No. 19-1445

In the Supreme Court of the United States

HI-TECH PHARMACEUTICALS, INC., ET AL., PETITIONERS

v.

FEDERAL TRADE COMMISSION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

After the Federal Trade Commission charged petitioners with falsely advertising dietary supplements, the district court permanently enjoined petitioners from, *inter alia*, making representations about the weight-loss potential of covered products unless they had "competent and reliable scientific evidence" to support those representations. When petitioners thereafter engaged in a similar marketing campaign, the district court found them in civil contempt and imposed monetary sanctions. The questions presented are as follows:

1. Whether the court of appeals correctly held that petitioners had waived their argument that the injunction was ambiguous.

2. Whether the injunction gave petitioners clear notice that they were prohibited from making weight-loss claims about their products unless those claims were substantiated by randomized clinical trials on the products themselves.

3. Whether the court of appeals correctly held that the district court had not abused its discretion in imposing the contempt order.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-26) is not published in the Federal Reporter but is reprinted at 786 Fed. Appx. 947. The order of the district court (Pet. App. 48-164) is not published in the Federal Supplement but is available at 2017 WL 6759868.

JURISDICTION

The judgment of the court of appeals was entered on September 18, 2019. A petition for rehearing was denied on January 29, 2020 (Pet. App. 46-47). On March 19, 2020, this Court extended the time within which to file a petition for a writ of certiorari to 150 days from the denial of a timely rehearing petition. The petition for a writ of certiorari was filed on June 26, 2020. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Section 5 of the Federal Trade Commission Act (FTC Act) prohibits "deceptive acts or practices in or affecting commerce" and directs the Federal Trade Commission (FTC or Commission) to prevent such practices. 15 U.S.C. 45. Under Section 12 of the FTC Act, prohibited deceptive acts include "any false advertisement" relating to "food" or "drugs." 15 U.S.C. 52(a) and (b). An advertisement violates Sections 5 and 12 of the FTC Act when it contains a representation that is likely to mislead consumers acting reasonably under the circumstances and is material to a consumer's decision to purchase the product. *FTC* v. *Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994), cert. denied, 514 U.S. 1085 (1995); see FTC, *Policy Statement on Deception*, 103 F.T.C. 174, 178 (1984).

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). An advertisement 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, 193 (D.C. Cir. 1986) (citation omitted), cert. denied, 479 U.S. 1086 (1987). 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, 1498-1499 (1st Cir. 1989); *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 560 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985). Whether an advertiser has satisfied that standard in a particular case is a question of fact. See, *e.g.*, *FTC* v.

Direct Mktg. Concepts, Inc., 624 F.3d 1, 8 (1st Cir. 2010); *Bristol-Myers*, 738 F.2d at 558-560.

2. a. Petitioners sell dietary supplements, which they advertise as causing weight loss and other health effects. Pet. App. 3. As relevant here, petitioners told consumers that one product (Thermalean) "causes rapid and substantial weight-loss, including as much as 30 pounds in two months," and that another (Lipodrene) was "clinically proven to enable users to lose up to 42% of total body fat." *Id.* at 291, 306 (citations omitted). The advertisements included numerous other claims of significant weight and fat loss, among other purported benefits. *Id.* at 289-320. In 2004, the Commission sued petitioners, alleging that they had made those health claims without adequate supporting evidence. *Id.* at 3.

The district court determined that petitioners lacked substantiation for their representations and granted summary judgment to the Commission. Pet. App. 257-346. The court explained that health-benefit claims must be substantiated by "competent and reliable scientific evidence," a flexible standard that requires evidence that "pertinent professionals would require for the particular claim made." *Id.* at 278-279. It then found that uncontroverted expert testimony 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 (RCTs) "on the product itself." *Id.* at 316. The court further found that petitioners had no such evidence and that studies examining only the ingredients in the advertised products, or similar products using different formulations, were not adequate to support petitioners' weight-loss claims. *Id.* at 316-317.

The district court permanently enjoined petitioners from making unsubstantiated claims with respect to any weight-loss product. Pet. App. 231-256. Section II of the injunction barred petitioners from making representations that their products cause a rapid or substantial loss of weight or fat, or that they affect human metabolism, appetite, or body fat, "unless, at the time the representation is made, [petitioners] possess and rely upon competent and reliable scientific evidence that substantiates the representation." *Id.* at 244. The injunction thus incorporated the "competent and reliable scientific evidence" standard that the court had just held required RCTs for weight-loss claims. The court's order defined "'[c]ompetent and reliable scientific evidence'" as "tests, 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 by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 234.

The district court gave petitioners an opportunity to object to the scope of the injunction and the definitions used therein. Pet. App. 85. Although petitioners challenged some terms and definitions, they did not object to the "competent and reliable scientific evidence" standard or its definition, as it applied to their weight-loss products. *Ibid.*; see *id.* at 4-5.

The court of appeals affirmed the district court's judgment, 356 Fed. Appx. 358, and this Court denied review, 562 U.S. 1003. At no time in the appellate proceedings did petitioners challenge the provisions in the injunction requiring competent and reliable scientific evidence for weight-loss claims. Pet. App. 5, 86.

b. Despite the district court's injunction, petitioners continued to promote their dietary supplements using the same types of unsubstantiated claims about weight loss. Pet. App. 5-6. Beginning in 2009, petitioners launched a new marketing campaign for four products—Fastin, Stimerex-ES, Benzedrine, and a reformulated version of Lipodrene. *Id.* at 5-6, 51-52.

Petitioner Hi-Tech touted its products' efficacy in causing weight loss in full-page advertisements in national publications, on its website, and on its product packaging and labels. See Pet. App. 62-68 (describing advertisements in detail). For example, the advertisements told consumers that Fastin is an "EXTREMELY POTENT DIET AID! DO NOT CONSUME UNLESS RAPID FAT AND WEIGHT LOSS ARE YOUR DESIRED RESULT." *Id.* at 62-63. Advertisements for Lipodrene similarly stated that "LIPODRENE WILL CAUSE RAPID FAT AND WEIGHT LOSS WITH USAGE" and encouraged consumers to "[t]ry Lipodrene® and watch the inches melt away." *Id.* at 64-65. Advertisements for Stimerex-ES likewise claimed that the product melts away body fat. *Id.* at 67-68. They also claimed that Stimerex-ES causes the same weight-loss and metabolic effects as products containing ephedrine alkaloids, which had been banned by the FDA, stating that "The benefits of ephedra are now 'Back in Black!'" *Ibid.* Finally, advertisements claimed that Benzedrine will "ANNIHILATE THE FAT" because of its "Unmatched Anorectic Activity to Manage Caloric Intake." *Id.* at 66. Petitioners did not conduct RCTs on any of the advertised products. See *id.* at 6.

Petitioners' lawyers warned petitioners that their advertisements would likely violate the district court's

injunction. Pet. App. 6-7, 80-84. They specifically advised petitioner Jared Wheat, the Hi-Tech CEO, that for weight-loss claims, the injunction required double-blind, product-specific clinical trials.* *Ibid.* The lawyers cautioned that "the express language in the FTC Injunction" required product-specific substantiation, and not simply evidence that certain ingredients could have biological effects. *Id.* at 6-7. They added that the district court would likely find that the injunction required "double-blind, clinical trials of the products" because that "is the premise upon which the FTC Injunction is based." *Id.* at 7. Those warnings were consistent with Wheat's own understanding that, if the injunction survived appeal, "there is nothing we can say without doing a double-blind placebo study." *Id.* at 15.

3. a. In light of petitioners' latest marketing campaign, the Commission moved the district court for an order directing petitioners to show cause why they should not be held in contempt. Pet. App. 6, 51. The court granted the motion. *Id.* at 7, 52.

The district court again determined that weight-loss claims must be supported by well-designed RCTs "on the product itself" or its equivalent. Pet. App. 223-225 (citation and emphasis omitted). The court did not allow petitioners to offer any substantiation evidence other than RCTs, finding that principles of issue preclusion applied. *Id.* at 225.

b. The court of appeals vacated the district court's ruling, holding that issue-preclusion principles did not

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* The FTC acquired Wheat's communications with his lawyers because they were transmitted using a monitored prison-email system. Pet. App. 6 n.1. The district court ruled that the communications were admissible, and petitioners did not challenge that ruling on appeal. *Ibid.*; see *id.* at 79-80.

apply because the contempt litigation involved different weight-loss products and claims. Pet. App. 37-38. The court of appeals remanded for the district court 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 38.

c. On remand, the district court conducted a bench trial to determine whether petitioners had "competent and reliable scientific evidence" to support their advertising claims. Pet. App. 10.

The Commission presented detailed expert testimony on what that standard requires for weight-loss claims—namely, RCTs on the products themselves. Pet. App. 124-133. Petitioners, meanwhile, offered various ingredient studies, measuring factors such as metabolism rather than weight or fat loss. See *id.* at 134. They also relied on clinical trials of other products with different formulations and different ingredients from the products at issue. See *id.* at 133-136. The Commission's experts testified that petitioners' proposed substantiation did not amount to competent and reliable scientific evidence of the weight- and fat-loss claims for the particular products at issue. See *ibid.* The district court also expressed "concerns regarding the credibility of the defendants' experts and their ultimate substantiation opinions." *Id.* at 136; see *id.* at 136-147.

The district court found petitioners in contempt for violating the injunction and imposed $40 million in sanctions. Pet. App. 7; see *id.* at 48-164.

The district court rejected petitioners' argument that its prior injunction was unclear. The court noted that petitioners "were given an opportunity to object to the scope of the injunction[] before [it was] entered, but

they did not object to any of the provisions they ostensibly challenge now." Pet. App. 85. The court observed that, if petitioners were unsure of what was required by "'competent and reliable scientific evidence,'" "they could have easily asked, but they did not." *Id.* at 84-85. It also determined that voluminous evidence, including the advice of their own lawyers, demonstrated that petitioners had understood what the injunction required. *Id.* at 74-85. In addition, the court emphasized that the context in which the injunction was entered made clear that any weight-loss claims needed to be supported by RCTs on the products themselves. *Id.* at 86-87. The court noted that its summary judgment order, issued just weeks before the injunction, had held that "'competent and reliable scientific evidence'" required RCTs for weight- and fat-loss claims, and that the injunction had used that "very same" language. *Id.* at 87.

The district court next determined that the Commission had shown by clear and convincing evidence that petitioners had violated the injunction, since no RCTs had been performed on any of the four products at issue. Pet. App. 104-151. The court ordered sanctions to compensate consumers for petitioners' violations, emphasizing petitioners' "intentional defiance" of the court's orders and "the pervasiveness of their contumacious conduct." *Id.* at 159-163.

4. The court of appeals affirmed. Pet. App. 1-26.

The court of appeals first held that petitioners had waived any objection to the clarity of the injunction. Pet. App. 12-19. It explained that petitioners were "calculating actors who stayed silent concerning the purported ambiguity about which they now complain" and then "deliberately engaged in self-serving activities they knew seriously risked violating the injunction." *Id.*

at 14-15. The court rejected petitioners' argument that 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." *Id.* at 18. The court explained that the requirement of a product-specific RCT for the types of claims at issue was not an "unexpected interpretation" but had been well known to petitioners and their lawyers for years. *Ibid.*

The court of appeals next held that the district court had not clearly erred in finding that petitioners' evidence failed to substantiate their claims. Pet. App. 19-23. The court of appeals emphasized the district court's "detailed," "extensive reasoning," finding it supported by the evidence. *Id.* at 20-22. The court of appeals further observed that the district court had found many of petitioners' experts to be either unqualified or not credible. *Id.* at 21-22.

Finally, the court of appeals rejected petitioners' argument that the district court had impermissibly shifted to them the burden of disproving contempt. Pet. App. 23. The court of appeals determined that the district court had properly placed the burden on the Commission to show, by clear and convincing evidence, that petitioners had violated the injunction. *Ibid.* The court of appeals concluded that the Commission had met that burden by proving that petitioners "were again making weight- and fat-loss claims about products without having RCTs on the products themselves, even though the [district] court had held that only RCTs on the products themselves could be 'competent and reliable scientific evidence' the last time." *Ibid.*

ARGUMENT

Petitioners challenge (Pet. 13-36) the court of appeals' holdings that they had waived their challenge to the injunction's clarity and that they had adequate notice of the substantiation standard required to comply with the injunction. The court of appeals' unpublished decision is correct and does not conflict with any decision of this Court or of any other court of appeals. Further review is not warranted.

1. Petitioners contend (Pet. 23-36) that they did not waive their challenge to the clarity of the injunction's requirement of "competent and reliable scientific evidence." The court of appeals correctly held that petitioners had waived any such challenge. Pet. App. 12-19.

a. Courts sometimes may be required to issue injunctions of a "generality * * * necessary to prevent further violations where a proclivity for unlawful conduct has been shown." *McComb* v. *Jacksonville Paper Co.*, 336 U.S. 187, 192 (1949). When that occurs, defendants cannot avoid civil contempt by "undert[aking] to make their own determination of what the decree meant"—knowing that "they acted at their peril"—and contending that "the plan or scheme which they adopted was not specifically enjoined." *Ibid.* Put differently, civil contempt sanctions are available if a defendant is not an "unwitting victim[] of the law" but rather has taken "a calculated risk * * * under the threat of contempt." *Id.* at 193.

The court of appeals here applied *McComb*'s "common-sense" conclusion that a defendant cannot avoid civil contempt by "staying silent about purported ambiguities" in an injunction, "deliberately engaging in activities that risk violating" it, and then "pleading ignorance after those risky activities are indeed found to

violate the injunction." Pet. App. 12. The court explained that petitioners were "calculating actors" who had "deliberately engaged in self-serving activities they knew seriously risked violating the injunction." *Id.* at 14-15. Although petitioners now suggest (Pet. 24) that they merely neglected to "immediately object to even latent uncertainties when [the] injunction [wa]s entered," the court found that they had affirmatively and repeatedly declined opportunities to contest the injunction's standard of "competent and reliable scientific evidence," and that they understood the consequences of that choice. See Pet. App. 15-16.

Petitioners contend (Pet. 25) that this case is governed not by *McComb* but by three subsequent decisions—*International Longshoremen's Ass'n* v. *Philadelphia Marine Trade Ass'n*, 389 U.S. 64 (1967), *Schmidt* v. *Lessard*, 414 U.S. 473 (1974) (per curiam), and *Granny Goose Foods, Inc.* v. *Brotherhood of Teamsters & Auto Truck Drivers*, 415 U.S. 423 (1974)—that they assert "painted" *McComb*'s holding "into a corner." But none of those decisions discussed *McComb* or addressed a failure to promptly apprise the district court of an alleged ambiguity in an injunction. In *Schmidt*, the parties had sought timely clarification from the district court. 414 U.S. at 476 n.1. In *Longshoremen*, counsel likewise asked the district court for clarification several times, yet the court "steadfastly refused to explain the meaning of the order." 389 U.S. at 70-71. And in *Granny Goose Foods*, the underlying temporary restraining order had expired by the time of the conduct that had allegedly violated it, so the Court did not interpret a duly issued injunction at all—much less one to which the bound party had failed to object. 415 U.S. at 431-433; see *Tivo Inc.* v. *Echostar Corp.*, 646 F.3d 869,

887 (Fed. Cir. 2011) (en banc) (distinguishing *Granny Goose* and *Longshoremen* on similar grounds).

In a related vein, petitioners contend (Pet. 27-28) that applying the waiver doctrine in civil contempt proceedings relieves the complaining party of its burden to show that the injunction was clear and unambiguous. That argument is incorrect. Here, the court of appeals was "satisfied that the FTC ha[d] carried its prima facie burden of showing the clarity of the injunction," Pet. App. 17, and the district court likewise properly placed on the Commission the burden to establish the elements of contempt, see *id.* at 69-70.

b. Petitioners assert (Pet. 25) that the court of appeals' decision deepens a circuit split over whether "defendants can challenge the specificity of an injunction in contempt proceedings." No such circuit split exists or is implicated here.

As an initial matter, the court of appeals' unpublished decision here does not establish binding precedent in the Eleventh Circuit. See Pet. App. 2. As a result, it cannot "add[] to" any circuit split, as petitioners contend (Pet. 25).

In any event, the court of appeals did not hold that defendants can *never* challenge the specificity of an injunction in contempt proceedings. Instead, it merely found that, on these facts, petitioners had affirmatively waived any challenge to the injunction's requirement of "competent and reliable scientific evidence." See Pet. App. 16 (finding waiver because petitioners "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 now

plead ignorance"). None of the decisions on which petitioners rely involved a defendant who failed to seek clarification of a known purported ambiguity despite several opportunities to do so. And none of those decisions held that the doctrine of waiver is categorically inapplicable in contempt proceedings—or even discussed waiver at all. See *H. K. Porter Co.* v. *National Friction Prods. Corp.*, 568 F.2d 24, 26-27 (7th Cir. 1978) (concluding that a judgment incorporating the parties' settlement agreement was not a true injunction that could trigger a contempt finding); *Williams* v. *United States*, 402 F.2d 47, 48-49 (10th Cir. 1967) (rejecting defendant's argument that an injunction was insufficiently specific); *Russell C. House Transfer & Storage Co.* v. *United States*, 189 F.2d 349, 351 (5th Cir. 1951) (finding that an injunction was not broad enough to prohibit defendant's conduct).

2. Petitioners contend (Pet. 28-36) that the court of appeals' waiver ruling "stripped" them of their right to appeal the injunction. Pet. 28 (emphasis omitted). They assert (Pet. 29) that, because the district court decided "on the merits" that the injunction was specific enough, the court of appeals was powerless to find waiver. That contention misapprehends both decisions below.

a. The court of appeals concluded that the district court *had* found waiver and had addressed the substance of petitioners' arguments only in the alternative. Pet. App. 17-18. The court of appeals observed that the district court had "expressed doubt that [petitioners' ambiguity] arguments were properly before it." *Id.* at 18. And the court of appeals stated that "there can be no doubt that the district court in fact concluded that the defendants had waived their ambiguity arguments." *Ibid.*

Petitioners contest (Pet. 34) the court of appeals' characterization of the district court's decision, relying in large part on the district court's statement that "the court does not find the absence of a timely appellate challenge dispositive," Pet. App. 86. But that observation does not indicate that the district court rejected waiver. Rather, it shows that the district court viewed the lack of an appeal as merely one of petitioners' several failures to "object to any of the provisions that they ostensibly challenge now." *Id.* at 85; see *id.* at 84-86. Given that, the court of appeals reasonably concluded that the district court in fact found waiver. See *id.* at 18. And in all events, that factbound question about the appropriate construction of the district court's decision does not warrant this Court's review.

If a district court relies on "multiple rationales"—including both waiver and a claim's lack of substantive merit—a court of appeals "can affirm on any basis." Pet. App. 18. This Court has never suggested to the contrary, as petitioners acknowledge. See Pet. 29; cf. *Washington* v. *Confederated Bands & Tribes of the Yakima Indian Nation*, 439 U.S. 463, 476 n.20 (1979) (explaining that a prevailing party is "of course free to defend its judgment on any ground properly raised below"). Petitioners instead rely (Pet. 29) on "another line of cases" concerning this Court's jurisdiction to review questions passed on by a state court, though not pressed by the parties there. See *Schad* v. *Arizona*, 501 U.S. 624, 630 n.2 (1991) (opinion of Souter, J.); *Orr* v. *Orr*, 440 U.S. 268, 274-275 (1979). Those decisions are inapposite. The question here is not whether a reviewing court has jurisdiction to review questions passed on by a lower court, but whether a reviewing court *must* address a merits question if a lower court has rejected

a claim both because it was waived and because it lacks merit.

b. Petitioners contend (Pet. 30) that the courts of appeals are divided over whether they are required, or merely permitted, to address a question that was waived or forfeited in the district court yet decided on the merits there. Even assuming that some division exists among the courts of appeals, this case does not implicate it.

First, as discussed, the court of appeals concluded only that it could find an issue waived on appeal where, as one of "multiple rationales," a district court had "in fact concluded that the defendants had waived their * * * arguments." Pet. App. 18. By contrast, petitioners identify (Pet. 31-32) decisions from six courts of appeals that treated an issue as preserved where a district court decided it solely on the merits despite circumstances that might have suggested waiver. See *United States* v. *Clariot*, 655 F.3d 550, 556 (6th Cir. 2011) (finding issue preserved where "[n]o one disagree[d] that the district court addressed the issue"); *PFS Distribution Co.* v. *Raduechel*, 574 F.3d 580, 598 (8th Cir. 2009) (finding appellate review appropriate where "the district court did address the arguments"); *Blackmon-Malloy* v. *United States Capitol Police Bd.*, 575 F.3d 699, 707 (D.C. Cir. 2009) (finding appellate review appropriate where the district court "clearly addressed the merits"); *Negrón-Almeda* v. *Santiago*, 528 F.3d 15, 26 (1st Cir. 2008) (finding issue preserved where the district court addressed it "head-on" and "without reservation"); *United States* v. *Hernandez-Rodriguez*, 352 F.3d 1325, 1328 (10th Cir. 2003) (considering issue that the district court "raised * * * *sua sponte*"); *Moriarty* v. *Svec*, 164 F.3d 323, 328 (7th Cir. 1998) (rejecting argument

that an appeals court "cannot consider the merits" of a theory that was actually "relied upon in deciding the case") (citation omitted). Far from discussing the merits "without reservation," *Negrón-Almeda*, 528 F.3d at 26, the district court here described in detail petitioners' repeated failures to object to the injunction. See Pet. App. 84-86.

Second, petitioners assert that the Eleventh Circuit itself has issued a published decision adopting their preferred rule, under which a litigant is "entitled to challenge" a district court ruling on an argument that the litigant failed to preserve before the district court itself. Pet. 33 (quoting *Hi-Tech Pharms., Inc.* v. *HBS Int'l Corp.*, 910 F.3d 1186, 1194 (11th Cir. 2018)). Even if the unpublished decision here could be construed to adopt a conflicting view, it would not affect the prevailing rule in the Eleventh Circuit. And to the extent petitioners rely on any "equivocation" within the Eleventh Circuit, Pet. 32, that would not justify this Court's review, as "[i]t is primarily the task of a Court of Appeals to reconcile its internal difficulties." *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957) (per curiam).

Finally, even if this case implicated a circuit conflict, this Court's review would not be warranted. The Court "do[es] not often review the circuit courts' procedural rules," including rules about waiver. See *Joseph* v. *United States*, 574 U.S. 1038, 1040 (2014) (Kagan, J., respecting the denial of certiorari).

3. Petitioners separately contend (Pet. 14-23) that the court of appeals erred in determining that they had fair notice of the injunction's requirements.

a. To the extent petitioners are repurposing the arguments made before the court of appeals "that the injunction is too ambiguous to be enforced," the court did

not reach that question. Pet. App. 12. Instead, as discussed above, the court found that this argument was waived. *Id.* at 12-19. And the court of appeals' waiver decision does not independently warrant this Court's review. See pp. 10-16, *supra*.

In any event, petitioners' challenge to the clarity of the injunction lacks merit. Federal Rule of Civil Procedure 65(d) requires an injunction to "state its terms specifically" and "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65(d)(1)(B) and (C). The Rule is meant "to prevent uncertainty and confusion" by those bound by an order "too vague to be understood." *Lessard*, 414 U.S. at 476; see *Abbott* v. *Perez*, 138 S. Ct. 2305, 2321 (2018) ("Rule 65(d) protects the party against which an injunction is issued by requiring clear notice as to what that party must do or refrain from doing.").

Petitioners received the required clear notice here. The injunction barred petitioners from representing that their products cause a rapid or substantial loss of weight or fat, or that they affect human metabolism, appetite, or body fat, unless those representations are supported by "competent and reliable scientific evidence." Pet. App. 244. It defined "[c]ompetent and reliable scientific evidence" as "tests, 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 by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 234.

Petitioners assert (Pet. 14-15) that "no reasonable person would have understood [the] text" of the injunction to require RCTs on the specific weight-loss products at issue. But in its then-recent order granting the Commission's motion for summary judgment, the district court had construed the term "competent and reliable scientific evidence" in precisely that way as applied to petitioners' weight-loss products. Pet. App. 316-317. The court's incorporation of the same standard into the injunction itself clearly apprised petitioners that weight-loss claims were required to be substantiated by RCTs, or at least equivalently reliable evidence. Petitioners' own lawyers interpreted the injunction the same way and advised petitioners accordingly. *Id.* at 6-7. And petitioner Wheat also understood the injunction that way, as he acknowledged in several communications. *Id.* at 15, 110 & n.23. To the extent the court of appeals addressed the clarity of the injunction in the course of its waiver determination, it thus properly observed that, "[a]t the very least, * * * the defendants were on notice that RCTs were likely to be required." *Id.* at 18-19.

Petitioners appear to contend (Pet. 12, 16-17, 23) that a party who is alleged to have violated an injunction cannot be subjected to contempt sanctions if a court or restrained party must look to *any* evidence outside the four corners of the injunction to determine its application to a particular factual context. But petitioner relies on decisions criticizing injunctions that did not impose the relevant standards in a standalone document, or that merely cross-referenced another document for their substance. See, *e.g.*, *Auto Driveaway Franchise Sys., LLC* v. *Auto Driveaway Richmond, LLC*, 928 F.3d 670 (7th Cir. 2019); *Farmer* v. *Banco Popular of N. Am.*,

557 Fed. Appx. 762 (10th Cir. 2014); *Max's Seafood Cafe ex rel. Lou-Ann, Inc.* v. *Quinteros*, 176 F.3d 669 (3d Cir. 1999). By contrast, the relevant standard at issue here ("competent and reliable scientific evidence") appears within the injunction itself. Pet. App. 244. And courts routinely uphold injunctions that use a term of art or otherwise require resort to outside sources to determine how the terms of the injunction apply to certain facts. See, *e.g.*, *Tivo Inc.*, 646 F.3d at 882-883 (explaining that, in patent cases, "[t]he primary question on contempt should be whether the newly accused product is so different from the product previously found to infringe that it raises 'a fair ground of doubt as to the wrongfulness of the defendant's conduct'") (citation omitted).

Indeed, this Court has recognized that the level of specificity that petitioners appear to demand is not practical for many injunctions. Requiring an injunction to delineate all possible specific violations—rather than identify a general class of identifiable, impermissible behavior—"would give tremendous impetus to [a] program of experimentation with disobedience of the law" and would "operate to prevent accountability for persistent contumacy." *McComb*, 336 U.S. at 192-193. The Court reaffirmed a similar principle in *FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374 (1965), where it rejected a challenge to the specificity of a Commission cease-and-desist order. The Court explained that such orders must be "'sufficiently clear and precise'" to be understood, but also broad enough to encompass possible variations in wrongdoing—especially where the bound parties have already "been caught violating the [FTC] Act." *Id.* at 392, 395 (citation omitted). The Court accordingly upheld the challenged order, which it found

was "as specific as the circumstances will permit." *Id.* at 393; see *Boyce Motor Lines, Inc.* v. *United States*, 342 U.S. 337, 340 (1952).

Petitioners' several other attacks on the clarity of the "competent and reasonable scientific evidence" standard likewise lack merit. First, petitioners contend (Pet. 2-3, 20-21) that the Commission "changed its mind" about the substantiation required for their claims and improperly sought to "reinterpret" the injunction by reading a more stringent requirement "backwards into" it. To the contrary, the Commission has maintained from the beginning of this litigation that weight-loss claims for petitioners' dietary supplements must be substantiated by product-specific RCTs. See D. Ct. Doc. 172-1, at 40 (Aug. 24, 2007). Indeed, the district court found that at "no point in the nine years after the summary judgment order and injunctions were entered did anyone from the FTC tell the defendants that *anything but* RCTs were required." Pet. App. 89.

Second, petitioners emphasize (Pet. 17) the general principle that the Commission's standard of "'competent and reliable scientific evidence'" is "flexible" and "varies by product." Although that is true, the district court found in 2008 that the same kinds of claims for the same kinds of products at issue here require product-specific RCTs. See Pet. App. 316. That finding, combined with several indicators of petitioners' actual knowledge "that RCTs were likely to be required" for the advertising claims at issue, *id.* at 18-19, made sufficiently clear the application of the "competent and reliable scientific evidence" standard in the circumstances here. And contrary to petitioners' repeated assertion (*e.g.*, Pet. i, 1, 2, 13), the district court did not require the equivalent of a drug-level clinical trial. See Pet.

App. 109-115. Indeed, the court of appeals found that the district court had not necessarily required RCTs themselves but had "used as the standard the level of reliability and competency afforded by RCTs on the advertised products." *Id.* at 23.

Third, petitioners suggest (Pet. 20) that the Commission was forbidden from taking the position in this litigation that RCTs are required for certain weight-loss products, because it should have made that stance clear in formal rulemaking. But agencies have broad discretion in deciding whether to proceed by case-by-case adjudication or rulemaking. See, *e.g.*, *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947). Petitioners provide no reason to cabin that discretion for the specific types of weight-loss marketing claims at issue here. And here, the Commission sought and obtained from the district court a summary-judgment decision holding that RCTs were required to substantiate petitioners' weight-loss claims.

b. The district court did not clearly err when it found that petitioners lacked competent and reliable scientific evidence to substantiate the particular claims at issue. Pet. App. 19-24. As the court of appeals observed, "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." *Id.* at 20. That analysis included the district court's assessment of the qualifications and credibility of the Commission's experts, as compared to the "lacking" credentials and "disturbing" credibility problems it perceived with some of petitioners' experts. *Id.* at 21. The court of appeals ultimately determined that the district court had not clearly erred

in finding that petitioners had failed to introduce substantiation evidence "as reliable and as competent as results derived from RCTs on the marketed products." *Id.* at 23. That factbound application of the clear-error standard was correct and does not warrant this Court's review.

4. Petitioners briefly suggest (Pet. 21 n.5) that this Court should grant the petition, vacate the decision below, and remand for further consideration in light of *Liu* v. *SEC*, 140 S. Ct. 1936 (2020). In *Liu*, the Court determined that Congress had incorporated equitable principles into 15 U.S.C. 78u(d)(5), so that the SEC in a civil enforcement action can obtain disgorgement only of "a defendant's net profits from wrongdoing." 140 S. Ct. at 1946. But petitioners' passing argument about the amount of the district court's contempt sanction here has been forfeited. Petitioners did not press below, and the court of appeals did not pass on, any argument that the $40 million sanction was improperly calculated based on gross revenues rather than net profits. In addition, the limitation announced in *Liu* does not apply to civil contempt proceedings, where a court's power extends to "the requirements of full remedial relief." *McComb*, 336 U.S. at 193; see Pet. App. 160-161, 163 (finding that "consumer redress in the amount of the gross receipts" was an appropriate contempt sanction, particularly in light of petitioners' "pattern of contemptuous conduct" and "intentional defiance of the court's injunctions").

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 2020