TRENDS IN FOOD AND NUTRITIONAL LAW

JEANINE D. CLARK

PHILADELPHIA OFFICE
170 S. Independence Mall West
The Curtis Center, Suite 400E
Philadelphia, PA 19106-3337
215-922-1100

HARRISBURG OFFICE
3510 Trindle Road
Camp Hill, PA 17011
717-975-8114

PITTSBURGH OFFICE
525 William Penn Place
Suite 3300
Pittsburgh, PA 15219
412-281-4256

WESTERN PA OFFICE
983 Third Street
Beaver, PA 15009
724-774-6000

MARGOLIS EDELSTEIN
Jeanine D. Clark, Esquire
100 Century Parkway
Suite 200
Mount Laurel, NJ 08054
856-727-6034
FAX 856-727-6010
jclark@margolisedelstein.com

SCRANTON OFFICE
220 Penn Avenue
Suite 305
Scranton, PA 18503
570-342-4231

CENTRAL PA OFFICE
P.O. Box 628
Hollidaysburg, PA 16648
814-224-2119

NORTH JERSEY OFFICE
Connell Corporate Center
Three Hundred Connell Drove
Suite 6200
Berkeley Heights, NJ 07922
908-790-1401

DELAWARE OFFICE
750 Shipyard Drive
Suite 102
Wilmington, DE 19801
302-888-1112

www.margolisedelstein.com

Trends in Food and Nutritional Law

Food and nutritional law is often consumer expectation-driven. Case law and legislation sometimes lacks behind as a result. Food and nutritional product law is a growing and rapidly changing area. This brief article is intended to provide an overview of the landscape in early 2016. This article recognizes that there are newly emerging issues which may substantially change some of this framework even before the end of 2016.

Consumers are increasingly health-conscious about consumption of food and use of nutritional products. A review of the FDA's website and e-mail list served on any given day will reveal various recalls for safety and undisclosed allergens. In recent years, there has been an immense growth in the nutritional supplement, nutraceutical and specialty food markets. With this growth we have seen some increase in litigation. However, as these once niche markets grow, we are likely to see an increase not only in personal injury, product, labeling and disclosure claims but also coverage litigation. Nutraceuticals are a broad category of products which can include anything from traditional nutritional supplements such as vitamins, minerals, compounds and antioxidants. They also include dietary supplements and food products other than those which are dispensed by prescription. Your regular vitamin shop or nutritional center sells a host of nutraceutical products. These can include certain energy bars, powders and herbal remedies. These include even those products which portray themselves as being natural alternatives to prescription medications. The National Institutes of Health provides a good overview of what constitutes a dietary supplement. Specifically, dietary supplements are intended to supplement the diet, contain one or more dietary ingredients such as vitamins, minerals, herbs or other botanical, amino acids or their constituents. In order to qualify as a dietary supplement, the product must be intended to be taken by mouth whether as a pill, capsule, tablet or liquid and is labeled on the front panel as a dietary supplement. See https://ods.od.nih.gov/factsheets/dietarysupplements-healthprofessional.

There is something of a cottage industry for companies who will manufacture private label nutritional supplements and develop the label to comply with FDA regulations. The FDA has specific requirements for food and nutritional label supplements where the product sets forth claims of high potency, antioxidant, sugar-free among others. Interestingly, the FDA's definition of "natural" is quite vague. This issue remains subject to agency review. If a more formal definition is adopted, we would anticipate that certain claims arising out of labeling of products as nutritional would likely be preempted.

The FDA website is a good source for labeling requirements and definitions. The FDA Standards **21 CFR 101.54(f)(1)(ii)** provides that the term "high potency" may be used in a claim on the label or in labeling to describe individual vitamins and minerals that are present at 100% or more of the referenced daily intake per reference amount consumed per 21 CFR 101.54(f)(1)(ii). As stated more simply, a supplement may be labeled as high potency where it provides 100% of the RDI per serving. An antioxidant statement is considered a nutritional content claim subject to the

regulations of 21 CFR 101.54(g). Antioxidant claims for supplements may only state that they are high in antioxidants if they contain 20% or more of the RDI per serving. A label may state that the supplement is a good source of antioxidants with an RDI of between 10% and 19%. Some specific antioxidants such as beta-carotene carry different requirements, however. Nutraceuticals are subject to regulation by the Federal Trade Commission and the Federal Food and Drug Administration (FDA).

An area which has resulted in a fair amount of litigation including a number of class-action lawsuits is Genetically Modified Organisms or "GMO". GMOs are or were living organisms whose genetic material was artificially altered and manipulated through genetic engineering. These can be anything from hybrid fruits and vegetables to commercial food products. They are sometimes engineered to withstand application of herbicides or insecticides, drought resistant. or increased nutrition/reduced world hunger. The United States lacks behind regulation of GMOs for human consumption when compared to other industrialized nations. Number of manufacturers, retailers and restaurants have gained market share by serving consumers who prefer or demand non-GMO ingredients. The problems arise where the purported non-GMO products do not meet consumer expectation. These claims arise in connection with failure to disclose the absence of some GMO ingredients, where non-GMO ingredients are unavailable, or in the context of failure to disclose. Others GMO-related litigation involves claims of essentially pollution by cross-pollination. Growers of non-GMO crops have alleged that nearby GMO crops have contaminated their product. These types of issues also arise in the context of organic crops as discussed in greater detail below. Other litigation has involved the fight between whether there should be individual state legislation addressing GMO requirements for growing and labeling of crops and food products versus whether there should be a less stringent national regulatory scheme. The proposed federal labeling scheme would generally not require GMO products to be labeled at all. Specifically, the American Medical Association is in accord with the FDA's position that there is no scientific justification for specialized labeling of foods containing genetically modified ingredients. Essentially, if the food product serves the same intended function and purpose as the non-genetically modified food product, no special labeling would be required. Those in favor of more comprehensive and/or state legislation referred to the proposed federal legislation as the Deny Americans the Right to Know Act or DARK Act. Opponents of more comprehensive individualized state regulations or a more comprehensive labeling requirement as part of a federal scheme state that increased labeling efforts would drive up individual family grocery costs by about $500 per year. They argue that the labeling would unnecessarily disparage one type of plant breeding over another. Notably, GMO food sources are not limited to plants and vegetables and your old-fashioned hybrid tomatoes. Rather, GM Salmon containing Eeel DNA is currently in production and the subject of litigation. GMO fish is not the same as farm raised non-GMO fish. The Grocery Manufacturers Association brought suit in Vermont to challenge Vermont Act 120. Vermont Act 120 provides a state specific comprehensive labeling scheme. The Grocery Manufacturers Association's challenge was denied and the matter is now on appeal to the Second Circuit as of the time this article is being written.

The United States Department of Agriculture is the official certifying organization for organic products within the United States. The National Organic Standards Board is a federal advisory board made up of 15 volunteers who make recommendations to the United States Department of Agriculture. Manufacturers seeking to use the USDA organic Seal or the word

"organic" on products such as food, feed or fiber must meet certification requirements. These certification requirements apply to farmers and producers. The National Organic Standards Board reviews and recommends changes to the national list of allowed and prohibited substances. For a more detailed overview of organic practices, see the USDA publication entitled "Introduction to Organic Practices."

Growers must follow a host of practices including no use of chemical herbicides or pesticides or other prohibited substances, the use of buffer zones between organic and non-organic crops, and no prohibited substances may have been used or applied to the land within the three years immediately prior to the harvest of the organic crops.

Antibiotics and hormones cannot be used in the feed, treatment or production of GMO products/food. If necessary, livestock may be treated with non-organic treatment such as antibiotics. However, once the animal is treated, that animal may not subsequently be sold as organic.

A product may be classified as 100% organic where all ingredients and processing aids are certified as organic. A product can be certified as having all "Organic" ingredients where no more than 5% of the combined ingredients make up non-allowed content. This excludes salt and water. Generally, non-agricultural ingredients are prohibited. There are a few exceptions such as baking soda, citric acid and certain enzymes. If an organic ingredient is not commercially available in the appropriate form, quality or quantity, under certain circumstances the non-organic equivalent may be used. The USDA provides examples such as carrot juice for color and fish oil.

A product may be classified as "made with organic" where at least 70% of the product is made with certified organic ingredients, again excluding salt and water. See the Organic Food Production Act, Title XXI of the 1990 Farm Bill. Penalties for mislabeling or inappropriate use of the USDA organic stamp may reach $11,000 per violation. Certain violations of food labeling regulations may also impose criminal penalties. A product may also simply list specific ingredients as being organic.

In addition to the Federal Food and Drug Administration, and the United States Department of Agriculture, there are various state organizations which either regulate or at least make information available regarding the requirements for food labeling. General food/nutritional supplement labeling requirements are found at 21 C.F.R. § 101.2, et seq. The Dietary Supplement Health and Education Act of 1994 and the Food Allergen Labeling and Consumer Act of 2004 include other federal regulations addressing food labeling and production. The most comprehensive state labeling scheme is California's so-called Proposition 65 also known as Chapter 1 of the Safe Drinking Water and Toxic Enforcement Act of 1986.

In addition to the state and federal statutes and regulations, there are a host of grassroots organizations which provide standards, seals of approval and general advocacy for everything ranging from non-GMO production, humane treatment of livestock, fair trade and other health/public policy interest groups.

This article provides only a very brief overview of the regulatory of the applicable regulations, and additional information and resources are available upon request from the author. As consumer expectations drive not only increase sales and the growth of products targeting the health-conscious consumer, further regulation is likely to follow. We are also likely to see an increase in claims from a failure to comply with labeling requirements, mislabeled, misbranded, and other regulatory litigation which may not provide a private right of action. We may also see an increase in the already present commercial, contract and tort claims for the bulk sale of materials advertised as organic or non-GMO for example, but which failed to meet the applicable standards. As additional research is performed and time passes we may ultimately see claims brought for personal injury or potentially for alleged increased risk of developing injury or disease. With the passage of time, the AMA and FDA's position may ultimately be reinforced that there is no meaningful or scientific distinction between GMO and non-GMO foods.

Jeanine Clark focuses her practice in civil litigation defense and insurance litigation. Jeanine is experienced in handling a variety of matters ranging from construction defect to bodily injury. She has experience handling catastrophic injury matters including commercial auto and multi-party litigation.