

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 17-15695

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D.C. Docket No. 1:04-cv-03294-CAP

FEDERAL TRADE COMMISSION,

Plaintiff - Counter Defendant - Appellee,

CERTUSBANK, N.A.,

Plaintiff,

versus

NATIONAL UROLOGICAL GROUP, INC.,  
d.b.a. Warner Laboratories, et al.,

Defendants - Counter Claimants,

HI-TECH PHARMACEUTICALS, INC.,  
corporations,  
JARED WHEAT,  
individually and as officers of the corporations,  
STEPHEN SMITH,  
individually and as officers of National Urological Group,  
Inc., and National Institute for Clinical Weight Loss, Inc.,

Defendants - Appellants,

THOMASZ HOLDA,  
individually and as officers of the corporations, et al.,

Defendants.

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Appeal from the United States District Court  
for the Northern District of Georgia

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(September 18, 2019)

Before MARTIN, ROSENBAUM, Circuit Judges, and MARTINEZ,\* District Judge.

PER CURIAM:

The defendants in this case were enjoined from making certain claims about health products without “competent and reliable scientific evidence” to substantiate those claims. The Federal Trade Commission (“FTC”) alleged that they violated the injunction when they publicized the weight- and fat-loss benefits of the four products at issue in this case. After a bench trial, the district court agreed with the FTC and found the defendant in civil contempt. The district court consequently imposed approximately \$40 million in sanctions.

Upon review, we conclude that the defendants have waived their challenge to the facial clarity of the injunction and that the district court committed no abuse of

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\* Honorable Jose Martinez, United States District Judge for the Southern District of Florida, sitting by designation.

discretion. Accordingly, we affirm the district court's order of contempt and entry of sanctions.

## I. BACKGROUND

### A. Initial Entry of the Injunction at Issue

Hi-Tech Pharmaceuticals, its chief executive officer ("CEO"), Jared Wheat, and its head of sales, Stephen Smith (collectively, "the defendants"), sold dietary supplements that advertised weight- and fat-loss benefits. They promised that one of their products, Thermalean, would help consumers lose "as much as 30 pounds in two months," and that another product, Lipodrene, was "clinically proven to enable users to lose up to 42% of total body fat." In 2004, the FTC charged the defendants with falsely advertising those products, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

The district court granted summary judgment for the FTC. *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1215 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009). Claims about the safety and efficacy of dietary supplements, the district court noted, "must be substantiated with competent and reliable scientific evidence." *Id.* at 1202. The FTC's guide for advertisers defined "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have 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.” *Id.* at 1190 (citation and quotation marks omitted).

The district court agreed with the FTC’s expert, Dr. Louis Aronne, that to satisfy the FTC’s definition of “competent and reliable scientific evidence” supporting weight- and fat-loss claims regarding any product, randomized clinical trials (“RCTs”) on the advertised products are necessary. *See id.* at 1202. As the defendants had not conducted any RCTs on Thermalean or Lipodrene, the district court concluded that the defendants’ weight- and fat-loss claims about those products were unfounded.

In its motion for summary judgment, the FTC had attached the proposed text of a permanent injunction against the appellants. Sections II and VII of the proposed injunction banned the defendants from making unsubstantiated claims, meaning they were to refrain from making any representation about the safety, efficacy, or health or weight-loss benefits of dietary supplements unless, “at the time the representation is made, [they] possess and rely upon *competent and reliable scientific evidence* that substantiates the representation.” (emphasis added). The proposed injunction adopted the definition for “competent and reliable scientific evidence” from the FTC’s advertising guide.

Complaining of “space limitations,” the defendants indicated that they would not object to the proposed injunction in their opposition to summary judgment. They

instead requested “that they be given further opportunity” to voice their objections later. The district court granted the defendants’ request. *Nat’l Urological Grp., Inc.*, 645 F. Supp. 2d at 1215.

And the defendants took advantage of their second chance. They objected to several provisions in the proposed injunction, including the definition of several terms, like “[c]overed product or service,” “drug,” or “manufacturing.” Notably, though, they did not object to the use of the phrase “competent and reliable scientific evidence.”

After overruling the defendants’ objections, the district court entered a permanent injunction against them. Just as the proposed injunction had, Sections II and VII of the final injunction prohibited the defendants from making fat- and weight-loss claims about covered products unless, at the time of the representation, the defendants relied on “competent and reliable scientific evidence that substantiates the representation.” That phrase was defined by reference to the FTC’s advertising guide, as it had been during the litigation.

The defendants appealed to this Court, raising a host of arguments. But again, significantly, they did not argue that the phrase “competent and reliable scientific evidence” was unclear. A different panel of this Court rejected the defendants’ arguments and affirmed the district court. *F.T.C. v. Nat’l Urological Grp., Inc.*, 356 F. App’x 358, 359 (11th Cir. 2009).

## **B. Contempt**

The ink had hardly dried on filings from the first injunction case when the defendants started a new marketing campaign in 2009. This time, they touted the fat- and weight-loss benefits of four products—a reformulated version of Lipodrene, Fastin, Benzedrine, and Stimerex-ES. For example, advertisements for Lipodrene warned users not to consume the product unless “fat loss and weight loss are your intended result”; advertisements for Fastin boasted that it was an “Extreme Fat Burner”; those for Benzedrine claimed that it would “annihilate . . . fat”; and advertisements for Stimerex-ES told users that this was a product “for those who want their fat-burner to light them up all day as their pounds melt away.”

The FTC moved for an order to show cause why the defendants should not be held in contempt for marketing those four products without proper substantiation, in violation of their injunction. *F.T.C. v. Nat’l Urological Grp., Inc.*, 785 F.3d 477, 479-80 (11th Cir. 2015). In response, the defendants argued that they had fully complied with the injunction. *Id.* at 481. Contending that RCTs on the products at issue were not required, the defendants offered *other* types of evidence that they claimed were competent and reliable scientific evidence to support their claims.

The FTC disagreed and pointed to several communications that revealed the defendants’ knowledge that the injunction could require them to conduct RCTs on

the advertised products.<sup>1</sup> In one email, Hi-Tech’s attorneys informed Wheat that “competent and reliable scientific evidence,” as used in the injunction, meant RCTs on the marked product:

[I]t is safe to say that Judge Pannell 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.” Rather, based upon Judge Pannell’s previous findings, it is reasonable to assume that he would take a position consistent with the FTC that double-blind, clinical trials of the products were necessary to substantiate the representation. Although we certainly have not and do not now agree with this position, at present, it is the premise upon which the FTC Injunction is based.

Wheat certainly heard his attorneys’ advice, telling another Hi-Tech employee that “[his attorney’s] opinion is anything short of a double-blind study on each product leaves [Hi-Tech] open to exposure to FTC.” But, Wheat said, “[he] s[i]mply [could] not quit advertising.”

The district court agreed with the FTC. Observing that the issue of what constituted “competent and reliable scientific evidence” in this context had already been determined to be RCTs on the products themselves, the district court held that, under the doctrine of collateral estoppel, only RCTs on the marketed products could

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<sup>1</sup> Wheat was incarcerated from March 16, 2009, to September 15, 2010. The FTC acquired communications sent between Wheat and other parties while he was in jail. The district court ruled that those communications were admissible, and the defendants do not challenge their admissibility on appeal.

count. Thus, the district court refused to consider the defendants' proffered evidence and granted the FTC's motion to show cause. *Nat'l Urological Grp., Inc.*, 785 F.3d 481.

After the defendants could not produce RCTs to support their claims, the district court found them in contempt for violating the injunction. *Id.* It consequently held the defendants jointly and severally liable for about \$40 million of sanctions, which reflected the defendants' total gross receipts from the sales of Fastin, Lipodrene, Benzedrine, and Stimerex-ES. *Id.*

The defendants then appealed to this Court, arguing that nothing within the four corners of the injunction automatically equated "competent and reliable scientific evidence" with RCTs. They clarified that they were not arguing that the "competent and reliable scientific evidence" standard was so facially unclear as to render the injunction unenforceable. Rather, they disputed only the notion that "competent and reliable scientific evidence" had to mean RCTs:

[T]he Contempt Defendants do not argue that the substantiation standard is, in and of itself, impermissibly vague. They do contend, however, that it is not sufficiently specific—without resort to documents beyond the four corners of the injunction—to require Contempt Defendants to produce double-blind, placebo-controlled clinical trials of their products to substantiate all future weight-loss claims.



Brief of Appellants at 39, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131).<sup>2</sup>

And when the FTC nonetheless pointed out that any challenge to the facial clarity of the injunction had been waived, the defendants criticized the FTC for missing the point. The defendants repeated that they were not challenging the facial validity of the injunction, only the notion that “competent and reliable scientific evidence,” without any discussion, had to mean RCTs:

[T]he FTC opens its brief by arguing that the injunction contains “reasonable detail” and that the competent-and-reliable-scientific-evidence standard “is sufficiently clear to enforce” and impose the unwritten randomized-clinical-trials requirement on Contempt Defendants. Contempt Defendants, the FTC says, have “already litigated and lost” a challenge to the vagueness of the injunction.

That argument is beside the point. The Contempt Defendants, as they explained in their opening brief (at 39), are not arguing that the “the ‘context specific’ substantiation standard may create unreasonable ambiguity on the face of the injunction.” Instead, they argue that the FTC cannot carry its burden to show that the competent-and-reliable-scientific-evidence standard clearly and unambiguously requires them to have randomized, double-blind, placebo-controlled clinical studies to substantiate their claims.

Reply Brief of Appellants at 7, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131) (citations omitted).

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<sup>2</sup> Smith adopted Wheat and Hi-Tech’s arguments here. Opening Brief for Appellant Smith at 5, *F.T.C. v. Nat'l Urological Grp., Inc.*, 785 F.3d 477 (11th Cir. 2015) (No. 14-13131).

We determined that the district court had erred when it applied the doctrine of collateral estoppel to hold that the “competent and reliable scientific evidence” standard automatically required RCTs. *Nat’l Urological Grp., Inc.*, 785 F.3d at 482. We remanded to the district court with instructions to “make findings about whether any evidence of substantiation, if admissible, satisfies the standard of the injunctions for ‘competent and reliable scientific evidence.’” *Id.* at 483. Before concluding, we emphasized that our holding was “only that the district court misapplied collateral estoppel when it barred [the defendants] from presenting evidence to prove their compliance with the injunctions.” *Id.*

### **C. Bench Trial on Remand**

After conducting a bench trial, the district court determined that the FTC had shown by clear and convincing evidence that the defendants lacked competent and reliable scientific evidence to substantiate their claims. The district court consequently found the defendants in contempt and re-imposed the sanction of approximately \$40 million on the defendants.

The defendants appealed. Wheat and Hi-Tech filed their own appeal, primarily to challenge the facial validity of the injunction. Alternatively, Wheat and Hi-Tech argue that the district court’s finding that they lacked competent and reliable scientific evidence was clearly erroneous. Smith filed a separate appeal, adopting

Wheat and Hi-Tech's arguments but also arguing that he lacked the ability to comply with the injunction.

We hold that the defendants have waived their challenge to the clarity of the injunction. We also conclude that the district court did not abuse its discretion in finding that the defendants lacked competent and reliable scientific evidence to substantiate the relevant claims and in imposing the order of contempt. Accordingly, we affirm the district court.

## **II. STANDARD OF REVIEW**

We must affirm the district court's judgment of civil contempt unless we find that the court abused its discretion. *Howard Johnson Co. v. Khimani*, 892 F.2d 1512, 1516 (11th Cir. 1990). We review any underlying factual findings for clear error, *Jove Eng'g, Inc. v. I.R.S.*, 92 F.3d 1539, 1545 (11th Cir. 1996), and we review any legal rulings *de novo*, *Ala. v. Ctrs. For Medicare & Medicaid Servs.*, 674 F.3d 1241, 1244 n.2 (11th Cir. 2012).

## **III. DISCUSSION**

The petitioning party has the initial burden in a civil-contempt case to clearly and convincingly show the district court that (1) the injunction was valid and lawful; (2) the order was clear, definite, and unambiguous; and (3) the contempt defendant had the ability to comply with the order (but did not do so). *McGregor v. Chierico*, 206 F.3d 1378, 1383 (11th Cir. 2000). Once this *prima facie* showing is made in the

district court, the burden shifts to the defendants to explain their noncompliance. *See F.T.C. v. Leshin*, 618 F.3d 1221, 1232 (11th Cir. 2010). In the civil-contempt context, “substantial, diligent, or good faith efforts are not enough; the only issue is compliance.” *Id.*

With these principles in mind, we examine the defendants’ arguments that the district court abused its discretion by holding them in contempt.

**A. The defendants have waived any objection to the clarity of the injunction.**

The defendants’ chief argument on appeal is that the injunction is too ambiguous to be enforced. They contend that that the “competent and reliable scientific evidence” standard and its accompanying definition are unclear, in violation of Fed. R. Civ. P. 65(d), which states that an injunction should “describe in reasonable detail” what is required without referring to another document. Fed. R. Civ. P. 65. Their argument, however, has been squarely foreclosed by *McComb v. Jacksonville Paper Co.*, 336 U.S. 187 (1949), where the Supreme Court illustrated the common-sense lesson that a defendant cannot defeat an injunction by employing the following formula: (1) staying silent about purported ambiguities; (2) deliberately engaging in activities that risk violating the injunction; and (3) pleading ignorance after those risky activities are indeed found to violate the injunction.

*McComb* was a civil-contempt case. *McComb*, 336 U.S. at 189. In 1943, the district court entered a decree ordering the defendants there to comply with the Fair

Labor Standards Act (“FLSA”) by (1) paying certain employees a minimum wage, (2) paying overtime compensation to certain employees, and (3) keeping certain records about hours worked and wages paid. *Id.* The contempt defendants did not appeal from the district court’s order. *Id.*

Three years after the district court entered its order, the government instituted contempt proceedings against the defendants, and the district court found that the defendants had violated the decree. *Id.* at 189-90. Among other things, the defendants had set up a “false and fictitious” method of calculating compensation, provided employees wage increases in the guise of bonuses to reduce the amount of overtime pay they had to give, and misclassified some employees. *Id.* Despite these findings, however, the district court did not hold the defendants in contempt, and the court of appeals upheld that decision. *Id.* According to the court of appeals, there was no “willful contempt” because “neither the [FLSA] nor the injunction *specifically* referred to or condemned the [defendants’] practices.” *Id.* at 191 (emphasis added).

The Supreme Court reversed, and its discussion applies forcefully in this case. First, the Court explained that “[t]he absence of wil[l]fulness does not relieve from civil contempt.” *Id.* This is because “the purpose [of civil contempt] is remedial, [so] it matters not with what intent the defendant did the prohibited act.” *Id.* The Supreme Court went on to explain that injunctions of some generality “are often

necessary to prevent further violations where a proclivity for unlawful conduct has been shown.” *Id.* at 192.

Significantly, the Court continued, if the contempt defendants had a problem with the injunction, they could have done a number of things, like appeal or ask the district court for “a modification, clarification[,] or construction of the order.” *Id.* But the defendants did none of those things, opting instead to “make their own determination of what the decree meant.” *Id.* Thus, the Court explained, the defendants “knew they acted at their peril.” *Id.*

To excuse the defendants years later, after they already took the questionable actions, the Court explained, would basically render the injunction useless and “give tremendous impetus to the program of experimentation with disobedience of the law”:

The instant case is an excellent illustration of how it could operate to prevent accountability for persistent contumacy. Civil contempt is avoided today by showing that the specific plan adopted by respondents was not enjoined. Hence a new decree is entered enjoining that particular plan. Thereafter the defendants work out a plan that was not specifically enjoined. Immunity is once more obtained because the new plan was not specifically enjoined. And so a whole series of wrongs is perpetrated and a decree of enforcement goes for naught.

*Id.* at 192-93. The Supreme Court refused to allow this never-ending cycle of violations, ruling that the defendants “knew full well the risk of crossing the forbidden line” and “took a calculated risk when under the threat of contempt they

adopted measures designed to avoid the legal consequences of the [FLSA].” *Id.* at 193. They were not, the Supreme Court said, “unwitting victims of the law” and could not escape punishment now. *Id.*

The *McComb* Court might as well have been talking about this case. The defendants here were likewise not “unwitting victims of the law” but were instead calculating actors who stayed silent concerning the purported ambiguity about which they now complain. Then they deliberately engaged in self-serving activities they knew seriously risked violating the injunction.

As we have recounted, during the original injunction proceedings, at the defendants’ request, the district court gave the defendants an opportunity to object to a draft version of the injunction that was ultimately entered. The defendants did not object that the phrase “competent and reliable scientific evidence” or its accompanying definition were unduly ambiguous. The district court then entered the injunction. The defendants also did not make a Rule 65 objection to the clarity of the injunction when they appealed to this Court (and even if they had, this Court affirmed the entry of the injunction).

They had, after all, just litigated what that phrase meant in the context of dietary supplements that touted weight- and fat-loss benefits, and the district court had explained that only RCTs on the products themselves would suffice. So they likely understood that, in the future, to make claims about weight- and fat-loss

benefits for dietary supplements, they would need RCTs. And even if they didn't, the defendants' attorneys expressly advised them on multiple occasions that only RCTs would satisfy the standard.

Wheat understood what his attorneys were telling him, as he conceded in an email to other Hi-Tech employees: "If the FTC verdict stands there is nothing we can say without doing a double-blind placebo study . . . ." But as Wheat expressed repeatedly, the RCT requirement put a heavy strain on his business. So knowing the risk, the defendants made a choice to continue to market products, relying largely on supporting evidentiary material the district court previously rejected and their own attorneys repeatedly advised Wheat was insufficient.

As *McComb* explained, injunctions sometimes need to be phrased with some generality, to give flexibility to cover the endless derivations of a specific kind of prohibited conduct. *McComb*, 336 U.S. at 192. And although Rule 65 specifies that the injunction should be self-contained, it is also impossible to spell out every imaginable detail. So those subject to an injunction can timely ask questions, seek modification or clarification, or object. That way, if some detail needs to be articulated more specifically, it will be. But a person facing an injunction cannot stay silent, take actions he has reason to believe are prohibited, and then complain about alleged "ambiguity" later.



Here, though, the defendants did precisely that. They stayed silent about the supposed ambiguity of which they now complain, were repeatedly informed by counsel that they risked contempt for using anything other than RCTs to substantiate their claims, knowingly proceeded anyway in the face of that risk—and reaped \$40 million in gross receipts—and now plead ignorance after being held in contempt. Injunctions are not so easily circumvented.

The defendants offer some theories about why they have not waived their ambiguity argument. We dismiss each in turn.

First, the defendants point out that the FTC bears the initial burden of making a prima facie showing that an injunction is valid and clear before the Hi-Tech defendants can be held in contempt. To the extent that the defendants make this argument to suggest that ambiguity objections can *never* be waived, we find that contention to be meritless. *See McComb*, 336 U.S. at 191-94. As for the injunction’s definition of “competent and reliable scientific evidence”—“tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that ha[ve] 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”—that appears on its face to be reasonable, particularly when we consider that the defendants did not object to the phrase, despite conceding it was the “operative command” in the substantiation requirement.

In short, we are satisfied that the FTC has carried its prima facie burden of showing the clarity of the injunction.

Next, the defendants note that in rejecting their claim that the injunction was not sufficiently clear, the district court discussed the defendants' assertions that the injunction was ambiguous and that it did no more than require them to obey the law.<sup>3</sup> Because the district court addressed these arguments, the defendants contend, they had a right to address those grounds on appeal. We don't disagree. But nothing about the district court's discussion of those issues absolves the defendants' waiver problem.

District courts can offer multiple rationales, sometimes in the alternative, for their decisions, and we can affirm on any basis. Here, before discussing the defendants' ambiguity arguments, the district court expressed doubt that those arguments were properly before it. Indeed, the court said that "the defendants were given an opportunity to object to the scope of the injunctions before they were entered, but they did not object to any of the provisions they *ostensibly* challenge

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<sup>3</sup> We have explained that an injunction that simply tells a defendant to obey the law can be too ambiguous to be enforced. But aside from concerns about clarity, there is nothing inherently wrong with an injunction that instructs a party to comply with a specific law. *S.E.C. v. Goble*, 682 F.3d 934, 950-51 (11th Cir. 2012) (explaining that obey-the-law injunctions often suffer from lack of specificity, but that "an injunction that orders a defendant to comply with a statute may be appropriate" when the enjoined activity remains clear). Thus, the defendants' complaint that the injunction tells them only to obey the law is just another way of voicing their ambiguity argument.

now.” (emphasis added). So there can be no doubt that the district court in fact concluded that the defendants had waived their ambiguity arguments.

Finally, the defendants contend that they did not have a fair opportunity to object to the “competent and reliable evidence” standard, since, according to them, they “could not reasonably have been expected to know in 2008 that the FTC would later seek to hold them in contempt for failing to substantiate *different* advertising claims with a product-specific RCTs standard not in the injunction.” We agree generally that, in some instances, a person subject to an injunction cannot fairly be expected to object to an ambiguity that becomes apparent only when, for example, a court evinces an unexpected interpretation of certain terms. But that’s not the case here, since the defendants’ attorneys literally told them that “it is *reasonable to assume*” that competent and reliable scientific evidence means RCTs on the marketed products. (emphasis added.) At the very least, then, the defendants were on notice that RCTs were likely to be required, and they were not permitted to assume the risk without accepting the consequences. *See McComb*, 336 U.S. at 192 (“They undertook to make their own determination of what the decree meant. They knew they acted at their peril.”).

**B. The defendants cannot show that the district court clearly erred when it found that they lacked competent and reliable scientific evidence to substantiate the claims at issue.**

As explained, we remanded to the district court with instructions to determine whether any admissible evidence presented by the defendants constituted “competent and reliable scientific evidence.” *Nat’l Urological Grp., Inc.*, 785 F.3d at 483. On remand, the district court conducted a bench trial, after which it determined that the defendants did not have competent and reliable scientific evidence that substantiated the claims at issue.<sup>4</sup> The defendants allege that the district court clearly erred in making this finding. We disagree.

The district court’s finding that the defendants’ evidence did not amount to competent and reliable scientific evidence to substantiate the relevant claims is a factual determination, which we review for clear error. *Jove*, 92 F.3d at 1545. On clear-error review, “[i]f the district court’s account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.” *Anderson v. City of Bessemer City, N.C.*, 470 U.S. 564, 573-74 (1985). And when a district judge’s factual finding “is based on his decision to credit the testimony of one of two or more witnesses, each of whom has told a coherent and facially plausible story that is not contradicted by extrinsic evidence,

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<sup>4</sup> The district court clarified that even if what the defendants presented could be “competent and reliable scientific evidence” that would suffice in other contexts, it was not “competent and reliable scientific evidence” that could substantiate the claims at issue here.

that finding, if not internally inconsistent, can virtually never be clear error.” *Id.* at 575.

Here, the district court detailed its extensive reasoning as to why the defendants’ evidence was inadequate and why protections offered by tests like RCTs would be necessary for the claims at issue. The district court considered the qualifications of the FTC’s experts, Dr. Aronne and Dr. Richard van Breemen, who urged that protections offered by RCTs were necessary. It considered all the beneficial characteristics of RCTs that are run on humans and on the specific products: they factor in the unique biochemical properties of humans; there are placebo controls and double blinding;<sup>5</sup> there is randomization;<sup>6</sup> the studies would be large enough to produce reliable results; the studies would be long enough to produce reliable results; the products and dosages tested would be the ones about which the company makes claims; the studies would measure the endpoints the company makes claims about; and the results would be statistically significant, so there is less of a chance that the outcome is a fluke.

The district court also explained why *not* having those beneficial properties would cause a study to be less reliable: results in animals or results in vitro would

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<sup>5</sup> A double-blind test is one where the test subjects do not know whether they are in the placebo group (first blind), and the researchers do not know which group is the placebo one, either (second blind).

<sup>6</sup> Randomization is the process by which test subjects are randomly assigned to either the treatment or the placebo group.

have to be extrapolated to humans (but certain biochemical reactions that occur outside the human body may not repeat in the same way inside the body); there would be no way to know whether any placebo effect contributed to the results; it would have to be assumed that different ingredients in other products did not affect the outcome; it would have to be assumed that different dosages of the ingredients in other products did not affect the outcome; and there would be no way to determine whether selection bias had occurred. Notably, many of the defendants' experts agreed with the district court's points here. And the district court noted that the defendants' evidence, which primarily consisted of studies on *ingredients* in the marketed products—as opposed to studies on the marketed products themselves—and RCTs of *other products*—as opposed to RCTs on the marketed products—lacked many of the safeguards of reliability mentioned above.

The district court also considered the credentials of the defendants' experts and found them lacking in many cases. Worse yet, the district court illuminated disturbing facts about the credibility of some of the defendants' experts. For example, one of their experts, Dr. Wright, was repeatedly reprimanded by the Georgia Composite Medical Board and, in a 2003 civil case, may have lied to the district court in the Northern District of Georgia when he said that Wheat was in Belize to recuperate from an illness when Wheat was actually there to illegally further a conspiracy to manufacture, import, and distribute drugs in the United

States. Another of the defendants' experts, Dr. Jacobs, admitted that he broke the blind<sup>7</sup> and re-administered dosages when one of the RCTs he was conducting on another Hi-Tech product was not turning out the way he expected—that is, he deliberately influenced the experiment's results.

It should come as no surprise, then, that in the end, the district court concluded that the FTC had shown, by clear and convincing evidence, that the defendants' collection of ingredient-specific studies and RCTs of other products (some of which were run by Dr. Jacobs) did not constitute competent and reliable scientific evidence to substantiate their claims. Far from clear error, the district court's findings were supported by the evidence.

The defendants' attempts to show that the district court committed clear error all fall flat. First, the defendants allege that the district court's "cursory analysis never explains what standard the Hi-Tech defendants somehow failed to meet in the alternative" if RCTs were not required. In this respect, the defendants argue, "Having failed to identify precisely what substantiation standard it would apply in the alternative," "the court surely could not objectively evaluate substantiation under that unarticulated standard." But the district court did not necessarily need to articulate a standard to recognize that what the defendants presented did not amount to competent or reliable scientific evidence. Moreover, it should be clear from the

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<sup>7</sup> To break the blind is to uncover the placebo group in an experiment.

district court's analysis that it used as the standard the level of reliability and competency afforded by RCTs on the advertised products. Put differently, what evidence the defendants presented had to be as reliable and as competent as results derived from RCTs on the marketed products.

Second, the defendants argue that “the district court impermissibly shifted the burden to [them] to *disprove* contempt in the first instance by proving that their product claims were substantiated.” Not so. The FTC met its prima facie burden of clearly and convincingly showing that the injunction was violated, when it pointed out that the defendants were again making weight- and fat-loss claims about products without having RCTs on the products themselves, even though the court had held that only RCTs on the products themselves could be “competent and reliable scientific evidence” the last time. So the burden shifted to the defendants to explain why RCTs were not necessary and why they had evidence that carried the same reliability and competency as the RCTs that were required the first time. *Howard*, 892 F.2d at 1516. Then at the bench trial, the FTC demonstrated by clear and convincing evidence that the evidence the defendants presented was not as reliable or as competent as RCTs on the marketed products would have been.

Finally, the defendants argue that “when experts reasonably disagree over whether representations are supported by competent and reliable scientific evidence, as they did here, the FTC has not carried its burden to establish contempt by clear



and convincing evidence.” This argument does not save the day for the defendants for two reasons. First, we have already explained the problems the district court found with the defendants’ experts—problems the district court reasonably could rely on to discount those experts’ views. And second, even setting aside the defendants’ experts’ deficiencies, a battle of the experts does not necessarily paralyze the district court and exonerate the defendant. Rather, a district court can decide for one side or the other even when both present plausible stories. *Anderson*, 470 U.S. at 573-74 (“If the district court’s account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.”).

The mere fact that a battle of experts exists goes more directly to the potential good faith of the defendant in attempting to comply with the injunction than to the defendant’s actual compliance. But as we have noted, good faith—even when it is demonstrated—is not enough, in and of itself, to escape civil contempt. *Leshin*, 618 F.3d at 1232 (explaining that in a civil contempt proceeding, “substantial, diligent, or good faith efforts are not enough; the only issue is compliance.”).

**C. Smith had the ability to comply with the injunction.**

Smith adopted the arguments we have already discussed, but he also made a separate argument: that he did not have the ability to comply with the injunction.

Smith claims he was merely “a salesman for Hi-Tech” who “never held a position with decision-making authority over Hi-Tech’s advertising, its product labels, or its testing of products.” According to Smith, “[t]he district court’s finding with respect to [him] is based on the actions of others . . . and must be reversed.” Specifically, “[r]ather than consider him individually, the district court effectively imputed the actions of Hi-Tech and Mr. Wheat to Mr. Smith.” We disagree.

The district court did not have to rely on imputing others’ actions to Smith. In laying out the findings that supported holding him in contempt, the district court explained why *Smith* took actions that were integral to Hi-Tech’s violation of the injunction. Smith was the senior vice president in charge of sales at Hi-Tech, as well as the head of the “Food, Drug, and Mass” division there. In that capacity, he was responsible for landing retail accounts, including advertising and promoting Hi-Tech products at trade shows. The district court found that Smith “oversaw the sales force that marketed Hi-Tech products to retailers and had the authority to decide which retailers sold their products.”

Smith protests that it was Wheat who designed the advertisements and that he had no power to order RCTs. “There was simply nothing [he] could have done to effect compliance,” he said, “because he did not have the power to change the advertising or the labels or to order double-blind, placebo-controlled clinical trials.” But Smith’s liability did not arise from his failure to order RCTs or design compliant

advertisements. His liability stemmed instead from his decisions to continue marketing and selling Hi-Tech's products without regard to his responsibility to ensure that those products did not carry unsubstantiated claims. Smith could have complied with the injunction simply by not participating in the infringing activities. That he chose to continue facilitating those prohibited activities sufficiently supported the district court's conclusion finding him liable.

#### **IV. CONCLUSION**

For the foregoing reasons, we affirm the district court.

**AFFIRMED.**