No. 25-959

IN THE

Supreme Court of the United States

CAREDX, INC.,

Petitioner,

v.

NATERA, INC.,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Third Circuit

BRIEF OF RESPONDENT IN OPPOSITION

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Question Presented

Whether the Third Circuit correctly held that, in a Lanham Act false advertising case, CareDx, Inc. could not avail itself of an inference that consumers were deceived and made purchasing decisions based solely on the defendant's intent where CareDx failed to object to an instruction that foreclosed that inference and did not challenge that instruction on appeal, and an inference would have been unreasonable in any event based on undisputed evidence that the consumers at issue, sophisticated transplant nephrologists, do not rely upon advertising in making medical decisions?

Parties to the Proceeding and Related Proceedings

There are no parties to the proceedings or related proceedings other than those identified in CareDx's Petition. *See* Pet.ii.

Rule 29.6 Statement

Natera, Inc. is a publicly traded corporation identified by the stock ticker NTRA. Natera, Inc. does not have a parent corporation, and no publicly held company owns 10% or more of its stock.

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Introduction

CareDx, Inc. claims the courts of appeals have split 6-1 over whether, in Lanham Act false advertising cases, evidence that a defendant engaged in deliberately false advertising gives rise to a rebuttable presumption that consumers were deceived by and relied upon the false advertising. *See* Pet.i. It argues this case is the "perfect vehicle" to resolve the split, claiming the Third Circuit has shown no interest in joining "the mainstream of false advertising law." *Id.* at 2, 10. And it claims that the issue is "outcome determinative here." *Id.* at 2. CareDx is wrong on all fronts.

The split CareDx claims is imagined. Although the Third Circuit has not adopted the presumption, it has not rejected it, either. CareDx understood this in the court below, insisting that the Third Circuit "has never held that it applies a different standard than" circuits that have adopted a presumption. CareDx 3d Cir. Br. 54. CareDx correctly recognized that the Third Circuit "*explicitly left open* the question whether to apply such a presumption" in *Johnson & Johnson – Merck Consumer Pharms. Co.* v. *Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125, 132 (3d Cir. 1994). *Id.* (emphasis added). And it emphasized at the rehearing stage that "*Johnson* declined to pass on the validity of the presumption itself and certainly never addressed the permissibility of a jury inference on the type of facts presented here." CareDx Rhrg. Pet. 12. Though CareDx now argues *Johnson* created the split, *see* Pet.2, 9-10, 14-16, its arguments to the Third Circuit about that decision—and *Johnson*'s express reservation on the issue of whether to adopt a presumption, 19 F.3d at 132—plainly contradict the position it is taking in this Court.

More problematic for CareDx, it never asked the Third Circuit or the district court to adopt a burden-shifting presumption, and this case therefore does not implicate the issue on which CareDx alleges there is a split. CareDx concedes it "did *not request the application of a presumption* of actual consumer deception." Pet.27 (emphasis added). In fact, it acquiesced to a contrary jury instruction. *See* Pet.App.26a-27a n.38.

Having forfeited the issue on which CareDx alleges there is a circuit split, CareDx belatedly asked the Third Circuit to decide a different, fact-bound question: whether "a jury may *infer* consumer deception and reliance upon finding that an advertising campaign is deliberately false." Pet.i (emphasis added). But there is no split on this point either, and in any event, this case is no vehicle to resolve the issue of a permissible inference—for multiple reasons.

As the Third Circuit noted, "the District Court instructed the jury, *without objection*, that (1) there was 'no presumption here for the [false advertising] damages question,' and (2) that [CareDx] was required to prove by a preponderance of the evidence that 'the defendant's false advertising *actually deceived a portion of the purchasing public in that customers relied on the false advertising in making a purchasing decision*,' and as a result, '[CareDx] sustained injury.'" Pet.App.26a-27a n.38 (emphasis added).

That instruction, which required proof of actual consumer deception, reliance, and injury, foreclosed the application of a permissible inference based solely on the defendant's intent. As the Third Circuit explained, and CareDx nowhere disputes, there was a complete "absence of evidence in the record to prove

actual deception." *Id.* As a result, the Third Circuit held that the district court did not err in vacating the damages award. *Id.* at 24a-27a & n.38.

There is no error in the Third Circuit's application of fact to the specific instructions CareDx agreed would govern its case. And CareDx does not claim otherwise.

CareDx argues instead that the panel applied an "entrenched" Third Circuit "rule" foreclosing the possibility of a "permissive inference" in that circuit. But that argument is premised on a view of *Johnson* that CareDx itself refuted below—nothing in *Johnson* foreclosed application of an inference; it was foreclosed by the jury instructions to which CareDx readily agreed. In any event, CareDx misreads the Third Circuit's decision below. There, the panel acknowledged that it "might be so" that an inference is reasonable in any given case—suggesting the possibility of an inference is not foreclosed in Third Circuit. Pet.App.26a-27a n.38. But, it pointed out, CareDx agreed to an instruction incompatible with the inference it later sought, and CareDx did "not challenge the instruction" on appeal. *Id.*

Besides, the panel's decision made no precedent. It was an unpublished decision that does not prevent future panels from adopting an inference based on knowingly false advertising if the evidence permits.

Compounding these problems for CareDx, neither a presumption nor an inference would have been appropriate on the facts of this case. The jury heard undisputed testimony from witnesses for both parties that the consumers at issue here, sophisticated

transplant nephrologists, do not rely upon advertisements in making medical decisions about their patients. And even if the record were otherwise, the jury was not instructed on the standard for deliberateness necessary to support a presumption or an inference. CareDx asks this Court to adopt an inference of actual deception and reliance based on a "deliberately false advertising campaign," but the only relevant instruction—a general instruction on intent and willfulness—permitted the jury to apply a lesser "should have known" standard.

The upshot is that nothing in the petition warrants review by this Court. There is no split, and CareDx concedes this case doesn't even implicate the split it purports to identify. CareDx agreed to jury instructions that foreclosed the question it actually presents to this Court. The issue of intent is not outcome determinative because the inference CareDx seeks would have been unreasonable on this record, and the jury was not properly instructed on the requisite deliberateness standard. Finally, it is far from obvious that the issues CareDx identifies are as important and recurring as it claims. The Third Circuit left open the issue of a presumption over 30 years ago, and yet no party—not even CareDx—has sought to revisit the issue since.

The Court should deny the petition.

Statement

1. In October 2017, CareDx launched AlloSure, a test for detecting organ transplant rejection based on DNA originating from the transplanted organ, known as donor-derived cell-free DNA ("ddcfDNA"). CareDx

marketed AlloSure to a small community of highly sophisticated physicians specializing in kidney transplants (transplant nephrologists).

Natera, long a pioneer in cell-free DNA testing, developed its own ddcfDNA test, which reached market in 2019 as Prospera. It was AlloSure's first competitor.

During development of Prospera, Natera's scientists worked with a highly regarded professor of surgery at the University of California San Francisco to test Prospera's efficacy using a biorepository of samples. Natera's marketing materials made comparisons between accurately recited, footnoted results from that study (referred to as "Sigdel") and accurately recited, footnoted results from a study carried out on AlloSure (referred to as "Bloom")—*e.g.*, Prospera's "AUC" (a composite measure of sensitivity and specificity) of 0.87 identified in Sigdel is greater than AlloSure's 0.71 AUC identified in Bloom. Some of these "cross-study" comparisons had appeared almost verbatim in Sigdel; others also cited different, non-Bloom studies.

At issue in this case were ten allegedly false representations of fact, nine of them based on cross-study comparisons. Of those ten, however, most involved variations of the same statement that Sigdel's measurements of Prospera's sensitivity and AUC were higher than Bloom's measurements of AlloSure's sensitivity and AUC. *See* Appx.668-77.

The jury found one of the ten statements true: Prospera was unique in its ability to detect T-cell mediated rejection; CareDx's test could not. Appx.676.

CareDx's petition focuses on two of the nine statements found false: (1) the comparative statement that Prospera was "more sensitive and specific" than AlloSure, which, if read as "more sensitive *and* [*also more*] specific," is inconsistent with the studies' findings that the tests were equally specific; and (2) a noncomparative representation, found by the jury to be implicit in a single slide of an industry-conference presentation, that Prospera was effective in pediatric patients.[1]

2. In April 2019, CareDx sued Natera under the Lanham Act and Delaware law, alleging that Natera's advertising was false and misleading. In response, Natera brought false advertising counterclaims.

Shortly before trial, CareDx abandoned by stipulation any argument that the advertising claims it challenged were "misleading." Pet.App.33a-34a. It would instead rely solely on a theory of "literal falsity"—specifically, the so-called "establishment claim" doctrine, which applies to advertisements based on scientific

[1] On cross-appeal below, Natera argued that accurate, explicit, footnoted cross-study comparisons cannot as a conceptual matter be "literally false," but only "misleading." *See* Pet.App.15a n.23. It also argued that the "more sensitive and specific" and pediatric claims were inherently ambiguous, especially to this specialized audience. Natera's construction of "sensitive and specific" refers to "AUC" (a composite measure of sensitivity and specificity), whereas CareDx's construction required the jury to add words to the phrase: "more sensitive and [*also* more] specific." *See* Pet.App.13a n.20. As for the purported pediatric claim, the slide in which it appears lists basic demographic information about study participants; it does not claim efficacy in pediatric populations. *See* Pet.App.21a. The district court and Third Circuit did not agree, and Natera has not sought further review of these rulings.

studies. *See* Pet.App.11a-12a. In one way, this made things easier for CareDx; had it pursued a misleadingness theory, it would have had to prove actual deception to establish liability for any relief, including an injunction. *E.g.*, *Warner-Lambert Co.* v. *Breathasure, Inc.*, 204 F.3d 87, 92 (3d Cir. 2000). But that tactical decision did not relieve CareDx's burden to prove Natera's liability for damages, which requires a separate showing that customers were actually deceived by and relied on a false statement when making a purchasing decision. *See Parkway Baking Co.* v. *Freihofer Baking Co.*, 255 F.2d 641, 648 (3d Cir. 1958).

As noted, the challenged advertisements—excerpts from brochures, press releases, and presentations—provided footnotes and references to the source and the underlying data for each proposition. The evidence showed that doctors find those important. As explained by Dr. Phillipe Gauthier, a practicing transplant nephrologist and Natera's director of organ health, kidney transplant physicians make decisions based on data and scientific literature, not advertisements. That is, physicians are "going to do the research independently of the marketing material before they make a decision regarding how to care for their patients," because "we're not talking laundry detergent here." Appx.1246-47 (Tr.625:21-626:7). CareDx's expert witness, Dr. Steven Weisbord, agreed that he orders tests based on "data"; he does not "order drugs or tests based on a brochure." Appx.1401-02 (Tr.780:24-781:11).

CareDx did not present any evidence to the contrary. It did not call or identify any doctors who had even seen Natera's brochures, presentations, or press releases—let alone a doctor who chose Prospera

instead of AlloSure based on any statement in those materials. It did not introduce any documents or customer communications concerning Natera's marketing claims that might have suggested any effect, let alone a *decisive* effect, on ultimate purchasing decisions. And at a more fundamental level, it failed to present evidence showing how or why a transplant nephrologist would rely on commercial advertising materials *at all* when choosing what test to order for a patient—particularly when the arrival of a first competitor in this small, specialized market would already motivate doctors to look at more than a leaflet.

CareDx focused instead on a collection of internal Natera communications and the remarks of Natera witnesses showing internal disagreements about what Natera should and should not claim, and in what terms it should make its claims—evidence the Third Circuit later found to support a jury finding of "willful conduct" under a knew-or-should-have-known standard. *See* Pet.App.25a-26a.

At the close of evidence, Natera moved for judgment as a matter of law on liability and damages. The district court "reserv[ed] judgment," stating it was "going to let the case go to the jury" but observing that it "s[aw] very, very weak claims": "I don't see the real falsity. I don't see the damages." Appx.1918 (Tr.1293:8-21). Nonetheless, because the district court "th[ought] [the jury]'d like to rule on the case," it let the claims go to the jury. Appx.1912 (Tr.1289:8-25).

CareDx did not seek jury instructions on the presumption or inference it now urges this Court to adopt. It did not request an instruction that actual deception and reliance could be presumed from a finding

of deliberate falsity. It did not request an instruction on a "permissive inference" of actual deception and reliance from deliberate false advertising, either. It did not object when the district court affirmatively told the jury there is *no* presumption. Pet.App.26a-27a n.38; Pet.App.34a-35a. Just as importantly, CareDx agreed to an instruction to the opposite effect: To obtain damages, CareDx had to prove by a preponderance of the evidence that customers had actually been deceived by and "relied on the false advertising in making a purchasing decision." Pet.App.26a-27a n.38; Pet.App.34a-35a.

Nor did CareDx request an instruction on the threshold scienter standard—a "deliberately false" advertising campaign—necessary for this Court to apply a presumption or inference. Instead, the jury was given a generic instruction asking it to find whether any of the false advertising statements were made "intentionally and willfully." And the instruction on willfulness defined that term to include a should-have-known standard: "When the person committing the violation knew or should have known that the conduct was of the nature prohibited." Appx.2084 (Tr.1459:16-21).

The jury found Natera liable for false advertising on nine of the ten claims. Pet.App.3a. It found no liability for an advertisement stating that Prospera had a "unique ability to identify T-cell mediated rejection," Pet.App.22a-23a n.36—the only product attribute for which the record showed Prospera's superiority could "make a big commercial difference." Appx.1627 (Tr.1004:5-14). The jury also found Natera had "intentionally and willfully" engaged in false advertising. Pet.App.7a. It awarded $21.2 million in compensatory

damages on all claims and $24.7 million in punitive damages under Delaware law. Pet.App.30a-31a.[2]

3. The district court granted Natera's renewed motion for judgment as a matter of law on damages and, in part, on liability. Pet.App.29a-43a. It ultimately held that there was a sufficient basis for the jury to find all nine statements both unambiguous and literally false, whether through the "establishment claim" doctrine or a falsity-by-necessary-implication theory. Pet.App.39a-41a, 50a-62a. At the same time, the district court held that the evidence CareDx identified in its briefing was insufficient to establish actual deception and reliance, which are required to prove liability for damages under the Lanham Act. Pet.App.34a-38a. This also precluded findings of causation and harm under Delaware common law. Pet.App.38a-39a, 41a-42a.

The issue of a presumption or an inference was barely before the district court. As noted, CareDx had not sought an instruction on a presumption or an inference. It did not affirmatively argue that the court should adopt or apply a presumption or an inference in its post-trial briefing. It broached the subject obliquely, observing that "[c]ourts routinely recognize that deliberately false advertising campaigns, in which substantial resources are devoted, support a reasonable inference that customers were actually deceived." *See* CareDx JMOL Opp. Br. 4-5. It cited cases from other circuits for that proposition, but beyond

[2] The jury found against CareDx on one of Natera's false advertising counterclaims, and CareDx did not appeal that ruling.

parenthetical quotations from several cases said nothing more on the subject. *Id.*

The district court correctly observed that the cases CareDx cited were from "circuits that have held that actual deception may be presumed," and that the Third Circuit is not one of them. Pet.App.37a-38a. It vacated the jury's award of damages but conditionally granted a new trial on damages and unfair competition liability in the event the Third Circuit disagreed. Pet.App.43a.

At the same time, because proof of actual deception and reliance is not necessary to enjoin a defendant from making statements deemed literally false, the district court entered a permanent injunction as to the nine advertising claims the jury found to be false. Thus, CareDx received an injunction, but the district court held it had failed to prove its entitlement to damages.

4. CareDx appealed the vacatur of the damages award, arguing that the Third Circuit could apply an inference on which the jury was never instructed to uphold the jury's award of damages. In doing so, CareDx did not argue for a presumption, but it was adamant that the Third Circuit had never ruled on one. The Third Circuit, CareDx explained, "has never held that it applies a different standard than" circuits with a presumption and "has explicitly left open the question." CareDx 3d. Cir. Br. 54. Both a presumption *and* a permissive inference, it clarified, were open questions: "That this Court has *not yet adopted* a legal presumption *hardly constitutes a rule* that a factual inference of reliance is impermissible." CareDx 3d. Cir. Resp./Rep. Br. 51 (emphasis added). It therefore

urged the panel to uphold the verdict by assuming the jury drew an inference on which it was never instructed, and hold that such an inference would have been reasonable based on the record below. *Id.*

The panel affirmed the district court's decision in an unpublished opinion, Pet.App.1a-28a, and rejected CareDx's argument in a footnote, *id.* at 26a-27a n.38. It noted that CareDx "point[ed] to out-of-circuit case law" while "conced[ing] that our Court has not adopted [a] presumption." *Id.* It then held that the jury instructions to which CareDx agreed foreclosed application of the inference it sought:

> [T]he District Court instructed the jury that that (1) there was "no presumption here for the [false advertising] damages question," and (2) that the plaintiff was required to prove by a preponderance of the evidence that "the defendant's false advertising actually deceived a portion of the purchasing public in that customers relied on the false advertising in making a purchasing decision," and as a result, "the plaintiff sustained injury." Although CareDx does not challenge the instruction, it asserts that other courts of appeals' adoption of a presumption suggests that the jury's inference was reasonable. This might be so, but it ignores the absence of evidence in the record to prove actual deception.

Id.; *see* Pet.App.34a-35a. Because "[n]one of [CareDx's] evidence . . . *show[ed]* reliance and actual deception," Pet.App.24a (emphasis added), "even viewing the evidence in CareDx's favor," Pet.App.27a, the panel affirmed the vacatur of the damages award.

CareDx then sought rehearing, casting the panel decision as an intra-circuit aberration. According to CareDx, the panel's unpublished decision "br[oke] new ground and create[d] a schism with six sister circuits." CareDx Rhng. Pet. 11. It explained that the Third Circuit "had previously left open" the question of a presumption: "*Johnson* declined to pass on the validity of the presumption itself and certainly never addressed the permissibility of a jury inference on the type of facts presented here." *Id.* at 12. CareDx also faulted the district court for "erroneously conclud[ing] that the Third Circuit, in *Johnson*, had already rejected the sufficiency of [intent] evidence" to sustain an award of damages. *Id.* That, CareDx argued, was a "misreading" of *Johnson*. *Id.* And it said the unpublished panel decision "adopted a legal rule," *id.* at 1, that the Third Circuit had "never previously adopted"—the *panel's nonprecedential decision*, in other words, had adopted an "out-of-step rule." *Id.*; *contra* Pet.8 ("CareDx petitioned for rehearing en banc and by the panel, on the grounds that *the Third Circuit* should revisit *its* out-of-step rule . . . ." (emphasis added)).

The Third Circuit denied CareDx's petition for rehearing without any noted dissent. Pet.App.63a.

Reasons for Denying the Petition

The Court should deny CareDx's petition for a writ of certiorari. There is no split on the application of a presumption, and the petition does not even implicate the split it purports to identify. Instead, CareDx seeks review of a different issue—whether to adopt an inference—on which there is no split, either.

Even on application of an inference, this case provides no vehicle to review the issue: CareDx agreed to an instruction that required it to prove for purposes of damages that consumers were actually deceived by and relied upon the advertising at issue—something it admittedly did not prove.

And even if CareDx had not waived the issue it now seeks to raise, this case would be an exceptionally poor vehicle to resolve it. The undisputed evidence established that transplant nephrologists do not rely upon advertising, defeating application of a presumption or an inference, and the jury was not instructed on the proper standard of intent to boot.

Finally, it is far from obvious that the adoption of a presumption or an inference is as important and recurring as CareDx claims. The Third Circuit left the question of a presumption open more than 30 years ago, and since that time, no party—not even CareDx—has sought to revisit the issue.

I. There is no split over the application of a presumption or a permissive inference.

CareDx's hook for this Court's review is a supposed "6-1" circuit split involving several interrelated issues—deception, reliance, causation, and injury—that bear on whether a plaintiff in a Lanham Act false advertising case is entitled to damages, not just injunctive relief. CareDx's claimed split, however, is illusory.

It is far from obvious that six circuits have adopted a presumption in Lanham Act cases that intentionally false statements shift the burden to the defendant to disprove the existence of real-world reliance and

damages. For example, the D.C. Circuit opined on a presumption only in the context of an enforcement action by the Federal Trade Commission, not in a case under the Lanham Act. *See Fed. Trade Comm'n* v. *Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 36-37 (D.C. Cir. 1985). Nor is it clear that circuits mentioning the presumption have considered the statutory language, including the provision referring to "actual damages." 15 U.S.C. § 1117.

But this is all beside the point: Even if one or more courts of appeal have adopted a rebuttable presumption of deception and reliance in Lanham Act false advertising cases based on a defendant's intent, the Third Circuit *has not rejected one*, and thus there is no circuit split.

The Third Circuit has simply not been presented with an opportunity to squarely decide the issue—including in this case. As CareDx concedes, "it did not request the application of a presumption," Pet.27 (emphasis removed), so the Third Circuit had no occasion to elucidate whether or how a presumption should apply in its courts. *See* Pet.App.26a-27a n.38 (noting CareDx "concede[d] that [the Third Circuit] has not adopted this presumption" and CareDx did not object to the district court's instruction that there was "no presumption").

Nor does CareDx argue that the unpublished opinion below created the split. Rather, CareDx purports to find its split in *Johnson & Johnson – Merck Consumer Pharms. Co.* v. *Rhone-Poulenc Rorer Pharms., Inc.*, 19 F.3d 125 (3d Cir. 1994), contradicting its characterization of that decision in the Third Circuit. *See* Pet.9, 14-18; *contra* CareDx Rhng. Pet.11. Whereas

previously, CareDx argued that *Johnson* left the issue of a presumption open, it now tells this Court that *Johnson* is "entrenched Third Circuit precedent" that rendered the "question" so sufficiently "settled" that CareDx did not need to raise it at all in the Third Circuit. Pet.27-28.

But as CareDx correctly recognized below, *Johnson* did not rule out application of a presumption. In *Johnson*, the plaintiff argued that the district court erred by not instructing the jury on a "burden-shifting presumption" as it was then formulated by the Second Circuit in *Johnson & Johnson – Merck Consumer Pharms. Co.* v. *SmithKline Beecham Corp.*, 960 F.2d 294, 298-99 (2d Cir. 1992)—specifically, that "deliberate conduct" of an "egregious nature" justifies shifting the burden. *Johnson*, 19 F.3d at 131-32; *see also* Appellants' Br. 21, *Johnson & Johnson – Merck Consumer Pharm. Co.* v. *Rhone-Poulenc Rorer Pharms. Inc.*, No. 93-1349 (3d Cir. June 14, 1993), *available at* 1993 WL 13013107 (arguing that the Third Circuit should adopt the standard articulated by the Second Circuit in *SmithKline Beecham* and *Resource Devs., Inc.* v. *Statue of Liberty – Ellis Island Found., Inc.*, 926 F.2d 134, 140 (2d Cir. 1991)). The Third Circuit held that it "need not decide whether to adopt the *Smithkline Beecham* presumption" because the plaintiff's evidence did not satisfy the egregiousness standard articulated in that case. *Johnson*, 19 F.3d at 132.

A split requires at least one court of appeals to both reach and answer a legal question in a way that necessarily conflicts with how other courts of appeal answer it. There is no such decision of the Third Circuit for this Court to review. *Johnson* decided only that the

conduct in question did not satisfy the specific test the plaintiff in that case asked it to adopt. *See id.* It did not foreclose the adoption of any presumption. To the contrary, the Third Circuit expressly left open the possibility of adopting a presumption in an appropriate case. *Id.*

CareDx repeatedly agreed that *Johnson* did not resolve the question—or at least CareDx did when it was arguing these issues to the Third Circuit. There, CareDx insisted that the Third Circuit "*has never held* that it applies a different standard than" those circuits that have adopted the "presumption," and it "has *explicitly left open* the question whether to apply such a presumption in the case of deliberate and egregious conduct." CareDx 3d Cir. Br. 54 (emphasis added) (citing and quoting the express reservation of this issue in *Johnson*, 19 F.3d at 132); *see* CareDx 3d Cir. Resp./Reply Br. 51 (arguing that the Third Circuit "has not yet adopted a legal presumption").

CareDx probably put it best in its Petition for Rehearing: "*Johnson* declined to pass on the validity of the presumption itself and *certainly* never addressed the permissibility of a jury inference on the type of facts presented here." CareDx Rhrg. Pet. 12 (emphasis added). It would therefore be "erroneous[]"—an outright "misreading"—to "conclude[] that the Third Circuit, in *Johnson*, had already rejected the sufficiency of [intent] evidence." *Id.* CareDx now embraces that "error[]" and invites this Court to "misread[]" *Johnson*

to manufacture a certworthy split that simply does not exist.[3]

Seeking this Court's review of a nonprecedential decision—which by definition cannot change the law in the Third Circuit—CareDx now argues the exact opposite of what it told the Third Circuit: that *Johnson* "held that deliberate false advertising by corporations does not provide a basis for a finding of actual consumer deception," calling that holding "entrenched." Pet.9, 27; *contra* CareDx 3d Cir. Br. 54 (arguing below the Third Circuit "has never held that it applies a different standard" than other circuits). *Johnson*, CareDx now argues, established a "*rule* favorable to false advertisers." Pet.26 (emphasis added); *contra* CareDx Rhrg Pet. 1, 12 (arguing the unpublished *panel decision* "adopted a legal rule" that the Third Circuit "has never previously adopted," especially not in *Johnson*). And it now argues that then-Judge Alito's dissent provides some support for a

[3] Like CareDx, Natera did not argue below that the Third Circuit had definitively ruled on the question. Rather, it correctly pointed out that the Third Circuit "has never recognized a presumption of actual deception from evidence of willfulness" while emphasizing that "CareDx waived such an argument." Natera 3d Cir. Br. 29. That is no less true now—CareDx's turnabout notwithstanding. To be sure, Natera argued that it would be incompatible with *Parkway Baking*, 255 F.2d at 648, for the Third Circuit to adopt a "permissive inference" of actual deception and reliance by consumers based on evidence of a defendant's mental state and objectives. But the Third Circuit did not decide that question because the panel concluded the jury instructions in this case foreclosed an inference from evidence of willfulness or intent alone. Pet.App.26a-27a n.38. And just as importantly, no other decision of the Third Circuit has held that *Parkway Baking* forecloses either a presumption or an inference.

presumption. Pet.14-18. Not one of these assertions is correct.

By holding that the plaintiff couldn't satisfy the Second Circuit's standard, *Johnson* left open the possibility of adopting the presumption in some future case. *See* 19 F.3d at 132. And that would include a showing less than what the Second Circuit's test at that time required—the Third Circuit, after all, was bound by the parties' framing of the issues in *Johnson*. *E.g.*, *United States* v. *Sineneng-Smith*, 590 U.S. 371, 375 (2020) (explaining that courts "'rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present" (citation omitted)).

Nor did then-Judge Alito have anything to say about the plaintiff's failure to satisfy the Second Circuit's formulation of the presumption in *Johnson*. Rather, Judge Alito believed that the plaintiff's *survey evidence* was sufficient to prove actual deception, calling that evidence "striking." *Johnson*, 19 F.3d at 136-37 (Alito, J., dissenting). He did not comment on the presumption, *id.*—as even CareDx grudgingly admits, *see* Pet.15-16.

At most, CareDx has shown that some number of district courts within the Third Circuit believe the presumption is foreclosed, either by *Johnson* itself or the logic of *Parkway Baking*, 255 F.2d at 648—a case that required evidence of actual deception and reliance but never addressed the application of a presumption or inference. *See* Pet.16-17. Intra-circuit disagreement, however, does not create an inter-circuit split, and the Third Circuit can easily clarify the availability of a presumption in a case where the issue is

properly presented to it. Since *Johnson*, however, no plaintiff has done so—CareDx included. *See* Pet.27.

Given all this, CareDx's assertion that the Third Circuit "refused to revisit its rule en banc," Pet.2, is mystifying. CareDx's Petition for Rehearing explicitly argued that there *was no rule in the Third Circuit*—from *Johnson* or anywhere else. *See* CareDx Rhng. Pet. 12. The Third Circuit cannot be expected to "revisit [a] rule en banc," Pet.2, when a central premise of the petition is that no such rule exists.

As it must, CareDx mentions as an afterthought that the door "might" still be left open to a presumption in the Third Circuit. Pet.22. It now attributes that "suggestion" to a "commentator" ("[a]t least one"). Pet.22-24. CareDx insists this would still create a split because no other circuit has imposed an "egregious conduct" threshold. Pet.23. But even assuming *Johnson could* be read to lay down a lasting rule, *contra* CareDx Rhng. Pet. 11-12 (that would be an "erroneous[]" "misreading"), this Court is not the forum to resolve, for the first time, the scope of *Johnson*'s holding. As CareDx admits, it chose "not [to] request the application of a presumption," Pet.27—not even one for "egregious" conduct—despite Third Circuit precedent expressly declining to "pass on the validity of the presumption itself." CareDx Rhng. Pet.12.

Finally, even if the panel in the decision below had taken a more hardline view, its opinion was nonprecedential. It does not foreclose future litigants from rearguing the presumption or the inference, especially given that the Third Circuit "has never held that it applies a different standard than" other circuits.

CareDx 3d. Cir. Br. 54. There is, in short, no split here.

II. Even if the courts of appeals are split, this case is not a vehicle to resolve it.

Even if the Third Circuit had adopted the "rule" CareDx newly extrapolates from *Johnson*'s explicit reservation of the issue (*see* 19 F.3d at 132), CareDx's petition should still be denied. CareDx acknowledges it failed to request that the district court instruct the jury on a presumption and therefore failed to preserve the issue. Pet.27.

Instead, CareDx argues that the Court should take this case to review a different issue: whether the Lanham Act implicitly allows damages based solely on an inference from the defendant's mental state and conduct.

But the decision below did not cleanly decide that issue either. Rather, it grounded its resolution of CareDx's argument in an unchallenged jury instruction requiring a plaintiff to *prove* actual deception and reliance. *See* Pet.6 (citing *Parkway Baking*, 255 F.2d at 648); Pet.App.26a-27a n.38 (same). CareDx's argument that the panel foreclosed an inference ignores an instruction to which it agreed and misreads the panel's decision. And even if there were some purchase to CareDx's misunderstanding of what the panel held, that decision could not—and did not—foreclose application of an inference, because it does not establish a precedent within the Third Circuit. As a result, even on the issue of whether to adopt an inference, this case is not a vehicle to resolve it.

A. CareDx concedes this case does not implicate the claimed split over a presumption.

CareDx concedes it "did not request the application of a presumption of actual consumer deception." Pet.27. Nor does it dispute that the district court expressly instructed the jury, without any objection, that there is '"no presumption."' Pet.App. 26a-27a n.38.

CareDx claims it did not object because the Third Circuit's view on the law was "entrenched." Pet.27. But that is impossible to square with its argument below that the Third Circuit "has never held that it applies a different standard than" those circuits that have adopted the "presumption," that the Third Circuit "has explicitly left open the question whether to apply such a presumption in the case of deliberate and egregious conduct," CareDx 3d Cir. Br. 54 (citing *Johnson*, 19 F.3d at 132), and that *Johnson* did not "pass on the validity of the presumption" and "certainly never addressed the permissibility of a jury inference," CareDx Rhng. Pet. 12. The failure on CareDx's part to preserve the issue was not because the Third Circuit had adopted an "entrenched" rule. Pet.27-29. Rather, CareDx simply declined to object to the district court's instruction—whether it was oversight or tactical judgment.

In any event, even a genuine belief that the "rule" was "entrenched" would not have relieved CareDx of the obligation to object when the district court instructed the jury to the opposite effect—that '"there is no presumption here for the [false advertising] damages question."' Pet.26a-27a n.38. CareDx therefore

waived any claim that the Third Circuit should adopt a presumption. *See, e.g.*, Fed. R. Civ. P. 51(d)(1)(A); *accord Robinson* v. *First State Cmty. Action Agency*, 920 F.3d 182, 187 (3d Cir. 2019) ("Waived arguments about jury instructions may not be resurrected on appeal.").

B. This case does not implicate the question of whether a defendant's intent can give rise to an inference.

Mindful that this case does not actually implicate any split—let alone one warranting review here and now—CareDx argues that it presents a different, but allegedly "inextricably intertwined" question: whether evidence of a defendant's willfulness or intent can, by itself, allow a jury to conclude that customers were actually confused and actually relied upon the statements at issue in making purchasing decisions. Pet.28. It submits that this Court can use that issue as an opportunity to clarify whether a presumption should in fact apply. But here, too, CareDx is mistaken.

Under the parties' agreed-upon jury instructions, to establish entitlement to damages, CareDx was required to "prove by a preponderance of the evidence that 'the defendant's false advertising *actually deceived* a portion of the purchasing public *in that customers relied on* the false advertising *in making a purchasing decision*,' and as a result, 'the plaintiff sustained injury.'" Pet.App.26a-27a n.38 (emphasis added) (quoting Appx.2087-88). CareDx simply failed to submit competent evidence on this point. As the Third Circuit noted, and CareDx no longer disputes,

there was a complete "absence of evidence in the record to prove actual deception." *Id.*

CareDx did not request an instruction that the jury could infer actual deception and reliance based on evidence of Natera's willfulness or intent. Only in response to Natera's post-trial motion for judgment as a matter of law, which exposed this hole in CareDx's case, did CareDx actually articulate its "permissive inference" argument—as an *ex post* exercise to rehabilitate the jury's verdict.

The Third Circuit rightly rejected CareDx's *post hoc* effort to save the jury's verdict because it contradicted the parties' agreed-upon instructions. *See id.* But it did not, as CareDx suggests, hold that a defendant's deliberate conduct can never support an inference of actual deception and reliance. Rather, the Third Circuit wrote that it "might be so" that an inference is appropriate in any given case. Pet.App.26a-27a n.38. The problem, as the Third Circuit correctly saw it, was that CareDx had agreed to instructions that foreclosed the possibility of that inference. *See id.* CareDx did "not challenge the instruction" requiring proof of actual deception and reliance on appeal, but "it assert[ed] that other courts' adoption of a presumption suggests that the jury's inference was reasonable." *Id.* While that "might be so" in a different case, the Third Circuit observed, CareDx's argument "ignore[d] the absence of evidence in the record to prove actual deception." *Id.*

That makes sense. Allowing an inference of *actual customer behavior* based solely on a conclusion about the defendant's *mental state* or *objectives*—particularly in light of an explicit instruction that required

proof that the false advertising "'*actually deceived* a portion of the purchasing public *in that customers relied on* the false advertising *in making a purchasing decision*,'" Pet.App.26a-27a n.38 (emphasis added)—requires a non-obvious inferential leap. To be sure, some courts have opined that the existence of an intentionally false advertising campaign justifies a "powerful inference" "that the defendant has succeeded in confusing the public." *Statue of Liberty-Ellis Island Found.*, 926 F.2d at 140. But they have done so as a predicate for, and in the course of, endorsing a burden-shifting presumption, which requires an explicit jury instruction explaining the deviation from the norm. A permissive inference would no less require some instruction to the jury on how to infer actual perceptions and actions of consumers from the uncommunicated *intent* of the defendant. But there was no such instruction here.

In any event, whatever justification other courts have found for recognizing a "powerful inference," it does not apply here. The customers were not "the public"; they were a "small audience" of sophisticated organ transplant doctors. Pet.1. Their "purchasing decisions," Pet.App.26a-27a n.38, were not buying consumer goods off the shelf, but ordering medical tests for their post-transplant patients. The lay jury's common sense—ostensibly the source of the "powerful inference"—could not properly inform a judgment about how organ transplant doctors actually make decisions. And more importantly, the unchallenged instruction in this case required *proof* of what actual customers did and why. *See id.* Absent an instruction on an inference (or, for that matter, a presumption), a jury would not reasonably understand that it could

decide *why* these organ transplant doctors purchased what they did based on whether Natera *meant* to mislead in its advertisements. Such an instruction would have been particularly necessary in this case: the standard CareDx posits here is "deliberately false," but it never asked the jury to make that finding. Rather, as discussed below, the instructions allowed for a finding of willfulness based on what Natera "knew or should have known." Appx.2084 (Tr.1459:16-21).

CareDx offers a different take on the Third Circuit's reasoning. According to CareDx, when the court said "that might be so," it was referring to the possibility of an inference being reasonable *in other courts of appeals*. Pet.8. But that reading does not make sense. The court paraphrased CareDx's argument precisely as it makes that argument here: other courts of appeal have adopted a presumption, therefore "the jury's inference [in this case, in the Third Circuit,] was reasonable." Pet.App.26a-27a n.38. Adding "that might be so" means CareDx's argument *about this case, in the Third Circuit*, "might be" right about an inference being reasonable. But in concluding that the "absence of evidence" of "actual deception" foreclosed such a conclusion in CareDx's appeal, the Third Circuit necessarily pointed back to its quotation of an agreed-upon jury instruction requiring proof of actual consumer deception and reliance. The sentence is not an observation about hypothetical out-of-circuit arguments; it is an observation about CareDx's litigation choices, which foreclosed any possibility of an inference in this case.

Finally, even had CareDx sought and obtained an instruction on an inference or a presumption, evidence of intent still would not have sufficed to entitle

CareDx to damages. That is because, as discussed below, all witnesses who testified on the topic agreed that transplant doctors *do not* rely upon advertising in making decisions about which tests to order; they rely on, among other things, the underlying studies, which Natera furnished to the doctors when it provided them with the advertising at issue. Appx.1247 (Tr.626:2-7); *accord* Appx.1245 (Tr.624:10-15, 21-23); Appx.1285-87 (Tr.665:1-666:15); Appx.1401-02 (Tr.780:24-781:11). This case is, in short, no vehicle to resolve any of the issues upon which CareDx seeks review; CareDx forfeited those issues.

III. Even were this case a vehicle for resolving the question presented, it is an exceedingly poor one because the issue was not outcome determinative.

Even if CareDx had preserved either issue on which it purports to seek review, the Third Circuit would not have erred in rejecting the application of a presumption or an inference on the facts of this case. In addition, the jury was not instructed on a standard of "deliberate[] fals[ity]," but rather one that allowed for a finding of willfulness based on what Natera "knew or should have known." Appx.2084 (Tr.1459:16-21). Either issue would defeat application of the presumption (or inference) and makes this case a bad vehicle for considering those issues.

On this first point, even if CareDx had preserved the issue and persuaded the Third Circuit to adopt—and apply after the fact—a presumption, it would have been easily rebutted. A presumption is a "bursting bubble"; producing evidence counter to the presumption means "the presumption disappears from

the case," *McCann* v. *Newman Irrevocable Tr.*, 458 F.3d 281, 288 (3d Cir. 2006) (quotation marks omitted), shifting back to the original party the burden to persuade by a preponderance. And here, the only evidence adduced at trial addressing reliance established that transplant nephrologists *do not rely* on advertising materials when selecting transplant-rejection assays. Dr. Gauthier, a practicing transplant nephrologist and Natera's director of organ health, explained that kidney transplant physicians make decisions based on data and scientific literature, not advertisements: Physicians are "going to do the research independently of the marketing materials before they make a decision regarding how to care for their patients." Appx.1247 (Tr.626:2-7); *accord* Appx.1245 (Tr.624:10-15, 21-23); Appx.1285-87 (Tr.665:1-666:15). CareDx's expert witness, Dr. Weisbord, agreed that he orders tests based on "data"; he does not "order drugs or tests based on a brochure." Appx.1401-02 (Tr.780:24-781:11).

Thus, the "bubble" would have "burst," and the question would have been whether CareDx provided sufficient evidence to prove that physicians were actually deceived by and actually relied on the false claims when they made their treatment decisions. As the district court and Third Circuit correctly held, they did not.

Nor could the jury in this case have reasonably inferred actual deception and reliance based on evidence of intent or willfulness. *See, e.g.*, *Reeves* v. *Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000) (recognizing a jury may "draw[ ] *legitimate* inferences from the facts" (emphasis added)); *Mancini* v. *Northampton Cty.*, 836 F.3d 308, 314 (3d Cir. 2016)

(reviewing court gives jury verdict the "advantage of every *fair and reasonable* inference" (citation omitted) (emphasis added)). The reasonableness of a jury's hypothetical inference is not judged in isolation. And here, the evidentiary record renders any such inference unreasonable. As noted, the "customers" were not unsophisticated shoppers—they were transplant physicians—and CareDx provided *zero evidence* suggesting that these doctors *ever* make treatment decisions based on statements made in advertisements. As Natera's transplant-physician witness put it, "we're not talking laundry detergent here." Appx.1246-47 (Tr.625:21-626:7). To the contrary (and as noted), undisputed evidence from both parties' experts established that they do not.[4]

CareDx understandably does not mention the record evidence of *non*-reliance, which came from both parties. Instead, it suggests that organ transplant doctors would not want to admit that they were "tricked by Natera's false claims." Pet.21. But this is pure speculation. Nothing in the record supports it. The only physicians who testified at trial agreed that they do not rely upon advertisements—not because doctors wouldn't want to admit as much, but because this small group of doctors simply does not order

[4] The record shows that, at most, advertisements might have piqued the doctors' interest in the underlying studies—but they would consider those studies, their underlying data, other medical literature, and the opinions of colleagues before making informed judgments about how to treat a patient. And that makes sense. No reasonable person would expect that doctors are easily influenced by advertisements and make treatment decisions based on them without considering the underlying science behind advertised medical tests, devices, and pharmaceutical products.

kidney transplant rejection tests based on commercial messages they may or may not have previously seen at a conference or read in brochures or press releases.

Independently, this case is not a good vehicle and the issue on appeal is not outcome determinative because CareDx did not seek a jury instruction satisfying the scienter standard it asks this Court to apply in adopting the inference it requests. The jury was given a generic instruction on intent and willfulness, which allowed the jury to make that finding if Natera "knew or *should have known* that the conduct was of the nature prohibited." *See* Appx.2084 (Tr.1459:16-24). But CareDx's question presented specifically describes the conduct required for the inference (or presumption) as "deliberate," *see* Pet.i—a finding the jury never made.

In favor of a rule that has no application here, CareDx and its *amici* also claim that there are various reasons why a party might need to invoke the presumption or inference in Lanham Act false advertising cases. But those policy-based arguments are not implicated here, either.

To begin with, although survey evidence can be expensive, CareDx does not claim that it lacked the resources to secure such evidence. Its decision not to introduce such evidence should be viewed for what it was—tactical. If it had the goods, one would have readily expected CareDx to have introduced survey evidence.

In any event, CareDx did not need a survey. It could have carried its burden here with direct evidence (*e.g.*, testimony from a physician) and/or

circumstantial evidence (e-mails or other communications suggesting physicians were deceived by a given statement and purchased Natera's product for that reason). *See, e.g.*, *Newborn Bros. Co.* v. *Albion Eng'g Co.*, No. 24-1548, 2025 WL 3560164, at *2 (3d Cir. Dec. 10, 2025) (nonprecedential) (noting surveys are "not essential" where "other evidence exists" of actual deception and reliance); *Parkway Baking*, 255 F.2d at 648 (explaining that a plaintiff need only prove "a portion of the buying public" was deceived by and relied upon the false advertisement). CareDx failed to introduce any such evidence.

Importantly, the relevant customer audience here was not unknowable. Quite the opposite, CareDx admits that the parties promote products to a "small audience" of transplant specialists, and CareDx knew where it was competing with Natera for those customers. *See* Pet.1-2. CareDx identified specific transplant centers by name in the record below, and its sales agents were in regular communication with those transplant centers. CareDx had access to direct evidence of their purchasing decisions. All it had to do was ask. The only evidence in the record—that transplant doctors do *not* rely upon advertising—suggests that CareDx didn't like the answer it received (or expected to receive, had it asked).

Finally, it is far from obvious that a presumption or inference would even get CareDx to a damages award given the numerous deficiencies in proving the required element of causation. Many aspects of the advertising in question were indisputably true. That includes Natera's representation that its test was unique in its ability to detect T-cell mediated rejection (CareDx's could not), which the jury expressly *found*

to be true. *See* Appx.676. Natera provided the underlying studies to the doctors. And as a new entrant in the market, Natera's Prospera would have necessarily reduced CareDx's sales. For example, in addition to selecting Natera's test based on its undisputed superiority on some metrics, doctors may have selected it based on price or other factors. CareDx, however, never connected any of the various specific statements it alleged to be false to any purchasing decision—meaning there was no basis to conclude that physicians were actually deceived by, and relied on, any *false* statement.[5]

The issue upon which CareDx seeks review is not, as it claims, "outcome determinative." Pet.2. The presumption would have been rebutted; the inference would have been unreasonable; the jury was instructed on a standard of "intent and willfulness" that allowed it to make such a finding based on a "knew or should have known" standard; and CareDx did not connect Natera's "intent and willfulness" involving any specific advertising statements to any actual real-world decisions by consumers in any event.

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[5] CareDx has relied on the same fuzzy generalization—a "false advertising campaign"—throughout the case and the appeal. But the Lanham Act applies to "false or misleading representation[s] of fact," 15 U.S.C. § 1125(a)(1), not "campaigns." There were ten allegedly false "representations of fact" in this case; the jury found one of them true. CareDx could not connect any one of the *false statements* with any actual deception or reliance. The permissive inference CareDx asks for is a way to bypass its burden to show, for an award of damages, that a false statement resulted in an adverse purchasing decision.

IV. If the issues discussed in CareDx's petition are as important and recurring as claimed, then a suitable case will present itself.

Sensitive to this case's shortcomings as a vehicle, CareDx tries to generate a sense of urgency. It argues that the Court should grant certiorari here because the issue is "important and recurring," Pet.25-26, a position echoed by its *amici*. That is incorrect.

CareDx points to only a handful of district court cases within the Third Circuit where the issue of a presumption has ever arisen, and *none* where an inference was raised. This is not surprising: Few Lanham Act cases involve no effort by a plaintiff to develop and introduce competent evidence of actual deception and reliance.

Even if this issue were as important and recurring as CareDx claims, a future plaintiff is free to advocate for a presumption (or permissive inference) given the Third Circuit's silence on whether, and under what circumstances, one is available. As CareDx correctly observed below, the Third Circuit "left open" the possibility of a presumption in *Johnson*, which was decided in 1994, and has not "rejected the sufficiency of [intent] evidence." CareDx Rhrg. Pet. 11-12. This Court should not be the first to reach and resolve that question of Third Circuit law.

The Third Circuit's more-than-30-year silence is itself telling. Since *Johnson*, no party—including CareDx—has properly brought either issue to the Third Circuit for review. That the Third Circuit has had no opportunity to decide them in over three decades suggests they are not as important and recurring

as CareDx and its *amici* say. Even if they are, though, a plaintiff who seeks a presumption, or to prove actual customer deception and reliance *solely* with evidence of the defendant's intent, is free to make, and preserve, those arguments. But the Third Circuit has to decide those questions before there is any issue worthy of this Court's limited time and resources.

Conclusion

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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