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DIETARY SUPPLEMENT LEGAL UPDATE

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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 recent developments are summarized below. For additional information, contact Kevin M. Bell or Richard J. Oparil of Porzio's Washington office.

Editors: Kevin M. Bell and Richard J. Oparil.

SENATE CONFIRMS FDA COMMISSIONER

On May 9, 2017, the Senate voted 57 to 42 to confirm the nomination of Dr. Scott Gottlieb to be FDA Commissioner. He served as an FDA Deputy Commissioner in President George W. Bush's administration. He has worked with venture capital firms engaged in financing healthcare start-ups and as a resident fellow at the American Enterprise Institute, a think tank. The Senate Health, Education, Labor and Pensions Committee held a hearing on the nomination on April 5. In response to a written question by Committee Chairman Orrin Hatch, Dr. Gottlieb wrote that: "As someone who uses dietary supplements every day, I believe they serve an important role in health promotion for millions of Americans, and I support consumer access to these products." He also wrote that FDA's current regulatory framework under the Dietary Supplement Health and Education Act (DSHEA) provides adequate enforcement tools to remove unsafe dietary supplements from the market and "if confirmed, I would commit to enforcing DSHEA, as intended by Congress."

President Trump named Commissioner Maureen Ohlhausen to be Acting Chair of the FTC. Even though the FTC is a five-member body, there are currently only two Commissioners. The President has not yet nominated anyone to fill the vacancies.

SUPREME COURT LIMITS WHERE PATENT

In This Issue

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INFRINGEMENT CASES MAY BE BROUGHT

For decades, courts held that accused patent infringers could be sued anywhere they make sales. However, the Supreme Court held on May 22 that the U.S. Court of Appeals for the Federal Circuit's expansive view of venue was based on a misinterpretation of the law. The justices unanimously held that domestic companies can only face patent cases where they are either (1) incorporated or (2) where they have committed infringement and have a "regular and established place of business." This decision will limit where infringement plaintiffs may file suit. The decision is expected to reduce the number of new cases filed in the Eastern District of Texas, which has the reputation of being plaintiff-friendly. The number of cases filed in Delaware and California are expected to increase. It is unclear what effect the decision will have on cases that have already been filed.

SUPREME COURT TO CONSIDER WHETHER PATENT OFFICE PROCEEDINGS TO REVIEW THE VALIDITY OF PATENTS IS CONSTITUTIONAL

In a surprise move, the Supreme Court has agreed to hear a case challenging the constitutionality of administrative proceedings in the Patent Trial and Appeal Board (PTAB), part of the U.S. Patent and Trademark Office, to review the validity of issued patents. The America Invents Act, passed in 2011, created a procedure, called *inter partes* review (IPR), to review whether claims of issued patents are invalid on the grounds that they are anticipated or obvious based on prior art. IPR proceedings are beneficial to parties challenging the validity of patents because they must be completed within a statutory deadline and are typically cheaper than federal court litigation. Recent statistics show the popularity of IPRs - the PTAB has instituted about 3,400 IPRs, issued over 1,500 final decisions, about 1,300 of which have invalidated at least some of the challenged claims.

In *Oil States Energy Services v. Greene's Energy Group*, the patent owner argued that only federal courts, not the PTAB, can decide whether an issued patent is invalid. It asserted that patents are private property rights, which can only be taken away by a federal court under Article III of the U.S Constitution, not public rights, which can be revoked by a government agency. The U.S. Court of Appeals for the Federal Circuit had ruled that patents are public rights and that IPRs are constitutional.

In recent years, the Supreme Court has reversed a number of patent law decisions by the Federal Circuit. The case will be argued before the Supreme Court later this year or in early 2018.

OREGON AG SETTLES DISPUTE WITH VITAMIN SHOPPE

The Oregon Attorney General, Ellen Rosenblum, settled a dispute with Vitamin Shoppe Inc. Under the settlement, Vitamin Shoppe is prohibited from selling any dietary supplement after the FDA has issued

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written notice that the product contains an ingredient that is unlawful or unsafe. Additionally, if the FDA, or any other governmental entity in the United States, United Kingdom, Canada, the European Union or Australia brings the safety or legality of a dietary supplement sold by Vitamin Shoppe into question, Vitamin Shoppe must conduct an independent investigation to confirm whether the product is safe. The company also specifically agreed not to sell products containing DMAA or picamillon in Oregon. The settlement requires Vitamin Shoppe to pay $545,000 to the State of Oregon to be used for consumer protection and other purposes.

The settlement is significant because it requires Vitamin Shoppe to monitor the activities of foreign regulators, which may dictate what dietary supplement products can be sold in Oregon. While the FDA regulates dietary supplements under DSHEA, this settlement essentially outsources regulation of product sales to foreign countries.

FDA IS POSTING ADVERSE EVENT REPORTS ONLINE

FDA has announced the online availability of data from adverse event reports from January 2004 to the present involving food (including food additives, color additives, and dietary supplements) and cosmetics regulated by the Center for Food Safety and Applied Nutrition (CFSAN). The data files are being made publicly available on FDA's web site to improve transparency about adverse event reports involving CFSAN-regulated products and increase awareness about reporting these adverse events to FDA.

The data files are provided in ASCII format and include information on the following topics (if provided):

- Demographic (e.g., age, gender) and administrative information regarding the adverse event;
- Date of event;
- Product role (suspect or concomitant);
- Reported brand/product name;
- Industry code/name;
- Reported symptoms; and
- Outcome information.

The data files are available at:
https://www.fda.gov/Food/ComplianceEnforcement/ucm494015.htm

FDA ISSUES WARNING LETTER FOR DRUG CLAIMS

On May 12, 2017, the FDA issued a warning letter to Formulife, Inc. and Purus Labs, Inc. for a series of regulatory violations, including promoting a product called "Organ Shield" intended for use in the cure, mitigation, treatment, or prevention of disease. Examples of improper website claims for Organ Shield include:

- "Silymarin [an ingredient in the product] ... is comprised of several flavonolignands that help repair liver cells damaged by toxins..."
- "Beta-Sitosterol [an ingredient in the product]...has been shown in clinical settings to lower cholesterol and has been used to treat hypercholesterolemia."
- "Beta-Sitosterol [an ingredient in the product] has also been used in many studies in treating BPH (benign prostatic hypertrophy)."

The full warning letter is available at:
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm558916.htm

FDA ISSUES 14 WARNING LETTERS TO 14 COMPANIES SELLING CANCER TREATMENT PRODUCTS

As of April 25, 2017, FDA has issued 14 warning letters and four online advisory letters to companies illegally selling more than 65 products that claim to prevent, diagnose, treat, mitigate or cure cancer. The products are marketed and sold without FDA approval, most commonly on websites or social media platforms. The warning letters are available at:
https://www.fda.gov/ForConsumers/ProtectYourself/HealthFraud/ucm533465.htm#T1

FDA WARNING LETTER ON CBD PRODUCT

The seller of cannabis oil received a warning letter from FDA regarding advertising its products on its website and Facebook page as helping AIDS and Alzheimer's patients, treating attention deficit disorder, Parkinson's and a host of other diseases. The company also claimed that its product "works as a natural chemotherapy and also alleviates the secondary effects of traditional chemotherapy, such as less appetite, nausea or vomits, fatigue, depression, anxiety, insomnia and pain. It's ideal for people looking for a preventive treatment since it has both oils. Both oils help ... anxiety." FDA wrote that such disease claims were not allowed. FDA also warned that CBD products are excluded from the statutory definition of dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B)(ii). The warning letter is available at:
https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm549298.htm

ELEVENTH CIRCUIT RULES ON FIRST AMENDMENT LABELLING ISSUE

The U.S. Court of Appeals for the Eleventh Circuit recently rules that the actions of the Florida Commissioner of Agriculture and the Chief of the Florida Bureau of Dairy Industry violated a dairy company's First Amendment rights relating to use of the term "skim milk."

The challenge before the court involved the interpretation as applied to Ocheesee Creamery LLC of Florida law that restricted the sale of milk and milk products that are not classified as Grade A. In order to receive the Grade A designation, vitamin A that is lost and/or removed through the skimming process must be replaced. Ocheesee Creamery sold an all-natural, additive-free skim milk that only contained skimmed milk, and labeled its product as "skim milk." However, the state of Florida notified Ocheesee that its skim milk did not fall within the definition of milk, and advised Ocheesee that it could only continue to sell its all-natural skim milk as long as it was labeled as "imitation milk product." Ocheesee did not agree to label its product as "imitation" because skimmed milk was the only ingredient in the product, and it refused to add vitamin A back into the product. Ocheesee argued that the regulators violated its free speech rights. Commercial speech is not protected if "the speech concerns unlawful activity," or if "the speech is false or inherently misleading." The Eleventh Circuit found that Ocheesee's conduct was not unlawful. The Court ruled that the term "skim milk" as used by Ocheesee was not inherently misleading or merely potentially misleading because it was a statement of objective fact. The Court found that the "State's mandate was clearly more extensive than necessary to serve its interest in preventing deception and ensuring adequate nutritional standards." Consequently, the restraint violated the First Amendment.

The decision in *Ocheesee Creamery LLC v. Putnam* is available at: https://scholar.google.com/scholar_case?case=16534059398691852543&q=ocheesee&hl=en&as_sdt=6,31

FTC REMINDS INFLUENCERS AND BRANDS TO CLEARLY DISCLOSE RELATIONSHIP IN SOCIAL MEDIA ENDORSEMENTS

The FTC recently sent out more than 90 letters reminding "influencers" - celebrities and athletes - and marketers to clearly and conspicuously disclose their relationships to brands when promoting or endorsing products through social media. The letters were in response to petitions filed by Public Citizen and affiliated organizations regarding influencer advertising on Instagram, and Instagram posts reviewed by FTC staff. They mark the first time that FTC staff has reached out directly to educate social media influencers themselves.

The FTC's Endorsement Guides provide that if there is a "material connection" between an endorser and an advertiser - in other words, a connection that might affect the weight or credibility that consumers give the endorsement - that connection should be clearly and conspicuously disclosed, unless it is already clear from the context of the communication. A material connection could be a business or family relationship, monetary payment, or the gift of a free product. The Endorsement Guides apply to both marketers and endorsers.

In addition, the letters addressed one point specific to Instagram posts -- consumers viewing Instagram posts on mobile devices typically see only the first three lines of a longer post unless they click "more," which many may not do. The staff's letters informed recipients that when making endorsements on Instagram, they should disclose any material connection above the "more" button. Also, noted that when multiple tags, hashtags, or links are used, readers may just skip over them. A disclosure placed in such a string is not likely to be conspicuous.

GUILTY PLEA IN DMAA CASE

The owner of Gentech Pharmaceuticals has pled guilty in connection with manufacturing, marketing and selling of dietary supplements containing unlabeled DMAA. Derek Vest founded the Ft. Myers, Florida, company to provide "non-prescription pharmaceuticals" for weight loss, cognitive function and sleep management. In 2013, Gentech sold DMAA in several supplements: the weight-loss products PhenTabz and PhenTabz-Teen, as well as AddTabz, a mental performance product advertised as an alternative to Adderall, an amphetamine drug for Attention deficit hyperactivity disorder. According to the plea agreement, Vest knowingly authorized the use of DMAA in the manufacturing of these products, but he did not disclose the presence of the ingredient on the products' labeling or marketing materials. Vest now faces up to three years in prison, a $250,000 fine and forfeiture of $2.5 million in assets. Sentencing is scheduled for July 3, 2017.

HI-TECH LOSES DEFAMATION CASE AGAINST HARVARD RESEARCHER

In 2014, FDA scientists found beta-methylphenethylamine (BMPEA) in nine purportedly all-natural supplements instead of the Acacia rigidula plant listed on the labels. However, the FDA did not disclose the products named or their manufacturers. Dr. Pieter Cohen, of Harvard Medical School, tried to replicate those findings and publicize the specific brands using BMPEA. In the resulting study published in the scientific journal *Drug Testing and Analysis* in April 2015, his team says they chemically analyzed 21 popular supplements, made by various manufacturers, all labeled as containing Acacia rigidula. Eleven of those were positive for BMPEA, in some cases at potentially dangerous levels.

The same month that report was released, the FDA issued warning letters to makers of dietary supplements, including Hi-Tech, whose products had accounted for a majority of the supplements that

tested positive for BMPEA in Cohen's study. The FDA then notified the makers of products to stop sales.

Hi-Tech filed a lawsuit in U.S. District Court in the company's home state of Georgia against Cohen and the study's three co-authors for $200 million. Hi-Tech blamed Cohen for costing the company an immediate $14 million in lost business. The Georgia Court dismissed that lawsuit in the spring of 2016 for lack of personal jurisdiction.

Hi-Tech then refiled the case against Cohen in Massachusetts District Court and demanded $200 million in damages. In discovery, Cohen turned over hundreds of pages of his notes, peer-review feedback, and his written correspondences with the journal, coauthors, and journalists. At the October 2016 trial, Hi-Tech accused Cohen of ignoring "fundamental canons and methods of scientific investigation," and of making allegedly false statements about BMPEA. The company maintained that the BMPEA in its products occurred naturally. On November 1, the jury returned a verdict in Cohen's favor. Hi-Tech has not appealed the adverse judgment.

OFFICIAL CLARIFIES THAT THE FTC DOES NOT REQUIRE TWO CLINICAL TRIALS FOR CLAIM SUBSTANTIATION

During the Natural Products Association (NPA)'s recent The Big Natural Conference, an FTC official said that the Commission does not require two double-blind, randomized controlled clinical trials (RCTs) to substantiate dietary supplement claims. Richard Cleland, the FTC's Assistant Director for Advertising Practices, was asked about the FTC's attempt to have a New Jersey federal judge hold Bayer in contempt, arguing that the company's claims that Phillips' Colon Health product helped defend against occasional constipation, diarrhea, gas, and bloating were not supported by competent and reliable scientific evidence. In the Bayer case, the FTC contended that the exact bacterial strains in the product were not tested by RCTs. Porzio filed a friend of the Court brief for NPA, expressing concerns about the government's position. The Court rejected the FTC's position and ruled in favor of Bayer.

Asked at the conference whether it was the FTC's position that claim substantiation required two RCTs, Mr. Cleland said no. He said that the Commission no longer imposes a requirement in consent orders that future advertising claims require two RCTs. He said that the FTC would look to whether there is one RCT to substantiate claims.