IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC., Plaintiff, v. NATERA, INC., Defendant.	Civil Action No. 19-662-CFC

MEMORANDUM

The Third Circuit remanded this case "for the limited purpose of having [me] consider on the merits whether judgment as a matter of law of no liability is warranted for Claims B, C, D, E, F, G, H, and J." D.I. 388 at 1. More specifically, the Third Circuit remanded the case "for [me] to consider whether there was sufficient evidence for the jury to conclude that [these] eight advertisements were literally false." D.I. 388-1 at 5–6.

I.

I note three things at the outset. First, the parties never mentioned, let alone discussed, in their post-trial briefing "Claims B, C, D, E, F, G, H, or J." *See* D.I. 340; D.I. 348; D.I. 354. Even though the jury's verdict form referred to the challenged advertisements by letter (Claim A, Claim B, etc.), neither party saw fit to use that nomenclature in its briefing before me. Moreover, instead of addressing

the jury's liability findings with respect to CareDx's advertisements individually, Natera treated the findings in the aggregate and in a conclusory fashion. *See* D.I. 340 at 11–18. CareDx understandably followed Natera's lead; and, thus, so did I. Accordingly, once I determined that there was record evidence from which a rational juror could find that the first challenged advertisement (i.e., Claim A) was false, I ended my analysis. It was only in their briefs filed with the Third Circuit that the parties addressed the jury's liability findings on a claim-by-claim basis. *See* Reply Brief for Appellant/Cross-Appellee at 20–48, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. May 1, 2024); Reply Brief of Natera, Inc. at 23–34, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024).

Second, Natera and CareDx jointly proposed that the "literally false" instruction that I gave to the jury include the following language:

> In order to succeed on a false advertising claim, CareDx . . . must prove that [Natera's] advertising statement is false on its face or literally false.
>
> *In deciding whether an advertising claim is literally false, you must decide, first, whether the claim conveys an unambiguous message and, second, whether that unambiguous message is false.* Only an unambiguous message can be literally false. The greater the degree to which a message relies upon the viewer to integrate its components and draw the apparent conclusion the less likely it is that a finding of literal falsity will be supported. This means, if a statement when read in context is

> ambiguous or susceptible of more than one reasonable meaning, it may not be found to be literally false.
>
> *If the challenged advertisement implicitly or explicitly refers to studies or data establishing a particular claim, the advertisement is literally false if (1) the studies or data were not sufficiently reliable to permit a conclusion that the claim is true; or (2) even though the studies or data are reliable, they do not establish the claim asserted by* [*Natera*].
>
> In some cases, a false statement is explicit or false on its face. *In other cases, a statement is false because it necessarily implies other messages that are literally false.* A message conveyed by necessary implication is one where the audience would consider the advertisement in its entirety and would recognize the message as being made as readily as if it had been explicitly stated. If such a message is untrue, it must be deemed literally false.

D.I. 322 at 26–28 (emphasis added).

Thus, to the extent any of the eight challenged advertisement claims explicitly or implicitly referred to the Sigdel and/or Bloom studies and data, *under the agreed-upon instructions*, the jury could have legitimately found that claim *to be literally false* (i.e., not simply misleading) even if it determined that the Sigdel and Bloom studies (and their data) were reliable, if the jury determined that the studies or their data did not establish those claims. And to the extent any of the eight challenged advertisement claims compared the Sigdel and Bloom studies and data, *under the agreed upon instructions*, the jury could have legitimately found

that claim to be *literally false* (i.e., not simply misleading) if it concluded that the claim necessarily implied a message that was literally false. Citing district court cases from outside the Third Circuit, Natera argued in its post-trial briefing (and also argues in its Third Circuit briefing) that an advertisement claim that "compar[es] accurately reported and footnoted study results cannot be '*false*,'" and "[a]t most, it could be *misleading*." D.I. 340 at 16 (emphasis in the original). But the jury instructions Natera itself proposed allowed the jury to make a finding of literal falsity of an advertisement claim that was based on a comparison of accurately reported and footnoted results from studies if the jury determined that the studies or data underlying the studies did not establish the claim or if a necessary implication of the comparison was literally false.

Third, there was record evidence from which a rational juror could have concluded both (1) that comparisons of the Sigdel and Bloom studies did not establish any claim that Prospera was superior to AlloSure in any respect because the data underlying the studies was not reliably comparable and lacked statistical significance and (2) that a necessary implication of Natera's comparisons of the Sigdel and Bloom studies and their data was that the studies and data were reliably comparable and statistically significant and that this implication was literally false.

A rational juror could have concluded that the studies were not reliably comparable based on, among other things:

- Admissions by Natera's corporate representative and former chief medical officer that "[t]here are problems with [the] design [of the Sigdel study] for sure," PTX 40-1; that "it is a huge mistake to risk over interpreting the quality of our data and set," PTX 40-1; that there are "differences in design between Bloom and [Sigdel], and there are problems in both designs," 3.8.22 Trial Tr. 455:20–21 (docketed as D.I. 367); and that "[t]here are problems and criticisms of [the Sigdel study's] design, *id.* at 455:25;

- Admissions by Natera's CEO that "[p]roviding consolidated performance data against these two very different populations [used in the Sigdel and Bloom studies] may be misleading," PTX 40-2; that "[o]ne disadvantage of th[e] design [used in the Sigdel study] is that it assesses the test solely on either known cases or known controls, whereas a real-world population [i.e., the type of population used in the Bloom study] may have more ambiguous or intermediate cases, affecting test performance," PTX 40-2; and that "[t]here are major risks with [the Sigdel] study[,]" PTX 507-1; and

- Testimony from numerous witnesses that the Sigdel and Bloom studies had fundamental differences, including in study design (Sigdel was a retrospective study whereas Bloom was a prospective study) and populations, *see, e.g.*, 3.8 Tr. 338:1–339:25, 342:1–25, 385:1–25; 3.9.22 Trial Tr. 643:5–644:19, 722:1–723:15 (docketed as D.I. 368); 3.10.22 Trial Tr. 982:1–25, 984:5–985:22 (docketed as D.I. 345).

A rational juror could have concluded that the data underlying the studies lacked statistical significance based on, among other things:

- The admission by the general manager of Natera's organ transplant group that he "cannot disagree" that a "statistical analysis does not support [the] claim" of "significantly better performance" by Prospera, 3.8 Tr. 427:12–21;

- Admissions by Natera's corporate representative that "there was no statistically significant difference between the AUCs of the [Sigdel study] and the AUC of the Bloom [study], 3.8 Tr. 498:25–499:2; and "that there's overlap in the AUCs and, therefore, you can't claim at this level of confidence interval statistically significant differences" between the studies, *id.* at 502:12–14;

- The admission by Natera's Vice President of R&D Data Science that "statistical analysis does not support claims of significantly better performance" by Prospera over AlloSure, 3.8 Tr. 393:12–19; PTX 502-1; and

- The admission by Natera's senior medical director of the organ health group that comparisons of Prospera's and AlloSure's sensitivity and specificity taken together as AUC based on the Sigdel and Bloom studies' data were "not statistically significant as defined by statisticians[,]" 3.9 Tr. 633:11–634:3.

II.

I turn then to the eight claims.

Claim B

Natera did not argue in its post-trial briefing or on appeal that Claim B is ambiguous. Accordingly, the only issue is whether there was sufficient evidence for the jury to conclude that Claim B is false.

Natera summarizes Claim B as follows:

> "Claim B" explicitly provides that, "[w]hen comparing published validation studies, Prospera demonstrated better performance" [than AlloSure] on the metric of sensitivity. Citing the Sigdel study for its finding of 89% sensitivity and the Bloom study for its finding of 59% sensitivity, [Claim B] shows those results side-by-side in infographics.

Reply Brief of Natera, Inc. at 25–26, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024) (first alteration in the original) (citation omitted). CareDx argued at trial that the assertion that "Prospera demonstrated better performance" with respect to sensitivity based on a comparison of the data in the Sigdel and Bloom studies is false because the data in the two studies are neither comparable nor sufficiently statistically significant to establish the claimed comparison. As discussed above, there was record evidence from which a rational juror could make that finding.

Claim C

Natera did not argue in its post-trial briefing or on appeal that Claim C is ambiguous. Accordingly, the only issue is whether there was sufficient evidence for the jury to conclude that Claim C is false.

According to Natera, "Claim C explains that the comparison of the results of the Sigdel study and Bloom study shows Prospera has 'higher sensitivity and nearly 18% higher area under the curve (AUC) than the competitive ddcfDNA assay [i.e., AlloSure].'" Reply Brief of Natera, Inc. at 27, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024). As discussed above, there was record evidence from which a rational juror could conclude that the underlying data of the two studies did not establish this claim and that the claimed comparison necessarily and falsely implied that the Sigdel and Bloom studies' data were reliably comparable and statistically significant. Thus, there was record evidence from which a rational juror could conclude that Claim C was literally false.

Claim D

Natera did not argue in its post-trial briefing or on appeal that Claim D is ambiguous. Accordingly, the only issue is whether there was sufficient evidence for the jury to conclude that Claim D is false.

Claim D has three statements. As Natera points out, one of those statements—"In its recently published clinical validation study, Natera reported higher sensitivity (89% vs. 59%) and higher area under the cur[v]e (0.87 vs. 0.74) than the competing dd-cfDNA assay"—is indisputably true. Reply Brief of Natera, Inc. at 27, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024). But that does not end the matter. In the other two statements in Claim D, Natera implicitly claimed that its Sigdel study demonstrated, based on comparisons of its results with the results of the Bloom study, that Prospera outperformed AlloSure. For the reasons discussed above, there was record evidence from which a rational juror could have concluded that the data underlying the studies did not establish those claims, and therefore, that Claim D was literally false.

Claims E and F

Natera did not argue in its post-trial briefing or on appeal that Claims E and F are ambiguous. Accordingly, the only issue with respect to these claims is whether there was sufficient evidence for the jury to conclude that they are false.

According to Natera:

> Claim E strictly compares numbers drawn from each study, depicting them on number lines. It correctly shows—citing the Bloom study—that AlloSure reported an NPV of 84%; because NPV reflects accurate detections, it also indicates 16% as the number of rejections "missed." It similarly shows, accurately citing the Sigdel study,

> percentages of 95% and 5% for NPV and "missed" rejections, respectively. And to the right, it indicates the relationship between those two percentages: 16% is approximately three times 5%. Claim F does the same thing, only with circles instead of lines. The underlying factual representations are the same, and they are based on accurate comparisons of juxtaposed study results.

Reply Brief of Natera, Inc. at 27–28, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024) (internal citations omitted). But although the statistics in Claims E and F Natera points to may have been "accurate[ly]" quoted in the claims, as discussed above, there was record evidence from which a rational juror could have concluded that the comparisons in Claims E and F necessarily and falsely implied that the Sigdel and Bloom studies' data were reliably comparable and statistically significant. Accordingly, there was record evidence from which a rational juror could have concluded that Claims E and F were literally false.

Claim G

As described by Natera in its appellate brief, Claim G is "a single slide from a Natera presentation[] [that] contains at least five cross-study comparisons of data from the Sigdel study and the Bloom study." Reply Brief of Natera, Inc. at 28, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. June 5, 2024). CareDx challenged in its appellate briefing only one of these comparisons—namely, that Prospera has a higher area under the curve (0.87) than does AlloSure (0.74). *See*

Reply Brief for Appellant/Cross-Appellee at 43, *CareDx, Inc. v. Natera, Inc.*, No. 23-2428 (3d Cir. May 1, 2024). But as discussed above, there was record evidence from which a rational juror could have found that this comparison necessarily and falsely implied that the Sigdel and Bloom studies' data were reliably comparable and statistically significant. Accordingly, there was record evidence from which a rational juror could have concluded that Claim G was literally false.

Claim H

Claim H is a slide that contains numerous statements. The central statement of the slide (both physically and substantively) consists of two sentences: "Unparalleled precision. Optimized by Prospera." D.I. 329 at 11; JTX 7-3.

Natera argued in its post-trial brief that Claim H is ambiguous as a matter of law because "CareDx's own expert testified that the term 'precision' is ambiguous—as used in the brochure, it 'includ[es] multiple different things.'" D.I. 340 at 12 (citing 3.9 Tr. 756:16–757:2) (alteration made by Natera). But the "unparalleled precision" and "optimized by Prospera" claims are positioned immediately next to and surrounded by assertions based on statistical comparisons of results from the Sigdel and Bloom studies that Prospera outperformed AlloSure in key metrics. And a rational juror could have concluded from that positioning

that "unparalleled precision" and "optimized by Prospera" unambiguously communicates that Prospera performs better than AlloSure with respect to these metrics.

Natera also argues that Claim H is not literally false. But, as discussed above, there was record evidence from which a rational juror could have concluded that comparisons of the Sigdel and Bloom studies did not establish any claim that Prospera was superior to AlloSure in any respect because the data underlying the studies was not reliably comparable and lacked statistical significance. That same record evidence provided a sufficient basis for a rational juror to conclude that Natera's comparisons of the Sigdel and Bloom studies and their data necessarily and falsely implied that the studies' data were reliably comparable and statistically significant. Accordingly, there was sufficient evidence for a rational juror to conclude that Claim H was literally false.

Claim J

Claim J is a slide used by Natera in presentations made to physicians to promote Prospera. The slide is titled "Highly sensitive across a range of rejection types and patients." Under the heading "Variety of ethnic & racial demographics," the slide has a sub-heading "Ages." Under that sub-heading, the slide has a bullet point that reads: "Below 18 years of age (n=49)." D.I. 329 at 13; JTX 21-8;

JTX 23-8. A footnote for that bullet point cites in support of this assertion an "SNP-based dd-cfDNA analys[i]s of 217 plasma specimens from 193 unique kidney transplant recipients." JTX 21-13. CareDx argued at trial that Claim J was literally false because the evidence showed that "[t]here is no indication that [Prospera] works in [pediatric patients], period." 3.14.22 Trial Tr. 1370:14–15 (docketed as D.I. 346).

Natera argues that Claim J contains "no unambiguous 'claims' of performance in pediatric populations." D.I. 340 at 13. In Natera's view, Claim J "does not assert pediatric performance" but "merely states, accurately, that 45 patients under 18 were in the Sigdel study." D.I. 340 at 13 (emphasis removed). But a rational juror could have concluded based on the slide's title,"[b]elow 18 years of age" bullet point, and footnote citation that Claim J unambiguously communicates that a study established that Prospera is highly sensitive for testing rejection in patients under the age of 18.

Moreover, there was record evidence from which a rational juror could have concluded that this communication was literally false. Dr. Weisbord, an expert in the field of nephrology, research study design and conduct, and medical publishing, testified at trial that "it's not accurate to say that [Prospera is] highly sensitive across a range of populations and include specifically the children there."

3.9 Tr. 760:25–761:2. As Dr. Weisbord explained, "[t]he children [in the study] did not have any rejections" and "if you have a patient group, in this case, pediatrics, who had no rejections, you can't determine the sensitivity of the test." 3.9 Tr. 760:21–761:3.

III.

In sum, for the reasons stated above, I find that there was sufficient evidence for the jury to conclude that Claims B, C, D, E, F, G, H, and J were literally false and that, therefore, judgment as a matter of law of no liability is not warranted for those claims.

Date: 12.23.24

COLM F. CONNOLLY
CHIEF JUDGE