17-3745(L)

17-3791(CON)

United States Court of Appeals for the Second Circuit

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

Plaintiffs-Appellants,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation,

Defendants-Appellees.

(*Caption continues on inside cover*)

On Appeal from the United States District Court
for the Southern District of New York

BRIEF FOR STATE APPELLANT

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Dated: February 28, 2018

(*Continued from front cover*)

QUINCY BIOSCIENCE, LLC, a limited liability company, PREVAGEN, INC., a corporation, DBA SUGAR RIVER SUPPLEMENTS, QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company, MARK UNDERWOOD, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC and Prevagen, Inc., MICHAEL BEAMAN, Individually and as an officer of Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, and Prevagen, Inc.,

Defendants-Appellees.

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PRELIMINARY STATEMENT

Defendants sell Prevagen, a dietary supplement that they claim improves memory. Defendants have repeatedly represented to the public that a clinical double-blind study supports their health claim. But that study actually showed no statistically significant evidence that Prevagen improved memory for the study population as a whole. Only when researchers plucked data from the numerous subgroups that they created from the broader study population did they identify a statistically significant effect—and only for two of the subgroups of the larger study population. Yet defendants falsely marketed Prevagen as though the study showed positive findings for all users, and never disclosed that subgroup comparisons are less reliable than typical double-blind studies. The Federal Trade Commission (FTC) and the State of New York sued defendants under federal and state law for their misleading advertising. The United States District Court for the Southern District of New York (Stanton, J.) dismissed the federal claims and declined to exercise supplemental jurisdiction over the state claims.

This Court should reverse. The complaint properly states deceptive-practices and false-advertising claims under the FTC Act, 15 U.S.C.

§§ 45(a)(1), 52(a), for the reasons given by the FTC and further set forth below. Specifically, the complaint alleges that defendants' health claims about Prevagen were misleading and unsubstantiated because their marketing suggested that Prevagen could improve memory for any user, while the study they conducted showed statistically significant results only for a sliver of the study population. The complaint also states FTC Act claims based on defendants' representations that Prevagen helps to supplement proteins in the human brain, when no evidence supports such an effect.

The district court's erroneous dismissal of the FTC Act claims led it to decline to exercise supplemental jurisdiction over the state-law claims. Because the predicate for the court's dismissal of the state-law claims was a legal error, the court necessarily abused its discretion. This Court should reverse the dismissal of the state-law claims, and further hold that the complaint states a claim under New York law. The same factual allegations that support the FTC Act claims necessarily support the State's claims under New York's consumer-protection and anti-fraud laws, which are at least as broad in scope as the FTC Act. This Court should thus directly hold that the complaint adequately pleads state-law

claims, rather than remanding for the district court to consider the adequacy of the state-law allegations in the first instance.

QUESTIONS PRESENTED

1. Does a complaint state a claim under the FTC Act by alleging that defendants represented that a product has been clinically shown to enhance memory when, in fact, the only clinical study conducted by defendants fails to support that claim?

2. Do those same allegations state a claim under New York's General Business Law §§ 349–350 and Executive Law § 63(12), which prohibit fraudulent and deceptive business practices?

STATEMENT OF JURISDICTION

Jurisdiction for the FTC's claims is proper under 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b). (Joint Appendix (J.A.) 15 (¶ 3).) Jurisdiction for the state-law claims is proper under 28 U.S.C. § 1367. (J.A. 15 (¶ 4).) The district court entered judgment on September 29, 2017. (Special Appendix (S.A.) 14–15.) The FTC filed a timely notice of appeal on November 15, 2017 (J.A. 377–378), and the State filed a timely notice of appeal on November 20, 2017 (J.A. 379–

380). *See* Fed. R. App. P. 4(a)(1)(B)(ii). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE CASE

A. Statutory Background

In 1938, Congress enacted the FTC Act's consumer-protection provisions, which prohibit "unfair or deceptive acts or practices in or affecting commerce," FTC Act § 5(a)(1), 15 U.S.C. § 45(a)(1), and dissemination of "any false advertisement" relating to "food, drugs, devices, services, or cosmetics," FTC Act § 12(a), 15 U.S.C. § 52(a). Congress enacted these prohibitions after determining that pre-existing common-law remedies, which were "likely to involve small sums per consumer," were insufficient to ensure that businesses would cease their abusive practices. *Holloway v. Bristol-Myers Corp.*, 485 F.2d 986, 1000 (D.C. Cir. 1973); *see also Fayne v. Vincent*, 301 S.W.3d 162, 172 (Tenn. 2009) (FTC Act's consumer-protection provisions "passed as a response to the inability of the common-law tort system to protect consumers in many everyday circumstances").

All fifty States and the District of Columbia eventually enacted similar consumer-protection laws to supplement the FTC's enforcement power. *See* Jack E. Karns, *State Regulation of Deceptive Trade Practices Under "Little FTC Acts": Should Federal Standards Control?*, 94 Dick. L. Rev. 373, 373 & n.2 (1990). New York's analogues to the FTC Act's consumer-protection provisions—enacted decades after Congress passed FTC Act §§ 5(a)(1) and 12(a)—are found in General Business Law (G.B.L.) §§ 349 and 350. G.B.L. § 349(a) parallels FTC Act § 5(a)(1) by barring "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state." And G.B.L. § 350, which parallels FTC Act § 12(a), prohibits "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state." A third New York statute, Executive Law § 63(12), enacted in 1956, also protects consumers by authorizing the Attorney General of the State of New York to obtain equitable and other relief against anyone who "shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business."

New York courts have held that "interpretations of the Federal Trade Commission Act are useful in determining" the meaning of G.B.L. §§ 349 and 350 and Executive Law § 63(12). *People ex rel. Spitzer v. Applied Card Sys., Inc.*, 27 A.D.3d 104, 107 (3d Dep't 2005), *aff'd on other grounds*, 11 N.Y.3d 105 (2008). Indeed, because G.B.L. §§ 349 and 350 are modeled after FTC Act §§ 5 and 12, New York courts routinely look to the FTC Act's definitions of deceptive acts or practices in construing GBL §§ 349 and 350. *See Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995) (definition of "deceptive acts and practices" under G.B.L. § 349 "complements the definition" in the FTC Act, "upon which the New York statute is modeled"); *State v. Colorado State Christian Coll. of Church of Inner Power*, 76 Misc. 2d 50, 53–56 (Sup. Ct. N.Y. County 1973) *see also* Joseph Thomas Moldovan, Note, *New York Creates a Private Right of Action to Combat Consumer Fraud: Caveat Venditor*, 48 Brook. L. Rev. 509, 520–23, 553 (1982). And the statutes' legislative history supports that approach.[1]

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[1] *See* Antitrust Law Sec. of the N.Y.S. Bar Ass'n, *A Proposed New State Law Making Deceptive Acts or Practices Unlawful* 8 (1967) (noting intent "to make the federal law and its interpretation of deceptive acts

B. Factual Background

1. Quincy's misleading marketing of Prevagen

Defendants are affiliates and officers of Quincy Bioscience Holding Company, Inc. (collectively, "Quincy"). (J.A. 16–19 (¶¶ 9–16).) Quincy labels, advertises, markets, promotes, distributes, and sells an orally administered dietary supplement called Prevagen. (J.A. 20 (¶¶ 19, 21).) Quincy has claimed that "our brains need" Prevagen's active ingredient—apoaequorin, a dietary protein originally obtained from a species of jellyfish—for "healthy function." (J.A. 20 (¶ 19), 25.) According to Quincy, taking Prevagen daily can improve brain function and memory. (*E.g.*, J.A. 27, 29.)

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and practices applicable to state enforcement"); Attorney General's Mem. for the Governor at 2 (Feb. 18, 1970), *reprinted in* Bill Jacket for ch. 43 (1970), at 6 (G.B.L. § 349 based on "study and recommendations of the Committee on New York State Antitrust Law of the Antitrust Section of the New York State Bar Association"); Governor's Mem. on Approval of ch. 813 1963 N.Y. Laws, *reprinted in* 1963 N.Y.S. Legislative Annual 466 (G.B.L. § 350 "adopts substantive standards which have been in comparable Federal Statutes since 1915 and thus will promote uniform application of State and Federal Law"); Attorney General's Mem. for the Governor at 1 (Apr. 15, 1963), *reprinted in* Bill Jacket for ch. 813 (1963), at 5 (G.B.L. § 350 "borrows the substantive standards of the Federal Trade Commission Act").

In 2010, Quincy sought to test its memory-enhancement hypothesis in a clinical trial known as the Madison Memory Study. (J.A. 33, 37 (¶ 28).) As part of that study, 218 subjects took either ten milligrams of Prevagen or a placebo, and then were evaluated on "nine computerized cognitive tasks, designed to assess a variety of cognitive skills, including memory and learning, at various intervals over a" ninety-day period. (J.A. 37 (¶ 28).) 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."[2] (J.A. 37 (¶ 28).)

After that initial failure, Quincy ran more than thirty "post hoc" analyses of the results, trying to find statistically significant differences between subgroups of the larger study population. (J.A. 37 (¶ 29).) A post hoc analysis is one in which researchers mine study data in an effort to locate statistically significant differences between subgroups of the broader study population. (*See* J.A. 37 (¶ 29).) These analyses still found

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[2] "A study that is statistically significant has results that are unlikely to be the result of random error . . . ." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 n.6 (2011) (ellipsis in original; quotation marks omitted); *accord M.O.C.H.A. Soc'y, Inc. v. City of Buffalo*, 689 F.3d 263, 270 n.7 (2d Cir. 2012) (citing *Matrixx*).

no statistically significant effects from taking Prevagen for almost all of the subgroups. (J.A. 37 (¶ 29).) The only statistically significant effects it did find were for "subjects within a normal cognitive range and those with mild to moderate impairment." (J.A. 33.) Those differences, however, were more likely due to chance than the result of genuine statistically significant findings—a problem inherent in post hoc subgroup analyses. (J.A. 37 (¶ 29).)[3]

Despite the Madison Memory Study's initial failure and extremely limited support for Prevagen's health effects, Quincy marketed Prevagen as a proven memory enhancer for broad segments of the population. The front of the packaging for a bottle of Prevagen, for instance, states that Prevagen "improves memory" and supports "healthy brain function," a "sharper mind," and "clearer thinking." (J.A. 22.) The side of that packaging likewise notes that Prevagen "supports healthy brain function" and that apoaequorin "uniquely supports critical brain

[3] *See also, e.g.*, Stephen W. Lagakos, *The Challenge of Subgroup Analyses—Reporting Without Distorting*, 354 New Eng. J. Med. 1667, 1668 (2006) ("the probability of a false positive result—that is, of appearing to find an interaction when none exists—can be greatly inflated" when performing "multiple subgroup analyses").

functions." (J.A. 23.) The side of the packaging also states that Prevagen "supplements" proteins that the human brain loses with age and that Prevagen "is clinically shown to help with mild memory problems associated with aging." (J.A. 23.) And the back of the packaging claims, "In a computer assessed, double-blinded, placebo controlled study, Prevagen® improved memory." (J.A. 23.) The back of the packaging does not mention that the study it refers to—the Madison Memory Study—actually failed to show statistically significant improvement in memory for participants as a whole or in the vast majority of subgroups tested. Nor does it say that the positive findings were limited to a fraction of the study's subjects.

Quincy's marketing was not limited to Prevagen's packaging. Quincy repeated its claims of memory improvement across a variety of media, including a short-form television advertisement, which aired on major television networks, touting that "Prevagen Improves Memory" (J.A. 24); a long-form infomercial claiming that "Prevagen can supplement" the "vital proteins" that human brains lose as they age and thus "support a healthy brain and a sharper memory" (J.A. 159); a bus, bearing the "Prevagen Improves Memory" slogan in large letters across

its right side, that traveled the country (J.A. 21 (¶ 26), 36); and a website advertisement claiming that "Prevagen has been tested and shown to improve memory" (J.A. 25).

Although several of these materials referred to the Madison Memory Study, none mentioned its limitations, and instead conveyed the impression that Prevagen could improve the memory of any user. For example, the website advertisement boasted that in "a large double-blind, placebo-controlled study using computers" to test Prevagen's effects on "218 adults over 40 years old," Prevagen "significantly improved learning and word recall." (J.A. 25.) Quincy repeated that claim in several other advertisements. (*See, e.g.*, J.A. 35 (long-form infomercial); J.A. 38 (¶ 30) (chart appearing on Prevagen labels and television advertisements).) Although one piece of marketing literature noted that the study's positive findings were for "subjects within a normal cognitive range and those with mild to moderate impairment" (J.A. 131), that statement—in the eleventh chapter of a twelve-chapter publication (*see* J.A. 110)—did not disclose that the study actually failed to show statistically significant improvement across the entire study population and for the vast majority of subgroups tested (*see* J.A. 130–131). Nor did

it disclose the risk of false positives for its subgroup findings. (*See* J.A. 130–131.) And other statements in the same chapter proclaiming the success of the Madison Memory Study did not reveal that the findings were limited to subgroups of the overall test population. (*See* J.A. 130 (claiming that "[s]ubjects taking Prevagen performed excellently" as compared with "the placebo group," without mentioning subgroups).)

Quincy's advertising campaign backed its sale of Prevagen through its websites and through online and physical retail stores, health stores, and pharmacies. (J.A. 20 (¶ 21).) Depending on the strength of the dose and the retailer, a single bottle of Prevagen—a thirty-day supply—could cost as much as $68. (J.A. 20 (¶ 20).)

2. Plaintiffs' complaint

In January 2017, in a joint complaint, the FTC sued Quincy for violating FTC Act §§ 5 and 12, and the Attorney General sued Quincy for violating G.B.L. §§ 349 and 350 and Executive Law § 63(12). According to the complaint's allegations, Quincy represented "that Prevagen improves memory, is clinically shown to improve memory, improves memory within 90 days, is clinically shown to improve memory within 90 days, reduces memory problems associated with aging, is clinically shown

to reduce memory problems associated with aging." (J.A. 37 (¶ 28).) In fact, Quincy lacked substantiation for these representations because the one clinical study on which it relies—the Madison Memory Study—showed no statistically significant memory improvement across the study population as a whole. (J.A. 37–38 (¶¶ 28–30).) The only statistically significant results in that study were confined to small subgroups, and thus "do not provide reliable evidence of a treatment effect." (J.A. 37 (¶ 29).)

The complaint also alleges that Quincy misleadingly advertised that apoaequorin, Prevagen's active ingredient, supplements proteins in the human brain (see *supra* at 10). According to the complaint, Quincy lacked evidence that orally administered apoaequorin could cross the human blood-brain barrier. (J.A. 38–39 (¶ 31).) "To the contrary," the complaint alleges, Quincy's "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," and thus has no direct effect on brain chemistry. (J.A. 38–39 (¶ 31).)

The complaint asserts two different claims under FTC Act §§ 5 and 12. First, it alleges that Quincy's representations about Prevagen's

benefits were "false or misleading" or "not substantiated" when made. (J.A. 39–40 (¶¶ 36–37).) Second, it alleges that Quincy's representations that those benefits were "clinically shown" was false. (J.A. 40 (¶¶ 39–40).)

The complaint also asserts two claims under New York law—one under Executive Law § 63(12) and the other under G.B.L. §§ 349 and 350. Both claims allege that Quincy's representations about Prevagen's benefits, as well as its representations that those benefits were "clinically shown," were "false or misleading, or were not substantiated at the time the representations were made." (J.A. 41–42 (¶¶ 42–45).)

3. Quincy's motion and the decision below

Quincy moved to dismiss the complaint. It argued that the complaint failed to state a claim, that the First Amendment protects Quincy's alleged statements about Prevagen, and that a quorum of the FTC had not authorized the filing of the complaint.[4] (*See* S.A. 8–9.)

[4] Two individual defendants also moved to dismiss for lack of personal jurisdiction. (*See* S.A. 8.) The district court did not reach the individual defendants' arguments (S.A. 13), and we therefore do not address them here.

The district court granted Quincy's motion. According to the court, the complaint did not allege that Quincy's statements about Prevagen were likely to mislead consumers—as is required for claims under FTC Act §§ 5 and 12. (S.A. 10–12.) The court suggested that the complaint could plead a misleading representation only by alleging that "actual errors occurred" during the Madison Memory Study's use of post hoc subgroup analysis. (S.A. 11.) While the court acknowledged the allegations that post hoc subgroup analyses were unreliable, it held that the complaint failed to allege that such analyses "affected the subgroups['] performance in any way or registered any false positives" here. (S.A. 11.) As for the assertion that Quincy misrepresented that apoaequorin supplements proteins in the human brain, the court held that the allegation was "contradicted by canine studies." (S.A. 7 n.3.) The court also discredited the allegation because the two positive subgroup findings made "it clear that something caused a statistically significant difference between those subjects who took Prevagen and those given a placebo." (S.A. 7 n.3.)

After dismissing the FTC Act claims, the district court declined to exercise supplemental jurisdiction over the complaint's state-law claims.

(S.A. 12 (citing 28 U.S.C. § 1367(c)(3)).) It thus dismissed those claims without prejudice to refiling in state court. (S.A. 12–13.)

STANDARD OF REVIEW

This Court reviews a district court's decision declining to exercise supplemental jurisdiction over state-law claims for abuse of discretion. *Delaney v. Bank of Am. Corp.*, 766 F.3d 163, 170 (2d Cir. 2014). "A district court abuses its discretion when its decision rests on an error of law or a clearly erroneous finding of fact." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 238 (2d Cir. 2016). Here, the district court's dismissal of the state-law claims was predicated on its erroneous dismissal of the FTC Act claims. The court therefore abused its discretion. *Cf., e.g.*, *Jus Punjabi, LLC v. Get Punjabi US, Inc.*, 640 F. App'x 56, 59 (2d Cir. 2016) (summary order) (no abuse of discretion in declining to exercise supplemental jurisdiction, "because the district court properly dismissed plaintiffs' federal claims"); *Castellano v. City of New York*, 142 F.3d 58, 74 (2d Cir. 1998) (same).

This Court reviews the district court's dismissal of the FTC Act claims for failure to state a claim de novo and seeks to determine whether

the complaint states "a claim to relief that is plausible on its face." *Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017) (quotation marks omitted). In doing so, the Court must accept the complaint's factual allegations as true and draw all reasonable inferences in plaintiffs' favor. *Id.*

SUMMARY OF ARGUMENT

The complaint states a claim under FTC Act §§ 5 and 12, and accordingly states a claim under G.B.L. §§ 349 and 350 and Executive Law § 63(12) as well. The complaint adequately alleges that Quincy's representations about Prevagen's ability to improve memory were misleading and unsubstantiated because the Madison Memory Study showed no statistically significant difference between the group that received Prevagen and the group that received a placebo. While the study did find statistically significant effects on two small subgroups of the study population, identified during post hoc analyses, Quincy's marketing of Prevagen misrepresented that a much broader swathe of the population would experience memory benefits, and failed to disclose the significantly narrower findings of the only clinical study that it

conducted. Quincy's claims about Prevagen's memory benefits were thus likely to mislead consumers.

Quincy's claims that Prevagen can supplement proteins in the human brain were also misleading. Prevagen lacked evidence that apoaequorin, Prevagen's active ingredient, can reach the human brain. On the contrary, the complaint points to studies showing that apoaequorin is broken down like a normal protein in the stomach and so does not reach the human brain at all. And although Quincy disclosed that canine studies formed the sole basis for its claim that apoaequorin could cross the blood-brain barrier, that disclosure—in a single paragraph on the Prevagen website—was insufficiently prominent to neutralize Quincy's repeated public assertions that Prevagen supplements brain proteins in humans.

The district court's errors thus require reversal of the dismissal of the FTC Act claims.

This Court should also reverse the district court's dismissal of the state-law claims. The district court dismissed the state-law claims on the ground that it had no reason to exercise supplemental jurisdiction over the state law claims once it had determined to dismiss the only federal

claims pleaded here. Because the predicate for that ruling—the dismissal of the federal claims—was legally erroneous, it follows that the dismissal of the state-law claims was also legal error, and constitutes an abuse of discretion.

This Court should simply reinstate the state-law claims rather than remanding for district court consideration of them, because the complaint's sufficiency as to the state-law claims necessarily follows from its sufficiency as to the FTC Act claims. New York's consumer-protection and anti-fraud laws were modeled on, and in some respects are broader than, the FTC Act. Commercial misconduct that violates the FTC Act thus also necessarily violates New York's parallel statutes.

ARGUMENT

The district court erred in dismissing both the FTC Act claims and the state-law claims. As explained below and in the FTC's separate brief, the complaint adequately alleges violations of the FTC Act based on Quincy's misrepresentations about Prevagen's memory benefits. And reversal of the district court's incorrect ruling on federal law requires reinstatement of the complaint's state-law claims, for two reasons. First, the district court abused its discretion in declining to exercise

supplemental jurisdiction over the state-law claims when its sole basis for doing so was the legally erroneous conclusion that the complaint states no claims under federal law. Second, because New York's consumer-protection and anti-fraud statutes encompass misconduct covered by the FTC Act, holding that the complaint adequately pleads the FTC Act claims necessarily compels the conclusion that the state-law claims are also adequately pleaded. Because the correct disposition of the state-law claims follows directly from the correct resolution of the FTC Act claims, this brief first discusses the FTC Act claims, and then addresses the adequacy of the state-law claims.

POINT I

THE DISTRICT COURT ERRED IN DISMISSING THE COMPLAINT'S CLAIMS UNDER THE FEDERAL TRADE COMMISSION ACT

To state a claim under FTC Act §§ 5 and 12, a complaint must allege "[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) (alterations in original;

quotation marks omitted); *see Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (applying identical elements to § 5 and § 12 claims). As the district court observed, Quincy does not dispute that the complaint satisfies the first and third elements. (S.A. 10.) The only question, then, is whether the complaint satisfies the second element by alleging that Quincy's advertisements are likely to mislead consumers acting reasonably under the circumstances. The complaint plausibly does so.

A. The Complaint Plausibly Alleges That Quincy's Statements About Prevagen's Effect on Memory Were Likely to Mislead Consumers.

At the complaint's core is the allegation that the Madison Memory Study failed to show that Prevagen improved memory across the population generally. For that reason, Quincy's sweeping statements that Prevagen could improve memory were unsubstantiated or misleading, and its assertions that Prevagen was clinically shown to improve memory were false. (*See* J.A. 40 (¶¶ 37, 40).)

As the complaint alleges, the Madison Memory Study showed no statistically significant difference between the group receiving Prevagen and the group receiving the placebo. (J.A. 37 (¶ 28).) Yet Quincy not only claimed publicly—without qualification—that Prevagen "[i]mproves

memory" and "supports healthy brain function," but cited a "double-blind, placebo-controlled study" as proof of those claims. (*E.g.*, J.A. 25, 27, 29.) Quincy described the study as one in which "Prevagen significantly improved learning and word recall" for the "218 adults over 40 years old" who "participated in the three month study." (J.A. 25.) But the study in fact proved the opposite: when tested across the entire 218-person study population, Prevagen *lacked* the general effect that Quincy later claimed. Quincy's marketing efforts were thus "likely to mislead consumers acting reasonably under the circumstances," *LeadClick*, 838 F.3d at 168, into believing that Prevagen could improve memory for all segments of the population and that it had been clinically shown to do so. *See* Br. of the FTC ("FTC Br.") Point I.A.

The district court's contrary holding rested on the faulty premise that Quincy's claims about Prevagen's benefits were substantiated by the Madison Memory Study's identification of a statistically significant difference between two subgroups.[5] (*See* S.A. 12.) But that holding

[5] In reaching that conclusion, the district court improperly made findings of fact, relied on evidence outside the complaint, and resolved factual issues that required expert testimony—as the FTC correctly

misconstrues the complaint's allegations. The gravamen of the complaint is that the breadth of Quincy's public claims about Prevagen's memory benefits did not match the narrow benefits found by the only clinical study that Quincy conducted. Specifically, while Quincy marketed Prevagen's salutary effects for the general population, the Madison Memory Study showed no such effects for both the study population as a whole and the "vast majority" of subgroups tested in post hoc comparisons. (J.A. 37 (¶ 29).)

As the FTC correctly argues (FTC Br. Point I.A–B), the two statistically significant findings at the subgroup level did not make Quincy's claims less likely to mislead. Quincy touted Prevagen's benefits not to the specific subgroups who showed improvement but to the public at large, including by running advertisements on major television and radio stations. (J.A. 21 (¶ 24).) And Quincy failed to disclose in nearly all of its marketing materials that Prevagen had been shown to help with memory problems only for people "within a normal cognitive range" or "with mild to moderate impairment" (J.A. 131). Thus, "at least a

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points out (*see* FTC Br. Points II.A.1, II.A.3–4, II.B–C). Those errors provide independent grounds for reversal. *See id.*

significant minority of reasonable consumers would likely interpret" Quincy's marketing materials to mean that Prevagen had been clinically shown to help reduce mild memory problems in all people, even those who also suffer from more serious memory problems. *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015) (quotation marks omitted), *cert. denied*, 136 S. Ct. 1839 (2016); *accord ECM BioFilms, Inc. v. FTC*, 851 F.3d 599, 610 (6th Cir. 2017).

Nor does Quincy's one-time disclosure that the Madison Memory Study's statistically significant findings pertained to only certain subgroups cure the misimpression caused by its much more broadly disseminated set of misleading advertisements. A qualification or disclaimer immunizes an advertisement from an FTC Act challenge only if "sufficiently prominent and unambiguous to change the apparent meaning of the claims and to leave an accurate impression." *FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 12 (1st Cir. 2010) (quotation marks omitted). The sole disclosure here was buried nearly sixty pages into a single piece of marketing literature (J.A. 131), and not attached to the vast array of other advertisements and marketing materials that Quincy disseminated. Such a disclosure is nowhere near prominent enough to

overcome the wealth of other statements Quincy made about Prevagen's efficacy, both in that piece of marketing literature and in its other advertisements. *See FTC v. E.M.A. Nationwide, Inc.*, 767 F.3d 611, 633 (6th Cir. 2014) ("Defendants cannot make considerable material misrepresentations to consumers and then bury corrections and disclaimers in subsequent communications."). As courts have emphasized, a marketer's qualifying statements and disclaimers should be viewed not "in isolation" but rather by reference to the totality of the marketer's statements. *Fanning v. FTC*, 821 F.3d 164, 171 (1st Cir. 2016), *cert. denied*, 137 S. Ct. 627 (2017); *see POM Wonderful*, 777 F.3d at 493 (disclaimers' "net impression" did "not neutralize the claims made when the specific results are otherwise described in unequivocally positive terms" (quotation marks omitted)). The net impression Quincy gave the public—by repeatedly touting Prevagen's benefits without disclosing the limitations of Quincy's clinical findings—is that Prevagen can enhance memory for all users.

The complaint also alleges an alternative basis for holding that Quincy's marketing of Prevagen's memory benefits lacked adequate substantiation. A complaint pleads an FTC Act violation by alleging that

a marketer touted a product's medical benefits and claimed that they were scientifically proven, without backing up its claim with reliable evidence, including "evidence sufficient to satisfy the relevant scientific community of the claim's truth." *POM Wonderful*, 777 F.3d at 491. The complaint in this case meets that standard by asserting that Quincy's representations about Prevagen "were not substantiated at the time the representations were made" (J.A. 40 (¶ 37)), because of serious, inherent problems with the reliability of post hoc analyses. Specifically, the complaint alleges that conducting numerous post hoc comparisons "greatly increases the probability that some statistically significant differences would occur by chance alone" (J.A. 37 (¶ 29)). See *supra* at 9 & n.3; *see also* FTC Br. Point I.B. By alleging that post hoc subgroup analyses are more likely to produce false positives, the complaint plausibly pleads that the statistically significant differences observed in just a few of the many analyses conducted failed to provide a sufficient basis for Quincy's claims about Prevagen's medical benefits. *See POM Wonderful*, 777 F.3d at 490 (an "advertiser must possess a reasonable basis" for its claim about a product's efficacy (quotation marks omitted)); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 194 (D.C. Cir. 1986) (same). At

the very least, the complaint's allegations warranted further fact development, including expert testimony, about the inherent flaws of post hoc analyses.

The district court erred by holding that these allegations were insufficient to withstand a motion to dismiss on the ground that the complaint did not allege that the Madison Memory Study produced inaccurate results. The critical issue in such cases is whether the *methodology* of the studies purportedly underlying a marketer's claims is sufficiently reliable—not whether that methodology happened to produce the right result in any particular case. The district court was thus wrong in holding that plaintiffs' allegations about the inherent deficiencies of post hoc subgroup analyses were irrelevant unless those deficiencies actually "affected" the Madison Memory study. (S.A. 11.)

B. The Complaint Also Plausibly Alleges That Quincy Misrepresented Prevagen's Ability to Supplement Proteins in the Human Brain.

The other principal misrepresentation alleged in the complaint is Quincy's marketing of Prevagen as able to supplement proteins in the human brain. (*See* J.A. 38–39 (¶ 31).) That claim was included on Prevagen's packaging, in a short-form television advertisement, on the

Prevagen website, and in marketing literature. (J.A. 23–25, 27, 32.) The problem with that claim, however, is that Quincy lacked any evidence that Prevagen's active ingredient—orally administered apoaequorin—could cross the human blood-brain barrier. (J.A. 38–39 (¶ 31).) On the contrary, Quincy's own studies showed "that apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other dietary protein"—thus never reaching the brain directly. (J.A. 39 (¶ 31).)

The district court gave two reasons for discounting this allegation, but neither has merit. First, the court observed that the allegation was "contradicted by canine studies." (S.A. 7 n.3.) But even if a canine study could adequately support a claim for improvement of memory in humans—a factual question to be resolved later in the litigation—the fact that canine studies were the sole basis for Quincy's claims was inadequately disclosed. Most of Quincy's statements about Prevagen tout its benefits for humans, without mentioning that the only support for its claims comes from canine studies. Indeed, the complaint alleges that the *only* reference to canine studies that Quincy has made is in a single paragraph on the Prevagen website, in support of the claim that

"[a]poaequorin is capable of crossing the blood brain barrier (BBB) and GI barrier." (J.A. 26.) That paragraph—one of many in the nearly fifty pages of website materials (J.A. 57–105)—does not change the "net impression" conveyed by Quincy's repeated claim that Prevagen supplements proteins that "our brain" loses "[a]s we age" (*e.g.*, J.A. 23). *See, e.g.*, *POM Wonderful*, 777 F.3d at 493.

Second, the court held that the statistically significant results for the two subgroups uncovered during post hoc analyses suggested that apoaequorin must reach the human brain because "something" must have "caused a statistically significant difference between those subjects who took Prevagen and those given a placebo." (S.A. 7 n.3.) That holding ignores the complaint's allegations that the Madison Memory Study's use of post hoc subgroup comparisons "greatly increase[d] the probability that some statistically significant differences would occur by chance alone." (J.A. 37 (¶ 29).) The "something" that caused the statistically significant difference (S.A. 7 n.3) may have thus been sheer chance rather than apoaequorin. At minimum, the complaint's allegations raise a question of disputed fact that should not have been resolved against plaintiffs at this threshold stage. *See* FTC Br. Points I.C, II.A.2.

POINT II

BECAUSE THE COMPLAINT STATES A CLAIM UNDER THE FTC ACT, IT ALSO STATES A CLAIM UNDER NEW YORK'S GENERAL BUSINESS LAW §§ 349 AND 350 AND EXECUTIVE LAW § 63(12), AND SUPPLEMENTAL JURISDICTION OVER THOSE STATE-LAW CLAIMS IS PROPER

If the Court reinstates the FTC's claims, then it should also reinstate the State's claims under New York law. The district court's sole basis for dismissing those claims (S.A. 12) was 28 U.S.C. § 1367(c)(3), which allows a district court to decline to exercise supplemental jurisdiction if it "has dismissed all claims over which it has original jurisdiction." Given that the district court's dismissal of the FTC Act claims was improper, the court abused its discretion in declining to exercise supplemental jurisdiction. This Court should therefore reverse the district court's dismissal of the state-law claims.

Rather than remand for the district court to reconsider whether the complaint adequately pleads the reinstated state-law claims, this Court should hold that the complaint does so. The state statutes at issue here cover the same misconduct as FTC Act §§ 5 and 12—and, if anything, are broader than their federal counterparts. *See, e.g.*, *Applied Card Sys.*, 27

A.D.3d at 107–08 (citing cases construing FTC Act in holding that Attorney General established violations under state consumer-protection statutes). The complaint relies on the same factual allegations to support both the FTC Act claims and its claims under New York law. (J.A. 41–42 (¶¶ 43, 45).) And in the district court, Quincy acknowledged that the state-law claims would survive if the federal-law claims did: its sole argument for dismissing the state-law claims was that those claims "must fail because the FTC's claims fail." (J.A. 222.) Because, as discussed above, the complaint adequately pleads claims under the FTC Act, it necessarily pleads claims under New York's consumer-protection and anti-fraud statutes as well.

This result makes sense given the history of New York's statutes. Like many other States, New York modeled its consumer-protection laws on the FTC Act (see *supra* at 5), and courts in these States regularly rely on case law interpreting the FTC Act to construe their state-law counterparts.[6] The alignment between federal and state laws in this area

[6] *See, e.g.*, Tenn. Code Ann. § 47-18-115 (law "shall be interpreted and construed consistently with the interpretations given by the federal trade commission and the federal courts pursuant to § 5(A)(1) of the

makes it especially important that this Court reverse the dismissal of the FTC Act claims and reinstate the state-law claims. Allowing the district court's erroneous ruling to stand could effectively limit other States' ability to enforce their own consumer-protection laws if the courts of those states follow the reasoning of the court below. And limiting such state-law protections would be especially harmful in the market in which Quincy operates—products designed to fight memory loss. Scientists estimate that "[m]ore than a third of people over age 70 have some form of memory loss." *Memory of One in Three People over 70 Is Impaired, Study Shows*, ScienceDaily.com (Mar. 18, 2008).[7] With companies seizing on consumers' fears of memory loss, the market has become "replete with products advertised to improve memory and ward off cognitive decline." Thomas Pahl, Acting Dir., FTC Bureau of Consumer Prot., Remarks at National Advert. Div. Annual Conference, 2017 WL 4585119, at *5 (Oct.

Federal Trade Commission Act"); Ga. Code Ann. § 10-1-391(b) (similar); Conn. Gen. Stat. Ann. § 42-110b(b) (similar); *see also FTC v. Neovi, Inc.*, 604 F.3d 1150, 1156 (9th Cir. 2010).

[7] *Available at* https://www.sciencedaily.com/releases/2008/03/080318124436.htm.

3, 2017); *accord* Maggie Fox, *What Can Prevent Alzheimer's? Here's What the Evidence Shows*, NBC News (June 23, 2017) (observing "explosion of online and commercial products—from supplements to memory games—that allege they can help" prevent memory loss).[8] State consumer-protection laws offer an important tool to combat companies that market memory-enhancing products based on dubious scientific support.

[8] *Available at* https://www.nbcnews.com/health/health-news/still-no-prevention-alzheimer-s-three-actions-can-fight-memory-n775526.

CONCLUSION

For the foregoing reasons, the Court should reverse the district court's dismissal of the complaint, and hold that the complaint states a claim under G.B.L. §§ 349 and 350 and Executive Law § 63(12).

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Will Sager, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 6,298 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7).

/s/ Will Sager