Dietary Supplement and Personal Care Products Regulatory and Litigation Highlights – April 2021

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Welcome to our monthly digest of litigation and regulatory highlights impacting the personal care product and dietary supplement industry. April saw a re-emphasis on restriction of COVID-related claims in advertisements for supplements and therapies, developments in various class action cases, including a win for consumers challenging hand sanitizer's claims of killing 99.99% of germs and a slew of new "natural" class actions, and finally a roller coaster ride for the FTC involving major blows and power moves.

Let's take a look….

NAD

NAD determined that certain advertising claims made by Zarbee's, Inc. for its cough products sufficiently identify that honey is the source of the cough soothing benefit and would not reasonably mislead consumers as to the reason for the product's cough soothing efficacy. However, NAD found that other claims, which could reasonably suggest that the cough soothing benefit was attributable to multiple ingredients, and recommended modification to clarify that the cough soothing benefit is attributable to the honey and not the combination of main ingredients. The efficacy of honey to soothe coughs was not at issue.

Supplement maker First Day Life, Inc., voluntarily discontinued a number of claims relating to its Daily Enrichment Vitamin, which were challenged by the Council for Responsible Nutrition. The challenged claims focused on nutritional deficiencies as the cause of a broad range of childhood behavior, including picky eating, distraction, tantrums, and hyperactivity. In addition to being a good reminder of the health claims substantiation requirements, i.e., competent and reliable scientific evidence, this case is notable because several of the claimed benefits were also tied to specific timeframes, e.g., improvement in 30 days or 45 days, which also requires substantiation.

Side-stepping from products used on the body to consumer health products used in the home, NAD examined claims made by NuWave, LLC, relative to its OxyPure Air Purifier product. Claims included:

- The claim on the advertiser's website, "Remove airborne coronavirus by 99.999%*" with a bottom-of-the page disclaimer stating "*The University of Minnesota tested the OxyPure's removal of the porcine respiratory coronavirus, a surrogate for SARS-CoV-2, the coronavirus that causes COVID-19"; and
- A YouTube video advertisement which touts the product as removing "virtually all indoor air pollutants" and notes, in relevant part, that "[a]sthma and allergies are at an all-time high. Sleeping problems are epidemic and carry their own health risks. Airborne pathogens, viruses, bacteria and mold are not far behind" (simultaneously showing a map of the world with the words "AIRBORNE VIRUSES" and lines originating from China to various cities around the world showing the spread of "airborne viruses").

NAD was "concerned that consumers who viewed the advertiser's website would reasonably take away the message that OxyPure Air Purifier is effective in killing 99.999% of COVID-19 without seeing the disclosure that testing of the product was on a coronavirus surrogate. NAD was similarly concerned that the challenged YouTube video communicates that the OxyPure Air Purifier is effective in removing airborne pathogens and viruses, and that the visual of the world map conveys the implied claim that the product is effective against COVID-19."

The advertiser agreed to modify its website advertising to state: "OxyPure is Calculated to Remove 99.999% of Coronavirus Surrogate from the Air in Areas up to 1,200 Square Feet in 6 Hours!* which is qualified by a clear and conspicuous disclosure directly underneath the claim, stating that "SARS-COV-2 was not used in the study conducted by the University of Minnesota for the efficacy of NuWave OxyPure." The advertiser also agreed to reach out to its affiliate to modify the YouTube video to remove the frame that features the aforementioned map and the onscreen and audio reference to "airborne viruses" to avoid conveying the unsupported message that OxyPure Air Purifier is effective in killing 99.999% of COVID-19.

Also of interest was NAD's challenge against New York Presbyterian Hospital relative to the Hospital's pre-COVID advertising campaign. NAD challenged claims such as "Best survival rates of any U.S. hospital" and the use of testimonials that NAD was concerned conveyed that patients facing a serious prognosis will achieve a better outcome at New York Presbyterian than at other hospitals. The Hospital modified the campaign in response to the challenge and NAD ultimately administratively closed the matter given the pandemic-related extenuating circumstances. The case serves as an important reminder about the unique relationship between healthcare providers and patients and the power that such claims may have in the market, particularly in the context of a pandemic.

FTC

April was a very busy and gut-wrenching month for the FTC.

In a stunning blow to the FTC's enforcement authority, the Supreme Court unanimously ruled in *AMG Capital Management v. FTC* that Section 13(b) of the FTC Act does not allow for the recovery of restitution, disgorgement, or any form of equitable monetary relief. Despite decades of final orders awarding, and settlements in which defendants agreed to pay, substantial monetary relief, Justice Breyer explained that the statute's emphasis on whether a defendant "is violating, or is about to violate, any provision of law enforced by the" FTC reflects a focus on "relief that is prospective, not

retrospective." Accordingly, the Court found that Section 13(b) was designed to "stop[] seemingly unfair practices from taking place while the Commission determines their lawfulness," not to compensate consumers for alleged economic harm. Courts and litigants across the country quickly reacted to the decision, with the Ninth Circuit vacating a preliminary injunction that had previously been entered to preserve the defendant's assets to satisfy a potential award of monetary relief and defendants filings motions for judgment on the pleadings to dismiss the FTC's claims for monetary relief. *AMG* is not the final word on the issue, though, and a number of legislative efforts are underway to restore the agency's enforcement authority. While there appears to be support for legislative action on both sides of the aisle, Republicans are advocating for a more measured statute that would restore the FTC's ability to obtain monetary relief while ensuring the due process rights of those affected, including the imposition of a statute of limitations and a specific direction that the statute only be applied to cases filed after its enactment instead of being applied retroactively to past and pending cases. We will continue to report on the judicial and legislative developments resulting from the *AMG* decision.

Despite all the turmoil, the FTC did take some action in other areas in April. As we reported earlier this month, the FTC filed its first case under the COVID-19 Consumer Protection Act, which gives the agency authority to seek civil penalties for deceptive COVID-related acts and practices. The new complaint alleges that, despite prior receipt of a letter warning of unsubstantiated COVID-19 efficacy claims, chiropractor Eric Anthony Nepute and his company Quickwork LLC deceptively marketed vitamin D and zinc products under the "Wellness Warrior" brand for the treatment, prevention, and cure of COVID-19.

The FTC also sent out 30 warning letters to companies regarding concerns about their COVID-related advertising claims. These letters were sent after the effective date of the COVID-19 Consumer Protection Act, and thus warn advertisers that anyone who makes deceptive claims about the treatment, cure, prevention or mitigation of COVID-19 is subject to civil penalties of up to $43,792 per violation. In response to these letters, it appears that all 30 companies have removed the claims that were identified as questionable. It is also important to note than in these letters a number of platforms including Facebook and Youtube were mentioned in the cc: field, indicating that some of the recipients' deceptive claims had run on these platforms at some point. Despite the fact that these letters were sent to 30 companies directly, all advertisers should take note of this loud and clear warning from the FTC.

Shifting gears from COVID-related matters, the FTC's settlement with BASF and DIEM Labs suggests that the FTC is holding firm to its position that post hoc analysis of clinical studies is not sufficient claim substantiation. The settlement concerns Hepaxa and Hepaxa PD, fish oil products marketed to treat Non-Alcoholic Fatty Liver Disease (NAFLD). The FTC alleged that BASF, the maker of the Hepaxa products; DIEM Labs, the exclusive US distributor of the products; and two DIEM Labs executives claimed without substantiation that Hepaxa reduces liver fat.

In general, advertisers must possess competent and reliable scientific evidence to substantiate health claims. With respect to Hepaxa, the FTC did not dispute that the defendants had conducted a "randomized, double-blind human clinical trial designed to evaluate whether Hepaxa . . . reduces liver fat in adults with NAFLD" or that they based their claims on results from the trial. The problem, according to the FTC, was that the clinical trial as constructed was unsuccessful. During the trial, 81 participants took Hepaxa and another 86 took an olive oil placebo. At the trial's end, MRI data did not show a statistically significant reduction in liver fat for Hepaxa patients as compared to placebo patients. The FTC alleged that the defendants then engaged in a post hoc analysis to salvage the trial by identifying a subset of participants with some type of positive result. Ultimately, the

defendants moved away from MRIs, grouped participants based on their Fatty Liver Index scores, and identified a statistically significant effect among participants with scores above 40—a subset containing five Hepaxa patients.

Because this case resulted in a settlement, it does not modify or create law. However, settlements are important markers of the FTC's thinking, and the FTC's four commissioners all voted to approve this settlement. It is notable, then, that the complaint contains the categorical assertion that results from post hoc analyses are "exploratory, at best" – an assertion that is notably absent from the FTC's own Advertising Guide for the Dietary Supplement Industry. As this statement shows, the FTC expects claims based on trial results to reflect the scope and design of the study as initially planned as opposed to statistically significant data identified after the trial has ended.

Finally, while the FTC's desire to hold individuals accountable for corporate violations of the FTC Act is no longer news, the allegations included in a complaint shed light on what conduct the FTC believes supports liability—and whom it is willing to hold liable. Here, the FTC sued DIEM Labs' co-owner/CEO, but it also sued DIEM Labs' Director of Sales, alleging that he was directly involved in identifying alternative analyses of the clinical trial, helped create advertising for Hepaxa, and claimed at conferences that Hepaxa successfully treats NAFLD. Individual liability can rest on control or authority to control corporate acts, as is commonly seen in allegations against owners or CEOs. But it can also rest on direct participation, and this settlement demonstrates the FTC's willingness to sue key actors—not just CEOs or owners—for corporate violations of the FTC Act.

Class Action Decisions and Settlements

A class of California consumers alleging that CVS brand hand sanitizer failed to live up to its promise of killing 99.99% of germs was certified by a judge in the Central District of California. The plaintiff's motion referenced the deposition of a purported microbial expert, who testified that the sanitizer does not kill 99.99% of the germs, and a purported marketing expert, who testified that consumer would find the claim material when deciding whether to purchase the product. The Court found that all of the requirements of Rule 23 had been met, and that the survey proposed by plaintiff's damages expert was adequate for purposes of class certification. *See Mier v. CVS Health*. Ironically, this decision came nearly two months after a judge in the Southern District of California dismissed a similar complaint in *Moreno v. Vi-Jon, Inc.*, which alleged that Vi-Jon's hand sanitizer products did not kill 99.99% of germs.

A proposed settlement we reported on last month involving Bayer Healthcare and Beiersdorf's Coppertone "mineral based" sunscreen products was denied preliminary approval by a judge in the Northern District of California. The Court found that the settlement, which provided for a $2.50 refund per unit purchased and injunctive relief, contained a number of flaws. First, the Court was concerned about the scope of the release provision. Contrary to Ninth Circuit precedent, which requires releases in a class action settlement to be limited to claims based on the identical factual predicate of the litigation, the proposed release extended to all claims that "were or could have been asserted in the Litigation." The Court also found that the settlement inappropriately released unnamed subsidiaries, successors, and other parties that class members would not be able to identify. Second, the Court wanted to know more about the parties' relationship with the *cy pres* beneficiary, Look Good Feel Better, and asked them to explain why there was no collusion or conflict of interest. Third, the Court questioned the parties' request for $530,000 in class administration expenses and the plaintiffs' request for attorneys' fees in an amount equaling one-third of the total settlement fund. The Court required that any subsequent motion for preliminary approval explain why the Court should depart from the Ninth's Circuit's 25% benchmark for attorneys' fees. Finally,

the Court found that the proposed class notice and claim form were insufficient insofar as they failed to comply with the Northern District's class action settlement guidelines. The Court denied the motion for preliminary approval without prejudice, and set a case management conference for the end of May.

New Class Action Filings/Trends

We saw a number of new "natural" filings in April. One such complaint was filed in the Western District of Pennsylvania alleging that JM Brands LLC's Purezero "natural" shampoo products contained a number of components derived from synthetic means (such as emulsifiers and fragrances). The other complaints were all filed in New York State Court and include allegations that: (1) Raw Elements USA's "natural" sunscreen and moisturizing products contain synthetic ingredients (including zinc oxide, tocopheryl acetate and sodium chloride); (2) Force Factor, LLC's Somnapure Natural Sleep Aid contains non-natural synthetic ingredients; (3) Plant Health Inc.'s Highland Farms "natural" or "all natural" CBD gummies, moringa capsules and bath bombs contain synthetic ingredients (including citric acid, sodium citrate, potassium citrate, and sodium bicarbonate); and (4) The Country Butcher and Jones Natural Chews (dog snacks and bones) contain synthetic ingredients.

Following up on last month's trends, there were two new cases filed against The Proctor and Gamble Company in April challenging "activated charcoal" and "gum repair" claims with respect to its toothpaste products, and seven new complaints involving Elanco Animal Health Inc.'s Seresto flea and tick products.

See you next month

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