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DIETARY SUPPLEMENT LEGAL UPDATE

August 2016

A variety of legal and regulatory challenges exist in the dietary supplement industry, including federal and state legislatures, agencies and courts. Some of the more significant developments are summarized below. For additional information contact: Richard J. Oparil and Kevin M. Bell of Porzio's Washington office.

Editors Richard J. Oparil and Kevin M. Bell

FDA ISSUES NDI DRAFT GUIDANCE

On August 11, 2016, the U.S. Food and Drug Administration (FDA) issued a revised draft guidance to improve dietary supplement companies' new dietary ingredient (NDI) premarket safety notifications to the agency.

The Dietary Supplement Health and Education Act (DSHEA) requires the manufacturer or distributor to notify the FDA at least 75 days before beginning to market a dietary supplement that contains a new dietary ingredient (i.e., one that was not marketed in the United States before Oct. 15, 1994), unless the NDI is used in the food supply without chemical alteration. Dietary supplements are considered adulterated if they contain an NDI not used in the food supply and the required notification has not been submitted to the FDA 75 days before marketing. However, the agency has received fewer than 1,000 NDI notifications since DSHEA was passed in 1994.

The initial draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," was released in 2011. The FDA has now revised the draft guidance to clarify several important points that were misunderstood or not fully explained, to describe the public health significance of the recommendations, and to request additional comment before publishing a final guidance. Electronic or written comments on the draft guidance are due by October 11, 2016.

The draft Guidance is available here.

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GMO LABELING BILL SIGNED INTO LAW

Legislation to create a federal labeling standard for foods with genetically modified organisms and to block states from issuing their own laws passed the House of Representatives and has been signed into law by the President. The bill, S. 764, directs the U.S. Department of Agriculture (USDA) to create a national labeling standard that allows food producers to choose how they want to disclose the presence of genetically modified ingredients. Under the legislation, manufacturers will be able to use text, symbols or a QR code that consumers must scan with a smartphone to relay the information. The QR code labeling provision was controversial, with some arguing that it hurt the poor who do not have smartphones.

Under the new law, USDA must begin the process of deciding what exactly food manufacturers will be required to label. It will be up to USDA to define which ingredients count as "genetically modified ingredients" for the purposes of the law. The agency is supposed to complete this process within two years.

The GMO law also will preempt all state-level labeling laws, including Vermont's GMO law, Act 120, which had taken effect on July 1. The state law required farmers and food manufacturers who sell their products in Vermont to label foods that have ingredients enhanced by genetic engineering (GE). Act 120 requires certain products with GE ingredients to include a label warning consumers that the products are or may be "produced with genetic engineering." Manufacturers are also precluded from using "natural" or similar words to describe the products.

In *Grocery Manufacturers Ass'n v. Sorrell*, plaintiffs sued Vermont to strike down Act 120. In April 2015, the U.S. District Court denied the motion to preliminarily enjoin the law from taking effect. They appealed the decision to the U.S. Court of Appeals for the Second Circuit, which heard oral argument on October 8, 2015. The appellate court's decision was still pending when the President signed the federal GMO law. Based on the preemption provision, the parties to the appeal agreed the case was moot and it was dismissed.

PUERTO RICO SECRETARY OF HEALTH ISSUES ADMINISTRATIVE ORDER ON DIETARY SUPPLEMENTS

On February 9, 2016, the Puerto Rican Secretary of Health issued Administrative Order No. 346 without any notice and comment period. The Order imposes a regulatory scheme for all distributors of dietary supplements in Puerto Rico. This Administrative Order was effective immediately.

The Order requires a burdensome registration that mirrors much of what is already currently filed with the Food and Drug Administration ("FDA") and a $25 fee for every variation of a supplement by size. Other fees include: (a) manufacturers must file an application and pay a $500 fee; (b) wholesale and retail distributors must also register and pay a $100 fee; (c) facilities are subject to inspection and must pay a $50 fee.

In June, the President signed into law the Puerto Rico Oversight, Management, and Economic Stability Act (S. 2328), that would create a fiscal control board to oversee Puerto Rico's budget. Part of the legislation established a Congressional Task Force on Economic Growth in Puerto Rico. The legislation requires that, by December 31, 2016, the Task Force issue a report to the House and Senate regarding, among other things, the economic effect of Order No. 346 or any successor or substantially similar order, rule, or guidance of Puerto Rico.

Senator Orrin Hatch of Utah, a sponsor of DSHEA, will serve as chairman of the eight-member Task Force. The other members appointed by House and Senate leadership are Representatives Tom MacArthur of New Jersey; Sean Duffy of Wisconsin; Nydia Velazquez of New York; and Pedro Pierluisi, of Puerto Rico; and Senators Marco Rubio of Florida; Bob Menendez of New Jersey and Bill Nelson of Florida.

The Task Force recently issued a statement seeking input from stakeholders. Submissions can be made at the Task Force's mailbox at prtaskforce@mail.house.gov. The deadline to respond is September 2, 2016.

FDA ISSUES MEDICAL FOOD GUIDANCE

FDA issued its final guidance on the definition and labeling of medical foods and provides responses to additional questions about the definition and labeling of medical foods, types of diseases and conditions that a medical food could be used to manage, and updates prior responses from the previous edition of the guidance. The "Frequently Asked Questions About Medical Foods; Second Edition" guidance is available at Guidance Documents.

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. § 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." According to the FDA, medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those foods simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition.

Medical foods do not require pre-market or drug-like approvals, they must be based on sound medical and nutritional principles, and the FDA subjects them to monitoring. The products have active ingredients derived from food products or dietary ingredients that are generally recognized as safe (GRAS) by FDA. The regulations that govern medical foods are summarized in the final guidance.

FDA DEEMING REGULATIONS MADE FINAL

On May 5, 2016, the FDA finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others. This rule helps implement the bipartisan Family Smoking Prevention and Tobacco Control Act of 2009 and allows the FDA to improve public health and protect future generations from the dangers of tobacco use through a variety of steps, including restricting the sale of these tobacco products to minors nationwide. The rule deems "tobacco products," including components and parts (in particular e-liquids; tank systems, flavors, and vials that contain e-liquids) but excludes accessories, to be subject to the Food Drug and Cosmetic Act. [1]

Before the rule, there was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco or cigars to people under age 18. The rule changes that with provisions aimed at restricting youth access, which go into effect in 90 days, including:

- Not allowing products to be sold to persons under the age of 18 years (both in person and online);
- Requiring age verification by photo ID;
- Not allowing the selling of covered tobacco products in vending machines (unless in an adult-only facility); and
- Not allowing the distribution of free samples.

The rule also requires manufacturers of all newly-regulated products to show that the products meet the applicable public health standard set forth in the law and receive marketing authorization from the FDA, unless the product was on the market as of February 15, 2007. The tobacco product review process gives the agency the ability to evaluate factors such as ingredients, product design and health risks, as well as their appeal to youth and non-users.

Under staggered timelines, the FDA expects that manufacturers will continue selling their products for up to two years while they submit - and an additional year while the FDA reviews - a new tobacco product application. The FDA will issue an order granting marketing authorization where appropriate; otherwise, the product will face FDA enforcement.

Other aspects of the regulation include:

- Registering manufacturing establishments and providing product listings to the FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring pre-market review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

To assist the newly-regulated tobacco industry in complying with the requirements being announced today, the FDA is also publishing several other regulatory documents that provide additional clarity, instructions and/or the FDA's current thinking on issues specific to the newly-regulated products.

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[1] The rule is available at Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act.

CHOBANI YOGURT LABELING APPEAL STAYED

In May 2012, a suit was filed on behalf of a putative class of people who had purchased Chobani Greek yogurt, alleging that the products were labelled "all natural" but in fact contained artificial ingredients, flavorings, coloring and chemical preservatives. Further, the labels referred to evaporated cane juice and did not disclose that is another term for sugar. The District Court dismissed the case, finding that the complaint did not sufficiently allege the plaintiffs were deceived by the term evaporated cane juice. On appeal to the U.S. Court of Appeals for the Ninth Circuit, plaintiffs' argued that they had been seeking out yogurt without added sugar. They were misled into buying the Chobani products because the labels did not refer to "sugar" or "syrup." Chobani countered that the labels were accurate under federal regulations because they disclosed the presence of "evaporated cane juice" and the use of "sugar" would be incorrect.

The appeal was argued in March 2015. However, the Ninth Circuit has now stayed the case until after the FDA completes its proceedings regarding the use of the terms "natural" and "evaporated cane juice" in food labeling. The Court noted that the agency with regulatory authority over the technical and policy questions should address the issue in the first instance.

SEN. McCASKILL MAKES INQUIRY AFTER STUDY SHOWS DIETARY SUPPLEMENTS CAN MAKE CHEMOTHERAPY LESS EFFECTIVE

After a recent study by the University of Minnesota[2] found that several widely used botanicals and dietary supplements can interfere with chemotherapy and other treatments for chronic conditions, Senator Claire McCaskill wrote to ten medical associations on May 17, 2016 to find out what guidance they are offering doctors regarding the possible risks associated with the use of supplements by patients being treated for serious medical conditions. Sen. McCaskill said that "[t]he fact is that we don't know enough about how dietary supplements interact with cancer treatments or with the treatment of other serious conditions. The lack of consumer protection in the dietary supplement industry has left patients facing life-threatening illnesses even more vulnerable. I can't sit by while their health and safety is compromised just because our regulatory scheme for dietary supplements is flawed."

McCaskill, the ranking Democrat on the Senate Special Committee on Aging, wrote to ten medical associations asking for any policies they have developed for when and how physicians assess dietary supplement use in patients prior to starting cancer treatment. The associations are: the American Medical Association, the American College of Physicians, the American Society of Clinical Oncology, the American Geriatrics Society, the American Cancer Society, the National Medical Association, the American Osteopathic Association, the Gerontological Society of America, the National Hispanic Medical Association, and the American Pharmacists Association.

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[2] Patients with cancer undergoing chemotherapy

UPDATE ON CBD

Cannabis plants contain two main cannabinoids: tetrahydrocannabinol (THC) and cannabidiol (CBD). THC produces psychoactive effects and is responsible for the "high" associated with marijuana ingestion. CBD, on the other hand, produces nearly no psychoactive effects but has been desirable for certain uses including treating seizures. Ambiguities related to these products exist in the marketplace for a variety of reasons. Low-THC strains of cannabis plants that are grown can be referred to as industrial hemp. Terms such as CBD, hemp, and industrial hemp are, at times, used interchangeably. Indeed, no federal agency appears to have a strict definition of "hemp" and certain statutes use terms with some inconsistency.

THC is still listed as a Schedule I drug of the Controlled Substances Act (CSA) meaning the federal government believes it to be a dangerous drug with no recognized medical benefit. Any CBD derived from marijuana is considered to be a Schedule I drug. The DEA nonetheless recently eased certain requirements related to the FDA. The updated requirements apply to FDA approved clinical trials, which now allow the DEA to grant waivers to registered researchers to alter the scope of their research under an FDA Investigational New Drug Application (IND). This change streamlines requests to change the scope of the research or granting access to more CBD. The prior procedure involved

multi-level and multi-agency review, which could take a long time. This change should aid in further research into CBD.

With regards to hemp, the CSA definition of marijuana does not include "the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." Hemp, which is created from these mature stalks, is thus exempt from DEA regulation. A 2004 case from the Ninth Circuit confirmed this interpretation of the CSA, finding improper the DEA's interpretive rule that considered industrial hemp to be a Schedule I substance under the CSA. Specifically, the court said, "[t]he non-psychoactive hemp in Appellants' products is derived from the "mature stalks" or is "oil and cake made from the seeds" of the Cannabis plant, and therefore fits within the plainly stated exception to the CSA definition of marijuana. *Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012, 1017 (9th Cir. 2004).

The DEA nevertheless has the authority to regulate hemp cultivation via restrictions to grow marijuana and the only exemption to this is the Agricultural Act of 2014. Section 7606 of the Act allows an institution of higher education (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. § 1001)) or a state department of agriculture to grow or cultivate industrial hemp if "(1) the industrial hemp is grown or cultivated for purposes of research conducted under an agricultural pilot program or other agricultural or academic research; and (2) the growing or cultivating of industrial hemp is allowed under the laws of the State in which such institution of higher education or state department of agriculture is located and such research occurs." This Act provides for an actual definition of "industrial hemp," saying "the term `industrial hemp' means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." Industrial hemp (i.e., low-THC cannabis or material derived from the stalks of mature plants) can thus only be obtained under this exemption or by importing industrial hemp produced outside of the United States. Therefore, this relatively recent Act may further allow for more research into CBD by allowing certain parties to grow industrial hemp under Section 7606.

The DEA will also be reviewing the classification of marijuana as a Schedule I drug in the near future. The DEA received a letter from eight senators that urged the federal government to facilitate research into marijuana's medical benefits to which the DEA responded with this review. While a change in the classification of marijuana will not alter the overall legality of marijuana, hemp or CBD per se, it may increase the ability to conduct testing and research.

With respect to CBD's use as a dietary supplement, the FDA regulates compounds that it considers to be drugs (i.e., when a firm makes a medical claim about a product) but does not regulate dietary supplements. Under the Dietary Supplements Health and Education Act (DSHEA), supplements cannot claim to "diagnose, treat, cure or prevent any disease."

FDA has determined that it considers marijuana to be a drug and not a dietary supplement. The FDA has specifically said:

> Based on available evidence, FDA has concluded that cannabidiol products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act. Under that provision, if an article (such as cannabidiol) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for cannabidiol.

Moreover, the FDA recently placed additional pressure on CBD products when it issued warning letters to eight marketers of CBD dietary supplements warning that it considered the CBD products to be illegal and found that these products were making false claims.

Firms have argued that these products were sold as dietary supplements prior to the filing of an IND by GW Research, which could allow CBD products to satisfy the exception mentioned above. This argument is yet to be settled, however. The legality of these products remains complex because of the intersection of state law and federal law coupled with nuances among federal agencies. To best avoid liability, a firm selling any CBD product should first be sure that it is derived from industrial hemp. The surest route to this may be to import industrial hemp produced abroad due to restrictions existing under Section 76066 of the Agricultural Act of 2014. Secondly, to avoid FDA issues, a firm must be sure that its hemp-derived CBD products are not labeled with any medical claims. As time moves on, the status of some of these products may change, which could facilitate additional marketing, but these issues remain a bit murky for now.

SUMMARY OF CALIFORNIA SUPREME COURT PROPOSITION 65 CASE, *ENVIRONMENTAL LAW FOUNDATION V. BEECH-NUT NUTRITION CORP*.

In 2011, the Environmental Law Foundation (ELF) sued Beech-Nutrition Corporation (Beech-Nut) alleging that Beech-Nut's products contained excessive levels of lead under California's Safe Drinking Water and Toxic Enforcement Act of 1986, which is commonly referred to as Proposition 65. The trial court found that Beech-Nut used an acceptable method to determine lead levels in certain products. ELF then appealed.

Proposition 65 requires that "'[n]o person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in [the safe harbor provisions of the statute]'". *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, 235 Cal.App.4th 307, 312 (2015). An accused party can avoid liability under the safe harbor if "'the person responsible can show ... that the exposure will have *no observable effect* assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical...'". *Id*. at 313.

At trial, an accused party must first establish the "no observable effect level" (NOEL). *Id*. To then procure protection under the safe harbor, the party must establish the level of exposure in question and that the level of exposure was 1,000 times below the NOEL. Id. The exposure that is 1,000 times below the NOEL is known as the maximum allowable dose level (MADL). *Id*. The issue in this case was the proper determination of the level of exposure based on the level in question. The level in question is the "'chemical concentration of a listed chemical for the exposure in question'". *Id*. at 312-313. The "'level of exposure' is determined by multiplying the level in question ... times the reasonably anticipated rate of exposure for an individual to a given medium." *Id*. at 327.

Both parties submitted expert reports regarding the determination of the level of exposure but these reports used conflicting methods. The experts disagreed as to whether maximum amounts for any given day should be used or whether using averages was more appropriate. *See id*. at 314-322. The court considered whether it was appropriate to use averages for analyzing both the amount of lead in multiple product lots and the exposure time period.

The court held that it was acceptable to determine the lead concentration in the products by averaging the concentrations found in multiple "lots" of products. *Id*. at 323-327. The court thus

determined that it was not required to evaluate each lot individually. *Id*. To then determine the rate of exposure, a party may also average the exposure over a period of time, instead of using a single day exposure amount. *Id*. at 327-329. This decision makes it easier for parties to establish exposure levels that allow it to qualify for the safe harbor by averaging the concentration of multiple product lots along with averaging exposure over a period of time.