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Wild Thing: Organic, Non-GMO, and Nutraceutical Products

I. INTRODUCTION

There is a growing trend toward greener and healthier. With this trend consumers are increasingly concerned with and educating themselves about food and nutritional products. These concerns center not only on health and nutritional aspects but also on fair trade/humane trade. With the growth of these market segments come unique and emerging claims and litigation challenges. Not only do we have the ever present risk of bodily injury/toxic tort, but also a host of labeling and regulatory issues. Associated with some but not necessarily all of these potential litigation sources are host of coverage issues. This handout, in conjunction with a roundtable presentation is intended to provide you with an overview of some basic terms and issues and will hopefully provide you with some secondary research resources. Members of the panel will be available to discuss any issues or questions following the discussion and their e-mails are provided along with this handout in the event of any follow up questions or issues.

II. DEFINITIONS

What is organic versus free range, and what exactly is a nutraceutical are questions you may have had when you registered for this roundtable discussion. While a number of the key terms are defined either legislatively, regulatory or by trading practice, some concepts such as free trade are a bit more loose. What follows below is a general description of some of the key terms we will be discussing during today's roundtable. Where appropriate, we have provided a link to secondary resources.

Nutraceutical:

Nutraceutical is a general term used to describe products derived from hopefully natural sources. The nutraceutical will typically be a nutritional supplement which may include anything from the vitamins, minerals to compounds, antioxidants. They include dietary supplements and may even include food products. Walk into any vitamin shop or GNC Nutritional Center and you will find a host of nutraceutical products. Certain energy bars and powders also fall under the broad umbrella of nutraceuticals. Herbal remedies purporting to provide similar benefits to pharmaceuticals may also be considered nutraceuticals.

The National Institute of Health provides a good overview of what constitutes a dietary supplement, noting that same is intended to supplement the diet, contains one or more dietary ingredients

(including vitamins; minerals; herbs or other botanical; amino acid; and other substances) or their constituents, is intended to be taken by mouth as a pill, capsule, tablet, or liquid; and is labeled on the front panel as being a dietary supplement. https://ods.od.nih.gov/factsheets/dietarysupplements-healthprofessional/

The Dietary Supplement Health and Education Act of 1994 is codified under Title 21 of the United States Code. It is part of the Federal Food, Drug and Cosmetic Act. FD&C Act Chapter IV regulates food whereas FT&C Act Chapter V regulates drugs and other devices. Chapter IX of the Federal Food Drug and Cosmetic Act, addresses standards for food, misbranding, labeling and dietary supplement exemptions. Drugs or pharmaceuticals are much more heavily regulated and have a complex approval process.

There are a host of companies that will manufacture private label nutritional supplement. For example see http://www.privatelabelnutra.com. See also www.consolidatedlabel.com/market/health-label/nutraceutical-label/. The FDA has special regulations for food labeling which includes nutritional content claims such as high potency, antioxidants and even sugarfree.

High Potency:

According to the FDA website 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). That is a supplement may be labeled high potency if it provides 100% of the RDI per serving.

Antioxidant:

An antioxidant claim is considered a nutrient content claim subject to the Regulations of 21 CFR 101.54(g). Antioxidant claims may not be made for food, but only for supplements which meet the specified RDI requirements. To describe a nutritional supplement as being high in antioxidants, it would have to contain 20% or more of the daily reference value or RDI per serving. A good source constitutes an RDI of between 10% and 19%. There are certain specific antioxidants such as beta-carotene which have different requirements.

Non-GMO:

Non-GMO refers to Non-Genetically Modified Organisms. GMOs are/were living organisms whose genetic material was artificially altered and manipulated through genetic engineering. These can be anything from hybrid products or commercial food products engineered to withstand application of herbicides or insecticides, resist drought, or purportedly increase nutrition. Some nations banned the use of GMOs for human consumption but there are no specific prohibitions on GMO foods/nutritional supplements which meet other existing criteria in the United States. See www.nongmoproject.org.

Organic:

The United States Department of Agriculture is the certifying organization for organic products in the United States. In order to use the word “organic” or the USDA organic seal on food, feed or fiber

products farmers or producers must meet the certification requirements. The National Organic Standards Boards, a U.S. Department of Agriculture Federal Advisory Board is comprised of 15 volunteers who review material and recommend changes to the national list of allowed and prohibited substances. Attached to this handout is a USDA publication entitled "Introduction to Organic Practices." It provides a good overview of the USDA's organic program and provides additional information regarding the benefits of meeting organic certification. It also contains information on how consumers can file complaints with the USDA for organic violations. Violations include use of organic seal by an uncertified operator, presence of prohibited pesticides or other prohibited substances in product sold, use of uncertified co-packers or other handlers, and the use of fraudulent organic certificates to market or sell agricultural product. GMOs cannot be used in organic products. No prohibited substance may be applied to the land within the three years immediately prior to the harvest of the organic products. While an animal may be treated with conventional medicine, if same fails and the animal is provided with non-organic treatment such as antibiotics, the animal may not then be sold as organic.

If a product is classified as 100% organic all ingredients and processing aids must be certified as organic. It a product is organic all ingredients must be organic and the product cannot exceed a combined total of 5% of allowed non-organic content excluding salt and water. Nonagricultural ingredients are prohibited with few exceptions such as baking soda, citric acid and enzymes. If an organic ingredient is not commercially available in the appropriate form, quality or quantity to replace its use, in certain circumstances a non-organic form may be used. The USDA gives examples such as carrot juice color and fish oil.

If a product is classified as "made with organic" at least 70% of the product must be certified organic ingredients excluding salt and water. See also Organic Foods Production Act, Title XXI of the 1990 Farm Bill. Penalties may include up to $11,000 per violation of USDA organic regulations.

Free Range:

Free range is the method of farming or animal husbandry where the animals either roam completely free outdoors or are permitted to roam freely outdoors for part of the day. Animal activists are quick to point out that despite being denominated as free range, conditions are still generally non-optimal with the ultimate goal being something of inhumane demise for the anticipated food animal. For example with egg farming, Kaytee may simply mean a larger mass enclosure and free range may mean very limited access to a small outdoor area. Certified humane is a program of humane farm animal care and thus free range certified humane is probably the only standard that would need the picture or expectations one would have of a free range egg hen. See, certifiedhumane.org.

Fair Trade:

Fair trade is a practice in which fair prices are paid to producers in developing countries. The goal is to avoid slave labor and mere slave labor like conditions, or other human rights violations in the production of goods or food products in Third World. Proceeds from products can be used directly to pay wages, or go into developing infrastructure in emerging communities. See, fairtradeusa.org.

III REGULATORY FRAMEWORK

As discussed above, there are various governmental and nongovernmental agencies and organizations which regulate and/or certify food, agriculture and products. The Federal Food and Drug Administration (FDA) is the primary regulatory body as it relates to food and nutritional supplements. The FDA regulates content and labeling. The United States Department of Agriculture, the USDA, operates the organic certification program. Various state organizations such as the California Department of Public Health, at least make information available regarding the requirements of food labeling. General food/nutritional supplement labeling requirements can be found at 21 C.F.R. §101.2, et seq. Others statutory schemes include the Dietary Supplement Health and Education Act of 1994 and the Food Allergen Labeling and Consumer Act of 2004. Individual states including California also have specific disclosure and labeling requirements such as the so-called Proposition 65. Same was enacted in 1986 to protect California citizens and its drinking water from chemicals known to cause cancer, birth defects and reproductive harm. Proposition 65 requires the State to maintain an updated list of chemicals known to cause cancer or reproductive harm. Regulation and enforcement are through California Office of Environmental Health Hazard Assessment. A cottage industry has developed as a result of alleged improper, incorrect, incomplete or misleading labeling. A complementary cottage industry in California producing the necessary signs for clear and reasonable warnings is also well-developed. Chapter 1 of the Safe Drinking Water and Toxic Enforcement Act of 1986, Article 6 pertain to warnings at § 25601 states in pertinent part:

> Clear and Reasonable Warnings.
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> Whenever a clear and reasonable warning is required under §25249.16 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the State to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in this article that satisfy the requirements of this article, or to require that warning to be provided separately to each exposed individual.

Various laboratories also offer their services for Proposition 65 analysis. The FDA maintains a regular listserv of recall and includes everything from drug recalls to undisclosed allergens. The Fair Trade Commission also plays a role in the regulation of advertising including social media.

IV OTHER STANDARDS, PRACTICES & NGOS

In addition to the non-GMO project, certifiedhumane.org, there are numerous certifying nongovernmental organizations, trade groups and humanitarian organizations providing standards and seals of approval. The American Grasfed Association www.americangrassfed.org promulgates and enforces standards for American Grassfed Association certification. In order to meet American Grassfed Association standards, cattle or other livestock must be raised 100% on grass and forages, never grain or grain based supplements. The animals must never be given antibiotics not hormone supplements, must be

treated humanely and who lived its life on a pasture. Other NGOs include the Association for Public Health Laboratories, the Council, State and Territorial Epidemiologists, the International Association for Food Protection, International Food Protection Training Institute, International Environmental Health Association and the Association of Food and Drug Officials.

V. CLAIM AND LITIGATION POINTS

The roundtable will discuss in detail potential, emerging and past claims and litigation scenarios. Recalls, mislabeling, misrepresentation, uncertified and non-compliant issues represent one end of the spectrum whereas bodily injury/toxic tort due to defective or mislabeled products represent the other end of the spectrum. Examples of recent litigation include the Chipotle lawsuit in which a group claims that it failed to disclose the continued presence of GMOs in its products. The class action alleged that Chipotle's menu had never been free of GMOs while Chipotle claims a lawsuit was meritless. The suit was filed in the United States District Court for the Northern District of California. The dietary supplement market/nutraceuticals are much less rigidly regulated and the rules of the game have not been fully established as they are with respect to pharmaceutical litigation. As such, we are likely to see an increase in litigation in this area. The lack of structure and marketing freedom provided too many factors in the nutraceutical area provides the consumer and his or her skilled counsel with substantial opportunity class-action lawsuits have thrived in Philadelphia with respect to nutraceutical or nutritional/dietary supplements.