17-3745 & 17-3791

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a Corporation, *Defendants-Appellees*.

(Caption continues on inside cover)

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)

REPLY BRIEF OF THE FEDERAL TRADE COMMISSION

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(*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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INTRODUCTION AND SUMMARY

As we showed in our opening brief, the complaint asserts three plausible claims that Quincy deceived consumers about Prevagen's benefits. *First*, Quincy's ads told consumers that Prevagen contains a "unique" protein that is "capable of crossing the blood brain barrier" to "supplement" brain proteins lost with age. JA57, 61. This claim was the sole premise of Prevagen's purported benefits, but was false. Quincy's own studies showed that the protein is broken down in the stomach and thus never enters the brain. JA38-39 ¶31. *Second*, Quincy stated without qualification that Prevagen is "clinically shown to improve memory." JA24. But Quincy's clinical trial failed to demonstrate any improvement for the overall study population on any of nine cognitive tasks. JA37 ¶28. *Third*, Quincy's subgroup analyses did not support its advertisements. The "vast majority" of those analyses turned up negative. JA37 ¶29. The few positive findings could have resulted from chance alone and thus did not justify the ads. *Id.*

When it dismissed the complaint, the district court committed basic and reversible errors with respect to each of those charges. Without the aid of a full record or expert testimony, it found facts adverse to the complaint on disputed issues of neuroscience, statistics, and clinical-trial methodology. The court rejected the allegation that Prevagen does not work because it cannot enter the brain, instead reasoning backward by assuming that the product works and finding

it "clear" that it must enter the brain because it works. SA7 n.3. The court also disregarded the complaint's allegations that Quincy made unsupported across-the-board claims that Prevagen improves memory and relied on extrinsic evidence to find Quincy's subgroup analyses reliable. SA11; *see also* SA5-6. Without a record, the court simply opined that the ads had support because subgroup analyses are "widely used in the interpretation of data in the dietary supplement field." SA11.

Quincy's brief fails to explain how the Madison Memory Study—which found no significant effects for the whole study population or the vast majority of subgroups—could *possibly* support the company's wholesale claims of improved memory within 90 days. Indeed, Quincy makes only a token four-page attempt to explain why the complaint's charges were implausible. Though Quincy denies telling consumers that Prevagen enters the human brain, the advertisements appended to the complaint show otherwise. Quincy argues that the complaint did not show that its subgroup analyses were unreliable, but the complaint clearly explains why running over 30 such analyses was likely to generate false positives and could not serve as the basis for clinical-proof and efficacy claims.

Quincy devotes the bulk of its brief to evidence outside the complaint, claims that the FTC and the State of New York waived their arguments, and unfounded legal arguments. For example, Quincy spends 14 pages arguing that it

had no duty to support its claims with the results of a randomized clinical trial. But that is not the question here. Quincy's ads *claimed* they were supported by such a trial, and the complaint plausibly charges that this representation was false. Quincy argues that the Government's legal theory is unprecedented, but it is hornbook law that advertisers may not distort the results of their research.

The Government preserved its arguments. Here, we challenge Quincy's "manipulation" of the statistical analysis; below, we used the closely synonymous term "cherry-picking" to refer to the same actions. JA315. We preserved objections to the district court's consideration of outside evidence by urging the court not to "make factual determinations as to the validity of the subgroup analysis—at the pleading stage, prior to the commencement of fact or expert discovery." JA318. That the court rejected that plea and considered extrinsic evidence shows not that the Government waived its objection but that the court committed reversible error by failing to give the Government notice and an opportunity to respond, as required by Rule 12(d).

With no other leg to stand on, Quincy asks the Court to affirm based on a company-prepared synopsis of the Madison Memory Study that omits the negative findings for the overall population and most subgroups. The synopsis is not "*the*" study (as Quincy repeatedly asserts), but a highly selective presentation of the results prepared years after the fact. Worse, Quincy mischaracterizes its synopsis

by claiming that the subgroups allegedly showing benefits comprised three-quarters of the study population when in fact they comprised fewer than half. *See infra* pp. 20-21. None of this evidence is properly before the Court, and none supports Quincy's position.

Quincy's alternative grounds for dismissal lack merit. Quincy's constitutional objections are premature. If the advertisements are proven deceptive at trial, they enjoy no First Amendment protection. The Commission acted with a proper quorum under its organic act and rules, which expressly contemplate the possibility of vacancies and enable the Commission to continue business. The district court had jurisdiction over individual defendants Underwood and Beaman because the FTC Act confers nationwide personal jurisdiction—as defendants directly *admitted* in another forum. The complaint sufficiently alleges facts showing that Underwood and Beaman, who ran the company and directed its advertising, are personally liable for Quincy's misrepresentations.

ARGUMENT

I. THE COMPLAINT PLAUSIBLY ALLEGES THREE SEPARATE WAYS IN WHICH QUINCY MISLED CONSUMERS

A. Quincy Falsely Told Consumers That Prevagen Enters The Brain

Quincy marketed Prevagen as a brain-protein supplement. The foundation of its sales pitch was that Prevagen's active ingredient, a protein (apoaequorin) derived from jellyfish, replaces brain proteins diminished with age. That was

Quincy's only explanation of how Prevagen worked, repeated in packaging, TV commercials, infomercials, Quincy's website, and its "Brain Health Guide." *See* JA23-24, 27, 32, 188. The complaint alleges that the pitch was untrue because Prevagen *cannot* work in this fashion. Quincy's own research showed that apoaequorin is digested and broken down in the stomach and therefore cannot enter the brain. *See* JA38-39 ¶31; FTC Br.36-38.

The district court was required to accept this allegation as true. *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230 (2d Cir. 2016). Instead, it found that Prevagen works as advertised, determining that it *must* enter the brain because "the results of the subgroup study … make it clear that something" about Prevagen improves memory. SA7 n.3. Given its topsy-turvy logic, the court never considered whether, as the complaint alleges, Prevagen does *not* work because it does not enter the brain. *See* FTC Br.40-42.

Quincy offers no serious response. It concedes it has no evidence that apoaequorin enters the human brain, but denies ever telling consumers otherwise. Br.22. That claim is flatly wrong given the sales pitch for Prevagen. Indeed, Quincy's website stated that "[a]poaequorin is capable of crossing the blood brain barrier." JA26, 61, 67-68. Quincy claims that a study conducted on *dogs* showed

entry into the brain,[1] Br.15-16, 22-23, but its website touted the product as supplementing *human* brain protein. Lacking evidence of that claim, the most Quincy can muster is speculation that Prevagen could have some *other* "positive effect on … memory." Br.23. That is not what Quincy said in its ads.[2]

After considering a full record, a factfinder could readily conclude that Quincy's express and implied claims that Prevagen enters the human brain were unsubstantiated. *See Kraft, Inc. v. FTC*, 970 F.2d 311, 318-22 (7th Cir. 1992) (express or implied misrepresentations can violate the FTC Act). Because the complaint states a valid claim, the district court's decision may be reversed on this ground alone.

B. The Madison Memory Study Does Not Support Quincy's Advertising Claims

The complaint charges—and Quincy does not deny—that Quincy made unqualified claims that Prevagen is "clinically shown" to "improve memory" within "90 days," to "reduce memory problems associated with aging," and to "provide other cognitive benefits." JA40 ¶39. Quincy told consumers that its *entire study population* saw these benefits. *See, e.g.*, JA25 ("218 adults over 40 years old participated in the three month study. Prevagen significantly improved

[1] The FTC will demonstrate at trial that the canine study proved no such thing.

[2] The Government did not acknowledge that Quincy's advertising regarding Prevagen entering the brain was "truthful[]." Br.22. The Government called these ads "false or unsubstantiated." JA315-16.

learning and word recall."); JA59 (the entire "Prevagen group" and "apoaequorin arm" experienced improvement).

The Madison Memory Study—the evidence Quincy cited in its ads—did not support those broad and unqualified claims. From Quincy's perspective, the study was a failure. The study found *no* benefits for the study population as a whole and no reliable evidence of benefits for any subgroups. JA37 ¶¶28-29. *See infra* Part I.C. In the absence of clinical proof, Quincy's blanket claims of benefit across the entire study population were false or misleading.

Given Quincy's advertising claims, the complaint's statement of a deception case is compelling. Yet the district court did not even assess whether the complaint sufficiently alleges that the Madison Memory Study did not support Quincy's claims.

Nothing in Quincy's brief salvages the court's error. Quincy contends the complaint lacked "substantive allegations" (Br.24), but ignores the allegations that its advertising claims were unsupported by the study. Nor does Quincy explain how the Madison Memory Study could have supported those claims. Quincy asserts (Br.41) that the subgroups with AD8 scores of 0-2 were its "target population," but does not deny pitching its ads to the *general population*. And, as described below, even the claimed benefits for those subgroups were suspect.

Quincy's remaining arguments are similarly unavailing. Quincy and its *amici* argue at length that Quincy did not need to support its claims with a randomized controlled trial (RCT) because the law and FTC guidance require only "competent and reliable scientific evidence." Br.18, 35-47. This argument is a red herring. Quincy's ads were misleading not because Quincy lacked an RCT to support them but because it told consumers that an RCT *did* support them, when the study did not show the advertised benefits. Indeed, Quincy *misrepresented the results* of its RCT. Because Quincy's ads "state[d] a specific type of substantiation," Quincy "must possess the specific substantiation claimed." *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 491 (D.C. Cir. 2015) (citation and quotation marks omitted).

FTC industry guidance, on which Quincy wrongly relies, reaffirms that principle: "If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate." FTC, *Dietary Supplements: An Advertising Guide for Industry* 9 (April 2001) ("*Dietary Supplement Guide*");[3] *see also id.* at 4, ex.1. The FTC will present expert testimony that the study is not competent and reliable scientific evidence of

[3] *Available at* https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf.

a benefit for any population. Having based an ad campaign on an RCT, Quincy must honestly portray it.

Quincy gets no help from the Dietary Supplement Health & Education Act of 1994. Br.35-36. That law neither applies to nor defines any standards under the FTC Act. If it were relevant, it is consistent with the FTC's position, since it authorizes labeling claims only when the manufacturer "has substantiation that such statement is truthful and not misleading," 21 U.S.C. § 343(r)(6)(B), which Quincy did not.

Quincy's repeated assertion that it performed a "gold-standard" clinical trial (Br.1, 9, 18, 38, 40, 43, 47) if anything *reinforces* its deception. Quincy's trial "failed to show a statistically significant improvement in the treatment group over the placebo group" on any of nine tasks. JA37 ¶28. Quincy couldn't ignore these "gold-standard" results and make blanket claims of clinical proof to consumers. As the FTC has advised, conducting an RCT does not provide carte blanche to misrepresent its results. "Claims that do not match the science … are likely to be unsubstantiated." *Dietary Supplement Guide* 16. Although Quincy invokes FDA guidance (Br.9, 40), it disregards that agency's warning to supplement manufacturers that "subgroup analysis" is a "[p]otential source[] of bias" that "can limit the reliability of the study." FDA, *Guidance for Industry: Substantiation for*

Dietary Supplement Claims, Part II.D. (Dec. 2008).[4] *See* FTC Br.52-53 & nn.28, 30 (describing similar FDA guidance). The FDA guidance shows that a "gold standard" trial showing no benefit for the study population can yield subgroup analyses of questionable luster.

By overlooking the main study results and the vast majority of subgroup results, Quincy failed to heed the FTC's admonitions against selective presentation of data. Advertisers "should make sure consumers understand both the extent of scientific support and the existence of any significant contrary evidence." *Dietary Supplement Guide* 7. Here, Quincy did not inform consumers that the study showed no evidence of benefit for the overall study population and indeed no reliable evidence of benefit for anyone. JA22-36; *see POM Wonderful*, 777 F.3d at 494 (advertiser violated FTC Act though "selective touting of ostensibly favorable study results and nondisclosure of contrary indications").

Because Quincy had ample notice of the standards that would apply to its advertising claims, it is wrong in asserting that the FTC "impermissibly … appl[ied] a new standard retroactively by means of litigation, rather than through notice and comment [rulemaking]." Br.35, 41-42.

[4] *Available at* https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm.

C. Quincy's Subgroup Analyses Were Unreliable

The complaint also states a claim that Quincy's few positive subgroup results were unreliable and did not substantiate the advertisements. Quincy does little to challenge the complaint's facial sufficiency, but contends that outside evidence renders the charge implausible. That evidence is not properly before the Court (and the district court was wrong to consider it), but even if it were, Quincy misrepresents its contents, which *support* the complaint.

1. The Complaint States A Claim

As we explained at pages 31-36 of our opening brief, the district court erred when it held that the complaint failed to explain why Quincy's subgroup methods had a heightened risk of false positives. The complaint alleges that false positives were likely because Quincy performed "more than 30 post hoc analyses of the results" after learning that the study's overall findings were negative, creating "several variations of smaller subgroups" for nine separate tasks. JA37 ¶29. That "methodology greatly increases the probability that some statistically significant differences would occur by chance alone." *Id.*

These contentions are rooted in the well-accepted principle that the more statistical tests performed, the likelier they are to generate a false positive. *See* FTC Br.34-35. Given that risk, the complaint charges that a "few positive findings on isolated tasks for small subgroups" are not "reliable" substantiation of Quincy's

claims in the face of the "vast majority" of negative findings from the same study. JA37 ¶29. These allegations, "construed liberally, [and] accepting all factual allegations … as true," *Nicosia*, 834 F.3d at 230, support a reasonable inference that Quincy's ads treating the subgroup results as definitive proof were misleading.

Beyond calling these allegations "bare" (Br.11), Quincy makes little effort to defend the district court's ruling that they are facially implausible. Quincy attacks the complaint for not defining "post hoc," but acknowledges that it uses this term in its ordinary sense to signify analyses performed "after the study's completion." Br.11. The complaint thus charges that Quincy ignored the results of the actual study in favor of new analyses "formulated after the fact." *Merriam-Webster Online* (defining "post hoc"), https://www.merriam-webster.com/dictionary/post%20hoc; *see* JA37 ¶¶28-29; FTC Br.33, 52-54 & nn.13, 27. A factfinder could reasonably determine that Quincy conducted these subgroup analyses in search of positive results to salvage a study that essentially refuted its advertising claims. Quincy further assails the complaint for "present[ing] a generalized rather than specific attack on subgroup analysis." Br.21. But the complaint explains why Quincy's 30-plus post hoc analyses in *this* study were unreliable, given the study's failure to show results for the overall population on any of nine tasks. JA37 ¶¶28-29.

Finally, Quincy wrongly claims that the Government waived its argument that Quincy's ads dishonestly presented selective data. The claim is that the FTC's brief uses the words "manipulation" and "data dredging" (and *amici* use the words "sliced and diced") but did not use those precise terms below. Br.3, 27-28. Thus, according to Quincy, the FTC and *amici* "appear[] to cast doubt for the first time on the Madison Memory Study's methodology or results." *Id.* at 3. The Government did not waive the argument.

From the start, the Government challenged Quincy's misuse of the Madison Memory Study in its ads. Specifically, our pleadings below charged Quincy with "*cherry-picking* from the numerous post-hoc comparisons." JA315 (emphasis added). The terms "manipulation," "data dredging," "slicing and dicing," and "cherry-picking," are essentially interchangeable ways to describe Quincy's basing clinical-proof claims on scant positive data drawn from a larger population with overwhelmingly negative results.

2. The FTC Preserved Its Objections To The District Court's Consideration Of Outside Evidence

Aside from its halfhearted challenge to the complaint's facial sufficiency, Quincy essentially concedes it can prevail only if the Court credits facts outside the complaint. Quincy asserts that the complaint was implausible because of other "government … studies" and because the AD8 0-1 and 0-2 subgroups "comprised

over 76% of the Madison Memory Study's population." Br.21.[5] We showed that Quincy's extrinsic evidence has obvious credibility gaps, *see* FTC Br.17-18, 46-49, 51-52, but Quincy claims the Government waived those objections. Br.17, 24, 26.

The Government preserved its argument. We urged the district court not to "make factual determinations as to the validity of the subgroup analysis—at the pleading stage, prior to the commencement of fact or expert discovery, and without the benefit of expert testimony." JA318. In three separate places, we stressed that the court's role was simply to assess the complaint's facial plausibility and not "the weight of the evidence that might be proffered in support." JA313, 317-19. We relied, with supporting authority, on the rule that a court resolving a 12(b)(6) motion may only review the complaint exhibits, documents the complaint incorporates by reference, and matters subject to judicial notice. JA313-14.

Those arguments preserved the right to challenge the extrinsic evidence on appeal because the district court never should have considered it in the first place. Quincy's waiver claim is inconsistent with Fed. R. Civ. P. 12(d), under which a court "must" convert a motion to one for summary judgment and give "[a]ll parties … a reasonable opportunity to present all material that is pertinent to the motion" before it considers "matters outside the pleadings." The point of the Rule is that

[5] The Court should disregard this assertion because it is new on appeal and misrepresents Quincy's outside evidence. *See infra* pp. 20-21.

plaintiffs should not have to rebut extrinsic evidence unless the court converts the proceeding. A court may not "bypass[] that procedure for the sake of expediency" by considering outside matters and summarily designating them "uncontroverted." *Kopec v. Coughlin*, 922 F.2d 152, 155 (2d Cir. 1991) (citations and quotation marks omitted). As Quincy would have it, the Government was required to offer rebuttal even though the court never converted the proceeding.

By considering outside evidence without converting the proceeding, the district court deprived the Government of "notice … that outside matters would be examined," *Global Network Communications, Inc. v. City of New York*, 458 F.3d 150, 155 (2d Cir. 2006), and "a fair chance to contest defendants' evidentiary assertions," *Amaker v. Weiner*, 179 F.3d 48, 50 (2d Cir. 1999). The Court should not preclude the Government from fully challenging the lower court's treatment of outside evidence when that court never alerted the Government it would consider such evidence.

For the same reasons, Quincy errs in objecting (Br.3, 17, 27) to the FTC's discussion of scientific literature casting doubt on the reliability of Quincy's subgroup analysis. *See* FTC Br.52-55. The literature illustrates the error in the district court's finding, based on Quincy's one-sided evidentiary proffer, that Quincy's subgroup analyses are reliable. The material shows that the court "foreclosed any serious debate on contested matters" and made scientific

judgments that "could well be proven wrong after proper consideration of expert testimony." FTC Br.52.

3. The District Court Committed Reversible Error When It Considered Quincy's Outside Evidence

Rule 12(d) is "strictly enforced whenever there is a legitimate possibility that the district court relied on material outside the complaint in ruling on the motion." *Friedl v. City of New York*, 210 F.3d 79, 83 (2d Cir. 2000) (quotation omitted). Here, there is more than a possibility; the court expressly considered extrinsic evidence. That was a reversible error in its own right. A district court "errs when it considers … exhibits submitted by defendants, or relies on factual allegations contained in legal briefs or memoranda in ruling on a 12(b)(6) motion to dismiss. Vacatur is required even where the court's ruling simply makes a connection not established by the complaint alone." *Id.* at 83-84 (citations, quotation marks, and alteration omitted).

Quincy's description of its extrinsic evidence has serious credibility problems that the Government easily could have demonstrated had the district court provided the required notice under Rule 12(d).[6] Quincy claims that subgroup analysis is reliable because the "government" has used it in "similar studies."

[6] Quincy's evidence is not judicially noticeable merely because it appears on public websites (Br.14, 17), since its accuracy and completeness are "subject to reasonable dispute." Fed. R. Evid. 201(b).

Br.13, 21. The district court relied on that assertion in finding that subgroup analyses are "widely used in the interpretation of data in the dietary supplement field." SA11. Yet the single NIH study that Quincy cited expressly warns that subgroup analyses conducted after negative primary findings must be "interpreted with caution" and may not be "generaliz[able] to the population as a whole." *See* FTC Br.51-52 (citation and quotation marks omitted). Quincy failed to inform the district court (or this one) about those warnings, which raise an issue of fact.

More importantly, Quincy represents its August 2016 "Clinical Trial Synopsis" (JA235-44) as "*the*" Madison Memory Study. Br.3, 6, 17, 24. It is not. As we explained in our opening brief, Quincy prepared the 2016 synopsis *five years* after completing the study, several years after launching its ad campaign, and shortly before the Government filed suit. *See* FTC Br.17-18, 45-49. The synopsis does not fairly present the study data; principally, it omits the negative findings for the overall population and most subgroups. The synopsis also contradicts other accounts Quincy has provided of the study and the test population.[7]

[7] Quincy claims on appeal—for the first time—that the study "excluded anyone with AD8 scores above 3." Br.7. But a 2011 paper relied on by Quincy elsewhere (JA59) refers to participants with scores of 5. *See* Mark Y. Underwood *et al.*, *The Effects of the Calcium Binding Protein Apoaequorin on Memory and Cognitive Functioning in Older Adults* 7 (July 2011), *available at* https://www.truthinadvertising.org/wp-content/uploads/2015/09/The-Effects-of-the-Calcium-Binding-Protein-Apoaequorin-on-Memory-and-Cognitive-Functioning-in-Older-Adults.pdf.

The district court nevertheless adopted the synopsis and all of its representations as fact without giving the Government a chance to respond. *See* SA4-6, 11-12. The court did not, as Quincy suggests (Br.17, 25), deem the synopsis "integral" to the complaint. It couldn't have, since a document is "integral" only if the complaint "relies heavily upon its terms and effect." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (citation and quotation marks omitted). While the complaint described the Madison Memory Study, it made no reference to Quincy's *2016 synopsis*, which did not even exist when Quincy ran most of the challenged ads. *See* FTC Br.46.

Moreover, as we explained, even if the synopsis *were* integral to the complaint, the district court could not rely on it to establish the truth of the matters it asserted. *See* FTC Br.47-49. Quincy fails to respond to this argument. In the face of "a dispute as to the relevance, authenticity, or accuracy of the documents relied upon, the district court may not dismiss the complaint with those materials in mind." *Nicosia*, 834 F.3d at 231.

The district court violated that principle in three ways. First, the Government alleged that Quincy's subgroup results did not reflect valid cognitive improvements and could have resulted from chance alone. JA37 ¶29, 315-16,

318.[8] The court adopted the synopsis's conclusion that members of the "AD 0-1 and 0-2 subgroups … displayed improvement in memory after taking the supplement." SA11. The court even declared that "something" other than chance must have caused these results. SA7 n.3. *See* FTC Br.39-40.

Second, the Government charged that Quincy possessed evidence showing that apoaequorin could not enter the human brain. JA38-39 ¶31, 316-17. The district court relied on Quincy's synopsis to find instead that "the subgroup study … make[s] it clear" that the protein *must* have entered the brain. SA7 n.3. *See* FTC Br.40-42.

Third, the Government contended that Quincy's ads were deceptive because the study failed to support Quincy's broad claims of efficacy and proof. JA21-42, 314-35. The district court held that the ads could *not* have been deceptive, adopting the synopsis's representation that the AD8 0-1 and 0-2 subgroups were the ones "most relevant to the efficacy of the product." SA4 (quoting JA236). The court even described its own outside research into the AD8 test. SA4 n.1. But Quincy's ads claimed that Prevagen helped the *entire study population*, not just subgroups. *See supra* pp. 6-7.

[8] Quincy falsely claims the Government conceded that the study showed a "meaningful benefit" for the subgroups with AD8 scores of 0 through 2. Br.41. This is *exactly* what the Government disputed in the complaint.

4. The Complaint Would State A Claim Even Considering Quincy's Synopsis

Quincy's synopsis demonstrates why the complaint is plausible. It concedes that "no statistically significant results were observed over the entire study population," and that the AD8 0-1 and 0-2 subgroups showed results only on three of nine cognitive tasks. JA239-43. These admissions *alone* create a triable issue of fact. As *amici* explain, "the *best* evidence available—the overall study results—contradict Quincy's marketing claims." Br. for Truth in Advertising, Inc., et al. 11. A factfinder could also reasonably conclude that Quincy cannot advertise memory "improvement" when even the cherry-picked subgroups showed no evidence of improvement on two-thirds of the tasks. *See* FTC Br.33-34. These matters are properly determined on review of a complete record, not on a 12(b)(6) motion.

Relying on the synopsis, Quincy's brief makes (and repeats six times) a new assertion that the AD8 0-1 and 0-2 subgroups comprised 76% of the study population. Br.1, 7-8, 11, 21, 26, 28. Quincy did not mention that statistic to the district court, nor is it in the data table cited by Quincy. *See* JA239 tbl. 2. The table makes clear that only 100 of the 211 participants who finished the study—fewer than half—had AD8 scores between 0 and 2. JA238-39. Quincy got to 76% by double-counting the 61 members of the AD8 0-1 subgroup, who, by definition, are subsumed within the AD8 0-2 subgroup. But even if 76% of the study

population showed results on one-third of the tasks assessed, a factfinder could *still* conclude those results do not support unqualified claims of improved memory.

II. APPELLEES' REMAINING ARGUMENTS LACK MERIT

This Court ordinarily declines to reach issues not passed upon below, though it will sometimes address pure questions of law. *United States v. Gomez*, 877 F.3d 76, 92 (2d Cir. 2017). If the Court considers appellees' remaining arguments, they fail.

A. It Is Premature To Address The First Amendment

Quincy claims its ads are truthful speech protected by the First Amendment. Br.47-49. Whether or not the ads are truthful is the very issue to be decided in this case, so this Court cannot assess the constitutional claim now.

"For commercial speech to come within [the First Amendment], it at least must … not be misleading." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). Advertising claims with "insufficient support" are "misleading" and "unprotected by the First Amendment." *POM Wonderful*, 777 F.3d at 500. If Quincy's ads were not misleading, then they did not violate the FTC Act and no court need ever reach the First Amendment question. But if the ads were misleading, then they enjoy no constitutional protection. At this point, it is premature to address the matter.

B. The Commission Acted With A Valid Quorum

When it filed the complaint, the FTC had three sitting Commissioners and two vacancies. Two Commissioners voted to authorize the complaint and one voted "not participating." That Commissioner did not recuse herself, but simply declined to vote yes or no. Three out of five Commissioners is a quorum under any understanding.

Quincy assumes that a nonparticipating Commissioner does not count towards a quorum, Br.32, but that is incorrect. "The quorum refers to the number of … members *present*, not to the number actually voting." *Robert's Rules of Order* § 40, p. 334 (10th ed. 2000). Thus, "an abstaining voter … is counted in determining the presence of a quorum." *Chamber of Commerce of U.S. v. NLRB*, 879 F. Supp. 2d 18, 27 (D.D.C. 2012) (alteration omitted) (quoting 59 Am. Jur. 2d *Parliamentary Law* § 9). Governmental authority "is not stopped by the mere silence and inaction of some of the law-makers who are present." *United States v. Ballin*, 144 U.S. 1, 9 (1892) (citation and quotation marks omitted).

Even if the nonparticipating Commissioner did not count, however, the vote still satisfied the FTC's longstanding quorum rule, which deems a quorum a "majority of the members of the Commission in office and not recused from participating in a matter." 16 C.F.R. § 4.14(b) (2005). Since the FTC had three Commissioners in office, two of them constituted a quorum. The rule further

provides that once a quorum exists, "Commission action … may be taken … with the affirmative concurrence of a majority of the participating Commissioners." *Id.* § 4.14(c). Since both participating Commissioners voted to adopt the complaint, it complied with the FTC's quorum rule.

Quincy does not deny that the vote complied with the rule. It argues instead that the rule is invalid under the "common-law." Br.31-34. Quincy is wrong, both because Congress gave the Commission wide latitude to adopt procedural rules and because there is no such governing common law.

Congress could have specified the number of members who must be present for a quorum, but it chose not to.[9] Instead, it directed that that a "vacancy in the Commission shall not impair the right of the remaining Commissioners to exercise all the powers of the Commission." 15 U.S.C. § 41. And, it authorized the Commission to "make rules and regulations for the purpose of carrying out the provisions of this subchapter." *Id.* § 46(g). The FTC therefore may "promulgate … rules of procedure." *Nat'l Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 678 (D.C. Cir. 1973). In other words, Congress left it to the Commission to define a quorum for itself.

[9] In contrast, Congress enacted an express quorum requirement into other statutes, such as the Communications Act, *see* 47 U.S.C. § 154(h).

The D.C. Circuit rejected an argument virtually identical to Quincy's when it upheld an SEC quorum rule that authorized action by two commissioners. *See Falcon Trading Grp., Ltd. v. SEC*, 102 F.3d 579, 582 (D.C. Cir. 1996). Like the FTC Act, the SEC's enabling legislation did not define a quorum but "specifically bestowed" the authority to issue rules carrying out its duties. *Id.* The court explained that "[t]his broad grant must be read to include authority to determine how many members constitute a quorum of the Commission." *Id.*

Quincy criticizes *Falcon Trading*, citing a district court case that upheld the SEC's quorum rule on a different ground and questioned that agency's "authority to establish [its] own internal procedures." Br.32-33 (quoting *SEC v. Feminella*, 947 F. Supp. 722, 726 (S.D.N.Y. 1996)). That decision is hard to square with the plain terms of the FTC Act empowering the FTC to adopt procedural rules.

Even if the "common law" could override a specific legislative grant of authority, it does no such thing. Under the common law, an agency may "permit a quorum made up of a majority of those members of a body *in office* at the time." *Falcon Trading*, 102 F.3d at 582 n.2. That is clear from a long line of cases defining a quorum of a "public body" as a majority of its "actual members" unless a statute provides otherwise. *See, e.g.*, *Lee v. Bd. of Ed. of City of Bristol*, 434

A.2d 333, 341 (Conn. 1980).[10] Quincy cites no common-law case to the contrary.[11] Black's Law Dictionary, which Quincy selectively quotes, explains in a passage omitted by Quincy that a quorum may legitimately be calculated based on "the number of sitting members (excluding vacancies)." *Quorum*, BLACK'S LAW DICTIONARY 1446 (10th ed. 2014).

Courts recognize that they should not apply quorum requirements to cripple multi-member agencies with vacancies. Thus, the Seventh Circuit held that a statute defining a quorum as a "majority of the Interstate Commerce Commission" required only a majority of members "actually in office." *Assure Competitive Transp. v. United States*, 629 F.2d 467, 472-73 (7th Cir. 1980). Because the ICC's statute, like the FTC Act, provided that vacancies shall "not impair" agency business, "Congress intended those Commissioners in office, however many there are, to be 'the Commission' for all purposes." *Assure*, 629 F.2d at 472-73.

Quincy's remaining arguments have no force. Quincy casts aspersions on the vote by describing the Commissioners' party affiliations, but cites no authority rejecting an agency decision on such grounds. Br.3, 17, 32. Some party-line votes

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[10] *See also Bd. of Comm'rs of Town of Salem v. Wachovia Loan & Tr. Co.*, 55 S.E. 442, 444 (N.C. 1906); *Nalle v. City of Austin*, 93 S.W. 141, 145 (Tex. Civ. App. 1906); *State ex rel. Att'y Gen. v. Orr*, 56 N.E. 14, 14 (Ohio 1899).

[11] Quincy relies on *FTC v. Flotill Products, Inc.*, 389 U.S. 179 (1967), which did not decide whether a "majority of a collective body" means a majority of current members or of authorized seats. *Id.* at 183.

are inevitable with any bipartisan commission regardless of quorum size. Nor does it matter that a Commissioner left the agency soon after the vote. *See Idaho v. ICC*, 939 F.2d 784, 788 (9th Cir. 1991). Finally, Quincy erroneously claims that the FTC has "never" taken action through a two-member quorum. Br.32. In fact, due to vacancies and recusals, the Commission has done so even in other major cases.[12]

C. The Court Has Personal Jurisdiction Over Underwood And Beaman

Individual appellees Underwood and Beaman assert that the district court lacked personal jurisdiction over them. Interestingly, they told the Judicial Panel on Multidistrict Litigation precisely the opposite. There, trying to get private-party lawsuits transferred to New York and consolidated with this case, they said, "[t]he FTC has nationwide jurisdiction, and could have filed its action anywhere." Mot. to Transfer at 10, *In re Prevagen*, MDL No. 2783 (J.P.M.L Mar. 30, 2017), ECF No. 1-1. A week later, they switched horses and told the Southern District of New York they are "not subject to personal jurisdiction in New York." JA260. That about-face alone should doom their argument.

[12] *See, e.g.*, *FTC Approves Final Consent Order in Case of Pfizer Inc. and Wyeth* (Jan. 29, 2010), https://www.ftc.gov/news-events/press-releases/2010/01/ftc-approves-final-consent-order-case-pfizer-inc-wyeth ("The FTC vote approving the final order was 2-0, with Commissioners Pamela Jones Harbour and William E. Kovacic recused.").

"Serving a summons" on a defendant "establishes personal jurisdiction" over him "when authorized by a federal statute." Fed. R. Civ. P. 4(k)(1)(C). The FTC's summonses for Underwood and Beaman were served under Section 13(b) of the FTC Act, which authorizes the FTC to serve process "on any person, partnership, or corporation *wherever it may be found*." 15 U.S.C. § 53(b) (emphasis added).

When, like Section 13(b), a statute uses the language "wherever the defendant may be found," it "explicitly authorize[s] nationwide service of process." *Omni Capital Int'l, Ltd. v. Rudolff Wolff & Co.*, 484 U.S. 97, 105-06 (1987). This Court has recognized that Congress uses phrasing like Section 13(b) when it "intends to permit nationwide personal jurisdiction." *Dynegy Midstream Servs. v. Trammochem*, 451 F.3d 89, 95-96 (2d Cir. 2006); *accord Mariash v. Morrill*, 496 F.2d 1138, 1142 (2d Cir. 1974). Indeed, the Supreme Court recently cited Section 13(b) as an example of Congress's having conveyed nationwide personal jurisdiction. *See BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1555-56 (2017). Other federal courts have routinely held that Section 13(b) confers such jurisdiction. *See*, *e.g.*, *FTC v. Americans for Fin. Reform*, 720 F. App'x 380, 383 (9th Cir. 2017).

Underwood and Beaman try to escape the implications of Section 13(b) on the ground that the statute applies only when venue is appropriate. Br.5, 19-30.

But *they do not argue that the district court lacked venue*, nor did they argue as much below (they told the JPML that New York is an ideal venue).

The cases that Underwood and Beaman rely on are inapposite because they concern Section 12 of the Clayton Act, a much narrower statute than Section 13(b) of the FTC Act. Section 12 allows nationwide service only "in such cases" that meet the statute's specific venue restrictions. 15 U.S.C. § 22. Thus in *Daniel v. American Board of Emergency Medicine*, 428 F.3d 408, 426-27 (2d Cir. 2005), this Court held that antitrust plaintiffs who establish venue under 28 U.S.C. § 1391, but not under the Clayton Act, may not take advantage of the Clayton Act's service provision. *Accord Goldlawr, Inc. v. Heiman*, 288 F.2d 579, 581 (2d Cir. 1961). These cases have no force here because Section 13(b) is not so limited: it permits nationwide service "[i]n *any suit* under this section" and it expressly incorporates Section 1391 as a basis for venue.[13] 15 U.S.C. § 53(b) (emphasis added). Indeed, *Daniel* distinguished statutes that, like Section 13(b), authorize service "in any action … under this chapter," explaining that such statutes enable nationwide jurisdiction. 428 F.3d at 427 (citation, quotation marks, and emphasis omitted).

[13] Underwood and Beaman assert that reading Section 13(b) to authorize nationwide process "render[s] meaningless the statute's threshold venue requirement," Br.21, but that is wrong because venue is not a threshold requirement but one separate from personal jurisdiction. And here, Underwood and Beaman concede that venue is proper.

Because Section 13(b) authorizes nationwide service, the district court had jurisdiction over Underwood and Beaman so long as they had minimum contacts with the country as a whole, which as United States residents, they do. *See Mariash*, 496 F.2d at 1143.

D. The Complaint States A Deception Claim Against Underwood And Beaman

As corporate officers, Underwood and Beaman are liable for "deceptive practices or acts if, with knowledge of the deception, [they] either directly participate[d] in a deceptive scheme or ha[d] the authority to control the deceptive content at issue." *FTC v. LeadClick Media, LLC*, 838 F.3d 158, 168 (2d Cir. 2016).[14] Underwood and Beaman call the complaint's allegations of personal liability "conclusory" (Br.33); in reality, they are overwhelming.

As the author of Quincy's "Brain Health Guide" and the star of its infomercials, Underwood personally and directly misled consumers. JA18 ¶14; 21 ¶23; 107-44; 146-91. He co-authored multiple Prevagen studies, serves on the "marketing creative team," "coordinates advertising claim language review with counsel, translates scientific data into marketing language, and directs research programs and activities." JA18 ¶14. Underwood is Quincy's co-founder, president, largest shareholder, and a board member. JA18 ¶13. He serves "as the

[14] Knowledge is only required for monetary relief, not injunctive relief. *POM Wonderful*, 777 F.3d at 498.

final decision maker on all advertising claims across all channels of distribution and media platforms." JA18 ¶14. Although Underwood denies without explanation that these roles show participation and control (Br.36), it is impossible to see why not.

Beaman also exercises control and participates directly in advertising and research. He is Quincy's CEO, co-founder, former president, second-largest shareholder, and a board member. JA18-19 ¶15. As chief executive, Beaman has "reviewed [Quincy's] advertising"—including the ads at issue—and "given media interviews, signed research agreements, [and] pre-approved research proposals." JA19 ¶16.

Beaman nonetheless denies his participation, claiming the complaint fails to specify whether he has "reviewed the results of the research." Br.35. But it is no stretch to infer that a CEO who signs research agreements and approves research proposals is also familiar with the results. Beaman posits that the complaint does not demonstrate that he "participated in the presently challenged conduct." Br.36. But the complaint clearly explains that Beaman is the *current* CEO and in that capacity reviews the company's ads, directs research, and gives media interviews.

The allegations of Beaman's control are even stronger. Beaman denies that his title as CEO matters (Br.32-34), but "[a]uthority to control the company can be evidenced by active involvement in business affairs and the making of corporate

policy, including assuming the duties of a corporate officer." *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). Indeed, an officer with "authority to sign documents on behalf of the corporation" possesses the "requisite control." *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997). A factfinder may readily conclude that Beaman, as CEO, "could have, but did not" put a stop to the deceptive ads. *LeadClick*, 838 F.3d at 169.

Underwood and Beaman also argue that, regardless of the allegations of participation and control, the complaint fails to show they had "actual knowledge" of the misleading ads. Br.36-37. But the FTC need not prove actual knowledge *at trial*, let alone in a complaint. The FTC can establish personal liability by showing that an officer "should have had knowledge," exhibited "reckless indifference to the truth or falsity of [the ads]," or was aware of a "high probability" of deception and "intentional[ly] avoid[ed] … the truth." *Amy Travel*, 875 F.2d at 574 (citation and quotation marks omitted). Knowledge can be inferred from "the degree of [an officer's] participation in business affairs." *Id.*

The complaint supports the reasonable inference that, having overseen research and advertising, Underwood and Beaman knew or should have known that Quincy's scientific research did not support the company's blanket claims of improved memory. Underwood's denial of knowledge is particularly far-fetched

since he personally made the deceptive claims and co-authored some of the research.

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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CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Local Rule 32.1(a)(4)(B) because it contains 6,999 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.

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I certify that on June 13, 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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