UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION
Case No. 20-cv-23564-MGC

DAVID WILLIAMS, et al.,

Plaintiffs,

vs.

RECKITT BENCKISER LLC, et al.,

Defendants.

TRUTH IN ADVERTISING, INC.'S SUPPLEMENTAL BRIEF
IN RESPONSE TO COURT'S AUGUST 18, 2021 ORDER

Truth in Advertising, Inc. ("TINA.org") submits this supplemental brief pursuant to the Court's August 18, 2021 Order (D.E. 105) directing the parties, objector, and TINA.org to submit additional information on the distinctions, if any, between how a reasonable consumer would understand a label or marketing reference for a Neuriva product described as "clinically proven" and how she would understand a label or marketing reference for the same Neuriva product described as "clinical studies have shown [some benefit to brain performance and/or brain health, including learning, memory, focus, reasoning, accuracy or concentration]." The following information is provided in addition to that provided in TINA.org's July 26, 2021 Brief of Amicus Curiae (D.E. 74) and its August 13, 2021 Supplemental Brief (D.E. 92).

Introduction

The key overarching issue vis-à-vis the proposed injunctive relief is whether the elimination of a single word ("proven") from Neuriva's marketing materials has any material impact on the deceptive message communicated to consumers. That is because, if the proposed settlement is approved, defendants will be permitted to use any other synonymous terms in their marketing of the supplement they choose, not just "clinically tested" or "clinically tested….and shown," but also, for example, "backed by science," as defendants currently do, or even "confirmed by science," "demonstrated," "validated," "verified," and any other equivalent terminology.

And on this question – i.e., whether such cosmetic changes in wording are sufficient to eliminate deception from defendants' marketing – the clear answer is no. *See Pearson v. NBTY, Inc.,* 772 F.3d 778 (7th Cir. 2014) (finding that replacing "support[s] renewal of cartilage" with "contains a key building block of cartilage" results in no substantive change, and reversing a lower court decision to approve a settlement agreement containing such terms, among others). As explained below, and in TINA.org's prior submissions, the term "clinically tested" is no different than "clinically proven."

U.S. Department of Health and Human Services: Office of Inspector General

According to the U.S. Department of Health and Human Services, Office of Inspector General, the term "clinically tested" is synonymous with "scientifically proven" in that consumers may perceive both terms to mean that a product bearing a label with that language has been proven safe and effective. *See* Janet Rehnquist, Dep't of Health and Human Servs. Office of Inspector Gen., OEI-01-01-00121 *Dietary Supplement Labels: An Assessment* 11 (2003), https://oig.hhs.gov/oei/reports/oei-01-01-00121.pdf.

> Auxiliary statements on labels may lead to false expectations about the purposes or efficacy of supplements. In our review of 100 supplement labels, we found 12 that claimed to be scientifically tested. While "clinically tested" or "scientifically proven" may be a valid claim, it also has the potential to mislead consumers into thinking that a supplement has been tested in a pre-market fashion akin to prescription drugs, and thus may create a false perception of proven safety and efficacy.

Id.

Additional Academic Studies

The Department of Health and Human Services' findings are echoed in the American Journal of Public Health, which found that the term "clinically tested" is a form of smoke and mirrors that has the capacity to mislead consumers and create a false sense of security.

> Consumers are drawn to dietary supplements as a result of their easy accessibility, cultural and historical uses, low cost, appeal as natural cures, and presumption of safety and efficacy; a desire for self-reliance in matters concerning their own health; or because they feel disenfranchised by traditional medicine. Consumers may be misled by words such as "natural" or "clinically tested" and be less likely to recognize dangers associated with products containing these on their labels.

Ranjani Starr et al, *Too Little, Too Late: Ineffective Regulation of Dietary Supplements in the United States*, 105 Am. J. Pub. Health 478, 481-82 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4330859/pdf/AJPH.2014.302348.pdf.

Global Council on Brain Health

This false sense of security is also a concern for the Global Council on Brain Health (GCBH). In 2019, the GCBH, an independent collaborative of scientists, health professionals, scholars, and policy experts from around the world working in areas of

brain health related to human cognition, issued a report on brain health supplements.[1] Global Council on Brain Health, *The Real Deal on Brain Health Supplements: GCBH Recommendations on Vitamins, Minerals, and Other Dietary Supplements*, (2019), https://www.aarp.org/content/dam/aarp/health/brain_health/2019/06/gcbh-supplements-report-english.doi.10.26419-2Fpia.00094.001.pdf. In the report, the GCBH stated that nearly half of older Americans mistakenly believe that the U.S. Food and Drug Administration (FDA) determines that dietary supplements are safe and effective before they are sold when that is not the case (the FDA's mandatory premarket evaluation does not apply to dietary supplements). *Id* at 3. This results in consumers having a "false sense of security when it comes to taking dietary supplements they find on store shelves or online." *Id.* This consumer perception problem is exacerbated by the fact that, according to the GCBH,

> There is no convincing evidence to recommend dietary supplements for brain health in healthy older adults. … Despite claims to the contrary, brain health supplements have not been established to maintain thinking skills or improve brain function.

Id at 20.

Health Canada

While not in the United States, Health Canada has published guidance that is relevant and instructive. According to Canada's Guidance on Labelling of Pharmaceutical Drugs for Human Use, the term "clinically tested" is synonymous with a "clinically proven" claim and the same standard of proof is required for either phrase. That is:

[1] GCBH is funded by the American Association of Retired Persons (AARP).

> (1) on drug product labeling when statistically significant efficacy data (obtained from a minimum of two separate, well controlled studies that reflect a representative population and are of sufficient duration) pertaining to the drug product has been reviewed and found acceptable by Canada's regulator of prescription drugs for human use (i.e., the Therapeutic Products Directorate); or
>
> (2) the product contains only one medicinal ingredient whose efficacy in a given dosage form and indication is well recognized and documented in authoritative literature.

Health Canada, Guidance Document: Labelling of Pharmaceutical Drugs for Human Use, Section 4.9.2 (2015), https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.pdf.

CONCLUSION

In its three separate briefs that address the injunctive relief in the proposed settlement agreement, TINA.org has provided authority from the Federal Trade Commission, the U.S. Department of Health and Human Services, the Global Council on Brain Health, the National Advertising Division, the American Bar Association, and Health Canada, as well as federal case law and several academic studies, all of which overwhelmingly support the conclusion that the elimination of a single word ("proven") from Neuriva's marketing materials is merely cosmetic and will have absolutely no impact on the deceptive message communicated to consumers.

Thus, for the reasons stated herein, as well as those stated in TINA.org's July 26, 2021 amicus curiae brief and August 13, 2021 supplemental brief, the proposed settlement should be rejected because, among other things, it would provide defendants with court-sanctioned approval for their continuing use of deceptive marketing claims.

Dated: September 9, 2021

Respectfully,

BY:_____

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CERTIFICATE OF SERVICE

I hereby certify that on September 9, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which sent notification to all parties registered to receive electronic notices via the Court's CM/ECF System.

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By: Jon Polenberg, Esq.