17-3745-cv(L), 17-3791-cv(CON)

United States Court of Appeals

for the

Second Circuit

FEDERAL TRADE COMMISSION, PEOPLE OF THE STATE OF NEW YORK, by Barbara D. Underwood, Attorney General of the State of New York,

Plaintiffs-Appellants,

– v. –

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation, QUINCY BIOSCIENCE, LLC, a limited liability company, PREVAGEN, INC., a corporation, DBA Sugar River Supplements, QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company, MARK UNDERWOOD, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC and Prevagen, Inc., MICHAEL BEAMAN, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CORRECTED BRIEF FOR DEFENDANTS-APPELLEES QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, PREVAGEN, INC. AND QUINCY BIOSCIENCE MANUFACTURING, LLC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Appellees Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC certify that there are no parent corporations or publicly held corporations owning 10% or more of their stock.

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PRELIMINARY STATEMENT

When Appellee Quincy Bioscience Holding Company, Inc. ("Quincy") and its affiliates marketed their "Prevagen" dietary supplement as improving memory, they did so based on what Appellant the Federal Trade Commission ("FTC") long has referred to as "gold standard" substantiation: The results of a randomized, double-blinded, and placebo-controlled human study.

Of the 218 older adults included in this "Madison Memory Study," two large and distinct subgroups had normal cognitive functions or mild-to-moderate cognitive impairment. Those two large subgroups undisputedly saw statistically significant and clinically meaningful cognitive improvements after taking Prevagen.

Neither the FTC nor its co-appellant the New York State Attorney General ("NYAG") contest the Madison Memory Study's methodology or outcomes. Instead, ignoring the FTC's binding guidance to advertisers and years of precedent, Appellants used this lawsuit to attack the common practice of subgroup analysis in dietary supplement studies and, on that unprecedented basis, to challenge Appellees' marketing based upon the study's favorable findings. Their attempt rightly failed.

When the government files a complaint in federal court, it must meet the same pleading standards as any other litigant. Here, just days before the Presidential transition, the FTC rushed to court with a complaint featuring only a handful of operative paragraphs. Those few paragraphs contained speculation, not facts. Appellants underestimated their pleading burden, but the District Court (Stanton, J.)

held them to the proper *Twombly/Iqbal* standard, finding that their Complaint had nothing but the type of "naked assertions devoid of further factual enhancement" that would doom any litigant's claim as insufficiently pleaded. SA-9.

As the District Court correctly found, Appellants' "challenge never proceeds beyond the theoretical." SA-11. Appellants attack Appellees' reliance on subgroup analysis, but they "neither explain the nature" of the purported risks associated with such analysis nor "show that [such risks] affected the subgroups' performance [in the Madison Memory Study] in any way or registered any false positives." *Id.* Appellants pointed to no precedent in support of their arguments because none exists: Never before has the FTC suggested that advertisers cannot advertise in reliance on positive results from subgroup analysis.

Presented fairly, the District Court's decision is unassailable. Appellants' brief therefore had to distort the District Court's decision. They contend that a highly experienced district judge "engaged in factfinding on scientific questions at the motion to dismiss stage." In fact, the District Court did no such thing. It applied the *Twombly/Iqbal* standard and determined that the Complaint failed to offer "more than a sheer possibility that a defendant has acted unlawfully." SA-9.

Unable to premise their appeal on arguments actually raised below, Appellants instead present a series of new arguments *they did not make to the District Court.* They now contend, for example, that the District Court should not have considered the Madison Memory Study in ruling on whether Appellees

appropriately advertised about it. Appellants, however, explicitly referenced the Madison Memory Study in their Complaint and premised their claims on the study's use of subgroup analysis. Appellants discussed the study extensively in their briefing below and never argued against the District Court's considering it. They cannot make that argument for the first time now, and it is meritless in any event.

Appellants' brief also references purported "facts" they never pleaded. They contend that unspecified "scientific literature" supports their position. They cite no such "literature" in their Complaint, however, and did not present any to the District Court. Appellants also pepper their briefs to this Court with the word "manipulation," appearing to cast doubt for the first time on the Madison Memory Study's methodology or results. They did not contest either below and they do not and cannot explain what they mean by claiming "manipulation" now.

If Appellants believe they have more to allege, they could have sought to amend their Complaint. The FTC did not vote to do so. In fact, the FTC did not properly authorize the filing of even the *initial* Complaint that the District Court dismissed. Instead, just 11 days before the Presidential transition, two Democratic Commissioners improperly declared themselves a quorum of the five-member FTC and purported to authorize the rushed filing of a bare-bones Complaint before a newly-constituted FTC could rethink the wisdom of bringing this lawsuit. One of those two voting Commissioners then almost immediately resigned.

The District Court did not have to reach whether only two members of the FTC can validly authorize a lawsuit because it found the Complaint deficient for other reasons. The District Court also did not reach two other issues that independently would have sufficed to warrant dismissal: Appellees' satisfaction of the FTC's existing guidance on the proper manner for substantiating dietary supplement claims and the First Amendment's prohibition on squelching *truthful* commercial speech. If this Court disagrees with the District Court's *Twombly/Iqbal* analysis—as it should not—the Court still should affirm the District Court's dismissal of Appellants' Complaint for one or more of these other reasons.

COUNTER-STATEMENT OF THE ISSUES PRESENTED

1. Did the District Court properly dismiss Plaintiffs-Appellants' Complaint because the Complaint failed to plausibly state a claim upon which relief could be granted pursuant to Fed. R. Civ. P. 12(b)(6)?

2. Did the Court properly decline to exercise supplemental jurisdiction over the NYAG's state law claims after dismissing the FTC's claims?

3. Should the dismissal of Appellants' Complaint be affirmed on alternative grounds because the FTC lacked a valid quorum to authorize the filing of the Complaint, thereby making it an *ultra vires* action?

4. Should the dismissal of Appellants' Complaint be affirmed on alternative grounds because Defendants' marketing statements complied with the

applicable FTC guidance provided to dietary supplement manufacturers concerning the requisite substantiation needed for such claims?

5. Should the dismissal of Plaintiffs-Appellants' Complaint be affirmed on alternative grounds because this action amounts to an impermissible restraint on truthful commercial speech in violation of the United States Constitution?

COUNTER-STATEMENT OF THE CASE

A. Prevagen and the Madison Memory Study

The corporate Appellees in this matter manufacture and market Prevagen, a dietary supplement. JA-20 ¶ 19. Prevagen's active ingredient is apoaequorin, a protein originally found in the *Aequorea Victoria* species of jellyfish. *Id.* Prevagen is available in various forms, including Prevagen Regular Strength, Prevagen Extra Strength, Prevagen Chewables, and Prevagen Professional. *Id.*

Appellants' advertising and marketing materials for Prevagen have stated, among other things, that Prevagen "is clinically shown to help with mild memory problems associated with aging," that Prevagen supports "Healthy Brain Function," including a "Sharper Mind" and "Clearer Thinking," and that "[i]n clinical studies Prevagen improved memory within 90 days." *See, e.g.*, JA-22 to JA-23 ¶ 27(A). In accordance with Food and Drug Administration ("FDA") requirements, Appellees accompanied each of those statements with the following disclaimer: "These statements have not been evaluated by the [FDA]. This product is not intended to diagnose, treat, cure or prevent any disease." *See id.*; *see also* 21 C.F.R. § 101.93.

Appellants acknowledge that Appellees based their marketing representations about Prevagen's efficacy "primarily" on the results of the Madison Memory Study. JA-37 ¶ 28. Appellants further acknowledge that the Madison Memory Study was a 90 day "double-blind, placebo-controlled human clinical study using objective measures of cognitive function," *id.*, designed "to determine whether Prevagen with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." JA-235 (Kenneth C. Lerner, *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults* (Aug. 1, 2016)).[1]

The Madison Memory Study included 218 participants, aged 40 to 91, who had self-reported memory concerns. JA-238. The study randomly assigned participants to the experimental group (administered apoaequorin capsules) or the placebo group. JA-236. At the outset of the study, participants also were segregated into analysis groups based on "levels of cognitive impairment as measured by the AD8 screening tool." JA-238. "The AD8 is a brief (8-question) screening tool that was developed to differentiate adults facing normal cognitive aging from those with early signs of dementia." JA-236.

[1] The Madison Memory Study, which Plaintiffs-Appellants' Complaint extensively references and relies upon, was submitted to the Court and is part of the record on appeal at JA-235 to JA-244. The Madison Memory Study was also publicly accessible at all relevant times. *See* http://www.prevagen.com/research/.

In the Madison Memory Study, "an AD8 score of 2 was used as a cut-off to discriminate between those people who are cognitively normal or very mildly impaired (AD8 0-2) *versus those with higher levels of impairment (AD8 3-8)*. *Id.* (emphasis added). Those with an AD8 score above 2 were not the focus of the study. *Id.* "Because Prevagen is a dietary supplement intended for healthy, non-demented individuals, results from the AD8 0-1 and AD8 0-2 [subgroups] are the most relevant to the efficacy of the product." *Id.* Those two subgroups included 100 out of the 211 participants that completed the Madison Memory Study. *See* JA-239, Table 2. (Seven participants did not finish the study.)

Participants in the Madison Memory Study completed nine quantitative, computerized tests to measure the effects of apoaequorin on their cognitive functions. JA-236 to JA-237. These tests—administered on days zero, eight, thirty, sixty and ninety—are part of the Cogstate Research battery and are well-accepted adaptations of standard neuropsychological tests. JA-236 to JA-237. The Cogstate tests were favored for the Madison Memory Study because they are "brief, repeatable, and have shown little or no practice effects." JA-236.

Nine Cogstate tests were used in the Madison Memory Study. Each of the nine—International Shopping List (ISL), to measure verbal learning; International Shopping List—Delayed Recall (ISRL), and Groton Maze Learning—Delayed Recall (GMR), to measure memory; Groton Maze Learning (GML), to measure executive function; Detection (DET), to measure psychomotor function;

Identification (IDN), to measure attention; One Card Learning (OCL), to measure visual learning; and One Back (ONB) and Two Back (TWOB), to measure working memory—is a distinct task. *See* JA-236 to JA-238. At the end of 90 days, the study's authors analyzed the results in order to, among other things, "assess whether sample selection bias occurred[,]" "prevent[] . . . false positive associations . . . and loss minimization of data[.]" JA-238.

The Madison Memory Study showed "statistically significant results in the AD8 0-1 and AD8 0-2 subgroups." JA-239. The AD8 0-1 and AD8 0-2 subgroups "contain individuals with either minimal or no cognitive impairment, and are the appropriate population for a dietary supplement intended to support people with mild memory loss associated with aging[,]" such as Prevagen. JA-239.

The results showed that, within the AD8 0-2 group, test participants showed statically significant improvements on the GML executive function test (p=0.02), IDN attention test (p=0.037) and OCL visual learning test (p=0.02) when compared to placebo. JA-243. The test participants also showed a trend towards statistical significance on the GMR memory test (p=0.107). JA-243.

In addition, participants in the AD8 0-1 subgroup experienced statistically significant improvement on the GMR memory test (p=0.011), DET (p=0.02) and OCL visual learning test (p=0.01) when compared to placebo recipients. JA-243. They also showed trends towards statistical significance on the GML executive function test (p=0.103) and the ISL verbal learning test (p=0.125). JA-243.

These statistically significant results demonstrated the efficacy of Prevagen in combating mild age-associated memory loss. The Madison Memory Study states that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment, as determined by AD8 screening." JA-243.

Appellants correctly pleaded that Appellees made their marketing statements "primarily rely[ing] on the…Madison Memory Study." JA-37 ¶ 28. Yet Appellants took no issue with the study's methodology and did not dispute that it found the results it claimed. The government regularly calls such double-blind, placebo-controlled studies—sometimes called "randomized clinical trials" or "RCTs"—the "gold standard" for substantiation. *See, e.g.*, FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 10 (issued Nov. 1998), *available at* https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry; FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008), available at* https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm ("The 'gold' standard is randomized, double blind, placebo-controlled trial design.").

B. Appellants' Claims

Much of Appellants' Complaint simply copied advertising statements Appellees made about Prevagen, JA-22-36, but did not identify anything in particular that Appellants considered actionable. The Complaint then alleged:

> To substantiate their claims that Prevagen improves memory, is clinically shown to improve memory, improves memory within 90 days, is clinically shown to improve memory within 90 days, reduces memory problems associated with aging, is clinically shown to reduce memory problems associated with aging, provides other cognitive benefits, and is clinically shown to provide other cognitive benefits, Defendants primarily rely on one double-blind, placebo-controlled human clinical study using objective measures of cognitive function. This study, called the Madison Memory Study, involved 218 subjects taking either 10 milligrams of Prevagen or a placebo. The subjects were assessed on nine computerized cognitive tasks, designed to assess a variety of cognitive skills, including memory and learning, at various intervals over a period of ninety days. The Madison Memory Study failed to show a statistically significant improvement in the treatment group over the placebo group on any of the nine computerized tasks. [JA-37 ¶ 28].
>
> After failing to find a treatment effect for the sample as a whole, the researchers conducted more than 30 post hoc analyses of the results, looking at data broken down by several variations of smaller subgroups for each of the nine computerized cognitive tasks. This methodology greatly increases the probability that some statistically significant differences would occur by chance alone. Even so, the vast majority of these post hoc comparisons failed to show statistical significance between the treatment and placebo groups. Given the sheer number of comparisons run and the fact that they were post hoc, the few positive findings on isolated tasks for small subgroups of the study

> population do not provide reliable evidence of a treatment effect. [JA-37 ¶ 29].

These are the Complaint's main substantive allegations. Appellants' bare contentions, in other words, are that subgroup analysis in the Madison Memory Study was "post hoc"; it involved only "small subgroups"; and subgroup analysis always should be considered subject to an increased "*probability* that *some* statistically significant differences would occur by chance alone," and therefore may not serve as the basis of advertising claims. JA-37 ¶ 29 (emphasis added).

The Complaint never explains what Appellants meant by "post hoc," other than the obvious—that the Madison Memory Study's authors necessarily analyzed the study outcomes, based on the groups created by the initial AD8 screening, after the study's completion. The District Court correctly called this "post hoc" description "never specified." SA-11 n.4. Appellants also never provided any basis for their claims that subgroup analysis should be considered generally suspect or that any general concerns about subgroup analysis manifested in this case, where the (not "small") subgroups comprised half the study population, were targeted based on their particular traits (normal cognitive function to only mild impairment), and showed statistically significant improvement on multiple distinct Cogstate tests.

According to Appellants, their bare assertions that such concerns *may* exist sufficed to state a claim. They contend that Appellees' representations about Prevagen's memory-enhancing benefits were made in violation of Sections 5(a) and

12 of the FTC Act, Sections 349 and 350 of the New York General Business Law, and Section 63(12) of the New York Executive Law. JA-39 to JA-42.

C. Judge Stanton's Decision to Dismiss Appellants' Claims

The District Court did not address the NYAG's state law claims and left the NYAG free to plead those claims in state court. With respect to the FTC's claims, it noted that "[t]o establish liability under Section 5(a) of the FTC Act, 'the FTC must show three elements: [including that]…a representation, omission, or practice…is likely to mislead consumers acting reasonably under the circumstances." SA-10. The District Court thus had to determine whether the Complaint "allege[d] facts from which it can be inferred that the representations at issue are false." *Id.*

The District Court began its analysis by calling it "common ground" that the Madison Memory Study "followed normal well-accepted procedures [and] conducted a 'gold standard' double-blind, placebo controlled human clinical study using objective outcome measures of human cognitive function using 218 subjects." SA-10 (citations omitted). It was equally common ground that the study found "[n]o statistically significant results…for the study population as a whole on any of the cognitive tasks." However, "statistically significant results were observed between the experimental and control groups among the AD8 0-1 and AD8 0-2 subgroups" in multiple cognitive tasks measured in the study. SA-5. The District Court correctly noted that the study's researchers said at the outset of the study that the

exact subgroups in which statistically significant improvement was found, AD8 0-1 and AD8 0-2, were "the most relevant to the efficacy of the product." SA-4; *see also* JA-236 (discussing that the study's researchers focused on the AD8 0-1 and AD8 0-2 subgroup members from the study's inception).

Because Appellants never disputed the study's methodology or results, the District Court found that Appellants necessarily "confined [their] attack to the studies of subgroups." SA-11. According to the District Court, "it is at that level that the complaint fails to do more than point to possible sources of error but cannot allege that any actual errors occurred." *Id*.

Looking at the two paragraphs in which Appellants pleaded their "by chance alone" theory, the District Court held that Appellants' "challenge never proceeds beyond the theoretical[,]… neither explaining the nature of [the] risks [of subgroup analysis] nor show[ing] that [such risks] affected the subgroups['] performance in any way or registered any false positives." *Id.* The court found this absence of support particularly glaring given undisputed evidence that the government itself used and endorsed subgroup analysis in analogous circumstances. *See* SA-11-12.

Appellees demonstrated in their briefing that subgroup analysis is common in nutrition research. The federal government's own National Institutes of Health ("NIH") has used subgroup analysis. For example, Defendants discussed the NIH's National Eye Institute ("NEI")-sponsored Age-Related Eye Disease Study 2 ("AREDS2") study, where researchers evaluated the addition of new elements to an

antioxidant and mineral mixture that had previously had been found effective in slowing age-related macular degeneration in certain populations. *See* National Eye Institute, *Age-Related Eye Disease Study 2 (AREDS2)*, *available at* https://www.nei.nih.gov/areds2. The government engaged in both subgrouping and post hoc analysis in this study and then touted its findings in a press release as follows: "[i]n AREDS 2, there was no overall additional benefit from adding omega-3 fatty acids or a 5-to-1 mixture of lutein and zeaxanthin to the formulation. However, the investigators did find some benefit when they analyzed two subgroups of the participants: those not given beta-carotene, and those who had very little lutein and zeaxanthin in their diets." National Eye Institute, *NIH Study Provides Clarity on Supplements for Protection Against Blinding Eye Disease* (May 2013), *available at* https://www.nei.nih.gov/news/pressreleases/050513. Appellants neither disputed this judicially-noticeable government report in their opposition to Defendants' motion to dismiss nor argued that the District Court had to ignore it.

Appellants, below as now, use the term "post hoc" as a pejorative, "to imply, as the District Court noted, "some deficiency in the [study's] integrity, never specified." SA-11 n.4. The court correctly held that simply using the term "post hoc" did not suffice to state a claim, and Appellants otherwise did no more than allege "that there are possibilities that the [Madison Memory Study's] results do not support its conclusion." SA-12. The Complaint, the court found, "does not explain how the number of *post hoc* comparisons run in this case makes the results as to

the…subgroups unreliable, or that the statements touting the [Madison Memory Study's] results are false or unsubstantiated." *Id.* For that reason, it "stops short of the line between possibility and plausibility of entitlement to relief." *Id.* The District Court held that the Complaint "fails to show that reliance on subgroup data 'is likely to mislead consumers acting reasonably under the circumstances,' as is necessary to state its claim." SA-11-12, *quoting FTC v. LeadClick Media, LLC,* 838 F.3d 158, 168 (2d Cir. 2016).

D. Appellants' "Blood-Brain Barrier" Allegations

Appellants' Complaint separately alleged that Appellees "do not have studies showing that orally-administered apoaequorin can cross the human blood-brain barrier and therefore do not have evidence that apoaequorin enters the human brain." JA-38 ¶ 31. Importantly, however, Appellants never alleged—nor could they—that Appellees ever advertised that they possessed such evidence regarding the *human* blood-brain barrier. In fact, Appellees *never* have advertised that apoaequorin (or any other ingredient of Prevagen) "enters the human brain."

One marketing statement referenced in the Complaint mentions *canine* Prevagen studies wherein "cerebrospinal fluid (CSF) and blood plasma samples were taken from a ***population of dogs*** to which apoaequorin was orally administered" and showed "quantifiable evidence that the supplement was present in the nervous and circulatory system of the [dogs]." JA-26 (emphasis added).

Appellees' marketing statement thus included only an indication "that apoaequorin is capable of crossing the blood brain barrier…in ***dog[s]***[.]" *Id.* (emphasis added).

Appellants have not challenged the methodology of those canine studies, the canine studies' results, Appellees' ability to market based on them, or the truthfulness of Appellees' contentions. Appellants also do not contend that a substance *must* cross the human blood brain barrier in order to affect human brain function. Their Complaint only speculated that the statistically-significant positive results of the Madison Memory Study could have resulted "from chance alone."

SUMMARY OF THE ARGUMENT

Judge Stanton correctly found that Appellants' Complaint failed to state plausible allegations. Appellants' attack on subgroup analysis in the Madison Memory Study failed to satisfy the *Twombly/Iqbal* pleading standard because it did not "proceed[] beyond the theoretical." The District Court held that the Complaint's sparse but sweeping indictment of subgroup analysis lacked any factual support, particularly in light of the multiple statistically significant results experienced by test participants relative to the placebo group. At best, Appellants claimed only "possibilities" that the Madison Memory Study's results could be attributed to "chance alone" rather than the product's efficacy. For those reasons, the Complaint did not sufficiently allege that Appellants are entitled to any relief.

Rather than appealing from what the District Court actually held, Appellants portray the District Court's opinion in a false light, contending that it reached merits

decisions on disputed issues of fact when it did not. Most of Appellants' contentions in this regard—including their new and unspecified reference to "scientific literature" that supposedly casts doubt on the validity of subgroup analysis (FTC Br. at 25)—are arguments they did not raise below and therefore cannot raise now.

Appellants separately contend that the District Court should not have considered the Madison Memory Study, but they did not argue that below, either. Appellants did not challenge the authenticity or integrity of the study documents, deny that the study was referenced in and integral to their Complaint, downplay the importance of the AD8 0-1 and AD8 0-2 subgroups from the outset of the study, or contend that the District Court could not judicially notice these materials. They cannot challenge any of this for the first time on appeal.

In short, Appellants offer no compelling reason why the District Court reached the wrong legal conclusions with regard to the limited allegations they actually pleaded. Additionally, this Court may uphold the dismissal of Appellants' Complaint on other grounds that were argued but not reached below.

One such separate and fatal weakness of the Complaint is that the FTC lacked proper authorization to file it. That green-light did not come from a valid three-member quorum of the five-member FTC, but from *two* Democratic Commissioners who, just days before the Presidential transition, improperly declared themselves a quorum. Congress did not delegate authority to the FTC allowing it to violate the

common-law quorum rule. The FTC, however, barely addressed this argument in its District Court briefing and did not address it at all in its brief to this Court.

One possible reason for the lack of bipartisan consensus at the FTC is that Appellees' substantiation for their marketing statements about Prevagen amply satisfied the FTC's "competent and reliable scientific evidence" standard set forth in the Commission's 1998 guidance to dietary supplement manufacturers. Appellants never disputed below that Appellees fully complied with this guidance. Their unprecedented attack on subgroup analysis in this lawsuit, therefore, was nothing less than an ambush. If the FTC wishes to change its substantiation guidance, it should do so *prospectively*, through the appropriate notice and comment procedure, and not retrospectively by means of a guidance-reversing lawsuit.

Finally, Appellants' claims fail because any attempt to preclude undisputedly *truthful* statements about the results of a "gold standard" RCT would constitute an impermissible restraint on commercial speech in violation of the Supreme Court's *Central Hudson* doctrine. Indeed, in analogous cases, courts have rejected on First Amendment grounds prior FTC attempts to block truthful marketing statements.

Because the dismissal of Plaintiffs-Appellants' Complaint should be affirmed for any or all of the foregoing reasons, the District Court correctly held that the FTC did not state a valid claim and then correctly declined to exercise supplemental jurisdiction over the NYAG's state law claims.

ARGUMENT

I. The District Court Correctly Found that Appellants' Allegations Failed to Satisfy Federal Pleading Standards

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), *quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id., citing Twombly*, 550 U.S. at 556. "A pleading that offers 'labels and conclusions' or a formulaic recitation of the elements of a cause of action will not do.'" *Id., quoting Twombly*, 550 U.S. at 555. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id., quoting Twombly*, 550 U.S. at 557.

This plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678, *quoting Twombly*, 550 U.S. at 556-67. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quotations and citation omitted). Further, "where a conclusory allegation in the complaint is contradicted by a document attached to the complaint, the document controls and the allegation is not accepted as true." *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 140 (E.D.N.Y. 2015), *quoting Amidax*

Trading Grp. v. S.W.I.F.T. SCRL, 671 F.3d 140, 146-47 (2d Cir. 2011); *see also TufAmerica, Inc. v. Diamond*, 968 F. Supp. 2d 588, 592 (S.D.N.Y. 2013) (citation omitted) ("[i]f a document relied on in the complaint contradicts the allegations in the complaint, the document, not the allegations control").

The District Court analyzed Appellants' Complaint and rightly concluded that it did not clear the *Twombly/Iqbal* bar. Appellants never pleaded *facts* as to why subgroup analysis supposedly is always unreliable or yielded misleading results in the Madison Memory Study, where *multiple* measures of cognitive performance showed statistically significant results in favor of the test group. Further undermining Appellants' "by chance alone" theory (FTC Br. at 22), *zero* measures in the Madison Memory Study showed statistically significant results or trends for the placebo group. *See* JA-239-243. Similarly, Appellants call Appellees' subgroup analysis "post hoc" without pleading *facts* as to why, even if true, the timing of the analysis mattered. This "stop[ped] short of the line between possibility and plausibility of entitlement to relief." SA-12, *quoting Iqbal*, 556 U.S. at 679.

This Court reviews *de novo* the District Court's legal conclusions to dismiss the FTC's claims pursuant to Rule 12(b)(6). *See Fink v. Time Warner Cable*, 714 F.3d 739, 740-41 (2d Cir. 2013). It reviews for an abuse of discretion the District Court's separate decision not to exercise supplemental jurisdiction over the NYAG's claims. *Salvani v. InvestorsHub.com, Inc.*, 628 Fed. App'x 784, 787 (2d Cir. 2015) (summary order).

Below, Appellants presented a generalized rather than specific attack on subgroup analysis, without explaining why they believed subgroup analysis must always be considered unreliable or why, if so, the government itself can rely on it in similar studies. Appellants' brief to this Court now seems to concede that such a generalized challenge is untenable. They therefore try to argue that their Complaint actually pleads a *specific* challenge to use of subgroup analysis in the Madison Memory Study. The basis of that argument, however—Appellants' implication that the subgroups here represented only a "sliver" or "fraction" of the overall study population (*e.g.*, NYAG Br. at 2, 10)—not only is an appellate invention appearing nowhere in the Complaint, but also is demonstrably wrong. In reality, the AD8 0-1 and AD8 0-2 subgroups—identified from the outset as the most relevant—together indisputably comprised roughly half of the Madison Memory Study's population. JA-239, Table 2. That is not a "sliver," and Appellants' haphazard attempt to recast their entire Complaint on the fly in an appellate brief should fail.

Alternatively, Appellants wrongly contend that the District Court "engag[ed] in factfinding on scientific questions at the motion-to-dismiss stage," and thereby strayed from the *Twombly/Iqbal* standard. FTC Br. at 1. The Madison Memory Study's multiple statistically-significant findings as to the AD8 0-1 and AD8 0-2 subgroups, however, were not in dispute; Appellants challenged only the propriety of Appellees' having engaged in subgroup analysis at all. The District Court thus did not decide and had no occasion to decide disputed issues of fact. It merely, and

correctly, concluded only that Appellants' challenge was too speculative to proceed. *See* SA-12; *Kardovich*, 97 F. Supp. 3d at 136, *quoting Iqbal*, 556 U.S. at 678 ("[a] complaint… must contain more than an unadorned…accusation") (internal quotation omitted).

Appellants also are wrong to contend that the District Court "found as fact" that apoaequorin can cross the human blood-brain barrier. FTC Br. at 23. Their Complaint (at ¶ 31) claims that Appellees "rely on the theory that…apoaequorin enters the human brain," but none of the marketing materials quoted in the Complaint actually referenced such a "theory," and the Complaint never specified a basis for this charge. The District Court therefore had no occasion to make any "finding" about apoaequorin crossing the human blood-brain barrier.

The District Court correctly credited Appellants' (undisputed) allegation that Appellees "have no studies showing that orally administered apoaequorin can cross the human blood-brain barrier." SA-7. Appellees' marketing only referenced ***canine*** studies demonstrating that apoaequorin crossed the ***canine*** blood-brain barrier, and Appellants acknowledged below that they did not challenge those studies' results, or the truthfulness of Appellees' marketing. *See* JA-314-317.

If Appellants now are contending that Appellees cannot make any advertisement statements *at all* regarding Prevagen's effect on memory *unless* Appellees have evidence that apoaequorin can cross the "human blood-brain barrier," NYAG Br. at 13, this is a new contention unsupported by any facts pleaded

in the Complaint. To the extent Appellants sought to assert as a purported fact that apoaequorin *cannot* have beneficial effects because it "is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein," the District Court correctly found that "this point…loses force" because of two other undisputed facts within its cognizance: the canine studies showing that apoaequorin crossed the blood-brain barrier in dogs and the Madison Memory Study's statistically significant results showing beneficial, memory protective effects. SA-7 n.3. Further, Appellants never alleged, nor could they, that a dietary supplement cannot have a positive effect on one's memory *unless* its active ingredient demonstrably enters the brain.

The District Court did not "find facts" on this issue and certainly did not find Appellees to be "inoculate[d]" against all deception charges. FTC Br. at 30. It found only that Appellants had not alleged facts sufficient to support their specific allegation about the supposed unreliability of subgroup analysis in the Madison Memory Study and their contention that Appellees could not market based upon the study's undisputed findings. It was correct to do so.

II. Appellants Waived Other Arguments By Not Raising Them Below

Appellants' brief to the District Court offered just a *pro forma* response to Appellees' *Twombly/Iqbal* arguments. They called their Complaint "more than sufficient to meet the liberal pleading requirements of the Federal Rules of Civil Procedure," pointing to the Complaint's "thirty-two page" length, but failing to

acknowledge that only four paragraphs (at most) of the Complaint contained substantive allegations. JA-314-315. Citing over and over again to the same two paragraphs (28 and 29) of their Complaint, Appellants argued that those paragraphs satisfied their burden because, supposedly, they "set[] out facts demonstrating why [the Madison Memory] study does not provide adequate scientific substantiation for the representations challenged in this proceeding." JA-315.

Then as now, Appellants said this was all they needed to plead to clear the *Twombly/Iqbal* plausibility bar. *See* JA-318-319. Now as then, they are wrong.

Beyond *ipse dixit* that Paragraphs 28 and 29 of their Complaint sufficed, Appellants made no other argument below. Consequently, every other argument in their appellate brief is inappropriately new. *See National Indemnity Co. v. IRB Brasil Reseguros S.A.*, 675 Fed. App'x 89, 91 (2d Cir. 2017) (summary order) (declining to address arguments first raised on appeal that were fully available and "should have been raised during District Court proceedings, not on appeal."). Appellants ask this Court to find, for example, that the District Court should not have considered the Madison Memory Study appended by Defendants to their motion to dismiss. *See* FTC Br. at 17. Appellants' new characterization of the Madison Memory Study as a "synopsis" and not representative of the study itself (FTC Br. at 47) is not alleged anywhere in the Complaint, nor was it argued below. Appellants themselves, moreover, cited and relied upon the same document below. *See, e.g.*,

JA-318 ("Defendants object to the Complaint's discussion of their clinical study, the Madison Memory Study.")

Appellants could not have objected to the District Court's consideration of the Madison Memory Study because it was integral to Appellants' Complaint. *See In re Merrill Lynch & Co., Inc.*, 273 F. Supp. 2d 351, 356 (S.D.N.Y. 2003) ("[i]n deciding a Rule 12(b)(6) motion, the Court may consider…documents attached to [the Complaint] or incorporated in it by reference,…documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference… [and] facts of which judicial notice may properly be taken"); *see also Kardovich*, 97 F. Supp. 3d at 138 (granting motion to dismiss where the court found plaintiff's misapplication of documents cited in the complaint to be conclusory and where "the science [of those documents] does not undercut [defendant's] statements regarding its health benefits, and thus plaintiffs have failed to raise a plausible claim that [defendant's] representations are…misleading"). Appellants cite *Global Network Comm'ns, Inc. v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006), but that case similarly acknowledged that a court may consider documents integral to the complaint without converting a Rule 12(b)(6) motion to one for summary judgment. This Court consistently has held it appropriate to consider a document where "read in its entirety, [it] would undermine the legitimacy of the plaintiff's claim [but] was not attached to the complaint." *Id.* at 157. That is the case here.

Appellants also take issue with the District Court's having quoted the Madison Memory Study authors' statement that the AD8 0-1 and AD8 0-2 subgroups were "the most relevant to the efficacy of the product." JA-236. Appellants, however, did not challenge *that* statement below, either. More importantly, Appellants' Complaint challenged *any and all* use of subgroup analysis, and they still cannot muster any *specific* challenge to its use here, other than falsely describing the AD8 0-1 and 0-2 subgroups as comprising only a "sliver." For that reason, the District Court's reliance on this particular "most relevant to the efficacy" statement is not relevant to Appellants' position.

Next, Plaintiffs make another argument they did not present below based on a mischaracterization of this Court's decision in *Ottaviani v. SUNY at New Paltz*, 875 F.2d 365 (2d Cir. 1989). Appellants contend that "[e]ven if Quincy found a statistically significant subgroup result with 95 percent confidence, this Court has recognized that results at that level occur by chance five percent of the time even when there is in fact no effect." FTC Br. at 32, *citing Ottaviani*, 875 F.2d at 371. This Court should not consider Appellants' new "95 percent confidence" argument, but even if it does, Appellants' reliance on *Ottaviani* is misplaced.

Ottaviani involved the use of statistical analysis in a disparate impact case, not an advertising challenge. This court noted that given "[t]he existence of a 0.05 level of statistical significance it is fairly unlikely that an observed disparity is due to chance." *Ottaviani*, 875 F.2d at 372. This confidence level, therefore, "can

provide indirect support for the proposition that disparate results are intentional rather than random." *Id.* At the same time, this Court held that the five percent probability of chance was not an "exact legal threshold" to establish a *prima facie* case of disparate impact. *Id.* The Court certainly did not render a sweeping indictment of statistically significant findings relied upon in advertising.

Separate from new legal arguments they did not offer below, Appellants' briefs also assert new purported "facts" that they never pleaded. As one example, the FTC's brief suggests the possible existence of "scientific literature" casting doubt on the validity of subgroup analysis. FTC Br. at 25. Appellants cite no such "literature" in their brief to this Court, and none is cited in the Complaint, either. *See* JA-37 ¶ 29 (merely alleging in conclusory fashion that subgroup analysis "greatly increases the probability that some statistically significant differences would occur by chance alone").

Appellants' brief also repeatedly uses the word "manipulation" with respect to the Madison Memory Study's subgroup analysis. FTC Br. at 21, 27. For good reason, however, Appellants never alleged "manipulation" of data to the District Court, nor does that word appear anywhere in their Complaint or briefing below. Appellants also now allege that Defendants engaged in "data dredging," whatever that is supposed to mean, with respect to the Madison Memory Study's analysis. *Id.* at 31. That allegation likewise appears nowhere in the Complaint.

Appellants' *amici* try to step into the breach by arguing that "[o]nce the study results are sliced and diced in multiple overlapping ways, the researchers have decreased their sample sizes and simultaneously increased the chances of getting a false positive." Brief of *Amici Curiae* Truth In Advertising, Inc., *et al*. ("TINA Br.") at 11). The TINA *amici* use a "Zodiac" example of dividing a sample population into twelfths. *Id.* at 12-13. Appellants themselves, however, never alleged that Appellees' "sliced and diced" any data. The two subgroups that showed statistically significant memory-enhancing effects comprised roughly half of the study population, not a twelfth. *See* JA-236, JA-239. The stark difference between *amici's* Zodiac example and the undisputed facts of this case illustrate why the District Court reached the correct conclusion: Appellants needed to plead actual facts as to why subgroup analysis supposedly yielded false positives in *this case*, not make a shotgun attack against subgroup analysis generally.

Another new argument made by Appellants is that Appellees cannot make truthful marketing claims about Prevagen if they do not have data that Prevagen specifically benefits those with "more serious memory problems." NYAG Br. at 24. The NYAG, in particular, makes the inflammatory new charge, not pleaded in the Complaint, that patients with Alzheimer's disease may believe that Prevagen is a cure or treatment for that disease. *See id.* The NYAG cites *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 483 (D.C. Cir. 2015), but unlike the defendants in that case—who advertised a fruit juice beverage as being able to "treat, prevent, or reduce the

risk of…heart disease, prostate cancer, and erectile dysfunction" without sufficient basis—Appellees here made *no* disease claims. "As long as the [dietary] supplement is not marketed as a drug—i.e, it is 'not claim[ed] to diagnose, mitigate, treat, cure, or prevent a specific disease…,' [21 U.S.C.] § 343(r)(6); *id.* § 343(r)(6)(C) (requiring disclaimer)—it is not regulated like a drug." *United States v. Bayer Corp.*, No. 07-01(JLL), 2015 WL 5822595, at *3 (D.N.J. Sept. 24, 2015) (citations omitted).

Because Appellees made no "disease claims," Appellants can point to none. To the contrary, Appellees have only made advertising statements concerning mild memory loss associated with aging *and* they included the express disclaimer that Prevagen "is not intended to diagnose, treat, cure or prevent any disease." *See, e.g.*, JA-23, JA-24, JA-26, JA-27, JA-29; 21 C.F.R. § 101.93. Appellants do not claim otherwise.[2] Appellants pleaded no facts, nor could they have, suggesting a reasonable consumer with a debilitating disease could have thought Prevagen to be a treatment or cure for that disease. *See* JA-236 (discussing study population subgroups with a higher level of impairment).

[2] The cases relied upon by the TINA *amici* are inapposite. *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232 (2d Cir. 2001), *Garden Way Inc. v. Home Depot Inc.*, 94 F. Supp. 2d 276 (N.D.N.Y. 2000), *McNeil-PPC, Inc. v. Pfizer, Inc.*, 351 F. Supp. 2d 226 (S.D.N.Y. 2005), and *Schick Mfg., Inc. v. Gillette Co.*, 372 F. Supp. 2d 273 (D. Conn. 2005), all involved the challenge of a competitors' advertising under the Lanham Act. None had anything to do with whether a dietary supplement manufacturer had adequate substantiation for its marketing claims—let alone when those marketing claims were in compliance with published government guidelines.

For all these reasons, the District Court correctly concluded that Appellants' Complaint failed to state a claim. Appellants' brief does not seriously dispute the District Court's analysis of arguments they *actually made* to that court, and this Court should disregard Appellants' new arguments, raised for the first time on appeal. Even if this Court considers those new arguments, they lack merit. This Court should affirm the District Court's dismissal of the FTC's claims and its decision to decline supplemental jurisdiction over the NYAG's claims.

III. This Court Also Can Uphold Dismissal on Alternative Grounds

This Court has discretion to affirm dismissal on alternative grounds briefed to, but not reached by, a district court. *See Smith v. United Fed'n of Teachers*, 162 F.3d 1148, 1998 WL 69756, at *2 (Table) (2d Cir. 1998) (district court erred in dismissing claim under *res judicata*, but dismissal was affirmed because conspiracy claim was still insufficient under 12(b)(6) as alternative grounds); *Sundwall v. State of Conn.*, 104 F.3d 356, 1996 WL 730287, at *1 (Table) (2d Cir. 1996) (affirming dismissal on alternative grounds for failure to state a claim).

It is well settled that "[this Court] may affirm on any grounds for which there is a record sufficient to permit conclusions of law, including grounds not relied upon by the district court." *Olsen v. Pratt & Whitney Aircraft Div. of United Techs. Corp.*, 136 F.3d 273, 275 (2d Cir. 1998). Failure to consider these alternative grounds for dismissal where both parties had the opportunity to fully brief the issues would "only result in delay and in additional, and unnecessary, expenditure of time and resources

by the parties, by the district court, and eventually by this Court on a subsequent appeal." *Rai v. WB Imico Lexington Fee, LLC*, 802 F.3d 353, 368-69 (2d Cir. 2015).

A. The FTC Lacked a Valid Quorum to Authorize This Suit

For the first 90 years of its existence, the FTC's internal procedures adhered to the "universally accepted common-law rule" that "a majority of a quorum constituted of a simple majority of a collective body is empowered to act for the body." *FTC v. Flotill Prods, Inc.*, 389 U.S. 179, 183 (1967). In the FTC's case, that means a quorum is no fewer than *three* seated Commissioners. Congress granted no authority allowing the FTC to vest all of its decision-making in a one- or two-member quorum and thereby contravene the common-law quorum rule.

In *In the Matter of Children's Advertising*, 93 FTC 323, 1979 FTC LEXIS 509, at *1 (Mar. 7, 1979), the FTC recognized that the departure of Commissioners might remove its ability to "properly exercise certain decision making authority[,]" but it nevertheless declined to try evading the common-law quorum rule. The FTC stated that "if at all reasonably possible, it is in the public interest that Commission decisions of significance…be taken with the participation of no fewer than three Commissioners." *Id.* In September 2005, however, the FTC purported to lower its quorum threshold from this "universal" common-law rule, providing instead that "[a] majority of the members of the Commission in office and not recused from participating in a matter…constituted a quorum for the transaction of business in that matter." *See* 70 Fed. Reg. 53296 (September 8, 2005) (codified at 16 C.F.R. §

4.14(b)). The FTC never invoked or tested this rule before this matter, and it is and always was invalid.

Here, in the final days of the prior administration, FTC Commissioners Ramirez and McSweeny, both members of the same party, declared themselves a quorum and purported to authorize staff to hurry up and file the bare-bones complaint that the District Court found lacking. *See* FTC, New York State Charge the Marketers of Prevagen With Making Deceptive Memory, Cognitive Improvement Claims (Jan. 9, 2017), *available at* https://www.ftc.gov/news-events/press-releases/2017/01/ftc-new-york-state-charge-marketers-prevagen-making-deceptive. Congressional intent, common-law rules, and the FTC's own policies precluded the FTC from acting based upon a vote of fewer than three Commissioners.[3] Because the FTC lacked a proper quorum, this Court should reject the Complaint as *ultra vires*.

In adopting its impermissible quorum rule in 2005, the FTC relied upon a Securities and Exchange Commission ("SEC") rule that permitted a two-member quorum in limited circumstances. *See* 70 Fed. Reg. 53296, at 53296-97 & n.2, *citing Falcon Trading Grp., Ltd. v. SEC*, 102 F.3d 579, 582 (D.C. Cir. 1996); *SEC v. Feminella*, 947 F. Supp. 722, 725-27 (S.D.N.Y. 1996). The SEC rule, however,

[3] *See* Quorum, BLACK'S LAW DICTIONARY (10th ed., 2014) ("The smallest number of people who must be present at a meeting so that official decisions can be made; specif., the minimum number of members (*a majority of all members, unless otherwise specified in governing documents*) who must be present for a deliberative assembly to legally transact business.") (emphasis added).

rested on authority that Congress *explicitly* delegated to the SEC. Congress did not provide a corresponding delegation of authority in the FTC Act.

In *Falcon Trading Group*, the D.C. Circuit relied on the SEC's rulemaking authority under 15 U.S.C. § 78w(a)(1) to find that the SEC had the power to determine how many of its members constituted a quorum. *See* 102 F.3d at 582. In *Feminella*, by contrast, the court *rejected* such a broad reading of the SEC's general rulemaking authority. *Feminella* held that general rulemaking provisions convey "authority to make substantive rules prohibiting certain acts under the statutes," but not "authority to establish the agency's own internal procedures," including how many Commissioners constituted a quorum. 947 F. Supp. at 726.

The *Feminella* court thus found it necessary to go beyond the SEC's *general* rulemaking authority and look instead for *specific* authorization to set aside the common-law quorum rule. It found such authority in 15 U.S.C. § 78d-1, which authorized the SEC "to delegate to a single Commissioner a decision whether or not to commence an enforcement action." *Feminella*, 947 F. Supp. at 726. Accordingly, the court held that "Congress envisioned circumstances under with the [SEC] would find it necessary to carry out its functions, other than rulemaking, on the authority of fewer than three Commissioners." *Feminella*, 947 F. Supp. at 726-27.

The FTC Act, unlike the SEC's enabling statute, contains no language that would satisfy the *Feminella* standard. The FTC's enabling statute requires the Commission to authorize certain business items, including the filing of Complaints,

but does not address how many Commissioners constitutes a quorum for the conduct of the FTC's business. *See* 15 U.S.C. § 53(b). In the absence of a specific delegation of authority, the common-law quorum rule applies. The FTC thus had no valid basis to adopt a rule similar to the SEC's, let alone a rule providing for even a one member "quorum" *without* the exigency requirement the SEC adopted. *See* 70 Fed. Reg. 53296, n. 3 (stating that the SEC rule "would not find a quorum in every situation where the FTC's new rule would"). Appellants do not contend that any exigency existed here requiring them to file the Complaint when they did, nor could they.

As the Supreme Court confirmed in 2010, federal agencies are not free to adopt unusual procedures absent an indication that Congress would have intended or permitted those procedures. *Cf. New Process Steel, L.P. v. NLRB*, 560 U.S. 674, 688 (2010) (refusing to read into the NLRB's enabling statute the authority to operate with a two-member quorum when that authority could not be found in the statute). Because the common-law rule prohibits the FTC from acting through a vote of fewer than three Commissioners, and because Congress expressed no intent to allow the FTC to evade the common-law rule, two Commissioners could not validly authorize the filing of Appellants' Complaint. That provides another basis to affirm the District Court's decision dismissing the Complaint.

B. Defendants' Advertisements Comply with the FTC's Requirements to Substantiate Claims Based on the "Competent and Reliable Scientific Evidence" Standard

Even had the FTC properly authorized this lawsuit, and even if Appellants could have satisfied the *Twombly/Iqbal* pleading standard, their Complaint had another fatal flaw: All of Appellees' marketing statements at issue complied with the FTC's longstanding "competent and reliable scientific evidence" standard. Appellants' briefs, like their Complaint, do not discuss this guidance, on which Appellees—like all dietary supplement marketers—reasonably relied. Instead, Plaintiffs seek impermissibly to apply a new standard retroactively by means of litigation, rather than through notice and comment.

With the Dietary Supplement Health & Education Act of 1994 ("DSHEA"), Congress first created "dietary supplements" as a product category and excluded dietary supplements from the more rigorous Food and Drug Administration ("FDA") approval process or the pre-authorization required for food additives. Pub. L. No. 103-417, 108 Stat. 4325 (1994); *see* 21 U.S.C. §§ 321(g)(1), (s); *see also Bayer Corp.*, 2015 WL 5822595, at *3. Under the DSHEA, dietary supplements may be promoted with "structure/function" claims such as those made by Appellees about Prevagen, *see* 21 U.S.C. § 321(g)(1), thereby creating a more lenient standard for advertising statements for dietary supplements than the one applicable to drugs intended to cure, treat, or prevent disease. 136 Cong. Rec. S16611 (daily ed. Oct.

24, 1990) (Statement of Sen. Hatch); *see also Bayer Corp.*, 2015 WL 5822595, at *3.

Structure/function claims "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function" of the body, while "disease claims" are those that "claim[] that a product diagnoses, treats, prevents, cures, or mitigates diseases." *Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 Fed. Reg. 1000-01, 1000-1001 (January 6, 2000) (codified at 21 C.F.R. § 101.93). Prevagen is a dietary supplement, not a drug. Dietary supplements and their labels may include structure/function claims when "the manufacturer of the dietary supplement has substantiation that such statement[s] [are] truthful and not misleading." 21 U.S.C. § 343(r)(6)(B). A claim to address "mild memory problems associated with aging" is such a structure/function claim. 65 Fed. Reg. 1000-01, at 1000.

The Madison Memory Study sufficed to render Appellees' claims truthful and not misleading. Below, all Appellants argued was that the DSHEA's dietary supplement product category is "irrelevant." They therefore dismissed it, without explanation, as just an "evidentiary standard." JA-319 n.8. The DSHEA, however, cannot be "irrelevant" to the analysis of Appellees' Prevagen claims: Because Prevagen is not a drug and explicitly is not marketed as a drug, Appellees only had to satisfy the DSHEA's "truthful and not misleading" standard.

After the passage of the DSHEA, the FTC issued advertising guidance to "explain[] the how-tos of making sure your [dietary supplement marketing] claims have appropriate scientific support." FTC, *Dietary Supplements: An Advertising Guide For Industry*, *available at* https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry (issued Nov. 1998) ("FTC Guidance"); *see also Bayer Corp.*, 2015 WL 5822595, at *3 (citing the FTC Guidance and noting that the DSHEA's standard "applies to the entire industry through agency guidance promulgated"). Courts around the country routinely cite the FTC Guidance to determine whether an advertisement is not false or misleading under the FTC Act. *See, e.g.*, *Bayer Corp*., 2015 WL 5822595, at *14 (rejecting the FTC's argument that claims were not sufficiently substantiated on the ground that the "[FTC] Guidance specifically refutes the standard the Government is seeking to impose"); *see also In re: Bayer Phillips Colon Health Probiotics Sales Practices Litig.*, No. 11-03017, 2017 WL 1395483, at *7-9 (D.N.J. Apr. 18, 2017) (discussing FTC Guidance as setting forth the correct legal requirements for dietary supplement substantiation); *Nat'l Urological Grp., Inc., infra*, 645 F. Supp. 2d at 1186-88; J. Howard Beales III, Timothy J. Muris, Robert Pitofsky, *In Defense of the Pfizer Factors*, George Mason University Law and Economics Research Paper Series, at 31 (May 2012), *available at:* http://ssrn.com/abstract=2087776 ("the Commission has relied on the flexibility of the reasonable basis standard to tailor substantiation

requirements to particular claims for dietary supplements"). Appellants cannot now simply ignore that guidance because it is inconvenient.

Rather than addressing these cases, which are fatal to Appellants' claims, Appellants and their *amici* place great weight on *POM Wonderful*. That case, however, does not support their claims, either. In *POM Wonderful*, the FTC sued because (1) those defendants made outlandish disease prevention and cure claims; and (2) those defendants did *not* base any of their efficacy claims on "one or more properly randomized and controlled human clinical trials." *POM Wonderful*, 777 F.3d at 483, 493-94 (quotations omitted). Here, by contrast, Appellees expressly made no disease prevention or cure claims and premised their structure/function claims on a gold-standard RCT, exactly what was missing in *POM Wonderful*.

Also in *POM Wonderful*, referencing a specific claim that pomegranate juice "improved blood flow to the heart" by "approximately 17%," the FTC asserted specific facts as to why the quoted study had a poor methodology. Their specific claims included that "patients in the placebo group began the study with significantly worse blood flow than patients in the treatment group." *POM Wonderful*, 777 F.3d at 486. The FTC has pleaded no such specifics here.

For dietary supplements, as distinct from drugs, the FTC has never required an RCT. The FTC's Guidance provides that under a "common-sense proposition[]" a dietary supplement advertising claim is "truthful and not misleading" when the manufacturer possesses "competent and reliable scientific evidence" to substantiate

the claim. FTC Guidance at 3.[4] The FTC defined its "competent and reliable scientific evidence" standard to be "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." FTC Guidance at 9.

The "FTC Guidance makes clear that this standard [for dietary supplements] is not the drug standard" that would apply to disease claims. *Bayer Corp.*, 2015 WL 5822595, at * 3. "Competent and reliable scientific" evidence is a "flexible" standard. FTC Guidance at 3, 8. For that reason, the FTC recognizes that "randomized clinical trials are not required" to substantiate dietary supplement marketing claims. *Bayer Corp.*, 2015 WL 5822595, at *3*; see also POM Wonderful, LLC*, 777 F.3d at 504 (even with respect to "disease claims," randomized clinical trials are "not necessarily" required). "There is no fixed formula for the number or the type of studies required or for more specific parameters like sample size and study duration" for a dietary supplement. FTC Guidance at 9. Rather, "advertisers must have a reasonable basis" for the product claims. *Id.* at 8.

The Guidance provides that "[t]he FTC will consider all forms of competent and reliable scientific research when evaluating substantiation[,"] including

[4] Citations to the FTC Guidance refer to the page numbers of the .pdf file available on the FTC's website.

"[r]esults obtained in animal…studies[.]" FTC Guidance at 10. Moreover, even though RCTs are not required, "[a]s a general rule, well-controlled human clinical studies are the most reliable form of evidence[,]" particularly those that are "carefully controlled, with [the] blinding of subjects and researchers." *Id.* at 10, 12.

When, as here, an advertiser premises claims on an RCT, the FDA and FTC agree that a "randomized, double-blind, placebo-controlled trial" is "the gold standard" for complying with the "truthful and not misleading" standard for dietary supplement structure/function claims. FDA, *Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act* (Dec. 2008), *available at* https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073200.htm, at § II.D. Appellants never questioned, nor could they, that the Madison Memory Study was a "gold standard" RCT—the *most reliable form of substantiation* one could have to substantiate Defendants' structure/function claims about Prevagen.

As discussed above, all Appellants' Complaint alleged was that courts should consider the Madison Memory Study's results unreliable because of its use of subgroup analysis. JA-37 ¶¶ 28, 29. Nowhere in the FTC Guidance, however—nor anywhere else—has the FTC proclaimed that statistical significance must be found for the entirety of the study's participants. The FTC Guidance specifically states that the study population should "reflect the characteristics and lifestyle of the

population targeted by the ad[.]" FTC Guidance at 16. The FTC said that "[t]here is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine." *Id.* at 12. A study's "results [need only] translate into a meaningful benefit for consumers," *id.*, which the Madison Memory Study did.

Those individuals with AD8 scores between 0 and 2 were "reflect[ive] [of] the characteristics and lifestyle of the population targeted" by Defendants' advertisements. The Madison Memory Study's results translated into a "meaningful benefit" for that target population. FTC Guidance at 12. Appellants never contended otherwise. Nor do Appellants plausibly dispute that the Madison Memory Study found statistically significant memory improvement in those with AD8 scores within the target population. *See id.* ("[s]tatistical significance of findings is also important" for substantiating claims).

The FTC, if it wishes, can promulgate new rules and regulations *prospectively* prohibiting dietary supplement manufacturers from relying on subgroup analysis. The Supreme Court, however, long has held that Appellants *cannot* conduct a litigation-by-ambush strategy in an attempt to *retroactively* redefine what it means for a dietary supplement manufacturer to possess the requisite competent and reliable scientific evidence. *See NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 295 (1974); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012) (regulators cannot impose retroactively liability when, as here, parties have relied in good faith on prior guidance and lacked "fair warning of the conduct [a regulation]

prohibits or requires"). As the Supreme Court warned, "[i]t 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." *Christopher*, 567 U.S. at 158-159. Appellants' lawsuit violates that standard and is not permissible.

Courts around the country repeatedly have rejected prior attempts by the FTC to require higher levels of substantiation for dietary supplements than what the FTC Guidance requires. For example, in *Bayer*, 2015 WL 5822595, at *5, the FTC challenged the manufacturer's claims that its probiotic supplement "promote[s] overall digestive health" and "helps defend against occasional constipation, diarrhea, gas and bloating." The manufacturer supported its advertising claims with scientific articles, but the FTC alleged that those articles were not sufficient because the "'competent and reliable scientific evidence' standard could only be met through 'human clinical trials that (1) are randomized, placebo-controlled, and double-blind; (2) use the specific product for which the claims are made; (3) are performed in the population at which the claims are directed; and (4) use validated methods and appropriate statistical methods to assess 'outcomes.'" *Id.* at *4.

The *Bayer* court rejected the FTC's position because the "[FTC] Guidance specifically refutes the standard the Government is trying to impose." *Id*. at *14.

The court specifically noted the statements in the FTC Guidance that "[t]here is no set protocol for how to conduct research that will be acceptable[,]" "[t]here is no fixed formula for the number or type of studies required" and "[t]he FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumer have access to information about emerging areas of science." *Id.* Because the "competent and reliable scientific evidence does not require drug-level clinical trials…the Government cannot try to reinvent this standard[.]" *Id*. *Bayer* confirms the FTC Guidance that an RCT is not required *at all* to substantiate structure function claims about a dietary supplement, yet here Plaintiffs-Appellants' Complaint contends that even having such a "gold standard" study is not sufficient. In *POM Wonderful*, the case upon which Appellants place so much weight, the D.C. Circuit rejected the FTC's attempt to require *more than one* RCT even for disease prevention claims, when it never had done so before. *POM Wonderful, LLC*, 777 F.3d at 502-05.

The Eleventh Circuit, in *FTC v. Garden of Life, Inc.*, 516 Fed. App'x 852 (11th Cir. 2013), rejected a similar attempt to litigate additional requirements into the "competent and reliable scientific evidence" standard. In *Garden of Life*, the FTC challenged the manufacturer's claims that its children's omega-3 dietary supplement "help[ed] support" a child's "[b]rain [d]evelopment," "[c]ognitive [f]unction," "[e]ye [h]ealth & [v]ision," and "[p]ositive [m]ood & [b]ehavior." 516 Fed. App'x at 854. The manufacturer supported its adverting claims with studies that tested the effect of omega-3 intake on young children, along with "two dozen

others that tested different populations, e.g., children with attention deficit disorder or malnutrition." *Id.* at 856. "According to the FTC, these advertising claims were inadequately supported by competent and reliable scientific evidence[,]" *id.* at 855, because the manufacturer purportedly "relied on insufficiently rigorous studies, or studies of populations other than healthy children over the age of two[.]" *Id.* at 856. The Eleventh Circuit rejected the FTC's argument, finding that to hold the manufacturer liable "solely because another well-respected expert defines 'brain development' differently or disagrees with certain aspects of a study's trial design would require [the court] to read additional requirements" into the FTC's "competent and reliable scientific evidence" standard. *Id.*

Similarly, in *Basic Research, LLC v. FTC*, No. 2:09-cv-0779 CW, 2014 WL 12596497, at *1 (D. Utah Nov. 25, 2014), the FTC challenged advertising claims that the manufacturer made about two of its weight loss dietary supplements. The FTC argued that the manufacturer's advertising claims were not adequately substantiated because the manufacturer's substantiation did not amount to the "gold standard" of a randomized double-blind, placebo controlled clinical study. *Basic Research, LLC*, 2014 WL 12596497, at *3. The court rejected the FTC's arguments because "the approach taken by the FTC through its expert requires a level of substantiation that exceeds the requirements" of the competent and reliable scientific evidence standard and the FTC Guidance. *Id.* at *13. That standard "does not require [the manufacturer] to only make representations that are supported by

uncontroverted evidence." *Id.* at *10; *see id.* (noting the "[u]nanimity of opinion in the scientific community . . . is extremely rare") Yet, that is exactly what Appellants attempted here.

Below, Appellants had no answer to *Bayer*, *Garden of Life*, or *Basic Research*, other than to ask the District Court not to consider them because "[n]one of these cases finds that a pleading should be dismissed for failing to allege non-compliance with the FTC's' 'competent and reliable' standard." JA-320. Undeniably, however, the same overreach is present here that caused those courts to dismiss the FTC's claims. Appellees' marketing claims here all were in line with the FTC Guidance, thereby providing another basis to uphold the District Court's decision.

Appellants also cannot reasonably rely on *Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), to support their argument that Appellees lacked substantiation for their marketing claims about Prevagen. *See, e.g.*, FTC Br. at 6, 8. *Thompson* involved the review of an FTC order regarding the efficacy claims of an over-the-counter *drug* (a pain reliever), not a dietary supplement like Prevagen. *Thompson Med. Co.*, 791 F.2d at 192-93. *Thompson* also was decided nearly 12 years before the FTC issued its Guidance and a nearly a decade before passage of the DSHEA. Moreover, *Thompson* upheld an FTC order finding that the drug manufacturer's claims were deceptive after "[t]he FTC adequately considered a large mass of technical evidence and concluded that [the manufacturer] had engaged in deceptive advertising." *Id.* at 197. To the extent *Thompson* is still applicable, it

certainly does not apply to dietary supplement manufacturers or to Appellants' purely conclusory allegations about Prevagen in this matter.

Appellants' citation to the FTC's Policy Statement Regarding Advertising Substantiation, 104 F.T.C. 839, 839 (1984), *see* FTC Br. at 6, is of no help to them, either. This Policy Statement does nothing to refute that Appellees' claims about Prevagen are supported by the Madison Memory Study and conform to the FTC Guidance issued 14 years *after* that policy statement's publication. The same is true for the remainder of Appellants' cases. None of *FTC v. QT, Inc.*, 512 F.3d 858, 860 (7th Cir. 2008), *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006), *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1090 (9th Cir. 1994), *Bristol-Myers Co. v. F.T.C.*, 738 F.2d 554, 556 (2d Cir. 1984), or *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 683 (3d Cir. 1982), involved dietary supplement marketing claims at all.

Similarly, *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 4 (1st Cir. 2010) involved marketing "products that [the advertiser] claimed cured literally every disease, from cancer to Parkinson's to obesity." That is a far cry from the truthful, limited, and fully substantiated structure/function claims Appellants made about Prevagen. Moreover, *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1186-87 (N.D. Ga. 2008), *aff'd*, 356 Fed. App'x (D.C. Cir. 2010), *confirms* that the FTC Guidance is the appropriate standard for dietary supplement manufacturers to follow regarding substantiation of their marketing claims. *See id*. (noting that the FTC's "[c]ompetent and reliable scientific evidence" standard has been defined in

"guidelines promulgated by the FTC" and discussing FTC Guidance). "The fact that different scientific evidence is required from different claims impacting different products does not mean that the FTC can enforce its act arbitrarily; instead it simply means that different claims require different substantiation." *Id.* at 1187. Appellees' marketing claims about Prevagen *exceed* the substantiation that the FTC Guidance requires for dietary supplements. Accordingly, this Court should affirm the District Court's decision on this independently sufficient basis.

C. Appellants' Claims Amount to an Improper, Unconstitutional Restraint On Truthful Commercial Speech

Finally, even if Appellants could contradict their own Guidance in a lawsuit rather than promulgating a new prospective regulation, their claims here—no matter how asserted—amount to an impermissible restraint on commercial speech under the test set forth by the Supreme Court in *Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 47 U.S. 557 (1980). Notwithstanding that Appellees relied on a "gold standard" study to substantiate their structure/function claims about Prevagen, Appellants improperly seek to restrict *truthful* speech about Prevagen's effects.

Under the *Central Hudson* test, a restriction on commercial speech is valid only if "the asserted governmental interest is substantial"; the restriction "directly advances the governmental interest asserted"; and the restriction "is not more extensive than is necessary to serve that interest." *Cent. Hudson*, 47 U.S. at 566. Although this test "'requires something short of a least-restrictive-means standard,'

…the [FTC] still bears the burden to demonstrate a 'reasonable fit' between the particular means chosen and the governmental interest pursued[.]" *POM Wonderful, LLC*, 777 F.3d at 502, *quoting Board of Trustees v. Fox*, 492 U.S. 469, 477 (1989).

Prior attempts by the government to bar truthful marketing statements have failed. *See, e.g., Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48, 62-64 (D.D.C. 2010) (FDA's complete ban on certain claims because the FDA alleges they are "misleading on their face" violates First Amendment where "the explanation the FDA offers to demonstrate that plaintiffs' claims are misleading—that the claims leave out pertinent information—is not support for banning the claims entirely"); *Pearson v. Shalala*, 130 F. Supp. 2d 105, 112-20 (D.D.C. 2001) (FDA's refusal to authorize plaintiff's folic acid claim violated First Amendment).

In *POM Wonderful*, the D.C. Circuit applied the *Central Hudson* test to an FTC order that prohibited the manufacturer from asserting its products "could treat, prevent, or reduce the risk of various ailments" unless those claims were substantiated by *at least two* randomized, controlled human clinical trials ("RCTs") that demonstrated statistically significant results. *POM Wonderful, LLC*, 777 F.3d at 484. The D.C. Circuit held that because the defendant in *POM Wonderful* had a history of making deceptive marketing statements, the FTC could impose some heightened substantiation requirements on that defendant. No such aggravating factors exist here. And even in *POM Wonderful*, with that aggravating circumstance

present, the court expressly rejected the FTC's attempt to mandate "two RCTs as an across-the-board-requirement for any disease claim." *Id.* at 502.

"If there is a categorical bar against claims about the disease-related benefits of a food product or dietary supplement in the absence of two RCTs, consumers may be denied useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease." *POM Wonderful*, 777 F.3d at 502. Accordingly, the D.C. Circuit held that "the consequences of mandating more than one RCT…would subvert rather than promote the object of the commercial speech doctrine." *Id.* Moreover, the D.C. Circuit noted that in most of the FTC's cases "over the past decade," the FTC has required only "competent and reliable scientific evidence"—not even one RCT, let alone more than one—"to substantiate disease claims[.]" *Id.* at 504.

Here, Appellees made "structure/function" claims that are subject to a *less stringent* substantiation standard than the disease claims at issue in *POM Wonderful*. *See Bayer*, 2015 WL 5822595, at *3; *POM Wonderful, LLC*, 777 F.3d at 490-93; 21 U.S.C. § 343(r)(6)(B). It is undisputed that Appellees made their marketing claims upon substantiation by the results of an RCT—the Madison Memory Study—which showed "statistically significant results" among Prevagen's target population. JA-239. Appellants' attempt to prohibit Defendants from marketing based on that RCT's results constitutes an impermissible restraint on truthful commercial speech. This provides another basis to affirm dismissal.

IV. The NYAG Has No Standing to Appeal

Because the District Court correctly found that Appellants' Complaint failed to state a claim under the FTC Act, dismissal of the NYAG's claims must also be affirmed "[b]ecause the correct disposition of the state-law claims follows directly from the correct resolution of the FTC Act claims." NYAG Br. at 20. District courts have broad discretion to decline to exercise supplemental jurisdiction when it "has dismissed all claims over which it has original jurisdiction." 28 U.S.C. § 1367(c)(3). Once "all bases for federal jurisdiction have been eliminated from a case so that only pendent state claims remain," there is a strong presumption to decline supplemental jurisdiction. *Bridgeman Art Library, Ltd. v. Corel Corp.*, 25 F.Supp.2d 421, 431 (S.D.N.Y. 1998). Thus, there is ordinarily no abuse of discretion when a district court declines supplemental jurisdiction over state-law claims following dismissal of all federal–or other original–jurisdiction claims. *See Salvani v. InvestorsHub.com, Inc.*, 628 Fed. App'x 784, 787 (2d Cir. 2015) (summary order); *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 33 (2d Cir. 2006). Subsection (c) of § 1367 "confirms the discretionary nature of supplemental jurisdiction by enumerating the circumstances in which district courts can refuse its exercise." *City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 173 (1997).

In *Salvani*, this court affirmed the district court's determination that the plaintiff failed to sufficiently plead the reliance element of a Securities and Exchange Commission Rule 10b-5 claim. 628 F. App'x 786. The court proceeded to dismiss

the plaintiff's state law claims, as is "the usual case" when "all federal-law claims are eliminated before trial." *Id*. at 787.

Similar to *Salvani*, the district court was fully within its discretion dismissing the NYAG's state law claims. As the District Court noted, "[t]he New York State courts may find merit in the remaining claims under New York statutes, which are best left to them." SA-12. Because the District Court did not opine at all on the merits of the NYAG's claims, and left the NYAG free to replead those claims, the NYAG has no standing to challenge the District Court's dismissal order.

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's dismissal of the Complaint.

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CERTIFICATE OF COMPLIANCE WITH FED. R. APP. P. 32(a)

1) This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,193 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2) This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, 14-Point font.

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