COVINGTON

Court Allows Vermont's GMO Labeling Law to Go into Effect

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Food & Drug

Earlier this week, Chief Judge Reiss of the U.S. District Court for the District of Vermont issued a decision denying a food industry effort to suspend enforcement of Act 120, Vermont's genetic engineering (GE) labeling law. The Act, slated to go into effect July 1, 2016, will require manufacturers and retailers to label GE foods that are sold in Vermont and will prohibit manufacturers from labeling or advertising these GE foods as "natural." Vermont released its final regulations to implement Act 120 last week.

While Judge Reiss dismissed many of the industry groups' constitutional challenges, she preserved some of their First Amendment claims and indicated that, if the case proceeds to trial, the Act's restrictions on the use of the term "natural" would likely be struck down. The judge was less encouraging, however, with respect to the ultimate likelihood of success of the First Amendment challenge to the GE labeling requirement under the standard of review she determined should apply.

While the plaintiffs have an opportunity to appeal this decision and to take the remaining portions of the case to trial, companies that sell food in Vermont may wish to consider preparing for the implementation of the GE labeling mandate for products to be sold in the state.

Key provisions of Act 120, its implementing regulations, and Judge Reiss's decision are summarized below.

I. Vermont GE Labeling Law Requirements

Vermont's GE labeling law, Act 120, imposes two main requirements with respect to genetically engineered food sold in Vermont. It requires certain manufacturers and retailers to identify raw and processed food sold in Vermont that was produced, either wholly or partly, with genetic engineering. In addition, it prohibits manufacturers from labeling GE foods as "natural," "naturally made," "naturally grown," "all natural," or with the term "nature."

The Act defines genetic engineering as "a process by which a food is produced from an organism or organisms in which the genetic material has been changed" through the application of either:

- In vitro nucleic acid techniques; or
- Fusion of cells or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, in a way that does not occur by natural multiplication or natural recombination.

Under the Act, genetic engineering does not include a change of genetic material through the application of traditional breeding techniques, conjugation, fermentation, traditional hybridization, in vitro fertilization, or tissue culture.

A. The Act's Scope

The Act applies to both raw agricultural commodities and processed foods intended for human consumption, but not to dietary supplements. In addition, the following foods are exempted from the Act's requirements:

- Certain alcoholic beverages
- Food not packaged for retail sale that is either: (1) a processed food prepared and intended for immediate human consumption; or (2) served, sold, or otherwise provided in any restaurant or other food establishment
- Medical food
- Food that has been verified by an independent organization as not knowingly or intentionally produced from or commingled with GE food or seed
- Food that consists of or is derived from an animal which was fed or injected with a GE food or substance but was not itself produced with genetic engineering
- Food "grown, raised, or produced without the knowing or intentional use of food or seed produced with genetic engineering"

The last exemption is a narrow one. In order to utilize this exemption, the manufacturer must obtain a sworn statement from his supplier, attesting that the food has not been knowingly or intentionally produced with genetic engineering or commingled with GE food. The Act provides civil penalties for the knowing submission of a false certification.

The Act applies to manufacturers who sell food in or into Vermont or who produce for sale food sold in or into State.

B. Labeling Requirement

If a packaged processed food was produced with genetic engineering, the manufacturer must disclose the food's GE status on the food's labeling. In the case of unpackaged processed food, the Vermont retailer is responsible for posting the appropriate statement on a label located on the bin, shelf, or container in which the food is displayed. For both packaged and unpackaged processed foods, the disclosure must state:

- "Produced with Genetic Engineering"; or
- "Partially Produced with Genetic Engineering," but only if the food contains less than 75% GE material by weight;
- "May be Produced with Genetic Engineering," but only if, after reasonable inquiry, the manufacturer does not know whether the food is produced with genetic engineering.

The Act, however, expressly states that it does not require the manufacturer to list or identify the ingredients that were genetically engineered, or to place the term "genetically engineered" immediately before or after any common name or primary product descriptor of a food.

Even if a food must be labeled as GE under the Act, the Act affirmatively provides that a person may "make other disclosures about the food on its packaging," including that FDA "does not consider food produced with genetic engineering to be materially different from other foods."

C. Restrictions on Use of the Term "Natural"

The Act prohibits manufacturers from labeling GE foods as "natural," "naturally made," "naturally grown," "all natural," or "any words of similar import" that "would have a tendency to mislead a consumer." Although "any words of similar import" could be interpreted broadly, the implementing regulation clarifies that this phrase means "the words nature, natural, or naturally." These restrictions also apply to advertising or signage used in "retail premises" in Vermont. They do not, however, extend to a food's trade, brand, or product name, or to any information required by the FDA.

D. Penalties and Enforcement

Violation of Act 120 will subject a manufacturer to civil liability. Any person who violates its requirements is "liable for a civil penalty of not more than $1,000.00 per day, per product." Penalties accrue and are assessed "per each uniquely named, designated, or marketed product," and are not "made or multiplied by the number of individual packages of the same product."

While Act 120 goes into effect July 1, 2016, any packaged processed food offered for sale in Vermont before January 1, 2017, is presumed to have been packaged and distributed prior to July 1, 2016. The manufacturer of such foods will not be liable for failure to comply with the Act unless there is evidence that the food was distributed on or after July 1, 2016.

II. Judge Reiss's Decision

A number of food industry groups, led by the Grocery Manufacturers Association, filed an action in federal court challenging the constitutionality of Act 120, claiming, among other things, that the Act is invalid under the First Amendment and Commerce Clause of the U.S. Constitution, and is preempted by federal law under its Supremacy Clause. The plaintiffs sought a preliminary injunction to block the State's enforcement of the Act in its entirety pending a resolution of their claims at trial.

While Judge Reiss concluded that some of the plaintiffs' claims were likely to succeed on the merits, she denied their motion for a preliminary injunction because the plaintiffs failed to show that enforcement of the GE labeling law would cause irreparable harm.

In addition to addressing the plaintiffs' motion, Judge Reiss's opinion also considered the State's motion to dismiss plaintiffs' complaint in its entirety for failure to state a claim upon which relief may be granted. Although Judge Reiss granted parts of the State's motion, she preserved some of the plaintiffs' claims for trial, as discussed herein.

With respect to the preemption issue, she dismissed plaintiffs' claim that Act 120 is preempted by the Federal Food, Drug, and Cosmetic Act (FDCA) and Nutrition Labeling and Education Act (NLEA) on three grounds. First, she concluded that, because Act 120 is "not identical" to any mandatory labeling requirement in those laws, Act 120 is not expressly preempted. Second, she determined that compliance with both federal and state regulations is not a physical

impossibility. Third, she determined that Act 120 did not stand as an obstacle to the accomplishment of federal objectives, essentially because she found no evidence reflecting particular federal objectives relating to the labeling of GE foods. Judge Reiss did, however, conclude that Act 120 was preempted as it would apply to foods subject to the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), due to the express preemption provisions in those statutes.

Though Judge Reiss also addressed and rejected all but one part of the plaintiffs' Commerce Clause claims, the focus of the decision was on the plaintiffs' First Amendment challenges.

A. Plaintiffs' First Amendment Challenge to Act 120's Mandatory Labeling Requirement

A key issue was what standard of review applied to the plaintiffs' First Amendment challenge to the Act's GE disclosure requirement. While lower courts have faced a number of First Amendment challenges to commercial speech disclosure requirements in recent years, the Supreme Court has had few opportunities to set clear standards for review of such requirements.

1. Strict Scrutiny

As a preliminary matter, Judge Reiss determined that strict scrutiny does not apply, because the mandatory labeling requirement neither compels political speech nor constitutes impermissible viewpoint discrimination.

Judge Reiss disposed of the plaintiffs' argument that the labeling requirement compels political speech because it is a "politically motivated speech regulation." Speech does not become political merely because it "emerged from an allegedly GE-hostile and politically-charged legislative environment," she explained.

Judge Reiss likewise rejected the plaintiffs' viewpoint discrimination argument, concluding it was "clear" that the labeling requirement "mandates disclosure of a fact: the presence or potential presence of GE ingredients." The mandatory disclosure does not "convey a 'preferred message' about that fact," she noted, and the requirement "applies regardless of a manufacturer's or retailer's own view of GE and GE foods."

While Judge Reiss did not cast doubt on the plaintiffs' assertion that the disclosure requirement might "give[] rise to a negative connotation regarding the safety of GE foods," she found that GE manufacturers and retailers' ability to add information reflecting their own opinions "renders it unlikely that a statute reflects impermissible viewpoint discrimination."

2. Intermediate Scrutiny vs. "Reasonable Relationship" Test

The bulk of Judge Reiss's First Amendment analysis was dedicated to whether intermediate scrutiny or the "less exacting scrutiny" of *Zauderer*'s[1] reasonable relationship test should apply. As set forth in *Central Hudson*,[2] intermediate scrutiny "requires that a statute restricting speech be no 'more extensive than is necessary,' and must 'directly advance' a 'substantial'

[1] *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985).

[2] *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

governmental interest." *Zauderer*'s reasonable relationship test, by contrast, requires only that the disclosure requirement be "reasonably related to the State's interest in preventing deception of consumers." As Judge Reiss noted, Second Circuit precedent has extended *Zauderer* to disclosures intended to "better inform consumers about the products they purchase."[3]

In determining which level of scrutiny to apply, Judge Reiss addressed three main issues: (1) whether the labeling requirement is "commercial" in nature, (2) whether it is purely factual and not "controversial," and (3) whether it is supported by a State interest beyond merely satisfying consumer curiosity.

a. Commercial Speech

The plaintiffs argued that the labeling requirement does not mandate commercial speech because it does not propose a commercial transaction, but instead conveys a message to consumers to avoid the product. Finding the plaintiffs' definition too narrow, Judge Reiss remarked: "Product labeling requirements are traditionally regarded as commercial speech even if they effectively discourage the product's consumption."

b. Controversial Speech

Judge Reiss then assessed whether the disclosure requirement compels controversial speech. In support of their argument that the labeling requirement compels their members to convey controversial information, the plaintiffs noted that "[i]t would be difficult to point to a current consumer issue more controversial than genetic engineering."

While she acknowledged the controversy surrounding GE foods, Judge Reiss explained that the focus of the court's inquiry must be the nature of the compelled information itself, "not the nature of the legislative debate that gave rise to its enactment." Because the mandatory label statements—"produced with genetic engineering," "partially produced with genetic engineering," and "may be produced with genetic engineering"—contain "only factual information," Judge Reiss determined that the requirement does not compel controversial speech.

c. Appeasing Consumer Curiosity

Finally, Judge Reiss addressed plaintiffs' argument that the sole purpose of the disclosure requirement is "appeasing consumer curiosity," an argument grounded in the Second Circuit case *International Dairy Foods Association v. Amestoy* (IDFA).[4] Under *IDFA*, a consumer's right to know does not overcome a commercial speaker's First Amendment right not to speak.

In *IDFA*, the Second Circuit sustained dairy manufacturers' First Amendment challenge to a Vermont statute that required disclosure of whether a particular synthetic hormone was used in the production of milk products sold in Vermont. Notably, the state conceded that its only purpose in enacting the hormone disclosure requirement was to satisfy consumer curiosity.

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[3] *National Electrical Manufacturers Assoc. v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001).

[4] *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2d Cir. 1996).

Judge Reiss distinguished *IDFA*, first by noting its limited application. *IDFA* has been "confined to its facts," she declared, reasoning that the "Second Circuit has repeatedly held that the application of *Central Hudson*'s intermediate scrutiny in that case was solely attributable to the State's concessions."

Unlike in *IDFA*, here the State made no such concession about its GE disclosure requirement. Indeed, the State asserted that it drafted the GE disclosure requirement with the *IDFA* precedent in mind, taking pains to ensure the Act was "readily distinguishable and supported by governmental interests beyond the public's right to know." The State thus asserted numerous rationales: to disclose information relevant to potential health consequences from human consumption of GE food; to accommodate religious beliefs and practices regarding GE and GE food; to promote informed consumer decision-making; and to address the potential unintended consequences from GE food production to non-GE crops and the environment.

Although Judge Reiss ultimately concluded that the State's interests were grounded "in an extensive legislative record" and extended beyond a desire to gratify consumer curiosity, she remarked that "some of the State's interests arguably border on the appeasement of consumer curiosity." Despite the apparent similarities between promotion of "informed consumer-decision making" and "appeasement of consumer curiosity," Judge Reiss did not discredit the State's asserted interests. Instead, she reasoned that "the Second Circuit has recently observed that commercial disclosure requirements that enhance consumer decision-making further First Amendment interests."

Accordingly, Judge Reiss concluded that *Zauderer*'s "reasonable relationship" test—the lowest level of scrutiny—should apply.

3. "Reasonable Relationship" Test

The plaintiffs put forth three reasons why the labeling requirement should fail even under the *Zauderer* "reasonable relationship" standard. First, the State's interest must be substantial, and the State's interest here is not. Second, the State's interests are not "real," because they are based upon speculation and conjecture, and "outdated, retracted, or debunked" science. Third, there is no reasonable relationship between the State's interests and disclosure requirement, because a disclosure that a product "may" contain GE ingredients does nothing to further the Act's findings and purpose. Judge Reiss rejected each argument in turn.

With respect to the plaintiffs' first argument, Judge Reiss noted that it is unclear whether *Zauderer* requires a state to identify a "substantial" government interest. She reasoned that "*Zauderer*, itself, does not impose this requirement," nor has the Second Circuit affirmatively stated that *Zauderer* requires such an interest. Nonetheless, because the Second Circuit's recent commercial disclosure cases have identified a "substantial" government interest, Judge Reiss assumed one was required.

Judge Reiss recognized the State's numerous articulated rationales for the labeling requirement. While she noted that at this stage in the proceedings, the court is required to view these asserted rationales with deference to the state, she also stated that she had "little difficulty in characterizing these interests as 'substantial.'"

Judge Reiss then addressed the plaintiffs' second argument—that the State's identified interests assert harms that are not "real." She responded that, because it is "undisputed that there are

studies supporting both 'sides' of the GE debate," plaintiffs failed to allege that the State's evidence is not "real"; they just asserted that it is not persuasive.

Finally, Judge Reiss rejected the plaintiffs' argument that the disclosure requirement fails for lack of a requisite "fit." The "reasonable relationship" test does not require the Act to be the best means of furthering its goal, she explained, nor does it require the Act to "get at all facets of the problem it is designed to ameliorate."

Accordingly, Judge Reiss concluded that the State had established that Vermont's GE disclosure requirement is reasonably related to the State's substantial interest and is therefore constitutional under *Zauderer*. Thus, because the plaintiffs failed to make a sufficient showing that they would succeed as a matter of law on their First Amendment claims, they were not entitled to injunctive relief. Judge Reiss did, however, acknowledge that the appropriate level of scrutiny is a contested question of law, and because the factual record is undeveloped, she did not grant the State's motion to dismiss plaintiffs' First Amendment challenge. This claim therefore may proceed to trial, although the current decision does not seem to foreshadow ultimate success for the plaintiffs under the *Zauderer* standard.

B. First Amendment Challenge to Act 120's "Natural" Restrictions

Judge Reiss agreed with the plaintiffs that the restrictions on the use of the term "natural" are invalid under the First Amendment. Because she found that the term "natural" is neither inherently nor actually misleading , Judge Reiss analyzed the restrictions under intermediate scrutiny. The restrictions do not pass muster under *Central Hudson*, she concluded, because the State has not identified a substantial state interest, nor has it shown that its restrictions will directly and materially advance its interest.

In reaching this conclusion, Judge Reiss addressed the fact that that Act 120 does not define "natural" or similar claims. She rejected the State's arguments that, however defined, "natural" cannot apply to GE foods because GE techniques are not "brought about by" or "existing in" nature but rather are "manmade" and brought about by "purposeful interference" and "artificial means." Judge Reiss observed that "green houses, fertilizers, pesticides, and even the watering, weeding, and pruning of plants" are "'manmade,' 'purposeful interference' in plant production, not 'existing in nature,' and thus can readily and reasonably be deemed an 'artificial means' of food production.'" She also noted the long history of altering seeds and plants from their "natural" state through techniques such as selective breeding, hybridization, cross pollination, and grafting. Judge Reiss therefore concluded that Act 120's "natural" restriction "subjects GE manufacturers to a standardless restriction that virtually no food manufacturer could satisfy."

While Judge Reiss did not grant the plaintiffs' request for a preliminary injunction of those restrictions, because she did not find evidence of irreparable harm, Judge Reiss expressly stated her expectation that the plaintiffs will prevail on the merits of that claim at trial.

III. Implications

Because Judge Reiss denied plaintiffs' motion for a preliminary injunction, Vermont will go forward with implementing its GE labeling law. Unless this decision is successfully appealed or the plaintiffs ultimately prevail at trial in the near term, companies that sell food in Vermont should consider plans for complying with Act 120 if they intend to continue sales in that state.

Judge Reiss's decision ultimately will affect both Vermont and other states, however. Many other states that had considered GE labeling laws, but tabled their efforts while awaiting the court's decision, may be more inclined to go forward with such legislation. Given Judge Reiss's conclusions about the constitutionality of Vermont's GE disclosure requirements, other states might consider modeling their GE labeling laws on those provisions, although many state bills under consideration (and those previously passed with trigger provisions, in Connecticut and Maine) contain slightly different requirements.

The risk of a patchwork of GE labeling requirements will prompt additional calls for uniform federal legislation. While such federal bills are pending, their prospects and timing are uncertain at present.

Given that the vast majority of processed foods will end up labeled as produced with genetic engineering, it is possible that Vermont's GE labeling law will not influence consumer decision-making. The ubiquity of such labeling also potentially could remove some of the controversy from the GE labeling debate over time.

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