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Genetically Modified Foods at the Intersection of the Regulatory Landscape and Constitutional Jurisprudence

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> *An ecosystem . . . [y]ou can always intervene and change something in it, but there's no way of knowing what all the downstream effects will be or how it might affect the environment. We have such a miserably poor understanding of how the organism develops from its DNA that I would be surprised if we don't get one rude shock after another.*[1]

I. INTRODUCTION

Breakthrough advancement in genetic engineering has ushered in a new era. An era where, unbeknownst to us, our diets may contain food derived from genetically engineered ("GE") substances or genetically modified organisms ("GMOs"). Such genetically modified ("GM") foods[2] have been introduced into the existing food distribution system without adequate warning to consumers. This inability to know about the foods consumers eat or the health risks they face is the stark reality of our contemporary food pyramid system. Within this system, the consumer resembles the participant in a blind experiment; the participant neither knows of nor consents to the participation. Emboldened by a two-prong transformation process, gene transfer

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[1] Michael Pollan, *Playing God in the Garden*, N.Y. TIMES, Oct. 25, 1998, (Magazine), at 49 (quoting Harvard Professor Richard Lewontin's discussion about a software metaphor related to DNA and GM foods.).

> "From an intellectual-property standpoint, it's exactly right," he said. "But it's a bad one in terms of biology. It implies you feed a program into a machine and get predictable results. But the genome is very noisy. If my computer made as many mistakes as an organism does" — in interpreting its DNA, he meant — "I'd throw it out."

Id.

[2] Throughout this Article, the expressions GM, GE, or GMO may be used synonymously to refer to foods or consumer products containing ingredients derived from genetic manipulation.

between species and adapting bio-technological research into everyday application, modern agriculture manifests itself in a pervasive commoditization of GM foods. The resulting uncertainty faced by the consumers of such commoditization can be traced to two distinct legal inadequacies: the supervisory regulatory mechanism's inability to protect public interest and existing law's inadequacy to issue appropriate labeling information for GM foods.

Lack of labeling for GM products is a serious concern for both consumers and farmers. Rampant usage of genetic engineering and widespread tinkering with bio-pesticides has greatly enhanced the risk of diseases that creep in through transgenic pathways while posing a real danger to the food distribution system.[3] With an abundance of GE crops flooding the U.S. food chain, consumers have become all too familiar with the alarming realities of the underlying regulatory process. First, the current process is not exhaustive enough to fully evaluate the long-term effects of GE foods on human health and the natural environment. Second, the regulatory approval mechanism lacks an adequate safety analysis to ward off the various calamitous consequences of human consumption. This failure to adequately balance the cost to both human and environmental health with the benefit of production efficiency of GE foods certainly calls for procedural safeguards, specifically in the form of enhanced disclosures.

Consumer protection calls for more disclosures than currently exist in the United States. These disclosures could range from additional nutritional information to content of GE products, to enhancing statutory warnings on GE foods. Absence of such enhanced disclosures on food labels has prompted legislative and executive responses in the United States. This has resulted in a new development. The perceived failure of the existing regulatory regime has ushered in the emergence of a new consumer-driven statutory framework. Poised to challenge the status quo of corporate dominance in food marketing, this framework has turned its focus to the adequacy of food labeling. This article examines how an emerging regulatory paradigm based on legislative enactments at the state level may be on a collision course with the existing corporate status quo.

Fundamentally, food law's contour must evolve through the interactive lens of procurement ease and process efficiency. Observing that process efficiency is a function of corporate ownership of the value chain, the inadequacy of the GM food regulatory regime invites us to take an introspective look at potential solutions. When legislators and governments respond by proposing a consumer-friendly regulatory regime through statutory enactments,[4] such initiatives immediately become subject to judicial scrutiny.[5] Legal challenges range from opposition based on the legislative

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[3] *See* Saby Ghoshray, *Food Safety and Security in the* Monsanto *Era: Peering Through the Lens of a Rights Paradigm Against an Onslaught of Corporate Domination*, 65 ME. L. REV. 491, 495-96 (2013) (examining food safety and security food throughout human civilization from an American legal perspective, emphasizing human rights, current regulatory schemes, and the current patent framework's contribution to the evolving menace of transgenic pollution).

[4] This Article will look at this issue through the prism of Vermont's Act 120, widely known as GMO labeling law. *See* Niraj Chokshi, *Vermont Just Passed the Nation's First GMO Food Labeling Law. Now It Prepares to Get Sued*, WASH. POST GOVBEAT (May 9, 2014), http://www.washingtonpost.com /blogs/govbeat/wp/2014/04/29/how-vermont-plans-to-defend-the-nations-first-gmo-law/ (noting that state officials preemptively created a $1.5 million legal defense fund in anticipation of future constitutional challenges).

[5] *See* Nancy Remsen, *Lawsuit Challenges Vermont's GMO Labeling Law*, USA TODAY (June 12, 2014, 8:58 PM), http://www.usatoday.com/story/news/nation/2014/06/12/lawsuit-challenges-vermonts-gmo-labeling-law/10402301/ (highlighting the fact that Vermont Attorney General, William Sorrell, openly anticipated constitutional challenges to the statute).

enactment's potential conflict with the commercial speech doctrine under the First Amendment jurisprudence.[6] This opens up many queries. Do the perceived failures and inefficiencies of the Food and Drug Administration ("FDA") provide a legitimate basis for the government to shape consumer dietary habits? Should the government step in to protect consumer interests? Does it matter that advertisers may have subjugated consumers in "marketing" their vision about consumer dietary habits? Do legislators have expertise with complex issues at the intersection of food safety and corporate interest? This article seeks to explore emerging food labeling issues residing at the intersection of constitutional jurisprudence and regulatory landscape.

This Article proceeds as follows. Part I has provided a backdrop on the current tension between lack of regulation on GM foods and consumers' fundamental right to know. Part II dissects the anatomy of the resulting food safety and its attendant security concerns. This discussion then sets the stage for presenting the applicable regulatory landscape in Part III, which leads into dissecting their inadequacy in Part IV. This then leads into providing the appropriate context for Vermont's GM labeling law in an attempt to chart a future course of regulatory actions in Part V, and Part VI provides a brief conclusion.

II. FOOD SAFETY AND SECURITY

Genetically modified crops arrived at the scene via scientific advancement in biotechnology. Despite concerns about the safety of genetic modification, the promise of solving world hunger by bringing efficiency in food production allowed its seamless introduction into the global food chain.[7] As GM crops began flooding the food system, the federal food safety regulations failed to cope with the growing sophistication of biotechnology. Issues arose. First, uncertainty over safety caused consternation among the consumers and trade safety groups.[8] Second, taking advantage of loopholes in intellectual property law, biotechnology companies began consolidating their stranglehold in food production, particularly in the seed industry.[9] This resulted in widespread usage of genetic engineering,[10] paving the way for rampant and unsafe

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[6] *See* Dan D'Ambrosio, *Nation Watching GMO Labeling Fight in Vermont*, BURLINGTON FREE PRESS (Dec. 1, 2014, 5:36 PM), http://www.burlingtonfreepress.com/story/news/local/vermont/2014/11/29/vermont-gmo-fight-nears-court/19639519/ (explaining that challengers argue that "Act 120, . . . violates the U.S. Constitution by compelling manufacturers to 'convey messages they do not want to convey,'" and because "constitutional issues are involved," if the state loses, it would be liable for the challengers' legal fees, which could easily reach $3 million).

[7] *See* Ghoshray, *supra* note 3, at 495.

[8] *See id.* at 495 n.15; *see also* A. Konig et al., *Assessment of the Safety of Foods Derived from Genetically Modified (GM) Crops*, 42 FOOD & CHEMICAL TOXICOLOGY 1047, 1048 (2004) (summarizing current regulatory frameworks and providing guidance on how to assess any "potential unintended effects" from a genetic modification).

[9] *See* Kristina Hubbard, *Out of Hand: Farmers Face the Consequences of a Consolidated Seed Industry*, FARMER TO FARMER CAMPAIGN ON GENETIC ENG'G 44-45 (Dec. 2009), http://farmertofarmercampaign.com/Out%20of%20Hand.FullReport.pdf (claiming that utility patents have facilitated the downward trend in the number of independent seed companies).

[10] Ghoshray, *supra* note 3, at 495 n.17 ("Genetic engineering . . . in the context of food production can be defined as crops produced by extracting genes from one species and inserting them into another using recombinant DNA . . . technology. Genetic [e]ngineering is also referred to as the process to develop transgenic or [GMOs]. Besides the gene or DNA fragments for the desired characteristics, genetic engineering inserts 'markers' which are used to determine if the desired characteristic was successfully inserted and 'promoters' that force such desired characteristics to express their protein(s) at all times. Genetic [e]ngineering is not the same as conventional breeding and has been in vogue for barely a quarter century.").

tinkering with bio-pesticides.[11] With the risk of diseases creeping in through transgenic pathways,[12] the food distribution system faced significant danger.[13] While the risk of disease and the threat to food safety affect the U.S. food distribution system, the underlying problem is the supervisory regulatory framework. The absence of robust regulatory oversight within the current framework has subjected consumers to corporate interests. Despite GM crops dominating the market, consumers have been largely kept in the dark about the content of such food source.

GM crops are a relatively new food source.[14] A new food source should have adequate labeling so that consumers can make informed decisions based on their understanding of the health implications that such labeling might reveal. Long beholden to corporate interests, the current regulatory framework imposes no such labeling requirement.[15] Such regulatory inadequacy ushered in a food regime where corporate interests predominated over the consumer safety and food security.[16] For example, GM crops were allowed to flood the U.S. food chain without prior studies on the long-term effects of their consumption on human health and the environment.[17] By advancing an unproven promise of production efficiency, food production companies created a consumption paradigm that bypassed many procedural safeguards to ensure sustained corporate profit.

A large question exists as to whether the pursuit of food security may have unleashed a global health and environmental catastrophe. Given the practical reality of the GM food regulatory regime, we may even ponder whether the future of U.S. food

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[11] *See* Charles M. Benbrook, *Genetically Engineered Crops and Pesticide Use in the United States: The First Nine Years*, BIOTECH INFONET (Oct. 2004), http://organic.insightd.net/reportfiles/Full_first_nine.pdf (finding that since 1996, herbicide tolerant crops have increased herbicide use by 138 million pounds); *see also* DENNIS T. AVERY, SAVING THE PLANET WITH PESTICIDES AND PLASTIC: THE ENVIRONMENTAL TRIUMPH OF HIGH-YIELD FARMING 13-19 (2d ed. 2000) (arguing that bio-pesticide agriculture promotes higher yields of farm products which in turn reduces world hunger issues and protects wildlife).

[12] *See* Eunice Chao & Daniel Krewski, *A Risk-Based Classification Scheme for Genetically Modified Foods III: Evaluation Using a Panel of Reference Foods*, 52 Regulatory Toxicology & Pharmacology 235, 241 (2008) ("[T]he allergenic potential of a food, in contrast with other adverse health effects, cannot be predicted entirely based on the characteristics of a novel gene product. An allergic response is an antigen-specific response in genetically susceptible individuals."). *But see* Ricki M. Helm, *Food Biotechnology: Is This Good Or Bad?*, 90 ANNALS ALLERGY ASTHMA & IMMUNOLOGY 90, 90 (2003) ("The estimation that more than two trillion transgenic plants have been grown in 1999 and 2000 alone, with no overt documented adverse food reactions being reported, indicates that genetic modification through biotechnology will not impose immediate significant risks as food allergen sources beyond our daily dietary intake of foods from crop plants.")

[13] *See* Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 442-43 (2007) (explaining that criticism of biotechnology stems from the unknown and possible health risks and the potential decrease in genetic diversity).

[14] *See* JORGE FERNANDEZ-CORNEJO & MARGRIET CASWELL, U.S. DEP'T. OF AGRIC., THE FIRST DECADE OF GENETICALLY ENGINEERED CROPS IN THE UNITED STATES 3-6 (2006) (reflecting on the first decade of GM crops, from 1996 to 2006).

[15] *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 97 (2001) ("The United States' position is further reinforced by the FDA's 1992 decision that foods produced using genetic transformation are the substantial equivalent of other foods and do not require labeling.").

[16] See Ghoshray, *supra* note 3, at 497-98 for a detailed explanation of the current regulatory framework and its inadequacy with respect to food safety.

[17] *See* Nina V. Fedoroff, *The Past, Present and Future of Crop Genetic Modification*, 27 NEW BIOTECH. 461, 464 (noting that since GM foods' 1996 introduction into the agricultural industry, only a few of the widely anticipated adverse effects have materialized).

safety has been compromised. Fundamentally, the lack of a robust consumer rights framework at the federal level precludes consumers from enjoying an effective food-labeling paradigm. Certainly, the absence of such labeling has thrown both farmers and consumers into a distribution system with unsafe and insecure food.[18] Lack of adequate labeling can have many consequences. Without adequate labeling of GM food, consumers remain unaware of threats from the unknown effects of bio-pesticides.[19] The pervasive use of genetic engineering in consumer food crops is well documented.[20] When the genetic makeup of crop seeds is tinkered with, sometimes to eliminate undesirable traits found in nature and sometimes to make them resistant to bio-pesticides, it introduces undesirable, poisonous, and disease-prone traits.[21] Without adequate labeling, we are therefore left with food sources that are largely unregulated within the supply chain.[22] This safety issue is the product of an inadequate and fragmented regulatory framework that currently oversees the entire food procurement system. Next, I highlight reasons this regulatory framework suffers from the inertia of moving lockstep with technology's advancement.

III. REGULATORY LANDSCAPE OF GM FOOD SYSTEM

Reacting to growing concern about GM food, governmental agencies across the globe have resorted to a wide range of rearguard actions. Such actions have ranged from creation of specific regulatory bodies to enactment of GM specific statues to labeling requirements on GM products.[23] European GM food regulations have been stringent and restrictive in providing for a high level of safety for protection of human life, health, animal welfare, and environmental sustenance—all of which contribute to a broader consumer interest.[24] On the other hand, the U.S. regulatory paradigm seems to have stalled into a confusing conundrum of inertia and corporate dominion. Shaped in part by corporate interests, and prompted in part by their own inefficiencies, the U.S. regulatory agencies have creatively manufactured regulatory authority based on

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[18] *See* Mairi Anne Mackenzie, *Industry Reaps GM Bonanza, but We Will Pay*, THE AGE (Apr. 15, 2006), http://www.theage.com.au/news/business/industry-reaps-gm-bonanza-but-we-will-pay/2006/04/14/1144521507502.html (noting how GM technology has given rise to an environment that has not only changed our way of life but has also created a sense of deep-rooted anxiety of over safety and security of the food we consume)*; see also* Hubbard, *supra* note 9, at 13 (emphasizing the adverse economic impact of GM food usage on independent farmers).

[19] *See* Hamilton, *supra* note 15, at 94.

[20] *See* Hubbard, *supra* note 9, at 20 fig. 4 (showing that in 2008, 85% of corn acreage and 92% of soybean acreage in the United States were planted with GE traits).

[21] Anita Bakshi, *Potential Adverse Health Effects of Genetically Modified Crops*, 6 J. TOXICOLOGY & ENVTL. HEALTH 211, 219-20 (2003).

[22] *See* Miroslaw Maluszynski et al., *Application of* In Vivo *and* In Vitro *Mutation Techniques for Crop Improvement*, 85 EUPHYTICA 303, 312 (1995) (describing the various genetic engineering techniques developed for crop enhancement that rely on changing mutation rates); NAT'L RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 27-28 (2004) (questioning the adequacy of the safeguard against the astounding development of more than 2300 different crop varieties using radiation-based mutation).

[23] *See generally Final Report of the Commission on the Evaluation of the EU Legislative Framework in the Field of GM Food and Feed* (July 12, 2010) *available at* http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf (providing a detailed overview of the current regulatory frameworks in Europe and compiling opinions from stakeholders and regulatory authorities).

[24] See *id.* at 6-14 for a detailed overview of the European regulatory framework and its objectives. *See also* Heather McCabe & Declan Butler, *European Union Tightens GMO Regulations*, NATURE, July 1, 1999, at 7, 7 (describing the European Union's 1999 adoption of increased regulation of GMOs).

arcane statutes.[25] Residing within these agencies' constant struggle to legitimize their oversight function has been a systemic and deep-rooted weakness of statutory incompleteness. Yet, the agencies have managed to create the illusion of adequacy, which has helped them prevail over the years despite doing a sub-optimal job in regulating the U.S. food procurement and distribution system.

A fundamental source of confusion within the U.S. regulatory process comes from the confusion over the scope and ambit of supervision of these agencies. First, the U.S. Department of Agriculture (USDA) typically oversees the distribution of GM food and products.[26] Although the USDA's basic responsibility has not changed since the original introduction of the Coordinated Framework,[27] the agency is concerned mainly with ensuring that GM products do not interfere adversely with agriculture.[28] Second, in an interesting regulatory twist, the Environmental Protection Agency (EPA) has been tasked with identifying and managing of transgenic pesticides. [29] Although these pesticides may come as transferred or naturally expressed by-products of genetic engineering, their regulation is handled by an agency that may not have the necessary expertise. Lastly, the supervisory scope of the identification, evaluation and overall management of GM food safety falls on the FDA.[30] In its supervisory capacity, the FDA shares the responsibility of ensuring food safety in the United States with the USDA.[31] Although the FDA, through the federal Food, Drug and Cosmetic Act (FDCA),[32] exercises its jurisdiction over biotechnology-based food products, the agency task definition does not provide the required specificity and necessary granularity within the FDCA.[33]

Despite the existence of many agencies, the regulatory scope does not include recombination, replacement, and substitution of genetic profiles associated with the

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[25] *See* Ghoshray, *supra* note 3, at 496 (noting that I have discussed this area extensively in my earlier work).

[26] Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2216-17 (2004).

[27] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (Exec. Office of the President June 26, 1986); *see also* Mandel, *supra* note 26, at 2216-17 (highlighting that once the Coordinated Framework for Regulation of Biotechnology was established in 1986, actual regulation of biotechnology was left to the administrative agencies).

[28] *See* FERNANDEZ-CORNEJO & CASWELL, *supra* note 14, at 4 ("[The USDA] plays a central role in regulating field-testing of agricultural biotechnology products . . . [by determining] whether the release will pose a risk to agriculture or the environment.").

[29] *See* 51 Fed. Reg. at 23, 303, 23, 313.

[30] *Id.* at 23,303, 23,309; Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (Food & Drug Admin. May 29, 1992).

[31] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,985.

[32] For example, the FDA is authorized to regulate only adulterated foods. Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 342 (2012 & Supp. I 2013). The controlling authority of the FDA comes from the statutory provision defining adulterated foods as that which "bears or contains any poisonous or deleterious substance which may render it injurious to health." *Id.* at § 342(a)(1).

> This language neither compels nor encourages the manufacturers of biotechnology-based food products to research adverse ramifications or potential hazardous implications of genetic modification. Rather, the onus of analyzing any poisonous or deleterious effects is clearly the domain of the agency. By implication, therefore, absent the FDA's intervention, the current regulatory framework does not provide a clear mandate for a biotechnology food producer to be extra vigilant towards consumer food safety.

Ghoshray, *supra* note 3, at 499-500.

[33] Ghoshray, *supra* note 3, at 499.

development of GM products.[34] Thus, in the absence of clearly identifiable laws governing these functionalities, the risk of injury to human health, environment, and ecology remain high, and as such, the need for labeling has become greater than ever before. Moreover, it has been suggested that GM food presents an even greater danger than that presented by poison or pesticide in the food distribution system.[35] Yet, while the FDA continues to be the sole regulator of GM products, there is no specific food labeling paradigm that follows the same framework currently in use for common pesticide. This has created a confusing regulatory conundrum that I highlight next.

First, without a robust labeling framework, the FDA attempts to regulate biotechnology-derived food by manipulating the statutory meaning of the FDCA term "food additives."[36] For example, Section 348 of the FDCA regulates food additives by controlling the functional implications of components within food that can render food adulterated.[37] Thus, whenever food contains a component that constitutes an additive within the meaning of the FDCA, it automatically triggers FDA oversight.[38] However, since such an oversight mechanism may not be able to distinguish between food additives that are biotechnology-derived and those that are not, it fails to regulate GM food products adequately.

Second, Section 321 of FDCA defines "food additive" as any substance that is intended for human consumption, which may reasonably be expected to become a component of food or may in any meaningful way affect the characteristic of food.[39] This component definition point of view does not have the functionalities, product definitions, or prohibitory mechanisms to address the nuances of GM foods directly. Without proper labeling laws, consumers are unable to distinguish between GM foods that are safe for consumption and GM foods that are unsafe. Lack of labeling also prevents consumers from deciphering the various side effects or potential deleterious consequences of GM foods. Clearly, lack of labeling leaves a huge regulatory gap, which food producers have created by aggressively marketing of their products.

Third, if we step away from the functionalities of food additives, it is apparent that the lack of labeling has caused the FDA to introduce imprecision within the statutory pronouncements of the FDCA. Such imprecise articulation is borne out of vagueness within FDA's policy statements and has caused significant implementation difficulties. For example, food safety has been severely compromised by the FDA's 1992 policy statement that GM crops "have been widely recognized and accepted as safe."[40] By removing many GM crops from the ambit of food additive regulation under Sections 348 and 321 of the FDCA,[41] the FDA has engaged in a scientifically flawed

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[34] *See* Michael Bennett Homer, Note, *Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83, 97-99 (2011) (arguing that the FDA's regulation of GE animals is inadequate due to the risk of loss of biodiversity in ecological environments).

[35] *See* Chao & Krewski, *supra* note 12, at 241 (suggesting that because the allergenic potential of a food product cannot be accurately predicted from gene characteristics, the potential for unintended adverse health effects is higher than non-GM food products); *see also* Konig et al., *supra* note 8, at 1048 (providing analysis of pesticide safety assessment methodologies and suggesting how to adapt these methods to GM food safety evaluations).

[36] 21 U.S.C. § 321(s).

[37] *Id.* § 348(a)(2).

[38] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22, 984, 22,985 (Food & Drug Admin. May 29, 1992).

[39] 21 U.S.C. § 321(s).

[40] Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990.

[41] 21 U.S.C. §§ 321, 348; *see* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed.

component-level analysis of GM crops.[42] It certainly provides a window through which to evaluate the impact of an absence of the food labeling laws.[43]

The absence of robust standards in the United States stand out among the developments surrounding the regulation of GM products in Europe and Asia.[44] Could a stringent food labeling law solve the GM foods conundrum in the United States? Would an adequate labeling paradigm be able to introduce the missing safety valve within the food distribution system? The confusions are plenty and the questions are many. Against this backdrop, it might be instructive to recognize that the confusion and uncertainty may not be due to lack of understanding of biotechnology-derived products. Rather, the confusion stems from corporate lobbying that has compelled the FDA to continue to evade responsibility.[45] Regulators have acquiesced to the wishes and manipulations of the very entities that produce GM products. The FDA's inability to enact rules has created an evolving paradigm where the regulatory onus has now been shifted from the agency to the producer. It is not difficult to discern how the FDA may have relinquished the responsibility of food safety to the food producers.[46] The food labeling issue has now become an area where either the food producer or the State might have to provide significant oversight. It follows that, in this case, either the producer or the government might have to determine whether a food additive is generally recognized as safe or should be further scrutinized for a nuanced determination.

IV. REGULATORY GAPS USHERING IN A NEW PARADIGM

The fragmented nature of U.S. food safety regulation calls for a retrospective look into the source of such confusion. It compels us to seek modernization of the federal regulatory framework that oversees GM crops. As the foregoing sections reveal, despite the enactment of the 2011 Food Safety Modernization Act,[47] the regulation of the food distribution framework continues to stall because it lacks an applicable statute, such as, adequate food labeling laws. For example, GM foods are regulated

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Reg. at 22,990.

[42] Ghoshray, *supra* note 3, at 500-01 ("According to the FDA, genetically engineered crops containing only nucleic acids as the active additional components are kept outside of the agency's regulatory ambit. By extolling the virtues of nucleic acid as essential to human existence, the FDA attempted to allay any safety concerns consumers might have. This misapplied interpretation of human biology is a result of faulty understanding of nucleic acid functionality, regardless of whether nucleic acid is taken in isolation or in collaboration with other elements. The scientific details of this analysis are beyond the scope of this essay, and I shall not belabor this argument further except to note that the FDA's argument is inconsistent with scientific viewpoints that have support in the literature.")

[43] *See infra* Part IV.

[44] *See* sources cited *supra* note 24.

[45] *See* Rebekah Wilce, *GMO Lobby Works Tirelessly Against Mandatory Labeling*, PR WATCH (Apr. 10, 2014), http://www.prwatch.org/news/2014/03/12431/gmo-lobby-works-tirelessly-against-mandatory-labeling (noting that a corporate trade group lobbying for voluntary GMO labeling recently found a Congressional sponsor for a bill that would preempt any state's mandatory labeling law).

[46] *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,991 ("Ultimately, it is the food producer that is responsible for assuring food safety.").

[47] FDA Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885 (codified as amended in scattered sections of 21 U.S.C.); *see also* Helena Bottemiller, *The Food Safety Modernization Act – One Year Later*, FOOD SAFETY NEWS (Jan. 20, 2012), http://www.foodsafetynews.com/2012/01/the-food-safety-modernization-act-one-year-later (discussing the FDA's failure to meet evaluative and regulatory deadlines promulgated by the statute).

under the broader rubric of biotechnology regulation.[48] This regulatory framework has been borne out of a manipulative paradigm of supervisory authority derived from an innovative interpretation of FDCA.[49] Such a forced paradigm causes fragmentation in the FDA's approach in regulating GM crops.[50] The framework is further fragmented due to the FDA's lack of expertise in dealing with agricultural, ecological, and environmental issues efficiently and effectively. Inability to incorporate timely enhancements in law based on technology's advancements has further weakened its current efforts, which is significantly backward compared to its European counterparts.[51] Whether or not food labeling for GM products is the logical next step in ensuring the safety of the U.S. food distribution system, the agency's inability to plug all the regulatory loopholes adequately also symbolizes a deeply rooted inertia within the U.S. regulatory framework. While identifying the root cause of such inertia would certainly be a necessary step in the right direction, the very recognition of such inertia calls for envisioning a new direction in regulating GM crops. However, before we chart such direction, we must trace the genesis of the inertia.

First, a review of existing regulatory inadequacy points to a colossal policy failure in the entire regulatory infrastructure. This failure "has not come by happenstance; rather, it is the culmination of long-standing policy inertia."[52] This policy inertia has gained momentum within the regulatory framework, as any acknowledgment of consumer rights was ultimately lost to more dominant corporate interests. Following similar patterns of regulatory inertia, various risk considerations related to ecological disaster,[53] environmental degradation,[54] biodiversity contamination,[55] or geological contamination[56] were swept under the overarching theme of production efficiency.

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[48] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,303 (Exec. Office of the President June 26, 1986); Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,985; *see also Biotechnology*, FOOD & DRUG ADMIN., http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ (last updated Dec. 9, 2014) (clarifying that the FDA's statement of policy applied to "all foods derived from all new plant varieties," including varieties that are developed from bioengineered foods).

[49] Food, Drug, and Cosmetic Act, 21 U.S.C. § 393 (2012) (creating the FDA and explaining its purpose and authority).

[50] *See* Mike Zelina et al., *The Health Effects of Genetically Engineered Crops on San Luis Obispo County: A Citizen Response to the SLO Health Commission GMO Task Force Report*, SAN LUIS OBISPO CNTY. CAL. (May 2006), http://www.slocounty.ca.gov/Assets/PH/HealthCommission/GMOTaskForce/Citizen+Response+on+the+Health+Effects+of+GE+Crops.pdf.

[51] *See* sources cited *supra* note 24.

[52] Ghoshray, *supra* note 3, at 501.

[53] *See* Mandel, *supra* note 26, at 2194-96 (highlighting the potential for gene flow into unintended environments and the risk of wild species extinction through hybridization); *see also* JOHN TUXILL, WORLDWATCH INST., NATURE'S CORNUCOPIA: OUR STAKE IN PLANT DIVERSITY 12 tbl.1 (1999) (arguing that bio-uniformity is rising as plant species' extinction-risk rates increase).

[54] *See* TUXILL, *supra* note 53, at 62 (noting that environmental degradation has already occurred in Guatemala, "where non-traditional vegetable production expanded . . . and displaced subsistence cultivation").

[55] *Frequently Asked Questions on Genetically Modified Foods*, WORLD HEALTH ORG. http://www.who.int/foodsafety/publications/biotech/20questions/en (last visited Mar. 10, 2015) ("Issues of concern include: the capability of the GMO to escape and potentially introduce the engineered genes into wild populations; . . . the susceptibility of non-target organisms . . . to the gene product; . . . [and] the reduction in the spectrum of other pants including loss of biodiversity."); *see also* Rick A. Relyea, *The Impact of Insecticides and Herbicides on the Biodiversity and Productivity of Aquatic Communities*, 15 ECOLOGICAL APPLICATIONS 618, 626 (2005) (finding that insecticides and herbicides had varying positive and adverse effects on ecological communities, with the most influential negative effect being reduction in biological diversity).

[56] *See* Katherine K. Donegan & Ramon J. Seidler, *Effects of Transgenic Plants on Soil and Plant*

Second, despite the existence of many regulatory agencies on paper, the fundamental problem remains unsolved due to adoption of two flawed regulatory approaches—the fragmented regulatory approach discussed before and the Coordinated Framework for Regulation of Biotechnology (the "Coordinated Framework") that I discuss next. Nonetheless, neither of these approaches has been able to distribute regulatory responsibilities based on any exhibited expertise.[57]

The Coordinated Framework is the original backbone of the regulatory structure in the United States.[58] Flaws within the GM regulatory system emanate from a fundamental weakness within this framework. At its inception in the 1980s, there was a severe lack of applicable statutes for the U.S. biotechnology industry. This created confusion and inadequacy among federal regulatory agencies.[59] Unfortunately, not only did such confusion continue, the recognition of its inadequacy gave way to vulnerability in dealing with new challenges. While the agencies sought a creative solution in envisioning a collaborative framework, the collaboration was only coordinated on paper. Due to the overlapping responsibilities with which the various federal regulatory agencies were entrusted, the resulting system was heavily fragmented. This overlapping jurisdiction was a result of inadequate infrastructures trying to catch up to technological innovations, which has been a characteristic of GM foods. As each agency embarked on diverging approaches to issues that the framework had not envisioned at its inception,[60] it suffered from faulty implementations and flawed policies. One such example of inadequate understanding of the scope and future of technological innovation resulting in sub-optimal policy was the policy behind the Coordinated Framework in 1986—the Office of Science and Technology Policy (OSTP).[61] Despite its failure to handle the perils and dangers of GM foods, OSTP continues to be the focal point of supervisory oversight related to biotechnology regulatory scheme for food crops.[62]

Absent a specificity of purpose, it is procedurally difficult to delegate supervisory responsibility, which is a structural weakness within the food regulatory framework. In drawing regulatory authority based on faulty statutory interpretations, the Coordinated Framework attempted to force-fit newly created sophisticated issues into existing

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Microorganisms, *in* 3 RECENT RESEARCH DEVELOPMENTS IN MICROBIOLOGY 415, 424 (S. G. Pandalai ed., 1999) ("The repeated use of transgenic plants in an area may also result in the accumulation of antimicrobial compounds in the ecosystem.").

[57] *But see* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (Exec. Office of the President June 26, 1986) ("These agency policies build upon experience with agricultural, pharmaceutical, and other commercial products developed by traditional genetic modification techniques.").

[58] *Id*.

[59] *See Guide to U.S. Regulation of Genetically Modified Foods and Agricultural Biotechnology Products*, PEW INITIATIVE ON FOOD & BIOTECH. 5-6 (Sept. 2001), http://www.pewtrusts.org/~/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsbiotech0901pdf.pdf (explaining that in the 1980s, because of the existence of several statutes that promulgated multiple agency jurisdictions over the biotechnology industry, the Reagan Administration offered the Coordinated Framework policy statement to clarify any confusion over the multi-jurisdictional structure).

[60] *See id.* at 6-7 (noting that the Coordinated Framework indicated the need for future periodic review of policies as technology developed).

[61] *See* Homer, *supra* note 34, at 101 ("In deciding that existing laws are sufficient for biotechnology regulation, [the OSTP, through] the Coordinated Framework[,] instructs the agencies to rely on laws for their regulatory authority that were enacted decades earlier, long before rDNA genetic engineering was even scientifically conceivable.").

[62] *See id.* at 100 ("Despite enormous advances in the GE field over the past few decades, the twenty-five year old Framework [which was promulgated by the OSTP] remains the cornerstone of the biotechnology regulatory scheme today.").

statutes.[63] When agencies attempted to expand its regulatory scope by staying within the existing statutory limit,[64] its expanded mandate may not have been conducive to older interpretations and thus failed to lend itself seamlessly into the evolving complexities of the new technology. Lacking process-specific regulatory authority, the decades-old law simply cannot do justice. New complexities require new laws and newer statutes. Thus, complexities and uncertainties of GM foods require new food labeling laws, as has been recognized by the State of Vermont.[65] Yet, the existing inertia causes consternation within the system and invites constitutional questions and judicial scrutiny that I examine next.

V. LAW'S FUTURE TRAJECTORY

On May 18, 2014, the legal landscape surrounding food law has come to a trailblazing intersection.[66] Against a myriad of deficiencies within the GM food distribution framework, ranging from absence of federal law requiring independent testing of safety,[67] to the lack of formal FDA protocol on determining outcome of industry funded studies,[68] the State of Vermont passed title 9, Sections 3401-3408 of the Vermont Statutes (Act 120).[69] Recognizing the regulatory inertia in addressing consumers' safety concerns, the State of Vermont stepped in where it perceived regulatory gaps. Prompted by recognition that the core constitutional values of the First Amendment are not threatened by a State requirement of GMO labeling, Vermont legislators enacted specific guidelines for GM food producers and retailers.[70] Despite growing consumer interest in knowing details about the food they consume, Vermont was the first state to require food producers to put a one-line label on their products containing GM ingredients. Intended to empower consumers with more information to make informed decisions about their food consumption, Act 120 has two main prongs. First, it requires labeling on food products containing GM ingredients starting July 1, 2016.[71] Second, it prohibits displaying labels such as "natural," "all natural," "naturally grown," and "naturally made" on foods containing GM ingredients.[72] With the demand for labeling of GM foods brewing for several years,[73] states have either

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[63] *See Issues in the Regulation of Genetically Engineered Plants and Animals*, PEW INITIATIVE ON FOOD & BIOTECH. 10–11 (2004), http://www.pewtrusts.org/~/media/legacy/uploadedfiles/phg/content_level_pages/reports/foodbiotechregulation0404pdf.pdf.

[64] *See id.*

[65] VT. STAT. ANN. tit. 9, §§ 3041-3048 (2014) (requiring labeling of food produced with genetic engineering, effective July 1, 2016).

[66] *See* 2014 Vt. Acts & Resolves 348 (codified as amended at VT. STAT. ANN. tit. 9, §§ 3041-3048 (2014)).

[67] *Id.* sec. 1(2).

[68] *Id.* sec. 1(1).

[69] *Id.* Because the Act was the 120th bill to be signed into law in 2014, Vermont officials and the public have nicknamed the statute "Act 120." *See, e.g.*, Press Release, Vt. Att'y Gen. William H. Sorrell, *Attorney General Announces Public Meetings to Introduce Draft Rules for Act 120 GE Food Labeling* (Oct. 10, 2014), http://ago.vermont.gov/focus/news/attorney-general-announces-public-meetings-to-introduce-draft-rules-for-act-120-ge-food-labeling.php.

[70] VT. STAT. ANN. tit. 9, §§ 3041-3048.

[71] *Id.* §§ 3041, 3043.

[72] *Id.* § 3043(c).

[73] *See* Gary Langer, *Poll: Skepticism of Genetically Modified Foods*, ABC NEWS (June 19, 2014), http://abcnews.go.com/Technology/story?id=97567 ("[N]early everyone, moreover — 93 percent — says the federal government should require labels on food saying whether it's been genetically modified, or 'bio-

passed regulatory measures or had ballot initiatives on GM food labeling.[74] Yet, Vermont's was the first comprehensive and mandatory GM food labeling law that can be dissected from both legal and scientific lenses.

The legal battle surrounding Act 120 has begun in earnest. As sides have been taken, issues are being drawn in diverging directions that promises to continue through many courts costing many millions. The labeling opponents include several prominent trade groups and producers such as the Snack Food Association (a Virginia trade group that represent over 400 global corporations consisting of chips, cereal, snacks), the International Dairy Foods Association (a Washington, D.C. group that represents over 500 national corporations consisting of dairy products), and the National Association of Manufacturers (the largest U.S. manufacturing association).[75] In a lawsuit filed in July 2014 against the State of Vermont seeking to invalidate its first-of-a-kind Act 120, the plaintiffs are being led by the Grocery Manufacturing Association, which represents large cereal makers like General Mills.[76] The plaintiffs seek to render Act 120 invalid on three broader legal grounds.[77]

First, the plaintiffs contend that Act 120's requirement of product labels is a burdensome new speech requirement for the producers and retailers and thus violates the First Amendment.[78] Second, by invoking both the Nutrition Labeling and Education Act of 1990 ("NLEA")[79] and the FDCA,[80] the plaintiffs pursue a line of argument that centers on preemption of Vermont's labeling requirement on grounds of conflict with federal law.[81] Third, the plaintiffs seek invalidation of Act 120 on grounds that it is in violation of the dormant Commerce Clause.[82]

Due to the space restriction in this article on this discussion, a detailed analysis of the above three prongs is out of scope. However, some fundamental observations will

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engineered' (this poll used both phrases). Such near-unanimity in public opinion is rare."). These results were part of an ABCNEWS.com telephone survey that was conducted during June 2014. A random sample of approximately 1000 adults were contacted. The results were collected and verified by the Pennsylvania group, TNS Intersearch. *Id.*

[74] While GM laws continue to be the exception, various states are calling for more regulations on such GE foods. For example:

> [V]oters in both California and Hawaii adopted measures in early November that ban the production of GMOs at the county level. In California, a ballot initiative prohibiting the propagation, cultivation, raising or growing of such products in Humboldt County passed with a vote of 59% to 41%, and in Hawaii, a similar measure prohibiting the cultivation or reproduction of GMOs within Maui County was approved by a vote of 51% to 49%.
>
> Currently, three US states require GMO labeling. Connecticut and Maine have both passed such laws, but they contain provisions stating that they can't be implemented unless several other states approve similar labeling laws. Vermont, meanwhile, has passed a labeling law that is slated to go into effect in 2016.

See Rebecca Trager, *U.S. States Reject GM Labeling Laws*, CHEMISTRY WORLD (Nov. 10, 2014), http://www.rsc.org/chemistryworld/2014/11/us-states-reject-genetically-modified-food-labeling.

[75] Elaine Watson, *GMA et al Seek Injunction to Stop Vermont Implementing GMO Labeling Law Until Legal Dispute Is Resolved*, FOODNAVIGATOR-USA.COM (Sept. 15, 2014), http://www.foodnavigator-usa.com/Regulation/GMA-seeks-injunction-to-stop-Vermont-implementing-GMO-labeling-law.

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

[77] *See id.* at 13-21.

[78] *Id.* at 13.

[79] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, sec. 6, 104 Stat. 2353 (codified as amended in 21 U.S.C. § 343-1).

[80] Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(a)(1) (2012).

[81] Complaint, *supra* note 76, at 20.

[82] *Id*. at 18.

assist in deconstructing the plaintiffs' position. On the issue of preemption, in various nuanced examinations by legal scholars, the vagueness and structural inadequacy on the portion of the NLEA that deals with the relationship between nutrition and human health has been well established.[83] As the argument for repealing part of the NLEA gains ground against a growing recognition for state-level legislative enactment,[84] the idea of using NLEA as the crutch to advance a preemption argument is fundamentally weak. Moreover, as I have shown elsewhere, FDA's creative interpretation of the FDCA does not meet the prudential standards for regulating GM food.[85] Therefore, invocation of the FDCA fails to satisfy the constitutional standard for federal preemption.

Confronting the violation of the Commerce Clause argument, the Supreme Court's recent trajectory in dealing with the Commerce Clause[86] and the federalism questions in interstate commerce cases could be guideposts. Despite a rich jurisprudential legacy of invalidating State laws for violating the Commerce Clause,[87] there has been a heightened awareness of possible overreach in state affairs by the expanded scope of the Commerce Clause. In this shifting paradigm, the trajectory of preemption of state laws are primarily animated and controlled by the interaction between the Supremacy Clause and the anti-commandeering doctrine of the Tenth Amendment,[88] which prompts various threshold questions. Does state law impose downward pressure on supply and demand in the national market? Is there a legitimate supervisory interest by the federal agencies in regulating interstate commerce?[89] Will the application of the Commerce Clause run afoul of the Tenth Amendment's provision on states' right to experiment?[90] To prevail under the Commerce Clause, the plaintiffs will have to establish stronger positions on many such fundamental questions surrounding state sovereignty and federalism, an area that certainly calls for a more enriching discussion than possible in this limited monograph. However, given the

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[83] *See generally*, Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA as a Failed Statute*, 89 TUL. L. REV. (forthcoming 2015) *available at* http://ssrn.com/abstract=2394250 (discussing the failure of NLEA to improve the quality of information available to consumers and arguing for its partial repeal).

[84] *Id.* at 46 (arguing against NLEA's preemption provisions because labeling laws are motivated by consumer interests and state law "can be tailored in response to the interests of the state's populace").

[85] *See* Ghoshray, *supra* note 3, at 494-496.

[86] U.S. CONST. art. I, § 8, cl. 3.

[87] See Saby Ghoshray, *From Wheat to Marijuana: Revisiting the Federalism Debate Post*-Gonzales v. Raich, 58 WAYNE L. REV. 63 (2012) for an overview of recent Supreme Court jurisprudence with respect to federal conflict preemption of state laws. *See also* Gonzalez v. Raich, 545 U.S. 1, 29 (2005) (holding that if a conflict exists between state and federal laws, the "Supremacy Clause unambiguously provides that . . . federal law shall prevail").

[88] Although the Commerce Clause enables Congress to regulate interstate commerce, the Tenth Amendment limits that inherent power by prohibiting the federal government from coercing states to enact laws that enforce federal regulatory initiatives. *See* Saby Ghoshray, *Brandeisian Experiment Meets Federal Preemption: Is Cooperative Federalism a Panacea for Marijuana Regulation*, N. ILL. U. L. REV. (forthcoming 2015) (manuscript at 11) (on file with author) ("[W]hile states are constitutionally prevented from stopping the federal government from enforcing federal law within their territory, the federal government cannot compel the state to enact laws criminalizing such conduct.").

[89] *See* Ghoshray, *supra* note 87, at 68-70.

[90] *Compare* U.S. CONST. art. I, § 8, cl. 3 (stating that Congress shall have the power to "regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes"), *with* U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.").

contextual richness of the First Amendment in legitimizing Act 120, it is important to examine some of the statute's First Amendment implications.

Prompted by genuine concerns and prevailing uncertainty over the health and environmental impacts of their food consumption, today's consumers seek to differentiate between processed and minimally processed food sources. Yet, in this age of information manipulation, corporate marketers tend to have an upper hand over nuanced scientific discussion over GM foods. Let us look at the information dichotomy: an abundance of corporate advertisements continue to present a wholesome image of GM foods that have been immensely instrumental in building positive consumer sentiments, yet lack of adequate labeling prevents consumers from receiving sufficient nutritional or scientific information related to such foods. Thus, public perception is being shaped by both information manipulation and asymmetric interplay between consumers' ability to discern the truth and the shaping effect of advertising ingenuity. Confusion can certainly creep into consumers' construct, which can pave the way for faulty assumptions when deciding between "natural" vs. "chemically induced" or "genetically modified" vs. "naturally made," which in turn may lead to erroneous conclusion on consumer selection. The key to alleviating such confusion and sustaining consumers' right to choose what they eat would be to increase flow of accurate information. Vermont's legislative enactment regulating GM foods, calling for enhanced disclosures and elimination of confusion-inducing terms, is a step in that direction. With its prohibition of labels such as "natural," "all natural," "naturally grown," and "naturally made" on GM foods, Act 120 attempts to align Vermont's interest in preventing consumer deception.[91] A two-tier inquiry will help determine whether Act 120's prohibition on a "natural" label is in a collision course with the settled constitutional principles.

To evaluate whether Act 120's "natural" prohibition is a burdensome restriction and requirement of free speech under the First Amendment, we begin by asking whether the plaintiffs can raise a First Amendment challenge to the restriction in question. This evaluation would automatically lead us into analyzing as to what level of scrutiny might be appropriate in the current context of commercial speech regulation. The plaintiffs asserted that the State of Vermont has the burden of establishing a "sufficiently strong governmental interest that justifies the intrusion on protected speech."[92] We are not required to fully evaluate the issue of free speech restriction on the speech in question due to fundamental weakness in the current premise. Act 120's "natural" prohibition would come into review only when food containing GM products are being marketed as "natural." Evidence points to a growing tendency of food producers and marketers to advertise GM food products as "natural" or any other variant of "natural" identified within Act 120.[93] Evidence also suggests that consumers have been intentionally deceived in the past by advertisements that are "false statements, erroneous statements, or statements that have a likelihood or tendency to deceive."[94] Such advertisements, therefore, meets the criteria of commercial speech under the *Central Hudson* test,[95] as the desired commercial

[91] VT. STAT. ANN. tit. 9, § 3043 (2014).

[92] Complaint, *supra* note 76, at 13.

[93] *See* Caryn Connolly, *Lawsuits Against Kashi and Naked Juice for Falsely Mislabeling "Natural" Products Continue*, ORGANIC CONSUMERS ASS'N (Jan. 10, 2013), https://www.organicconsumers.org/news/lawsuits-against-kashi-and-naked-juice-falsely-mislabeling-natural-products-continue.

[94] Ass'n of Private Sector Colls. & Univs. v. Duncan, 681 F.3d 427, 457 (D.C. Cir. 2012) (holding that "deceptive" commercial speech is not protected under the Constitution).

[95] Cent. Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980) ("At the

message the plaintiffs seek to keep outside the scope of Act 120 which is "more likely to deceive the public than to inform it."[96] This therefore makes the case for the plaintiffs' First Amendment challenges falling outside of the First Amendment protection. This will foreclose any discussion on whether such commercial speech needs constitutional protection.

Such eventuality might not have escaped the plaintiffs. They seek to enhance the level of scrutiny beyond what is typically accorded to commercial speech of this nature.[97] Disseminating accurate information falls under the broader category of signaling[98] that serves a secondary First Amendment function. This type of speech has a long-standing jurisprudence legacy of limited constitutional protection[99] and as such, has historically enjoyed an intermediate scrutiny.[100] The labeling requirement of Act 120 calls for signaling to an intended target—the consumers.[101] Thus, the disclosure requirement has an explicit premise of empowering consumers with information they can use to make decisions about what foods they should consume. Absence of any existing mandate of labeling GM food products by either the FDA or the U.S. Congress further enhances Vermont's legitimate state interest in both eliminating consumer confusion and preventing consumer deception by the producers and marketers. The act of enhanced labeling promotes the secondary First Amendment function as it resides at the convergence of the states' and consumers' interests. On the other hand, a strict scrutiny is typically reserved for speeches or expressions that are designed to propagate the First Amendment's core primary values. Therefore, the plaintiffs' line of argument seeking a strict scrutiny for such labeling requirement is an attempt to conflate the First Amendment's core values with its secondary values.

The questions have been posed as to whether mere consumer interest in GMO labeling can elevate to a legitimate right of consumers in asserting a state interest. This requires identifying a threshold where a quantum of interest elevates to the status of legitimate right. The Vermont legislators took great pain in crafting a framework to define such right by asserting a multitude of interests that are implicated by a paradigm without labeling of GM products. By aggregating a set of disparate interests stemming from "multiple health, personal, religious, and environmental reasons," legislators

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outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.").

[96] *Id.* at 563.

[97] Complaint, *supra* note 76, at 13 (arguing that Act 120 places both content and speaker based restrictions on speech); *see also, e.g.*, United States v. Edge Broad. Co., 509 U.S. 418, 426 (1993) ("The Constitution . . . affords a lesser protection to commercial speech than to other constitutionally guaranteed expression." (citing *Cent. Hudson Gas & Elec, Co.*, 447 U.S. at 563)). *But see* Sorrell v. IMS Health, Inc., 131 S. Ct. 2653, 2664 (2011) (holding that when a state law is designed to impose "content-based" restrictions on speech, "heightened judicial scrutiny" is warranted).

[98] *See* Jennifer M Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 J. CONST. L. 539, 554 (2012) ("The First Amendment protects commercial speech because of its informational value to consumers, not because the commercial speaker has a right to promote his products in whatever manner he see fit.")

[99] *See id.* at 555-56 (explaining that when regulation compels disclosure of information that a commercial speaker would otherwise choose to not disclose, the speaker's First Amendment interest "in *not* providing any particular factual information in his advertising is minimal" (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985))).

[100] *E.g.*, *Edge Broad. Co.*, 509 U.S. at 426; *Cent. Hudson Gas & Elec. Co.*, 447 U.S. at 566.

[101] VT. STAT. ANN. tit. 9, § 3043 (2014).

established a rights-based narrative in seeking labeling requirements for GM products.[102] Yet, opposition towards this labeling requirement is not without reasoned support. Such support comes from commentators' willingness to discount scientific studies that have established the harmful impact of GM foods.[103] Despite many countries banning consumption of GM foods[104] and scientific studies demonstrating a range of ill effects from their consumption,[105] commentators do not support legislative enactment of labeling requirement on GM foods. Thus, grounded in First Amendment, prompted by increasing consumer awareness, enabled by the consolidation of multiple interests, and alarmed by the continued uncertainty of their long-term consumption, the enactment of Act 120 is a step in the right direction.

Act 120 may be the harbinger of interesting constitutional and regulatory possibilities. If the plaintiffs' lawsuit continues to travel through the legal system, how will the various courts decide on the labeling law's constitutional inheritance, or how will the courts define the right to not speak at all? Act 120 intersects in both ways—the right to speak in its "natural" labeling and the right to be silent in its lack of GMO labeling. The legal questions in Act 120 may also provide a more nuanced interpretive gloss on the future pathway for commercial speech jurisprudence. Of course, charting that course comes with a set of challenges. First, in the context of commercial speech, the line between regulating the marketing of a product and regulating such product's advertising is not clear. Second, regulatory vagueness and inconsistent jurisprudence call for indexing the dichotomy of the communicative content of commercial speech—where the path diverges between the scope of regulation that focuses on positive disclosures and that which focuses on negative disclosures—as the jurisprudence goes from a relaxed norm to a more stringent constitutional scrutiny. Despite the existence of a widely applicable constitutional test like the *Central Hudson* test,[106] the precise nature of these rules continues to be complex, elusive, and thus contested. This, however, might change once Act 120 completes its cycle through the Supreme Court, if it reaches that destination.

VI. CONCLUSION

Against the backdrop of a fragmented regulatory landscape for GMOs, this article draws its motivation from the tension between consumers' right to know and corporations' right to speak. As consumer awareness collides with corporate marketing, searching for an appropriate locus for the commercial speech becomes

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[102] 2014 Vt. Acts & Resolves 348, sec. 1(5).

[103] *See* Administrative Law Panel at the American Journal of Law & Medicine Symposium: The Iron Triangle of Food Policy (Feb. 9, 2015) (noting the discussion challenging the validity of consumer interest premised on health impact of GMO foods).

[104] *See* sources cited *supra* note 24.

[105] *See, e.g.*, Aziz Aris & Samuel Leblanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, 31 REPROD. TOXICOLOGY 528, 532 (2011) (revealing the presence of pesticides associated with GM foods in pregnant and non-pregnant women's blood); Sandor Spisak et al., *Complete Genes May Pass from Food to Human Blood*, 8 PLOS ONE, July 2013, at 9 (reporting evidence of DNA fragments' ability to carry complete genes into the human circulatory system); Siriporn Thongprakaisang et al., *Glyphosate Induces Human Breast Cancer Cells Growth Via Estrogen Receptors*, 59 FOOD & CHEMICAL TOXICOLOGY 129, 135 (2013) (revealing additive effects of glyphosate contamination in GM soybeans); *GMOs Linked to Gluten Disorders Plaguing 18 Million Americans*, RT.COM (Nov. 28, 2013, 8:20 PM), http://rt.com/usa/gmo-gluten-sensitivity-trigger-343/ (observing the possibility of maladies from GM foods).

[106] *Cent. Hudson Gas & Elect. Co. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557, 566 (1980).

constitutionally imperative. Looking through the lens of Act 120, this Article focused on identifying a set of binaries. Is the speech in question legal or misleading? Is there a substantial state interest or it is prompted by consumers' mere curiosity? Is consumers' right to know mutually exclusive with corporations' right not to speak?

First, GM food controversy prompts us to contextualize the debate under the rubric of First Amendment's commercial speech doctrine. Here, we recognize that the commercial speech doctrine might be shaped by two powerful forces. Acting as proxy for the executive branch, regulators bring in their expansive supervisory power. Prompted by public outcry, the legislators bring in more laws. Second, recognizing the link between constitutional soundness of Act 120 and its appropriate level of scrutiny, I examined whether the patrimonial essence of this legislative overture is consistent with an intermediate scrutiny analysis.

Finally, this Article prompts us to look into the future trajectory of commercial speech on food labeling. Food labeling requirements are certainly here to stay. However, how pervasive or how cursory such labeling will become depends on finding equilibrium amongst the many controlling forces. These include various limits and restrictions on commercial speech, the Supreme Court's applied distinctions for disclosure requirements, allowable limits of substantial governmental interest, and the shaping effect of publics' right to know. While the future direction of commercial speech is unclear, its regulatory framework and constitutional inheritance will both play an important role.