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CALIFORNIA’S PROPOSITION 37: WILL ITS FAILURE FORECAST THE FATE OF THE GM FOOD LABELING MOVEMENT IN THE UNITED STATES ONCE AND FOR ALL?

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I. INTRODUCTION

The need for mandatory labeling on food products indicating the presence of genetically modified organisms ("GMOs") is a controversial debate in the field of agricultural biotechnology.¹ Proponents of genetically modified ("GM") labeling argue, "[m]andatory labeling responds to consumers' rights, offers greater choice, and provides more information on food content."² In rebuttal, anti-labeling groups contend that providing a label on GM food is unnecessary for several reasons, most importantly, the lack of a "science-based justification for mandatory labeling of GM food because there is no evidence that such foods pose any risks to human health."³ There is no substantial difference between bioengineered food and other traditionally grown products.⁴ The Food and Drug Administration ("FDA") and the American Medical Association ("AMA") unequivocally support this latter view.⁵ If GM labeling is required, opponents assert increased cost on producers and consumers would be significant. Depending on the strictness of the labeling criterion, fear of litigation exposure may leave manufacturers and retailers reluctant to supply GM

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¹ Throughout this Note, "GMO" or "GM" will refer to genetically modified organisms, or "genetically modified" or "modification," respectively. In particular, "GM" refers to "the human alteration of the genotype of an organism, particularly food, through mutagenic techniques or recombinant DNA ("rDNA") techniques." See Carl R. Galant, Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure, 42 HOUS. L. REV. 125, 127 n.5 (2005) (citing Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1992) (refusing to mandate labeling)).


³ Id.

⁴ U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING; DRAFT GUIDANCE (2001), available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm [hereinafter DRAFT GUIDANCE FOR INDUSTRY] (explaining that to the extent that there is a difference between traditional and GM food products, the FDA does require labeling in an appropriate form).

products, which may affect the availability and price of remaining food products on the market.\(^6\)

In recent years, state and local governments have attempted to pass ballot initiatives requiring GM labeling in some form.\(^7\) However, despite "strong consumer interest in mandatory labeling of bioengineered food,"\(^8\) significant legislation in the United States requiring GM labeling remains unsuccessful. Ineffective lawmaking was subject to change in California with the state’s "Proposition 37" ("Prop 37") entitled "Mandatory Labeling Genetically Engineered Food," which was introduced on the November 6, 2012 voting ballot as an "initiated state statute."\(^9\) However, supporters of Prop 37 were disappointed when the initiative was defeated.\(^10\) Although Prop 37 failed, the GM labeling movement considered the media attention it garnered a success in terms of GM awareness,\(^11\) and supporters vowed to pursue the fight for consumer rights. Beyond trying to find success in state legislatures, pro-labelers have petitioned courts with legal claims concerning GM labeling; for example, legislation was initiated regarding whether omitting a GM label constitutes false or deceptive advertising. In response, anti-labelers suggest GM labels "will be interpreted as . . . warnings" and "would imply a food safety risk that does not exist, and this in itself would be misleading to consumers."\(^12\)

Before evaluating state regulation and the effect of Prop 37’s failure on the “Right to Know” food movement in the United States, this Note will first provide a brief historical analysis of agricultural biotechnology to explain the impact of mandatory GM labeling on the food industry. Part II will discuss the policies of various federal agencies regarding federal regulation of GM food products. In Part III, this Note will examine case law to determine if the FDA could preempt state legislation mandating GM labeling.\(^13\) Finally, in Part IV, the food labeling movement’s future in the U.S. will be explored with proposed suggestions regarding compromise between consumers and the food industry on the labeling

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\(^6\) See Carter et al., supra note 2.
\(^7\) See Valery Federici, Note, Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws, 35 BROOK. J. INT’L L. 515, 536 & n.124 (2010) ("Despite the lack of a federal labeling law, there is some form of labeling requirement under the laws of nine U.S. states, and other states are debating laws.").
\(^8\) AMA, REPORT 2, supra note 5, at 7.
\(^10\) Id.
\(^12\) Carter et al., supra note 2.
\(^13\) Part III will also include an in-depth discussion of California’s Proposition 37 and the effect of its failure on the GM food movement in the United States.
issue. The solution to the problem involves educating the public in the field of agricultural biotechnology, which will likely ease consumers’ fear of the unknown.\textsuperscript{14} The AMA also provides valuable insights, which could pacify those behind the “Right to Know” movement. While there are many potential benefits and drawbacks to labeling, the failure of the United States to develop labeling laws, may signal that there are legitimate reasons for not enacting such laws.

II. A HISTORY OF GMOs: BIOTECHNOLOGY IN THE FIELD OF AGRICULTURE

Decades before Prop 37 was recommended, scientists made important advances in the field of genetic modification, developing “transgenic technology,” which “involves the introduction of an advantageous genetic trait into a plant or animal via the direct transfer of a gene or other construct conferring expression of that trait.”\textsuperscript{15} The FDA refers to food crops produced through transgenic technology as “bioengineered,” a term the AMA also adopts.\textsuperscript{16} In contrast, traditional plant breeding is a “process by which scientists select particular plant specimens with desirable traits ‘from a great variety of naturally occurring types of plants’ and reproduce them by pollinating other plants with the pollen carrying desirable traits.”\textsuperscript{17} At a rudimentary level, bioengineering involves directly modifying an organism’s genes, an inherently more controversial procedure, while traditional crop production only indirectly modifies an organism’s genes.\textsuperscript{18}

Direct gene modification reveals positive effects through bioengineering, including “tolerance to herbicides, toxicity to certain pests, resistance to viruses, increased yields, tolerance of extreme growing conditions,” and “increased vitamin content.”\textsuperscript{19} Although bioengineering generates opposition, its benefits are undeniable. For example, using the \textit{Bacillus thuringiensis} gene (“Bt”) allows farmers to produce Bt crops without using “synthetic chemical pesticides,” or by using extremely low levels of the pesticides.\textsuperscript{20} Other genes allow farmers to utilize “herbicide glyphosate” more effectively, which is “preferable to chemical herbicide alternatives used in conventional agriculture” due to low toxicity and safe

\textsuperscript{14} See Federici, \textit{supra} note 7, at 522 (“This desire for labels is likely the result of the popular fear of the unknown. People are often skeptical of the unfamiliar, so it is not surprising that most consumers are against eating GM food . . . .”).
\textsuperscript{15} See AMA, \textit{REPORT 2, supra} note 5, at 1-2.
\textsuperscript{16} Id. at 2.
\textsuperscript{17} Federici, \textit{supra} note 7, at 522-23.
\textsuperscript{18} Id. at 523.
\textsuperscript{19} Id.
\textsuperscript{20} Id. at 523-24.
consumption for humans and animals. As demonstrated, a significant advantage derived from bioengineering is a decline in the use of chemical pesticides. As a result, the environment and workers’ health are better protected and plant biodiversity is promoted. Furthermore, consumers benefit because a reduction in the use of such pesticides leads to a reduction of pesticide residue on produce available in grocery stores.

Proponents of bioengineering technology contend that mandatory GM labeling should be avoided because of these positive effects. If such laws were implemented, it is probable manufacturers might “look for alternative, and possibly inferior, non-GM substitute ingredients to avoid labeling.” Unfortunately, likely alternatives to GM ingredients, such as imported palm oil, are linked with possible “health problems...and environmental concerns.” Despite the potential negative effects of mandatory labeling, proponents maintain “the potential human health effects of consuming bioengineered food have not been fully explored,” justifying cautious resistance to GM technology. The AMA observes, however, that in the past twenty years in which bioengineered foods have been consumed, no harmful effects on human health “have been reported and/or substantiated in the peer-reviewed literature.” Nevertheless, “a small potential” for harmful consequences still exists; particularly in relation to horizontal gene transfer, allergenicity, and toxicity, which all pose conceivable risks to human health.

A. Potential GM Threats to Human Health

The AMA describes horizontal gene transfer (“HGT”) as a “process by which an organism transfers genetic material to another organism other than its offspring and which is followed by integration and expression of the genetic material.” The concern is that when humans ingest a bioengineered food produced from a transgenic plant expressing antibiotic-resistance markers (“ARMs”), “it is theoretically possible that the ARM could be taken up and stably integrated into enteric bacteria” present in the human mouth, “resulting in bacteria that are resistant to specific antibiotics.” That is, through the HGT process, consumers could ingest

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21 Id. at 524 (explaining that herbicide glyphosate is a safer, better alternative to many other herbicides and is currently marketed under the Roundup brand).
22 Id. at 525.
23 Id.
24 See Carter et al., supra note 2, at 4.
25 Id.
26 See AMA, REPORT 2, supra note 5, at 2.
27 Id.
28 Id.
29 Id. at 3.
30 Id.
bioengineered food that decreases the ability to respond to antibiotics. Although the integration described may be technically possible, such an occurrence is unlikely and has never been reported.\textsuperscript{31} Another fear involves ingesting “foreign” DNA existing in the transgenes.\textsuperscript{32} This fear is also unfounded. DNA breaks down during food processing, is exposed to “degradation enzymes . . . when consumed,” and lastly, is “subjected to bacterial restriction enzymes that cleave foreign DNA.”\textsuperscript{33} As a result of these removal processes, the likelihood of stable integration of foreign DNA through HGT is practically nonexistent.

Possible toxicity levels in protein products of transgenes alarm consumers as well,\textsuperscript{34} but the AMA indicates safety assessments performed by producers “based on the concept of ‘substantial equivalence’” should eliminate concern for potential harm in this area.\textsuperscript{35} Producers compare “the new transgenic crop with its conventionally bred counterpart that is generally accepted as safe based on a history of human consumption.”\textsuperscript{36} A transgenic crop is substantially equivalent to its counterpart if it retains “similar levels and variations of critical nutrients and toxicants,” and thus, is safe for human consumption.\textsuperscript{37} To the extent a transgenic crop is materially different from its counterpart, it undergoes additional testing.\textsuperscript{38}

Perhaps the most significant threat to human health involving bioengineered food products, however, relates to allergenicity problems. Consumers are apprehensive a “transgene expressed by transgenic crops has the potential to encode a protein that is allergic to humans.”\textsuperscript{39} Two documented cases reported a potential allergen concern, but due to “pre- and post-market safety procedures,” human exposure was avoided.\textsuperscript{40} The AMA emphasizes the importance of thorough pre-market evaluation as the “most effective tool to protect the public.”\textsuperscript{41} Current safety procedures require appraising each food product “based on a ‘weight-of-evidence’ approach” in which various factors are considered to determine if concern regarding potential allergenicity is warranted.\textsuperscript{42} These procedures have proven successful, but “absolute avoidance of all risk is not achievable;” thus, “research to examine more effective methods of allergenicity is ongoing.”\textsuperscript{43}

While the AMA supports the use of agricultural biotechnology, it still
advocates for regular safety assessments and updated research on GMOs' impact on human health and the environment.\textsuperscript{44}

B. Pro-Labelers v. Labeling Opponents: Who Has the Better Argument?

Notwithstanding the scientific evidence indicating human consumption of bioengineered food is safe, anti-GM proponents strongly protest transgenic technology, mainly out of concern over potential risks associated with such products, or more aptly, a fear of the unknown.\textsuperscript{45} GMO opponents include: various religious sects, organic food cooperatives, and certain environmental organizations including Greenpeace.\textsuperscript{46} These opponents advocate for informed consumer choice, claiming a right to know whether foods have been “tampered with” through bioengineering production methods.\textsuperscript{47} Moreover, beyond human health effects, environmental groups contend that “certain risks to the environment of gene pollution and reduction of biodiversity are in fact already occurring and significantly outweigh the benefits of GMOs.”\textsuperscript{48} In the United States, opposition to transgenic technology has materialized as a mandatory GM labeling crusade, echoing the anti-GM attitude heralded overseas. Pro-labelers argue if producers and manufacturers of food products were required to disclose GM content, consumers could effectively make an informed food choice and avoid any potential health risks associated with GMOs. While this argument may carry weight on a personal and individual level, science-based evidence suggests “traditional breeding methods, not genetic engineering” have resulted in “the only known cases of increased or new harmful compounds.”\textsuperscript{49} One reason for this, as previously stated, is genetic engineering reduces, and in some cases, eliminates the need for the use of harmful chemical pesticides.

Conversely, anti-labelers rely heavily on the fact that transgenic technology provides numerous benefits to consumers and agriculture in general. Although biotechnology poses potential health risks, these problems also exist in traditional plant breeding, perhaps to an even greater degree. Additionally, mandatory labeling would entail serious costs, which consumers would likely bear.\textsuperscript{50} The AMA estimates mandatory labeling “would increase the average household’s annual grocery bill by $140-200 per year.”\textsuperscript{51} Most importantly, GM proponents trust science-based evidence

\textsuperscript{44} \textit{Id.} at 8.
\textsuperscript{45} Federici, \textit{supra} note 7, at 526-27.
\textsuperscript{46} \textit{Id.}
\textsuperscript{47} \textit{Id.} at 517, 527.
\textsuperscript{48} \textit{Id.} at 527.
\textsuperscript{49} \textit{Id.} (“Thus, as opponents of genetic modification through biotechnology do not oppose traditional plant breeding, their arguments against biotechnology are specious.”).
\textsuperscript{50} AMA, \textit{REPORT} 2, \textit{supra} note 5, at 7.
\textsuperscript{51} \textit{Id.}
validated by the FDA and the AMA indicating that GM products are safe for human consumption.

Anti-labelers have a more persuasive argument under current federal regulations. While pro-labelers maintain the importance of “informed choice” in food consumption, the U.S. government regards a consumer’s “right to know” what they are putting in their bodies as an insufficient reason to require states to label GM products accordingly. Currently, consumers are privy to material information regarding the nutritional composition of food, but the FDA’s definition of materiality versus what is perceived as material by many consumers varies considerably. Labeling proponents would answer questions regarding “whether genetic modification of food is material to consumers in their decisions to purchase and consume food” in the affirmative. However, the FDA does not consider “public demand for disclosure of GM content” material information for consumers. If there is no actual distinction between a conventionally produced food item and a GM food product, then the costs imposed by a mandatory labeling scheme weigh in favor of pursuing alternative measures to achieve informed consumer choice in the food industry.

III. FEDERAL REGULATION OF BIOENGINEERED FOOD PRODUCTS

As techniques in genetic plant and animal modification progress, the FDA and other federal agencies intensify regulation. Currently, approximately one dozen transgenic crops are “marketed for human consumption,” but more than eighty crops have “regulatory clearance in the [United States].” The most commonly used crops include soybeans, corn, sugar beets, and cotton; surprisingly, “approximately 70% of processed foods sold in U.S. grocery stores contain ingredients derived” from these commonly used GM crops. FDA regulations concerning food labeling are delineated in the Federal Food and Drug Cosmetic Act (“FD&C Act”). The FDA’s scientific approach to nutritional labeling applies to “all food, whether or not they are derived from transgenic crops or animals” and, “the FDA has the authority to initiate regulatory action if a product fails to meet the requirements for the FD&C Act.”

Two sections in the FD&C Act affect GM food product labeling. First, Section 403(i) requires the food product to assume a “common or usual name” or “an appropriately descriptive term;” otherwise, the food is

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52 Federici, supra note 7, at 530.
53 Id.
54 AMA, REPORT 2, supra note 5, at 2.
55 Id.
56 Id. at 5.
57 Id.
considered "misbranded," and therefore, the label is false or misleading. A GM food product only requires a name change if the transgenic food is "significantly different" from its conventional counterpart. If the new GM product is not significantly different from its traditional counterpart because, for example, it does not differ in nutritional quality or taste, then a name change is not appropriate and the FDA has no basis for regulatory action.

Second, Section 201(n) requires food labels contain all material information concerning the product. The FDA defines material facts as "information about the attributes of the food itself." If a label fails to disclose all material facts, it is considered misleading, and the FDA may take regulatory action. The FDA concludes "the fact that a food or any of its ingredients were produced using transgenic methods is not considered material, and therefore does not constitute information that must be disclosed in labeling." However, labels must reveal the presence of allergens that "consumers would not expect to be present based on the name of the food." The FDA does permit voluntary labeling indicating production methods, but such information cannot be false or misleading.

In response to manufacturers' desire to provide advisory statements on labels indicating the presence of GMOs in their products, the FDA provided nonbinding recommendations in a 2001 policy report ensuring such statements would not be misleading to the consuming public. The FDA acknowledged the concern surrounding biotechnology, but it stated that, unless the transgenic product is materially different from its traditional counterpart or poses a new safety risk, the FDA "has neither a scientific nor a legal basis to require such labeling" under Sections 403(a) or 201(b) of the FD&C Act.

In addition to enforcing its labeling policies, the FDA utilizes pre- and post-market evaluations to guarantee the safety of bioengineered foods. Specifically, companies planning to market GM food products approach the FDA, discuss "relevant safety issues," and submit a "safety

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58 DRAFT GUIDANCE FOR INDUSTRY, supra note 4, ¶ 4-5.
59 Id. ¶ 5.
60 AMA, REPORT 2, supra note 5, at 5.
61 DRAFT GUIDANCE FOR INDUSTRY, supra note 4, ¶ 5.
62 AMA, REPORT 2, supra note 5, at 6.
63 Id.
64 DRAFT GUIDANCE FOR INDUSTRY, supra note 4, ¶ 5.
65 AMA, REPORT 2, supra note 5, at 6.
66 DRAFT GUIDANCE FOR INDUSTRY, supra note 4, ¶¶ 8, 10 (providing guidance as to how "informative statements on labels" can be made "without being misleading," including the example, "[t]his product contains high oleic acid soybean oil from soybean developed using biotechnology to decrease the amount of saturated fat.").
67 AMA, REPORT 2, supra note 5, at 5, 6.
68 Id. at 6.
assessment report containing test data on the food in question.” Currently, consultation between the FDA and such companies is not mandatory but very common considering “to date, all manufacturers...have engaged in the voluntary notification process.” The AMA recommends, however, “pre-market safety assessment should shift...to a mandatory requirement,” despite the fact that manufacturers intending to market new bioengineered products already routinely follow the notification process. Aside from this suggestion, the AMA fully supports the FDA’s labeling policies and safety measures, but it advises the agency to “remain alert to any new data on the health consequences of bioengineered foods and update its regulatory policies accordingly.”

Advocating on behalf of farmers and consumers, the United States Department of Agriculture (“USDA”) agrees that bioengineering is a “precise and predictable method” utilized to improve the sustainability of crops through the introduction of a variety of traits. Accordingly, the USDA’s Animal and Plant Health Inspection Service (“APHIS”) “has safely deregulated or approved more than 70 GE products.” The deregulation process is essential to producing GM products commercially, but with the combined efforts of the APHIS, the FDA, and the EPA, the USDA believes certified bioengineered food products can be developed with no risk to human health or the nation’s environment. Like the AMA, the USDA stresses the importance of continued research in the field of agricultural biotechnology to capitalize on its numerous potential benefits. Significantly, the AMA’s position on bioengineered food was rendered in the spring of 2012, eleven years after the FDA’s most recent guidance report on the subject. In their report, the AMA confirms no new scientific evidence has surfaced suggesting harmful health consequences from the consumption of bioengineered foods, more than a decade after the FDA declined to require special labeling regulations.

Despite scientific confirmation that mandatory labeling of GM food products is unnecessary, support for the “Right to Know” food movement continues to grow. In addition to local community collaboration, national organizations, like the Center for Food Safety (“CFS”), strongly support
labeling campaigns. The CFS condemns the United States for lagging behind the E.U. and developed countries regarding the adoption of labeling laws for bioengineered foods, arguing consumers must be provided the "information they overwhelmingly believe to be important, for a host of health, environmental, ethical and religious reasons." In 2011, the CFS submitted a petition to the FDA, demanding mandatory labeling, and in early 2012, the FDA responded, "it had not yet made a decision . . . and would continue to consider" the request. Of course, this begs the question of whether the FDA even has the authority to require mandatory labeling on GM products, considering its position on transgenic production methods.

In Alliance for Bio-Integrity v. Shalala, the federal District Court for the District of Columbia ruled the FD&C Act "grants the FDA limited authority to require labeling of genetically modified foods." Essentially, the court concluded, "absent risks to consumer health or uniform changes to food derived through recombinant technology, the FDA is not authorized to impose food labeling." The court made this conclusion because the FDA does not consider the production process of food items material information that must be disclosed under its misbranding laws. The court explained it would be misleading to label a GM product as different from its traditionally-produced counterpart if it does not materially vary, even though consumers may "misperceive[e] the product as different" due to the presence of GMOs. The plaintiffs in Alliance asserted the FDA wrongly interpreted the scope of the phrase material facts under the FD&C Act and, further contended "widespread consumer interest" should have been given greater weight in consideration of mandatory labeling regulations. However, the court found consumer apprehension of the undetermined potential health effects of biotechnology insufficient to require mandatory labeling on GM products.

In addition to federal agency regulations, members of the U.S. Senate and House of Representatives have endorsed mandatory labeling at the federal level, but these legislative attempts have failed. For example, in 2008, a bill entitled the "Genetically Engineered Food Right to Know

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77 AMA, REPORT 2, supra note 5, at 6.
80 Id. at 231.
81 Id. at 230.
82 Id.
83 Id.
84 Federici, supra note 7, at 535.
Act" was introduced in the House of Representatives that would modify sections of the FD&C Act and require that foods containing GMOs or foods produced with genetically modified material "be labeled with the text 'Genetically Engineered' or '[t]his product contains a genetically engineered material.'" However, several exemptions were incorporated into the bill, including exceptions for "food served in restaurants or retail establishments," but the Act "would institute civil penalties and authorize private suits for violations." Prior versions of this bill have "all died in subcommittees," but the bill is reintroduced every year. Significantly, provisions of this Act closely mirrored various portions of a state bill proposed and defeated several years later: California's Prop 37.

IV. STATE REGULATION: CASE LAW AND CALIFORNIA'S PROPOSITION 37

A. Legislation Proposed by Other States and the Fundamentals of Proposition 37

In addition to federal regulation, state legislatures have also "considered legislation focused on mandatory labeling of bioengineered" foods; however, only a few states have passed laws requiring labeling of bioengineered foods. For example, several states have enacted statutes "relating specifically to genetically-modified fish species, reflecting the large fish industries in those states." Some states "have either mandatory or voluntary labeling guidelines for both agricultural or food products," while twenty-two states "provide either funding, tax credits, or other support for biotechnology development in their state." A large number of bills have been proposed in state legislatures since 2002, "ranging in form from economic incentives to prohibitions." The rationale for state legislation has varied. Hawaii, for example, proposed a GM bill concentrated on the public's right to know, while in West Virginia, policymakers sought to ban bioengineered foods in public schools.

85 Id. (citing H.R. 5269, 109th Cong. (2006)).
86 Id. at 536.
87 Id.
88 AMA, REPORT 2, supra note 5, at 6-7 ("Only Alaska has passed a law, requiring that bioengineered salmon be labeled (bioengineered salmon are not currently marketed."); see ALASKA STAT. ANN. § 17.20.040(a)(12)(A), (2)(14) (West 2013).
90 Id. at 459 & n.164 (explaining that the mandatory guidelines on GM products imposed by various states often relate to bioengineered fish species, while other labeling regimes, such as that of Maine, "provide voluntary guidelines for labeling foods that contain one percent or less genetically engineered ingredients.").
91 Id. at 459-60 (stating that approximately 350 bills relating to GM technology regulation have been introduced in thirty-six separate states, nineteen of which have enacted the proposed laws).
92 Id. at 460.
Despite some success at the state level, "as the public demand grows," many of these state actions will be subject to federal preemption by USDA, EPA, or FDA regulations.93 A recent demand for mandatory labeling on GM products was voiced in California, resulting in the "California Right to Know Genetically Engineered Food Act," an initiated state statute also known as Prop 37.94 Prop 37 differed from previous attempts by state legislatures to pass labeling laws due to its expansive scope and rigorous requirements. The initiative would have taken effect in July 2014 and required labeling of GM foods sold in retail stores, enforceable by the California Department of Public Health.95 The proposed exemptions from labeling included: alcoholic beverages; organic food derived entirely from animals like meat, eggs and some dairy products; restaurant food; and specific raw foods produced inadvertently through GE seed.96 If it had passed, Prop 37 would have executed "a zero tolerance policy for accidental presence of small amounts of GM substances, even if the U.S. government ha[d] approved the GM material for human consumption."97 Specifically, the initiative would have imposed extremely low tolerance levels for the "adventitious presence" of GM ingredients from 2014 to 2019, and as of July 2019, the zero tolerance policy would have been enforceable.98 California’s strict regulation proposal placed very high compliance expectations on farmers and the food industry. Opponents claim such extensive restrictions are not practical in the U.S. “due to the technicalities of grain production, handling, processing, and storage,” especially since GM crops are increasingly prevalent.99 However, mandatory labeling schemes employed abroad demonstrate that very low or zero tolerance GM substance policies “fail[ ] to result in consumer choice because stores have chosen not to sell foods” with GM components to avoid the required compliance with strict labeling requirements.100 Instead, food manufacturers are incentivized to use substitute ingredients like “imported palm oil to replace soybean or canola oil,” which are correlated with “potential health problems.”101 The strict policies behind Prop 37 would have likely resulted in a similar situation in California.

93 Farquhar & Meyer, supra note 89, at 461.
94 See California Proposition 37, supra note 9.
95 See Carter et al., supra note 2, at 4.
96 Id.
97 Id. at 3.
98 Id. at 4.
99 Id. at 3.
100 AMA, REPORT 2, supra note 5, at 7.
101 Carter et al., supra note 2, at 4.
B. Case Law and Potential Federal Preemptive Effect on State GM Labeling Legislation

Prop 37 would have also prohibited utilizing terms such as “natural,” “naturally made,” “naturally grown,” and “all natural” in the labeling and advertising of GM products and possibly even all foods. This provision was most likely formulated in response to California case law regarding bioengineered food labeling. Consumers in lawsuits involving mandatory labeling statutes raised arguments regarding their right to know the contents of food products. For example, in *Briseno v. ConAgra Foods, Inc.*, a class action lawsuit was filed against ConAgra Foods, the plaintiffs contended that ConAgra’s labeling and advertising of certain cooking oils as “100% Natural” was deceptive and likely to mislead the public. *Briseno*, on behalf of the class, claimed that contrary to ConAgra’s representations, the cooking oils were produced from “plants grown from genetically modified organism seeds;” and thus, the products were inherently unnatural. Specifically, the plaintiffs demanded an order from the court requiring ConAgra to make “appropriate disclosure of genetically modified ingredients and/or remov[e] . . . misleading natural claims” in compliance with California law.

In response, ConAgra claimed the FD&C Act preempted Briseno’s claims because the FDA “has repeatedly concluded that bioengineered foods are not meaningfully different from foods developed by traditional plant breeding, and thus that the fact that a food product is derived from bioengineered plants need not be reflected on a product’s label.” However, the District Court found federal preemption was only applicable to one portion of Briseno’s claim. The court held the plaintiff’s request for an order requiring ConAgra to adopt and enforce a policy requiring disclosure of GM substances in its food products could not be granted, since the order “would impose a requirement that is not identical to federal law.” However, the complaint primarily alleged that the use of the phrase “100% Natural” was misleading, not that ConAgra should include additional information in its cooking oil labels.

In similar cases, courts held marketing food products as “natural” could be misleading, and the plaintiff’s deceptive advertising accusations may not suffer preemption since no conflict existed between FDA policy.
and state law regarding the term "natural." Accordingly, the court in *Briseno* held ConAgra failed to reference an applicable provision in either the FD&C Act or in an FDA regulation involving the phrase "100% Natural" or stipulating "a product cannot be labeled 'natural' despite being produced from genetically modified plants." The FDA has declined to establish a definition for the word "natural," despite strong consumer and industry interest regarding the term's "confusing and misleading" nature. Alternatively, ConAgra relied on an FDA guidance report discussing bioengineered foods and asserted the agency had made no distinction between natural oils and those made from bioengineered plants. The court, however, interpreted the FDA report in exactly the opposite manner, stating:

If anything, the guidance reinforces the view that a food producer's statement as to whether a product contains genetically modified ingredients can be misleading, and supports Briseno's assertion that there is a distinction between affirmatively representing that a product is 100% Natural and omitting the fact that the product contains bioengineered foods from its label. As a result the document does not support ConAgra's assertion that the FDA has concluded that there is no distinction between natural and bioengineered foods, or that statements concerning genetic modification, or the lack thereof, cannot be misleading.

Furthermore, the court clarified that even if the FDA report buttressed ConAgra's argument, no preemption could occur because the guidance report does not possess "the force of federal law," as "it is merely a non-binding draft distributed for comment purposes." *Briseno* is an important case because it establishes the boundaries of federal preemption from the FD&C Act and FDA regulation. At a minimum, California courts determined manufacturers might not be compelled to adopt and enforce

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110 Id. at *15 (quoting Wright v. General Mills, Inc., No. 08CV1532 L(NLS), 2009 U.S. Dist. LEXIS 90576, at *2-3 (S.D. Cal. Sept. 30, 2009)); see also Farquhar & Meyer, supra note 89, at 468 ("[C]ourts require either explicit preemption or conflict preemption in order to preempt a state or local regulation. No state may completely exclude federally licensed commerce...but it may put limits on that commerce unless preempted by federal legislation. If both regulations may be enforced without impairing the federal regulation, and it is possible to comply with both regulations, then the state regulation may stand.")


112 Id. at *16.

113 Id. at *20-21.

114 Id. at *21-22.

115 Id. at *22.
policies requiring disclosure of genetically modified ingredients and federal law preempts such a court order. However, states have avoided this restriction, “by setting up standards for voluntary labeling,” which “give both producers and consumers a uniform guide for the use of certain terms.” A plaintiff may potentially argue a food company’s label is misleading if it is branded as “Natural” or “100% Natural,” when the product contains GMOs; to succeed, the plaintiff must plead such a claim with particularity of “when, where, and how the alleged misrepresentations were communicated” to him or her.

Other jurisdictions have provided different justifications for dismissing plaintiffs’ claims or granting injunctions against statutes designed to enforce labeling of certain GM food products. In *International Dairy Foods Ass’n v. Amestoy*, the Second Circuit granted a preliminary injunction on the basis of a violation of free commercial speech against enforcement of a Vermont statute requiring labeling of certain dairy products produced through the use of a synthetic growth hormone. In 1993, the FDA approved for use the hormone at issue in *Amestoy*, recombinant *Bovine Somatotropin* (“rBST”), because it was “undisputed the dairy products derived from herds treated with rBST” were “indistinguishable from products derived from untreated herds;” the difference was that treated herds experienced increased milk production. The statute presented various labeling options for rBST-enhanced dairy products, and, in response, dairy manufacturers and others filed suit, alleging the statute was unconstitutional because it infringed on guaranteed First Amendment rights. Vermont did not claim any “health or safety concerns” as justifications for promoting the labeling law because there was no scientific basis for such an assertion. The FDA had already conducted exhaustive studies on the effects of the rBST hormone and concluded there was no risk to human health from consumption.

Thus, the *Amestoy* court agreed with the dairy manufacturers, holding that strong public interest in the consumer’s right to know is an inadequate justification for “compromising protected constitutional

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116 *Farquhar & Meyer, supra* note 89, at 469 (“Congress has expressed a desire to preempt state labeling requirements through the National Uniform Nutritional Labeling clause of the FDCA . . . state regulations of food labels must be identical to FDA regulations . . .”).
117 *Id.* at 471 (“Other states have chosen to incorporate the use of genetically-modified ingredients into their definitions of ‘organic,’ requiring that organic products be produced with minimal or no biotechnology.”).
118 *Briseno, 2011 U.S. Dist. LEXIS 154750, at *37-38* (holding that plaintiff failed to plead his claim with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure).
119 *Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67, 69 (2d Cir. 1996)* (distinguished by *New York State Restaurant Association v. New York City Board of Health, 556 F.3d 114 (2d Cir. 2009)*).
120 *Id.*
121 *Id.* at 69-70.
122 *Id.* at 73.
123 *Id.*
rights.” The court acknowledged the state’s interest in educating its public, but found such interest is, “insufficient to permit . . . Vermont to compel the dairy manufacturers to speak against their will.”125 Unless the material requested by consumers “bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern,” manufacturers cannot be forced to disclose such information.126 The rBST hormone is one such example of a bioengineered gene where no concern for health and safety exists through its use, yet many consumers want an informational label.

Case law in California and Vermont may be an indication of potential legal responses if legislation similar to Prop 37 is eventually passed, in light of current FDA regulatory policies. Federal preemption will likely occur if plaintiffs petition the court for mandatory labeling on GM products based solely on public interest, rather than on concerns involving risks to consumer health and safety.127 Furthermore, complaints based on misleading statements on labels will likely suffer dismissal, especially in class action disputes, if the plaintiffs cannot provide specific information about when and how the alleged misrepresentations were communicated. The case law discussed above reflects the consumer right to know argument, which courts have repeatedly found unconvincing.

The AMA agrees with the reasoning behind these decisions, stating “consumer curiosity alone is not enough to require special labeling.”128 Mandatory labeling “may mislead consumers into thinking that bioengineered foods are less safe than their conventional counterparts” and, “it places a burden on the FDA itself, which would have to . . . address consumer curiosity,” instead of focusing on more important, safety-based labeling measures.129 Furthermore, as mentioned in Amestoy as a potential concern, introducing special labeling could create the opportunity for unreasonable, informational consumer requests for manufacturer disclosure.130 In addition to the potential liability manufacturers and the food industry already face, Prop 37 would have exposed these actors to even more consumer-based litigation.131 Specifically, in a Prop 37-based claim, consumers could potentially recover damages equal to or greater

124 Id.
125 Amestoy, 92 F.3d at 74.
126 Id.
127 Farquhar & Meyer, supra note 89, at 469-70 (“Because the FDA has determined that information about biotechnology used in the production of food is not necessary nutritional or safety information, it is unlikely it will find the general public of a state has a particular need for information; and thus, it is unlikely that the FDA will grant an exemption for mandatory labeling.”).
128 AMA, REPORT 2, supra note 5, at 7.
129 Id.
130 Id.; see also Amestoy, 92 F.3d at 74 (“Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods.”).
131 See Carter et al., supra note 2, at 4.
than the retail price of each package or product alleged to be in violation of the proposed statute.\textsuperscript{132} Moreover, consumers would not even need to prove specific damages from the alleged violation to successfully sue under the proposed initiative.\textsuperscript{133}

According to the Giannini Foundation of Agricultural Economics, "mandatory labeling is unnecessary because voluntary labeling now gives California consumers a choice to purchase food products that do not contain GMOs."\textsuperscript{134} Consumers have the option to purchasing USDA organic food products if they wish to avoid substantial GMO consumption. However, unlike the zero tolerance policy in Prop 37, "the USDA has not established a threshold level for adventitious presence of GM material in organic foods."\textsuperscript{135} Therefore, organic farmers strongly supported the California initiative for two reasons. First, its passage would have greatly expanded their market share to the detriment of consumers "since the per-unit cost of producing non-GM crops is less than organic crops."\textsuperscript{136} Second, if Prop 37 had passed, it would have exempted organic products from mandatory labeling requirements entirely. Thus, as agricultural economists suggest, "a food product could be labeled as organic and escape the testing and litigation issues facing a similar non-organic product even if both products contained identical accidental trace amount of GM material."\textsuperscript{137} Additionally, certain products sold by Whole Foods and Trader Joe's "are formulated to avoid GE Ingredients," although they may not be organic.\textsuperscript{138}

Shopping at one of these retailers provides consumers another option to avoid buying GM products. Some of their items are marketed as "GM-free products," voluntarily labeled through the "Non-GMO Project," a verification procedure controlled by store retailers utilizing a 0.9% threshold for trace GM substance.\textsuperscript{139} For example, Whole Foods receives a premium for selling various GM-free products; furthermore, all food items sold under Trader Joe's label are produced from non-GM ingredients, but Trader Joe's is not a participant in the Non-GMO Project.\textsuperscript{140} However, unlike organic farmers, food retailers such as Whole Foods and Trader Joe's did not avidly support Prop 37, despite their apparent commitment to selling GM-free food.\textsuperscript{141} Such retailers likely withheld their support because, as in the case of Trader Joe's, certain processed food products or

\textsuperscript{132} Id.
\textsuperscript{133} Id.
\textsuperscript{134} Id. at 5.
\textsuperscript{135} Id.
\textsuperscript{136} Id. at 4 (explaining that consumers will have been disadvantaged since "overall food prices" would have risen "as non-GM food products" were replaced).
\textsuperscript{137} Id. at 5.
\textsuperscript{138} Id.
\textsuperscript{139} Id.
\textsuperscript{140} Id.
\textsuperscript{141} Id.
those not privately labeled "would likely require the new cautionary label under Prop 37," along with "all of the products under the Trader Joe's line that w[ould] not meet the zero tolerance."\textsuperscript{142} If Prop 37 had passed, agricultural economists predicted a large number of conventionally produced foods would have disappeared from the shelves.\textsuperscript{143} Instead, stores would have been stocked with either organic products or properly labeled GM products.\textsuperscript{144} The initiative included a labeling exception for highly processed foods, but employing the non-labeled option may have only been sensible "using either lower grade or more expensive alternative ingredients."\textsuperscript{145}

Ultimately, Prop 37 would not have affected organically certified products, animal products, alcoholic beverages, restaurant food, or fruits and vegetables. The food sources that would have sustained the most significant impact account for the majority of foodstuffs found in grocery stores. Processed foods containing soy and corn ingredients and non-GM labeled foods with trace amounts of GM substances above the threshold would have either had to be properly labeled, produced with alternative ingredients, or converted to certified organic; otherwise, food manufacturers, suppliers and retailers would be risking the possibility of costly litigation.\textsuperscript{146} The California initiative would have negatively impacted the food industry by increasing consumer prices, introducing confusing labels, and eliminating less expensive, perfectly safe food items. However, if Prop 37 had survived the vote, it is very likely the state action would have been preempted under certain FDA regulation. Labeling activists supporting the "Right to Know" food movement undoubtedly have legitimate, personal reasons for doing so, but the concern is largely unfounded, and the imposition of a strict labeling regime would ultimately result in a significant burden on consumers.

V. THE FUTURE OF THE GM FOOD MOVEMENT IN AMERICA: ALTERNATIVES TO MANDATORY LABELING

Labeling proponents vowed to expand the "Right to Know" food movement despite Prop 37's defeat in California. In a statement released after Prop 37 failed, a "Right to Know Campaign" spokesperson declared, "we showed that there is a food movement in the United States, and it is strong, vibrant and too powerful to be stopped."\textsuperscript{147} A similar initiative is

\textsuperscript{142} Id.
\textsuperscript{143} Id. at 4.
\textsuperscript{144} Id.
\textsuperscript{145} Id.
\textsuperscript{146} Id. at 7.
\textsuperscript{147} Victoria Cavaliere, \textit{California Voters Reject Measure Labeling Genetically Engineered Food; Supporters Vow to Fight On}, \textit{N.Y. DAILY NEWS} (Nov. 7, 2012, 4:01 PM),
already gathering momentum in Washington. Named “The People’s Right to Know Genetically Engineered Food,” the proposed Act seeks to establish mandatory labeling for GM food products.\textsuperscript{148} The Washington initiative will likely imitate the rigorous labeling policies presented in Prop 37. Pro-labelers emphasize the California initiative was only defeated by a narrow margin of about 52\% to 47\%, indicating massive support for the Right to Know campaign.\textsuperscript{149} Those supporting Prop 37 further argue that a media blitz, funded by the food industry and strategically timed several weeks before the vote, explains the initiative’s failure. Pro-labelers maintain the food industry is worried the American public will be alarmed after discover the contents of its food products, and, thus it is willing to spend millions to impede the labeling movement.\textsuperscript{150} Following the failure of Prop 37, the future of the labeling crusade is unclear, but as the “Right to Know” movement permeates Washington, the food industry and concerned consumers brace for another battle in the war on GM food.

Even though labeling activists pledge to continue fighting, more than the passage of a vote stands in the way of their ultimate goal. The food movement in the United States faces a significant challenge due to “deeply rooted” federal regulatory policies and “various constitutionally volatile and statutorily preemptive hurdles facing legislatively compelled labeling.”\textsuperscript{151} Alliance demonstrates that, “courts will show extreme deference to the FDA’s judgment and . . . GM-food critics have little legal ground upon which to stand when attempting to compel GM-food labeling.”\textsuperscript{152} This case and others established the current precedent that “a consumer’s limited right to know is insufficient” to demand mandatory labeling from the FDA.\textsuperscript{153} Therefore, even if initiatives similar to Prop 37 eventually succeed, these “legislative attempts at mandatory GM food labeling” will likely face immediate appeal in the courts and will most likely be invalidated.\textsuperscript{154}

From the perspective of a neutral bystander, arguments underpinning the consumer’s right to know philosophy are compelling. Eating food is a personal, basic human function, and claiming a right to know the ingredients of one’s meal seems reasonable. Upon closer analysis,


\textsuperscript{149} California Right to Know Campaign, Prop 37: Vote Count and Results, YES ON 37 RIGHT TO KNOW BLOG (Nov. 10, 2012, 4:12 PM), http://www.carighttoknow.org/151504/vote_count.


\textsuperscript{151} See Galant, supra note 1, at 128.

\textsuperscript{152} Id. at 152.

\textsuperscript{153} Id.

\textsuperscript{154} Id. at 159.
however, it is apparent “mandatory GM food labeling is not a viable option.” Using agricultural biotechnology in the United States is too important and its benefits are too numerous to ignore. Despite years of scientific study and research indicating the safety of GMOs for human consumption, “emotionally charged consumers deman(d)” a mandatory labeling scheme. A compromise must be met to quell the labeling conflict; otherwise, the labeling crusade will garner strength, potentially resulting in destructive changes in federal regulation. The question still remains, can major players in the food industry realistically continue to spend millions in an effort to halt the labeling movement?

The potential unknown risks associated with GM food products most directly inflame consumer fear surrounding agricultural biotechnology. As a result, “negative public sentiment” correlates with a “general lack of knowledge” about transgenic methods, but “even when consumers do receive information about GM foods, they are vulnerable to the high impact marketing of public interest groups and ‘media sensationalization.’” Therefore, a possible solution involves exploring “existing protections and alternatives and helping” consumers “understand the limitations that mandatory GM-food labeling faces.” In its recent recommendation, the AMA “supports efforts for the mandatory pre-market systematic safety assessments” of GM foods; currently, the FDA permits voluntary pre-market notification processes, and all manufacturers who want to market new bioengineered products have resolutely followed this practice. Nevertheless, consumer fears may be eased if the FDA modified its policy and required a mandatory notification process. Moreover, the AMA “urges government, industry, consumer advocacy groups, and the scientific and medical communities to . . . improve the availability of unbiased information and research activities on bioengineered foods.” Survey evidence indicates roughly 70-75% of consumers would be more likely “to purchase GM foods if they were notified that the modifications were for the purposes of providing healthful fats . . . requiring less pesticide, reducing content of saturated and trans fats, or producing better-tasting or fresher foods.” Therefore, if, as the AMA suggests, unbiased, science-based information is disseminated to the American public, significant strides can be made to inform consumers without the institution of mandatory labeling.

155 Id. at 164.
156 Id. at 128.
157 Id. at 129-30.
158 Id. at 128.
159 AMA, REPORT 2, supra note 5, at 8.
160 Id. at 9.
161 Federici, supra note 7, at 534.
Alternatively, opponents of agricultural biotechnology argue labeling may be the most effective avenue to educate the public "about the large array of genetic modifications and altered attributes of GMOs so they may make informed choices and may avoid GMOs if they wish." Further, "[a]s consumers acquire more information and more familiarity with GM foods, they are likely to become more comfortable" and more supportive of the technology, while "[a]t the same time . . . producers would still be permitted to grow GMOs." However, if a labeling regime were implemented in the United States, it would be most effective if it permitted a higher, more practical threshold for trace levels of GMO substances in food products. As an alternative, the United States could adopt a more practical approach, allowing for more flexible thresholds "to cope with the practicalities of low levels of unintended" of GM substances. For example, in Japan, "the legal labeling tolerance level for accidental presence of GM ingredients in non-GM food is 5% of the top three ingredients." This margin of error enables consumers to purchase non-GM food rather than be forced to purchase organic products; Prop 37 would have basically eliminated this option for California consumers. Conversely, the probable costs imposed on the public through enacting a zero tolerance GM policy would significantly outweigh the benefits of labeling.

VI. CONCLUSION

Although many individuals consider what they choose to eat an extremely important and personal decision, mandatory labeling of GM food products is an unnecessary and burdensome resolution to secure a consumer’s right to know the ingredients in his or her diet. Various alternatives to labeling exist in which a compromise between consumers and the food industry can be formed, ensuring public confidence in the safety of agricultural technology while maintaining scientific progress in this field. State action in the form of regulatory measures like Prop 37 may continue, but under current federal regulation, preemption is likely to occur if the proposals extend beyond permissible limits enforced by agencies such as the FDA, USDA, and EPA. However, consumers should be reassured because these "regulatory agencies administer their policies using the most current and sound scientific data available," and until there is a scientific justification for mandatory labeling based on proven health risks, voluntary

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162 Id. at 532.
163 Id. at 532-33.
164 See Carter et al., supra note 2, at 3.
165 Id.
166 Id. at 5.
167 See Galant, supra note 1, at 159.
labeling with FDA guidance is the most practical option to strike a balance between food consumer and food supplier rights.