Dietary Supplement Advertising-July 13, 2016

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Please find below the latest edition of our monthly newsletter specifically for our clients marketing dietary supplements. We hope this helps you stay out in front of regulatory challenges.

FTC DEVELOPMENTS

Bayer-ing Down on the Question of Clinical Testing

BY JOHN VILLAFRANCO

At the recent ACI/CRN dietary supplements conference, a panel on claim substantiation sparked debate over whether dietary supplement claims require clinical studies. One of the main points of contention was exactly what *U.S. v. Bayer* held on that point.

Industry representatives contended that the case held that clinical testing is not required. A representative from the FTC countered that the case was not about the need for clinical testing and, in fact, held only that Bayer was not required to possess strain-specific testing. Let's take a look back at the case.

The FTC alleged that Bayer had violated a prior FTC order by disseminating unsubstantiated claims for its probiotic supplement, Phillips Colon Health. The prior order required Bayer to possess "competent and reliable scientific evidence" for dietary supplement claims. In promoting Phillips Colon Health, Bayer had used claims, such as, "Helps defend against occasional constipation, diarrhea, gas and bloating."

In support of its allegations that the Phillips Colon Health claims were unsubstantiated, the FTC offered "an expert in gastroenterology and clinical research." He opined that "competent and reliable scientific evidence," as specified in the prior order, required a "human clinical study" that is randomized, double-blind, and placebo-controlled; "done in the target population" for the product, using "the specific product at issue"; and "designed with the desired outcome as the primary endpoint" and with "appropriate statistical methods."

This expert was, self-admittedly, not expert in probiotics, was "not paying attention to the law or regulations about the difference between dietary supplements and drugs" in forming his opinion, and had not reviewed the FTC's guidance specifically on substantiation for dietary supplement claims.

In support of its claims, Bayer offered nearly 100 studies, including at least seven "strain-specific randomized controlled trials" showing the effects of the probiotics in Phillips Colon Health on GI symptoms in various populations. Because these studies did not meet his specific criteria – including not being on

the full product formulation – the FTC's expert opined that Bayer's claims lacked adequate support.

Two experts who testified for Bayer were both experienced physicians and researchers with expertise in probiotics and the conduct of clinical studies. Each expert had "understood and relied upon the FTC [dietary supplement] Guidance and the distinction it draws between supplements and drugs." The two experts concluded that Bayer's claims were properly supported.

The court sided with Bayer and found that by offering "one expert who seems to require a higher-level RCT," the FTC had not met its burden to prove an order violation. The court further observed that two prior dietary supplement cases, *FTC v. Garden of Life* and *Basic Res. v. FTC*, "held [that] competent and reliable scientific evidence does not require drug-level clinical trials." The court stated that the "Government cannot try to reinvent this standard through expert testimony." The court, likewise, noted that the FTC's dietary supplement guidance "specifically refutes the standard the Government seeks to impose." The court quoted the passage in the guidance stating that "[t]here is no fixed formula for the number or type of studies required."

Takeaway 1: There is no mistaking that the *Bayer* court rejected any categorical determination that dietary supplement claims require a fixed number or type of studies. Given the fact-driven nature of advertising cases, the *Bayer* decision could not – and has not – stopped the FTC from continuing to argue that particular supplements and claims require controlled trials. However, post-*Bayer*, the FTC carries a heavier burden in proving its position in each such case. That is especially so where basic structure/function claims, similar to Bayer's, are at issue.

Takeaway 2: *Bayer* did not turn on strain-specific support although there was a question as to whether, as the FTC expert posited, Bayer must have tested its entire product formulation (i.e., all three of its probiotic strains together). In accepting Bayer's evidence, the court rejected the proposition that full product testing was required. The FTC's guidance – and FTC orders on supplements – also allow testing on either the product or certain ingredients.

LEGISLATION

Senators Reach Compromise on GMO Labeling Bill

On June 23, U.S. Senate Agriculture Committee Chairman Pat Roberts, R-Kan., and Ranking Member Debbie Stabenow, D-Mich., announced a bipartisan compromise bill regarding labeling of bioengineered foods, sometimes referred to as "genetically modified organisms" or "GMOs." They stated, "This bipartisan agreement is an important path forward that represents a true compromise. Since time is of the essence, we urge our colleagues to move swiftly to support this bill."

The bill provides for a national uniform labeling standard for the disclosure of bioengineered foods. Recognizing that label

space is limited, in addition to allowing disclosure in text or a symbol on the label, the bill would alternatively allow disclosure through a digital link to a website (i.e., QR code or similar technology).

With regard to voluntary labeling, the agreement expressly allows products that do not contain bioengineered ingredients – such as organic foods – to be labeled "non-GMO."

The law, if passed, would prevent a patchwork of state standards by preempting inconsistent state laws such as Vermont's controversial labeling rule. Notably, while the Vermont law exempts dietary supplements, the proposed federal law does not appear to do so. It applies to foods "subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)."

Before being signed into law, the bill needs to be approved by the Agriculture Committee, the full Senate, and the House.

We have previously written about FDA's position on voluntary GMO-related claims here.

NAD CASES

A Case Study in Changes Needed to NAD Admissibility Rule

BY JOHN VILLAFRANCO

The Council for Responsible Nutrition filed an NAD challenge against the sellers of ionDEFENDER dietary supplement. *See Advanced Nutritional Innovations, Inc.*, NAD Case No. 5959 (May 25, 2015). The advertising at issue included claims that the supplement will boost superoxide dismutase (SOD) in the body, reduce oxidative stress, and provide protection against radiation. The NAD recommended discontinuation of almost all of the claims.

In support of claims to boost SOD levels, the advertiser had offered two studies testing the effects of the primary ingredient in its product on blood levels of SOD. The NAD, however, concluded that the studies were inadequate given that they were described only in short abstracts and appeared to have methodological flaws, such as a lack of between-group statistical analysis.

With these findings, the case highlights an ongoing issue with NAD rules in that in any compliance proceeding, the NAD prohibits new evidence related to the claims that were reviewed. That means that even if this advertiser takes into consideration the NAD's findings on its SOD studies and conducts a reanalysis of its data or creates more formal and complete study reports, those materials will not be admissible. With this admissibility rule, the NAD effectively bars future claims that may be entirely truthful and reflect a company's diligence in responding to NAD criticisms.

Over a year ago, an ABA working group reviewed the NAD's procedures and recommended changes to various rules, including the admissibility rule. Although other recommendations were implemented, no changes have been made to the admissibility rule. John, who led the ABA working group, discussed its efforts and findings in an interview with Metropolitan Corporate Counsel.

CLASS ACTIONS

Who's Still "Standing" Following *Spokeo, Inc. v. Robins*?

BY LAURI MAZZUCHETTI

From the first months of district court decisions issued since the United States Supreme Court decided *Spokeo, Inc. v. Robins*, No. 13-1339, 2016 WL 2842447, *3 (U.S. May 16, 2016), it appears the needle on Article III standing has moved slightly, but so far only slightly, in favor of the defense. *Spokeo* held that (i) in order to establish Article III standing, a plaintiff must allege an injury-in-fact that is both "concrete and particularized," and (ii) the plaintiff cannot "automatically satisf[y] the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right." Courts have begun to give that requirement teeth, dismissing claims where a defendant may have violated a statute's technical requirements, but where the plaintiff suffered no adverse consequence as a result. At the same time, however, courts have recognized *Spokeo*'s other holding that a "concrete" injury is not necessarily synonymous with a "tangible" injury, and that the "risk of real harm" counts as such an injury (even when such harm has not materialized). Dismissals on *Spokeo* grounds, therefore, have been sparse.

Just days after *Spokeo* was decided, U.S. District Judge Theodore Chuang cited the decision while remanding a data breach class action against the Children's National Health System to Maryland state court. *See Khan v. Children's Nat'l Health Sys.*, No. 8:15-cv-02125, 2016 WL 2946165, at *7 (D. Md. May 19, 2016). In that suit, plaintiff alleged that her sensitive personal information had been compromised, and that defendant did not take sufficient steps to protect it; however, despite plaintiff's "concern" that her personal information would be misused, she did not claim that she or anyone else had actually been affected by the data breach. Judge Chuang found that under these circumstances, plaintiff did not satisfy *Spokeo*'s newly articulated injury-in-fact standard, because there were no allegations indicating: "either actual misuse of the personal data or facts indicating a clear intent to engage in such misuse with plaintiffs' data…" *Id.* at 8. The court concluded that it lacked subject matter jurisdiction, and remanded the case to state court.

Most recently, in *Stoops v. Wells Fargo Bank, N.A.*, No. 3:15-cv-00083-KRG, 2016 U.S. Dist. LEXIS 82380 (W.D. Pa. June 24, 2016), a case involving the Telephone Consumer Protection

Act ("TCPA"), a district court granted the defendant summary judgment because the plaintiff lacked both constitutional and prudential standing. The plaintiff in *Stoops*, far from being "disturbed" by unwanted calls, actually purchased wireless phones with numbers from economically depressed areas out-of-state, hoping to receive misdirected debt collection calls, meant for the former owners of those numbers, so that she could bring TCPA claims regarding those calls. Her interests therefore fell outside the statute's protected zone of interests —"privacy, peace, and quiet"—and she lacked standing.

But, in two other TCPA cases involving more conventional plaintiffs, district courts have refused to dismiss and/or remand for lack of Article III standing. In *Booth v. Appstack, Inc.*, No. 13-1533, 2016 U.S. Dist. LEXIS 68886, * 16-17 (W.D.Wash. May 25, 2016), neither party had briefed *Spokeo*, but the Court nevertheless analyzed the opinion and considered whether Plaintiff's TCPA allegations of robocalling demonstrated a sufficiently "concrete injury," as described in *Spokeo*. The Court believed if the violations alleged were proven, plaintiffs suffered the injury of "wast[ing] time answering or otherwise addressing widespread robocalls." *Id.* Subsequently, in *Rogers v. Capital One Bank (USA), N.A.*, No. 1:15-cv-4016, 2016 U.S. LEXIS 735605, (N.D. Ga. June 3, 2016), another TCPA class action, the Court determined that plaintiffs had sufficiently alleged facts to support standing because the alleged calls were to plaintiffs' "personal cell phone numbers, [and] they have suffered particularized injuries because their call phone lines were unavailable for legitimate use during the unwanted calls."

We expect that many more cases will address standing, post-*Spokeo*, in the coming months, and will continue to report on these matters.