Legal Backgrounder

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State and Federal Food-Labeling Reforms Impose Unappreciated Complexities and Compliance Challenges

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Food product labels are under intense scrutiny from consumers, regulators, class action lawyers, and non-governmental organizations (NGOs). Demands for more information, as well as changes to or prohibitions on labels' use of certain terminology, are on the rise. But do label-reform advocates fully appreciate the legal and regulatory complexities and burdens food-labeling revisions impose on the industry, especially when those changes involve state-specific rules? This Legal Backgrounder focuses on these complexities and burdens and advocates for alternative, less burdensome solutions that harness technology to inform consumers.

Labeling Regulatory Compliance: A Costly, High Priority

Under the Federal Food, Drug, and Cosmetic Act (FDCA), a food is misbranded if it fails to comply with the myriad requirements that have been established by the Food and Drug Administration (FDA).[1] The FDCA prohibits the introduction into commerce or receipt of a misbranded product.[2] The Food Safety Inspection Service of the U.S. Department of Agriculture administers similar requirements under other statutes.[3] The rules facilitate the flow of consumer information and maintain a level playing field between competitors by preventing companies from gaining an unfair competitive advantage through unlawful practices.

Food-company regulatory-affairs experts spend hundreds of hours scouring finely-detailed labeling regulations and work directly with their marketing departments when developing labels for new products or making label revisions. Regulatory-affairs professionals not only need a comprehensive understanding of the existing rules, but they must stay abreast of emerging mandates as the law changes. Once regulatory affairs officials approve a label, the legal department traditionally conducts a final compliance review.

Legislators and regulators can easily overlook the significant amount of time needed for the regulatory-affairs professionals to read, learn, and understand new requirements so they can be incorporated into the label-review process efficiently and effectively. Consider, for instance, the recently finalized update to the nutrition facts panel (NFP), which prescribes new reference amounts and serving sizes for foods. The preambles to the two final regulations are hundreds of pages and the FDA guidance documents, many of which are still pending, will be similarly voluminous. Review of these documents can take hours, if not hundreds of hours, to fully understand the complexities of the new requirements.

[1] FDCA § 403; 21 U.S.C. § 343.
[2] FDCA § 301(a); 21 U.S.C. § 331(a).
[3] *See* Federal Meat Inspection Act, 21 U.S.C. § 610, and Poultry Products Inspection Act, 21 U.S.C. § 458.

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The time regulatory-affairs specialists must invest to learn and keep abreast of new rules is merely one cost of label changes. A new label must be designed by the creative and marketing departments. In many instances months of design testing are needed to make certain the label graphics and claims will resonate well with consumers. Once the new design is finalized, the graphics are shared with the packaging company that will create new plates to make the labels. FDA has estimated there are close to 800,000 universal product codes (UPCs) for conventional food and beverage products that will require changes under the new nutrition labeling rules.[4] The Grocery Manufacturer's Association (GMA) has estimated that the average cost for changing one label is approximately $3,000.[5] Therefore, for FDA's estimated volume of products that will require label changes, the cost to industry is expected to be over $2 billion.

New Requirements Bring New Uncertainties

Gray areas in need of interpretation are inevitable with a new regulation. While FDA has done a laudable job of providing direction in the preamble and guidance documents for the updated NFP, the agency cannot address every possible labeling nuance and variation. Where ambiguity occurs, a company must make a judgment call on how to interpret the regulations. When FDA issued the mandatory nutrition labeling regulations in 1993, companies had to make many such judgments with regard to the proper interpretation of the regulations. When FDA disagreed with a company's interpretation of the labeling practices, the agency expressed its concerns in "483 inspectional observations," untitled letters, or Warning Letters.

Those agency actions initiate dialogue with companies on the proper interpretation of the requirements. FDA generally adopts a pragmatic approach, particularly when a company has reasonable arguments in its defense. FDA routinely provides the company a reasonable amount of time to transition to a new label. What FDA considers "reasonable" has traditionally depended on how compelling a business's argument is for their request. Such an approach worked well during implementation of the 1993 rules. The agency recognized that in most instances companies needed to exhaust existing inventories before transitioning to the new label. While companies incurred significant costs to develop new labels, they could do so with the knowledge that they would not have to waste thousands (if not tens of thousands) of dollars in non-compliant label inventory.

Today, the consequences of a Warning Letter are significantly different than in the 1990s or 2000s. In many instances, an FDA Warning Letter alerting companies to a labeling violation generates class action lawsuits under state consumer-protection laws. Unlike the FDA process, where there is an opportunity to engage in a dialogue in a cost effective manner, litigation is extremely time consuming, expensive, and confrontational. Plaintiffs' lawyers will not be satisfied with merely a commitment to revise the label. They generally will insist on some payment as part of any settlement, which can be from a few thousand dollars to millions depending on the nature of the allegations.

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[4] Regulatory Impact Analysis for Final Rules on "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" and "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," at 9, https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM506797.pdf.

[5] Grocery Manufacturers Association, Comments on Proposed Rule, Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments; Proposed Extension of Compliance Dates, Nov. 1, 2017, https://www.regulations.gov/document?D=FDA-2012-N-1210-2099.

The potential litigation exposure of failing to "get the label right" will place tremendous pressure on companies to make certain they are fully compliant with the new NFP requirements. That, in turn, requires clear FDA guidance. And this guidance is needed well in advance of the compliance date so companies will have time to implement changes across essentially every packaged FDA-regulated product in the portfolio.

Additional State Requirements Impose Unnecessary Complexity

Over the past decade, state regulators have shown an increasing interest in imposing additional labeling mandates. Experience demonstrates a patchwork of varying state requirements for food labels is unworkable. Under the current food-industry distribution system, most food processors have little or no control over where their products are ultimately sold. State-specific labeling rules thus create a litany of logistical and legal headaches for such businesses.

The genetically engineered (GE) food-disclosure law Vermont enacted in May 2014 for food products sold in-state gave rise to such logistical and legal problems. The state finalized the law's implementing regulations in April 2015, and established an effective date of July 1, 2016. Initially, companies explored whether they could prevent the sale of their products in Vermont. They quickly discovered this was not a workable solution. Next, manufacturers explored whether retailers would help keep products off the shelves that did not bear the required disclosure statement. Retailers understandably did not wish to bear that responsibility. They would have been forced to hire additional workers for label review, and, in any event, retailers could only conduct such a task if the producers identified each SKU that required the disclosure. With approximately 800,000 UPCs available in the United States, the logistics of having the retailer implement the labeling disclosure proved to be insurmountable.

As the effective date for the Vermont GE-disclosure law approached, it became clear companies would have to label each product sold in the United States with the Vermont disclosure to be in full compliance. Further, with other state GE-disclosure laws on the horizon that could feature subtle differences in the definition of GE foods and the labeling language required, businesses that followed Vermont's law would not necessarily be in compliance with other state laws.

Ultimately, Congress intervened with a federal solution that would create national uniformity in the labeling of GE foods by preempting state disclosure laws. In July 2016, Congress enacted the National Bioengineered Disclosure Law to establish a single national standard for disclosing bioengineered foods.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (also known as Proposition 65) provides another example of a state disclosure law that deeply complicates food processors' national labeling practices. Proposition 65 requires warnings on products that contain substances, including foods, "known to the state of California" to cause cancer. While the warnings can be provided at point of sale by the retailers or as part of an active electronic disclosure, the product label has been found to be the only practicable location. Because of the logistical barriers to California-market-only production, businesses whose products contain Proposition 65 substances are forced to label all of their products with carcinogen warnings. One state, and its perception of what causes cancer, in essence dictates labeling standards for all 50 states.

In addition to state laws, food processors face the specter of judicially imposed labeling mandates from private class actions filed under state consumer-protection laws. Lawsuits by the hundreds have been filed in federal and state courts throughout the country alleging that such on-label terms as "natural," "no preservatives," and a myriad of other claims are false, misleading, illegal, or "unfair." Judges and juries issue decisions on a case-by-case basis and are unconcerned with whether those decisions create a uniform

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body of law. In addition, each state consumer-protection statute and court decisions interpreting that law are different. Therefore, a court in California could offer a different interpretation of "natural" than a court in New York. Companies could be forced to comply with the requirements established in these various jurisdictions or risk litigation from class action challenges. A patchwork of state court decisions would force companies to gravitate toward the most conservative interpretation to make sure their nationally marketed products' labels are fifty-state compliant.

A Practical Approach to Federal and State Labeling Compliance

The means now exist for food producers that market nationally to comply with both a single federal standard for what must appear on their labels and state laws that mandate the disclosure of additional information. The National Bioengineered Disclosure Law discussed above sets out the path for such dual compliance by allowing disclosure through digital methods. Congress recognized that in the age of smartphones, mobile tablets, and wireless technology, digital disclosures are an effective way of communicating information about foods.

The new federal law allows companies to disclose that a food is bioengineered through "a text, symbol, or electronic or digital link."[6] Food manufacturers are afforded some flexibility with respect to the means of disclosing the GE content of the product and would be able to use a scannable technology on a label. AMS recently issued its proposed regulation promulgating this provision, which, if finalized, would also allow for the use of a text-message disclosure option. AMS's proposed rule demonstrates that regulators can embrace technology to find creative solutions that ensure that information is flowing to consumers in a way that does not overburden food companies with costly label changes.

This type of approach would be ideal, for instance, for conveying the information California demands under Proposition 65. If a California resident is truly interested in knowing whether a food contains a substance known by her home state to cause cancer, she could be prompted by a code or other directions on a label to find the warning Proposition 65 requires. Such an approach reflects the reality of how today's consumer is accessing information online. When the average consumer wishes to learn the ingredients or nutrition data for food products they have in their pantry, they are likely now more inclined to seek the information on their smartphone rather than reading the box.

Conclusion

Congress's passage of the National Bioengineered Disclosure Law, and the Agriculture Department's proposed implementing rules, indicate that some federal elected officials and regulators are beginning to appreciate the burdens and costs associated with alterations of food labels. A broader and deeper understanding is needed from those involved in the regulatory process not only at the federal level, but also at the state level, for an overdue revolution in food labeling to occur.

As consumers increasingly rely upon web-based technologies to access information, legislators and regulators should embrace those technologies when setting food-labeling rules. Companies should be allowed to place disclosures in digital forums or use digital codes such as QR codes. Legislators and regulators would, of course, need to use reasonable discretion when determining what disclosure is truly *necessary* for consumers so information overload, and the phenomenon of overwarning, could be avoided. Ultimately, a digitally-focused approach to labeling would simplify and speed up the process of updating information, lowering production costs and improving the quality of the disclosures.

[6] National Bioengineered Food Disclosure Standard, 7 U.S.C. § 1639b(b)(2)(D).

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