17-3745 & 17-3791

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

FEDERAL TRADE COMMISSION *et al.*,
Plaintiffs-Appellants,

v.

QUINCY BIOSCIENCE HOLDING CO. *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York
No. 1:17-cv-00124-LLS (Hon. Louis L. Stanton)

BRIEF OF THE FEDERAL TRADE COMMISSION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

OTHER AUTHORITIES

STATEMENT OF JURISDICTION

The district court had jurisdiction over claims brought by the Federal Trade Commission under 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b). It had supplemental jurisdiction over claims brought by the State of New York under 28 U.S.C. § 1367. The district court entered final judgment on September 29, 2017. The Federal Trade Commission timely appealed on November 15, 2017, and the State of New York timely appealed on November 20, 2017. This Court has jurisdiction under 28 U.S.C. § 1291.

QUESTION PRESENTED

Whether the district court erred by failing to accept the complaint's factual allegations as true and instead engaging in factfinding on scientific questions at the motion-to-dismiss stage.

STATEMENT OF THE CASE

This is an appeal from an order of the district court for the Southern District of New York (Stanton, J.) dismissing for failure to state a claim a complaint filed by the Federal Trade Commission and the State of New York against Quincy Bioscience Holding Co., three of its subsidiaries, and two of its officers. *FTC v. Quincy Bioscience Holding Co.*, 272 F. Supp. 3d 547 (S.D.N.Y. 2017), SA1.[1] The complaint charges the defendants with violating the Federal Trade Commission

[1] "SA" refers to the Special Appendix at the end of this brief. "JA" refers to the separately bound Joint Appendix.

Act and analogous state law through false or unsubstantiated advertising claims made in connection with a memory enhancement product.

Quincy sells Prevagen, a dietary supplement containing apoaequorin, a synthetic version of a protein found in jellyfish. JA20 (Compl. ¶ 19). Quincy's national advertising campaign touted Prevagen as clinically proven to improve memory within 90 days, reduce memory problems associated with aging, and provide other cognitive benefits. JA20-36, 39-40 (Compl. ¶¶ 21-27, 36, 39). Quincy's ads claimed that Prevagen works by replacing "vital proteins" that "decline in the natural process of aging." JA159, 167-68 (Compl. Exh. E, Infomercial Tr., pp. 14, 22-23). Quincy told consumers that it had verified these benefits through a "large double blind, placebo-controlled trial," which "show[ed] statistically significant improvements in word recall, in executive function, and also in short-term memory." JA155 (Compl. Exh. E, p. 10).

The complaint alleges that contrary to Quincy's claims, its clinical trial did not show that Prevagen improved memory. Quincy's trial, known as the Madison Memory Study, "failed to show a statistically significant improvement in the treatment group over the placebo group on any of the nine . . . cognitive tasks" assessed by the study. JA37 (Compl. ¶ 28).

The complaint alleges that after the Madison Memory Study failed to demonstrate memory improvement, Quincy's researchers searched for ways to spin

the data in a favorable light. JA37 (Compl. ¶ 29). They "conducted more than 30 post hoc analyses of the results, looking at data broken down by several variations of smaller subgroups for each of . . . nine computerized cognitive tasks." *Id.* Prevagen had no significant beneficial effect on the "vast majority" of these subgroups. *Id.* But there were a "few positive findings on isolated tasks" for certain narrow subgroups. *Id.* Quincy thus rested its advertising claims on those scant results even though the results of the study were in fact overwhelmingly negative. The complaint charges that Quincy's cherry-picked findings "do not provide reliable evidence" to support the company's advertising claims; indeed, the results may have been false positives that "occur[red] by chance alone." *Id.*

The complaint further alleges that Quincy lacked evidence to support its claim that Prevagen's protein replaces brain proteins lost with age. JA38-39 (Compl. ¶ 31). In fact, other Quincy studies showed that the protein, like other dietary proteins, is rapidly digested and breaks down in the stomach before it ever enters the bloodstream. *Id.* Thus, Quincy has no evidence that the Prevagen protein, taken as advertised, can even enter the human brain.

The district court dismissed the complaint for failure to state a claim. Despite the court's recognition that the study "failed to show a statistically significant improvement in the experimental group over the placebo group as a whole" or for "most" of the subgroups, it found that two of the subgroups showed

"improvement in memory after taking the supplement." SA10-11. The court based these findings on a "Clinical Trial Synopsis" that Quincy prepared long after the study and proffered as an exhibit to its motion to dismiss. *See* JA235-44 (ECF No. 35).

The district court rebuffed the complaint's charge that Quincy's subgroup analyses were unreliable, opining that such analyses are "widely used in the interpretation of data in the dietary supplement field." SA11. The court condemned as "theoretical" the allegation that Quincy's few positive subgroup results did not substantiate the advertising claims and may have resulted from chance alone. *Id.* It held instead that "[a]ll that is shown by the complaint is that there are *possibilities* that the study's results do not support its conclusion." SA12 (emphasis added).

The court also rejected the allegation that Prevagen's active ingredient cannot reach the brain, circularly reasoning that "something" must have caused improved memory for the subgroup members. SA7 n.3. In other words, the court assumed that the subgroup members in fact experienced improved memory, and thus that the protein must have reached their brains.

As shown below, the district court committed fundamental legal errors when granting the motion to dismiss. It failed to accept as true the complaint's factual allegations, ignored key allegations, and drew unwarranted inferences in favor of

the defendants. The court also improperly relied on evidence outside the complaint. All those errors led the court to resolve complex scientific questions without a factual record or expert testimony, which are essential to determine whether an advertiser had a sufficient factual basis for its health claims.

A. The Legal Framework For Deceptive Advertising

Section 5 of the FTC Act prohibits, and "direct[s]" the FTC "to prevent," "deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a). In Section 12 of the Act, Congress specifically prohibited "any false advertisement" relating to "food" or "drugs." *Id.* § 52(a), (b). The Act broadly defines "false advertisement" to include any "advertisement, other than labeling, which is misleading in a material respect," whether through affirmative "representations made or suggested" by the advertisement or through a "fail[ure] to reveal facts material in light of such representations." *Id.* § 55(a)(1). Thus, "a false advertisement need not even be false; it need only be misleading in a material respect." *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1099 (9th Cir. 1994) (quotation omitted).[2]

An advertisement violates Sections 5 and 12 of the FTC Act when it (1) contains a representation that (2) is likely to mislead consumers acting reasonably

[2] Congress authorized the FTC to seek relief for deceptive advertising by issuing an administrative complaint, *see* 15 U.S.C. § 45(b), or—as here—by pursuing equitable remedies in district court, *see* 15 U.S.C. § 53(b).

under the circumstances and (3) is material to a consumer's decision to purchase the product. *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006) (citing FTC, *Policy Statement on Deception*, 103 F.T.C. 174, 178 (1984)[3]); *Pantron I*, 33 F.3d at 1095.

When an advertiser makes objective claims about a product's performance or functions, it represents "explicitly or by implication that the advertiser has a reasonable basis supporting these claims." FTC, *Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839, 839 (1984) (*Substantiation Statement*). An ad "is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it." *Thompson Med. Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986). The advertiser must have evidentiary substantiation, sufficient under the circumstances, for making the claims at issue. *See id.*; *POM Wonderful*, 155 F.T.C. 1, 28 (2013), *enforced in relevant part*, *POM Wonderful, LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015). Without adequate substantiation, an ad is "deceptive as a matter of law." *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010). *See also Bristol-Myers Co. v. FTC*, 738 F.2d 554, 560-61 (2d Cir.

[3] Page citations are to the official FTC Decisions volumes, which are available at https://www.ftc.gov/enforcement/cases-proceedings/commission-decision-volumes. The Westlaw and Lexis versions of FTC decisions are not paginated consistently with the official reporter.

1984) (upholding FTC remedial order requiring advertiser to support its claims with a "reasonable basis").

Advertising claims fall into two basic categories for substantiation purposes. An *efficacy claim* represents that a product successfully provides the advertised benefit, such as improving memory. Advertisers must possess "competent and reliable scientific evidence" for their health-related efficacy claims. *See, e.g.*, *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009); *Daniel Chapter One*, FTC No. 9329, 2009 WL 5160000, at *26 (Dec. 24, 2009), *enforced*, *Daniel Chapter One v. FTC*, 405 F. App'x 505 (D.C. Cir. 2010). To determine the level of substantiation required in a given case, the FTC employs a multifactor analysis. *See POM Wonderful*, 777 F.3d at 490-91 (discussing *Pfizer Inc.*, 81 F.T.C. 23, 62-64 (1972)).[4]

An *establishment claim* represents that the advertiser has scientific evidence backing up its efficacy claim. *POM Wonderful*, 777 F.3d at 490; *see Bristol-Myers*, 738 F.2d at 557. For establishment claims, the advertiser typically "must possess evidence sufficient to satisfy the relevant scientific community of the claim's truth." *POM Wonderful*, 777 F.3d at 491 (quoting *Bristol-Myers Co.*, 102

[4] Relevant factors include "(1) the type of claim; (2) the type of product; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable." *POM Wonderful*, 155 F.T.C. at 55.

F.T.C. 21, 321 (1983), *enforced*, *Bristol-Myers*, 738 F.2d 554). But if an establishment claim "states a specific type of substantiation"—for example, that a randomized controlled trial proved the advertised benefits—the "advertiser must possess the specific substantiation claimed." *POM Wonderful*, 777 F.3d at 491 (quoting *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492 n.3 (1st Cir. 1989)); *see Thompson Med.*, 791 F.2d at 194; *Substantiation Statement*, 104 F.T.C. at 839.[5] In the present case, the complaint alleges that Quincy made both efficacy and establishment claims resting on the Madison Memory Study. JA37-40 (Compl. ¶¶ 28, 30, 36, 39).

Whether an advertiser has adequate substantiation for its claims is a question of fact. *Bristol-Myers*, 738 F.2d at 559, 562. These cases often require complex scientific analysis, ordinarily supplied by expert testimony addressing what level of substantiation the scientific community would demand for the claims under review and whether the advertiser possessed it. Thus, in *Direct Marketing Concepts*, the First Circuit affirmed summary judgment for the FTC based on "four expert declarations . . . compar[ing] the Defendants' evidence to the available literature and conclud[ing] in each case that the Defendants' evidence was woefully inadequate." 624 F.3d at 10-11. Likewise, in *Bristol-Myers*, this Court upheld the

[5] When an advertiser makes an establishment claim without possessing the level of proof conveyed in its ads or demanded by the scientific community, the claim is not simply unsubstantiated, but "false." *POM Wonderful*, 155 F.T.C. at 28.

FTC's finding, based on a medical expert's testimony, "that only well-controlled clinical studies could establish that Bufferin causes less stomach upset than aspirin." 738 F.2d at 559.

Ads that make health claims typically require a high level of substantiation because consumers cannot readily verify the claims for themselves. *See, e.g.*, *POM Wonderful*, 155 F.T.C. at 56. Memory and cognitive problems in particular make consumer verification difficult, as they "may prevent reliable comparisons by a consumer between different [products] taken on different occasions." *Am. Home Prods. Corp. v. FTC*, 695 F.2d 681, 698 (3d Cir. 1982). And even if a consumer *does* experience positive results from a dietary supplement, that could be a placebo effect. "[E]ven a product of no inherent merit whatsoever will often have some degree of effectiveness in treating the condition for which it is employed, for psychological or other reasons." *Pantron I*, 33 F.3d at 1090 n.1. Thus, an advertiser's "[p]roof is what separates an effect new to science from a swindle." *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008).

Even if the advertised product is "safe," health claims lacking adequate substantiation can injure consumers in several ways. Consumers waste money when they buy a product that does not work as advertised (here, as discussed on page 10 below, consumers spent over $165 million on Prevagen, paying up to $70 for a monthly supply). Consumers will pay premium prices when they believe that

a product will help remedy serious health conditions. *See, e.g.*, *Thompson Med. Co*, 104 F.T.C. 648, 824 (1984), *enforced*, *Thompson Med.*, 791 F.2d 189; *see also QT*, 512 F.3d at 863 ("One important reason for requiring truth is so that competition in the market will lead to appropriate prices."); *Pantron I*, 33 F.3d at 1100 (deceptive advertising "create[s] a substantial economic cost"). More importantly, unfounded claims that a supplement will remedy a health problem may lead consumers to forgo other, better treatments and to skip medical supervision. *See, e.g.*, *QT*, 512 F.3d at 863; *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1210. Serious diseases may go undetected or untreated.

B. Quincy's Sale And Marketing Of Prevagen

Since 2007, Quincy has sold Prevagen online and through major retail stores and pharmacy chains. JA20 (Compl. ¶ 21). Quincy charged $60 for a monthly supply of Prevagen at "regular strength" and $70 for "extra strength." JA90, 94 (Compl. Exh. C, Dec. 2016 Website Capture, pp. 34, 38). Between 2007 and mid-2015, Quincy sold $165 million worth of Prevagen. JA20 (Compl. ¶ 21). According to Quincy, "Prevagen is now the number one selling brain support supplement in chain pharmacies across America." JA63 (Compl. Exh. C, p. 7).

Between 2013 and 2015, Quincy ran an infomercial, the "Better Memory Show," featuring Quincy's co-founder and president, defendant-appellee Mark Underwood. JA21 (Compl. ¶ 23). Underwood lamented, "[a]s the baby boomers

continue to age, we see more and more people that are struggling with day-to-day activities," and "lose their car keys or their cell phone" or "walk into a room and forget where we're going." JA151 (Compl. Exh. E, Infomercial Tr. p. 6). He declared that Prevagen can help solve these problems because it contains a "unique protein found in the jellyfish to . . . help our memory improve, and that's offering a lot of hope to people." JA152 (Compl. Exh. E, p. 7).

Underwood told his audience that Quincy has clinical proof of Prevagen's memory-restoring benefits. He explained, "[a] large double blind, placebo-controlled trial that we completed . . . showed great efficacy for Prevagen, showing statistically significant improvements in word recall, in executive function, and also in short term memory." JA155 (Compl. Exh. E, p. 10). Underwood added: "In the clinical trial, we were showing those benefits after the first month and those continued to improve after the second and third months." JA156 (Compl. Exh. E, p. 11). Underwood claimed that even though Prevagen users had "different levels of health," "the majority of people see the benefit of Prevagen very quickly." JA164 (Compl. Exh. E, p. 19).

Quincy also aired ordinary TV commercials—on CNN, Fox News, NBC, and similar outlets (JA21 (Compl. ¶ 24))—in which an announcer asked, "Can a protein originally found in the jellyfish improve your memory? . . . Our scientists say yes." JA52 (Compl. Exh. B, TV Commercial Tr., p. 4). The announcer

explained that "[a]s we age, we lose proteins that support our brain. . . . Prevagen supplements these proteins and has been clinically shown to improve memory." JA52-53 (Compl. Exh. B, pp. 4-5).

Quincy's website elaborated on Prevagen's claimed effects and proof. According to the site, "Prevagen was tested in a large double-blind, placebo-controlled study using computers to assess brain performance," and the study showed that "Prevagen improved memory for most subjects within 90 days." JA57, 62 (Compl. Exh. C, Dec. 2016 Website Capture, pp. 1, 6). The website also claimed that the entire "apoaequorin arm" of the study—*i.e.*, those who received Prevagen—"showed a statistically significant improvement." JA59 (Compl. Exh. C, p. 3). Quincy repeated these broad claims in a "Brain Health Guide" sent with product orders and available online, which similarly asserted that the entire "Prevagen group" of the study saw improved memory. JA18, 21 (Compl. ¶¶ 14, 26); JA127-28 (Compl. Exh. D, pp. 21-22).

Quincy's website also explained how Prevagen purportedly works. It claimed that memory loss occurs when the brain "can't make enough [protein] to keep up with the brain's demands. Prevagen supplements these proteins during the natural process of aging to keep your brain healthy." JA62 (Compl. Exh. C, p. 6). The site suggested, based on a study performed on dogs, that apoaequorin enters the brain via the nervous and circulatory systems. Apoaequorin, Quincy stated, "is

capable of crossing the blood brain barrier (BBB) and GI [gastrointestinal] barrier." JA61 (Compl. Exh. C, p. 5).

C. The FTC And New York Enforcement Complaint

The FTC and the State of New York charged Quincy, three subsidiaries, Underwood, and Quincy's co-founder and CEO, Michael Beaman, with false and deceptive advertising. JA14-45.[6] According to the complaint, Quincy's ads made express and implied claims that Prevagen (1) improves memory, (2) does so within 90 days, (3) reduces memory problems associated with aging, and (4) provides other cognitive benefits, and that (5) all of these benefits are clinically proven. JA37 (Compl. ¶ 28). The complaint alleges that Quincy lacked support for any of these claims.

The complaint charges that Quincy's advertising campaign "primarily rel[ied] on" the Madison Memory Study, a 90-day-long "double-blind, placebo-controlled human clinical study using objective outcome measures of cognitive function." JA37 (Compl. ¶ 28). But the study "failed to show a statistically

[6] The complaint alleges that the corporate defendants "operated as a common enterprise . . . through an interrelated network of companies that have common ownership, officers, managers, business functions, employees, and office locations." JA19 (Compl. ¶ 17). Beaman and Underwood "directed, controlled, had the authority to control, or participated in" the alleged violations. *Id.*

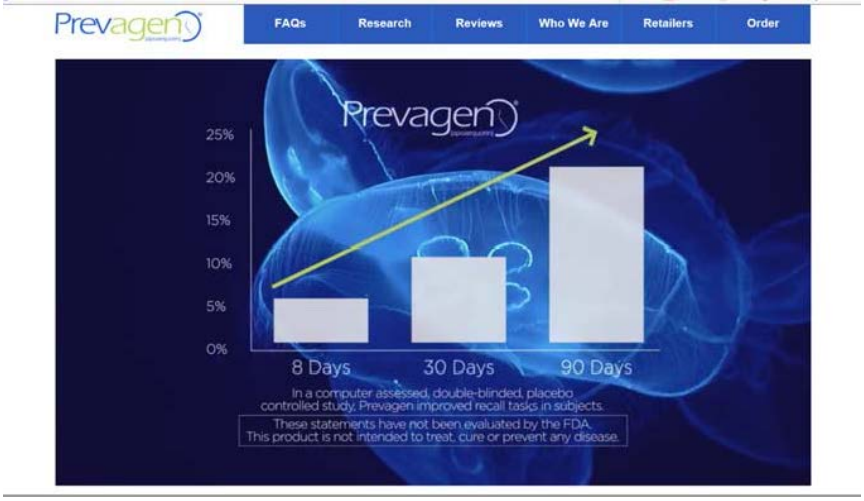
significant improvement in the treatment group over the placebo group on any of the nine . . . tasks." *Id.*[7]

Once Quincy's researchers discovered that their study "fail[ed] to find a treatment effect for the sample as a whole," they embarked on a quest to mine the study data for some positive result. JA37 (Compl. ¶ 29). To that end, they "conducted more than 30 post hoc analyses" by splitting the study population into "smaller subgroups" of participants for each of nine separate cognitive tasks. *Id.* Even then, the "vast majority" of Quincy's subgroup analyses "failed to show statistical significance between the treatment and placebo groups." *Id.* The post hoc analyses did show a "few positive findings on isolated tasks for small subgroups," but these findings "d[id] not provide reliable evidence" that Prevagen could improve memory or provide the other advertised benefits. *Id.* Instead, Quincy's methodology of running numerous after-the-fact comparisons "greatly increase[d] the probability" that results that appeared "statistically significant" were actually false positives "occur[ring] by chance alone." *Id.*

Despite Quincy's failure to find positive results for the study population at-large, the vast majority of "subgroups," or the vast majority of tested cognitive tasks, Quincy made the Madison Memory Study the centerpiece of its advertising

[7] Statistical significance is "a measure of the probability that a disparity is simply due to chance, rather than any other identifiable factor." *Ottaviani v. SUNY at New Paltz*, 875 F.2d 365, 371 (2d Cir. 1989).

campaign. JA38 (Compl. ¶ 30); *see* Part B, *supra*. For example, Quincy used the following graphic on its product labels, TV ads, and website:



JA38 (Compl. ¶ 30). The graphic shows a dramatic improvement in recall tasks; in fact, the Madison Memory Study showed no statistically significant improvement in recall. *Id.* In addition, Quincy omitted from the chart one of the four data points in the study—day 60—likely because the participants in fact had *lower* recall scores at day 60 than they did at day 30 (and performed worse than the placebo group). *Id.*

Quincy also lacked adequate substantiation for its claims about how Prevagen works. Quincy represented that the jellyfish protein apoaequorin enters the brain to replace lost proteins. JA38 (Compl. ¶ 31). Yet Quincy had no evidence that apoaequorin "can cross the human blood-brain barrier" and thus "enter[] the human brain." *Id.* In fact, Quincy's own "safety studies show that

apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein." JA38-39 (Compl. ¶ 31).

Count I of the complaint charges Quincy and its co-defendants with making false or unsubstantiated claims about Prevagen's benefits in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52. JA39-40 (Compl. ¶¶ 36-38). Count II alleges that the defendants violated the same laws by falsely depicting Prevagen's benefits as clinically proven. JA40 (Compl. ¶¶ 39-41). Counts III and IV allege violations of analogous New York statutes. JA41-42 (Compl. ¶¶ 42-45).

D. Quincy's Motion To Dismiss And Evidentiary Proffer

Quincy moved to dismiss, arguing that the complaint failed to state a claim because its advertising had a "more-than-sufficient" factual basis as a matter of law. JA203 (ECF No. 34 at 6).[8] Quincy premised the motion on facts and evidence extrinsic to the complaint, and the district court relied on that material in dismissing the case. Although the district court should never have considered this

[8] For ease of description, we will use "Quincy" when referring to arguments advanced by all of the defendants. Quincy also argued that the Commission's decision was *ultra vires* because it lacked a sufficient quorum to authorize the complaint, and that the relief sought would be an unconstitutional restraint on commercial speech. Individual defendants Underwood and Beaman filed a separate motion to dismiss arguing that the court lacked personal jurisdiction and that they should not be held personally liable for any corporate wrongdoing. The district court did not address these issues.

information (*see* Part II, below), we describe it here so the Court may fully understand the matter.

First, Quincy described a National Institutes of Health clinical study concerning the effects of dietary supplements on macular degeneration where the researchers examined data on subgroups. Quincy claimed that the researchers' analysis and report showed that subgroup analyses are "common in nutrition research and [are] often used by reputable organizations, including the federal government's own [NIH]." JA204, 208-09, 218 (ECF No. 34 at 7, 11-12, 21).

Second, Quincy proffered a company-prepared "Clinical Trial Synopsis" of the Madison Memory Study. JA235-44 (ECF No. 35). The synopsis was neither published nor peer-reviewed. Quincy created it in August 2016, more than five years after the study had ended, several years after the advertising campaign had begun, and a few months before the FTC filed its complaint. JA235 (ECF No. 35 at 4). Consistent with the complaint, the synopsis acknowledged that Quincy gave participants nine cognitive tests to measure verbal learning, memory, and similar tasks, and found "no statistically significant results" for the study population on any of the tests. JA236, 239 (ECF No. 35 at 5, 8).

The synopsis also described how Quincy created subgroups using an eight-question screening tool known as AD8 in which individuals self-reported their levels of cognitive aging. JA236 (ECF No. 35 at 5). According to the synopsis,

Quincy focused its attention on subgroups of participants with AD8 scores of 0 through 2, who—in Quincy's view—were "cognitively normal or very mildly impaired." *Id.* The synopsis attempted to justify this decision on the ground that "[b]ecause 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.*; *see also* JA238-39 (ECF No. 35 at 7-8). Left unexplained, however, was the fact that under the original study design, the *entire study population*—including those with AD8 scores above 2—were "healthy" individuals without "significant neurological disease." *See* JA238 (ECF No. 35 at 7) (describing the "Study Sample").[9]

The synopsis concluded that participants in the AD8 0-1 and 0-2 subgroups who took Prevagen showed statistically significant improvements over the placebo on three out of nine cognitive tasks. JA243 (ECF No. 35 at 12). These subgroups showed no significant results on any of the other six tasks. The synopsis did not report the results for study participants with AD8 scores *above* 2, even though, they, too, were, by the study's design, healthy and disease-free.

[9] Indeed, Quincy advertised that the study population consisted of people who were "experiencing some mild memory problems associated with aging," JA59 (Compl. Exh. C, Prevagen Website, p. 3), and were "undiagnosed with any type of memory disorder," JA126 (Compl. Exh. D, Brain Health Guide, p. 20).

E. The District Court's Decision

The district court dismissed the complaint for failure to state a claim. SA1-13. The court acknowledged that Quincy did not contest the allegations that its ads made the claims at issue and that those claims were material to consumers' decisions to purchase Prevagen. SA10. Instead, the sole question was whether the complaint "allege[s] facts from which it can be reasonably inferred that the representations at issue are false or unsubstantiated." *Id.* On this issue, the court rejected the complaint's charge that the Madison Memory Study did not support the advertising claims.

The court recognized that (1) the Madison Memory Study "failed to show a statistically significant improvement in the experimental group over the placebo group as a whole" and that (2) most of Quincy's analyses of small subgroups "showed no statistical significance between the treatment and placebo groups." SA10-11. Nevertheless, the court relied on Quincy's study synopsis to make a factual finding that the AD8 0-1 and 0-2 subgroups "displayed improvement in memory after taking the supplement," thus rejecting the charge that such results were unreliable and may have been false positives. SA11; *see also* SA5-6 (finding

that members of these subgroups "showed statistically significant improvements . . . in three of the nine tasks").[10]

The court held that the complaint failed to explain why Quincy's decision to run more than 30 "*post hoc* exploratory analyses [produced] an increased risk of false positives" or how such false positives "affected the subgroups[']performance." SA11. The court found the complaint's challenge to the reliability of the subgroup analyses to be merely "theoretical" and faulted the complaint for not demonstrating that any "actual errors occurred" in the study. *Id.* The court further explained that the complaint had not alleged that the risks of false positives were "so large in the abstract that they prevent any use of the subgroup concept," which, the court opined, is "widely used in the interpretation of data in the dietary supplement field." *Id.* The court thus proclaimed, "All that is shown by the complaint is that there are possibilities that the study's results do not support its conclusion." SA12.

The court also rejected the complaint's allegation that Quincy's own internal research showed that Prevagen could not work as advertised because its active ingredient broke down in the stomach before even reaching the brain. Weighing

[10] The court also adopted the synopsis's conclusion that certain other non-significant results showed a "*trend* toward significance." SA5-6 (emphasis added), discussing JA240-43 (Clinical Trial Synopsis). As discussed below, "trends" towards significance are arguably not a valid statistical concept, *see* note 17, *infra*.

the evidence, the court found that the Madison Memory Study "ma[d]e it clear that *something* caused a statistically significant difference between those subjects who took Prevagen and those given a placebo." SA7 n.3 (emphasis added). The court added that allegations that Prevagen did not enter the human brain were "contradicted by canine studies." *Id.*

SUMMARY OF ARGUMENT

This case is a classic example of a district court violating basic principles governing motions to dismiss. The court improperly drew inferences against the complaint, appointed itself as an expert, and rendered factual findings—all fundamental errors of law. The truthfulness of advertising claims that are based on scientific studies and statistical analyses is a quintessential matter for expert opinion and analysis. The claims can be properly assessed only after the development and consideration of a full record. Yet the district court erroneously jumped the gun and held that Quincy's manipulation of the statistical analysis was scientifically sound and that the scant positive results of that analysis supported its claims as a matter of law.

1. Quincy told consumers that Prevagen would boost their memories within 90 days, reduce age-related memory loss, and provide other cognitive benefits—and that it had proof of those effects. The complaint states a plausible case that those claims violated the FTC Act because they were deceptive. The Madison

Memory Study showed no statistically significant treatment effect, either for the entire study population or for the vast majority of subgroups. The complaint plausibly alleges that experts would not accept cherry-picked data showing a few positive findings for small subgroups on isolated tasks as support for unqualified claims of improved memory. A factfinder could conclude, after hearing expert testimony and reviewing a fully developed record, that Quincy's claims were not supported by the science that it touted as showing that Prevagen improves memory.

The district court rested its decision on data showing that some subgroups of study participants showed statistically significant positive effects on some discrete tasks. But the complaint alleges that the positive subgroup results could have stemmed from chance alone. Even "statistically significant" results can be false positives, and the probability of encountering a false positive "greatly increases" with the number of additional statistical tests performed. JA37 (Compl. ¶ 29). A factfinder, after hearing expert testimony, could conclude that Quincy's methodology of performing multiple statistical tests produced a high likelihood of false positives. An expert could deem the few positive results here particularly unreliable because they were at odds with the negative results for the study population as a whole and for the vast majority of subgroups.

The complaint also sufficiently alleges that Quincy deceived consumers because it knew from its own safety studies that Prevagen's active ingredient was

digested in the stomach and thus could not enter the brain to supplement lost brain proteins as advertised. Yet Quincy told consumers that Prevagen's protein enters the brain after crossing the blood-brain barrier. The complaint states a plausible claim of deceptive advertising on that independent ground alone.

2. The district court failed to take the complaint's allegations as true and draw reasonable inferences in the plaintiffs' favor. Instead, the court resolved disputed questions of neuroscience, statistics, and clinical-trial methodology in the absence of a factual record or expert testimony. To make matters worse, the court reached its factual judgments on the basis of evidentiary submissions Quincy provided with its motion to dismiss.

The district court improperly resolved four key factual disputes: *First*, although the complaint charges that the subgroup results were unreliable, the court found that the subgroup members "displayed improvement in memory" (SA11), and that "something" other than chance must have caused those results (SA7 n.3). *Second*, although the complaint pleads that Prevagen's active ingredient is digested in the stomach, the court found as fact that the ingredient enters the brain (SA7 n.3). *Third*, although the matter is one for expert evidence, the court determined that subgroup analyses are "widely used in the interpretation of data in the dietary supplement field" and that the alleged "risks" of these analyses did not outweigh the benefits. SA11. *Fourth*, although the court lacked before it most of the results

from the overwhelmingly negative Madison Memory Study or any testimony about the study design, the court adopted Quincy's assertion that the positive results for two small subgroups were the data "most relevant to the efficacy of the product." SA4 (quoting JA236).

Several of these factual findings rested on evidence outside the complaint. The district court explicitly relied on a "Clinical Trial Synopsis" that Quincy appended to its motion to dismiss to reach its conclusions about proven improvement in memory and the relevance of the few positive study results. Quincy prepared the synopsis as an advocacy document long after the conclusion of the Madison Memory Study. The synopsis only described the results for two subgroups and left out the negative data for the study population as a whole and the vast majority of subgroups. In addition, the court appears to have based its finding about the "widely used" nature of subgroup analyses on a single study that Quincy cited in its motion to dismiss. In fact, the authors of that study warned that the subgroup results should be used with caution and may not be generalizable to the broader public. The court's reliance on Quincy's extrinsic materials wrongly deprived the plaintiffs of "an opportunity to contest" the new evidence "by submitting material that controverts it." *See Global Network Commc'ns, Inc. v. City of New York*, 458 F.3d 150, 155-56 (2d Cir. 2006); Fed. R. Civ. P. 12(d).

The district court substituted its own opinions for those of expert witnesses, whose testimony is critical in a case that requires interpretation of scientific studies and statistical evidence. Expert testimony could show, for example, that a robust scientific literature cautions that after-the-fact subgroup analyses conducted in the wake of a failed study can be unreliable. According to these scientists, post hoc analyses at most provide tentative data points that researchers must confirm through future study.

The district court violated nearly every principle governing motions to dismiss. Its decision should be reversed.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's dismissal of a complaint under Rule 12(b)(6), "construing the complaint liberally, accepting all factual allegations [in the complaint] as true, and drawing all reasonable inferences in the plaintiff's favor." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230 (2d Cir. 2016). A complaint will survive a motion to dismiss if it "contain[s] 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 is facially plausible "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.* A complaint need not contain

a detailed recitation of facts, but only "a short and plain statement . . . showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2).

ARGUMENT

The district court committed serious and fundamental errors in dismissing this case. A motion to dismiss "challenges the complaint as presented by the plaintiff, taking no account of its basis in evidence." *Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016). The purpose is to test the complaint's "formal sufficiency . . . without resolving a contest regarding its substantive merits." *Halebian v. Berv*, 644 F.3d 122, 130 (2d Cir. 2011) (quotation omitted). The court violated these basic constraints, serving as its own expert, weighing the evidence, and deciding which side was right.

Compounding its error, the district court also relied on facts outside the complaint. To resolve a motion to dismiss, a court should consider the "narrow universe" of facts stated on the face of the complaint, documents that the complaint appends or incorporates by reference, and matters of which judicial notice may be taken. *Goel*, 820 F.3d at 559. The district court here considered—and gave dispositive credence to—Quincy's synopsis of the Madison Study, which meets none of those criteria.

The Supreme Court has admonished that Rule 12(b)(6) does not require a plaintiff to demonstrate a "probability" of success. *Twombly*, 550 U.S. at 556. As

this Court has applied that principle, the question is whether the complaint "states a plausible version of . . . events," even if the "court finds a different version more plausible." *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) (citation omitted). The district court's disposition of this case collides with those basic principles.

The complaint allegations, taken as true, more than plausibly show that Quincy's ads were deceptive in several ways. Quincy made across-the-board claims that Prevagen improves memory within 90 days and reduces age-related memory loss, but its own clinical trial showed that the product had no statistically significant positive results for the study population as a whole or for the vast majority of subgroups. Manipulating the study data yielded a few positive results from that predominantly negative set of findings, but the methods used greatly increased the probability that those results were false positives stemming from chance alone. The complaint raises a triable factual question whether the scientific community would accept Quincy's findings as sufficient support for its claims. In addition, Quincy knew from internal company research that Prevagen could not work as advertised because its active ingredient is broken down and digested in the stomach and therefore could not enter the brain. The Court should vacate the district court's dismissal and hold that the complaint states a plausible deception claim under the FTC Act.

I. THE COMPLAINT STATES A PLAUSIBLE CLAIM OF DECEPTIVE ADVERTISING

A court assessing whether an advertisement is deceptive must undertake three tasks. First, it must examine the specific claims made by the ads. Second, it must determine what type and amount of substantiation was required to support those specific claims. Third, the court must determine whether the advertiser had the requisite substantiation. *See Direct Mktg. Concepts*, 624 F.3d at 8, 11; *POM Wonderful*, 777 F.3d at 490-91; *POM Wonderful*, 155 F.T.C. at 10-11, 28-29, 34. The complaint, taken as true and with reasonable inferences drawn in its favor,[11] plainly states a claim under that framework.

A. The Complaint Plausibly Alleges That The Failed Madison Memory Study Does Not Support Quincy's Advertising Claims

The complaint charges that Quincy represented without qualification that Prevagen is "clinically shown" to (A) "improve memory," (B) do so "in 90 days," (C) "reduce memory problems associated with aging," and (D) "provide other cognitive benefits." JA40 (Compl. ¶ 39). The ads declared that the Madison Memory Study's entire "Prevagen group" or "apoaequorin arm" saw these results. *See* JA59 (Compl. Exh. C., Prevagen Website, p. 3); JA127-28 (Compl. Exh. D, Brain Health Guide, pp. 21-22). The ads targeted a large segment of the

[11] All of the facts discussed in the Argument section of this brief assume the truth of the allegations of the complaint.

population—including "baby boomers"—and asserted that Prevagen could ease their "struggl[e] with day-to-day activities." JA151 (Compl. Exh. E, Infomercial Tr. p. 6). The ads assured consumers that even though they may have "different levels of health . . . the key is that the majority of people see the benefit of Prevagen." JA164 (Compl. Exh. E, p. 19).

In addition to those efficacy claims, Quincy also made the establishment claim that its study proved the effects were real. Quincy must therefore "possess the specific substantiation claimed," and that evidence must be "sufficient to satisfy the relevant scientific community of [the claims'] truth." *POM Wonderful*, 777 F.3d at 491 (citations and quotation marks omitted).

The complaint plausibly charges that Quincy lacked proof of the specific claims made in its advertisements. The Madison Memory Study showed *no scientifically reliable benefits for any of its participants*. For the study population as a whole, the study "failed to show a statistically significant improvement in the treatment group over the placebo group on any of the nine computerized cognitive tasks." JA37 (Compl. ¶ 28). And even after Quincy carved up the data through "more than 30 post hoc analyses of the results," it *still* found that the "vast majority" of subgroup comparisons "failed to show statistical significance between the treatment and placebo groups." JA37 (Compl. ¶ 29). Finally, as described further in Part I.B, below, even though Quincy's post hoc analyses revealed a "few

positive findings on isolated tasks for small subgroups," that evidence did "not provide reliable evidence of a treatment effect." *Id.*

These allegations, taken as true and with inferences drawn in the plaintiffs' favor, clearly raise a triable question of fact about whether Quincy's advertisements were supported by the "specific substantiation claimed" and whether that substantiation was "sufficient to satisfy the relevant scientific community." *See POM Wonderful*, 777 F.3d at 491 (citations and quotation marks omitted). A factfinder could conclude after hearing evidence on statistics, study design, data analysis, neuroscience, or similar topics that Quincy's advertising claims did not match its science.

The district court failed to even consider what claims Quincy was actually making and whether the Madison Memory Study supported those claims. *See* SA10-12. *See also Moll v. Telesector Res. Grp., Inc.*, 760 F.3d 198, 203 (2d Cir. 2014) (vacating 12(b)(6) dismissal because the district court "failed to consider all allegations in the Complaint in their totality"). Instead, the court simply assumed that if Quincy's post hoc analysis of the study found *some* results for *some* people, that would be enough as a matter of law to inoculate Quincy from all deception charges. *See* SA11. That assumption was incorrect. The question is not whether a study produced any results in the abstract, but whether those results support the specific claims at issue. *See POM Wonderful*, 777 F.3d at 494. Had the district

court analyzed Quincy's specific advertising claims, it hardly could have avoided drawing the inference that they were deceptive.

B. The Complaint Plausibly Alleges That A Few Positive Subgroup Results Are Not Reliable Evidence That Prevagen Works As Advertised

The complaint also sufficiently alleges that the positive subgroup results did not support Quincy's advertisements because they were unreliable and may have resulted from chance alone. *See* JA37 (Compl. ¶ 29). Those allegations state a plausible claim that could be resolved only on a full factual record including expert testimony.

Quincy's post hoc analyses carved up the data into "several variations of smaller subgroups for each of the nine computerized cognitive tasks." *Id.* Like the study itself, the "vast majority" of these analyses "failed to show statistical significance between the treatment and placebo groups." *Id.* The data dredging turned up a "few positive findings on isolated tasks for small subgroups." *Id.* But, as the complaint alleges, performing so many subgroup analyses "greatly increase[d] the probability that some statistically significant differences would occur by chance alone." *Id.* Those facts, if proven, would show that the subgroup analysis did not support the claims Quincy made about its product. A factfinder could plausibly conclude after considering supporting evidence, including expert testimony, that the study did not show meaningful benefits and that the few

positive results likely consisted either of statistical noise or of random outliers that could not be generalized to the population as advertised.

The district court was wrong to hold that the complaint failed to explain why conducting multiple subgroup analyses heightened the risk of false positives. SA11-12. Even 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. *Ottaviani v. SUNY at New Paltz*, 875 F.2d 365, 371 (2d Cir. 1989). It follows that the odds of a study generating one or more false positives increase each time experimenters consider an additional independent outcome. Here, the probability of finding one or more false positives was high, because Quincy's researchers "conducted more than 30 post hoc analyses of the results," slicing up the data set into "several variations of smaller subgroups" and assessing their performance on nine distinct tasks. JA37 (Compl. ¶ 29).[12] As the complaint alleges, Quincy's methodology of conducting multiple subgroup analyses "greatly increases the probability" of false positives. *Id.*

[12] For example, statisticians have calculated that when experimenters conduct 10 independent analyses of subgroup outcomes, the probability of drawing a false positive is 40 percent and that with 20 independent analyses, those odds rise to 64 percent. *See* Richard M. Simon, *Subgroup Analysis* at 3, in Wiley Encyclopedia of Clinical Trials (2008), available at http://onlinelibrary.wiley.com/doi/10.1002/9780471462422.eoct356/pdf (last visited Feb. 27, 2018).

That Quincy conducted its subgroup analyses after the study failed to show results for the treatment group provides an additional reason to doubt their validity. *See* JA37 (Compl. ¶ 29) (explaining that these results were unreliable "[g]iven the sheer number of comparisons run and the fact that they were post hoc").[13] Such an approach was suspect because it relied on findings contradicted by the main results of Quincy's study—results from the analysis that it actually planned as part of the experimental design. JA37 (Compl. ¶ 28). This mode of after-the-fact analysis has been described as "placing a bet on a horse after watching the race."[14] Of course, the specifics of this study and its analysis can be resolved only with the benefit of a full record, including expert testimony on this inherently technical subject. At this point, however, the complaint clearly sets forth a plausible claim that the subgroup results do not support the advertisements Quincy based on them.

Likewise, a factfinder could reject the reliability of the subgroup results on which Quincy relies simply because they were at odds with the "vast majority" of

[13] The district court faulted the complaint for using the words "post hoc" to allege "some deficiency in integrity, never specified." SA11 n.4. In fact, the complaint uses "post hoc" in its ordinary sense: "[a]fter this; subsequently." BLACK'S LAW DICTIONARY (10th ed. 2014). As the complaint explains, the subgroup results were "post hoc" because Quincy decided to perform them only "[a]fter failing to find a treatment effect for the sample as a whole." JA37 (Compl. ¶ 29). Scientists commonly describe post hoc analyses in terms similar to the complaint. *See, e.g.*, Peter M. Rothwell, S*ubgroup Analysis in Randomised Controlled Trials*, 365 Lancet 176, 181 (2005) (describing "[s]elective reporting of post hoc subgroup observations, which are generated by the data rather than tested by them").

[14] Rothwell, *supra* note 13, at 181.

the subgroup analyses, which failed to show the advertised effects. JA37 (Compl. ¶ 29). Indeed, the results of subgroups showing an effect were *themselves* equivocal, since they did not show significant results across-the-board, but only on "isolated tasks." *Id.*[15] The complaint's specific allegations give more than enough reason to infer that the subgroup results were not a reliable basis for Quincy's advertising claims of improved memory within 90 days.

Had they been given the chance (as they should have been), the plaintiffs could have supported these allegations with expert testimony about the problems with the multiple subgroup comparisons that Quincy performed in this case. For example, the Federal Judicial Center's *Reference Manual on Scientific Evidence* explains that "[r]epeated testing complicates the interpretation of significance levels. If enough comparisons are made, random error almost guarantees that some will yield 'significant' findings, even when there is no real effect." David H. Kaye & David A. Freedman, *Reference Guide on Statistics*, in *Reference Manual*

[15] Quincy's study synopsis (submitted only with its motion to dismiss, and which the district court improperly considered, see Part II.B, *infra*) concedes that "no statistically significant results were observed over the entire study population" and that even the subgroups displaying some potential benefits showed no statistically significant results for six out of nine cognitive tasks. *See* JA239-43 (ECF No. 35 at 8-12).

on Scientific Evidence 256 (Federal Judicial Center 3d ed. 2011).[16] In fact, "[a]lmost any large dataset . . . will contain some unusual pattern that can be uncovered by a diligent search." *Id.* When an experimenter then performs a statistical test for that pattern, "[s]tatistical significance is bound to follow," even if the results are due to random chance. *Id.* Because of the problems that arise when experimenters take "multiple looks at the data," "courts should not be overly impressed with claims that estimates are significant. Instead, they should be asking how analysts developed their models." *Id.* at 256-57.

But without asking such questions or waiting for expert answers, the district court explained that it was rejecting the complaint's allegations because they were merely "theoretical" and failed to "allege that any actual errors occurred" by detailing which "subgroups . . . registered any false positives." SA11. The court thus drew inferences against and rebuffed an unmistakably plausible claim because it was not accompanied by a rigorous description of corroborating evidence. But Rule 12(b)(6) does not "require the pleading of specific evidence or extra facts beyond what is needed to make the claim plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120-21 (2d Cir. 2010).

[16] Federal courts commonly rely on the *Reference Manual* when confronting scientific and statistical questions. *See, e.g., Comcast Corp. v. Behrend*, 569 U.S. 27, 38 (2013).

In fact, the district court imposed an unfair pleading burden on the FTC, because it is not possible to prove with certainty that an isolated finding from a subgroup analysis is a false positive. The science of statistics deals with probability, not certainty. An expert can assess the reliability of a study's findings by evaluating whether the methods used to obtain them adequately reduce the probability of error and by considering whether other evidence is supportive. Here, the complaint shows why Quincy's subgroup methods *were likely to* produce false positives, a question to be addressed by expert witnesses at trial, and thereby provides "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see* Fed. R. Civ. P. 8(a).

C. The Complaint Plausibly Alleges That Prevagen Cannot Work As Advertised Because Its Active Ingredient Does Not Enter The Brain

Even apart from the allegations about the Madison Memory Study, the complaint plausibly alleges that Quincy's ads were deceptive because Quincy's other studies showed that Prevagen cannot reach the brain and therefore cannot replace brain proteins lost with age, as Quincy's ads claim.

The complaint charges that Quincy's ads "rely on the theory that the product's dietary protein, apoaequorin, enters the human brain to supplement endogenous proteins that are lost during the natural process of aging." JA38 (Compl. ¶ 31). Quincy's website declared explicitly that Prevagen's active

ingredient "is capable of crossing the blood brain barrier." JA61 (Compl. Exh. C at 5). In fact, the complaint charges, Quincy lacks "evidence that apoaequorin enters the human brain," and no study shows "that orally-administered apoaequorin can cross the human blood brain barrier." JA38 (Compl. ¶ 31). Indeed, Quincy's own "safety studies show that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein." JA39 (Compl. ¶ 31).

These allegations create a reasonable inference that Quincy's claims about Prevagen's mechanism of action—and thus its effects—were deceptive. An advertisement is misleading when it claims that a product has a certain mechanism of action but the seller has "no credible theory explaining how the[] products work." *See Pantron I*, 33 F.3d at 1097 (emphasis omitted). Here, Quincy not only lacked evidence that Prevagen works as advertised, but knew from its own safety studies that Prevagen's active ingredient *cannot* reach the brain. It nevertheless built an advertising campaign around the proposition that Prevagen improves memory by supplementing brain proteins lost with age.

The district court did not assess the plausibility of these allegations; instead, it simply determined that the facts did not support them. The court undertook two factfinding missions. First, it employed bootstrap logic by assuming that the Madison Memory Study proved Prevagen worked and then reasoning by backward

induction that (as a matter of fact) it *had* to enter the brain precisely because it worked. SA7 n.3 (concluding that "something" must have caused improved memory for the subgroup members). Second, the court found that the complaint's allegations about Prevagen not reaching the brain were "contradicted by canine studies." *Id*. As discussed in Part II.A.2 below, such findings of fact were improper for a motion to dismiss.

II. THE DISTRICT COURT ERRED BY MAKING FINDINGS OF FACT, CONSIDERING OUTSIDE EVIDENCE, AND RESOLVING SCIENTIFIC QUESTIONS PROPERLY RESERVED FOR EXPERT TESTIMONY

The district court did not merely fail to accept the complaint's plausible allegations. It erred even further by making improper factual findings that (1) Quincy's study demonstrated bona fide improvements in memory; (2) Prevagen's dietary protein is capable of entering the human brain; (3) post hoc subgroup analyses are scientifically sound; and (4) the subgroups Quincy cherry-picked for its ads were the appropriate population when evaluating the factual basis for its advertising claims. SA4-6, 7 n.3, 11. The error in those actions was particularly glaring because the court reached its conclusions by weighing evidence outside the complaint and assuming the role of an expert witness. Even worse, the court uncritically adopted Quincy's one-sided evidentiary submissions without giving the plaintiffs an opportunity to present their own evidence and expert testimony.

A. The District Court Inappropriately Made Findings Of Fact

The district court was required to take the complaint allegations as true and draw reasonable inferences in the plaintiffs' favor. *Nicosia*, 834 F.3d at 230. Instead, on four separate issues, the court made factual findings adverse to the complaint. But a 12(b)(6) motion "is not an occasion for the court to make findings of fact." *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007).

1. The Court Improperly Found That Members Of Quincy's Subgroups Experienced Improvement In Memory

As described above, the complaint alleges that the positive results from Quincy's subgroups were not "reliable evidence of a treatment effect" and may have "occur[red] by chance alone." JA37 (Compl. ¶ 29). Given the statistical complexity of that allegation, it is inherently a question of fact, to be determined on a complete evidentiary record. Yet the district court rebuffed the allegations of the complaint and made its own factual determination that in Quincy's study, members of the "AD 0-1 and AD 0-2 subgroups . . . *displayed improvement in memory after taking the supplement*." SA11 (emphasis added). The court further concluded that members of these subgroups "*showed statistically significant*

improvements over those who received the placebo in three of nine tasks" and "*showed a trend toward significance*" in other tasks. SA5-6 (emphasis added).[17]

Indeed, the district court made an explicit finding that Quincy's subgroup results were *not* the product of chance. "[T]he results of the subgroup study . . . make it clear that *something* caused a statistically significant difference between those subjects who took Prevagen and those given a placebo." SA 7 n.3 (emphasis added). These findings were error, because in considering a motion to dismiss, "it is not the province of the court to dismiss the complaint on the basis of the court's choice among plausible alternatives." *Anderson News*, 680 F.3d at 190.

2. The Court Improperly Found That Prevagen's Protein Enters The Brain As Advertised

When the district court opined that "something" caused Prevagen users to experience improved memory, it thereby made a contested finding that Prevagen's protein can enter the brain and supplement lost proteins. *See* SA7 n.3. The complaint charges that Prevagen's protein cannot enter the brain because it is rapidly digested in the stomach—and that Quincy's own safety studies proved this.

[17] With the last finding, the court enmeshed itself in a specialized dispute of clinical-trial methodology. Experts have questioned whether a "trend toward significance" is even a valid statistical concept. Describing a non-significant result as "trending" towards significance "is not just inappropriate but actively misleading," since the results "would be quite likely to become less significant if extra data were collected." John Wood et al., *Trap of Trends to Statistical Significance*, 348 BMJ g2215 (Mar. 31, 2014), *available at* http://www.bmj.com/content/348/bmj.g2215.full.print (last visited Feb. 27, 2018).

See JA38-39 (Compl. ¶ 31). But the court believed that it simply had to be the case that Prevagen entered the brain, Quincy's safety studies notwithstanding. *See* SA7 n.3 (opining that the complaint allegations "lose[] force" because the Madison Memory Study showed that Prevagen improved memory for subgroup members). This logic was precisely backwards, since the court was required to take as true the allegations that Quincy's safety studies proved that Prevagen could *not* reach the brain.

The district court also found that these allegations were "contradicted by canine studies whose relevance plaintiffs challenge." SA7 n.3. In other words, when it considered the motion to dismiss, the court acknowledged a dispute of fact and resolved it anyway. Such disputes are a reason to *deny* a motion to dismiss, not to grant one. The question whether Quincy's canine research is generalizable to humans—and whether it refutes Quincy's other studies showing that Prevagen *cannot* enter the brain—is one for an expert witness, not a judge deciding a 12(b)(6) motion.

The district court thus took sides in a disputed matter of neuroscience when it found that Prevagen's dietary protein enters the brain. A court can resolve such a dispute only after hearing expert testimony. The district court's decision to bypass such testimony and serve as its own expert was a gross violation of the law governing motions to dismiss. *See Anderson News*, 680 F.3d at 185 (rejecting

"dismissals based on a judge's disbelief of a complaint's factual allegations") (quoting *Twombly*, 550 U.S. at 556).

3. The Court Improperly Found That Subgroup Analyses Are Scientifically Sound

The district court also engaged in contested factfinding when it concluded—without citing any evidence—that the alleged "risks" of subgroup analyses were not "so large in the abstract that they prevent any use of the subgroup concept, which is widely used in the interpretation of data in the dietary supplement field." SA11. The complaint nowhere alleges or suggests that subgroup analyses are "widely used" in the dietary supplement field; as shown in Part I.B above, it states a plausible case that the particular subgroup results at issue *here* were unreliable. The district court seems to have adopted this finding from Quincy's briefing papers, which asserted—citing only a single study—that "the use of subgroup analysis is common in nutrition research." JA204, 208-09 (ECF No. 34 at 7, 11-12). But the proper use of subgroups, in general or as employed in the Madison Memory Study, was a matter for resolution after expert testimony, not upon a motion to dismiss.

The district court also balanced the "risks" and benefits of subgroup analyses, *see* SA11, another task wholly improper in considering a motion to dismiss, which tests only the complaint's "formal sufficiency." *Halebian*, 644 F.3d at 130 (*quoting Global Network*, 458 F.3d at 155). In making these findings,

the court again effectively substituted itself for scientific expert witnesses. *See also* Part II.C, *infra* (explaining why expert testimony was necessary to determine whether the subgroup analyses were reliable).

4. The Court Improperly Found That Specific Subgroups Were The Appropriate Population For Evaluating Quincy's Advertising Substantiation

The district court adopted Quincy's assertion that data from the AD8 0-1 and 0-2 subgroup members—who Quincy claims displayed positive results on three of the nine tasks—were the findings "most relevant to the efficacy of the product." SA4 (quoting JA236, Quincy's Clinical Trial Synopsis). The court thereby gave the failed results for the overall treatment group and other subgroups less (or no) weight. These findings were error because the weight properly accorded to different aspects of the Madison Memory Study is a question of fact.

Quincy's advertising representations suggest that the results for all of the Madison Memory Study participants—not just the AD8 0-1 and 0-2 subgroups—are relevant when assessing the factual basis for its advertising claims. Quincy's website told consumers that its *entire study population*—not just the AD8 0-1 and 0-2 subgroups—consisted of people "experiencing some mild memory problems associated with aging." JA59 (Compl. Exh. C, p. 3). And Quincy's "Brain Health Guide" explained that the study population featured people with "mild memory concerns" who were "undiagnosed with any type of memory disorder." JA126

(Compl. Exh. D, p. 20). These descriptions suggest that a factfinder would need to review *all* of the study results when evaluating Quincy's claimed substantiation, not just the results credited by the district court.

Here, the district court did not even have before it the results from other subgroups that showed no statistically significant results from Prevagen. The complaint does not mention the results of specific subgroups, but does allege that the "vast majority" of subgroups showed no significant effects. JA37 (Compl. ¶ 29). Which findings deserve to be credited and to what extent are classic questions of fact to be resolved on a complete evidentiary record. The court could not properly resolve these questions at the motion to dismiss stage. *See Societe des Hotels Meridien v. LaSalle Hotel Operating P'ship, L.P.*, 380 F.3d 126, 132 (2d Cir. 2004) ("[O]n a motion under Rule 12(b)(6)[,] the inquiry is into the sufficiency of the pleading, not of the evidence.").

B. The District Court Incorrectly Relied On Evidence Outside The Complaint

The district court's factual findings constitute reversible error in their own right. Worse, the district court explicitly relied on Quincy's August 2016 synopsis of the Madison Memory Study—proffered with the motion to dismiss—to support two key findings: that two subgroups of Quincy's study participants experienced improved memory, and that those subgroups were the appropriate population for evaluating the factual basis for Quincy's advertising claims. *See* SA4-6, *citing*

JA235-44 (ECF No. 35). As discussed at pages 17-18 above, the synopsis was an advocacy piece that Quincy prepared more than five years after completing the study, several years after beginning to run the ads at issue, and only a few months before the plaintiffs filed their complaint. The complaint does not reference the synopsis, nor does it provide any details about the AD8 test or specific subgroups or cognitive tasks.[18] *See* JA37 (Compl. ¶¶ 28-29). The district court's reliance on the AD8 subgroup results thus amounts to its adoption of Quincy's synopsis—without consideration or acknowledgement that its proper weight or relevance might be in dispute.

The district court thus committed a serious error of law by making contested findings based on evidence outside the complaint. These errors mirrored the court's mistakes in *Global Network*, where this Court vacated a Rule 12(b)(6) dismissal that "consider[ed] external material" and "relied on those materials to make a finding of fact that *controverted* the [plaintiffs'] own factual assertions set out in [their] complaint." *Global Network*, 458 F.3d at 156 (emphasis in original). When a "trial judge considers evidence [outside] the complaint" in resolving a motion to dismiss, the court deprives the plaintiffs of "an opportunity to contest

[18] The complaint includes a screen capture of Quincy's website that references the Madison Memory Study, but the capture is dated December 10, 2015, eight months *before* the August 2016 synopsis. *See* JA59 (Compl. Exh. C, p. 3)

defendant's relied-upon evidence by submitting material that controverts it." *Id.* at 155.

The district court could properly consider Quincy's outside evidence only if it converted the motion to dismiss into one for summary judgment and gave the parties an opportunity to conduct discovery and submit a full record under Rule 56. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 154 (2d Cir. 2002); *see also Goel*, 820 F.3d at 557. That requirement is "strictly enforced" and "mandatory" under Federal Rule of Civil Procedure 12(d). *Global Network*, 458 F.3d at 155 (quotation omitted).[19]

Quincy argued below that the district court should consider its synopsis because the complaint "extensively references" the study and because the study was "central[]" to the allegations. JA206 n.2 (ECF No. 34 at 9 n.2). But while the complaint references the *study*, it makes no mention of the *synopsis*, a self-serving, unpublished document that Quincy prepared to advocate its viewpoint years after completing the study and after most of its ads had already been running. Although courts may consider documents that are "integral" to a complaint when deciding a Rule 12(b)(6) motion, this narrow exception applies only "where the complaint

[19] Rule 12(d) provides that "[i]f, on a motion under Rule 12(b)(6) . . . , matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Fed. R. Civ. P. 12(d).

relies heavily upon [the documents'] terms and effect." *Goel*, 820 F.3d at 559 (quoting *Chambers*, 282 F.3d at 153).[20] On that definition, the synopsis was not "integral" here.

Even if the synopsis *were* integral to the complaint, the district court was wrong to consider it. Courts may not rely on "integral" documents when resolving a motion to dismiss if there is any dispute regarding the document's "relevance, authenticity, or accuracy." *Nicosia*, 834 F.3d at 231. Here, the synopsis's accuracy, credibility, and relevance are squarely at issue. The FTC is entitled to probe—through expert testimony and other discovery—the methodologies behind, and statistical validity of, Quincy's conclusion that certain subgroups experienced improvements in memory on a limited number of cognitive tasks. The district court simply assumed that these findings were valid and accurate.

Another open question is whether the synopsis, prepared years after the study, is a reliable source, since it omits any description of the results for the vast majority of subgroups Quincy analyzed. The synopsis fails to report the outcomes for participants with AD8 scores above 2, conveniently withholding a large set of presumably negative results. When researchers conduct numerous post hoc

[20] Courts typically apply this exception where "the incorporated material is a contract or other legal document containing obligations upon which the plaintiff's complaint stands or falls, but which for some reason . . . was not attached to the complaint." *Goel*, 820 F.3d at 559 (quotation omitted).

analyses and "deliberately report only the significant analyses . . . the reader might falsely conclude that there is a difference in treatment effect because they consider the results to be fairly reliable when they are not."[21] Quincy's synopsis reports only the few potentially favorable results that Quincy was able to mine from a large—and overwhelmingly unfavorable—set of findings. In proving their case, however, the plaintiffs are entitled to analyze *all* of the study results, not just those for 0-1 and 0-2 subgroups, to determine which ones are in fact relevant to Quincy's advertising claims, and whether the results actually support those claims.[22]

Finally, the relevance of the synopsis is also in question. Its findings rest on the disputed premise—improperly adopted by the district court (*see* Part II.A.4, *supra*)—that "[b]ecause 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." JA236 (ECF No. 35 at 5). But this assertion is not germane to the legal question here, which is whether the study

[21] Bernadette Dijkman et al., *How to Work with a Subgroup Analysis*, 52(6) Can. J. Surg. 515, 520 (2009).

[22] The synopsis does not just omit potentially critical results, but it is rife with scientifically irrelevant statements. For example, the synopsis repeatedly claims that participants who took Prevagen showed improvements "compared to Baseline"—*i.e.*, before they used any product for memory loss—even though those same participants failed to show significant improvement over the placebo group. JA240-42 (ECF No. 35 at 9-11). An advertiser cannot claim that its product is effective if "scientific research demonstrates that the product has no force beyond its placebo effect." *Pantron I*, 33 F.3d at 1097.

results support Quincy's *advertising claims*, which the complaint says they do not. *See* Part I, *supra*. The synopsis describes but a small fraction of the results from the Madison Memory Study that could be relevant to the advertising claims.

When the district court relied on Quincy's study synopsis to find that Prevagen improved memory for certain subgroups and that those subgroups were the relevant population for Quincy's advertising claims, the court "deprive[d]" the FTC and the State of New York "of a fair adjudication of the claims by examining an incomplete record." *Chambers*, 282 F.3d at 155. The court "improper[ly] transform[ed] . . . the Rule 12(b)(6) inquiry into a summary-judgment proceeding—one featuring a bespoke factual record, tailor-made to suit the needs of defendants." *Goel*, 820 F.3d at 560.

C. The District Court Wrongly Addressed Matters That Could Be Resolved Only After Expert Testimony

The district court improperly assumed the role of an expert witness when it made the four factual findings described in Part II.A, above. Questions about the sufficiency of advertising substantiation are not proper matters for ruling on a motion to dismiss; they are within the realm of expert testimony—either at trial or in summary-judgment affidavits. *See Oneida Indian Nation of N.Y. v. State of N.Y.*, 691 F.2d 1070, 1086 (2d Cir. 1982) (vacating dismissal because the district court "drew heavily upon" extrinsic evidence that should have been subject to "cross-examination or analysis through expert testimony").

The factfinder in an advertising substantiation case must consider "the amount of substantiation experts in the field would consider reasonable" (for efficacy claims), and whether the "evidence [is] sufficient to satisfy the relevant scientific community of the claim's truth" (for establishment claims). *POM Wonderful*, 777 F.3d at 490-91 (internal citations and quotation marks omitted). Litigation over advertising substantiation thus virtually always turns on case-specific expert testimony on the required level of substantiation and whether the advertiser met the standard. For example, in *Bristol-Myers*, this Court upheld the FTC's finding, based on the testimony of "an expert in the field of gastroenterology," that "only well-controlled clinical studies" could support the claim that "Bufferin was proven to cause less stomach upset than aspirin." 738 F.2d at 559. In *Charles of the Ritz Distributors Corp. v. FTC*, 143 F.2d 676 (2d Cir. 1944), this Court sustained the Commission's reliance on expert testimony that "there was nothing known to medical science" that could establish the benefits of the advertiser's skin cream. *Id.* at 678-79 ("[T]he . . . medical and pharmacological knowledge of the doctors qualified them to testify as to the lack of therapeutic value of the cream.").[23]

[23] *See also POM Wonderful*, 777 F.3d at 495 (upholding FTC's reliance on testimony that "experts in the fields of cardiology and urology require randomized, double-blinded, placebo-controlled clinical trials to substantiate any claim that a product treats, prevents, or reduces the risk of disease"); *Direct Mktg. Concepts*, 624 F.3d at 9-10 (crediting expert testimony that the claims could only be

The district court short-circuited the inquiry and purported to discern the scientific community's views in the absence of any record evidence, including expert evidence about clinical-trial methodology. For example, the court opined that subgroup analyses are a "widely used" form of proof in the field of dietary supplements. SA11; *see* Part II.A.3, *supra*. As discussed, the court likely gained this impression from a single NIH study cited in Quincy's motion. JA204, 208-09, 218 (ECF No. 34 at 7, 11-12, 21). But Quincy failed to mention—and thus the court likely did not know about—the NIH researchers' warning in that very study that "[b]ecause these benefits [of the supplements] are based on subgroup analyses, they should be interpreted with caution."[24] The NIH researchers also made clear that a key "limitation" of their study was that "several of the reported results are based upon secondary exploratory analyses in the setting of negative primary

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"substantiated by double-blind, placebo-controlled human studies," and that the defendants' evidence was "woefully inadequate"); *Pantron I*, 33 F.3d at 1097 (relying on testimony by three physicians that "the consensus of the medical and scientific community is that polysorbate-based products have no effectiveness beyond their placebo effect in combatting male pattern baldness"); *Justin Haynes & Co. v. FTC*, 105 F.2d 988, 989 (2d Cir. 1939) (upholding FTC's finding, "supported by the testimony of . . . three expert witnesses," that "petitioner's compound is . . . of little or no therapeutic value for the various pains and ailments . . . it is represented to relieve").

[24] NIH, National Eye Institute, *For the Media: Questions and Answers about AREDS2* (May 2013), *available at* https://nei.nih.gov/areds2/MediaQandA (last visited Feb. 27, 2018).

findings."[25] Thus, "[q]uestions still remain" concerning "whether or not the findings can be generalized to the population as a whole."[26]

The court's faulty reliance on a partial understanding of the NIH study shows by itself how courts can go astray when they engage in factfinding on an incomplete record. Indeed, as shown below, when the district court uncritically accepted Quincy's assertions about its subgroup statistics, it foreclosed any serious debate on contested matters and instead reached conclusions that could well be proven wrong after proper consideration of expert testimony.

An extensive scientific literature describes how false positives occur when researchers "exclud[e], combin[e], or split[]" treatment groups after a study's main analysis is complete, "try[ing] out several statistical analyses . . . and then selectively report[ing] those that produce significant results."[27] When "so many

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[25] Mary E. Aronow and Emily Y. Chew, *AREDS2: Perspectives, Recommendations, and Unanswered Questions*, author manuscript (May 2015), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4096000/ (last visited Feb. 27, 2018).

[26] *Id.*

[27] Megan L. Head et al., *The Extent and Consequences of P-Hacking in Science*, 13(3) PLOS Biology e1002106, *available at* http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1002106 (last visited Feb. 27, 2018); *see also* Siddhartha Mukherjee, *A Failure to Heal*, N.Y. TIMES (Nov. 28, 2017) (describing post hoc analyses as a "search-and-rescue mission" in which researchers, after a failed study, "go hunting for groups of patients that happened to respond . . . and then . . . turn around and claim that the drug 'worked' on . . . those very patients").

tests of significance are run, it becomes quite likely that at least one such analysis will show a 'statistically significant' difference as a result of chance."[28] As a result, "[t]he play of chance often produces qualitatively wrong answers in particular subgroups of trials . . . that could, if interpreted incautiously, lead to millions of people being treated inappropriately."[29]

The results of post hoc subgroup analyses therefore should "be interpreted cautiously" and may not be reliable evidence of "treatment efficacy."[30] In one famous example, researchers demonstrated that aspirin can reduce the risk of death after heart attacks compared to placebo—but in a post hoc subgroup analysis, aspirin (implausibly) "appeared totally ineffective" for those whose astrological signs were Gemini or Libra.[31] In fact, several scientists have concluded that the

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[28] Robert Temple and Gordon W. Pledger: *Special Report: The FDA's Critique of the Anturane Reinfarction Trial*, 303 New Eng. J. of Med. 1488, 1492 (1980).

[29] R. Peto, *Current Misconception 3: That Subgroup-Specific Trial Mortality Results Often Provide a Good Basis for Individualising Patient Care*, 104(7) Brit. J. of Cancer 1057, 1057 (2011).

[30] FDA, *International Conference on Harmonisation; Guidance on Statistical Principles for Clinical Trials; Availability*, 63 Fed. Reg. 49,583, 49,595 (Sept. 16, 1998). We do not suggest that the FDA's guidance and other statements establish the proper level of substantiation, *see Bristol-Myers*, 738 F.2d at 559, but only that they reflect the broader scientific consensus concerning the use of post hoc analyses.

[31] Peto, *supra* note 29, at 1057.

results of post hoc subgroup analyses must be replicated in future studies "irrespective of plausibility or significance."[32]

The risks of relying on subgroup analyses are compounded when researchers fail to limit "the number of subgroups and the number of outcomes analyzed,"[33] and make "exaggerated claims" by "selectively report[ing] only the more interesting subgroup analyses."[34] The reliability of a subgroup finding therefore "depends to a great extent on whether [the subgroups] were predefined and how many other analyses were done but not reported."[35] Here, Quincy allegedly performed numerous subgroup analyses that were not predefined and selectively reported only a few of them.

This scientific guidance—which seemingly conflicts with the district court's conclusions—illustrates why the court should not have opined at the motion-to-dismiss stage that Quincy's subgroup analyses were reliable evidence that

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[32] Rothwell, *supra* note 13, at 182; *see also id.* at 181; Bert Spilker, *Guide to Clinical Trials* 476 (1991); Harvey J. Motulsky, *Common Misconceptions about Data Analysis and Statistics*, 351 J. of Pharmacology & Experimental Therapeutics 200, 201 (2014); Dijkman, supra note 21, at 517; Xin Sun et al., *How To Use a Subgroup Analysis*, 311(4) JAMA 405, 408 (2014).

[33] Dijkman, *supra* note 21, at 517, 519; *see also* Susan F. Assmann et al., *Subgroup Analysis and Other (Mis)uses of Baseline Data in Clinical Trials*, 355 Lancet 1064, 1069 (2000); Sun, *supra* note 32, at 408.

[34] Assmann, *supra* note 33, at 1068; *see also* Dijkman, *supra* note 21, at 520.

[35] Rothwell, *supra* note 13, at 181.

Prevagen improves memory. Such matters are quintessential factual issues to be resolved only after expert testimony and full briefing and argument. By jumping the gun and appointing itself an expert, the district court wrongly deprived the plaintiffs of an opportunity to make their case.

CONCLUSION

The Court should vacate the judgment of the district court and remand the case to the district court for further proceedings.

Respectfully submitted,

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February 28, 2018

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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Local Rule 32.1(a)(4)(A) because it contains 12,834 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), and that it 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 was prepared using Microsoft Word 2010 in 14 point Times New Roman type.

February 28, 2018

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17-3745 & 17-3791

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

FEDERAL TRADE COMMISSION *et al.*,
Plaintiffs-Appellants

v.

QUINCY BIOSCIENCE HOLDING CO. *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York
No. 1:17-cv-00124-LLS (Hon. Louis L. Stanton)

SPECIAL APPENDIX

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Special Appendix—Table of Contents

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by Eric T. Schneiderman, Attorney General of the State of New York,

Plaintiffs,

- against -

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ 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.; and

MICHAEL BEAMAN, individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc.

Defendants.

17 Civ. 124 (LLS)

OPINION & ORDER

Plaintiffs Federal Trade Commission ("FTC") and the People of the State of New York, by Eric T. Schneiderman, Attorney General of the State of New York, seek injunctive and other equitable relief for alleged violations of federal and state deceptive advertising laws. All defendants move to dismiss the complaint for failure to state a claim upon which relief can

be granted. The two individual defendants, Mark Underwood and Michael Beaman, also move to dismiss for lack of personal jurisdiction.

BACKGROUND

Defendant Quincy Bioscience Holding Company, Inc. ("Quincy") is a Wisconsin based corporation. Compl. (Dkt. No. 1) ¶ 9. Defendants Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, also Wisconsin based companies, are wholly owned subsidiaries of Quincy. Id. ¶¶ 10-12. Quincy and its subsidiaries operated as a common enterprise in engaging in the conduct alleged in the complaint. Id. ¶ 17.

Underwood and Beaman are Quincy's co-founders and its two largest shareholders; Underwood owns 33% and Beaman owns 22% of its stock. Id. ¶¶ 13, 15. Underwood is Quincy's president and Beaman is its chief executive officer and former president. Id. Each is also a director of Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC, and an officer of Quincy Bioscience, LLC and Prevagen, Inc. Id. The complaint alleges that "acting alone or in concert with others," Underwood and Beaman "formulated, directed, controlled, had the authority to control, or participated in the acts and practices of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc., including the acts

and practices set forth in this Complaint." Id. ¶¶ 14, 16.

Defendants manufacture and sell a dietary supplement known as Prevagen. Id. ¶ 21. Prevagen's active ingredient, apoaequorin (pronounced: ā-poe-ē-kwôr-ĭn), is a dietary protein originally derived from the jellyfish Aequorea victoria. Id. ¶ 19. Prevagen is sold in Regular Strength, Extra Strength, and Prevagen Professional, containing respectively 10, 20, or 40 milligrams of apoaequorin. Id. Prevagen is sold directly to consumers through defendants' websites, and indirectly through a host of pharmacies and retail establishments. Id. ¶ 21. Between 2007 and mid-2015, sales of Prevagen in the United States totaled $165 million. Id.

Defendants advertise Prevagen on their websites, through infomercials, short-form television commercials, social media, newspapers, and magazines. Id. ¶ 22. Their advertising includes representations that "Prevagen improves memory," that it "has been clinically shown to improve memory," that "A landmark double-blind and placebo controlled trial demonstrated Prevagen improved short-term memory, learning, and delayed recall over 90 days," that Prevagen "Helps with memory problems associated with aging," that "Prevagen is clinically shown to help with mild memory problems associated with aging," and that Prevagen can support "healthier brain function, a sharper mind and clearer thinking." Id. ¶ 27, Exs. A-F

Those representations rely primarily on the results of the Madison Memory Study. Id. ¶ 28. "The Madison Memory Study was a randomized, double-blind, placebo-controlled study designed to examine the effect of apoaequorin on cognitive function in older adults." Graham Decl. (Dkt. No. 35) Ex. 1 at 2; see Compl. ¶ 28. The study involved 218 adults between the ages of 40 and 91. Graham Decl. Ex. 1 at 4; see Compl. ¶ 28. "The primary objective of the Madison Memory Study was to determine whether Prevagen® with apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." Graham Decl. Ex. 1 at 1.

Because Prevagen is intended for healthy, non-demented individuals, its examiners used the AD8 screening tool[1] to differentiate between adults facing normal cognitive aging and those with early signs of dementia. Id. at 2. Participants were assigned AD8 scores of 0 through 8, with an AD8 score of 2 used to differentiate between those who are cognitively normal or very mildly impaired (with scores of 0-2) and those with higher levels of impairment (with scores of 3-8). Id. According to the examiners, "results from the AD8 0-1 and AD8 0-2 subgroups are the most relevant to the efficacy of the product." Id.

[1] "The AD8 is a brief, sensitive measure that reliably differentiates between nondemented and demented individuals." James E. Galvin, MD, MPH, et al., The AD8: a brief informant interview to detect dementia, 65 Neurology 559, 559 (American Academy of Neurology) Aug. 23, 2005, available at https://www.ncbi.nlm.nih.gov/pubmed/16116116 (last accessed Sept. 28, 2017).

Participants were divided into two groups: the experimental group received Prevagen, and the control group received a placebo. Id.; see Compl. ¶ 28. Both groups were instructed to take one capsule per day. Graham Decl. Ex. 1 at 2. At various intervals during the trial (days 0, 8, 30, 60, and 90), participants were assessed on a variety of cognitive skills using nine quantitative computerized cognitive tasks.[2] Id. at 2-4; see Compl. ¶ 28. No statistically significant results were observed for the study population as a whole on any of the cognitive tasks. Graham Decl. Ex. 1 at 5; Compl. ¶ 28. However, statistically significant results were observed between the experimental and control groups among the AD8 0-1 and AD8 0-2 subgroups. Graham Decl. Ex. 1 at 5-9; see Compl. ¶ 29. Participants in the AD8 0-1 subgroup who received Prevagen showed statistically significant improvements over those who received the placebo in three of the nine tasks (measuring memory, psychomotor function, and visual learning), and showed a trend toward significance in two more tasks (measuring verbal

[2] The nine cognitive measurement tests were, Graham Decl. Ex. 1 at 2, Table 1:

Tasks	**Cognitive Domain Measured**
International Shopping List (ISL)	Verbal Learning
International Shopping List - Delayed Recall (ISRL)	Memory
Groton Maze Learning (GML)	Executive Function
Groton Maze Learning - Delayed Recall (GMR)	Memory
Detection (DET)	Psychomotor Function
Identification (IDN)	Attention
One Card Learning (OCL)	Visual Learning
One Back (ONB)	Working Memory
Two Back (TWOB)	Working Memory

learning and executive function). Graham Decl. Ex. 1 at 6-9. Participants in the AD8 0-2 subgroup who received Prevagen showed statistically significant improvements over those who received the placebo in three of the nine tasks (measuring executive function, attention, and visual learning), and showed a trend toward significance in one more task (measuring memory). Id. Based on those findings, the study concluded 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." Id. at 9.

Plaintiffs take issue with the study's conclusion. They allege that "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," and that post hoc subgroup analysis "greatly increases the probability that the statistically significant improvements shown are by chance alone." Compl. ¶ 29. They conclude that "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." Id.

Plaintiffs also allege that defendants' marketing campaign,

and their claims that Prevagen improves memory and cognition, rely on the theory that apoaequorin enters the human brain to supplement endogenous proteins that are lost during the natural process of aging. Id. ¶ 31. The complaint says that defendants have no studies showing that orally-administered apoaequorin can cross the human blood-brain barrier. Id. According to the complaint, studies conducted by defendants show that orally-administered apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein. Id.[3]

Plaintiffs allege that the representations that Prevagen improves memory, improves memory within 90 days, reduces memory problems associated with aging, and provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and cleared thinking, "are false or misleading, or were not substantiated at the time the representations were made," id. ¶¶ 36-37, and representations that Prevagen is clinically shown to improve memory, to do so within 90 days, to reduce memory problems associated with aging, and to provide other cognitive benefits, including but not limited to, healthy brain function, a sharper mind, and clearer thinking, "are

[3] This point, contradicted by canine studies whose relevance plaintiffs challenge, loses force when applied to the results of the subgroup study which make it clear that something caused a statistically significant difference between those subjects who took Prevagen and those given a placebo.

false," id. ¶¶ 39-40.

Plaintiffs claim that in making those representations defendants violate (1) section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits "unfair or deceptive acts or practices in or affecting commerce," (2) section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertising of food or drugs, (3) section 63(12) of the New York Executive Law, which allows the Attorney General to apply for an order enjoining the continuance of repeated or persistent fraudulent or illegal acts, including misrepresentations, in the carrying on, conducting, or transaction of business, and directing restitution and damages, and (4) sections 349 and 350 of the New York General Business Law, which prohibit deceptive acts or practices and false advertising "in the conduct of any business, trade, or commerce or in the furnishing of any service in this state."

Defendants move to dismiss the complaint on the following grounds: (1) the complaint fails adequately to allege that the representations in the marketing materials violate sections 5(a) and 12 of the FTC Act; (2) the complaint fails to allege that the representations violate New York law; (3) the relief sought amounts to an unconstitutional restraint on commercial speech; (4) the action was commenced ultra vires as the FTC lacked a quorum to authorize it; (5) the court lacks personal jurisdiction over the individual defendants; and (6) the complaint fails

adequately to allege that the individual defendants personally participated in or had authority to control any unlawful conduct.

DISCUSSION

1. Failure to State a Claim upon Which Relief can be Granted

Legal Standard

"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, 129 S. Ct. 1937, 1949 (2009), quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 1974 (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, 127 S. Ct. at 1965. "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, 127 S. Ct. at 1965. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id., quoting Twombly, 550 U.S. at 557, 127 S. Ct. at 1966 (brackets in Iqbal).

"The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. 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., quoting Twombly, 550 U.S. at 556-57, 127 S. Ct. at 1965-66.

Alleging a Violation of the FTC Act

To establish liability under section 5(a) of the FTC Act, "the FTC must show three elements: '[1] a representation, omission, or practice, that [2] is likely to mislead consumers acting reasonably under the circumstances, and [3], the representation, omission, or practice is material.'" FTC v. LeadClick Media, LLC, 838 F.3d 158, 168 (2d Cir. 2016), quoting FTC v. Verity Int'l, Ltd., 443 F.3d 48, 63 (2d Cir. 2006).

Defendants do not challenge the complaint's sufficiency as to the first and third elements. With respect to the second element, however, they argue that aside from saying that the representations are false or unsubstantiated, the complaint does not allege facts from which it can be reasonably inferred that the representations at issue are false or unsubstantiated.

It is common ground that the Madison Memory Study followed normal well-accepted procedures, conducted a "gold standard" double blind, placebo controlled human clinical study using objective outcome measures of human cognitive function using 218 subjects, and that it failed to show a statistically significant improvement in the experimental group over the placebo group as

a whole. See, e.g., Compl. ¶ 28. That confined plaintiffs' attack to the studies of subgroups, and 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. It points to the conduct of more than 30 post hoc[4] analyses of possible subgroups, most of whom showed no statistical significance between the treatment and placebo groups, but did show a statistically significant difference between the groups in the AD 0-1 and AD 0-2 subgroups whose members displayed improvement in memory after taking the supplement. That, of course, is the study relied upon by defendants. Here, plaintiffs' challenge never proceeds beyond the theoretical. They say that findings based on post hoc exploratory analyses have an increased risk of false positives, and increased probability of results altered by chance alone, but neither explain the nature of such risks nor show that they affected the subgroups performance in any way or registered any false positives. Nor do they give any reason to suspect that these risks are so large in the abstract that they prevent any use of the subgroup concept, which is widely used in the interpretation of data in the dietary supplement field. Thus, the complaint fails to show that reliance upon the subgroup data "is likely to

[4] This term seems to be used to imply some deficiency in integrity, never specified. It probably refers to no more than that the analytical work was done after the information-gathering process was completed.

mislead consumers acting reasonably under the circumstances," as is necessary to state its claim. FTC v. LeadClick Media, LLC, 838 F.3d at 168.

All that is shown by the complaint is that there are possibilities that the study's results do not support its conclusion. It does not explain how the number of post hoc comparisons run in this case makes the results as to the AD8 0-1 and AD8 0-2 subgroups unreliable, or that the statements touting the study's results are false or unsubstantiated. That "stops short of the line between possibility and plausibility of 'entitlement to relief.'" Iqbal, 556 U.S. at 678, 129 S. Ct. at 1949.

2. New York Law Claims

The federal law claims being dismissed, there is no satisfactory basis for the exercise of supplemental jurisdiction over the state law claims, and I decline to do so. 28 U.S.C. § 1367(c)(3) (district court may decline supplemental jurisdiction if it "has dismissed all claims over which it has original jurisdiction"); Bridgeman Art Library, Ltd. v. Corel Corp., 25 F. Supp. 2d 421, 431 (S.D.N.Y. 1998) ("When, as here, the federal claim is dismissed early in the litigation process, 'the presumption to decline jurisdiction is strong.'"). The New York State courts may find merit in the remaining claims under New York statutes, which are best left to them.

3. Defendants' Remaining Arguments

All claims being dismissed, there is no need to consider the defendants' remaining arguments, or the Underwood and Beaman motion denying jurisdiction.

CONCLUSION

The motions to dismiss (Dkt. Nos. 33, 36) are granted as to the federal law claims, and plaintiffs' state law claims are dismissed without prejudice.

So ordered.

Dated: New York, New York
September 28, 2017

Louis L. Stanton

LOUIS L. STANTON
U.S.D.J.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------X
FEDERAL TRADE COMMISSION and
THE PEOPLE OF THE STATE OF NEW YORK,
by Eric T. Schneiderman, Attorney General of the
State of New York,

Plaintiffs, 17CV124 (LLS)

-against- **JUDGMENT**

QUINCY BIOSCIENCE HOLDING COMPANY,
INC., a corporation; QUINCY BIOSCIENCE, LLC,
a limited liability company; PREVAGEN, INC.,
a corporation d/b/a/ 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.; and
MICHAEL BEAMAN, individually and as an officer
of Quincy Bioscience Holding Company, Inc.,
Quincy Bioscience, LLC, and Prevagen, Inc.,

Defendants.
----------X

Whereas all defendants having moved to dismiss the complaint for failure to state a claim upon which relief can be granted (Docs. # 33 and 36), and the matter having come before the Honorable Louis L. Stanton, United States District Judge, and the Court, on September 28, 2017, having rendered its Opinion & Order (Doc. # 45), granting Defendants' motions, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion & Order dated September 28, 2017 (Doc. # 45), the motions to dismiss (Dkt. Nos. 33,

36) are granted as to the federal law claims, and plaintiffs' state law claims are dismissed without prejudiced.

DATED: New York, New York
September 29, 2017

RUBY J. KRAJICK

Clerk of Court

BY: ____________________

Deputy Clerk

STATUTORY TEXT

15 U.S.C. § 45. Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations, except banks, savings and loan institutions described in section 57a (f)(3) of this title, Federal credit unions described in section 57a (f)(4) of this title, common carriers subject to the Acts to regulate commerce, air carriers and foreign air carriers subject to part A of subtitle VII of title 49, and persons, partnerships, or corporations insofar as they are subject to the Packers and Stockyards Act, 1921, as amended [7 U.S.C. 181 et seq.], except as provided in section 406(b) of said Act [7 U.S.C. 227 (b)], from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

(3) This subsection shall not apply to unfair methods of competition involving commerce with foreign nations (other than import commerce) unless—

(A) such methods of competition have a direct, substantial, and reasonably foreseeable effect—

(i) on commerce which is not commerce with foreign nations, or on import commerce with foreign nations; or

(ii) on export commerce with foreign nations, of a person engaged in such commerce in the United States; and

(B) such effect gives rise to a claim under the provisions of this subsection, other than this paragraph.

If this subsection applies to such methods of competition only because of the operation of subparagraph (A)(ii), this subsection shall apply to such conduct only for injury to export business in the United States.

(4) **(A)** For purposes of subsection (a), the term "unfair or deceptive acts or practices" includes such acts or practices involving foreign commerce that—

(i) cause or are likely to cause reasonably foreseeable injury within the United States; or

(ii) involve material conduct occurring within the United States.

(B) All remedies available to the Commission with respect to unfair and deceptive acts or practices shall be available for acts and practices described in this paragraph, including restitution to domestic or foreign victims.

* * *

15 U.S.C. § 52. Dissemination of false advertisements

(a) Unlawfulness

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.

(b) Unfair or deceptive act or practice

The dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of section 45 of this title.

* * *

15 U.S.C. § 55. Additional definitions

For the purposes of sections 52 to 54 of this title—

(a) False advertisement

(1) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among

other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.

* * *

CERTIFICATE OF SERVICE

I certify that on February 28, 2018, I served the foregoing on the following counsel of record using the Court's electronic case filing system and by FedEx. All counsel of record are registered ECF filers.

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Dated: February 28, 2018

/s/ Bradley Grossman

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