No. 17-15695

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

FEDERAL TRADE COMMISSION,
Plaintiff-Appellee

v.

HI-TECH PHARMACEUTICALS, INC., JARED WHEAT, AND STEPHEN SMITH
Defendants-Appellants,

On Appeal from the United States District Court
for the Northern District of Georgia
No. 1:04-cv-3294

BRIEF OF PLAINTIFF-APPELLEE FEDERAL TRADE COMMISSION

ALDEN F. ABBOTT
General Counsel

JOEL MARCUS
Deputy General Counsel

LESLIE RICE MELMAN
Assistant General Counsel

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
(202) 326-2478
lmelman@ftc.gov

Of Counsel:
AMANDA C. BASTA
EVAN M. MENDELSON,
Attorneys
Division of Enforcement
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

CERTIFICATE OF INTERESTED PERSONS

Pursuant to 11th Cir. R. 26.1-2, Plaintiff-Appellee Federal Trade Commission (FTC), lists all trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of this case or appeal:

Abbott, Alden F., Acting General Counsel, Federal Trade Commission

Akin Gump Strauss Hauer & Feld LLP, Garnishee

American Pride Bank, Garnishee

Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C., Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc.

Bank of America, N.A. (NYSE: BAC), Garnishee

Barnes, David M., Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat

Basta, Amanda C., Counsel, Federal Trade Commission

Benson, Matthew Parks, Counsel for Garnishee Brand Bank

Best Bank/Guaranty Bank, Garnishee

Bloomston & Callaway, Counsel for Stephen Smith

Bloomston, Brett M., Counsel for Stephen Smith

Blythe, Russell Edward, Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat

Branch Banking and Trust Company (BB&T) (NYSE: BBT), Garnishee

Brand Bank, Garnishee

Bridgers, Charles Ronald, Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Garnishee

Burris, Cheryl Kawezya, Counsel, Federal Trade Commission

CertusBank, N.A., Garnishee

Chief Media, LLC, Garnishee

Cleveland, Adam L., Counsel for Garnishee Community & Southern Bank

Community & Southern Bank (OTC US: CMUY), Garnishee

Compassionate Hearts Alliance, Garnishee

Crosby, L. Clint, Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc.

Cynergy Data, LLC, Garnishee

Davis, Tawana E., Counsel, Federal Trade Commission

DeLong Caldwell Bridgers & Fitzpatrick, LLC, Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, Terrill Mark Wright

Dowdell, Stephen C., Counsel, Federal Trade Commission

Dunnigan, E. Vaughn, Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith

Dymecki, Kimberly Alice, Counsel for the National Urological Group, Inc., Jared Wheat

E. Vaughn Dunnigan, P.C., Garnishee and Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith

East West Bank (NASDAQ: EWBC), Garnishee

Epstein Becker & Green, P.C., Counsel for Hi-Tech Pharmaceuticals, Inc.

Elavon Global Acquiring Solutions, Garnishee

Fawal & Spina, Counsel for Tomasz Holda

Federal Trade Commission, Plaintiff-Appellee

Fidelity Bank, Garnishee

Fifth Third Bank (NASDAQ: FITB), Garnishee

First Citizens Bank & Trust Company (NASDAQ: FCNA), Garnishee

Flagstar Bank (NYSE: FBC), Garnishee

Froelich, Jerome J., Counsel for Tomasz Holda

Fulmer, Timothy Melvin, Counsel for National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc.

Glennon, Edward B., Counsel, Federal Trade Commission

Hanson, Jennifer Sullivan, Counsel for Terrill Mark Wright

Harris, Michelle V., Garnishee

Harvey, Bruce S., Counsel for Stephen Smith, Terrill Mark Wright

Hi-Tech Pharmaceuticals, Inc., Defendant-Appellant

Hillman, Windy Angela, Counsel for Garnishee JP Morgan Chase Bank, N.A.

Holda, Tomasz, Defendant

Hoppock, Theodore H., Counsel, Federal Trade Commission

Howell, Michael, Defendant

JP Morgan Chase Bank, N.A. (NYSE: JPM), Garnishee

Jampol, Melissa Lyn, Counsel for Hi-Tech Pharmaceuticals, Inc.

Johnson, Mary Lucile, Counsel, Federal Trade Commission

Kelley, Victor, Counsel for Jared Wheat, Garnishee

King & Spalding LLP, Garnishee and Counsel for Appellants Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

Kish & Lietz, P.C., Counsel for Jared Wheat

Kish Bank (OTCQB: KISB), Garnishee

Knight, Sydney, Counsel, Federal Trade Commission

Kostner, Amanda B., Counsel, Federal Trade Commission

Kovacic, William E., Counsel, Federal Trade Commission

Law Office of Arthur W. Leach, Counsel for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

Law Office of Bruce Harvey, Counsel for Stephen Smith, Terrill Mark Wright

Law Office of J. Stephen Salter, Counsel for National Urological Group, Inc., Jared Wheat

Law Offices of Murrin & Wallace, LLC, Counsel for Stephen Smith

Leach, Arthur W., Counsel for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

Liebes, Cindy A., Counsel, Federal Trade Commission

Lietz, III, Warren C., Counsel for Jared Wheat

Mahaffey Pickens Tucker, LLP, General Counsel for Garnishee Brand Bank

Marcus, Joel, Deputy General Counsel, Federal Trade Commission

McAlister, Merritt E., Appellate Counsel for Jared Wheat, Hi-Tech Pharmaceuticals, Inc.

McCormick, Theodore Titus, Counsel for Jared Wheat

Miller & Martin PLLC, Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat

McKenney & Froelich, Counsel for Tomasz Holda

Melman, Leslie Rice, Assistant General Counsel, Federal Trade Commission

Mendelson, Evan M., Counsel, Federal Trade Commission

Morochnik, Paul J., Counsel for Garnishee Bank of America, N.A.

Murrin, Stephen Bart, Counsel for Stephen Smith

Natter & Fulmer, P.C., Counsel for the National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Garnishee

National Institute for Clinical Weight Loss, Inc., Defendant

National Urological Group, Inc., d/b/a Warner Laboratories, Defendant

Nuechterlein, Jonathan E., former General Counsel, Federal Trade Commission

NOA Bank, Garnishee

Northeast Georgia Bank, Garnishee

Novotny, Edmund J., Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, Terrill Mark Wright

Office of Kimberly Alice Dymecki, Counsel for the National Urological Group, Inc., Jared Wheat

Office of Nicolette S. Templer, Counsel for Claimant Kasey Wheat

Pak, Byung J., U.S. Attorney for the Northern District of Georgia

Pannell, Jr., Charles A., District Court Judge

Parsley, Robert F., Appellate Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat

Piedmont Bank (OTC: PCBN), Garnishee

Quantum National Bank, Garnishee

Regions Bank (NYSE: RF), Garnishee

Rodriguez, Edwin, Counsel, Federal Trade Commission

Rohrer, James T., Counsel, Federal Trade Commission

Rosenberg, Alejandro G., Counsel, Federal Trade Commission

Salter, J. Stephen, Counsel for the National Urological Group, Inc., Jared Wheat

Schilleci, Jr., Joseph Paul, Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith, Garnishee

Schilleci Law Firm, LLC, Counsel for the National Urological Group, Inc., National Institute for Clinical Weight Loss, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Stephen Smith

Shonka, David C., former Acting General Counsel, Federal Trade Commission

Sibley, Erica, Counsel for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

Smith, Stephen, Defendant-Appellant

Sommerfeld, Lawrence R., Counsel, Federal Trade Commission

Spina, Thomas J., Counsel for Tomasz Holda

SunTrust Banks (NYSE: STI), Garnishee

Templer, Nicolette Susan, Counsel for Claimant Kasey Wheat

Thompson O'Brien Kemp & Nasuti, P.C., Counsel for Garnishee Community & Southern Bank

United Central Bank, Garnishee

United Community Bank (NASDAQ: UCBI), Garnishee

United States Attorney General's Office for the Northern District of Georgia

Verduce, Valerie M., Counsel, Federal Trade Commission

Victor Kelley, LLC, Counsel for Jared Wheat

Voigts, Anne M., Counsel for Hi-Tech Pharmaceuticals, Inc. and Jared Wheat

Wachovia Bank (NYSE: WB), merged with Wells Fargo & Co. (NYSE: WFC), Garnishee

Wargo & French LLP, Counsel for Garnishee JP Morgan Chase Bank, N.A.

Wargo, Joseph D., Counsel for Garnishee JP Morgan Chase Bank, N.A.

Weissmann Zucker Euster Morochnik, P.C., Counsel for Garnishee Bank of America, N.A.

Wells Fargo Bank, N.A. (NYSE: WFC), Garnishee

Wenik, Jack, Counsel for Hi-Tech Pharmaceuticals, Inc., Jared Wheat

Wheat, Kasey, Claimant

Wheat, Jared, Defendant-Appellant

Wheat, Lindsey E., Garnishee

Woodforest National Bank, Garnishee

Wright, M.D., Terrell Mark, Defendant-Appellant

STATEMENT REGARDING ORAL ARGUMENT

The Commission believes that oral argument will assist the Court in its consideration of this appeal.

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STATEMENT OF JURISDICTION

The district court had jurisdiction to issue the underlying injunctions at issue pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345 and 15 U.S.C. § 53(b). The district court had jurisdiction to enter the contempt orders under review pursuant to its inherent power to enforce compliance with its decrees. *See Spallone v. United States*, 493 U.S. 265, 276 (1990); *Serra Chevrolet, Inc. v. Gen. Motors Corp.*, 446 F.3d 1137, 1147 (11th Cir. 2006). Appellants filed a timely notice of appeal on December 21, 2017. Doc.979.[1] This Court has jurisdiction to review the contempt judgment under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES PRESENTED

1. Whether appellants forfeited their claims that the injunction is facially invalid under Rule 65(d) by failing to raise them in their prior appeals.

2. Whether (assuming they may pursue a collateral attack on the injunction on appeal from contempt sanctions), appellants have

[1] "Doc." refers to the consecutively numbered entries on the district court docket. "PX" refers to the exhibits offered by the Federal Trade Commission at trial; "DX" refers to appellants' exhibits. "Br." refers to appellants' opening brief. Citations to pages in the docketed entries are to the pages as they appear in the ECF header.

shown that they were unable to understand what the injunction required of them.

3. Whether the district court abused its discretion when it found that appellants lacked "competent and reliable scientific evidence," as defined in the 2008 injunction, to support their claims that their product would cause weight and fat loss.

4. Whether the district court abused its discretion in holding appellant Smith in contempt.

STATEMENT OF THE CASE

Hi-Tech Pharmaceuticals, Inc., Jared Wheat, its owner and CEO, and Stephen Smith, its Senior Vice-President, challenge an order holding them in contempt of an earlier judgment of the district court and imposing on them a contempt sanction of $40 million. The underlying order permanently enjoined appellants from, *inter alia*, claiming Hi-Tech's products cause a rapid or substantial weight or fat loss unless they had "competent and reliable scientific evidence" that substantiates the representation. Doc.230 at 12-13.

Appellants ignored the injunction and continued to promote weight-loss products using some of the very same unsubstantiated

claims that the district court declared illegal and barred in the injunction. They knew they were violating the injunction – their own lawyers told them so, and Wheat directly admitted as much in emails and phone calls. The district court held them in contempt and imposed compensatory sanctions. *FTC v. Nat'l Urological Grp., Inc.*, No. 1:04-cv-3294-CAP, 2014 U.S. Dist. LEXIS 67426 (N.D. Ga. May 14, 2014). After a remand, *see FTC v. Nat'l Urological Grp., Inc.*, 785 F.3d 477, 483 (11th Cir. 2015), the court re-imposed the judgment in the order on review. *FTC v. Nat'l Urological Grp., Inc.*, No. 1:04-cv-3294-CAP, 2017 U.S. Dist. LEXIS 182256 (N.D. Ga. Oct. 10, 2017).

The district court's detailed, 132-page decision summarized the two-week trial and expert testimony and held that clear and convincing evidence showed that appellants violated the injunction by marketing weight-loss products without "competent and reliable scientific evidence." Doc.966. The court found all three appellants jointly and severally liable for compensatory contempt sanctions. *Id.* at 130; Doc.969.

The central question in this appeal is whether appellants made a showing that "satisfied the standard of the injunctions for 'competent

and reliable scientific evidence'" of the efficacy of Hi-Tech's weight-loss products. *Nat'l Urological Grp., Inc.*, 785 F.3d at 483.

A. The Legal Framework For False Advertising

Section 5 of the FTC Act prohibits "deceptive acts or practices in or affecting commerce" and "direct[s]" the FTC "to prevent" such practices. 15 U.S.C. § 45(a)(2). Section 12 of the Act, 15 U.S.C. § 52, prohibits "any false advertisement" relating to "food" or "drugs." *Id.* § 52(a), (b). The Act broadly defines "false advertisement" to include any "advertisement, other than labeling, which is misleading in a material respect," whether through affirmative "representations made or suggested" by the advertisement or through a "fail[ure] to reveal facts material in light of such representations." *Id.* § 55(a)(1).

An advertisement violates Sections 5 and 12 of the FTC Act when it (1) contains a representation that (2) is likely to mislead consumers acting reasonably under the circumstances and (3) is material to a consumer's decision to purchase the product. *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); FTC, *Policy Statement on Deception*, 103 F.T.C. 174, 178 (1984). Under the statute, "a false advertisement

need not even be false; it need only be misleading in a material respect." *Pantron I Corp.*, 33 F.3d at 1099 (internal quotation marks omitted).

When an advertiser makes objective claims about a product's performance, it represents "explicitly or by implication that the advertiser has a reasonable basis supporting these claims." FTC, *Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839, 839 (1984) (*Substantiation Statement*). An ad thus "is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it." *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986). The advertiser must have evidentiary substantiation, sufficient under the circumstances, for making the claims at issue. *See id.* Without adequate substantiation, an ad is "deceptive as a matter of law." *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010).

To determine whether an advertiser has a "reasonable basis" for a claim, a court must first determine what level of substantiation is appropriate for the particular claim made. *See*, *e.g.*, *Pantron I*, 33 F.3d at 1096. For safety- and health-related claims, a "reasonable basis" means "competent and reliable scientific evidence." *See*, *e.g.*, *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1492-93 (1st Cir. 1989);

Bristol-Myers Co. v. FTC, 738 F.2d 554, 560 (2d Cir. 1984). Whether a marketer has satisfied this standard in a particular case is a question of fact that is established by evidence. *See*, *e.g.*, *Direct Mktg. Concepts, Inc.,* 624 F.3d at 8 ; *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 558-60 (2d Cir. 1984); *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1143-44 (9th Cir. 1978). Where advertisers lack adequate substantiation evidence, they necessarily lack any reasonable basis for their claims. *See Removatron,* 884 F.2d at 1498. And where advertisers lack a reasonable basis, their ads are deceptive as a matter of law. *Direct Mktg. Concepts*, 624 F.3d at 8; *Removatron*, 884 F.2d at 1498.

Some claims made on product labels fall under the Dietary Supplement Health and Education Act of 1994 (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325, a separate (but complementary) scheme administered by the Food and Drug Administration (FDA). Although DSHEA changed how the FDA regulates supplement *labelin*g, it did not alter the "long-standing FTC policies and enforcement practices relat[ing] to dietary supplement *advertising*." FTC, *Dietary Supplements: An Advertising Guide for Industry*, at 1 (Apr. 2001) (Doc.701-3 (DX3)) (emphasis added).

Under a longstanding liaison agreement, the FTC has primary responsibility for claims in dietary supplement advertising; the FDA has primary – but not exclusive – responsibility for claims on labeling of dietary supplements. *See* Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18539 (Sept. 16, 1971). The two agencies promote consistent standards in their respective programs, Doc.701-3 at 5, but use different enforcement procedures. The FTC acts mainly through retrospective enforcement actions against individual cases of deception; the FDA typically adopts general rules governing labeling claims. *See*, *e.g.*, *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).

The FTC also publishes guidance to marketers of dietary supplements on how they can avoid deception in dietary supplement ads. As most pertinent here, the *Dietary Supplement Guide* advises marketers about the need to ensure that "the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised." Doc.701-3 at 20. To make that determination, advertisers must consider a number of factors, including: (1) how the dosage and formulation of the

advertised compares to what was used in a study and (2) whether the advertised product contains additional ingredients that might alter the effect of the ingredient in the study. *Id*.

B. The Commission's 2007 Complaint Results In Issuance Of The Underlying Injunction

In November 2007, the FTC sued appellants and others for false and deceptive advertising of two weight-loss supplements, Thermalean and Lipodrene, and an erectile performance supplement, Spontane-ES. The Commission alleged that appellants had violated Sections 5 and 12 of the FTC Act by making (1) false and deceptive efficacy and safety claims; and (2) false claims about nonexistent research and medical facilities. Doc.1. The FTC also sued Hi-Tech's paid endorser, Dr. Mark Wright.

In June 2008, the district court found that Hi-Tech lacked substantiation for its claims and granted summary judgment in favor of the Commission. The court recognized that what constitutes competent and reliable scientific evidence depends on "what pertinent professionals would require for the particular claim made." Doc.219 at 26. Uncontroverted testimony by a nationally renowned expert in weight loss and obesity showed that "to substantiate weight-loss claims

for any product, including a dietary supplement," an advertiser must have well-designed, randomized, double-blind and placebo-controlled clinical trials "*on the product itself*." Doc.219 at 65 (emphasis added).

In December 2008, the district court granted summary judgment in favor of the Commission, Doc.219, and entered a Final Order and Judgment for a Permanent Injunction against Hi-Tech, Jared Wheat, and Stephen Smith.[2] Doc. 230. As pertinent here, Section II of the injunction prohibits appellants from making "Unsubstantiated Claims for Weight Loss Products" – specifically, representations unsupported by "competent and reliable scientific evidence" that weight-loss products cause a rapid or substantial loss of weight or fat, or that they affect human metabolism, appetite, or body fat. Doc.230 at 13. The injunction defines "competent and reliable scientific evidence" to mean:

> Tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

[2] The court entered a separate Final Order and Judgment for a Permanent Injunction against Dr. Wright based on his unsubstantiated endorsements of Hi-Tech weight-loss products. Doc.229.

Doc.230 at 5.[3] Section VI of the injunction requires appellants to clearly and prominently include a health warning on each package and label containing efficacy claims for products containing yohimbine, a stimulant derived from tree bark. Doc.230 at 15-16. With respect to each such product, appellants are required to add the following text: "**WARNING:** This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product." *Id.* at 16.

Appellants did not object to the terms of the injunction before it was entered, although the district court gave them an opportunity to do so. *See* Doc.220. In particular, they did not challenge the injunction's definition of "competent and reliable scientific evidence." In fact, they objected to Section II of the injunction only as to Hi-Tech's erectile dysfunction products, which are not now at issue. *See* Doc.966 at 42; Doc.220 at 2-4. Nor did appellants challenge the definition of "competent and reliable scientific evidence" before this Court on appeal. They argued instead that the district court had wrongly found that they

[3] That same definition appears in hundreds of litigated and consent orders and is discussed in the Commission's guidance for marketers of dietary supplements. *See* Doc.703-3 at 13.

operated as a common enterprise and had improperly resolved disputed issues of material fact, and that the First Amendment protected their advertising. Brief for Appellants, *FTC v. Nat'l Urological Grp., Inc.*, No. 09-10617 (April 27, 2009).[4]

This Court affirmed the judgment, and the Supreme Court denied review. *FTC v. Nat'l Urological Grp., Inc.*, 356 F. App'x 358 (11th Cir. 2009), *reh'g denied*, 401 F. App'x 522 (11th Cir. 2010), *cert. denied*, 562 U.S. 1003 (2010).

C. Hi-Tech's Contempt of the 2008 Injunction

In 2010, while incarcerated after pleading guilty to wire fraud and money laundering charges, Jared Wheat launched a new nationwide promotion for four Hi-Tech weight-loss products – Fastin, Lipodrene, Stimerex-ES, and Benzedrine. The $4 million campaign included full-page ads in national publications as well as promotions on the Hi-Tech website and on product packaging and labels. In deciding to proceed with its plans, Hi-Tech acted against the advice of its lawyers, who,

[4] In their unsuccessful petition for rehearing, appellants also argued that the injunction was an improper expansion of the FTC's jurisdiction. Petition for Rehearing En Banc, *FTC v. Nat'l Urological Grp., Inc.*, No. 09-10617 (Jan. 29, 2010).

after reviewing the ads, had "grave concerns" they would violate the injunction. Doc.700-105 (PX117).

The new ads, echoed on the product packaging and labels, touted the products' efficacy in causing weight loss. One ad, labeled "WARNING!" told consumers (in all caps) that Fastin is an "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." Doc.700-42 at 3 (PX46); Doc.700-46 at 3 (PX50).

Like its earlier ads, Hi-Tech's Fastin print ads included an endorsement by Dr. Wright, whose earlier endorsements were found to be unsubstantiated (and who is subject to his own injunction). *See*, *e.g.*, Doc.700-39 at 3 (PX43) ("As a Weight Loss Physician I am proud to join Hi-Tech Pharmaceuticals in bringing you a Truly Extraordinary Weight Loss Product. I believe Fastin® is the Gold Standard by which all Fat Burners should be judged.").

Hi-Tech's ads for Lipodrene similarly exclaimed, in all caps, that the product was a "REVOLUTIONARY FAT ASSASSIN." Doc.700-48 at 3 (PX52). The ads encouraged consumers to "[t]ry Lipodrene and watch the inches melt away," *see id.*, and promised, also in all caps, that

"LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE," *see* Doc.700-218 at 15 (PX272). *See also* Doc.700-50 at 3 (PX54) (promising "ADVANCED APPETITE CONTROL AND METABOLIC STIMULATION").

Hi-Tech's promotion for Stimerex-ES featured express claims that the product melts away body fat. *See*, *e.g.*, Doc.700-57 at 3 (PX61) ("Fat Burner/Energizer"); *see also* Doc.700-61 at 2 (PX65) ("High Performance Thermogenic Intensifier for Maximum Fat Loss"). Hi-Tech also claimed that Stimerex-ES causes the same weight-loss and metabolic effects as products containing the ephedrine alkaloids banned by the FDA in 2004. *See* Doc.700-57 at 3 (PX61) ("The benefits of ephedra are now 'Back in Black!'"). To like effect, Hi-Tech claimed that Benzedrine will "annihilate the fat" (Doc. 700-53 at 3 (PX57)) because of its "Unmatched Anorectic Activity to Manage Caloric Intake." *See* Doc.700-54 at 3 (PX58).

In addition, for the period January 1, 2009 through December 1, 2012, appellants separately violated the injunction's requirement that appellants place a specific health-risk warning on any advertisement,

product, package, or product label that makes efficacy claims relating to products containing yohimbine. Doc.966 at 129.

In November 2011, the FTC moved for an order directing Hi-Tech, Wheat, and Smith to show cause why they should not be held in contempt. Doc.332. The FTC separately moved to hold Dr. Wright in contempt for his unsubstantiated endorsement of Fastin. Doc.377.

In May 2012, the district court directed Hi-Tech to show cause. In the course of that ruling, the court held that the testimony of the FTC's principal expert, Dr. Louis Aronne, in the underlying enforcement action was "broad enough to establish what constituted substantiation of weight-loss claims 'for any product, including dietary supplements * * *.'" Doc.390 at 9 (quoting expert report).[5] As Dr. Aronne had explained, all weight-loss claims must be supported by well-designed, randomized, double-blind and placebo-controlled clinical trials "on the product itself" or its duplicate. *Id.* at 9-10.

The district court held appellants and Dr. Wright in contempt of the 2008 injunction, Doc.524, and held Hi-Tech, Wheat, and Smith

[5] Dr. Aronne is the Sanford I. Weill Professor of Metabolic Research at Weill-Cornell Medical College and Director of the Comprehensive Weight Control Center at Weill Cornell. Doc.945 at 33-34; Doc.941-1 at 1 (PX695); Doc.941-2 at 212 (PX581).

jointly and severally liable for compensatory sanctions in the amount of $40 million – Hi-Tech's gross receipts for the relevant time period, less refunds and returns. Doc.650 at 18-19, 22-23 & n.17. The court found Dr. Wright liable for $120,000 – his earnings for his endorsement of Fastin. Doc.650 at 23-24 & n.19.

D. First Appeal

Appellants appealed the contempt sanctions, contending that, as applied by the district court, the injunction did not comply with Fed. R. Civ. P. 65(d). This Court did not address that issue, holding instead that the district court had erred in denying appellants an opportunity to make a factual record on substantiation. *Nat'l Urological Grp., Inc.*, 785 F.3d at 483. It vacated the contempt order and remanded, instructing the district court to "exercise its discretion to determine the admissibility of any evidence offered by the [litigants] and make findings about whether any evidence of substantiation, if admissible, satisfied the standard of the injunctions for 'competent and reliable scientific evidence.'" *Id.*

E. Proceedings on Remand

The court conducted a two-week bench trial between March 27 and April 7, 2017. To address the components of "competent and

reliable scientific evidence" for Hi-Tech's causal efficacy claims, the FTC relied on Dr. Aronne. The FTC also presented the testimony of Dr. Richard van Breemen, a Professor of Pharmacy at the University of Illinois at Chicago (UIC), as a rebuttal witness. Dr. van Breemen has served as the Director or co-Director for the UIC/NIH Center for Botanical Dietary Supplements Research since 1999. *See* Doc.966 at 85; Doc.952 at 130-131. Consistent with the mandate of this Court, the district court granted appellants leave to designate multiple expert witnesses, notwithstanding concerns about their credentials.[6] *See* Doc.966 at 101-112.

[6] For example, one of Hi-Tech's witnesses, Dr. Gaginella, has experience in the field of weight loss derived solely from his work as a consultant for Hi-Tech. He has never conducted or worked as an investigator in a human clinical trial, and the last time he participated in lab research was in 1994, when he worked mainly in the field of gastroenterology. Doc.966 at 102; Doc.944-1 at 7-8. Another Hi-Tech witness, Dr. Lee, likewise has "very little experience in the field of weight loss." Doc.966 at 103; Doc.947 at 52-53. He has not published any papers or made presentations on the topic of weight management, and has never conducted relevant clinical or in vitro studies. Doc.966 at 103; Doc.947 at 53-55. These deficiencies are crucial because the injunction specifies that "competent and reliable scientific evidence" that will substantiate a health-related claim means evidence "based on the expertise of professionals in the relevant area." A third Hi-Tech witness, Dr. Jacobs, has financial difficulties and depends on income from Hi-Tech and therefore had an obvious bias. Doc.966 at 106; Doc.950 at 91-94 (Jacobs); Doc.941-5 (PX696).

Dr. Aronne described several qualities that evidence must have before experts in the field of weight loss and metabolism will consider it "competent and reliable" to support a claim that a product will cause its user to lose weight. *See generally* Doc.945 at 42-125; Doc.946 at 4-24, 123-135. Dr. Aronne offered his expert opinion, supported by the scientific literature. *See*, *e.g.*, Doc.941-2 at 81-92 (PX580); Doc.945 at 50-53, 60, 66-67, 69, 72. As shown below, much of his testimony was supported by Hi-Tech's own expert witnesses.

First, studies must involve human clinical trials. In vitro studies (those conducted in test tubes) and animal studies can provide useful information, but "do not directly translate to efficacy in humans * * *." Doc.952 at 146-147 (van Breemen); Doc.945 at 48-50 (Aronne). Many ingredients have appeared to work on animals but failed as a treatment for humans. *See* Doc.946 at 50, 54-55 (Aronne).

Appellants' experts agreed. *See* Doc.944-1 at 44-45 (Gaginella)); Doc.948 at 51-52 (La Puma), 199, 217 (Hoffman); Doc.947 at 72-73, 77-78 (Lee). Dr. Gaginella described in vitro studies as a mere "screening tool" for "whether there's any reason to continue evaluating whatever

substance you're looking at." Doc.944-1 at 44. Dr. Lee confirmed that to be sure "a substance actually has efficacy in humans * * * you would need to test that substance in humans." Doc.947 at 77. And Dr. La Puma admitted that "you can project what will likely happen physiologically in a person if you look at laboratory studies and animal studies, but you can only know what happens in a person by studying people." Doc.948 at 51-52.

Second, Dr. Aronne testified that experts in the field require efficacy studies to be *placebo-controlled – i.e.*, they must contain a "control group" – and be *double-blinded*. *See* Doc. 966 at 89-90; Doc.945 at 53; Doc.941-2 at 81-83 (PX580). As Dr. Aronne explained, when human subjects know that a treatment is being tested to determine its effect on a condition, that knowledge alone can influence the results of a study. Doc. 941-2 at 82-83 (PX580); *see also* Doc.945 at 50-53. Using a placebo control mitigates that risk. Doc.941-2 at 82-83 (PX580). To avoid "selection bias," subjects must be assigned to the treatment group or control group at random. Doc.945 at 52 (Aronne); Doc. 941-2 at 84 (PX580). Again, Hi-Tech's experts, Drs. Gaginella, Lee, and Hoffman agreed that such procedures are "generally accepted in the profession to

yield accurate and reliable results." Doc. 966 at 90; Doc.947 at 69-71 (Lee); Doc.944-23 at 64-65 (DX132); Doc.948 at 223 (Hoffman); Doc.944-1 at 42-43 (Gaginella); Doc.941-10 at 3 (PX536).

Third, studies must be *appropriately sized*. Doc.966 at 91; Doc.941-2 at 84-85 (PX580); Doc.945 at 53-54 (Aronne); Doc.952 at 168-69 (van Breemen).[7] A study must test enough subjects to ensure that the results are generalizable. Doc.966 at 91; Doc.941-2 at 84-85 (PX580); Doc.945 at 53-55 (Aronne). Because, as even appellants' experts agreed, small or "underpowered" studies are more likely to yield results that in reality occurred randomly, *see, e.g.*, Doc.951 at 142 (Heuer); Doc.948 at 205 (Hoffman), researchers must statistically calculate the number of participants needed to generate robust results. Doc.941-2 at 84-85 (PX580); Doc.945 at 54-55 (Aronne); Doc.946 at 37-38 (Aronne); Doc.952 at 168-69 (van Breemen).

Fourth, Dr. Aronne testified – and appellants' experts again agreed – that studies must be of sufficient *duration* to rule out the possibility of transient results. *See* Doc.941-2 at 85-86 (PX580), 215-

[7] While large-scale studies are often needed to test for side effects, they are not required to substantiate the efficacy of dietary supplements. *See* Doc.946 at 36-38; Doc.945 at 55-56.

216, 224-226 (PX581); Doc.945 at 58-62 (Aronne); Doc.946 at 62 (Aronne); Doc.948 at 206-207 (Hoffman); Doc.950 at 75-76 (Jacobs); Doc.944-1 at 44 (Gaginella); Doc.944-23 at 64 (DX132). For example, antidepressants appeared effective for weight loss in short-term studies, but the effect was disproven in longer duration ones. *See* Doc.966 at 91-92; Doc.941-2 at 215-216 (PX581); Doc.945 at 60.

Fifth, experts require efficacy studies to be *product-specific*.[8] Doc.966 at 93-95. As Dr. Aronne explained, even where a particular ingredient has been proven effective for treating a condition, it may be less effective or ineffective when it is combined with other ingredients. *See* Doc.945 at 68; Doc. 941-2 at 86-87 (PX580). Thus, to substantiate a claim of efficacy, a study must test the product itself and *not just the constituent ingredients*. Doc.941-2 at 81, 86 (PX580). Dr. van Breemen concurred, explaining that "mixtures of ingredients can have very different effects than those of the individual ingredients," particularly in dietary supplements because plant-derived chemicals are so diverse.

[8] *See* also Doc.941-2 at 81, 86-89 (PX580); Doc.945 at 69-71 (Aronne); Doc.944-26 at 11-15 (DX140); Doc.952 at 142-143, 149-150 (van Breemen).

Doc.952 at 142; *see also id*. at 143, 149-150; Doc.944-26 at 12-15 (DX140). Appellants' own experts corroborated these views.[9]

For similar reasons, studies must be "*dosage-specific*." Doc.966 at 95: Doc.941-2 at 89 (PX580). In other words, a study that shows a 100 mg dose to be effective does not provide "competent and reliable scientific evidence" that 50 mg of the same product will be equally (or proportionately) effective. *See* Doc.941-2 at 89; *see also* Doc.945 at 71-72 (Aronne); Doc.948 at 198, 211, 221-222 (Hoffman).

Sixth, a competent and reliable study must examine an *appropriate endpoint*. Doc.966 at 96; Doc.945 at 60-65 (Aronne); Doc.946 at 28, 31, 57 (Aronne). Thus, for example, if the purpose of a study is to determine whether a product leads to weight-loss, the investigators must determine whether weight-loss actually occurred – not another result, such as a faster metabolism. Doc.966 at 96; Doc.945 at 60-63 (Aronne).[10] Finally, studies must achieve statistically significant results. Doc.966 at 96-97. As Dr. Aronne explained – and

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[9] *See* Doc.944-1 at 45-46 (Gaginella); Doc.941-3 at 270 (PX596), 292 (PX598); Doc.947 at 75 (Lee); Doc.948 at 52-53 (La Puma), 188, 223-225 (Hoffman); Doc.950 at 165-167 (Jacobs).

[10] *See also* Doc.946 at 28, 31, 57 (Aronne); Doc.950 at 75-76 (Jacobs); Doc.944-1 at 35 (Gaginella); Doc.948 at 208-210 (Hoffman).

appellants' experts agreed – it is difficult to draw any conclusion about a substance's efficacy in the absence of a statistically significant difference. *Id*; Doc.941-2 at 89-90 (PX580); Doc.945 at 66-67 (Aronne); Doc.944-23 at 13 (DX130), 64 (DX132).

The Commission's experts concluded that appellants lacked "competent and reliable scientific evidence," as described above. In response, appellants put forward testimony of witnesses with dubious credentials, some of whom were "particularly suspect" because of their financial ties to Hi-Tech. Doc.966 at 101-112; *see* n.6, *supra*. They offered various ingredient studies, which measured endpoints, such as metabolism, that cannot be extrapolated to weight or fat loss. They also relied on clinical trials of other products whose results could not be applied to the four products at issue here because they had different formulations and different ingredients, and the studies suffered from methodological flaws that discredited their reliability. Doc.966 at 97-100. Appellants did not offer any studies of the four Hi-Tech products at issue. Doc.966 at 66-67; Doc.534-10 at 104-105, 109-110, 118 (Wheat Dep. at 97-98, 102-103, 111).

F. The Order On Review

In October 2017, the district court issued the 132-page order and decision now before the Court, again finding Hi-Tech, Wheat, and Smith jointly and severally liable for $40 million in compensatory contempt sanctions. The court reviewed the factual record in great detail and concluded that it was "replete with evidence * * * showing an intentional defiance of the court's injunctions." Doc.966 at 131.

a. *The Injunction Was Clear*. The court first addressed appellants' principal claim that the injunction was not enforceable in contempt because it incorporated a substantiation standard outside of its four corners, was not clear and unambiguous, and amounted to an "obey-the-law" injunction. Doc.966 at 29-30.

The court explained that an injunction can be enforced if the party subject to it *understands* what it requires. Doc.966 at 30-31. "[V]oluminous documentary evidence" showed that Wheat and Smith understood that "the only way for Hi-Tech to substantiate advertising claims under the injunction was to do [well-controlled clinical tests] *on the products*." Doc.966 at 36 (emphasis added). "[M]ost telling" of Wheat's understanding of the injunction's requirements," the court

explained, was a memorandum Hi-Tech's attorney's provided to Wheat while he was incarcerated. Doc. 966 at 37. Four Hi-Tech attorneys advised Wheat that several proposed Fastin claims "would run afoul of the injunction."[11] *Id*. (citing Doc.700-105 at 2-6). *See also* Doc.618 at 101-102, 113, 119-121 (Kelley).

The "context" of the injunction when it was entered in June 2008 also showed that appellants understood its requirements. It contained "the very same 'competent and reliable scientific evidence' language that [the district court had] discussed in the summary judgment order" issued earlier. Doc.966 at 43. The summary judgment order ruled that "competent and reliable scientific evidence" meant the standard described by Dr. Aronne "because [appellants] had failed to challenge that level of substantiation with their own expert evidence." Doc.966 at 43. After finding that injunctive relief was appropriate in that same order, the court cautioned appellants that the injunction "[might] be broader [in scope] than the violations alleged in the complaint." *Id*.

[11] The district court had previously ruled that the memo was admissible because appellants had waived attorney-client privilege. *See* Docs.365, 433, 470, 845, 935. Appellants do not challenge that ruling here.

(quoting *FTC v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1215 (N.D. Ga. 2008)).

The district court found yet "another indication that [they] understood their obligations" in appellants' failure to object to the definition of "competent and reliable scientific evidence" at the time the injunction issued. Doc.966 at 39-41. Appellants had objected to Section II of the injunction (which includes the injunction's standard of substantiation) only as to erectile dysfunction products, and not as to weight-loss products. Doc.966 at 42.

The court also rejected appellants' contention that the injunction was an invalid "obey-the-law" injunction. Doc.966 at 57-59. The court held that an order requiring appellants to substantiate their efficacy claims is a prohibition of specified conduct. *Id*.

b. *Hi-Tech did not substantiate its claims*. The court determined that appellants had failed to substantiate their claims. Doc.966 at 63-117. As an initial matter, the district court firmly rejected appellants' "baseless" efforts to exclude Dr. Aronne's testimony. Doc.966 at 82. The court cited the "precise detail" and consistency with which Dr. Aronne has addressed the relevant issues – *i.e.*, (a) what constitutes

"competent and reliable scientific evidence" sufficient to substantiate causal efficacy claims; and (b) whether appellants' studies met that standard. The court also rejected appellants' efforts to exclude Dr. van Breemen, citing his "helpful" descriptions of "numerous examples" of experts in the field of pharmacology "doing precisely what [appellants] claimed to be virtually impossible." Doc.966 at 84-85.

Turning to appellants' efforts to substantiate their claims, the court observed "it was clear that *no one*, whether retained by Hi-Tech or not," performed a controlled clinical study of any kind on any of the four products at issue. *Id*. at 64. Although Hi-Tech relied on clinical studies of a different supplement known as "Meltdown," those studies did not support claims for Fastin, Stimerex-ES, Lipodrene, and Benzedrine because Meltdown has "significantly different ingredients, potencies, and formulations than the products at issue in this case." *Id*. at 65. The court also found that the Meltdown studies could not substantiate Hi-Tech's advertising claims because they did not measure weight loss, fat loss, or appetite suppression. *Id*. at 65, 99.

The court similarly rejected appellants' reliance on studies of two other Hi-Tech products (*i.e.*, Fastin-XR and Fastin-RR) on the ground

that those products "have ingredients that are not common to Fastin and of the common ingredients, the ingredients are not present in identical amounts as those in Fastin." Doc.966 at 65. *See also id*. at 99-100; Doc.941-2 at 328-330 (PX513), 332-335 (PX514); Doc.700-63 (PX67). The court also found that both the Fastin-XR and Fastin-RR studies were riddled with methodological flaws that undermined their credibility and that the studies' investigator, Dr. Jacobs, was "not a person in the field qualified to conduct these types of studies." Doc.966 at 100.[12] Thus, the court concluded that the Fastin-XR and Fastin-RR studies did not satisfy the requirement that appellants have "competent and reliable scientific evidence" to substantiate the claims made for the products at issue, as the injunction required.[13]

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[12] *See also* Doc.945 at 117-124 (Aronne); Doc.946 at 4-11, 13-25, 74 (Aronne); Doc.941-2 at 94 (PX580), 228-233 (PX581); Doc.941-3 at 273 (PX596), 294, 295; Doc.941-12 at 22-26 (PX612), 31 (PX615), 35 (PX617), 42-43 (PX620), 51-56 (PX621), 58-59 (PX622); Doc.944-14 at 54 (DX110); Doc.944-21 at 10-11 (DX120); Doc.949 at 164 (Jacobs); Doc.950 at 47-48, 73-75, 102, 104-06, 113-114, 119-124, 126-127, 168-169 (Jacobs).

[13] The court also rejected appellants' contention that their failure to substantiate their claims could be excused because the Commission's expert called for studies that were too expensive to conduct. The court found meritless appellants' claim that the clinical trials described by the Commission's expert were infeasible. Doc.966 at 69-74.

On that record, the district court concluded that appellants had not bridged the "analytical gap" between their product claims and their purported substantiation. Doc.966 at 115. The court explained that appellants "very clearly" represented that their products caused a specific result – *e.g.*, weight loss, fat loss, or effect on metabolism or appetite. *Id*. And appellants' experts did not address whether their evidence substantiated their claims. Instead, they testified only to whether the products would "aid" or "support" a certain effect. Appellants' claims "[did] not match the science." Doc.966 at 114.

Appellants' evidence therefore failed a fundamental requirement of the injunction – that Hi-Tech support its claims for *products*, not ingredients. *See* Doc.230 at 12. In the absence of competent and reliable scientific evidence for their causal claims, appellants were in contempt of the injunction.

c. *Contempt sanctions*. The court found Hi-Tech, Wheat, and Smith jointly and severally liable for $40 million in contempt sanctions,

which it calculated as the gross sales receipts from the four products, less refunds and returns.[14] *See* Doc.966 at 127-32.

STANDARD OF REVIEW

This Court reviews the district court's decision to impose contempt sanctions for abuse of discretion. *FTC v. Leshin*, 618 F.3d 1221, 1231 (11th Cir. 2010). The Court reviews the underlying factual findings for clear error. *United States v. Coulton*, 594 F. App'x 563, 565 (11th Cir. 2014). The Court reviews the district court's construction of an injunction for an abuse of discretion, and "great deference" is due to the court that issued and must enforce it. *Med. Assoc. of Ga. v. WellPoint, Inc.*, 756 F.3d 1222, 1234 (11th Cir. 2014); *see also Schering Corp. v. Illinois Antibiotics Co.*, 62 F.3d 903, 908 (7th Cir. 1995) (district court's construction entitled to "particularly heavy weight").

SUMMARY OF ARGUMENT

1. The bulk of appellants' brief is devoted to an attack on the injunction, but they waived their claims long ago by failing to raise

[14] The court denied the FTC's request for a separate sanction of $34 million for appellants' violations of Section VI of the injunction. The court denied that request because there was an overlap of time in which both violations occurred. Doc.966 at129. The Commission did not cross-appeal that ruling.

them either before the district court when it entered the injunction and called for objections to it or before this Court in their initial appeal. *See McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192-93 (1949) . They do not get another bite at the apple.

Nothing supports appellants' contention that they should be excused from waiver because they could not have known until trial that the standard of substantiation prescribed by the injunction is "hopelessly vague." Br. 37. Their own communications, with each other and with their lawyers, consistently show that they understood exactly what the injunction required, including product-specific tests. They nevertheless decided, quite knowingly, to ignore those requirements and risk contempt in favor of a marketing potentially lucrative products. Accepting appellants' theory would allow anyone bound by an injunction to experiment with contempt and then claim confusion once they are caught. This Court and others have repeatedly rejected that approach.

2. The injunction requires appellants to have "competent and reliable scientific evidence" to support their causal claims of weight- and fat-loss. The injunction itself provides a definition of "competent

and reliable scientific evidence:" "[t]ests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner * * * using procedures generally accepted in the profession to yield accurate and reliable results." Doc. 230 at 5. Despite ample opportunity to make a factual record on remand, appellants did notsatisfy the standards prescribed by the injunction.

Their methodologically flawed studies assessed only ingredients and products with different formulations from the ones at issue. Testimony by a renowned expert in weight-loss and obesity showed that appellants' studies did not support their claims under the requirements of the injunction. Appellants' own experts did not fundamentally disagree; their testimony stopped short of concluding that the results of appellant's studies substantiated the claims that the products caused weight loss.

3. The district court did not impute to Smith the conduct of others when it held him jointly and severally liable for compensatory sanctions. Smith, Hi-Tech's Senior Vice-President in charge of sales, participated directly and substantially in Hi-Tech's promotion of its

weight-loss products. He is individually bound under the injunction and thus is obliged to ensure that advertising claims for his products had the substantiation required by the injunction. He failed to do so and is therefore individually culpable.

ARGUMENT

I. Appellants Forfeited Their Facial Challenges To The Injunction, But Their Claims Are Meritless

Appellants devote the bulk of their brief to an attack on the injunction. They claim that they cannot be held in contempt because the injunction was insufficiently specific and could not be understood within its four corners. Appellants waived that claim by failing to raise it at the proper time below, but it is wrong in any event.

A. Appellants Did Not Challenge The Injunction In Their Initial Appeal And May Not Do So In a Contempt Proceeding

An alleged contemnor may not await contempt proceedings to challenge an injunction if it had an earlier opportunity to seek clarification of the injunction's constraints. Thus, where the subject of an injunction "could have petitioned * * * for a modification, clarification or construction of the order," but instead "undertook to make [its] own determination of what the decree meant," it waived any

challenge to the injunction. *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192-93 (1949). Allowing contemnors to raise in contempt proceedings claims that could have been raised earlier "presents the prospect of perpetual relitigation" – an apt description of this case, which has been in constant litigation for more than a decade. *See Halderman v. Pennhurst State Sch. & Hosp.*, 673 F.2d 628, 637 (3d Cir. 1982). Persons bound by injunctive orders thus may not experiment with contempt. *See TiVo, Inc. v. Echostar Corp.*, 646 F.3d 869, 885 (Fed. Cir. 2011) (en banc).[15]

Appellants' challenges to the injunction founder on that principle. They had multiple opportunities before now to contest the injunction's compliance with Rule 65(d). They could have done so at the time it was entered in the underlying enforcement action. Indeed, when the FTC submitted a proposed injunction, the district court directed appellants

[15] *Accord John Zink Co. v. Zink*, 241 F.3d 1256, 1260 (10th Cir. 2001) (disallowing collateral attack on injunction during contempt proceedings because earlier review was available); *W. Water Mgmt, Inc. v. Brown*, 40 F.3d 105, 108 (5th Cir. 1994) (same); *Szabo v. U.S. Marine Corp.*, 819 F.2d 714, 718 (7th Cir. 1987) (precluding alleged contemnor who failed to appeal from grant of injunction from arguing in defense allegations that it is too vague to be enforced); *see also G. & C. Merriam Co. v. Webster Dictionary Co.*, 639 F.2d 29, 34 (1st Cir. 1980) (validity and terms of injunction are not reviewable in contempt proceedings even when injunction was entered by default).

to submit "*any* objections they [had] to the proposed orders presented by the FTC." Doc.219 (emphasis added). Although they submitted objections, Doc.220 at 2-4, appellants did not object to the injunction's definition of "competent and reliable scientific evidence." Their objection to Section II of the injunction (which includes the now-contested text), pertained only to erectile dysfunction products and not to the weight-loss products now at issue. Doc.966 at 42. Even there, they did not challenge the definition of "competent and reliable scientific evidence."

They could have asked the district court for reconsideration on that issue, but they did not. They could have argued on direct appeal that the injunction failed to adequately specify its requirements, but again they did not. *See* pp. 10-11, *supra*. Having failed to raise the issue when it had the opportunity, Hi- Tech may not do so now. *See United States v. Fiallo-Jacome*, 874 F.2d 1479, 1481-82 (11th Cir. 1989); *United States v. Davis*, 280 F. App'x 845, 847 (11th Cir. 2008). Indeed,

as appellants concede (Br. 37), they did not even make the challenge in their first appeal of the district court's contempt order. Br. 37.[16]

Even when appellants were about to embark on their new advertising campaign, they did not seek clarification of the injunction from the district court. Instead, and against the advice of their own lawyers, they went ahead with the campaign, fully aware of the risks. Rather than following sound legal advice, they decided to "swing for the fence" and "go for broke advertising Fastin and HT products." Doc.966 at 76 (quoting Doc.700-92 at 3). Now, facing contempt sanctions, it is too late in the season to attack the injunction.

The Federal Circuit, sitting en banc, addressed virtually identical circumstances in *TiVo*. It held that an alleged patent infringer could not defend against contempt charges by claiming the injunction was insufficiently specific and did not comport with Fed. R. Civ. Proc. 65(d). The court held instead that, "[w]here a party faced with an injunction perceives an ambiguity in the injunction, it cannot unilaterally decide to

[16] The FTC argued that that that Hi-Tech could not properly raise a facial challenge to the injunction in that appeal, and Hi-Tech disavowed doing so in its reply brief, telling the Court that they "Are Not Challenging the Facial Vagueness of the Injunction." Reply Brief at 7, No. 14-13131, *FTC v. Hi-Tech Pharmaceuticals, Inc.* (Feb. 17, 2015).

proceed in the face of the injunction and make an after-the-fact contention that it is unduly vague." *TiVo, Inc.*, 646 F. 3d at 885 (citing *McComb*, 336 U.S. at 192) . That holding applies here foursquare.

B. The Injunction is Valid and Enforceable

But even if appellants may challenge the injunction now, their claims fail.

First, appellants are wrong that the underlying order is an unenforceable "obey the law injunction." An "obey the law injunction" directs compliance with a statute or regulation without providing those enjoined with standards by which their conduct will be judged. *See*, *e.g.*, *SEC v. Smyth*, 420 F.3d 1225, 1233 n.14 (11th Cir. 2005) (order tracking provisions of statute or regulation); *Burton v. City of Belle Glade*, 178 F.3d 1175, 1200-01 (11th Cir. 1999) (order prohibiting discrimination on the basis of race in municipal annexation decisions).

The applicable law, the FTC Act, prohibits "unfair" and "deceptive" acts or practices. 15 U.S.C. § 45. The injunction plainly does not merely command appellants to obey that law. Recognizing as much, appellants rely on the Commission's Dietary Supplement Guide to argue that "the terms of [the] injunction * * * are as general as the

contours of the [FTC] law itself." Br. 54. Nothing in the Guide supports that contention. It does not have the force and effect of law. It was not published in the Federal Register or issued under the rulemaking procedures of the Administrative Procedure Act. It merely describes how principles of ad interpretation and substantiation apply in the general context of dietary supplement advertising, using examples that "have been simplified to illustrate one or two specific points." Doc. 701-3 at 7. None of appellants' cited cases show to the contrary. *See* Br. 56-57 & n.10.

Moreover, the standard that appellants were required to satisfy to support their causal efficacy claims was established by the injunction, not the Guide. The district court described the standard in the definitional provisions of the order. *See* Doc.230 at 5. The standard was informed by unchallenged testimony by nationally recognized experts regarding the meaning of "competent and reliable scientific evidence." Doc.219 at 64-66.

Thus, the injunction here stands in contrast to cases on which appellants rely that involved a bare prohibition, with no further definition or guidance. *See* Br. 37-38. In *American Red Cross v. Palm*

Beach Blood Bank, Inc., 1143 F.3d 1407 (11th Cir. 1998), for example, the Court vacated a preliminary injunction because the defendant could not discern whether it was engaging in prohibited conduct. *American Red Cross*, 1143 F.3d at 1411-12. Similarly, in *Hughey v. JMS Dev. Corp.*, 78 F.3d 1523 (11th Cir. 1996), cited repeatedly by appellants , the injunction prohibited *any* discharges of stormwaters in "violation of the Clean Water Act." The defendant could not know which of numerous mechanisms for stopping discharges might suffice. It was "incapable of enforcement as an operative command." *Hughey*, 78 F.3d at 1531-32. Similarly, in *Gates v. Shinn*, 98 F.3d 463, 467 (9th Cir. 1996), the injunction required prison officials to identify "appropriate psychiatric evaluation and treatment * * * as medically indicted," as required by a consent decree. There was a bona fide dispute as to competing standards of care, but nothing in the decree itself to provide further guidance. *Id.* at 471-72. Appellants cannot credibly claim such confusion, as the district court discussed at length and as we discuss next.[17]

[17] Appellants' other cases are likewise inapposite. In *H.K. Porter Co. v. National Friction Prods. Corp.*, 568 F.2d 24 (7th Cir. 1977), the order at issue did not even impose an operative command. As the court

Second, appellants are wrong that because the district court did not specify within the "four corners" of the injunction all the attributes of "competent and reliable evidence," the injunction does not strictly comply with Rule 65(d) and is unenforceable. That is not the test for enforceability. The relevant question is "whether the parties subject [to the injunction] understand their obligations." *Planetary Motion, Inc. v. Techsplosion, Inc.*, 261 F.3d 1188, 1203 (11th Cir. 2001); *see Combs v. Ryan's Coal Co.*, 785 F.2d 970, 978-79 (11th Cir. 1986) (no question "as to whether appellants understood their obligations, for they complied * * * for almost three months"). The "four corners" inquiry is one way of answering that question, but it is not the only one.

Thus, even if the injunction's substantiation requirement does not strictly comply with Rule 65(d), the district court was correct to enforce it. The enforceability inquiry is firmly rooted in concerns of due process and fair notice. The Court has long recognized that those concerns are

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described, the case "resemble[d] one where a court issues a declaratory judgment as to obligations under a contract." *Id.* at 27. In *FTC v. Southwest Sunsites, Inc.*, 665 F.2d 711, 723 (5th Cir. 1983), the court required the district court to type specific portions of a magistrate's report found wholly outside the preliminary injunction. It did not reverse on that basis, however, but remanded the matter for the district court to complete that mechanical task. *Id.* at 724.

satisfied where evidence demonstrates that the enjoined party *subjectively understood* what conduct was prohibited. In that circumstance, technical flaws will not preclude enforcement of an injunction. For example, in *Williams v. City of Dothan, Ala.*, 818 F.2d 755, 761 (11th Cir. 1988), the Court found that an injunction requiring the City of Dothan to provide black citizens equal treatment in the provision of "government services" was sufficiently definite even though the specific violation alleged – discriminatory street paving and sewer services – were not specified in the injunction. *Williams*, 818 F.2d at 761. In concluding that the City understood its obligations to include those services, the Court pointed to the City's compliance reports, which listed sewer and paving projects to demonstrate its compliance. *Id.*

Similarly, in *United States v. Sarcona*, 457 F. App'x 806 (11th Cir. 2012), the Court affirmed a criminal conviction resulting from the defendant's failure to comply with an injunction prohibiting him from making representations that a product would cause weight loss and requiring him to post a bond before engaging in certain activities. *Sarcona*, 457 F. App'x at 809. Even though the Court found that the injunction did not comply with the precise terms of Rule 65(d), the

Court relied on "evidence that [the defendant] understood these obligations well" to conclude that the order was valid and enforceable. *Id*. at 812. *See also Tom James Co. v. Morgan*, 141 F. App'x 894, 897-98 (11th Cir. 2005) (order prohibiting ex-employee from selling "clothing and wardrobe accessories" of the type sold by company was sufficiently definite in light of ex-employee's familiarity with company's merchandise).

Here, the evidence overwhelmingly demonstrates that "both Wheat and Smith understood that in order for their advertising claims to be substantiated by 'competent and reliable scientific evidence' the injunctions required RCT's of the products." Doc.966 at 32 (citing "voluminous documentary evidence"). Appellants' own communications tell the story. For example, Wheat complained to several of his employees that he was unable to obtain legal clearance for his Fastin advertising, stating "*there is nothing we can say without doing a double-blind placebo study so nobody would sign off on that.*" Doc.700-88 at 3 (PX94) (emphasis added). Similarly, he emailed Smith acknowledging that, due to the district court's summary judgment decision, the FTC could win "*any advertising case* that a company has not done *a double-*

blind study on the product itself." Doc.700-90 at 3 (PX96) (emphasis added); *see also* Doc.700-94 at 3 (PX100) (acknowledging that "a double-blind placebo study would be required"). In a phone call with Smith, Wheat delineated prohibited claims such as "fat loss" and "increasing the metabolic rate." Doc.700-100 at 7 (PX106). Wheat admitted, "[w]e can't say that." *Id*; *see also id*. at 10-11 (with regard to the rapid fat burner claim, "we can't say rapid that's part of our consent decree").[18]

Wheat's already-clear understanding was confirmed by four Hi-Tech lawyers, who advised him point-blank that the injunction required double-blind, placebo-controlled, product-specific trials before the company could make any weight-loss claim. These lawyers cautioned Wheat that "it is safe to say that [the district court] did not then and would not now find this form of ingredient-specific substantiation to be consistent with the *express language in the FTC Injunction requiring 'competent and reliable scientific evidence*.'" Doc.700-105 at 4 (PX117) (emphasis added). They further warned that "it is reasonable to

[18] The FTC gained access to Wheat's monitored emails and telephone calls transmitted via a Bureau of Prisons system in which a prisoner has no expectation of confidentiality. When Wheat and Hi-Tech invoked an advice-of-counsel defense, the district court ruled that they had waived any privilege over the communications. *See* Doc.365 at 1-3; Doc.470 at 14; Doc.845 at 5-8.

assume that [the district court] would take the position consistent with the FTC that double-blind, clinical trials of the product were necessary to substantiate the representation" precisely because that "is the premise upon which the FTC Injunction is based." *Id.*[19] Given that straightforward advice, appellants cannot credibly claim they could not understand the attributes of 'competent and reliable scientific evidence until "years after the fact." Br. 32.

Appellants contend that the district court's ruling amounts to "a variation of the estoppel argument previously rejected by this Court." Br. 43. The argument is that the court rejected appellants' unsupported disclaimers of knowledge on the ground that "the scope of the injunction's substantiation standard has been a decided issue in this litigation for almost a decade." Doc.966 at 56-57. To appellants, that means that the court effectively gave its earlier ruling preclusive effect.

Appellants are wrong. When this Court reversed the earlier judgment, it did not nullify the proceedings on which the disputed injunction was based and that informed its provisions. Rather, it

[19] Appellants try to dodge the devastating effect of these communications on the ground that they were "made without expectation of disclosure to the FTC," Br. 47, but that only underscores their credibility.

rejected only the district court's refusal to allow appellants to make a factual record that they satisfied the standard of the injunction. *Nat'l Urological Grp., Inc.*, 785 F.3d at 483. The district court addressed that problem on remand when it scrupulously followed this Court's mandate by allowing appellants to present six separate substantiation experts and devoted 34 pages of written opinion to consideration of the evidence they presented. Doc.966 at 78-112. The court appropriately considered the long history of the case as further evidence that appellants understood the injunction's requirements. Doc.966 at 57.

In the underlying enforcement action, the district court, citing uncontroverted expert testimony, found that "to substantiate weight-loss claims for any product, including a dietary supplement," an advertiser must have "independent, well-designed, well-conducted, randomized, double-blind, placebo-controlled clinical trials, given at the recommended dosage involving an appropriate sample population in which reliable data on appropriate end points are collected over an appropriate period of time." Doc.219 at 65. The court also credited unchallenged expert testimony that such trials must be conducted "on the product itself," and not on a different product with a different

combination of ingredients or lower doses of the active ingredient. *Id.* Thus, the court held further, evidence relating only to constituent *ingredients* cannot substantiate advertising claims made for a *product*. *Id.* at 64-67. On that record, the district court granted the Commission's motion for summary judgment, Doc.219, and entered the permanent injunction. It was these events that informed appellants' understanding of the order, as evidenced by their repeated references to the district court's decision.

Appellants' demonstrated familiarity with the requirements of the injunction fatally undercuts their claim that the injunction is not enforceable in contempt because the substantiation standard was not specific enough for them to understand what it required. *See* Br. 47-50. This case thus stands in contrast to *United States v. Bayer Corp.*, cv 07-01(JLL), 2015 WL 5822595 (D.N.J. Sept. 24, 2015), relied on by appellants, which involved not a fully litigated judgment but a settlement agreement, and where the government did not disclose its substantiation standard until after the injunction was entered. Here, appellants obviously understood their obligation to substantiate their weight-loss claims with product-specific and randomized clinical trials,

yet they made a conscious decision to forge ahead anyway. They nonetheless invite the Court to disregard the record and excuse blatant contempt due to supposed technical flaws. Such a result would not serve any understanding of due process, but would turn Rule 65(d) into a straightjacket. Appellants cite nothing to support such an absurd outcome. Even under the more stringent standards applicable to criminal contempt, technical flaws in an injunctive order can be excused. *See Sarcona*, 457 F. App'x at 811.

Finally, appellants are wrong that "competent and reliable scientific evidence" is unlawfully vague because the specific type of evidence required to meet the standard could vary depending on the specific product and claim made. Br. 65-67. To begin with, for all the reasons discussed above, appellants understood exactly what the injunction required of them; its requirements were not vague at all. Moreover, the injunction applies not only to weight- and fat- loss products, but to "any health-related service or program," and "any dietary supplement, food, drug, or device." Doc.230 at 9 (Definition 11). Claims for all such products must be supported by "competent and reliable scientific evidence," but what constitutes such evidence depends

on the product at issue and the claim made about it. In these circumstances, the requirements prescribed by the district court for such evidence "[were] as specific as the circumstances [ ] permit[ted]." *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 393 (1965).

To require the district court to delineate – in the injunction itself – the specific scientific substantiation applicable to every conceivable claim for every conceivable covered product would demand implausible feats of prognostication. In *other* cases and *other* contexts, it might be both possible and appropriate for the district court to craft such an order.[20] But to conclude that the district court was required to do so here would unjustifiably intrude on the discretion of the district courts to craft orders that protect the public from marketers who offer multiple products, each requiring a specific degree of scientific substantiation, and who can readily transfer their practices from one product to another, just as appellants did here. Courts have long recognized the

[20] For these reasons, it proves nothing that other injunctions in different cases covering different products are drafted differently. *See* Br. 15 n.2. All of those injunctions were consented to by the parties and were not entered in the context of a full-blown summary judgment proceeding, complete with expert declarations, that fleshed out the meaning of the operative clause. *See* Br. 8. And no matter what, none of those other injunctions remotely undermines the fact that appellants understood the one that applied to them.

need for flexibility in crafting injunctive orders intended to prevent recurrence of illegal conduct. *See*, *e.g.*, *Colgate-Palmolive Co.*, 380 U.S. at 394-95 ; *FTC v. Grant Connect, LLC*, 763 F.3d 1094, 1105 (9th Cir. 2014).

The injunction here easily satisfies the standard recently applied by this Court in *LabMD, Inc. v. FTC*, 2018 WL 2714747 (11th Cir. June 6, 2018). In *LabMD*, the Court reaffirmed that prohibitions in an injunction "must be specific," and it vacated an order that it viewed as commanding a company "to overhaul and replace its data-security program to meet an indeterminable standard of reasonableness." Here, by contrast, the injunction contains not a directive to overhaul a program but a specific *prohibition* on conduct: appellants were barred from making their weight loss claims *unless* they had "competent and reliable scientific evidence." They always could have complied with the injunction by refraining from making the claims. Thus, even if they were uncertain as to what constituted "competent and reliable scientific evidence" – which they were not, *see* pp. 42-43, *supra* – appellants could have complied with the injunction without "experiment[ing] with disobedience." *See CFTC v. Wellington Precious Metals, Inc.,* 950 F.2d

1525, 1528-29 (11th Cir. 1992) (citing *Maggio v. Zeitz*, 333 U.S. 56, 59 (1948)).

Furthermore, in *LabMD*, the Court focused on the absence of a "meaningful standard" as to "what constitutes a 'reasonably designed' data security program." *LabMD*, 2018 WL at *11. But the injunction entered by the court here provides a "meaningful standard" because it specifically defines "competent and reliable scientific evidence." The definition, which requires the district court to determine – based on the "expertise of professionals in the relevant area" – whether studies relied on by marketers were conducted in accordance with "procedures generally accepted in the profession to yield accurate and reliable results" provides the touchstone for evaluating evidence that the Court found lacking in LabMD.[21]

[21] The district court properly exercises discretion in determining whether appellants have "competent and reliable scientific evidence." For example, the determination whether a particular professional is an expert in the "relevant area" is a matter of order interpretation that is committed to the discretion of the district court. *See FTC v. Garden of Life, Inc.*, 516 F. App'x 852, 857 (11th Cir. 2013). The district court's evaluation of expert evidence to determine compliance is a "quintessentially factual determination" that is disturbed only for clear error. *Id.* at 856-57; *see also Tom James*, 141 F. App'x at 898 (finding district court appropriately considered expert testimony in contempt proceeding through proffers).

II. Appellants Did Not Have Competent And Reliable Scientific Evidence To Support Their Advertising Claims

The injunction requires appellants "to 'possess and rely on competent and reliable scientific evidence that *substantiates* the representation.'" Doc.966 at 79 (emphasis added). The only remaining question therefore is whether appellants had substantiation for their claims that their products cause weight loss. *Nat'l Urological Grp., Inc.*, 785 F.3d at 483. They did not.

The injunction required supporting research that pertained "to the specific product being promoted and to the specific benefit being advertised." Doc.966 at 113 (quoting Doc.701-3 at 20) (emphasis added). Thus even if appellants could credibly argue that they did not understand all the parameters of "competent and reliable scientific evidence," the injunction left no doubt – as Hi-Tech's lawyers' advised – that they needed substantiation for the claims they actually made. As the district court explained, it is necessary to look at the claims that *were actually made* and then determine whether the support they offered substantiated *those same claims*. Doc.966 at 115.

Appellants claimed that Hi-Tech's products caused the specific results of weight loss and fat loss. *See* Doc.966 at 115 and pp. 11-13,

supra. Thus, the injunction required them to offer evidence that Hi-Tech's products *caused* the advertised effects. But of six experts designated by appellants themselves, five testified that Hi-Tech's evidence did not show that the products cause *any* weight or fat loss. Not one would say either that studies of specific *ingredients* or clinical trials of products with formulations different from the products at issue could substantiate appellants' claims that their products caused weight and fat loss. Doc.966 at 97-117.

For example, Dr. Gaginella was flatly unwilling to opine that the claims for Fastin were substantiated; at best, he suggested that "it's quite possible, but I—I can't say absolutely yes it would or it wouldn't." Doc.966 at 103; Doc.944-1 at 34. Dr. Lee similarly testified that "the products, based on the mechanism of action, *could* cause weight loss." Doc.966 at 103; Doc.947 at 57-59.[22] Dr. La Puma also testified that Hi-Tech's products "would *aid* in fat loss and weight loss," not – as Hi-Tech told consumers – that they would *cause* those effects. *See* Doc.966 at 104; Doc.948 at 39-41, 44-46. Dr. Jacobs similarly admitted that his

[22] In his expert report, Dr. Lee opined that the products could "aid" in rapid or substantial weight or fat loss "as part of [a] program of diet and exercise." *Compare* Doc.944-23 (DX132) *with* Doc.947 at 57-59.

opinion was limited to whether the Hi-Tech products would "aid" in weight or fat loss. Doc.950 at 66-67, 69-70. He repeatedly conceded that "it was inappropriate to use the word 'cause' in connection with any of the Hi-Tech products." Doc.966 at106; Doc.950 at 67, 70, 78, 179. Such testimony does not show that appellants had substantiation for their unequivocal causal claims under any reading of "competent and reliable scientific evidence."

Dr. Hoffman's testimony directly undercuts appellants' case. He admitted outright that several of Hi-Tech's claims were not substantiated. Doc.948 at 183-186; Doc.966 at 105. They included claims that "[Fastin] [i]ncreases the release of norepinephrine and dopamine for dramatic weight loss," "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULTS," and "[Benzedrine] simply blows fat away!" He also acknowledged that he was not offering any opinion at all on the Hi-Tech products, and was merely opining that the ingredients in the products had the "potential" to cause weight loss. Doc.948 at 175.

Even the most supportive of appellants' experts, Dr. Heuer, needed to extrapolate – from acute to long-term effects and from animal and in vitro studies to humans – and then assume that a faster heart rate and faster metabolism cause weight loss. *See* Doc.966 at 107; Doc.951 at 162-164. At the same time, he admitted that he knew no scientist who would use such methods to justify a claim of causation. Doc.951 at 131, 135. Given that admission, Dr. Heuer's testimony is not "evidence" supporting appellants' claims, but is at most "speculation and conjecture" or a "leap of faith" that does not support a claim of causation. *Rider v. Sandoz Pharms. Corp*., 295 F.3d 1194, 1201-02 (11th Cir. 2002); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (a court may conclude there is too great an analytical gap between the data presented and the opinion proffered).[23]

Clinical studies of a different dietary supplement, "Meltdown," do not support appellants' claims. To begin with, the studies are methodologically flawed, as the district court found, Doc.966 at 99, and

[23] Additionally, all of Dr. Heuer's opinions regarding claim substantiation referred to dietary supplement *manufacturers*, not scientists, researchers, and clinicians. Doc.951 at 37-38, 57-58. By definition, their views are not "competent and reliable scientific evidence," as required by the injunction.

the experts reported.[24] Even if the studies were sound, however, the two products are not "materially identical." Br. 36. The district court observed,[25] and the evidence shows, [26] that Meltdown has ingredients, including yerba mate and tetradecylthioacetic acid (TTA), that Hi-Tech's products do not contain. Both sides' experts agreed that a claim of causation could be substantiated only by tests conducted on the product itself, in the dosages recommended, and without confounding additional ingredients.[27] As appellants' expert Dr. Hoffman explained, Meltdown seemed to have some transient effect on metabolism, but that was attributable to the combination of ingredients that Hi-Tech's products do not contain. Doc.944-14 at 32 (DX108). Moreover, he conceded, the studies, which lasted only six hours, were far too short to

[24] Doc.945 at 103-113 (Aronne); Doc.946 at 50 (Aronne); Doc.947 at 82 (Lee); Doc.948 at 213-216 (Hoffman); Doc.941-2 at 110 (PX580), 234-235 (PX581).

[25] Doc.966 at 64-65, 99.

[26] Doc.944-14 at 12 (DX106), 32 (DX108); Doc. 941-2 at 235-237 (PX581), 328-330 (PX 513), 331-335 (PX 514); Doc.944-1 at 36 (Gaginella); Doc.951 at 149-150 (Heuer).

[27] Doc.941-2 at 86-89 (PX580); Doc.944-26 at 12-15 (DX140); Doc.945 at 68-71 (Aronne); Doc.946 at 124-125 (Aronne); Doc.947 at 77 (Lee); Doc.948 at 52-53 (La Puma); Doc.948 at 188, 223-225 (Hoffman); Doc. 950 at 165-167 (Jacobs); Doc.952 at 142-143, 149-150 (van Breemen); Doc.944-1 at 45-46 (Gaginella); Doc.941-3 at 270 (PX596), 292 (PX 598).

permit any conclusions about Meltdown's effect on metabolism over a longer time period. Doc.944-14 at 35 (DX108); Doc.948 at 213 (Hoffman). Dr. Hoffman also agreed with Dr. Aronne that because the Meltdown studies did not *directly* measure weight or fat loss, they could not substantiate weight loss or fat loss claims for any product (even Meltdown). Doc.948 at 215-216; *see also* Doc.944-14 at 35 (DX108)

For similar reasons, clinical studies of Fastin XR and Fastin-RR also fail to support the claims made. Like Meltdown, Fastin-XR contains ingredients that are absent from regular Fastin. In addition, the common ingredients are present in different amounts in the two products. Doc.941-2 at 95-97 (PX580), 333 (PX514). Hi-Tech recognized that the difference was significant, claiming in its ads for Fastin-XR that the product was more potent than regular Fastin because of its different formulation. Doc.700-63 at 3 (PX67). In addition, the Fastin-XR study measured metabolism over only three hours. Thus, it could not substantiate weight loss, fat loss, or appetite claims, and could not substantiate any metabolism claim beyond three hours. Doc.945 at 117-118 (Aronne); Doc.941-2 at 94 (PX580), 228 (PX581).

Studies of Fastin-RR are similarly unsupportive. Like Fastin-XR, Fastin-RR has a significantly different formulation than the products at issue. Doc.941-2 at 95-97 (PX580); Doc.941-3 at 291-292 (PX598). In addition, one of the studies of Fastin-RR studied metabolism, not weight or fat loss, and it lasted for only six hours – too short to draw any meaningful conclusions. Doc.946 at 14-15 (Aronne); Doc.950 at 75-76 (Jacobs); Doc.941-2 at 228, 231 (PX 581). Another study of Fastin-RR, which lasted eight weeks, also was too short to substantiate causal weight and fat loss claims.[28] Doc.945 at 59-60 (Aronne); Doc.941-2 at 85-86 (PX 580), 216-216 (PX 581). The consensus among experts in the field is that studies shorter than six months may show results that are merely transient. Doc.945 at 58-60 (Aronne); Doc.941-2 at 85-86 (PX 580), 215-216, 224 (PX 581).

[28] Eight weeks was too short for the additional reason that appellants' print and web ads did not contain an eight-week qualification. *See, e.g.,* Docs.700-40 (PX 44), 700-41 (PX 45), 700-48 (PX 52), 700-49 (PX53), 700-54 (PX 58), 700-57 (PX 61), 700-58 (PX 62). An eight-week restriction appeared only on the safety warning on some of the products' packaging, often on the inside of the peel away label. *See, e.g.,* Docs.700-43 at 4-5 (PX 47), 700-50 at 3-4 (PX 54), 700-51 at 2-3 (PX 55). These non-proximate, buried disclaimers cannot overcome the net impression created by Hi-Tech's unqualified claims.

Finally, as the district court found, all the Fastin-XR and Fastin-RR studies suffered from pervasive methodological flaws. Doc.966 at 100.[29] Contrary to good clinical practice, the study investigator, Dr. Jacobs, participated as a study subject at the same time that he was carrying out the studies, a fact he concealed. Doc.966 at 100. He also concealed the fact that his results were less favorable than those of the other study participants. *Id.* As Dr. Aronne explained, Dr. Jacobs' methods reflected a "consistent pattern" that was "biased towards a positive result." Doc.946 at 24 (Aronne). Dr. Jacobs ran the studies so that if he [didn't] like the result, he [did] it again until he [got] the result that [he was] looking for and [did not] report it. *Id.* The studies are therefore not "competent and reliable scientific evidence" sufficient to support the opinions of appellants' experts regarding claims that are far more limited than Hi-Tech's causal efficacy claims.

III. The District Court Properly Held Smith In Contempt

[29] *See* Doc.945 at 116-125 (Aronne); Doc.946 at 4-25, 74 (Aronne); Doc.941-2 at 94-96 (PX 580), 228-234 (PX 581); Doc.941-3 at 273 (PX 596), 294-295 (PX598); Doc.941-12 at 22-26 (PX612), 31 (PX615), 35 (PX617), 42-49 (PX620), 51-56 (PX621), 58-64 (PX622); Doc.944-14 at 54 (DX 110); Doc.944-21 at 10-11 (DX120); Doc.949 at 164 (Jacobs); Doc.950 at 47-48, 73-75, 102-127, 168-169 (Jacobs).

Appellant Smith separately contends that the district court improperly imputed the actions of others to him in finding him jointly and severally liable for compensatory sanctions. The contention is baseless.

The district court did not impute the conduct of others to Smith. It did not need to. Smith is individually bound by the injunction and is thus obliged to ensure that the claims he used to market Hi-Tech were substantiated. Instead of obeying, he participated directly in Hi-Tech's unlawful promotion of the four products at issue and contributed substantially to Hi-Tech's success in doing so. As the court found, "Smith [was] the senior vice-president in charge of sales of Hi-Tech products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES." Doc.650 at 7; *see also* Doc.966 at 12; Doc.700-13 at 12-16, 22-26, 33, 35 (PX18). He oversaw the sales force, had the authority to decide which retailers would sell Hi-Tech Products (including Fastin, Lipodrene, and Benzedrine), and was responsible for acquiring retail accounts with food stores, drug chains, and mass merchandisers for those products.

Doc.966 at 12.[30] Except for Wheat, he was at the top of the chain of command for sales. Doc.534-10 at 41-42 (Wheat Dep. at 34-35); Doc.700-9 at 3 (PX14). He managed day-to-day operations while Wheat was incarcerated, Doc.966 at 13; Doc.700-71 (PX75), and attended trade shows where, using images of Hi-Tech product labels and packaging with violative claims, he made presentations to brokers. Doc.618 at 82-84 (Smith).

Smith helped to disseminate advertising for Fastin, Lipodrene, Benzedrine, and Stimerex-ES that violated the injunction against him. Doc.650 at 7-8; Doc.966 at 13; Doc. 700-13 at 35 (PX18) (identifying Smith as responsible for placing advertisements for Fastin, Lipodrene, Benzedrine, and Stimerex-ES); Doc.700-83 at 2 (PX89); Doc.700-84 at 3 (PX90) (discussing placement of Fastin print ad); Doc.534-10 at 314-316 (Smith Dep. At 34-36) (discussing negotiating prices for and placing Fastin, Lipodrene, and Stimerex-ES print ads).

The record fatally undermines Smith's attempt to portray himself as having inconsequential responsibilities at Hi-Tech. Smith Br. 2-3. Smith denies drafting ad copy. But he was involved in placing

[30] Doc.618 at 69-70, 80 (Smith); Doc.700-9 at 3-4 (PX14); Doc.534-10 at 307-308 (Smith Dep. at 27-28) 322-23 (Smith Dep. at 42-43).

advertising for the products at issue. *See* Doc.700-13 at 12-16, 22-26, 33, 35 (PX18). This included negotiating prices, developing monthly advertising plans, and signing ad insertion orders. *See* Doc.700-83 at 2 (PX89); Doc.700-84 at 3 (PX90); Doc.534-10 at 314-316 (Smith Dep. at 34-36).[31]

Retailers and brokers viewed Smith as someone with authority, as reflected in their practice of contacting Smith when they were concerned about Hi-Tech's claims – including specifically whether Hi-Tech had substantiation for Fastin's weight-loss claims. *See*, *e.g.*, Doc.700-82 at 3 (PX88); Doc.700-170 at 2-5 (PX223); Doc.700-171 at 2 (PX224). Despite their concerns, Smith continued to fill retail orders and promote the products. The compensation he received – $375,000 in 2012 alone – reflects his stature in the company. Doc.618 at 65.

In short, ample and uncontroverted evidence establishes that Smith directly engaged in the sale and promotion of weight-loss products in violation of the 2008 injunction. He objects that he "did not have the power to change the advertising or order double-blind, placebo-

[31] *See* Doc.534-10 at 314-17, 349-52, 392 (Smith Dep. at 34-37, 69-72, 112); Doc.700-13 at 12, 16, 22-23, 27, 33, 35 (PX18); Doc.700-83 at 2 (PX89); Doc.700-84 at 3-7 (PX90).

controlled trials." Smith Br. 24. But his liability for contempt sanctions does not turn on that factor. He is individually prohibited by the underlying injunction from marketing and selling Hi-Tech products using unsubstantiated causal weight-loss claims – a prohibition he flouted.[32] He is therefore jointly and severally liable with the other appellants for contempt sanctions. *See*, *e.g.*, *Leshin*, 618 F.3d at 1236-37 (11th Cir. 2010) (quoting *NLRB v. Laborers' Int'l Union of N. Am.*, 882 F.2d 949, 955 (5th Cir. 1989) ("Where * * * parties join together to evade a judgment, they become jointly and severally liable for the amount of damages resulting from the contumacious conduct.")).

[32] Smith could have avoided violating the injunction by refraining from participating in the marketing and sale of Hi-Tech's weight-loss products.

CONCLUSION

The decision of the district court should be affirmed.

Respectfully submitted,

ALDEN F. ABBOTT
General Counsel

JOEL MARCUS
Deputy General Counsel

/s/ *Leslie Rice Melman*
LESLIE RICE MELMAN
Assistant General Counsel

FEDERAL TRADE COMMISSION
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-2478
lmelman@ftc.gov

Of Counsel:

AMANDA C. BASTA
EVAN M. MENDELSON
Attorneys

FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure Rule 32(a), I certify that this brief complies with the length limitations set forth in Fed. Rule App. Proc. 32(a)(7) because it contains 12,,089 words, as counted by Microsoft Word, excluding the items that may be excluded under Federal Rule 32(a)(7)(B)(iii).

I further certify that this Brief was filed in electronic format through the Court's CM/ECF system on the 14th day of June, 2018.

/s/ *Leslie Rice Melman*
Leslie Rice Melman

Attorney for Plaintiff – Appellee
Federal Trade Commission

CERTIFICATE OF SERVICE

I certify that on June 14, 2018, I served the foregoing brief of Plaintiff - Appellee Federal Trade Commission upon all counsel of record by and through the Court's CM/ECF system.

/s/ *Leslie Rice Melman*
Leslie Rice Melman

Attorney for Plaintiff – Appellee
Federal Trade Commission