Dietary Supplement and Personal Care Products Regulatory and Litigation Highlights – May and June 2021

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The dietary supplement and personal care product space continued to see enforcement on false CBD, COVID, and fertility claims as well as related litigation involving "germ-killing" claims on hand sanitizers and wipes. Messy stuff…Let's take a look…

LITIGATION

Personal Care Products

In a blow to the trending "pink tax" theory of liability in consumer class actions, in May, the Eighth Circuit ruled that various personal care product manufacturers and retailers did not violate Missouri's anti-discrimination laws by charging more for products marketed towards women as compared to allegedly identical products that were either marketed towards men or utilized gender-neutral marketing. The Court found that the plaintiff "mistakes gender-based marketing for gender discrimination" and, in the process, ignores numerous differences between the products that account for the higher price tag. There has been a handful of similar "pink tax" cases filed over the last year or two, but this is the first appellate court to rule on the issue.

In another victory for industry, the Southern District of California dismissed a putative class action complaint filed against Edgewell Personal Care Company alleging that its Wet Ones wipes don't kill 99.99% of germs as advertised. The complaint pointed to the products' active ingredient, benzalkonium chloride, and alleged that it was not able to destroy a number of disease-causing microbes, including bacteria spores and certain viruses, that make up far more than 0.01% of germs. The court ruled that many of the germs identified in the complaint are sexually transmitted, food-borne, or otherwise not expected to be found on people's hands and, therefore, reasonable consumers would not expect the wipes to be effective against those diseases. The court also

dismissed claims challenging the products' "hypoallergenic" and "gentle" marketing claims. While the plaintiff alleged that the product contained some ingredients that are "known allergens or skin irritants," the court ruled that a reasonable consumer would not interpret "hypoallergenic" and "gentle" to mean that the hand wipes were *entirely free* of allergens or skin irritants.

In terms of new class action filings, May and June saw a continuation of previously-reported trends:

- Gum Repair: One class action was filed against The Proctor & Gamble Co. challenging gum repair claims made in connection with certain toothpaste products.
- Sunscreen: Two class actions were filed challenging "mineral-based" sunscreen marketing claims on the grounds that the products (Blue Lizard and CVS brand) actually contain less desirable chemical ingredients that can cause skin irritation and allergic reactions. Two other class actions were filed alleging that Banana Boat and Neutrogena sunscreen products contain benzene, a human carcinogen, and therefore are unfit for their intended purpose.
- Oil Free: Two new class actions were filed challenging "oil free" representations relating to Sun Silk Crème and Clinique's skincare products.
- Natural: Six new class actions were filed challenging "natural" and "organic" marketing claims relating to various hair products, dietary supplements, pet shampoos, and reusable menstrual hygiene products.
- Lidocaine: One new class action was filed against Sanofi US Corp. alleging that its aspercreme patches are deceptively marketed as providing "fast acting" and "max strength" pain relief when other patch products deliver more lidocaine to the affected areas, are more effective, and are approved by FDA for more purposes.
- Hand Sanitizer: Two new actions were filed alleging that certain hand sanitizer products are falsely marketed as killing 99.99% of germs when, in fact, alcohol-based sanitizers do not kill many types of viruses (one against Goja Industries re Purell hand sanitizer products and one against Target Corporation regarding its "up&up" sanitizer products).

Links from Law360, subsc. req'd.

Dietary Supplements

We previously reported that a number of CBD class actions have been stayed over the past year under the primary jurisdiction doctrine while the FDA considered potential new CBD regulations. (See posts dated January 10, 2020, June 5, 2020, June 20, 2020 and March 2021.) Breaking from this trend in May, the Central District of California ruled that a proposed class action alleging that Just Brands USA Inc. and other companies overstated the amount of CBD contained in their products could proceed without waiting for the FDA to promulgate new regulations. The court ruled that the proposed regulations were likely to involve the legality and safety of CBD products sold as medicine or dietary supplements, and that it was unlikely that the guidelines were unlikely to address the labeling issues raised in this action. Accordingly, the court found that it was competent to resolve the matter without waiting for the FDA to weigh in.

June also saw a number of new putative class action complaints filed involving allegedly misbranded dietary supplement products. Two such actions were filed in California federal court alleging that St. John's Wort products could treat depression, anxiety and other issues without side effects. These filings occurred a few months after the FDA sent a warning letter that the products were making

unauthorized drug claims. Another putative class action was filed in the Eastern District of New York against Pure Nootropic LLC, alleging that its nootropics were advertised as boosting mental energy, but contained unapproved ingredients and did not deliver the promised benefits. A third action was filed in New Jersey state court against Trimark Holdings LLC, alleging that its Trizene product was falsely advertised as curing erectile dysfunction.

NAD

We highlight two recent cases in which NAD focused on details of claim substantiation.

NerveRenew

NAD recommended the discontinuation of three express claims made by Neuropathy Treatment Group (NTG) about its NerveRenew dietary supplement.

- “These special forms of vitamin B are effective, but 100% Stabilized R-Alpha Lipoic Acid (R-ALA) is our most important ingredient.”
- “It contains the most powerful and clinically studied forms of B vitamins, Stabilized R Alpha Lipoic Acid, anti-oxidants and herbal extracts. All the ingredients have been included in clinical studies and provide a synergistic effect when taken together.”
- “3X Greater Bioavailability.”

NAD recommended that NTG discontinue the first claim, because it reasonably conveys that R-ALA plays a critical role in improving nerve health, which was further conveyed by website FAQs, but which the advertiser did not substantiate.

Two clinical studies assessed ALA’s (not R-ALA’s impact) impact on diabetic neuropathy, but a study for ALA cannot be used to support a claim for a product containing R-ALA—there is no evidence in the record that ALA and RALA are interchangeable. And these studies tested ALA in amounts greater than the amount found in NerveRenew. Even if the ALA is interchangeable with R-ALA in the product, studies which assess an ingredient dose in excess of what is found in the product will not be sufficiently reliable to support an efficacy claim for that product.

NAD recommended that the claim “It contains the most powerful and clinically studied forms of B vitamins, Stabilized R Alpha Lipoic Acid, anti-oxidants and herbal extracts” be discontinued because the advertiser did not provide evidence demonstrating that any of the product’s ingredients are the most powerful or clinically studied of their ingredient forms. Moreover, NTG provided clinical studies of only some ingredients in the product. For studies on an ingredient to support qualified claims, the studies must test the ingredient in amounts that are contained in the product and the test must involve the correct study population. The study must also include relevant endpoints, and elicit statistically significant and clinically meaningful results. Therefore, even though it is true that the ingredients have been included in clinical studies, if the studies are flawed, the claim could be misleading. Here, none of studies submitted on individual ingredients or a combination of ingredients assessed non-diabetic neuropathy or other types of nerve pain. Therefore, the studies do not support the challenged claim.

NAD recommended that the claim “All the ingredients have been included in clinical studies and provide a synergistic effect when taken together” be discontinued because there is no evidence in the record properly assessing all of the ingredients to determine they all confer the claimed nerve health benefits. Two studies assessed more than one of the ingredients found in the product, but

neither was conducted with the appropriate population. They instead assessed individuals with diabetic neuropathy, and thus do not support claims directed to a different target audience.

Lastly, NAD also recommended that NTG discontinue the "3X Greater Bioavailability" claim. Bioavailability in dietary supplements concerns the proportion of the administered substance capable of being absorbed and available for cellular uptake, use, or storage. Superior absorption claims are health-related claims that must be supported by competent and reliable scientific evidence. NTG provided three clinical studies on the bioavailability of benfotiamine and other thiamin derivatives, but only one compared the bioavailability of benfotiamine and thiamin hydrochloride. That one study, however, only included Chinese male subjects—too narrow a population to relate to NerveRenew's broader target population.

Crest Whitening Emulsion

NAD assessed Smile Direct Club LLC's (SDC's) challenge to claims made by The Procter & Gamble Company (P&G) about its Crest Whitening Emulsions. NAD found the following claims to be substantiated: (1) Crest Whitening Emulsions provides "better" or "100% whiter" results and "whitens better" than the ARC Pen; and (2) Emulsions whitens with "virtually no sensitivity."

However, NAD cautioned P&G's use of or recommended P&G discontinue the following claims: (1) Whitens "Faster"; (2) "Best In Class Results"; (3) "Virtually No Sensitivity"; (4) Stays on teeth "10x longer"; (5) "Starts working instantly" and "whiter smile in seconds"; (6) "stop stains before they set in"; and (7) "Unlike toothpastes and paint-on gels which dilute and wash away quickly, Crest Whitening Emulsions includes 5X active peroxide droplets suspended in a hydrating base to whiten teeth."

In support of its "100% Whiter" and "Better" claims, P&G submitted an executive summary of a clinical trial that sought to assess tooth color changes with the use of Emulsions as compared to the ARC Pen. SDC argued that statistically significant changes in the study's technical measurements may not actually correlate to visible differences in tooth whitening. However, NAD concluded P&G provided statistically significant evidence that evaluated the whitening benefits over the ARC Pen, and further demonstrated that the Emulsions' whitening measurement translated to "noticeability." Conversely, SDC failed to demonstrate that P&G's measurements were flawed or that other bleaching shade guides were superior for measuring whitening. Thus P&G provided a reasonable basis for claims that Crest Whitening Emulsions provides "better" or "100% whiter" results and "whitens better," than the ARC Pen.

NAD analyzed the "Faster" claim, determining that Emulsions achieves a whitening benefit at 15 days, while the ARC pen does not. Therefore Emulsions necessarily achieves "Faster" whitening. NAD also found that in context ("Better…Faster…100% Whiter"), consumers would not reasonably understand it as a message about the application and wear time of the product. However, it might convey such a message in other contexts. Because that message is not supported by evidence in the record, P&G should avoid conveying it to consumers. P&G's "virtually no sensitivity" claim was sufficiently reliable because, through some subjects using Emulsions reported "oral irritation" or "treatment related tooth sensitivity," P&G makes no claims regarding "oral irritation"—only tooth "sensitivity." In so finding, NAD was mindful that P&G's claim regarding tooth sensitivity is not absolute but, rather, qualified by the word, "virtually."

NAD concluded that P&G should discontinue or modify its other claims for insufficient evidence. NAD recommended P&G discontinue its "Best in Class Results" claim because it found no evidence of a comparative measured "win" over P&G's competitors with respect to a particular attribute. P&G

provided no testing against any whitening products other than the ARC Whitening pen, and there is no evidence that the Emulsions are a “class unto themselves” consistent with consumers understanding of the “class” of tooth whitening applications. Neither the underlying clinical study results nor the fact that the product employs a new patented technology provides a reasonable basis for the superior whitening results message reasonably conveyed by a “Best in Class Results” claim. NAD deemed P&G’s basic, undated summary of a “substantivity” study to be insufficiently reliable to provide a reasonable basis for P&G’s “stays on 10x longer,” claim and recommended that this claim be discontinued. P&G summarized a study conducted on a hydrogen peroxide test strip to show its Emulsions’ instant impact to support its claims that Emulsions “starts working instantly,” and that consumers can achieve a noticeably “whiter smile in seconds.” But because there is no evidence that P&G’s demonstration replicates conditions in the human mouth or that the strip replicates tooth enamel surface, it does not establish that Emulsions “starts working instantly” or achieves “white smile[s] in seconds.”

NAD determined that consumers will reasonably interpret the “stops stains before they set in” claim not as a statement about Emulsions ability to remove existing staining, but as a claim that it can prevent future stains. P&G did not demonstrate that Emulsions acts as a barrier to stop or prevent new “stains” from setting in, as will be reasonably understood by consumers. Therefore, NAD recommended that P&G discontinue or modify its “stops stains before they set in” claim to more accurately reflect that Emulsions reverses existing staining and avoid any implication that Emulsions prevents “stains” from common teeth staining compounds from “setting in.”

Despite P&G’s claims that Emulsions “delivers 5x more active hydrogen peroxide compared to other whitening gels and pens,” both Emulsions and the ARC Pen appear to contain the same 3% hydrogen peroxide, with the hydrogen peroxide in Emulsions redistributed into “droplets” of higher concentration compared to the ARC Pen gel. Even if it is technically true that Emulsions contains five times more “active hydrogen peroxide,” NAD determined that consumers are likely to understand P&G’s claims to mean that Emulsions contains five times more overall hydrogen peroxide than competing products. Therefore, NAD recommended that P&G discontinue those claims. If the above claim is modified to make clear that this comparison is to the ARC Pen, then the “5x active peroxide droplets suspended in a hydrating base to whiten teeth,” claim would be supported.

FTC

Federal Trade Commission

The FTC announced a law enforcement action to halt deceptive health and efficacy claims in the growing market for cannabidiol (CBD) products. In the action, Arizona-based Kushly Industries LLC (Kushly) and the company’s sole officer, Cody Alt, agreed not to make false or unsupported claims or falsely claim that scientific evidence exists to back them up. The FTC alleges Kushly and Alt made false or unsubstantiated claims that their CBD products could effectively treat or cure conditions ranging from acne and psoriasis to more serious diseases, like cancer and multiple sclerosis. Respondents will pay the FTC more than $30,000 in consumer redress.

This is the seventh case the FTC has brought against CBD sellers for making unsupported health claims. According to the FTC’s complaint, the respondents have used these false or unsubstantiated claims to market or sell a range of products containing CBD, including gummies, softgel capsules, and topical ointments. They promoted their products on their website, kushly.com, and social media. The complaint alleges that Alt participated directly in promoting and advertising Kushly’s CBD products and has been featured in articles about the company and its CBD products.

The proposed administrative order covers any dietary supplement, drug, or food product that the respondents sell, including CBD products. It prohibits Kushly and Alt from making any representations about the health benefits, efficacy, safety or side effect of such products, unless the representations are true when they are made, are not misleading, and rely on competent scientific evidence. The order requires respondents to secure and keep any human clinical tests or studies used to substantiate their claims. The order also prohibits Kushly and Alt from misrepresenting that a covered product is clinically proven to treat, alleviate, or cure: chronic pain, multiple sclerosis, anxiety, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema. Respondents may not misrepresent that scientific evidence exists to back up these claims. Finally, the order requires the respondents to pay the FTC $30,583.14—the amount consumers paid Kushly for products sold using deceptive marketing. The FTC finalized the settlement earlier this month.

Fertile Ground

The FTC joined the U.S. Food and Drug Administration (FDA) in sending warning letters to five companies that may be making false or unsubstantiated claims that their products can cure, treat, mitigate, or prevent infertility and other reproductive disorders in violation of the FTC Act, and that are unapproved and misbranded.

Continuing with the enforcement on allegedly fraudulent products, the FTC also announced a settlement with Dr. Steven Meis, the medical director of Golden Sunrise Nutraceutical involving allegations that he took part in deceptively advertising a $23,000 treatment plan as a scientifically proven way to treat COVID-19. Dr. Stephen Meis will be barred from making similar unsupported health claims in the future and will pay $103,420 to provide refunds to defrauded consumers.

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Thanks for reading. See you in August!

Summer Associate Elizabeth Hamner contributed to this update.