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DIETARY SUPPLEMENT LEGAL UPDATE

April 2017

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 Kevin M. Bell or Richard J. Oparil of Porzio's Washington office.

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REGULATORY ENVIRONMENT

President Trump's Executive Orders and vacancies in key positions, including at the Food and Drug Administration (FDA) and Federal Trade Commission (FTC), have slowed new regulatory activities in the dietary supplement industry. For example, in September 2016, FDA requested comments on its tentative conclusion that vinpocetine is not a dietary ingredient (despite having received five NDI notifications). Despite having received hundreds of comments, it has not announced any action on the issue.

President Trump has nominated 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, 2017. 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." The Senate Committee is currently scheduled to consider the nomination on April 26, 2017.

In This Issue

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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.

COURT APPROVES DMAA CONSENT DECREE

While there has been little recent activity on regulatory issues, federal agencies continue to engage in enforcement proceedings. For example, a judge in the Central District of California entered a consent decree enjoining VivaCeuticals Inc., doing business as Regeneca Worldwide, and its owner from selling supplement products that contain DMAA. In 2012, the FDA sent Regeneca a warning letter for marketing a dietary supplement containing DMAA. Despite assurances that Regeneca was correcting violations, Regeneca continued to distribute a dietary supplement that was found to contain DMAA. The government then sued.

The consent decree prohibits Regeneca from marketing unapproved new drugs, and adulterated and misbranded dietary supplements. Before Regeneca can resume operations, the company must implement procedures to comply with good manufacturing practice and labeling requirements (including hiring experts in those areas) and obtain the FDA's permission to resume operations. The decree also requires Regeneca to destroy all remaining products.

LOUISIANA COURT SHUTS DOWN SUPPLEMENT COMPANY

A judge in the Western District of Louisiana entered a consent decree against Pick and Pay Inc./Cili Minerals, a manufacturer and distributor of drugs and dietary supplements, and its owners, requiring the business to immediately cease operations. The products, sold over the internet and in a Louisiana store, were marketed under the names ADD-Ease, Bone Structure, CilZinCo, Calcium, Boron, Potassium, Cilver, Sulfur, and Germanium.

The FDA inspected the company four times since 2012 and found it was manufacturing and distributing misbranded and unapproved new drugs, as well as misbranded and adulterated dietary supplements. The defendants marketed their products with claims that they could treat medical conditions such as cancer, cardiovascular disease, multiple sclerosis, autism, bipolar disorder, brain injury and epilepsy. The FDA inspectors also found numerous cGMP violations, including failing to establish specifications for supplement components and to test or verify that components and finished products meet product specifications for identity, purity, strength or composition. The government eventually sued, seeking a permanent injunction against the company and its owners for unlawfully manufacturing and distributing unapproved new drugs, misbranded drugs, adulterated dietary supplements and misbranded dietary supplements.

The consent decree prohibits the company and its owner from marketing and distributing misbranded or unapproved new drugs and adulterated or misbranded dietary supplements. Before the company and its owners can resume operations, they must recall and destroy their existing stock of drugs and dietary supplements, hire labeling and good manufacturing practices experts, and receive written permission from the FDA to resume operations.

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 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.

FTC AND MAINE AG SETTLE MAINE CASE INVOLVING DECEPTIVE ADVERTISING

The FTC and the Maine Office of the Attorney General settled a case against six of nine defendants who used radio infomercials that were deceptively formatted as talk shows and print advertisements featuring fictitious endorsers to advertise supplements to improve memory and to reduce back and joint pain.

The defendants allegedly made false and misleading claims that their CogniPrin product reverses mental decline by 12 years and improves memory by 44 percent in as little as three weeks. They promoted a product called FlexiPrin as reducing joint and back pain, inflammation, and stiffness in as little as two hours, rebuilds damaged joints and cartilage, and has been clinically proven to reduce the need for medication in 80 percent of users and to reduce morning joint stiffness in all users. The defendants used 30-minute radio advertisements formatted to sound like educational talk shows featuring two of the defendants as purported experts who made unsubstantiated claims about the benefits of the products. The ads also failed to disclose that one of the defendants, who was presented as an objective medical expert, was paid a percentage of revenues generated from product sales.

In addition, the defendants allegedly used fictitious testimonials in print ads and on the internet to claim the products worked. The complaint further alleged that they falsely represented that consumers could try CogniPrin free for 30 days, even though consumers actually would have to enroll in a continuity plan to qualify for the offer, and that they would actually have only 14 days or less to try the product.

The agencies alleged the defendants violated the FTC Act, the Electronic Fund Transfer Act (EFTA), the Telemarketing Sales Rule, and the Maine Unfair Trade Practices Act. The settling defendants agreed to injunctions against making unsubstantiated health claims and to have competent and reliable scientific evidence when making health-related claims. They also require the defendants to preserve all scientific evidence supporting claims they make, and bar them from failing to disclose a material connection to a paid endorser. The orders further bar these defendants from misrepresenting the terms of any negative-option, continuity plans, or "free trial" offers, and require them to get consumers' express consent before charging them. Two of the defendants were banned from direct response marketing of foods, dietary supplements, or drugs for 20 years. The Court entered $6.57 million judgment against defendants, with all but $556,000 suspended due to the defendants' financial condition.

FTC AND NEW YORK AG SUE ON MEMORY IMPROVEMENT CLAIMS

In January, the FTC and New York Attorney General filed suit in the Southern District of New York against the sellers of a product called Prevagen for allegedly making false and unsubstantiated claims that the product improves memory, provides cognitive benefits, and is "clinically shown" to work. The national advertising campaign featured charts showing rapid improvement in memory for users of the product. In fact, the complaint alleges, the marketers relied on a study that failed to show that

Prevagen works better than a placebo. The active ingredient in Prevagen is a protein derived from jellyfish. Sales of the supplement at retailers such as Amazon, CVS, the Vitamin Shoppe, and Walgreens, and on the defendants' websites have exceeded $165 million.

The agencies allege that the defendants' marketing claims have violated the FTC Act and New York statutes. The agencies are seeking refunds for consumers who bought the product, civil penalties and injunctive relief. A response to the complaint by the defendants is due in April.

PUERTO RICO LEGISLATION ON DIETARY SUPPLEMENT REGISTRATION

A bill has been introduced in the Puerto Rican Senate to require registration of dietary supplements and payment of fees to the Commonwealth. The legislation is similar to last year's Administrative Order No. 346, which imposed a regulatory scheme for all distributors of dietary supplements in Puerto Rico. The Secretary of Health announced a moratorium on that administrative action. The Congressional Task Force on Economic Growth in Puerto Rico had expressed concerns with the regulations. While the legislation is ostensibly intended to address potential harm "if combined with other supplements, if used as drugs or taken in excess," it is believed that the real purpose is to raise revenue for the cash-starved government.