CLIENT ALERT

Dietary Supplements: The Role of Ingredients in Recent Litigation

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This month, our dietary supplement team identifies four recurrent ingredient-related issues arising in enforcement actions and in private litigation: protein spiking, dosage, DNA barcode testing, and federal preemption. These issues present potential labeling, supply chain, and risk management issues.

1. "Protein Spiking" Cases Continue to Crowd Courts.

Several cases working through the courts have challenged so-called "protein-spiking," which plaintiffs describe as using lower cost amino acids and other nitrogen-containing substances to boost the measurable amount of protein in dietary supplements. Although the FDA expressly permits manufacturers to include all nitrogen-containing agents in calculations of total protein content, *see* 21 C.F.R. § 101.9(c)(7), plaintiffs in several jurisdictions are suing manufacturers and retailers for allegedly misleading consumers regarding the quality and type of protein contained in a supplement. One manufacturer, MusclePharm, has faced two lawsuits against other defendants in the past two years on the issue, with both ending in settlement. Two other lawsuits are currently active. In *Gubala v. CVS Health Corp.*, the plaintiff alleged that CVS Brand Whey Protein Powder was "spiked" with low-quality amino acids and thus that the label claim of "26 grams of high-quality protein" misled consumers. The Court recently denied CVS's motion to dismiss and ordered the parties into mediation. *See Gubala v. CVS Health Corp.*, No. 14-cv-09039 (D. Ill. Nov. 11, 2014). Additionally, in *Dabish et al. v. 4 Dimension Nutritional, Inc. et al*, No. 1:14-cv-08781 (D. Ill. Feb. 18, 2015), the plaintiff alleged that protein manufacturer 4 Dimension and retailer, GNC misled consumers by labeling a nitrogen-spiked protein blend as "100 percent whey protein."

We will continue to monitor the protein-spiking cases and any FDA reactions regarding the methods currently used to calculate protein content.

2. Recommended Dosages Can Trigger Litigation.

Recent cases demonstrate the importance of matching the recommended supplement dosage to studies that support the claimed effect.

First, defendants can be held liable for health claims if the product dosage is too small to be effective. In these cases, however, the plaintiff has the burden of affirmatively proving that the recommended dosage is ineffective.

In *Segovia v. Vitamin Shoppe, Inc.*, the plaintiff alleged that Vitamin Shoppe had "dramatically under-dose[d]" the digestive enzyme Aminogen in its Whey Tech Pro 24 protein mix and had falsely claimed on the product label that the 100 percent Casein is 'Enhanced with Aminogen, an enzyme that helps your body breakdown and absorb protein." Plaintiff supported its allegation with two studies that set forth two possible measures of a "clinically effective dose" – either "2.5 grams of Aminogen per 50 grams of whey protein" or "1.2 grams of Aminogen per 40 grams of whey protein." Plaintiff alleged that defendant's product had only 25 milligrams or less of Aminogen – a "fraction of the clinical dosing needed to provide the efficacy claims made by

defendant." Nevertheless, the court granted in part Vitamin Shoppe's motion to dismiss after noting that the plaintiff had failed to allege that the studies established the *minimum* effective clinical dosage. Without that evidence, the court stated, the plaintiff had not alleged a false claim that the Whey Tech Pro 24 had provided an insufficient dosage. *See* Opinion and Order at 7, *Segovia v. Vitamin Shoppe, Inc.*, No. 14-CV-7061 (S.D.N.Y. Feb. 5, 2016). The parties engaged in discovery and Vitamin Shoppe is expected to submit a motion for summary judgment in September.

Second, defendants can be liable for health claims on product labels when the dietary supplementation is insufficient or unnecessary. For example, in *Gershman v. Bayer HealthCare LLC*, the plaintiffs alleged that Bayer misrepresented the brain benefits of Flintstones "Healthy Brain Support" gummies and alleged that the "daily dosage" of 50mg to 100mg of Omega-3DHA was "incapable of providing any brain function or brain support benefit." Plaintiffs noted in the complaint that the FDA does not consider DHA to be an "essential nutrient" and that the brain itself contains about 5,000 mg of DHA that children and adults can obtain from a variety of dietary sources, making supplementation unnecessary. (Am. Compl. at ¶ 5). The Court recently denied Bayer's motion to dismiss and found that statements regarding a supplement's benefits are false when the dosage for a given ingredient is unnecessary because consumers do not need supplementation at all. *See* Order Denying in Part and Granting in Part Motion to Dismiss First Amended Complaint at 7, *Gershman v. Bayer HealthCare LLC*, No. 14-CV-05332-HSG (N.D. Cal. May 8, 2015). The parties spent months in discovery before agreeing to a settlement earlier this month.

3. The Validity of DNA Barcode Testing for Confirming the Presence of Herbal Ingredients Remains an Active Area of Inquiry

For the past year and half, the viability of DNA barcode testing for determining the presence of botanical ingredients in dietary supplements has been at the center of governmental action, industry focus, and, now, private litigation. New York Attorney General Schneiderman used the technique to test common dietary supplements for the presence of herbal ingredients on the shelves of New York retailers and sent out warning letters to a number of retailers, including GNC. In March 2015, AG Schneiderman announced an agreement with GNC to implement reforms, under which GNC would institute DNA barcoding to authenticate plants used in supplements and adopt new testing standards to prevent contamination. AG Schneiderman then sent cease and desist letters to thirteen additional retailers in September 2015, after DNA barcode testing revealed that most supplements did not contain *any* of their purported main botanical ingredients. The AG's findings prompted an ongoing massive lawsuit against three of the nation's largest supplement retailers. The case, *In Re: Herbal Supplements Marketing and Sales Practices Litigation*, No. 15-CV-05070 (D. Ill. Nov. 5, 2015), is a class action against Walgreens, Target, and Walmart. Similar testing in Oregon led to a shareholder lawsuit against GNC, which was voluntarily dismissed shortly after its filing. *See Gorrie v. GNC Holdings, Inc. et al*, No. 15-2037 (D. Or. Oct. 29, 2015).

At the outset of AG Schneiderman's actions, the trade associations challenged the efficacy of DNA barcode testing for botanical product, and provided a number of resources to explain the test's shortcomings, particularly when applied to processed materials. A recent study provides even more information about the limitations of DNA bar code testing. In a recent article for *Planta Medica*, scientists note that DNA barcode testing has limited applicability to the processed herbal products that have been the focus of the investigations and lawsuits. The article suggests that common manufacturing processes destroy botanical DNA or degrade it into smaller fragments that cannot be detected with conventional DNA barcode testing.

As enforcement scrutiny increases and as the dietary supplement industry responds by increasing its focus on transparency and on centralizing information about label claims and ingredients, testing at multiple stages to confirm the presence of active ingredients and absence of contaminants can significantly reduce the risk of enforcement actions and private class actions.

Dietary supplement manufacturers and retailers should be familiar with commonly used tests with the risks and limitations of each and select the test(s) most appropriate for validating raw ingredients and finished products.

4. Federal Labeling Preemption, State Law, and POM Wonderful.

The federal Food, Drug, and Cosmetic Act (FDCA) contains a provision that expressly preempts state law variances from certain FDCA food labeling requirements. *See* 21 U.S.C. § 343-1. However, some FDCA labeling requirements, including the requirement that food and supplement labels not be "false or misleading," does not entirely preempt a plaintiff from raising state law claims. *See id.* at § 343(a). As a result, cases show defendants unsuccessfully arguing that the FDCA preempts state law actions for false or misleading label claims. In *Bruaner v. MusclePharm Corp.*, the plaintiff alleged that MusclePharm misled consumers by falsely representing that they did not spike their protein. The Court denied MusclePharm's motion to dismiss because the FDCA does not expressly preempt misleading label claims. *See* Order Re: Motion to Dismiss Plaintiff's Second Amended Complaint at 12, *Bruaner v. MusclePharm Corp.*, No. CV148869FMOAGRX (C.D. Cal. Aug. 11, 2015). The case settled shortly thereafter. Similarly, in *Eashoo v. Iovate Health Sciences U.S.A., Inc.*, the plaintiff alleged that Iovate misled consumers by double-counting amino acids in its MuscleTech protein powders. In response to Iovate's motion to dismiss, the plaintiff explained the FDCA does not preempt these claims. Last year, Iovate paid $2.5 million to settle the case and the court approved the class settlement this past April. *See Eashoo v. Iovate Health Sciences U.S.A., Inc.*, No. 2:15-cv-01726 (C.D. Cal. Mar. 10, 2015).

A related issue is the extent to which FDCA preempts Lanham Act claims. The Supreme Court in *Pom Wonderful* held that the FDCA does not preclude a Lanham Act claim. *See POM Wonderful LLC v. Coca-Cola Co*., 134 S. Ct. 2228, 2233 (2014). However, the Court significantly narrowed its holding by explicitly noting that the case was not about preemption, but about interpreting the Lanham Act. *See id.* at 2236. The only case that mentions *Pom Wonderful* and deals directly with the Lanham Act reflects that narrow holding. In *ThermoLife Int'l, LLC v. Gaspari Nutrition Inc.*, a case challenging the labeling of ThermoLife's testosterone boosters, the Ninth Circuit overturned the district court's ruling that the FDCA preempted a Lanham Act claim. *See ThermoLife Int'l LLC v. Gaspari Nutrition Inc.*, No. 14-15180, 2016 WL 1460171, at *1 (9th Cir. Apr. 14, 2016).

Until the federal law is revised, dietary supplement retailers and manufacturers must continue to consider the impact of state consumer protection law and the Lanham Act on labeling and ingredient claims. A risk management program that includes not only FDCA compliance review but also sound supply chain management, appropriate testing, and careful review of label and marketing claims against existing substantiation will significantly reduce the risks associated not only with federal enforcement actions, but also with proceedings by competitors and private litigants.

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