June 30, 2016), <https://www.nytimes.com/2016/07/01/business/gmo-labels-vermont-law.html>.

105. tit. 9, § 3043.

106. Robert King, *Vermont GMO Labeling Law May Become the Norm*, WASH. EXAMINER (Apr. 18, 2016, 12:01 AM), <http://www.washingtonexaminer.com/vermonts-gmo-labeling-law-may-become-the-norm/article/2588527>.

107. *Id.* (reporting that the pending Vermont law prompted Kellogg, General Mills, and Mars to re-label all their products).

108. William Maire, Letter to the Editor, *The Law of Unintended Consequences*, CALEDONIAN REC. (Aug. 8, 2016), http://www.caledonianrecord.com/opinion/letters/the-law-of-unintended-consequences--william-maire/article_2797bbe8-8a9c-52b8-b812-45e5051dfc20.html (“No research, paperwork, affidavits from suppliers and no additional costs to be passed on to the consumer.”).

109. Mary Clare Jalonick, *Obama Signs Bill Requiring Labeling of GMO Foods*, ASSOCIATED PRESS (July 29, 2016), <https://apnews.com/65c61c63e3df4b74bb90a2187122d744>.

laws would emerge, Congress was determined to enact a uniform federal GMO labeling standard.¹¹⁰ The House of Representatives (“House”) put forth a voluntary labeling bill while the Senate favored a mandatory labeling approach (spoiler alert: in the eleventh hour, the Senate prevailed).

In July 2015, the House passed H.R. 1599, the “Safe and Accurate Food Labeling Act (SAFLA).”¹¹¹ Sponsors promised that the Bill would prevent the patchwork of conflicting laws,¹¹² eliminate misinformation and confusion,¹¹³ and help control food costs.¹¹⁴ They noted the importance of agricultural biotechnology, and argued that mandatory labeling “has no basis in legitimate health or safety concerns, but is a naked attempt to impose the preferences of a small segment of the populace on the rest of us.”¹¹⁵ H.R. 1599 mandated what was previously a voluntary FDA safety consultation for all GMO foods,¹¹⁶ established a voluntary user-fee based labeling program at the USDA,¹¹⁷ and preempted state GMO labeling laws.¹¹⁸ H.R. 1599 was vilified by GMO opponents who dubbed it the DARK (Denying Americans the Right to Know) Act,¹¹⁹ since it preempted mandatory state labeling laws but established only a voluntary federal standard. H.R. 1599 was sent to the Senate in July 2015, where it languished in the Committee on Agriculture.¹²⁰ A Republican effort to introduce a companion Senate version was blocked by Democrats in March 2016.¹²¹ The Senate instead scrambled to come up with its own federal labeling law, just as Vermont’s law was coming into effect.

On June 23, 2016, members of the Senate Agriculture Committee introduced a bipartisan compromise bill to create a mandatory federal GMO

110. 161 CONG. REC. H5416 (daily ed. July 23, 2015) (stating that one objective of a pending GMO labeling bill is to “prevent the creation of what would be the unworkable patchwork of State-by-State—or even county-by-county or city-by-city—mandatory GE labeling laws”).

111. H.R. 1599, 114th Cong. (2015).

112. H.R. REP. NO. 114–208, pt. 1, at 11 (2015).

113. *Id.*

114. 161 CONG. REC. H5416 (daily ed. July 23, 2015) (“State GE labeling laws could raise the cost of the average family’s food bill by, roughly, \$500 per year.”).

115. *Id.*

116. H.R. 1599 §§ 101, 111.

117. *Id.* § 201; H.R. REP. NO. 114–208, pt. 1, at 17 (“Section 201 establishes a voluntary genetically engineered food certification program within USDA to govern label claims with respect to the use or non-use of genetic engineering in the production and processing of food”).

118. H.R. 1599 § 113.

119. *E.g.*, *The DARK Act*, JUST LABEL IT, <http://www.justlabelit.org/dark-act/> (last visited Mar. 25, 2017).

120. *See H.R. 1599 – Safe and Accurate Food Labeling Act of 2015*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/house-bill/1599/all-actions?overview=closed#tabs> (last visited Oct. 7, 2017).

121. *See Puneet Kollipara, Opposition Stalls U.S. Senate Bill Aimed at Blocking GMO Food Labels*, SCI. (Mar. 17, 2016, 11:45 AM), <http://www.sciencemag.org/news/2016/03/opposition-stalls-gmo-food-labeling-bill-us-senate> (“Democrats in the U.S. Senate . . . blocked a mostly Republican-led effort to bar state from requiring labels for foods made with genetically modified organisms (GMOs).”).

labeling standard.¹²² Tradeoffs in the compromise included a mandatory labeling scheme offset by a narrow definition of bioengineering and an option to use digital codes rather than on-package labels. With a sense of great urgency,¹²³ the Senate inserted the compromise language into an unrelated pending bill, S. 764.¹²⁴ The amended S. 764 passed with minimal discussion in the Senate (July 7) and House (July 14), and the National Bioengineered Food Disclosure Standard was signed into law by President Obama on July 29, 2016.¹²⁵

C. The National Bioengineered Food Disclosure Standard (NBFDS)

The NBFDS provides for mandatory labeling of bioengineered food.¹²⁶ Food is “bioengineered” under the NBFDS if it (a) contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques, and (b) the modification could not otherwise be obtained through conventional breeding or found in nature.¹²⁷ Labels can be in the form of text, a symbol, or a digital link.¹²⁸ Two preemption provisions prohibit states and localities from enacting non-identical labeling laws for either bioengineered foods¹²⁹ or for genetically engineered foods generally.¹³⁰ The USDA is charged with developing and implementing detailed disclosure

122. Press Release, U.S. Senate Comm. on Agric., Nutrition, & Forestry, Chairman Roberts: Biotechnology Compromise Protects Producers, Informs Consumers (June 23, 2016), <https://www.agriculture.senate.gov/newsroom/rep/press/release/chairman-roberts-biotechnology-compromise-protects-producers-informs-consumers>.

123. *Id.* (“Unless we act now, Vermont law denigrating biotechnology and causing confusion in the marketplace is the law of the land.”).

124. *See S.764 – A Bill to Authorize and Amend the National Sea Grant College Program Act, and for Other Purposes*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/764/all-actions> (last visited Oct. 7, 2017). S. 764 initially sought to reauthorize the Sea Grant Program. *Id.* In September 2015, the House stripped the Sea Grant language and replaced it with language to defund Planned Parenthood. *Id.* In July 2016, the Senate stripped the Planned Parenthood language and replaced it with the federal GMO labeling standards. *Id.*

125. National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified at 7 U.S.C. § 1639).

126. National Bioengineered Food Disclosure Standard, 7 U.S.C. § 1639b(a) (2016).

127. *Id.* § 1639(1)(A)–(B).

128. *Id.* § 1639b(b)(2)(D).

129. *Id.* § 1639b(e).

130. *Id.* § 1639i(b). “Genetically engineered” is not defined by the statute but is presumably much broader than “bioengineered.” The U.S. Department of Agriculture website unofficially defines “genetic engineering” as “[m]anipulation of an organism’s genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.” *Glossary of Agricultural Biotechnology Terms*, U.S. DEP’T OF AGRIC., <https://www.usda.gov/topics/biotechnology/biotechnology-glossary> (last visited Mar. 27, 2017).

regulations within two years.¹³¹

D. Problems with the NBFDS

Conceptually, no good rationale supports a mandatory GMO labeling scheme. GMOs as a class do not cause adverse health or environmental effects, so they are best regulated based on individual product characteristics rather than on the technology used to create them.¹³² Labels do not provide actionable information for most people, are costly for producers, sellers, and consumers, and mislead consumers about potential risks in the foods they are choosing. A voluntary labeling scheme adequately serves the needs of, and shifts costs to, those who would avoid GMOs for subjective reasons of personal preference. Beyond this big picture problem, the NBFDS definition of “bioengineered” is ambiguous as to the scope of the statute’s coverage.

Under the NBFDS definition, bioengineered foods must contain genetic material (DNA),¹³³ but most of the products currently processed from GMOs—including sugars, starches, and oils—do not contain DNA. Under the NBFDS definition, bioengineered foods must have a modification that could not be obtained through conventional breeding or found in nature,¹³⁴ but it is extremely difficult to prove that something, *anything*, could not happen in nature.¹³⁵ The FDA raised these issues, and its concern that the USDA and FDA might adopt conflicting positions on food labeling, while the NBFDS was being drafted.¹³⁶ The USDA immediately adopted a conflicting position (“as the lead implementing agency”) that the NBFDS would cover all GMOs and

131. *Id.* § 1639b(a). It is curious that the USDA is charged with implementing the disclosure mandate since the FDA is generally responsible for food labeling pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2012).

132. Individual GMOs may have characteristics that raise concerns and those need to be examined on a case-by-case basis. As noted in Section III.A *supra*, the FDA already requires GMOs that are materially different from their traditional counterparts to be labeled pursuant to the FDCA’s prohibition of misbranded food.

133. 7 U.S.C. § 1639(1)(A).

134. *Id.* § 1639(1)(B).

135. Perusing organisms over the evolutionary timescale, one sees that a plethora of genetic modifications have occurred in nature and in agriculture. As one interesting and relevant example, cultivated sweet potatoes from around the world produce hormones from genes that were transferred naturally from soil bacteria and then selected by farmers. Tina Kyndt et al., *The Genome of Cultivated Sweet Potato Contains Agrobacterium T-DNAs with Expressed Genes: An Example of a Naturally Transgenic Food Crop*, 112 PROC. NAT’L ACAD. SCI. 5844, 5844–49 (2015). In another interesting example, scientists recently reported on a naturally occurring genetic exchange between a virus, parasitic wasps, butterflies, and moths. Laila Gasmi et al., *Recurrent Domestication by Lepidoptera of Genes from Their Parasites Mediated by Bracoviruses*, 11 PLOS GENETICS e1005470 (2015), <http://journals.plos.org/plosgenetics/article/file?id=10.1371/journal.pgen.1005470&type=printable>.

136. U.S. FOOD & DRUG ADMIN., FDA/HHS TECHNICAL ASSISTANCE ON SENATE AGRICULTURE COMMITTEE DRAFT LEGISLATION TO ESTABLISH A NATIONAL DISCLOSURE STANDARD FOR BIOENGINEERED FOODS (EDW16734) (June 27, 2016), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/fdacommentsgmobill.pdf (last visited Mar. 27, 2017).

all products from GMOs.¹³⁷

Even GMO labeling proponents are not happy with the NBFDS. They object to its confusing definitions and potentially limited applicability, the fact that its preemptive scope is much broader than its labeling mandate, its acceptance of digital codes rather than requiring text labels, and the way it was rushed through Congress and to the President with little substantive debate.¹³⁸

In summary, almost no one is satisfied with the NBFDS.¹³⁹ But political changes brought on by the 2016 elections, including the new administration's hostility toward federal regulation, may offer an opportunity to revise or repeal the statute.¹⁴⁰

V. RECOMMENDATIONS AND OPPORTUNITY FOR A DO-OVER

A. Recommendation to Return to a Voluntary Labeling Scheme

The NBFDS is in need of a do-over. It is not science-based,¹⁴¹ has both economic and non-economic costs, and does not even meet the stated needs of labeling proponents. The United States should return to a voluntary federal GMO labeling program for both principal-based and experience-based reasons.

In principle, genetic engineering is just one method for altering the characteristics of foods, falling on the same continuum as more traditional (and long-employed) methods like crossbreeding, hybridization, mutagenesis, and

137. See 162 CONG. REC. S4994 (daily ed. July 12, 2016). Jeffrey M. Prieto, General Counsel for the U.S.D.A. explained the scope of the GMO labeling legislation in a letter to Sen. Debbie Stabenow, the Ranking Member of the Senate Committee on Agriculture, Nutrition & Forestry. *Id.*

138. See, e.g., Andrew Kimbrell, *Why the GMO 'Labeling' Bill That Obama Just Signed into Law Is a Sham—and a National Embarrassment*, CTR. FOR FOOD SAFETY: BLOG (Aug. 4, 2016), <http://www.centerforfoodsafety.org/blog/4441/why-the-gmo-labeling-bill-that-obama-just-signed-into-law-is-a-shamand-a-national-embarrassment>; Stephen Dinan, *Obama Signs Bill Overturning Vermont's GMO Labeling Law*, WASH. TIMES (Aug. 2, 2016), <http://www.washingtontimes.com/news/2016/aug/2/obama-signs-bill-overturning-vermonts-gmo-labeling/>.

139. A possible exception is the food industry. The NBFDS, with its nationwide applicability and broad preemption, a potentially narrow scope, and the option to use digital codes rather than text labels, may be a palatable substitute for the industry's preferred option of no mandatory labeling. See, e.g., Rob Coleman, *Food Lobby Spends \$101 Million in 2015 to Avert GMO Labeling*, ENVTL. WORKING GROUP (Feb. 25, 2016), <http://www.ewg.org/research/lobbying-anti-labeling-groups-tops-100m>.

140. See *infra* Section V.B.

141. Whereas this paper largely focuses on scientific analysis, economic analysis leads to similar conclusions. See Cass R. Sunstein, *On Mandatory Labeling, with Special Reference to Genetically Modified Foods*, 165 U. PA. L. REV. 1043 (2017). Under the economic analysis, mandatory labeling cannot be justified unless there is a market failure, i.e., relevant information is not being voluntarily disclosed, and the benefits of labels justify the costs. *Id.* at 1080. Professor Sunstein leaves open a small window for GMO labeling as justified by environmental harms. *Id.* at 1049. But as discussed in Part III *supra*, the process of genetic engineering is no more likely to cause environmental harm than any other natural or traditional modification process.

tissue culture selection. GMO foods, like foods developed by other methods including evolution, may have small or large changes in endogenous or exogenous genes, leading to an almost infinite universe of changed food characteristics. Genetic engineering does not inherently give rise to more harmful products than other methods. GMO foods as a class are not more harmful than foods produced by other methods. And the FDA does already require labeling for material changes to a (GMO or non-GMO) food's characteristics.

On experience, after more than two decades of growing and studying GMO crops, there have been no verified instances of health or environmental harms specifically attributed to GMOs. Beyond not causing harm, GMOs offer the promise of consumer-driven improvements and of feeding a hungry world¹⁴² through the development of crops that can thrive in inhospitable conditions, require fewer chemicals, and provide micronutrients to undernourished populations.

Bambauer et al. have analogized mandated disclosure laws to education, arguing that in order to be valuable and not wasteful, disclosures must be material, proportional, and suitable.¹⁴³ But a label indicating that a food does or does not contain GMOs does not convey any useful information about the characteristics of that food. It says nothing about safety, or quality, or nutrition, or harm to the environment. And labeling raises the costs of foods for both producers and consumers.¹⁴⁴ Mandated GMO labels raise unfounded concerns that demonize a valuable technology and threaten to withhold its benefits from those who want or need them. Moreover, mandating labels containing non-material information because of consumer demands opens the door to an ever-

142. See, e.g., Borlaug: "It Is Impossible to Be Anti-Hunger and Anti-Technology," TRI-STATE NEIGHBOR (Apr. 28, 2017, 2:51 PM), http://www.tristateneighbor.com/news/regional/borlaug-it-is-impossible-to-be-anti-hunger-and-anti/article_0dee30f4-2c4c-11e7-9656-d3abfbdf49a2.html. In a speech at South Dakota State University, anti-hunger advocate Julie Borlaug noted that there are approximately 10.9 million hunger-related deaths per year worldwide and commented that biotechnology holds the key to helping to feed a hungry world: "It is impossible to be anti-hunger and anti-technology." Bangladesh, one of the poorest nations in the world, has embraced GMOs to boost crop production and reduce the use of insecticides and herbicides; success there will hopefully lead to more acceptance of GMO crops in other countries. Steven Cerier, *Bangladesh's Embrace of GMO Technology May Embolden Innovation in Developing Countries*, GENETIC LITERACY PROJECT (May 9, 2017), <https://geneticliteracyproject.org/2017/05/09/bangladeshs-embrace-gmo-technology-may-embolden-innovation-developing-countries/>.

143. Jane Bambauer et al., *A Bad Education*, 2017 U. ILL. L. REV. 109, 127–34 (2017). Materiality means the ability to affect better-informed choices. *Id.* at 127. Proportionality means insuring that disclosures do not cause over-reaction. *Id.* at 130. Suitability means that there is broad consensus that *this* disclosure, within the universe of potentially relevant disclosures, should be mandated. *Id.* at 132.

144. See Bruce Chassy & Jon Entine, *The Real Cost of Mandatory GMO Labeling*, HUFFINGTON POST: BLOG (Dec. 23, 2016, 9:55 AM), http://www.huffingtonpost.com/jon-entine/the-real-cost-of-mandator_b_8865742.html ("[Food producers] would have to create separate handling and processing facilities, cope with increased cost of ingredients, formulate new products, fight for scarce space on supermarket shelves, and hope that they have made the right choices so they will be able to sell their products to a confused and skeptical public.").

widening scope of subjective demands.¹⁴⁵ Objectively unreasonable consumer anxiety simply does not create a right to know.

While there are no objective justifications for labeling GMO foods, those with subjective personal preferences and those asserting curiosity or a naked right to know can already choose foods labeled as GMO-free and appropriately bear the increased costs of labeling. Producers can choose to voluntarily label the GMO status of their foods,¹⁴⁶ and there are private organizations that certify GMO status.¹⁴⁷ Moreover, those who wish to avoid GMOs can select USDA organic foods.¹⁴⁸

A federal voluntary labeling law, much like H.R. 1599 that passed the House but stalled in the Senate,¹⁴⁹ would permit voluntary labeling, establish uniform nationwide labeling standards, and preclude a patchwork of conflicting laws from being enacted by individual states and localities. Before passage of the NBFDS, the USDA had developed a voluntary, user-fee based government program for the certification and labeling of GMO foods,¹⁵⁰ and a voluntary labeling law could build on those efforts.

In ordinary times, it might seem foolish to propose rolling back a federal statute that is less than a year old. But we do not live in ordinary times. The election of 2016 shifted political power to a regime that is more than willing to revisit major legislation and scale back what it views as undue regulation.

B. Donald Trump and Republican Views on GMO Labeling

Donald Trump's surprise ascendency to the presidency, combined with a

145. For example, some consumers may demand to know which chemicals were applied to food crops; others may demand to know whether the crops were harvested by undocumented workers, or if those workers were paid a living wage. Some consumers may demand to know if the farmer used any Monsanto products, or may only want to buy foods from farmers living in pink houses.

146. Producers must walk a fine line when deciding whether to voluntarily label foods as non-GMO, as Cargill Inc. discovered when it announced a partnership with the Non-GMO Project and faced outrage from both scientists and farmers. Kristen Leigh Painter, *How a Moment That Looked Like PR Win for Cargill Turned into a Kerfuffle*, STAR TRIB. (MINNEAPOLIS, MINN.) (Apr. 1, 2017), <http://www.startribune.com/how-a-moment-that-looked-like-pr-win-for-cargill-turned-into-a-kerfuffle/417818843/>.

147. *E.g.*, *Verification FAQs*, NON-GMO PROJECT, <https://www.nongmoproject.org/product-verification/verification-faqs/> (last visited Oct 9, 2017) (offering third party non-GMO food and product verification; verified products can include the Non-GMO Project butterfly seal on their packaging).

148. 7 C.F.R. § 205.105(e) (2017) (requiring that product to be sold or labeled as "organic" must be produced and handled without the use of excluded methods); *Id.* § 205.2 (including use of recombinant DNA technology as an excluded method); *see also* U.S. DEP'T OF AGRIC., CAN GMOS BE USED IN ORGANIC PRODUCTS? 1 (2013).

149. *See supra* Section IV.B (discussing H.R. 1599, the voluntary GMO labeling bill passed by the House).

150. Mary Clare Jalonick, *USDA Creates Certification, Label for GMO-Free Food*, SEATTLE TIMES (May 14, 2015), <http://www.seattletimes.com/nation-world/usda-creates-certification-label-for-gmo-free-food/>.

Republican majority in both houses of Congress, ushered in a frenetic era of GOP attempts to undo both law and policy choices from the Obama administration. This political and ideological change may affect the course of the NBFDS, since the 2016 GOP Platform and Trump both oppose mandatory GMO labeling.

The Republican Platform, rolled out at the party convention in July 2016, states: “We oppose the mandatory labeling of genetically modified food, which has proven to be safe, healthy, and a literal life-saver for millions in the developing world.”¹⁵¹ Republicans who preferred voluntary GMO labeling are said to have backed the NBFDS only reluctantly, driven by an urgent need to preempt the Vermont GMO labeling law.¹⁵² And, although GMOs were not mentioned as an issue on Trump’s presidential campaign site,¹⁵³ he responded affirmatively to the 2016 Iowa Farm Bureau Survey question, “Do you support the use of biotechnology in food products and oppose efforts to require mandatory labeling for foods simply because they contain ingredients derived from biotechnology?”¹⁵⁴ Republican opposition to mandatory GMO labeling may manifest as direct or indirect attempts to undermine the NBFDS.

The Republicans could try to mount a wholesale repeal of the NBFDS, analogous to their efforts to repeal Obama’s signature healthcare legislation.¹⁵⁵ This seems unlikely in the near term since the Republicans have their hands full with healthcare and tax reform, infrastructure spending, federal spending authority, and other policy shifts, and do not enjoy a filibuster-proof majority in the Senate.¹⁵⁶ More likely, the NBFDS will be watered down through Trump’s and the Republican Party’s general hostility toward regulation.

Since taking office, Trump has signed several executive orders aimed at reducing regulation and controlling regulatory costs. Executive Order No. 13,771¹⁵⁷ requires that each new federal regulation be offset by the repeal of two other regulations and limits the amount of incremental regulatory costs for

151. Republican Party, Republican Platform 2016 17 (2016), <http://src.bna.com/gT7>.

152. Casey Wooten, *Republicans Target SNAP, Labeling Rules in Platform*, BLOOMBERG BNA: DAILY REP. FOR EXECUTIVES (July 20, 2016), <https://www.bna.com/republicans-target-snap-n73014445033/> (reporting that Republican lawmakers preferred a voluntary labeling regime, but with a pressing need to preempt the Vermont statute, time had run out to strike a more agreeable deal with democrats who largely backed mandatory labeling).

153. See *Policies*, DONALDJTRUMP.COM, (Nov. 4, 2016), <https://www.donaldjtrump.com/policies> [<https://web.archive.org/web/20161108080437/https://www.donaldjtrump.com/policies>] (including policies related to infrastructure, cyber security, and trade, among others, but not GMOs).

154. *Read the Candidates’ Positions*, IOWA FARM BUREAU, <https://www.iowafarmbureau.com/News/2016-Farmers-Caucus/Read-the-Candidates-Positions> (last visited Apr. 10, 2017).

155. See generally Timothy Jost, *Day One and Beyond: What Trump’s Election Means for the ACA*, HEALTH AFF. BLOG (Nov. 9, 2016), <http://healthaffairs.org/blog/2016/11/09/day-one-and-beyond-what-trumps-election-means-for-the-aca/>.

156. The Senate is critical because, as noted *supra* in Section IV.B, the House was able to pass the voluntary GMO labeling standard H.R. 1599 (SAFLA) in July 2015.

157. Exec. Order No. 13,771, 82 Fed. Reg. 9339 (Jan. 30, 2017).

each agency. Executive Order No. 13,777¹⁵⁸ directs each agency to form a Regulatory Reform Task Force to evaluate regulations and make recommendations regarding repeal, replacement, or modification of “unnecessary regulatory burdens.”¹⁵⁹ Executive Order No. 13,790¹⁶⁰ establishes the Interagency Task Force on Agriculture and Rural Prosperity, headed by newly-installed Secretary of Agriculture Sonny Perdue, to “identify and eliminate unnecessary regulations that hurt our nation’s farmers and rural communities.”¹⁶¹

This anti-regulatory agenda is widely expected to hinder the ability of the USDA to develop regulations implementing the NBFDS, which the USDA is charged with promulgating by July 2018.¹⁶² That task includes drafting regulations to flesh out the definition of “bioengineered,” to specify threshold amounts of bioengineered ingredients that trigger labeling, to provide reasonable disclosure options for small packages and small manufacturers, and to conduct a study identifying technological challenges that may impact consumer access to electronic or digital disclosures.¹⁶³ USDA rulemaking is reportedly behind schedule and without a budget.¹⁶⁴ Coupling definitional

158. Exec. Order No. 13,777, 82 Fed. Reg. 12,285 (Feb. 24, 2017).

159. Exec. Order No. 13,777, 82 Fed. Reg. 12,286 (Feb. 24, 2017) (“At a minimum, each Regulatory Reform Task Force shall attempt to identify regulations that: (i) eliminate jobs, or inhibit job creation; (ii) are outdated, unnecessary, or ineffective; (iii) impose costs that exceed benefits; (iv) create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies; (v) are inconsistent with the requirements of section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), or the guidance issued pursuant to that provision, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or (vi) derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.”).

160. Exec. Order No. 13,790, 82 Fed. Reg. 20,237 (Apr. 25, 2017).

161. Press Release, White House Office of the Press Sec’y, Remarks by President Trump in Farmers Roundtable and Executive Order Signing Promoting Agriculture and Rural Prosperity in America (Apr. 25, 2017), <https://www.whitehouse.gov/the-press-office/2017/04/25/remarks-president-trump-farmers-roundtable-and-executive-order-signing>.

162. Beyond a deadline issue, Professor Sunstein has pointed out the substantive challenges that face the USDA in this task. While the agency is required by statute to develop mandatory GMO labeling regulations, it will be difficult to justify those regulations as satisfying the requirements of: (a) a market failure and (b) benefits justifying costs. Sunstein, *supra* note 141, at 1079–81.

163. National Bioengineered Food Disclosure Standard, 7 U.S.C. § 1639b (2016) (requiring USDA to conduct a study and establish GMO labeling regulations within two years of enactment of the statute).

164. See Emilee Hargis & Ashley Jaros, *Update: GMO Labeling Regs Get Trumped*, JD SUPRA (Feb. 3, 2017), <http://www.jdsupra.com/legalnews/update-gmo-labeling-regs-get-trumped-35276/> (asserting that Trump’s regulatory stance essentially freezes USDA’s ability to conduct research required by the NBFDS, and that the USDA may need to cut existing regulations in order to promulgate new ones); see also Chelsey Davis, *GMO Labeling May Be Dead on Arrival Due to Trump Requirement*, TRACEGAINS: INSIGHTS BLOG (Mar. 15, 2017, 4:55 PM), <https://www.tracegains.com/blog/gmo-labelling-may-be-dead-on-arrival-due-to-trump-requirement> (reporting that an unnamed USDA source believes Trump’s Executive Order on Reducing Regulation spelled the end of GMO labeling and that the USDA’s Notice of Proposed Rulemaking was withdrawn under the new administration).

ambiguities in the statute¹⁶⁵ with the new administration's anti-regulatory and pro-business agenda, a final USDA rule package may be significantly delayed. The resulting rules may require that only a few types of foods be labeled and permit labeling in the form of a digital link to further information.¹⁶⁶ Because the NBFDS already provides strong preemption, and third party voluntary GMO certification services are already available, the practical outcome would look very much like a voluntary GMO labeling standard.

C. Need for Scientists to Better Inform Both Legislators and the Public

The experience with GMOs, GMO labeling, and the NBFDS illuminates some big picture educational questions: How can we better incorporate science into, and exclude uninformed opinion from, our technically-based law and policy choices? How can we better educate both Congress and the public about complex topics like genetics and genetic engineering, evolution, vaccines, climate change, energy, and the environment?

1. Recommendation to Resurrect the Office of Technology Assessment

In 1972, Congress passed the Technology Assessment Act,¹⁶⁷ and created an Office of Technology Assessment (OTA) to provide “competent, unbiased information concerning the physical, biological, economic, social, and political effects of such applications.”¹⁶⁸ From 1972 to 1995, the OTA produced over 750 reports on science and technology issues ranging from Alzheimer's disease to acid rain to human gene therapy to wireless technology.¹⁶⁹ The OTA was overseen by a bipartisan committee of senators and representatives. OTA reports were known for being authoritative and independent, and for outlining pros and cons for a range of policy choices without being judgmental so that members of Congress could intelligently weigh and make their own choices.¹⁷⁰ The OTA has been characterized as a “defense against the dumb,” but it was defunded by a Republican House majority under Speaker Newt Gingrich in 1995, a move likened to a “stunning act of self-lobotomy.”¹⁷¹

165. See *supra* Section IV.D (describing ambiguity in the statute's definition of the term “bioengineered”).

166. 7 U.S.C. § 1639b (permitting GMO disclosure by text, symbol, or electronic or digital link).

167. Technology Assessment Act of 1972, Pub. L. No. 92-484, 86 Stat. 797 (codified as amended at 2 U.S.C. §§ 471–81 (1994)).

168. *Id.* § 471(d)(1).

169. See *OTA Publications*, PRINCETON U., https://www.princeton.edu/~ota/ns20/topic_f.html (last visited Apr. 11, 2017) (listing all official OTA assessments from 1974–95 by topic).

170. See Seán Finán, *Congressional Ignorance and the OTA*, HARV. L.: BILL OF HEALTH (Jan. 19, 2017), <http://blogs.harvard.edu/billofhealth/2017/01/19/congressional-ignorance-and-the-ota/>; Kim Zetter, *Of Course Congress Is Clueless About Tech—It Killed Its Tutor*, WIRED (Apr. 21, 2016, 7:00 AM), <https://www.wired.com/2016/04/office-technology-assessment-congress-clueless-tech-killed-tutor/>.

171. Chris Mooney, *Requiem for an Office*, 61 BULL. ATOMIC SCIENTISTS 40, 42 (2005), <https://www.princeton.edu/step/seminars/previous/fall-2005/Mooneyreading2005No2Requiem>

Congress has not had a single dedicated source for scientific and technical assessment since that time.¹⁷² Today's Congress is asked to legislate in a number of increasingly complex areas of science and technology, like GMOs and synthetic biology and healthcare economics, data encryption and computer security, government surveillance and missile defense, climate change and natural resources. We need to bring back the OTA so that our legislative legal and policy choices will be informed by a modicum of competent and unbiased expertise.¹⁷³ We also need to insure that uninformed public opinion does not get imported into legislative policy.

2. Recommendation to Develop Improved Methods of Public Science Education

GMOs, evolution, vaccines, and climate change all involve complex science. But the average layperson (including most lawmakers) does not have a high level of fluency with these subjects, or with risk, probability, or the scientific method, and is susceptible to pseudoscientific arguments¹⁷⁴ by activists pushing ideological anti-science agendas.¹⁷⁵ Scientists must therefore do a better job of both engendering trust in their methods and conclusions¹⁷⁶ and in making technical subjects more accessible to non-scientists.¹⁷⁷

foranoffice.pdf. The official reasons for dismantling OTA were to save money and because reports were not generated quickly enough, but more political reasons were likely also at play. *Id.* at 43.

172. See generally *Scientific and Technical Advice for the U.S. Congress: Hearing Before the H. Comm. on Sci.*, 109th Cong. (2006) (examining how Congress receives advice about scientific developments and whether systems to provide advice needed to be improved). Multiple participants lamented the lack of a dedicated source of scientific and technical advice and assessment since the OTA was eliminated. *Id.*

173. The new administration is, unfortunately, moving in the opposite direction. One of Trump's key advisors has recommended the elimination of the Office of Science & Technology Policy, which advises the President on technical issues. See Cecilia Kang & Michael D. Shear, *Trump Leaves Science Jobs Vacant, Troubling Critics*, N.Y. TIMES (Mar. 30, 2017), <https://www.nytimes.com/2017/03/30/us/politics/science-technology-white-house-trump.html>. In addition, many science and technology positions remain unfilled. *Id.*

174. In pseudoscience, facts and arguments that are inconsistent with the scientific method are imbued with an air of scientific authenticity. Pseudoscience includes the presentation of unsupported or discredited information as well as the unprincipled rejection of well-supported facts and theories.

175. See, e.g., Tagliabue, *supra* note 11, at 908 (describing a pseudoscientific publication where misinformation, errors, and misunderstanding are used to argue that GMOs are a "cataclysm waiting to happen"); Blancke, *supra* note 36, at 417 (describing how anti-GMO activists continue to cite long discredited studies claiming that GMOs per se damage health, the environment, or small farmers, and concluding "[a]s such, they cloak their arguments under a scientific veil, thus exploiting the cultural authority of science.").

176. See Mathew D. Marques et al., *Attitudes to Genetically Modified Food over Time: How Trust in Organizations and the Media Cycle Predict Support*, 24 PUB. UNDERSTANDING SCI. 601, 610 (2015) (reporting that higher trust in scientists and regulators is associated with significantly more positive attitudes toward GMOs in a ten-year study of public opinion toward GMO foods in Australia).

177. See McFadden & Lusk, *supra* note 33, at 3093–94 (finding that consumers overestimate their understanding of GMOs, but merely asking objective knowledge questions can cause respondents to reassess how much they know and shift their beliefs); see also Brandon R.

Scientific researchers and educators are exploring several innovative strategies for conveying technical information to those without specialized training. Two promising ideas have emerged from studies on how to effectively teach the topics of climate change and evolution.

As with GMOs, there are large differences in the views of scientists and the public about climate change.¹⁷⁸ Researchers have found that the use of narrative elements, i.e., explanations that include characteristics like setting, plot, characters, and policy solutions, can capture attention, increase retention, and change public perception of climate change and climate risk policy.¹⁷⁹ Similarly, there is a gap between the views of scientists and the public about evolution,¹⁸⁰ but scientists at the University of Pennsylvania (Penn) are testing the hypothesis that a “behind the scenes discussion” documentary style (similar to the after-credit clips of a nature documentary) may be one of the most effective ways to convey evolutionary concepts to the public.¹⁸¹ The Penn group is also examining how the use of more pointed survey questions can be used to tease out people’s beliefs and understandings of complex scientific subjects.¹⁸² These and other creative methods of public science education may prove advantageous in promoting better-informed public opinions about GMOs and GMO labeling.

VI. CONCLUSION

GMO foods should be regulated based on what they are rather than how they were produced because GMOs as a class do not inherently cause any more health or environmental harms than other types of foods. Labeling GMO foods has direct financial costs. Labeling also confuses consumers and demonizes

McFadden & Jayson L. Lusk, *Cognitive Biases in the Assimilation of Scientific Information on Global Warming and Genetically Modified Food*, 54 FOOD POL'Y 35 (2015). This study assessed how the public assimilates and integrates scientific information. *Id.* at 36 It found declarative scientific information was ineffective in updating prior beliefs and that “(s)tories, emotional appeals, or alternative formatting may have more pronounced effects.” *Id.* at 43.

178. PEW RESEARCH CTR., *supra* note 46, at 47. In a 2015 Pew Research survey, fifty percent of U.S. adults surveyed said the earth is getting warmer because of human activity. *Id.* In comparison, eighty-seven percent of American Association for the Advancement of Science (AAAS) scientists surveyed said the earth is getting warmer because of human activity. *Id.*

179. Michael D. Jones, *Cultural Characters and Climate Change: How Heroes Shape Our Perception of Climate Science*, 95 SOC. SCI. Q. 1, 22 (2014). Interestingly, scientists at the University of Washington have found that even peer-reviewed scientific literature is more accessible and has a higher impact factor (citation frequency, journal prestige) when reported in a more narrative style. Aleenah Ansari, *Storytelling in the Sciences: Introducing Narrative Elements in Every Medium of Science Writing*, DAILY UNIV. WASH. (Jan. 30, 2017), http://www.dailyuw.com/science/article_228e40b0-e6a3-11e6-83f3-e786d677735a.html.

180. PEW RESEARCH CTR., *supra* note 46, at 43 (finding sixty-five percent of U.S. adults surveyed said humans and other living things evolved over time in comparison with ninety-eight percent of scientists).

181. Michele Berger, *Following in Darwin’s Footsteps to Teach the Public About Evolution*, OMNIA, Fall/Winter 2016, at 28.

182. *Id.* at 26–27.

technology that can help feed a hungry world, lead to more environmentally-friendly farming practices, and provide novel consumer-friendly products. While many consumers demand GMO labeling, the majority do not understand what GMOs are and cannot explain why labeling would be useful. Those who want GMO labeling for subjective reasons, including those who assert a naked right to know, should bear the direct costs through a voluntary labeling law. Although the U.S. recently passed a mandatory GMO labeling statute, that may be undone following the 2016 Republican election victory. The GMO labeling issue epitomizes the need to find improved ways to educate both legislators and the public about science and technology, so that our laws will reflect informed policy choices.