25-12-cv(L),
25-16-cv(CON), 25-274-cv(XAP)

United States Court of Appeals

for the

Second Circuit

FEDERAL TRADE COMMISSION,

Plaintiff-Appellee,

PEOPLE OF THE STATE OF NEW YORK, by Letitia James,
Attorney General of the State of New York,

Plaintiff-Appellee-Cross-Appellant,

– v. –

(For Continuation of Caption See Inside Cover)

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

PAGE PROOF BRIEF FOR DEFENDANTS-APPELLANTS-CROSS-APPELLEES QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, PREVAGEN, INC., and QUINCY BIOSCIENCE MANUFACTURING, LLC

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QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation,
QUINCY BIOSCIENCE, LLC, a limited liability company,
PREVAGEN, INC., a corporation doing business as 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.,

Defendants-Appellants-Cross-Appellees,

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

Defendant.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy"), states as follows:

Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC are wholly owned subsidiaries of Quincy Bioscience Holding Company, Inc. No publicly held corporation owns more than 5% of Quincy Bioscience Holding Company, Inc.'s stock.

STATEMENT OF PRIOR APPEALS

There were two prior, consolidated appeals before the Second Circuit, Case Nos. 17-3745, 17-3791. By Summary Order dated February 21, 2019, this Court vacated an order dismissing the Federal Trade Commission's ("FTC") and New York Attorney General's ("NYAG") (together with the FTC, "Plaintiffs") complaint for failure to state a claim, entered by the United States District Court for the Southern District of New York (the "District Court"), and remanded the matter for further proceedings. *FTC v. Quincy Bioscience Holding Co., Inc.*, 753 Fed. App'x 87, 90 (2d Cir. 2019).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

PRELIMINARY STATEMENT

This appeal involves two government agencies who—despite *losing* on the majority of the marketing claims that they challenged—were nonetheless handed an overall victory on all claims by the District Court in a series of decisions that overlooked evidentiary failures and were premised on significant errors of law.

To prevail in this action, Plaintiffs had the burden to prove that each of the eight challenged marketing statements for Prevagen®, a dietary supplement marketed for brain health, were "materially misleading" under the "reasonable consumer" standard that applies under the Federal Trade Commission Act (the "FTC Act") and New York General Business Law Sections 349 and 350 (the "GBL"). They failed to meet this burden. The jury found that six of the eight challenged marketing statements did not violate the GBL, and the District Court later held that the same six "acquitted" statements did not violate the FTC Act.

Despite this failure of proof on the majority of Plaintiffs' case, the District Court inexplicably entered a nationwide injunction prohibiting Quincy and its CEO, Defendant-Appellant Mark Underwood (together, "Defendants") from making *all eight* Challenged Statements (as defined below)—i.e., the same injunctive relief Plaintiffs would have obtained had they obtained a *full victory* at trial. This injunction is overbroad because it prohibits Defendants from using six marketing claims nationwide that the District Court found to *not* violate the FTC Act. The

District Court used the jury's findings under New York Executive Law Section 63(12) (the "Executive Law") to justify the breadth of the injunction in violation of New York's presumption against extraterritoriality of its statutes, as well as the Dormant Commerce Clause. But there is no theory of law to support applying a New York fraud standard outside of its borders. And although the Executive Law might vest the NYAG with additional remedies for an underlying predicate violation of law (here, the GBL), it does not provide a standalone claim for relief in the *absence* of predicate liability (let alone with a nationwide reach). Thus, to the extent the injunction is based on the jury's Executive Law findings, it cannot stand. The injunction is also impermissibly vague in violation of the specificity requirements of Federal Rule of Civil Procedure 65(d) because it prohibits statements that are "similar" to the ones specifically enjoined without providing any detail or guidance as to its scope.

The District Court also made a number of crucial legal errors in denying Defendants' motion for summary judgment and Quincy's motion for judgment as a matter of law. First, the District Court erred in ruling that the Executive Law provides the NYAG with an independent, standalone claim for fraud in the absence of predicate liability. Because the jury found that there was no GBL liability for six of the Challenged Statements, Quincy was entitled to judgment as a matter of law

for those six claims. The District Court also failed to apply the reasonable consumer standard, to the extent such a claim could exist (it could not).

Second, the District Court erred in awarding the FTC injunctive relief because this is not a "proper case" for permanent injunctive relief under Section 13(b) of the FTC Act. Section 13(b) only permits the FTC to obtain a permanent injunction if it previously sought a temporary injunction at the outset of the case, prevailed in a consecutive administrative proceeding, and proves its entitlement to a preliminary injunction. Here, the FTC never sought a preliminary injunction and never even commenced an administrative proceeding, so it is not entitled to a permanent injunction. The District Court's denial of summary judgment and entry of a permanent injunction were in error.

Finally, the District Court erred when it failed to recognize Plaintiffs' repeated failure to offer any evidence of deception in response to Defendants' motion for summary judgment or at trial. This continued failure of proof should have resulted in judgment for Defendants at either stage of the case.

The District Court's judgment and nationwide injunction were premised on and followed numerous instances of prejudicial error, so this Court should either vacate the injunction and enter judgment in Defendants' favor or, at a minimum, remand to the District Court to narrow the ordered relief.

STATEMENT OF JURISDICTION

The District Court had subject-matter jurisdiction over the FTC's claims against Defendants under the FTC Act. 28 U.S.C. §§ 1331, 1337(a), 1345; 15 U.S.C. §§ 45(a), 53(b). The District Court exercised supplemental jurisdiction over the NYAG's claims, which arose out of the same case and controversy as those brought by the FTC. 28 U.S.C. § 1367.

This Court has appellate jurisdiction because the District Court's November 18, 2024 Memorandum and Judgment, as clarified by the December 6, 2024 Order, is final for purposes of appeal. 28 U.S.C. § 1291.

STATEMENT OF ISSUES PRESENTED

1. Whether the District Court erred in issuing a nationwide permanent injunction as a remedy under the FTC Act to the extent the injunction prohibited conduct the District Court correctly found did not violate the FTC Act.

2. Whether the District Court erred in issuing a nationwide permanent injunction that fails to comply with Rule 65(d) because it is vague and does not describe in reasonable detail the acts restrained.

3. Whether the District Court erred in ruling that the Executive Law creates an independent, standalone cause of action for fraud and in failing to apply the reasonable consumer standard if such a cause of action exists.

4. Whether the District Court erred in denying summary judgment and issuing a permanent injunction because this is not a "proper case" under Section 13(b) of the FTC Act.

5. Whether the District Court erred in denying Defendants' motion for summary judgment and Quincy's motion for judgment as a matter of law given that:

a. Plaintiffs failed to present any evidence of consumer deception;

b. the NYAG failed to rebut Quincy's expert opinion that the scientific evidence relating to Vitamin D presented at trial constitutes competent and reliable scientific evidence to substantiate the Challenged Statements; and

c. Plaintiffs' experts failed to analyze the substantiation for the Challenged Statements under the appropriate standard and instead created their own, heightened standard for substantiation.

STATEMENT OF THE CASE

I. Quincy Developed, Manufactured, and Marketed Prevagen

This case involves Prevagen, a dietary supplement manufactured and marketed by Quincy to support brain health. The active ingredient in Prevagen's original formula—apoaequorin—is a calcium-binding protein derived from aequorin, which was originally discovered in *Aequorea Victoria*, a jellyfish found in the Puget Sound. [Trial.Tr.170:12-25.] In 2016, Quincy added 50 micrograms of

vitamin D3 to Prevagen's formula, which is equivalent to 2000 IU of vitamin D. [JX-0095_at_1 ¶5.] Prevagen's target market is, and always has been, healthy, community-dwelling adults who are cognitively normal or who have mild cognitive impairment due to the normal aging process. [JX-31_at_9.]

II. FDA and FTC Adopted a Flexible Standard for Substantiation of Dietary Supplements

In recognition of the health benefits of dietary supplements, Congress enacted the Dietary Supplement Health Education Act of 1994 to establish standards with respect to dietary supplements and to create a new category for dietary supplement marketing called "structure/function claims." [Dkt.222-9]; *see also* 21 U.S.C. §§ 343(g)(1), 343(r)(6). Structure/function claims do not require pre-approval from the Food and Drug Administration ("FDA") and require a much lower level of substantiation than drug claims, which require "significant scientific agreement." [Dkt.222-10_at_4.] FDA guidance provides several examples for what constitutes an acceptable structure/function claim, including that a product improves "mild memory loss associated with aging." [*Id.*]

In 1998, the FTC issued a document called "Dietary Supplements: An Advertising Guide For Industry" (the "FTC Guidance") to answer the "many questions" that businesses had "about the FTC's approach to dietary supplement advertising" and to explain[] the how-tos of making sure your claims have appropriate scientific support." [DX-526_at_1; JX-0095_at_6-7 ¶¶40-41.]

Under the FTC Guidance, marketing claims relating to dietary supplements should be supported by "competent and reliable scientific evidence," which is defined as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area." [DX-526_at_9.] The FTC Guidance provides that this substantiation standard is "flexible" and looks to the "totality of the evidence," including, but not limited to, animal studies, *in vitro* studies, epidemiological evidence, and all forms of human studies. [DX-526_at_8; DX-526_at_14.] There is no set number or type of study required and, of particular importance to this case, randomized controlled human trials ("RCTs") are not required. [DX-526_at_12.]

III. Quincy Conducted Extensive Research on Prevagen and Apoaequorin

In accordance with FDA and FTC guidance, Quincy dedicated years to researching and accumulating safety data and scientific substantiation before bringing Prevagen to market. [Trial.Tr.797:1-15.] That research continued well after the first sale of Prevagen and continues to this day. [Trial.Tr169:9-24.]

Animal and *In Vitro* Studies: Beginning in 2004 and continuing to date, Quincy has sponsored numerous research studies on apoaequorin in rats and canines, which have consistently reported that apoaequorin provides neuroprotective effects and cognitive benefits. [*See* DX-299; DX-461; DX-465; DX-483; DX-484; DX-485; DX-486; DX-487; DX-489; DX-490; DX-491; DX-492; *see also*

Trial.Tr166:16-168:8; Trial.Tr.753:21-754:10.] Some of this research has been published in peer-reviewed journals. [*See* DX-299.]

Open Label Human Research: Beginning in 2008, several open-label human clinical trials assessed the impact of apoaequorin on general health and quality of life, including cognitive function. [DX-256_at_2; DX-462_at_2.] One such trial, titled Impact of Prevagen on Memory, reported a statistically significant benefit on cognitive function, fatigue, sleep, and general health. [DX-462_at_5.] In 2014, Sunsho Pharmaceuticals, Ltd. (a company completely independent from Quincy) conducted an open label clinical trial testing Prevagen's efficacy on cognitive function and quality of sleep. [DX-256_at_2-3.] The Sunsho trial reported that, after 30 days of intake of Prevagen, there was a "a confirmed rise in the score which showed a statistically significant difference from the score before intake," and that "the effect of 'Prevagen' can be considered to be favorable from the viewpoint of its use as a brain supplement." [DX-256_at_2-3.]

The Madison Memory Study: Despite no FDA or FTC requirement to do so, Quincy conducted an RCT beginning in 2009 to further test Prevagen's efficacy in humans. [JX-31.] The Madison Memory Study ("MMS") was a 90-day, "randomized, double-blind, placebo-controlled human clinical study using objective measures of cognitive function," designed "to determine whether Prevagen with

apoaequorin (10 mg) improves quantitative measures of cognitive function in community dwelling, older adults." [JX-31_at_2.]

The MMS included 218 participants aged 40 to 91, each of whom had self-reported memory concerns. [JX-31_at_4.] The study randomly assigned participants to either receive apoaequorin or a placebo. [JX-31_at_2.] At the outset of the study, a validated eight-question screening tool called the "AD8" was used to determine the participants' baseline level of cognitive impairment. [*Id.*; Trial_Tr.314:19-23.] Of the 218 participants, 100 people had AD8 scores between 0 and 2, which are considered reflective of normal aging or "very mild" cognitive impairment—i.e., the healthy, community-dwelling adults in Prevagen's target market. [JX-31_at_2; Trial_Tr.213:22-24] This was consistent with the MMS protocol, which identified a planned sample size of 100 participants. [JX-34_at_1.]

On days 0, 8, 30, 60, and 90, participants completed nine quantitative computerized tests from the Cogstate Research Battery, a widely used and validated battery of neuropsychological computerized tests designed to measure a variety of aspects of cognitive function, including verbal learning, memory, executive function, visual learning, psychomotor function, and working memory. [JX-31_at_2-4.]

While Quincy analyzed the data from all 218 participants, it was most interested in the 100 individuals with AD8 scores of 0 to 2—i.e., the population of

community-dwelling adults with little or no self-reported cognitive impairment—because those individuals align with Prevagen's target market. [JX-31_at_4; JX-32_at_6; Trial.Tr. 825:7-13.]

The results of the MMS showed that, within Prevagen's target market, apoaequorin had a "statistically significant effect" on a number of different cognitive tasks (including memory-related tasks) as compared to placebo recipients. [JX-31_at_5.] Accordingly, the MMS concluded, among other things, 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." [JX-31_at_9; *see also* JX-32_at_10.] Results of the MMS were first published on Quincy's website and later in a peer-reviewed journal. [*See* JX-31; JX-32; JX-50; JX-93.]

There is also a vast body of scientific literature supporting a relationship between vitamin D and improved cognitive function. This support includes RCTs, meta-analyses, cross-sectional and prospective studies that demonstrate beneficial associations between both higher vitamin D *intake* and cognitive function and higher vitamin D *levels* and cognitive function. [Trial_Tr.1007:7-1016:8.]

IV. Prevagen's Marketing Evolved to Reflect Quincy's Research Efforts

Prevagen's marketing evolved over time to reflect Quincy's continued research. In its early years, Prevagen was labeled with the taglines "Jellyfish Fight

Aging," "Brain Cell Protection," and "Clearer Thinking." [PX-0587_3-5 ¶¶12-24.] In 2012, after the MMS was completed, Prevagen was labeled with the tagline "Improves Memory." [PX-0587_at_5-6 ¶¶25-27.]

Regardless of the specific marketing tagline, Prevagen's label always made clear that it is a "dietary supplement" included the requisite FDA disclaimer that it "is not intended to diagnose, treat, cure or prevent any disease." [PX-0587_at_2 ¶¶7-8.] Additionally, in 2020, Quincy added a qualifying statement to Prevagen's labels and marketing, which noted that the claims were "[b]ased on a clinical study of subgroups of individuals who were cognitively normal or mildly impaired." [PX-0587_at_9 ¶42.]

V. The FTC and NYAG Challenged Prevagen's Marketing

After a lengthy pre-suit investigation, in January 2017, the FTC and the NYAG jointly filed a Complaint against Quincy and two of its executives, Mark Underwood and Michael Beaman. [*See* Dkt.1.] The Complaint alleged that the following eight marketing claims were either explicitly or implicitly made and violated the FTC Act, the GBL, and the Executive Law:

1. Prevagen improves memory;
2. Prevagen is clinically shown to improve memory;
3. Prevagen improves memory within 90 days;
4. Prevagen is clinically shown to improve memory within 90 days;

5. Prevagen reduces memory problems associated with aging;

6. Prevagen is clinically shown to reduce memory problems associated with aging;

7. Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking; and

8. Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking.

(collectively, the "Challenged Statements"). [Dkt.1_at_26-29 ¶¶36-45.] Plaintiffs did not seek preliminary injunctive relief and did not commence simultaneous administrative proceedings. [Docket_Sheet.]

In September 2017, the District Court granted the defendants' motions to dismiss, finding that the Complaint failed to state a claim under the FTC Act and declining to exercise jurisdiction over the NYAG's state law claims. [Dkt.45_at_13.] Plaintiffs appealed, and this Court vacated the District Court's judgment and remanded for further proceedings. *See Quincy Bioscience Holding Co.*, 753 Fed. App'x at 90. Following remand, the District Court denied the renewed motions to dismiss filed by Quincy and Mr. Underwood but granted Mr. Beaman's motion to dismiss for failure to state a claim. [Dkt.72_at_1, 18.]

After extensive fact and expert discovery, Defendants moved for summary judgment. [Dkts.210-14, 220-28.] The District Court granted Mr. Underwood's partial motion for summary judgment on the NYAG's claims, finding that he was

not subject to personal jurisdiction in New York but otherwise denied the motions. [Dkt.272._at_1; Dkt. 331_at_2.]

VI. Quincy Prevailed at Trial under the GBL for Six of the Eight Challenged Statements

Quincy and the NYAG[1] proceeded to a jury trial in February and March 2024 to resolve the NYAG's claims under the GBL and Executive Law. Both parties showed the jury a number of advertisements and presented fact and expert testimony concerning the substantiation for the Challenged Statements. The NYAG did not introduce any evidence showing how consumers interpreted the Challenged Statements, did not introduce testimony from any consumers who claimed to have been deceived or harmed by the Challenged Statements, and did not introduce evidence that the Challenged Statements caused any harm or economic injury. [Dkt.457_at_2; Dkt.513_at_2.]

At the conclusion of the trial, the jury found that only two of the eight Challenged Statements violated the GBL: "Prevagen reduces memory problems associated with aging," and "Prevagen is clinically shown to reduce memory problems associated with aging." [Dkt.421_at_2.] The jury found that the other six

[1] In 2020, the Supreme Court held in *AMG Capital Management, LLC v. Federal Trade Commission*, 593 U.S. 67 (2020), that the FTC was not entitled to seek monetary relief and therefore not entitled to a jury trial. Thus, only the NYAG's claims against Quincy were presented to the jury, although the District Court permitted the FTC and counsel for Mr. Underwood to participate in the trial. [Dkt.377.]

Challenged Statements were not "materially misleading" and therefore did not violate the GBL (the "Acquitted Statements"). [Dkt.421_at_2-3.] In the District Court's words, the jury found that there "was no claim" for the six Acquitted Statements; the District Court then declared that "[i]t wasn't just a shortage of proof, it's an acquittal." [5.10_Tr.10:14-15.]

The District Court instructed the jury that if it did not find liability under the GBL for any one of the Challenged Statements, it should not reach the Executive Law claim for that statement because "in effect, that charge has already been disposed of." [Trial_Tr._1447:19-1448:2.] But despite acquitting Quincy under the GBL for the six Acquitted Statements, the jury deliberated under the Executive Law for all eight Challenged Statements and found that they all had the "capacity or tendency to deceive" "the unthinking or gullible consumer, one who does not stop to analyze, but is governed by appearances and general impressions." [Dkt.421_at_8; Trial_Tr.1448:20-23.]

The District Court subsequently denied Quincy's and the NYAG's motions for judgment as a matter of law [Dkt.457_at_3], and ordered post-trial briefing on two questions: (1) whether the jury's findings under the Executive Law for the six Acquitted Statements could stand without a predicate finding of liability under the GBL—i.e., whether the Executive Law provides an independent, standalone cause

of action; and (2) whether the jury's factual determinations under the GBL were dispositive of the FTC's claim under the FTC Act.

On August 20, 2024, the District Court answered the first question, found that the Executive Law provided a standalone cause of action, and upheld the jury's verdict that all eight Challenged Statements violated the Executive Law despite the jury's finding that the six Acquitted Statements did not violate the GBL. [Dkt.491_at_1-2.]

Several days later, the District Court answered the second question and held that because the GBL and FTC Act were both analyzed under the same "reasonable consumer" standard, the jury's findings for the GBL claims were dispositive of the FTC's claims. [Dkt.493_at_2-3.] As a result, the District Court ruled that the two Challenged Statements for which the jury found GBL liability also violated the FTC Act but that the six Acquitted Statements did not violate the FTC Act. [Dkt.493_at_1-2.]

VII. The District Court Entered a Nationwide Injunction but Denied the NYAG's Request for Monetary Relief

Following the District Court's rulings on liability, the NYAG moved for a permanent injunction. [Dkts.502-04.] The NYAG made clear that its proposed relief did not apply nationwide and was limited to "conduct in or affecting the ***State of New York or any New York consumer***." [Dkt.502-1_at_2; Dkt.512-1_at_2

(emphasis added).] The FTC did not join the NYAG's motion and did not otherwise file a motion for injunctive relief. [Dkt. 502.]

On November 18, 2024, the District Court granted the NYAG's motion, entered a permanent injunction, and issued final judgment (the "November Judgment"). [Dkt.513_at_2.] Despite the District Court's acknowledgement that "[t]he jury acquitted all but the two aging memory statements of being materially misleading," the District Court nevertheless enjoined Quincy from making *all eight* Challenged Statements:

> The full, fair and proper determination of this action is that the defendants must immediately remove all of the statements (and any others similar to them) from use in connection with any and all forms of promotion of Prevagen, and cease their use in the promotion of Prevagen in any way.

[Dkt.513_at_2.]

The District Court also denied the NYAG's request for monetary relief, finding that "[t]here was no evidence that Prevagen, or the challenged statements, had actually caused harm or economic injury," and that "[t]here [was] no evidence to support the occasionally discussed but unarticulated, unmade claims for disgorgement." [Dkt.513_at_2.]

Shortly thereafter, Quincy sought to clarify that, consistent with the NYAG's motion, the November Judgment was limited to New York. [Dkt.515_at_3.] The FTC, despite failing to affirmatively seek injunctive relief, opposed Quincy's motion

and argued that a nationwide injunction was proper under the FTC Act pursuant to the "fencing-in" doctrine. [Dkt.523_at_7.] The NYAG did not substantively oppose Quincy's motion. [Dkt.522.]

On December 6, 2024, the District Court issued an order clarifying the scope of the November Judgment (the "December Order" and, collectively with the November Judgment, the "Injunction"). [Dkt.524.] The District Court clarified that the Injunction applied to all eight Challenged Statements—including the six Acquitted Statements—and that it applied nationwide. [Dkt.524_at_2.] In justifying this extraordinary relief, the District Court held that the FTC Act permits it to enjoin "otherwise legitimate conduct in order to prevent future violations." [Dkt.524_at_2.] The District Court further stated that "[e]ach of the Challenged Statements asserts similar, unsupported claims regarding memory or cognition, and although only two statements were materially misleading, all have the capacity or tendency to deceive, which is inconsistent with the purpose of the FTC Act." [Dkt.524_at_3-4.] Thus, the District Court permanently enjoined Defendants from using any of the eight Challenged Statements "in any way and wherever the [FTC Act] reaches." [Dkt.524_at_5.]

On December 19, 2024, Quincy timely filed its Notice of Appeal. [Dkt.525.]

SUMMARY OF ARGUMENT

The District Court erred in at least five different, independent ways throughout this eight-year litigation.

First, the District Court erred in entering a permanent nationwide injunction under the FTC Act and prohibiting Defendants from disseminating marketing claims nationwide that the District Court found did *not* violate the FTC Act. The District Court ruled the six Acquitted Statements did not violate the FTC Act, but it nevertheless enjoined Defendants from using those six statements nationwide pursuant to the FTC Act because the jury found that those claims had the "capacity to deceive" an "unthinking" and "gullible" consumer under an outdated New York Executive Law standard. Moreover, to the extent the Injunction—which was grounded in a violation of a New York statute (which was in turn based on the wrong standard)—purports to apply outside of New York, it violates the Dormant Commerce Clause. Accordingly, the Injunction is overbroad and should be vacated.

Second, the District Court erred in ordering a permanent injunction that violates the specificity requirements of Rule 65(d). The Injunction prohibits Defendants from making all eight Challenged Statements, as well as "any others similar to them," without providing any guidance as to what may or may not be deemed "similar" to the Challenged Statements. Because the Injunction does not specify the precise conduct to be enjoined, it should be vacated.

Third, the District Court erred when it denied Defendants' motion for summary judgment and Quincy's motion for judgment as a matter of law on the Executive Law claim because there is no standalone cause of action under the Executive Law that can survive absent predicate statutory or common law fraud liability. Moreover, to the extent there is a standalone cause of action, the District Court erred in failing to apply the "reasonable consumer" standard for such claims.

Fourth, the District Court erred when it entered a permanent injunction under the FTC Act because this is not a "proper case" within the scope of the act. Section 13(b) of the FTC Act gives the FTC authority to file suit in federal court to obtain a preliminary injunction while the parties engage in the administrative process and to seek permanent injunction only in "proper cases" and upon "proper proof." A "proper case" is one where the FTC has sought a temporary injunction pending the resolution of an administrative proceeding and proves its entitlement to a permanent injunction. Here, the FTC did not commence an administrative action against Defendants and did not seek a preliminary injunction at any time during this eight-year litigation. Accordingly, this is not a "proper case" for permanent injunctive relief and the District Court erred when it denied Defendants' motion for summary judgment and when it entered the Injunction.

Finally, the District Court erred when it denied Defendants' motion for summary judgment and/or Quincy's motion for judgment as a matter of law because

(i) Plaintiffs failed to present any evidence on summary judgment or at trial that a consumer would be deceived by the Challenged Statements; (ii) the NYAG's experts failed to rebut Quincy's expert opinions at trial that the scientific literature on vitamin D substantiates the Challenged Statements; and (iii) Plaintiffs' experts repeatedly analyzed the substantiation for the Challenged Statements under an incorrect, heightened standard of substantiation.

STANDARD OF REVIEW

This Court reviews the District Court's legal determinations *de novo*, including questions of statutory interpretation, interpretations of underlying orders and judgments, and whether an injunction complies with Federal Rule of Civil Procedure 65(d). *See United States v. Epskamp*, 832 F.3d 154, 160 (2d Cir. 2016) (statutory interpretation); *Flo & Eddie, Inc. v. Sirius XM Radio, Inc.*, 821 F.3d 265, 269 (2d Cir. 2016) (summary judgment and reconsideration); *Legg v. Ulster Cnty.*, 979 F.3d 101, 114 (2d Cir. 2020) (judgment as a matter of law); *Capstone Logistics Holdings, Inc. v. Navarrete*, 838 Fed. App'x 588, 590 (2d Cir. 2020) (compliance with Rule 65(d)).

This Court reviews "legal holdings [underlying an order granting a permanent injunction] *de novo* and its ultimate decision for abuse of discretion." *Goldman Sachs & Co. v. Golden Empire Schs. Fin. Auth.*, 764 F.3d 210, 214 (2d Cir. 2014).

A party's challenges to the "language and format" of a jury verdict sheet are reviewed for abuse of discretion. *Lore v. City of Syracuse*, 670 F.3d 127, 160 (2d Cir. 2012). However, "[t]he instructions for a verdict form are reviewed *de novo*." *E.R. Squibb & Sons, Inc. v. Lloyd's & Cos.*, 241 F.3d 154, 167 (2d Cir. 2001).

ARGUMENT

I. The District Court Erred by Issuing a Nationwide Injunction That Prohibited Lawful Conduct

The Injunction is impermissibly overbroad because it prohibits Defendants from making all eight Challenged Statements nationwide, even though the District Court ruled that the six Acquitted Statements did not violate the FTC Act. *See, e.g.*, *City of N.Y. v. Mickalis Pawn Shop, LLC*, 645 F.3d 114, 144 (2d Cir. 2011) (finding that "district courts must take care to ensure that injunctive relief is not overbroad" and collecting cases regarding equitable principles underlying prohibition on overbroad injunction). At a minimum, the Injunction should be modified to permit Defendants to make the six Acquitted Statements outside the State of New York because: (1) the Acquitted Statements do not violate the FTC Act; and (2) the Injunction essentially enforces a uniquely New York statute (using the wrong standard) nationwide, in violation of the Dormant Commerce Clause and basic notions of federalism.

a. The Injunction Is Overbroad Because It Enjoins Legal Conduct

The Injunction prohibits Defendants from engaging in conduct the District Court previously held to be *lawful* in this very action. The Injunction covers all eight Challenged Statements even though the District Court expressly held that six of those claims, the Acquitted Statements, did *not* violate the FTC Act because they were *not* "materially misleading" to reasonable consumers. [*Compare* Dkt.493_at_3, *with* Dkt.524_at_3-4.] In other words, the FTC failed to prove liability under the FTC Act with respect to these six statements, but Defendants were nevertheless enjoined from making them nationwide.

An injunction that prohibits conduct held to be lawful in the same proceeding far exceeds the District Court's discretion. As this Court has held, "[a]n injunction is overbroad when it seeks to restrain the defendants from engaging in legal conduct." *Mickalis*, 645 F.3d at 145; *see also Victorinox AG v. B&F System, Inc.*, 709 Fed. App'x 44, 52 (2d Cir. 2017) (vacating injunction as overbroad where it prohibited even "arguably legal conduct").

The District Court attempted to justify the overbroad Injunction by referencing the "fencing in" doctrine—a doctrine that permits an injunction to "extend[] beyond the immediate facts" of the case to "prevent similar and related violations from occurring in the future." *Trans World Accts., Inc. v. FTC*, 594 F.2d 212, 215 (9th Cir. 1970) (citing *FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 392

(1959)). But the Injunction's flaws cannot be salvaged by the "fencing in" doctrine, which is intended to prevent future *illegal* conduct reasonably related to the *illegal* conduct at issue—not to punish conduct that was already found to *not* violate the law. *See ITT Cont'l Baking Co. Inc. v. FTC*, 532 F.2d 207, 221 (2d Cir. 1976) (reversing FTC "fencing in" order that attempted to prevent the defendant from using marketing claims found not to violate the FTC Act); *Mandel Bros., Inc.*, 359 U.S. at 392 (indicating that the FTC "may fashion its relief to restrain other like or related *unlawful* acts" (cleaned up) (emphasis added)). The "fencing in" doctrine is not a license to enjoin conduct *known to be lawful* based on factual findings in the very same proceeding.

Indeed, this Court's decision in *ITT Continental Baking* confirms that injunctions are overbroad where they "fence in" lawful marketing. In *ITT Continental Baking*, the FTC brought an administrative action alleging that a business made several deceptive marketing claims in advertising its food products. 532 F.2d at 212. The administrative law judge found that only one of the challenged marketing claims was misleading and ruled that the other challenged statements did not violate the FTC Act. *Id.* at 214. Despite "the exoneration of the petitioners with respect to eleven out of twelve nutritional misrepresentations charged by complaint counsel," the FTC issued an expansive cease and desist order preventing the company from making *all twelve challenged* statements—including those that the

fact-finder found *not* to be misleading. *Id.* at 221. On direct review, this Court held that the order was overbroad because it was "framed to remedy wrongs . . . found not to have been committed" and struck portions of the order prohibiting the eleven acquitted claims. *Id.* at 221-22.

ITT Continental Baking was binding on the District Court. Nonetheless, the District Court declined to follow it and attempted to justify its sweeping, nationwide injunction by stating: (1) the Injunction was consistent with the "purpose of the FTC Act"; (2) it was necessary to "prevent future misconduct" under the FTC Act; and (3) while recognizing that only two statements were found to violate the FTC Act, "all [the Challenged Statements were found by the jury to] have the capacity or tendency to deceive, which is inconsistent with the purpose of the FTC Act." [Dkt.524_at_3-4.] None of these justifications hold water.

First, the District Court's subjective interpretation of the "purpose of the FTC Act" does not allow it to rewrite the FTC Act and thereby create a new standard for FTC Act liability, to find liability where there was none, or to ignore this Court's binding precedent on the permissible scope of relief. *See, e.g.*, *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 63 (2d Cir. 2006) (interpreting the FTC Act to be limited to representations that are both likely to mislead and material). If a Challenged Statement does not violate the FTC Act, it is hard to imagine how enjoining that statement furthers the "purpose" of the FTC Act.

Second, the District Court's claim that the Injunction is necessary to prevent future violations of the FTC Act ignores that the District Court already held that the same conduct did *not* violate the FTC Act. Enjoining a specific, lawful advertising claim does nothing to prevent other, unspecified, potentially unlawful advertising claims from being made.

Third, the jury's finding that all eight Challenged Statements "had the capacity to deceive" the "unthinking" and "gullible" consumer under the Executive Law, even if properly made (which Defendants dispute), is irrelevant to fashioning a remedy for FTC Act violations. The jury's "capacity to deceive" findings were only relevant to the NYAG's Executive Law claim—a uniquely New York law that the jury should not even have reached for the six Acquitted Statements based on the District Court's instructions—and which were assessed under an (outdated and incorrect) lower standard than the one that governs FTC Act claims. (*See, infra,* Section III.D.) Indeed, FTC Act liability is not determined by considering a statement's "capacity to deceive" a "gullible, unthinking consumer," but rather after determining whether the statement is "materially misleading" to a "reasonable consumer." (*Id.*) Accordingly, the jury's findings under the Executive Law should have no bearing whatsoever on the FTC Act remedy, and the Injunction should be vacated to the extent it enjoins the Acquitted Statements outside of New York.

b. The Injunction Is Also Overbroad Because It Impermissibly Applies a New York Statute Nationwide

Defendants maintain that the District Court erred in instructing the jury to assess the Executive Law claims under the lens of a "gullible consumer." (*See, infra,* Section III.D.) But even if that instruction was correct, the jury's findings *on the Executive Law* could not be used to support nationwide relief for violations of *the FTC Act*, which unquestionably applies the higher "reasonable consumer" standard. The District Court's application of an outdated New York standard to conduct outside of New York presents a second, independent ground to vacate the Injunction.

First, the District Court's nationwide application of a New York statute offends New York's well-established presumption against extraterritorial application of its state statutes. In *Goshen v. Mutual Life Insurance Company of New York*, the New York Court of Appeals considered whether "originating a marketing campaign in New York" that deceived consumers in other states could violate the GBL, or whether application of that statute required that "the consumer be deceived in New York." 98 N.Y.2d 314, 324-25 (2002). Following examination of the plain language of the statute—which explicitly limited the "deceptive acts or practices" prohibited to those conducted "in this state"—and the legislative history of the statute, the Court of Appeals concluded that the GBL protects only consumers deceived in New York. *Id.* at 325. Critically, the Court of Appeals observed that a

contrary interpretation "would tread on the ability of other states to regulate their own markets and enforce their own consumer protection laws." *Id.*

The same concerns infect the nationwide reach of the Injunction. The Executive Law, too, is meant to redress conduct affecting New York—it only provides the NYAG "standing to recover for New York consumers." *State of N.Y. v. Sirius XM Radio Inc.*, No. 453325/2023, 2024 WL 4877083, at *4 (N.Y. Sup. Ct. Nov. 21, 2024). And New York courts have repeatedly emphasized "[t]he established presumption … against the extraterritorial application of New York law." *Glob. Reinsurance Corp. U.S. Branch v. Equitas Ltd.*, 18 N.Y.3d 722, 735 (2012) (citation omitted). The District Court's imposition of an outdated and lenient Executive Law standard outside of New York's borders disrupts the ability of those other states to regulate conduct in their borders according to their own standards.

Second, the nationwide application of the (incorrect) Executive Law standard violates the Dormant Commerce Clause, which "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982)). At least one circuit has cited the Dormant Commerce Clause in this specific context—i.e., as a basis to vacate a nationwide injunction issued to address adjudicated violations of state law. In *Allergan, Inc. v. Athena Cosmetics, Inc.*, the Federal Circuit assessed the propriety of a nationwide permanent injunction

meant to remedy adjudicated violations of California's unfair competition law. 738 F.3d 1350, 1358 (Fed. Cir. 2013). In vacating the injunction, the Federal Circuit noted that "[n]either the California courts nor the California legislature are permitted to regulate commerce entirely outside of the state's borders" because "do[ing] so would violate the Commerce Clause, which … dictates that no State may force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." *Id.* at 1359; *see also Herman Miller, Inc. v. Palazetti Imports & Exports, Inc.*, 270 F.3d 298, 327 (6th Cir. 2001) (finding that "it would be unjust" to impose Michigan law "in New York and other states that have explicitly refuse[d]" to adopt a similar standard); *Senne v. Kansas City Royals Baseball Corp.*, 934 F.3d 918, 930 (9th Cir. 2019) ("Nor does the Constitution permit one state to project its regulatory regime into the jurisdiction of another state.").

The same rationale applies here. The District Court issued the nationwide injunction as a remedy for violations of the FTC Act, which applies a "reasonable consumer" standard, but it fashioned the relief by applying the jury's findings under the Executive Law, which the jury (erroneously) assessed under a "gullible, unthinking consumer" standard. Contrary to New York's presumption *against* extraterritoriality, the District Court effectively extended the Executive Law to every other state in the nation. No authority supports this result, and the Injunction prohibiting the Acquitted Statements outside of New York should be vacated.

II. The District Court Erred in Issuing an Injunction That Violates the Specificity Requirements of Rule 65(d)

The District Court independently erred in issuing the Injunction because it fails the specificity requirements of Rule 65(d). The Injunction is impermissibly vague because it prohibits Defendants from making the Challenged Statements "and any others similar to them" without providing any guidance about what statements would be considered "similar to" the Challenged Statements.

Rule 65(d) provides that "[e]very order granting an injunction . . . must (A) state the reasons why it issued; (B) state its terms specifically; and (C) describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1). The Supreme Court has cautioned:

> The specificity provisions of Rule 65(d) are no mere technical requirements. The Rule was designed to prevent uncertainty and confusion on the part of those faced with injunctive orders, and to avoid the possible founding of a contempt citation on a decree too vague to be understood…. Since an injunctive order prohibits conduct under threat of judicial punishment, basic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed.

Schmidt v. Lessard, 414 U.S. 473, 476 (1974); *see also United States v. Apex Oil Co., Inc.*, 579 F.3d 734, 739-40 (7th Cir. 2009).

Rule 65(d) is designed to prevent district courts from issuing "vague or general injunctions [that] cannot be easily obeyed or effectively and fairly enforced." *Perfect Fit Indus., Inc. v. Acme Quilting Co., Inc.*, 646 F.2d 800, 809 (2d Cir. 1981);

see also Mickalis, 645 F.3d at 145; *Sanders v. Air Line Pilots Ass'n Intern.*, 473 F.2d 244, 247 (2d Cir. 1972). Its specificity requirements are grounded in notice to the enjoined party and can be "satisfied only if the enjoined party can 'ascertain from the four corners of the order precisely what acts are forbidden.'" *Fonar Corp. v. Deccaid Servs., Inc.*, 983 F.2d 427, 430 (2d Cir. 1993) (quoting *Sanders*, 473 F.2d at 247); *see also Reliance Ins. Co. v. Mast Const. Co.*, 159 F.3d 1311, 1316 (10th Cir. 1998) ("[A]n injunction cannot be so general as to leave the party open to the hazard of conducting business in the mistaken belief that it is not prohibited by the injunction and thus make him vulnerable to prosecution for contempt."); *Scott v. Schedler*, 826 F.3d 207, 212 (5th Cir. 2016) ("The rule embodies the elementary due process requirement of notice.").

But the Injunction is not "specific in terms," nor does it "describe in reasonable detail . . . the act or acts sought to be restrained." Fed. R. Civ. P. 65(d)(1)(C). It does not provide any guidance to help Defendants determine in what way other claims might be "similar" to the Challenged Statements such that they would violate the Injunction. It is unclear if the "similarity" needs to be with respect to the language used, the structure-function claim being advanced, the medium, or the audience—or all or none of the above. Indeed, what is or is not "similar to" each or any of the Challenged Statements is susceptible to an unknown number of subjective interpretations. As a result, the Injunction does exactly what Rule 65(d)

seeks to avoid: it leaves Defendants without specific guidance to "ascertain from the four corners of the order precisely what acts are forbidden." *Fonar*, 983 F.2d at 430 (quoting *Sanders*, 473 F.2d at 247); *see also Petrello v. White*, 533 F.3d 110, 116 (2d Cir. 2008) (vacating order that failed to describe "in any detail, much less 'in reasonable detail'" the acts it required); *Corning Inc. v. Picvue Elecs., Ltd.* 365 F.3d 156, 158 (2d Cir. 2004) (vacating injunction in which the enjoined party "would have to resort to extrinsic documents to comply with the order's commands")

Circuit courts across the country have vacated injunctions with near-identical language, deeming prohibitions of "similar" or "related" conduct impermissibly vague. *See, e.g.*, *McCarthy v. Fuller*, 810 F.3d 456, 461, 462-63 (7th Cir. 2015) (vacating injunction in defamation case that vaguely prohibited "any similar statements that contain the same sorts of allegations or inferences, in any manner or forum" and asking "[h]ow could such vague terms as 'similar' and 'same sorts' provide guidance as to the scope of the injunction?"); *Rocket Jewelry Box, Inc. v. Quality Int'l Packaging, Ltd.*, 90 Fed. App'x 543, 548 (Fed. Cir. 2004) (vacating injunction that vaguely prohibited "marketing and selling 'any similar such [jewelry] boxes'" under trademarks at issue); *ALPO Petfoods, Inc. v. Ralston Purina Co.*, 913 F.2d 958, 961 (D.C. Cir. 1990) (vacating injunction broadly prohibiting advertising claims that are "false, misleading, deceptive or made without substantiation" as it was not "closely tailor[ed]" to the harms adjudicated).

In reaching these conclusions, fellow circuits have cited the tenets built into Rule 65(d)—namely, the importance of "tailor[ing] injunctions to the harm that they address," *ALPO Petfoods, Inc.*, 913 F.2d at 972, and the importance of "prevent[ing] uncertainty and confusion on the part of those faced with injunctive orders" and "avoid[ing] the possible founding of a contempt citation on a decree too vague to be understood," *Fed. Election Comm'n v. Furgatch,* 869 F.2d 1256, 1263-64, 1276 (9th Cir. 1989) (quoting *Schmidt*, 414 U.S. at 476).

As it stands, the Injunction fails to provide Defendants with any measure of certainty as to whether a new marketing claim for Prevagen is "similar" to the Challenged Statements and puts Defendants at risk of arbitrary challenges to any future marketing claims for Prevagen. Accordingly, the Injunction violates Rule 65(d) and should be vacated.

III. The District Court Erred in Holding that Executive Law Section 63(12) Creates an Independent, Standalone Cause of Action for Fraud

The District Court committed further error when it concluded that Section 63(12) of New York's Executive Law creates an independent, standalone cause of action for fraud under New York law. As the Court of Appeals recognized, as multiple Appellate Departments have confirmed, and as is clear from the statute's plain text, the Executive Law has a specific application: it permits the NYAG to seek preliminary injunctive relief and expedited discovery while the merits of a predicate claim are adjudicated. When liability on the predicate claim is found, the Executive

Law may permit the NYAG to seek additional relief for those violations. But it does not create an independent, standalone, and amorphous cause of action for fraud in the absence of predicate liability.

The jury concluded that all eight of the Challenged Statements violated the Executive Law—even the six Acquitted Statements for which it found no predicate liability under the GBL. Following the verdict, the District Court declined to conform the jury's findings to the law and denied Quincy's motion for judgment as a matter of law on the question of whether the jury should have reached the Executive Law for the Acquitted Statements in the absence of a finding of GBL liability. [Dkt.457_at_3.] In doing so, the District Court implicitly decided that the Executive Law does, in fact, create an independent, standalone cause of action for fraud under New York law, even absent predicate liability and even though the Executive Law applies a lower standard than the GBL, FTC Act, and the consumer protection statutes in the other 49 states.[2] The District Court's refusal to grant

[2] Notably, the District Court's decision was a departure from its earlier conclusion that the Executive Law does not create an independent cause of action. At the charge conference, the District Court indicated that the Executive Law is "not freestanding," and rejected efforts by the NYAG to instruct the jury that the Executive Law creates an independent cause of action for fraud under New York law. [Trial_Tr.1346:21-22.] The District Court then instructed the jury that if it did not find liability under the GBL for any one of the Challenged Statements, it should not reach the Executive Law claim for that statement because "in effect, that charge has already been disposed of." [Trial_Tr.1447:19-1448:2.]

judgment as a matter of law in Quincy's favor as to the six Acquitted Statements found not to violate the GBL—i.e., those claims lacking predicate liability to support violations of the Executive Law—was in error and should be reversed.

a. The Second Circuit Should Predict How the New York Court of Appeals Would Resolve this Issue

When presented with questions of state law, this Court "carefully review[s] available resources to predict how the New York Court of Appeals would resolve" the issue. *Travelers Ins. Co. v. 633 Third Assocs.*, 14 F.3d 114, 119 (2d Cir. 1994). In doing so, the Court "give[s] fullest weight to the decisions of a state's highest court and proper regard to the decisions of a state's lower courts" and should also consider "the decisions of federal courts construing state law." *Yukos Cap. S.A.R.L. v. Feldman,* 977 F.3d 216, 241 (2d Cir. 2020). This Court may also consider the "statutory language, pertinent legislative history, the statutory scheme set in historical context, [and] how the statute can be woven into the state law with the least distortion of the total fabric." *Travelers*, 14 F.3d at 119.

b. The New York Court of Appeals Has Confirmed That the Executive Law Does Not Provide a Standalone Cause of Action for Fraud

In *State of New York v. Cortelle*, the Court of Appeals concluded that the Executive Law does not create a standalone cause of action for fraud under New York law. 38 N.Y.2d 83, 86 (1975). The Court of Appeals found that the statute is,

instead, a procedural vehicle providing standing and expanded relief for adjudicated violations of a *predicate* common law or statutory cause of action. *Id.* at 85.

In *Cortelle*, the NYAG pled promissory fraud and Executive Law claims. [Dkt.485-1.] Initially, the trial court dismissed the Executive Law claim as time-barred under the three-year statute of limitations for liabilities "created or imposed by statute." *Cortelle*, 38 N.Y.2d at 85. On appeal, the NYAG argued that, because the Executive Law "did not create a new liability by making illegal conduct that would otherwise be unlawful"—exactly what *Quincy* is arguing here—its Executive Law claim should be governed by the six-year statute of limitations that governed the predicate promissory fraud claim. [Dkt.474-4_at_9.] Ultimately, the Court of Appeals agreed with the NYAG, finding that the statute of limitations for the predicate promissory fraud claim also applied to the Executive Law claim. In reaching that conclusion, the Court of Appeals reasoned that the Executive Law merely expanded the remedies that the NYAG could obtain for the "classic wrong" of promissory fraud, and that "[s]tatutory provisions which provide only additional remedies do not create or impose new obligations." *Cortelle*, 38 N.Y.2d at 87. In other words, the Court of Appeals held—based on the NYAG's own argument—that the Executive Law did not "make unlawful the alleged fraudulent practices" but rather "provided standing to the Attorney-General to seek redress and additional

remedies *for recognized wrongs which pre-existed*" the statute. *Id.* at 85-86 (emphasis added).

Two years after deciding *Cortelle*, the Court of Appeals was presented with an opportunity to abrogate its holding. It did not. In *State of New York v. Princess Prestige Company*, the NYAG obtained injunctive relief under the Executive Law based on violations of the Home Solicitations Sales Act (the "HSSA") despite the respondent's argument that the HSSA was suspended "and thus afforded no predicate for the present proceeding." 42 N.Y.2d 104, 107 (1977). The Court of Appeals concluded that the HSSA was not suspended and that the Executive Law claim could survive with that source of predicate liability intact. Indeed, the Court of Appeals framed the question in a way that unquestionably tethered the Executive Law claim to predicate liability under the HSSA: "[t]he disposition of the cross appeals in this case turns on the right of the Attorney-General, *under subdivision 12 of section 63 of the Executive Law*, to injunctive relief *to prevent future violations of [the HSSA].*" *Id.* (emphasis added).

The Court of Appeals again affirmed the Executive Law's function—as set forth in *Cortelle*—in *People v. Credit Suisse Securities (USA) LLC*, 31 N.Y.3d 622, 633-34 (2018). There, as in *Cortelle*, the Court of Appeals considered the proper statute of limitations for claims brought under the Executive Law. *Id.* at 633-34. And there, as in *Cortelle*, the Court of Appeals explained that the Executive Law

"gives the Attorney General standing to redress liabilities *recognized elsewhere in the law*, expanding the scope of available remedies," and concluded that courts assessing the timeliness of claims under the Executive Law must "look through [the Executive Law] and apply the statute of limitations applicable to the underlying liability." *Id.* (emphasis added). Notably, the Court of Appeals acknowledged that the parties disagreed as to whether Executive Law created a standalone cause of action under New York law but declined to revisit the issue. *Id.* at 633.

Consistent with *Cortelle* and its progeny, New York's intermediate appellate courts consistently dismiss claims brought under the Executive Law when the predicate liability claims were dismissed, thereby recognizing that it did not provide a freestanding cause of action absent the predicate claim. *See, e.g., People ex rel. Schneiderman v. One Source Networking, Inc.*, 125 A.D.3d 1354, 1355-56 (4th Dep't 2015); *People ex rel. Spitzer v. Frink Am., Inc.*, 2 A.D.3d 1379, 1380 (4th Dep't 2003); *State of N.Y. v. Wolowitz*, 96 A.D.2d 47, 61 (2d Dep't 1983).

Against this backdrop, the First Department decided *People v. Trump Entrepreneur Initiative LLC.*, 137 A.D.3d 409 (1st Dep't 2016). As *Trump Entrepreneur* could not avoid the binding precedent of *Cortelle*, it attempted to limit the scope of *Cortelle*'s holding to the applicable statute of limitations for the Executive Law. *Id.* at 416. But tellingly, even *Trump Entrepreneur* did not permit the Executive Law claim to proceed alone. Instead, it proceeded *alongside* a

common law fraud claim, and the First Department subjected both claims to six-year statute of limitations as a result. *Id.* at 418-19 (denying summary determination for the NYAG's fraud claims "under either the common law or the statute" because material issues of fact existed as to both).

In rendering its decision below, the District Court relied solely on *Trump Entrepreneur* and its improperly constrained interpretation of *Cortelle* to find that the Executive Law "provides an independent cause of action that does not depend on the Quincy defendants' liability under other claims." [Dkt.491_at_2.] But its analysis misinterpreted *Cortelle*, misapplied *Trump Entrepreneur*, and ignored *Princess Prestige* and *Credit Suisse* altogether. As a result, the District Court answered the wrong question: whether the Executive Law "empowers the New York Attorney General to bring a cause of action." [Dkt.491_at_4.] That is not in dispute. Here, the District Court had to make a different determination: whether the NYAG can maintain an independent, *standalone* cause of action under the Executive Law where the predicate cause of action (here, the GBL) has been dismissed. And as the New York Court of Appeals recognized in *Cortelle* and its progeny, the NYAG cannot do so.

Accordingly, this Court should reverse the District Court's decision below and enter judgment as a matter of law in Quincy's favor as to the six Acquitted Statements for which no predicate liability under the GBL was found.

c. The Legislative History of the Executive Law Confirms That It Does Not Provide a Standalone Cause of Action

The District Court further erred by ignoring the "pertinent legislative history" of the Executive Law and its "statutory scheme set in historical context," both of which confirm that the Executive Law is intended to serve as a procedural vehicle rather than a standalone, substantive cause of action. *See Travelers*, 14 F.3d at 119. As discussed by both legislators and the then-attorney general, the Executive Law was intended to close a loophole in Article 8 of the Corporations law; at the time of its enactment, the NYAG could seek injunctions or dissolution of corporations, "but no similar remedy [was] available as respects unincorporated companies engaged in similar conduct." [Dkt.474-8_at_11.] With that purpose in mind, the bill's sponsor clarified that the proposed section "conforms to the powers to which now reside in the Attorney General with respect to corporation under Article 8 of the General Corporation Law." [Dkt.474-8_at_4.]

Far from creating any new substantive causes of action, the Executive Law merely expanded the procedural mechanisms through which other statutes or common law claims can be enforced. [*Id.*] Indeed, before the Executive Law was enacted, the Article 8 Corporations Law required the NYAG to "procure a judgment" for a predicate violation under another statute or the common law in order to obtain relief. [Dkt.474-9_at_4.] The comments to the rule expressly confirm that "the section contains no rule of corporate liability whatever, but points out simply a

mode of procedure to enforce duties or punish misconduct elsewhere and otherwise settled and determined, and it is said to accomplish nothing to say that the action is brought under this section." [Dkt.474-9_at_5.] Thus, the Corporations Law did "not determine, much less enlarge, existing rules of corporate liability." [*Id.* (quoting *People v. Atlantic Ave. R.R. Co. Brooklyn*, 125 N.Y. 513, 516-17 (1891)).]

By conforming Executive Law to the Corporations Law, the Legislature intended that the Executive Law require a predicate violation "elsewhere and otherwise settled and determined." [*Id.*]

d. The District Court's Interpretation of the Executive Law Yields Absurd Results

The District Court's decision would upend decades of New York and federal caselaw construing consumer protection statues. The New York legislature has enacted two primary statutes for the NYAG to pursue consumer fraud: the GBL and the Executive Law. [Dkt.474-6_at_2.] As the NYAG itself argued previously, these two acts were intended to be given "a parallel construction." [Dkt.474-6_at_5.] And New York courts have applied the same deception standard to both statutes. *See Guggenheimer v. Ginzburg*, 43 N.Y.2d 268, 272-73 (1977). In *Guggenheimer*, a case concerning Executive Law claims with a GBL predicate, the Court of Appeals explained that "[i]n weighing a statement's capacity, tendency or effect in deceiving or misleading customers, we do not look to the average consumer, but to the vast

multitude of which the statutes were enacted to safeguard—including the ignorant, the unthinking and the credulous." *Id.* at 273.

When *Guggenheimer* was decided in 1977, the Court of Appeals adopted this subjective, "unthinking consumer" standard from the FTC which, at that time, applied that standard to its own statute. *See Floersheim v. Weinburger*, 346 F. Supp. 950, 957 (D.D.C. 1972) (collecting cases). Indeed, New York courts construing the GBL regularly "tracked the actions of the FTC with respect to interpretation and enforcement of the Federal Trade Commission Act." *Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330, 352 (1999) (Bellacosa, J., dissenting). Shortly after *Guggenheimer*, in 1983, the FTC "clarified" its interpretation of the FTC Act and stated that, to be deceptive, the representation must "be likely to mislead reasonable consumers under the circumstances." *FTC Policy Statement on Deception*, Consumer Protection and the Law Appendix 10A (Oct. 14, 1983).

In 1995, the Court of Appeals again followed the FTC's lead and, in a case involving GBL liability, abandoned the "unthinking" consumer standard used in *Guggenheimer* in favor of a more "objective definition" that "complements the definition applied by the [FTC]." *Oswego Laborers' Loc. 214 Pension Fund v. Marine Midland Bank, N.A.,* 85 N.Y.2d 20, 26 (1995). Thus, rather than viewing the representations from the perspective of the unthinking consumer, the Court of Appeals held that GBL liability is "limited to those likely to mislead a reasonable

consumer acting reasonably under the circumstances."[3] *Id.* This Court has followed *Oswego's* application of the "reasonable consumer" standard to GBL claims. *See Fink v. Time Warner Cable*, 714 F.3d 739, 741 (2d Cir. 2013). New York courts are not an anomaly: "[c]ourts have previously surveyed consumer protection statutes from states across the country" and found that each state requires that the representation be misleading to a reasonable consumer. *See Hoffman v. Kraft Heinz Foods Co.*, No. 7:22-cv-00397, 2023 WL 1824795, at *9 (S.D.N.Y. Feb. 7, 2023) (collecting cases).

Despite the NYAG previously recognizing that the GBL and the Executive Law should be given a parallel construction, and despite the Court of Appeals' express adoption of the reasonable consumer standard for GBL claims, the District Court erroneously instructed the jury and awarded relief to the NYAG under the Executive Law based on that lower "unthinking" consumer standard that the Court of Appeals has long-abandoned. The District Court offered no justification for holding, in essence, that the ignorant, unthinking, and credulous consumer standard does not apply to GBL claims but does apply to Executive Law claims. This error

[3] While the court did not expressly abrogate *Guggenheimer*, multiple courts have recognized the Court of Appeals' "retreat[] from" its standard. *See Hollander v. Metro. Transp. Auth.,* 48 Misc. 3d 1206(A), at *4 n.2 (N.Y. Sup. Ct. 2015); *McVetty v. TomTom N. Am., Inc.*, No. 7:19-cv-04908, 2021 WL 965239, at *3 n.3 (S.D.N.Y. Mar. 13, 2021).

is particularly striking in this case, where the two claims were based on the exact same allegations.

It is telling that the District Court did not cite a single case holding that marketing claims—or any conduct, for that matter—can violate the Executive Law but not the GBL. To the contrary, courts dismiss Executive Law claims where the predicate violation is dismissed. *See, e.g., City of N.Y. v. FedEx Ground Package Sys.*, 175 F. Supp. 3d 351, 363-64 (S.D.N.Y. 2016) (that the predicate claim fails "compels dismissal of this claim for relief [under the Executive Law] as well"); *People v. Mashinsky*, 79 Misc. 3d 1237(A), at *16 (N.Y. Sup. Ct. 2023) (Executive Law claim and its substantive predicate "stand and fall together").

If allowed to stand, the District Court's error would have far-reaching policy ramifications. Indeed, if the NYAG can pursue ***"fraud"*** claims based solely on the Executive Law's "unthinking" and "unknowing" consumer standard, there would be no reason for the NYAG to ever pursue claims under the GBL or other Article 22-A provisions. Why would the NYAG need or want to challenge claims under the "reasonable consumer" standard when it could obtain the same relief under the Executive Law using a much lower burden of proof? This scenario alone renders the District Court's interpretation absurd, particularly given the Court of Appeals' admonition that courts "cannot interpret one statute to nullify another when both are part of the same statutory scheme." *In re Goodman*, 95 N.Y.2d 15, 22 (2000).

The District Court's decision also puts New York at odds with every other state in the country, as well as with federal standards. Allowing consumer fraud to be prosecuted in New York under the lax "unthinking consumer" standard would effectively subject companies to a much lower standard of liability under New York's consumer protection statutes than under any other state or federal law, potentially casting a chilling effect on businesses who choose to operate in New York. If the Legislature intended to upend New York's entire consumer protection regime by enacting the Executive Law and creating a lower standard of liability for businesses operating in New York, it could have and would have done so explicitly.

For all these reasons, this Court should reverse the District Court's erroneous decision below and enter judgment for Defendants as to the six Acquitted Statements for which no predicate liability under the GBL was found.[4]

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[4] *Cortelle* is clear and binding precedent. However, this Court has discretion to certify that question to the New York Court of Appeals if it finds that: "(1) the New York Court of Appeals has not squarely addressed [the] issue and other decisions by New York courts are insufficient to predict how the Court of Appeals would resolve it; (2) the statute's plain language does not indicate the answer; (3) a decision on the merits requires value judgments and important public policy choices that the New York Court of Appeals is better situated [] to make; and (4) the questions certified will control the outcome of the case." *Adar Bays, LLC v. GeneSYS ID, Inc.*, 962 F.3d 86, 93 (2d Cir. 2020) (quoting *Penguin Grp. (USA) Inc. v. Am. Buddha*, 609 F.3d 30, 42 (2d Cir. 2010)), *certified question accepted*, 35 N.Y.3d 996 (2020), and *certified question answered*, 37 N.Y.3d 320 (2021). This case will certainly implicate important value judgment and public policy choices, as resolution of this question will have significant effects beyond these parties and potentially implicate

IV. This Is Not a "Proper Case" for Permanent Injunctive Relief Under Section 13(b) of the FTC Act

The District Court also erred when it denied summary judgment and later entered a permanent injunction on the FTC's claims despite the fact that this is not a "proper case" for permanent injunctive relief under Section 13(b) of the FTC Act.

a. The FTC's Enforcement Authority Under Section 13(b) of the FTC Act Is Limited

The FTC is not entitled to seek a permanent injunction in every case it files under Section 13(b). Rather, like all administrative agencies, the FTC's enforcement powers are limited to those granted by Congress. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957); *Arrow-Hart & Hegeman Elec. Co. v. FTC*, 291 U.S. 587, 598 (1934).

When the FTC Act was originally enacted in 1914, Section 5 allowed the FTC to commence an administrative adjudicatory proceeding if it had "reason to believe" that a party "has been or is using any . . . unfair or deceptive practice in or affecting commerce." 15 U.S.C. § 45(b); *AMG*, 593 U.S. at 72. If a violation was found, the FTC could issue a cease-and-desist order. *See AMG*, 593 U.S. at 72.

In 1973, Congress added Section 13(b), titled "Temporary Restraining Orders; Preliminary Injunctions," permitting the FTC to file an action in a district court and

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all consumer-facing companies who conduct business in New York. *See, e.g.*, *Banque Worms v. BankAmerica Int'l,* 928 F.2d 538, 541 (2d Cir. 1991).

obtain an injunction pending the issuance of an administrative complaint if it had reason to believe that the defendant "is violating, or is about to violate, any provision of law enforced by the [FTC]." 15 U.S.C. § 53(b)(1). The preliminary injunction was to stay in effect until the administrative complaint was dismissed or set aside, or until the administrative proceeding reaches a final order. *See id.*

But Congress imposed two provisos to Section 13(b). Relevant here, the second proviso states that, "in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction." *Id.* The statute does not elaborate on what constitutes a "proper case" or "proper proof."

b. The Supreme Court Rejected the FTC's Attempt to Expand Its Enforcement Authority

In the late 1970s, the FTC began to file Section 13(b) actions to obtain more relief than is provided for under the statute—namely, permanent injunctions and equitable monetary relief—without commencing administrative proceedings or seeking a preliminary injunction. *See AMG,* 593 U.S. at 73 (citing *FTC v. Va. Homes Mfg. Corp.*, 509 F. Supp. 51, 59 (D. Md. 1981)). In 2020, however, the Supreme Court put an end to at least part of the FTC's attempted expansion of its enforcement powers. Despite decades of courts awarding equitable monetary relief under Section 13(b), the Court ruled that, because Section 13(b) "focuses upon relief that is prospective, not retrospective," the FTC was not permitted to obtain monetary relief such as restitution or disgorgement. *Id.* at 76-77.

c. A "Proper Case" for Permanent Injunctive Relief Is a Case Where the FTC Seeks and Obtains a Preliminary Injunction Pending Resolution of Administrative Proceedings and Later Satisfies the Requirements for a Permanent Injunction

AMG did not address whether the FTC is permitted to obtain permanent injunctions without corresponding administrative proceedings and/or seeking a preliminary injunction from the district court in the first instance. However, it did offer some guidance regarding the second proviso of Section 13(b):

> [T]he appearance of the words "permanent injunction" (as a proviso) suggests that those words are directly related to a previously issued preliminary injunction. They might also be read, for example, as granting authority for the Commission to go one step beyond the provision and ("in proper cases") dispense with administrative proceedings to seek what the words literally say (namely, an *injunction*).

AMG, 593 U.S. at 76-77 (emphasis in original).

Defendants submit that the Supreme Court's first interpretation is correct, and that a "proper case" for a permanent injunction is one where, at a minimum, the FTC has previously sought a temporary injunction pending the resolution of an administrative proceeding and has offered "proper proof" that the requirements for a permanent injunction have been met at the conclusion of the litigation (including that the challenged conduct is ongoing or has cognizable danger of reoccurring).

This construction makes perfect sense in the context of the FTC's regulatory regime. As the Supreme Court has held, Section 13(b) is prospective—it is intended to stop ongoing violations or violations that are likely to recur while administrative

proceedings move forward—and provides for a permanent injunction in some subset of cases filed under Section 13(b). *AMG*, 593 U.S. at 76. If Congress had intended to allow the FTC to seek a permanent injunction in all cases, it would not have provided this remedy in a proviso to Section 13(b), which is titled "Temporary Restraining Orders; Preliminary Injunctions." It would be clear through a standalone provision authorizing permanent injunctive relief without any conditions or provisos. There is no such provision.

This construction is also necessary to comply with the "surplusage canon" of statutory interpretation, which provides that "every word and every provision is to be given effect. . . . None should be ignored. None should needlessly be given an interpretation that causes it to duplicate another provision to have no consequence." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 154 (2012); *see also SEC v. Govil*, 86 F.4th 89, 100 (2d Cir. 2023) ("[T]he canon against surplusage requires that we be hesitant to adopt an interpretation of a congressional enactment which renders superfluous another portion of that same law." (quoting *Republic of Sudan v. Harrison*, 139 S. Ct. 1048, 1058 (2019))). If the FTC is permitted to seek a permanent injunction in every case filed under Section 13(b), "proper cases" and "proper proof" would have no meaning and would be rendered superfluous.

Legislative history also supports Defendants' interpretation of Section 13(b). Specifically, Congressman Harold Johnson wrote that, "[i]n especially aggravated cases, it is essential that the Commission have authority to prevent the aggregation of serious public harm ***during the period required for the Commission to complete cease and desist order proceedings and attendant appeals***." 119 Cong. Rec. 36610 (1973) (emphasis added). This comment confirms that Section 13(b) was intended to provide only for temporary relief while the administrative process moved forward.

Here, while the FTC conducted a lengthy pre-suit investigation involving the production of thousands of documents and other information, it filed the Complaint *without* requesting a preliminary injunction and *without* commencing an administrative adjudicatory proceeding. If the FTC did not believe there was a basis for a preliminary injunction at the outset of the case, there is certainly no reason to conclude that this was a "proper case" for a permanent injunction over seven years later. The FTC should not be permitted to obtain a permanent injunction after side-stepping the initial requirements for filing in federal court in the first place.

Accordingly, this Court should reverse the District Court's denial of summary judgment and/or vacate the Injunction on the grounds that this is not a "proper case" for permanent injunctive relief under Section 13(b) of the FTC Act.

V. The District Court Erred When It Denied Defendants' Motions for Summary Judgment and Quincy's Motion for Judgment as a Matter of Law Regarding the NYAG's Failure to Prove That the Challenged Statements Were Unsubstantiated or Deceptive

a. Plaintiffs Failed to Proffer Any Extrinsic Evidence of Consumer Deception

The District Court erred in denying Defendants' motions for summary judgment, judgment as a matter of law, and reconsideration on the issue of the Plaintiffs' failure to prove that any of the Challenged Statements were deceptive under the GBL. To prove deception, Plaintiffs were required to "present admissible evidence establishing how the challenged statement . . . tends to mislead reasonable consumers acting reasonably." *Bustamante v. KIND, LLC*, 100 F.4th 419, 426 (2d Cir. 2024); *see also Chufen Chen v. Dunkin' Brands, Inc.*, 954 F.3d 492, 500 (2d Cir. 2020) (quoting *Fink*, 714 F.3d at 741); *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 872 (E.D.N.Y. 2018) ("[A] plaintiff must adduce extrinsic evidence—ordinarily in the form of a survey—to show how reasonable consumers interpret the challenged claims."). Because Plaintiffs failed to present any evidence—be it a consumer survey, expert testimony, or otherwise—at summary judgment or at trial about how reasonable consumers interpreted Quincy's advertisements, the District Court erred in denying these motions. [*See* Dkt.331_at_16; Dkt.457_at_3-4; Dkt.481_at_5.]

In *Bustamante*, the plaintiffs alleged under the GBL and other similar laws that they were deceived by an "All Natural" claim on the packaging of various snack products. 100 F.4th at 423. In an effort to prove how a reasonable consumer would interpret "All Natural," the plaintiffs proffered a consumer survey prepared by an expert, but the district court excluded the survey as biased and irrelevant. *See id.* at 428-30. Because there was no other evidence demonstrating how reasonable consumers interpreted the challenged claims, the district court granted summary judgment to the defendant. *See id.* 423-24. This Court agreed and affirmed the grant of summary judgment because there was no evidence in the record[5] establishing how reasonable consumers would perceive the challenged advertising claims. *Id.* at 432-34.[6]

It is undisputed that Plaintiffs failed, as required by *Bustamante*, to present any evidence at summary judgment that "a reasonable consumer acting reasonably would be deceived" by the Challenged Statements. *See id.* at 434. And, at trial, the

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[5] This Court also considered—and rejected—the plaintiffs' attempt to defeat summary judgment through reliance on their own allegations and deposition testimony about how they interpreted the challenged advertising, on internal documents showing how KIND interpreted the phrase, or on dictionary definitions. *See Bustamante*, 100 F.4th at 432-34.

[6] Lanham Act claims, which are governed by the same "reasonable consumer" standard, also require extrinsic evidence of deception. *See, e.g., Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007).

NYAG did not call a single fact or expert witness to testify about consumer perception.

Rather than finding in Defendants' favor as a result of this repeated failure of proof, the District Court tried to distinguish *Bustamante*, holding that its ruling applies only to cases brought by a private plaintiff, and not to cases brought by the NYAG. [Dkt.481_at_3-4.] But the law does not support that proposed distinction and, indeed, nothing in the GBL or *Bustamante* suggests that the NYAG has a lower evidentiary burden in proving deception than a private plaintiff. The District Court therefore erred in its legal analysis of the NYAG's burden.

The District Court also stated that "the jury was not asked to appraise consumer reactions" in this case and so no extrinsic evidence was required. [Dkt.481_at_4.] But that is precisely what the jury was asked to do, both by the NYAG and by the District Court itself. [Trial_Tr.1416:5-8; Trial_Tr.1424:10-1425:1; Trial_Tr.1447:14-18.] In order to render findings under the GBL, the jury *necessarily* had to determine how reasonable consumers would interpret Quincy's advertisements in order to determine whether or not they were materially misleading, and was forced to do so without considering any admissible evidence on this issue.

In light of this evidentiary void, the District Court should have granted Defendants' motion for summary judgment and Quincy's motion for judgment as matter of law, either when such motions were initially filed or on Defendants'

motion for reconsideration of the same. Those denials should be reversed, and judgment should be entered in Defendants' favor.

b. The NYAG Failed to Rebut Quincy's Evidence Regarding Vitamin D

The District Court also erred by denying Quincy's motion for judgment as a matter of law, in which Quincy sought dismissal of all the NYAG's claims to the extent they were related to the post-2016 version of Prevagen containing Vitamin D. In 2016, Prevagen was reformulated to include a second active ingredient—Vitamin D—in addition to apoaequorin. [Trial_Tr.867:6-10.] In order to prevail on its claims, the NYAG had to prove that there was no competent and reliable scientific evidence that *either* active ingredient in Prevagen—apoaequorin or Vitamin D—supported the Challenged Statements. The NYAG understood its burden and promised the jury during opening statements that its "experts will tell you that there's just no evidence that vitamin D improves memory or provides any other cognitive benefit *for the general population*." [Trial_Tr.45:6-8 (emphasis added).]

The NYAG failed to live up to that promise because it never produced such evidence. Dr. Mary Sano was the NYAG's sole expert to testify about Vitamin D. But Dr. Sano only testified about the purported inefficacy of Vitamin D in the segment of the American population that is *not* Vitamin-D deficient. [Trial_Tr.322:1-323:3.] She did not offer any testimony regarding the effect of Vitamin D in a Vitamin D-deficient population—which is roughly *half* of the

American population, and likely the very consumers who would most benefit from Prevagen. [Trial_Tr.322:1-323:3, 1007:25-1008:8.] In other words, Dr. Sano's testimony could—*at most*—support an argument about whether there was competent and reliable scientific evidence to support the Challenged Statements in the portion of the population that was not Vitamin D deficient. But a dietary supplement need not benefit every single person who takes it to support an efficacy claim. *See, e.g., Greenberg v. Target Corp.*, 985 F.3d 650, 656 (9th Cir. 2021) (holding that "manufacturers may make structure/function claims about a nutrient's general role on the human body without disclosing whether the product will provide a health benefit to each consumer" in the general population).

The only expert who testified about the efficacy of Vitamin D in the American population *as a whole* was Quincy's expert, Dr. Mindy Kurzer, and her testimony was unrebutted.

At trial, Dr. Kurzer testified that she conducted a literature search and reviewed 86 peer-reviewed studies involving the relationship between Vitamin D and cognitive function, including randomized controlled trials, epidemiological studies, and meta analyses. [Trial_Tr.1007:7-10, 1008:9-13, 1009:21-1011:24; 1014:11-1015:1] Dr. Kurzer testified that the vast majority of the information that she reviewed showed a beneficial association between Vitamin D and cognitive function and substantiates the Challenged Statements. [*Id.*]

In sum, the District Court erred in denying Quincy's motion for judgment as a matter of law because the NYAG did not offer any opinion to rebut Dr. Kurzer's conclusion that the Challenged Statements were supported by competent and reliable scientific evidence encompassing the entire American population, including the substantial portion (nearly *half*) of that population with Vitamin D deficiencies.

This Court should reverse the District Court's denial of Quincy's motion for judgment as a matter of law, and enter judgment in Defendants' favor.

c. Plaintiffs' Experts Applied an Incorrect and Heightened Substantiation Standard

The District Court also erred in denying Defendants' motion for summary judgment and Quincy's motion for judgment as a matter of law on the "deception" element of Plaintiffs' claims because Plaintiffs' experts analyzed Defendants' substantiation for its claims under an incorrect, heightened standard.

The FTC Guidance mandates a "flexible" standard of competent and reliable scientific evidence for dietary supplement marketing claims. It does not require a set number or type of studies, and it specifically states that the FTC will consider the "totality of the evidence" including, but not limited to, animal studies, *in vitro* studies, human studies, and epidemiological studies. *See United States v. Bayer Corp.*, No. 2:07-cv-00001, 2015 WL 5822595, at *3-4 (D.N.J. Sept. 24, 2015) ("'competent and reliable scientific evidence' is a 'flexible' standard, and '[t]here is no fixed formula for the number or type of studies required"; RCTs "are not

necessary"; "animal and in vitro studies will also be examined;" "'[e]pidemiologic evidence may be an acceptable substitute for clinical data' in some circumstances"; "one should look to 'the totality of the evidence'"); *see also* [DX-526_at_10-11.]

Defendants' experts were familiar with the flexible substantiation standard set forth in the FTC Guidance, reviewed *all* of the voluminous scientific research behind Prevagen and both of its active ingredients (apoaequorin and vitamin D), and concluded that the Challenged Statements were substantiated by competent and reliable scientific evidence. [*E.g.,* Dkt.222-15_at_3-4 ¶¶5-8; Dkt.222-18_at_2-3 ¶¶7-11; Dkt.222-23_at_3 ¶¶11-15.] In fact, one of Defendants' experts, David Schwartz, is a neuroscientist that has spent most of his career researching marketing claims for dietary supplements to determine whether they are properly substantiated. [Dkt.222-23_at_1 ¶¶1-6; Trial_Tr.1118:21-1129:2.]

Plaintiffs' experts, on the other hand, were completely in the dark regarding the flexible substantiation standard set forth in the FTC Guidance. None of them had read the FTC Guidance, and none of them had any experience substantiating dietary supplement marketing claims. Instead, Defendants' primary expert, Dr. Sano, created her own, heightened standard of substantiation, (which ignored Quincy's animal, *in vitro*, and open-label studies), and opined that, "in this case, competent and reliable scientific evidence means randomized, controlled human clinical studies ('RCTs') that are well-designed, well-conducted, and properly

analyzed according to standards generally accepted by experts in the relevant fields." [Dkt.222-20_at_6 ¶24; Trial_Tr.304:6-315:10; Dkt.308-4_Dep.36:16-21-41:13.] Another of Plaintiffs' experts, Janet Wittes, Ph.D., presumed that an RCT was required and testified about various purported flaws in Quincy's RCT (i.e., the MMS).[7] [*See* Dkt.222-27_at_9 ¶¶15-16; Trial_Tr.397:1-424:15; Dkt.308-8_Dep.35:19-37:18.] In other words, Plaintiffs and their experts set up a scientific strawman argument just to strike it down based on an RCT requirement that is not found anywhere in any state or federal law, regulation, rule, or guidance.

Courts routinely hold that an expert's awareness and consideration of the relevant substantiation standard is required to understand the degree of scientific substantiation evidence typically required in the dietary supplement industry and to ensure that the experts' opinions are relevant to, and consistent with, that standard. *See, e.g., Bayer*, 2015 WL 5822595, at *3, 14 ("[C]ompetent and reliable scientific evidence does not require drug-level clinical trials, and the Government cannot try to reinvent this standard through expert testimony."); *Basic Rsch., LLC v. FTC*, No. 2:09-cv-00779, 2014 WL 12596497, at *13 (D. Utah Nov. 25, 2014) (granting summary judgment to the defendant where the FTC's expert "failed to

[7] Plaintiffs' third expert, Jeremy Berg, Ph.D., opined about potential mechanisms of action for apoaequorin, and did not address substantiation of the Challenged Statements.

apply the proper standard" and required "a level of substantiation that exceeds" the competent and reliable scientific evidence standard for dietary supplements); *FTC v. Garden of Life, Inc.*, 516 Fed. App'x 852, 854 (11th Cir. 2013) (rejecting the FTC and its expert's attempt to read additional requirements into the competent and reliable scientific standard for dietary supplements).

Because Plaintiffs' experts were unaware of the applicable "flexible" substantiation standard and instead applied a heightened standard of their own creation, Plaintiffs failed to create a genuine issue of fact at the summary judgment stage and failed to rebut Quincy's expert testimony at trial. Thus, the District Court erred in denying Defendants' motion for summary judgment and in denying Quincy's motion for judgment as a matter of law.

Moreover, Plaintiffs' attempt to hold Quincy to a different, higher and never-before-announced substantiation standard for dietary supplement advertising also violates due process. *See, e.g.*, *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158-59 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference."); *NLRB v. Majestic Weaving Co.*, 355 F.2d 854, 860 (2d Cir. 1966) ("[A] decision branding as 'unfair' conduct

stamped 'fair' at the time a party acted, raises judicial hackles . . . [where the conduct] might even have been taken in express reliance on the standard previously established."); *Stroller v. Commodity Futures Trading Comm'n*, 834 F.2d 262, 267 (2d Cir. 1987) (reversing agency order that "abruptly changed [the agency's] interpretation in the middle of proceedings"). This due process violation presents another basis to reverse the District Court's decision and grant summary judgment to Defendants.

CONCLUSION

For the reasons set forth herein, the District Court erred in the following respects: (1) ordering nationwide permanent injunctive relief enjoining conduct that was found to be lawful under federal law; (2) entering a vague permanent injunction that fails to put Defendants on notice of the specific conduct that falls within its scope; (3) denying Defendants' motion for summary judgment and judgment as a matter of law and ruling that the Executive Law creates a standalone cause of action for fraud in the absence of predicate liability under the GBL or, to the extent such a cause of action exists, failing to apply the "reasonable consumer" standard; (4) denying Defendants' motion for summary judgment and entering permanent injunctive relief despite this not being a "proper case" under the FTC Act; and (5) denying Defendants' motions for summary judgment and for judgment as a matter of law given Plaintiffs' failure of proof on the deception element of their claims.

Each of the District Court's determinations were in error, and judgment should either be entered in Defendants' favor in its entirety or the case should be remanded with direction to the District Court to narrow the relief granted.

Date: April 3, 2025

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CERTIFICATE OF COMPLIANCE

The undersigned counsel of record hereby certifies that:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure Rule 28.1 because it contains 13,813 words, excluding the portions exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface in 14-point Times New Roman.

Dated: April 3, 2025

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CERTIFICATE OF SERVICE

The undersigned counsel of record hereby certifies that that on April 3, 2025, the foregoing document was served via the Second Circuit's ACMS filing system, which electronically transmits copies to all counsel of record.

Dated: April 3, 2025

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