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December 21, 2021

Via ECF
Hon. Louis L. Stanton, U.S.D.J.
United States District Court, Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *FTC, et al. v. Quincy Bioscience Holding Co., Inc., et al.*
Case No. 1:17-cv-00124-LLS

Your Honor:

We represent defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy") and respectfully request a pre-motion conference with respect to a motion for summary judgment pursuant to Federal Rule of Civil Procedure 56. The anticipated bases for Quincy's motion are set forth below.

I. The Challenged Claims are Clearly Substantiated Structure/Function Claims

After over six years of investigation and litigation, the record shows that there is no material disputed fact that Quincy has met the legal standard required to substantiate its claims. Summary judgment is therefore appropriate.

There is no dispute that Prevagen is a dietary supplement pursuant to the Dietary Supplement Health & Education Act of 1994 ("DSHEA") (Complaint ¶ 19), which permits "structure/function" claims without prior approval from the FDA. *See* 21 U.S.C. § 321(g)(1); 21 U.S.C. § 343(r)(6). Structure/function claims "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," 21 U.S.C. § 343(r)(6), and include claims relating to "mild memory problems associated with aging." 65 Fed. Reg. 1000, 1000-01 (Jan. 6, 2000). As long as a dietary supplement is not marketed as a drug—i.e., does "not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of disease[,]" it is not regulated like a drug. 21 U.S.C. § 343(r)(6). Prevagen is not marketed as a drug.

In response to DSHEA, the FTC released guidance for supplement manufacturers: "Dietary Supplements: An Advertising Guide For Industry" ("Guidance"), Exhibit A. The Guidance was designed to advise industry that the substantiation standard for marketing claims for dietary supplements is "competent and reliable scientific evidence," defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area." Guidance at 3, 9. The Guidance makes clear that the FTC's standard is "flexible" with "no fixed formula for the number or type of studies required." *Id.* at 8-9. Randomized, controlled trials are *not* required. Indeed, other types of scientific evidence can substantiate dietary supplement marketing claims, including (among others): animal studies, *in vitro* studies, epidemiological evidence, and other human studies. *Id.* at 10. In contrast, the FDA *does* require randomized clinical trials for new *drug* applications. 21 C.F.R. § 314.126 (2002).

Plaintiffs do not claim that Prevagen was marketed as a drug, but nevertheless attempt to hold Quincy to that higher drug substantiation standard—a standard that the Guidance makes clear is *not required* for dietary supplements. This novel approach would turn the dietary supplement industry on its head and should be rejected. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference.").

Plaintiffs allege that that following claims for Prevagen are false and misleading: (1) improves memory; (2) improves memory within 90 days; (3) reduces memory problems associated with aging; (4) provides other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking; and (5) is clinically shown to have such effects (the "Challenged Claims"). (Complaint ¶¶ 36-45.) These claims, which have been discontinued or substantially qualified as of the summer of 2020, are textbook structure/function claims, and are substantiated in accordance with the FTC's own standard.

The undisputed record shows that Quincy engaged a university research laboratory to conduct animal and *in vitro* studies, which showed the beneficial efficacy and safety of apoaequorin (the active ingredient in Prevagen). Quincy then moved to open label human studies that further substantiated the Challenged Claims. Following this positive evidence, Quincy conducted the Madison Memory Study—a double-blind, placebo controlled human clinical trial—that demonstrated that Prevagen improved memory and other cognitive function in its intended audience, namely healthy, older adults. In other words, even though a randomized clinical trial is not required, Quincy conducted one and its results substantiate the Challenged Claims. This Court has already determined based on Plaintiffs' admissions in the Complaint that "the complaint fails to show that reliance upon the subgroup data 'is likely to mislead consumers acting reasonably under the circumstances.'" ECF No. 45 at 11-12. Despite extensive discovery, nothing has changed since the Court arrived at that determination.

Five of Defendants' expert witnesses (in the relevant fields of internal medicine, nutrition, dietary supplement substantiation, epidemiology, and biostatistics) all confirm that the Madison Memory Study, and the earlier *in vitro* and animal studies, substantiate Prevagen's marketing claims in accordance with the Guidance. On the other hand, two of Plaintiffs' purported experts (in biostatistics and cognitive function) failed to even *consider* the standard as set forth in the Guidance, and ignored Quincy's animal and *in vitro* studies altogether. Instead, they nitpick aspects of the design and execution of the Madison Memory Study as if it were a clinical drug trial. None of Plaintiffs' experts even tested Prevagen, nor are they treating physicians, and Plaintiffs have proffered no extrinsic evidence about how consumers perceived the challenged marketing claims. In short, Plaintiffs merely urge their own judgment, having failed to adduce *any* evidence that the Madison Memory Study could *possibly* mislead consumers.

At most, Plaintiffs' third expert (a chemist)[1] disputes one *potential* "mechanism of action" for Prevagen but has not substantively opined on *several other* plausible "mechanisms of action" described by Quincy's experts. In any event, the law does not require a known "mechanism of action" for dietary supplement products (indeed, the FDA does not even require known "mechanisms of action" for *drug* approvals). The fact that Quincy has *several* plausible mechanisms only bolsters the extensive behavioral, clinical, and other substantiation showing Prevagen's beneficial effects.

There is also a vast body of scientific, epidemiologic and mechanistic evidence that Vitamin D, which has been an ingredient in Prevagen since 2016, can improve memory and/or cognitive function.

[1] Quincy's papers will make clear that Plaintiffs failed to proffer evidence from the relevant experts in this matter.

Plaintiffs' experts discount this evidence because they do not believe it satisfies the FDA's heightened substantiation standard for drugs. But again, these criticisms are misplaced and ignore the FTC's own standard as well as the regulatory regime under DSHEA.

Put simply, there can be no dispute that the Challenged Claims are supported by "competent and reliable scientific evidence" as defined in the Guidance. Other courts have rejected similar attempts by the FTC to require more substantiation than is required. *See*, *e.g.*, *U.S. v. Bayer Corp.*, 2015 WL 5822595, at *3-4 (D.N.J. Sept. 24, 2015); *Basic Rsch., LLC v. FTC*, 2014 WL 12596497, at *10 (D. Utah Nov. 25, 2014) ("the FTC must do more than present an expert who simply disagrees with the scientific literature upon which [the defendant] relied. The FTC must present evidence that shows how [defendant's] evidence fails to meet" the definition of competent and reliable scientific evidence); *FTC v. Garden of Life, Inc.*, 516 F. App'x 852, 856 (11th Cir. 2013) (rejecting FTC's argument that defendant could be liable because the FTC's expert "disagrees with certain aspects of a study's 'trial design'" because doing so "would require this Court to read additional requirements" into the competent and reliable scientific evidence standard). The same result is warranted here.

II. Plaintiffs Lack the Ability to Pursue Injunctive Relief

The text of Section 13(b) of the FTC Act only contemplates prospective relief. *See* 15 U.S.C. § 53(b)(1) ("Whenever the Commission has reason to believe that any person, partnership, or corporation *is violating, or is about to violate*, any provision of law . . . .") (emphasis added). Courts have understood that language pursuant to its plain terms, holding that the FTC may not obtain injunctive relief where alleged violations are not ongoing or imminent. *FTC v. Qualcomm Inc.*, 969 F.3d 974, 1005 (9th Cir. 2020); *FTC v. Shire ViroPharma, Inc.*, 917 F.3d 147, 160 (3d Cir. 2019); *FTC v. Facebook, Inc.*, 2021 WL 2643627, at *19 (D.D.C. June 28, 2021). This past term, the Supreme Court interpreted the language the same way, noting that the statutory "provision focuses upon relief that is prospective, not retrospective." *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1348 (2021).

It is undisputed that the Challenged Claims are no longer being disseminated in the form challenged in the Complaint. In 2020, Defendants entered into a nationwide class action settlement in *Collins v. Quincy Bioscience, LLC*, No. 1:19-cv-22864 (S.D. Fla.), in which they agreed to add language that Prevagen's marketing claims are "based on a clinical study of subgroups of cognitively normal or mildly impaired individuals" i.e., healthy, older adults. All of Quincy's advertisements now contain this or a similar language, and therefore, even accepting Plaintiffs' allegations as true, there can be no dispute that Quincy is no longer "violating" or "about to violate" the FTC Act.

III. The NYAG's State Law Claims Fail for Additional Reasons

Because the Challenged Claims comply with DSHEA and the Guidance, the NYAG's GBL claims fail under the statute's safe harbor provisions (*see* N.Y. Gen. Bus. Law §§ 349(d), 350-d) and because they are preempted by DSHEA and the Food, Drug, and Cosmetic Act ("FDCA"). *See*, *e.g. In re PepsiCo, Inc. Bottled Water Mktg. and Sales Pracs. Litig.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008). In addition, in light of the *Collins* class action settlement, the NYAG's claims for restitution must be enjoined or dismissed. *See In re Baldwin-United Corp.*, 770 F.2d 328, 337 (2d Cir. 1985); *California v. IntelliGender, LLC*, 771 F.3d 1169, 1172 (9th Cir. 2014) ("the appropriate State officials were notified, but they chose not to participate in the settlement approval process. The State cannot now obtain a duplicate recovery in the form of restitution on behalf of those individuals who are bound by the bargained for restitution in the CAFA class settlement."); *FTC v. AMREP Corp.*, 705 F. Supp. 119, 123 (S.D.N.Y. 1988).

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Respectfully submitted,

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