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The Future of Food Labeling Consumer Claims: A Recipe for Disaster?

Inside

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Executive Summary

In 2014, consumers unleashed an array of litigation against food companies which included claims that reduced fat Kettle Brand Chips® labeling was misleading, that the term "natural source of cocoa flavanols" on dark chocolate products was unlawful, and that the use of the term "evaporated cane juice" in a variety of products was improper. While this upswing of litigation is not breaking news, consider this collection of cases in the current landscape of FDA food labeling regulation—these consumer cases are challenging labeling that is bound by a system of rules which were promulgated by the FDA and which have not been altered, with the exception of trans-fat labeling, since their inception in 1990. As such, the dynamics of food labeling amidst this litigation could be even further confused by changes to the food labeling regulations proposed by the FDA in early 2014. Further, as initiatives tied to genetically modified organism (GMO) labeling gain momentum in certain states, it is necessary to also consider the role these initiatives will play in the future of the consumer perspective on FDA food labeling and any resulting opportunities for litigation.

Introduction

This White Paper will look at the recent history of food litigation through the lens of FDA labeling, or lack thereof. It will then consider the proposed changes to labeling announced by the FDA in 2014 and consider the extent to which new rules, if adopted, will have an effect on litigation brought by consumers. This White Paper also will investigate initiatives to include GMO labeling regulations in certain state laws and the effect that could have on consumer-driven food litigation as well as federal action in making changes to food labels with regard to the inclusion of GMOs in products.

Background

An FDA Consumer report from June of 1981 described the relationship between the FDA's historical regulatory power and consumers this way: "The history of the Food and Drug Administration is also the history of consumer protection as applied to food, drugs, and other products now regulated by the Agency." To fully understand this relationship, it is necessary to review the recent history of food labeling changes, or lack thereof, as well as the recent wave of food labeling-based claims brought by consumers.

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Overview of recent labeling regulations. In 1990, the Nutrition Labeling and Education Act (NLEA) (P.L. 101-535) was adopted and subsequently required that all packaged foods bear nutrition labeling. In addition, all health claims made on that labeling must be consistent with certain terms that are identified by the Secretary of HHS. Specifically, the FDA has explained that the NLEA "preempts state requirements about food standards, nutrition labeling, and health claims, and for the first time, authorize(d) some health claims for food." Final regulations based on nutrition labeling according to the provisions of the NLEA became effective on May 8, 1994 (58 FR 2302, January 6, 1993).

The required labeling based on the NLEA should be familiar to most consumers because the labeling is essentially the same labeling used today, with one exception. In 2003, the FDA issued a final rule that required trans-fatty acids to be included on a products nutrition label (68 FR 41434, July 11, 2003). That rule went into effect in 2006. Other than this amendment, only recently have substantive changes to the FDA Nutrition Facts Label been proposed. These proposed changes will be discussed in depth below.

Food litigation summary

By the close of 2013 it was clear that the Northern District of California, dubbed by practitioners and industry stakeholders as the "Food Court," was the venue where most of the nations' consumer fueled food litigation would play out. It was this court, where the consumer-protection laws are more expansive and the jury pool tends to skew towards the nutrition-conscious, that heard the majority of consumer's food labeling claims in that year (see *California 'food court' dominates 2013 food litigation on misleading and deceptive labeling claims*, December 23, 2013).

Overall, these claims, rather than alleging physical or large economic injury, focused on misleading health claims contained on the labels of a variety of food products as consumers brought cases against such entities and products as Ben & Jerry's ice cream, Chobani yogurt, Kraft's Trident gum, Ocean Spray beverages, and Hershey's chocolates.

While a significant amount of the litigation appeared to be focused on the use of the term "all natural" in certain labeling, a handful of cases made allegations regarding the use of the term "evaporated cane juice" (ECJ) or "dried cane syrup" (DCS) as a replacement for sugar on food labels. In particular, with respect to the alleged misuse of ECJ or DCS, consumers brought cases against Wholesoy & Company's soy yogurt labels (*Hood v. Wholesoy & Co.*, N.D. Cal., July 12, 2013) and Chobani Inc.'s Greek yogurt products (*Kane v. Chobani*, N.D. Cal., September 19, 2013).

The federal court in California dismissed the case against Chobani based on a lack of evidence that the consumers failed to understand that the language used was another term for sugar. Yet, in regard to the *Wholesoy* claims, the court explicitly deferred to the FDA under the doctrine of primary jurisdiction, which allows a court to stay or dismiss a case to defer to the expertise of a more qualified regulatory body when that body is currently resolving an issue that is at the heart of the litigation before the court.

Types of claims. 2014 proved to be a continuation and extension of the trends that began in 2013 in California, as consumer-plaintiffs continued to bring claims against food manufacturers and distributors based on deceptive and misleading labeling. These cases also increasingly focused on the use of ECJ as a term on food labeling. For instance, consumers bringing a class action suit against products from the grocery chain Trader Joe's were allowed to proceed based on a sufficient showing that they had believed ECJ to be something that was not sugar and was preferable to sugar in terms of health benefits (*Gitson v. Trader Joe's Company*, N.D. Cal., March 14, 2014). The court also put the final nail in the coffin of the consumers' claims against Chobani in *Kane v. Chobani*, when the court dismissed amended complaints finding that it was not plausible, based on the assertions of the consumers, that the individuals bringing the suit did not believe ECJ was a form of sugar.

Primary jurisdiction. Later in 2014, the treatment of health claims brought by consumers and the success of attempts to dismiss these claims under the doctrine of primary jurisdiction resulted in mixed outcomes. In two of these cases, consumers alleged that "no sugar added" claims or the inclusion of ECJ in products that had "all-natural" claims on labels violated state advertising and labeling laws (*Rahman v. Motts LLP*, N.D. Cal., April 8, 2014; *Pratt v. Whole Foods Market California, Inc.*, N.D. Cal., March 31, 2014). In *Rahman*, the court denied a motion to dismiss based on primary jurisdiction finding that the FDA was not currently undertaking rulemaking that would resolve any issues related to the use of the term "no sugar added." With respect to the *Pratt* case, the court determined that the FDA policy, to the extent that it describes what constitutes misleading or deceptive labeling with regard to all-natural and ECJ claims, was clear enough for the court not to defer to the expertise

of the agency with regard to these claims (see *Unfair competition claims, primary jurisdiction dominate food litigation in 2nd quarter of 2014*, June 26, 2014).

On the other hand, the same court began employing the doctrine of primary jurisdiction and granting motions to dismiss consumer claims based on that theory more prevalently. In opposition to motions to dismiss filed by food manufacturers and distributors in many of these cases, consumer plaintiffs would often cite a 2009 FDA draft guidance that stated the following: the "term 'evaporated cane juice' is not the common or usual name of any type of sweetener, including dried cane syrup." Yet, the court in *Swearingen v. Pacific Foods of Oregon, Inc.,* dismissed and in *Gitson v Trader Joe's Company,* postponed the consideration of claims regarding the use of the ECJ on food labeling (*Swearingen v. Pacific Foods of Oregon*, N.D. Cal., July 30, 2014; *Gitson v. Trader Joe's Company*, N.D. Cal., August 7, 2014). In *Gitson*, the court noted that the FDA re-opened the comment period for the 2009 draft guidance on ECJ and that before making a decision on the claims stated it would be necessary to first see if the agency released a final guidance on that use (see *Food Fight: GMOs, label claims add to Q3 litigation recipes*, Oct. 2, 2014).

Other health claims. In non-ECJ related claims, the Northern District of California considered whether to allow certain labeling claims to proceed based on the role of consumer reliance. For instance, in a consumer challenge of allegedly misleading labeling against Kettle Brand Chips®, the court found that the claims against the product based on the use of the term "all-natural" could proceed because the consumers had sufficiently shown there were questions regarding the propriety of that term. Yet, the same consumers' claims regarding the term "reduced fat" on the chips' packaging were blocked because it was not clear what specific statements the individuals purchasing the products relied upon when purchasing them.

GMOs. Besides the emphasis on health claims and especially ECJ-related claims, 2014 also saw the rise of another issue as some states began to focus on labeling restrictions for GMOs. GMOs are plant and animals which have been modified using DNA from other plants and animals and bacteria. This genetic engineering results in new combinations of genes, which are purposefully produced in order to develop a set of specific characteristics and often are used in a variety of different manners including for biological and medical research and for the development of pharmaceutical drugs and medicinal treatments. Perhaps the most controversial area in which GMOs have been put to use is in the development of new types of agricultural products that are intended to be used as new food sources.

A review of state actions regarding this labeling will be addressed below. However, it is necessary to note that GMOs also played a role in consumer claims in 2014 food litigation. In particular, in *Ault v. J.M. Smucker Co.*, consumers focused on the issue of GMOs in products with "all natural" labels (*Ault v. J.M. Smucker Co.*, S.D.N.Y., May 15, 2014). Although *Ault* was not heard by a California federal court but instead brought before the District Court for the Southern District of New York, the New York court also considered the theory of primary jurisdiction to determine whether it would allow the consumer claims to proceed over Smuckers' motion to dismiss. Finding that the FDA was previously faced with this issue and had refused to consider the question of whether a product containing GMOs could properly contain labeling claims that used the term "all-natural," the court declined to exercise the doctrine of primary jurisdiction and allowed the claims to proceed.

According to Smitha G. Stansbury, a partner at King & Spaulding, most of the action in the regulation of GMOs has been at the federal congressional and state levels and the FDA "hasn't necessarily been getting into the game." Indeed, the last guidance that the FDA released in regard to GMOs was in January of 2001.

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Hamburg confirmed the FDA's thoughts on the subject in testimony before the House Committee of Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, stating that the FDA's position is that "it is unnecessary to mandate labels for foods that contain genetically engineered ingredients."

However, in a hearing held by the House Energy and Commerce Committee's Subcommittee on Health entitled, "Examining the FDA's role in the Regulation of Genetically Modified Food Ingredients," Representative Joseph R. Pitts (R-Penn) commented on how the lack of action regarding GMOs on the federal level, in light of the state initiatives that are attempting to create state laws on this issue, could be problematic. Specifically, Pitts noted, "Food labeling is a matter of interstate commerce and is therefore clearly a federal issue that rightfully resides with Congress and the FDA. I'm concerned that a patchwork of 50 separate state labeling schemes could be impractical and unworkable. Such a system would create confusion among consumers and result in higher prices and fewer options." An FDA director's testimony responded that the FDA was supportive of voluntary labeling of GMOs and intended on updating its guidance on the topic so as to further explain such labeling.

The food litigation of 2013 and 2014, which was heavily focused in the Northern District of California, is part of a larger "surge" in food litigation according to a study from the Brookings Institute on food labeling litigation. Indeed, as the that study reports, since 2011, "consumer advocacy groups and plaintiffs have filed more than 150 food labeling class action lawsuits against food and beverage companies," and "the number of these consumer protection class actions brought in federal court climbed from 19 cases in 2008 to more than 102 in 2012." Given the varying levels of success of such cases and the uncertainty with regard to both the use of certain terms as well as the FDA's future actions as to these uses, it is unlikely that this surge in litigation will subside in the future.

FDA's Proposed Labeling

In March of 2014, the FDA issued two Proposed rules that included changes to the Nutrition Facts label (Food Labeling: Revision of the Nutrition and Supplement Facts Label and Serving Sizes of Foods that can Reasonably be Consumed at One-Eating Occasion (79 FR 11879, March 3, 2014); Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily (79 FR 11989, March 3, 2014)). The FDA summarized the changes that would go into effect if the proposed changes were adopted on its website in a Proposed Nutrition Facts Label-At-A-Glance fact sheet. The fact sheet separates the changes into the following categories: (1) a greater understanding of nutrition science; (2) updated serving size requirements and new labeling requirements for certain package sizes; and (3) a refreshed design.

Greater understanding of nutrition science. Included in this category of changes, according to the FDA, is the requisite inclusion of "added sugars" in the new labeling. As clarified in the Proposed rule: "Considering current science and recommendations related to 'added sugars,' we are also proposing to require the declaration of 'added sugars,' that will provide consumers with information they need to implement the dietary recommendations of the *Dietary Guidelines for Americans*, 2010." The FDA also explained in its fact sheet that the inclusion of information regarding added sugars is necessary due to expert recommendations of limiting calories consumed from added sugar "because they can decrease the intake of nutrient-rich foods while increasing calorie intake." The following changes are also described as part of the effort to increase understandings of nutrition among consumers of products: (1) update of daily values for nutrients such as sodium, dietary fibers, and Vitamin D; (2) the required inclusion of the amounts of potassium and Vitamin D on labeling due to their new status as "nutrients of public health significance;" and (3) the removal of "calories from fat" due to research that indicates that the type of fat is more significant than the amount.

Updated serving size and new requirements for certain packaging. Perhaps the most ground-breaking aspect of this category is the recommendation that serving sizes be adjusted. The FDA explained that the proposed change would adjust "the serving size requirements to reflect how people eat and drink today, which has changed since serving sizes were first established 20 years ago. By law, the label information on serving sizes must be based on what people actually eat, not what they 'should' be eating." The FDA further stated that serving sizes, including those for beverages, should be relevant to what people actually eat or drink in a typical sitting. Specifically, those packaged foods that are typically consumed in one sitting should be labeled as such and packaged foods meant for one or multiple sittings should contain dual column labeling for "per package" and "per serving" calories and other nutrition information.

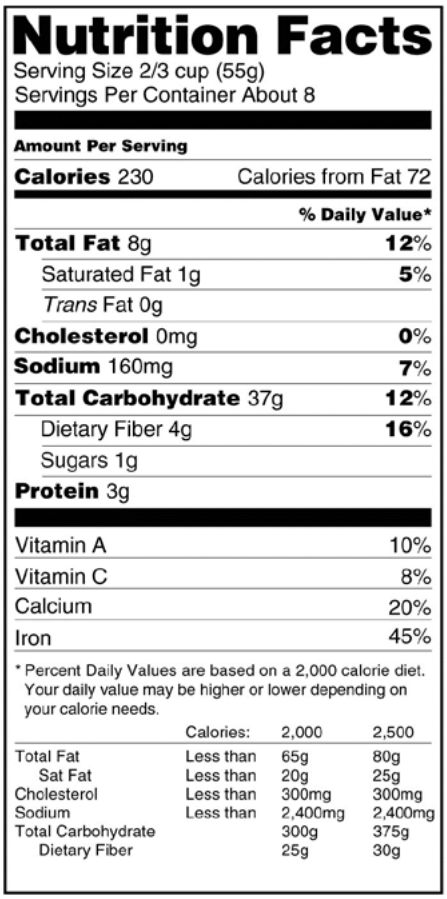
Refreshed design. As part of the recommended changes, the FDA also proposed a new design for the Nu-

trition Facts label. According to the FDA, these changes would emphasize calories and serving sizes so as to target factors that contribute to certain widespread public health concerns including obesity, diabetes, and cardiovascular disease. Also, the FDA proposed moving the Percent Daily Value to the left of the label—in an effort to make these percentages of the nutrients contained in the specific product more prominent. Finally, the FDA also stated that the footnote of the Percent Daily Value should be clarified as to more clearly explain what this factor means.

Design compared. In an infographic produced by the FDA, other changes to the design of the Nutrition Facts label are highlighted. Included in these proposed design changes are larger and bolder font for the number of servings per container and larger font for calories. Further, many of the recommendations mentioned within the FDA's categories of changes above are also incorporated into the design and highlighted in the infographic. For example: (1) the Daily Values are updated and located to the left of the other information so as to been seen first by consumers; (2) there is a new row of information regarding added sugars; (3) the serving sizes are updated; and (4) the percentage of nutrients required is changed and actual amounts of those nutrients within the serving sizes of the products are listed. The infographic also indicates that the footnote for the term Daily Values will be updated but it does not show what the new footnote will entail.

Proposed changes, closing comments. The FDA provides a good amount of detail as to the reasoning behind the proposed changes to labeling on its website, including a lengthy set of Questions and Answers on the topic. Also available are sound clips from FDA Commissioner Margaret Hamburg regarding the recommendations. According to Hamburg, the new Nutrition Facts label is "grounded in science and will help Americans make healthy decisions about the foods they eat every day." The labeling is meant to "reflect the latest scientific information including the link between diet and chronic diseases, such as obesity and heart disease." However, despite the fact that the comment period for the proposed changes ended in August of 2014,

Original Label



Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

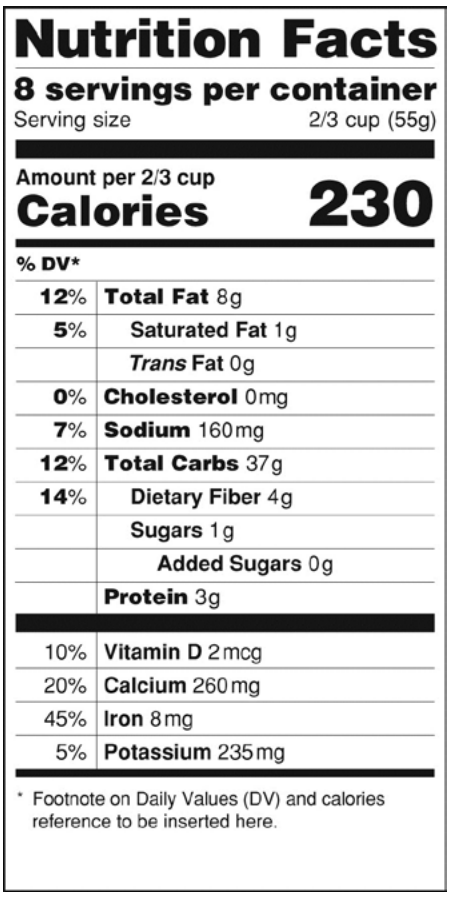
Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 1g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Proposed Label



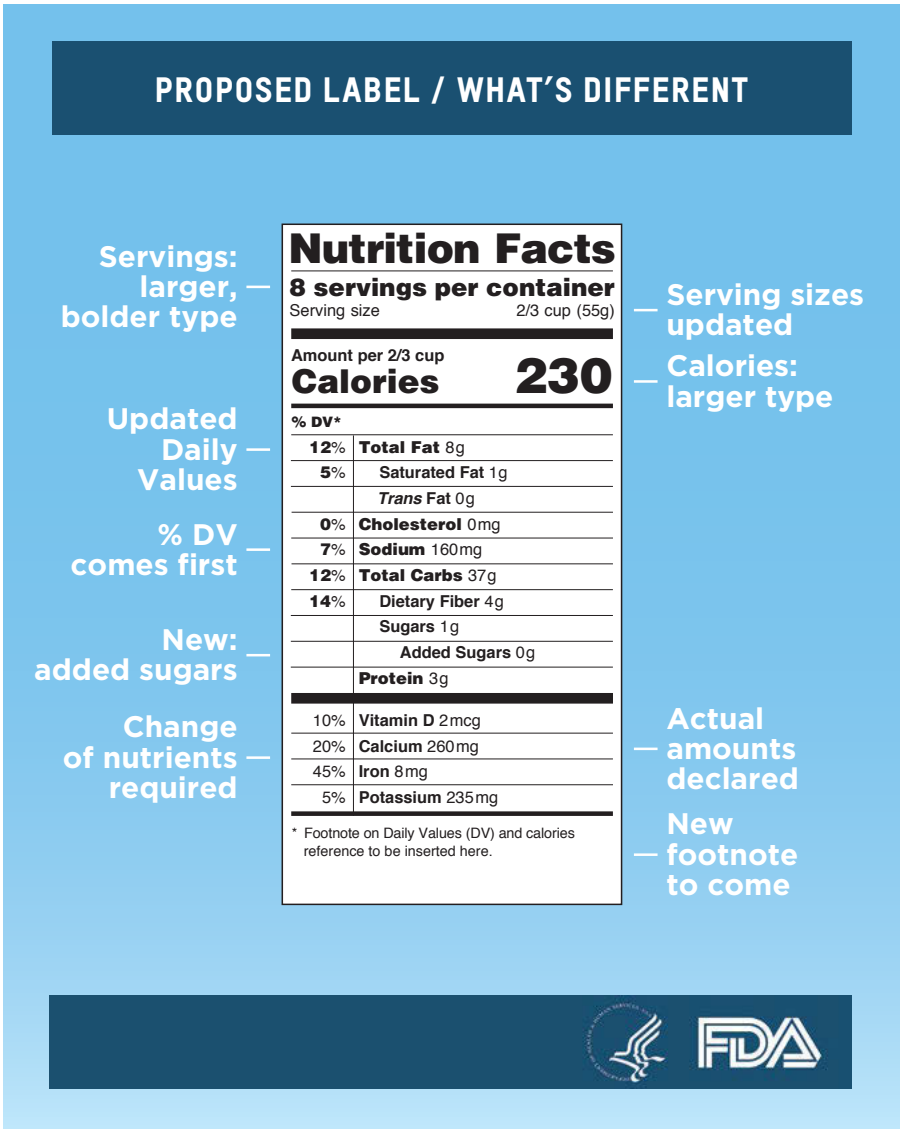
Nutrition Facts

8 servings per container
Serving size 2/3 cup (55g)

Amount per 2/3 cup
Calories 230

% DV*	
12%	**Total Fat** 8g
5%	Saturated Fat 1g
	Trans Fat 0g
0%	**Cholesterol** 0mg
7%	**Sodium** 160mg
12%	**Total Carbs** 37g
14%	Dietary Fiber 4g
	Sugars 1g
	Added Sugars 0g
	Protein 3g
10%	**Vitamin D** 2mcg
20%	**Calcium** 260mg
45%	**Iron** 8mg
5%	**Potassium** 235mg

* Footnote on Daily Values (DV) and calories reference to be inserted here.



there is no information available regarding the timeline of implementing any final changes to food labeling requirements. Moreover, as the next sections will discuss, there are areas that are not addressed in these proposed changes that have been prominent in consumer-fueled food litigation over the past years.

Discussion: New Labeling and the Potential to Impact Food Litigation

While the FDA proposed regulations focus on the same general areas of interest that have arisen lately in food litigation, specific issues, such as the definition of the ECJ, may not be covered by the FDA's proposed rules. Thus, it is necessary to ask, to what extent will the new labeling make an impact on food litigation or topics that are prevalent in food litigation recently? On the other hand, to what extent does the new labeling fail to capture issues that are at the heart of food litigation? In order to explore these questions, the prominent topics of recent food litigation consumer claims will be considered. First, however, it is necessary to turn to the issue of when and how these changes may occur.

FDA action. When asked when the new nutrition labeling Final rules should be expected from the FDA, Stansbury stated: "Frankly, the timing is completely

up in the air." Specifically, Stansbury warned that there is "tremendous variation" in terms of time frames for FDA creating and finalizing rules and that many factors, including priority in relation to other matters and resources, play a large role in determining how long it can take for the FDA to issue Final rules. With regard to priority of matters, Stansbury noted that while the nutrition label regulations certainly have priority over some matters, other issues, such as the implementation of the Food Safety Modernization Act (FSMA) may trump this issue for now. This was especially true, according to Stansbury, due to the issuance of a court order that requires the FSMA Final rules to be published by certain dates in 2015 and 2016 (see *Court imposes deadlines on FDA for publication of regulations related to food safety*, June 25, 2013). In addition, she discussed the role that the White House Office of Management and Budget (OMB) plays in the process of Final rule promulgation. The FDA is required to have the Final rules approved by the OMB and that approval can be a very lengthy process, according to Stansbury.

To provide an explanation as to what specifically in the expected rules for nutrition labeling would cause delays, Stansbury noted that the re-structuring of Nutrition Facts will take a significant amount of time, especially due to the large number of comments that are expected in response to the Proposed rule. Moreover, the changes that were proposed to the serving sizes could have a lot of complications, in her opinion, due to the implications they could have on claims related to serving sizes, which is a popular avenue of consumer litigation.

Implications of changes. Once the Final rules are issued, the changes may have an impact on the consumer litigation that was so prevalent in 2014 and the proceeding years. However, the extent of these changes, and more specifically, the areas of litigation in which these changes will be felt, vary considerably.

Added sugars. The proposed changes in the area of "added sugars" could have an effect on the types of consumer litigation that have been brought recently in California and in other venues. Streamlining the requirements as to what must be declared with regard to added sugars on nutrition labels could, for instance, have an effect on cases that were brought with respect to the phrase "no added sugar" as the true contents of the product in question would presumably be related to the consumer in the new nutrition labeling. Stansbury noted, however, that the direction the FDA will go in terms of the Final rule is unclear, as she noted that this was a "hot topic" and there was a lot of pressure on the FDA from a policy perspective to ensure positive outcomes in this area.

ECJ. However, with respect to the issue of ECJ, the Proposed rules may not make a noticeable impact on consumer litigation, as the proposals did not address this issue directly. It is more likely that the FDA would follow up on the draft guidance that was already released and was discussed above. What is interesting and notable about this uncertainty is that courts have been acting under the impression that a decision with regard to the propriety of the term is eminent. In particular, as was evidenced in the reviewed decisions above, the federal court in California has based judgments on the theory of primary jurisdiction to either stay or dismiss consumer claims that challenge the use of ECJ on food labels in anticipation of the FDA issuing rules as to this term and its proper use. Extrapolating Stansbury's comments regarding priority, resources, and actions of other entities such as the OMB, however, implies that perhaps this reliance by the courts on eminent action in the near future by the FDA is misplaced.

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GMOs and state initiatives

As discussed previously, much of the action regarding GMOs has been at the state level, while the FDA has remained effectively silent on the issue. In this sense, since the FDA has not made any indication that it will

promulgate rules with regard to labeling and advertising of products that contain GMOs, the courts have, in contrast to ECJ judgments, exercised authority to make rulings in this area. The question then becomes: to what extent will state actions impact consumer litigation in this area?

In the beginning of 2014, predictions were made that GMO labeling initiatives in the states had a real chance to gain momentum and become state regulation that could replace the void that currently exists in this area. In the midterm elections in late 2014, however, many initiatives that would have stood to change food labeling requirements in the states, especially with regard to GMO labeling, were defeated. Below some of these initiatives are discussed in turn.

Vermont, Connecticut, and Maine. Before discussing states that are attempting to adopt GMO labeling requirements, it is necessary to mention and consider the labeling regulations that have already been adopted in Vermont, Connecticut, and Maine. While the regulations in Connecticut and Maine require additional triggers before being put in place, the Vermont legislation, known as Act 120, is set to go into effect on July 1, 2016. Yet, the Vermont regulations are currently being challenged in federal court by the Grocery Manufacturers Association.

Act 120. In its preamble, Act 120 states that federal law "does not provide for the labeling of food that is produced with genetic engineering," and also states the following to support that assertion: (1) federal labeling laws do not require manufacturers of food produced with GMOs to list it as such on advertising, labeling, or packaging; (2) that according to testimony, the FDA does not consider genetically modified foods to be materially different than their traditional counterparts; and (3) the FDA has not adopted a formal policy as to the labeling of products containing GMOs. As such, Act 120 provides for the establishment of a "system by which persons may make informed decisions regarding the potential health effects of the food they purchase and consume, and by which, if they chose, persons may avoid potential health risks of food produced from genetic engineering." In turn, the legislation requires that products that are "produced entirely or in part from genetic engineering," must be labeled as such if it is offered for sale in the state of Vermont.

Challenge. Although Act 120 has yet to take effect in Vermont, the Grocery Manufacturers Association and several other trade associations brought suit against the state challenging the law and requesting a temporary injunction to prevent the state from beginning its implementation. According to local sources, the associations argued in their complaint that the law "violates the Constitution by compelling manufacturers to 'convey messages they do want to convey' among other arguments." While oral arguments before the U.S. District Court in Vermont are tentatively set for early 2015, the local source reported that the matter, plus expected appeals, will likely be drawn out over a long period of time.

Colorado, Oregon, and California. The Colorado Right to Know Act and the Oregon Measure 92, both of which provided for explicit labeling of products that are produced with genetic engineering, were also included on their respective state's 2014 ballots. Specifically, the Colorado Act noted that "the labeling of genetically modified food is intended to provide consumers with the opportunity to make an informed choice of the products they consume and to protect the public's health, safety, and welfare." However, both proposals included a plethora of exceptions in regard to what types of products the proposed regulations would apply. While both initiatives were heavily publicized and appeared to gain momentum as the elections neared, both were defeated in the midterm vote.

Specifically it was reported that while two-thirds of Coloradoans voted "no" to the Right to Know Act, the vote on Oregon's Measure 92 was tighter, with the 'no's' outnumbering the 'yes's' by just over one percent. Indeed, the vote over the Oregon initiative was so close that a recount was ordered. While that recount has shown that the original voting breakdown was correct, some Oregon residents continue to challenge that finding. According to local sources, in early December a group of supporters of Measure 92 filed a request for a temporary injunction to prohibit the government from certifying the result of the recount. Specifically, these litigants seek the injunction based on the claim that over 4,600 ballots were not counted.

In 2012, California also put a GMO labeling initiative on the ballot. Proposition 37, or the California Right to Know Genetically Engineered Foods Act, like the other state measures, provided for mandatory labeling of certain products and exceptions for many other product categories. Further, like the measures in Oregon and California in 2014, this measure was also rejected by voters.

Thus, it appears that while experts indicate there has been action with regard to GMOs on the state level, such action has yet to be accepted by many jurisdictions. Where state action has been passed by the voters, it has yet to come into effect and is subject to contingencies

and challenges. As such, it will be necessary to watch the jurisdictions where GMO labeling requirements are still alive in order to see how these regulations will function and to what extent these provisions will affect consumer claims against certain products, if at all.

Conclusion

While it is possible to identify the relationship between consumer litigation and FDA action, or inaction, in order to predict how this area of the law will proceed in the upcoming years, much uncertainty remains. Some of this uncertainty lies in the timing of the finalization of the proposed nutrition labeling rule or other FDA guidance. Indeed, Stansbury's comments further explain and rationalize the FDA's action on these topics as she noted that the "FDA is working diligently to release rules on a timely basis," but it is bound by its own time and resource limitations as well as the required clearance by the OMB, which Stansbury says is "completely out of their hands."

Another large source of uncertainty as to the relationship between FDA proposed rules and consumer litigation is the issue of whether these rules will truly make an impact on consumer litigation. In certain areas, such as the proper use of the ECJ, the courts' use of the theory of primary jurisdiction seems to indicate that FDA action is eminent and will make a large enough impact to wait for that guidance before hearing these types of claims fully. Yet, Stansbury argues, "lawsuits for misleading advertising will always be there" and the "slew of litigation" involving the dispute of "all-natural" and "wholesome" are going to continue on as well. In that sense, if these FDA changes were meant to positively influence Americans' health decisions when it comes to food but also clarify topics that have become a large pool of ambiguity in the courts, the Proposed rules could use modification.