IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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MEMORANDUM OPINION

May 7, 2021
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Pending before me is Defendant Natera, Inc.'s *Daubert* motion to exclude at trial the opinions of Plaintiff CareDx Inc.'s expert James Malackowski relating to "corrective advertising damages." D.I. 170.

I. BACKGROUND

CareDx's Lanham Act claims rest on allegations that Natera falsely represented that Natera's Prospera kidney transplant test is superior to CareDx's AlloSure Kidney test. CareDx seeks to offer Malackowski's testimony at trial in support of CareDx's claims for damages under § 1117(a)(2) of the Lanham Act. D.I. 204 at 4. According to CareDx, "[u]nder 15 U.S.C. § 1117(a)(2), a successful false advertising plaintiff can recover the costs of any completed advertising that actually and reasonably responds to the defendant's offending ads." D.I. 204 at 4 (internal quotation marks and citations omitted). Malackowski has opined that (1) "CareDx has incurred $18 million to $21 million in past corrective advertising costs in 2019 as a result of Natera's false advertising," (2) CareDx incurred the same amount of corrective advertising costs in 2020, and (3) CareDx will incur future corrective advertising costs of "at least $9 million [to] $21 million." D.I. 174, Ex. 1 at 34–36, 45–46. Natera seeks to exclude these opinions under Rule 702 and Rule 403. D.I. 170.

II. LEGAL STANDARD

Under Federal Rule of Evidence 702,

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. "Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). As the Court explained in *Schneider*:

> Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his on her belief. In sum, *Daubert* [*v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)], holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that Rule 702's 'helpfulness' standard requires a

> valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Id. (internal quotation marks and citations omitted).

Even if expert testimony meets the requirements of Rule 702, there is still "some room for Rule 403 to operate independently." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir. 1994). Under Rule 403, "[t]he court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

III. DISCUSSION

CareDx says that it wants to offer Malackowski's opinions at trial to establish the actual cost of the corrective advertising efforts it undertook in 2019 and the first half of 2020 and the projected cost of its corrective advertising efforts for the second half of 2020 and 2021. In calculating those costs, Malackowski relied solely on the deposition of CareDx CEO Peter Maag. D.I. 174, Ex. 1 at 34. Maag's deposition testimony reads as follows:

> Q. So what I'm asking is what, specifically, you did to identify correlation between Natera's statements and any effect on CareDx's financial results.
> A. You know, I think this is a -- this is a good question. For example, the amount of in- --incremental marketing and sales spend or marketing of sales spend that was delegated to defend our activities

towards these claims from Natera -- I was trying to build and form an opinion about what would be the damages concern[ing] this type of marketing claims. *Roughly, [in 2019], you know, we spent $20 million on AlloSure marketing and sales, $10 million of field force activities, so overall about $30 million of marketing and sales spend, and, you know, I was trying to triangulate how much of that spend was dedicated towards defending counter- -- with these -- these claims that -- that Natera was making. So I was -- I was trying to build -- to build in my -- in my mind a representation about what is the damages occurring and our marketing and sales spend, for example.* Does that --

Q. Is that --

A. -- answer your question? I want to be helpful, so I'm -- I'm -- I'm going into --

Q. No, you are.

A. -- more than direct --

Q. No, that's very helpful. That's very interesting as well. *Do you have any documents or a spreadsheet showing that analysis?*

A. *No. I -- you know, I think this is -- it's relatively easy. Like I said, it's a 30-million-dollar spend.* We are actually having an operation which is somewhat dedicated to transplantation, and so, you know, it's -- it's -- it's not that difficult to -- to -- to triangulate these numbers.

Q. *So what number did you come up with after you triangulated?*

A. *I would say probably 60 to 70 percent of our entire activity was -- was initiated towards defending the marketing and sales spend. I can give you -- I can give you, for example, investor relations activity, just so -- about 90 percent of all our communications to investors, in some form or fashion, were -- were -- were -- were defending the Natera claims about having a superior test.* So -- so there was a substantial, substantial effort spend in the company trying to counter these -- these outrageous claims.

D.I. 174, Ex. 5 at 29:2–31:5 (emphasis added).

Thus, according to Maag, CareDx spent "roughly" $30 million in 2019 on marketing, sales, and investor relations and "probably 60 to 70 percent" (i.e., 0.6 to 0.7) of that $30 million was directed "in some form or fashion" to "defending" against Natera's alleged claims about AlloSure. Malackowski wrote on page 34 of his expert report that "[b]ased on Mr. Maag's testimony, CareDx has incurred $18 million to $21 million in past corrective advertising costs in 2019 as a result of Natera's false advertising." D.I. 174, Ex. 1 at 34. In Malackowski's words: "$30m * 0.6 = $18m. $30m * 0.7 = $21m." D.I. 174, Ex. 1 at 34 n.175. Malackowski used these same calculations to determine CareDx's future corrective advertising costs. D.I. 174, Ex. 1 at 45–46.

Malackowski's corrective advertising opinions fail to meet all three of Rule 702's requirements. The challenged opinions do not contain specialized knowledge outside a juror's common understanding and therefore they fail to meet the "qualification" and "fit" requirements. The opinions are not, to use the language of Rule 702, "scientific, technical, or other specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Malackowski's "opinions" are simple math calculations. Malackowski merely performed the multiplication Maag outlined in his deposition testimony—i.e., $30m * 0.6 = $18m and $30m * 0.7 = $21m.

Multiplication is not a specialized form of knowledge that a jury lacks or a scientific technique that a jury is incapable of performing. Accordingly, Malackowski's opinions are inadmissible under Rule 702. *See United States v. Dewitt*, 943 F.3d 1092, 1096 (7th Cir. 2019) ("If the matter is within the jurors' understanding, the expert testimony is not 'specialized knowledge' that 'will help the trier of fact,' as required by Federal Rule of Evidence 702.").

The opinions are also inadmissible because they are not reliable. They were not reached by application of a scientific method or procedure and the underlying rough data supplied by Maag's testimony does not provide a reliable basis on which to make a scientific opinion. Malackowski did not engage in reasonable, let alone scientific, efforts to verify Maag's cost estimates. His efforts were limited to reading Maag's deposition, interviewing Maag for less than 55 minutes, and reviewing a 2019 SEC filing that showed "how much CareDx spent on sales and marketing in 2019, and how much was allocated to AlloSure." D.I. 204 at 8–9. Notwithstanding the vague, undocumented, and back-of-the-envelope nature of the estimates provided in Maag's testimony, Malackowski did not review CareDx's ledger or any CareDx invoices to test Maag's estimate; nor did he interview any marketing or other personnel at CareDx who could provide more specific data. These failures, in my view, preclude the admission of Malackowski's proffered testimony under Rule 702. *See ZF Meritor LLC v. Eaton Corp.*, 646 F. Supp. 2d

663, 667 (D. Del. 2009) (excluding expert's damages testimony as based on unreliable data where the expert "relied on the [party's] estimates without knowing . . . the validity of the underlying data and assumptions on which the [party's] estimates were based").

I also find that even if Malackowski's testimony were admissible under Rule 702, it should be excluded under Rule 403. The probative value of Malackowski's corrective advertising testimony is substantially outweighed by the dangers of unfair prejudice, misleading the jury, and needlessly presenting cumulative evidence. Fed. R. Evid. 403. Allowing Malackowski to present to the jury the multiplication set forth in Maag's testimony would essentially place the imprimatur of an expert on Maag's undocumented and dubious damages calculation. In light of the unreliable nature of Maag's estimate in the first place, allowing Malackowski to endorse that estimate by repeating it creates a substantial danger of misleading the jury and would be unfairly prejudicial to Natera.

IV. CONCLUSION

For the reasons stated above, I will grant Natera's motion and exclude Malackowski's testimony under both Rule 702 and Rule 403.

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ORDER

Pending before me is CareDx's Motion to Exclude Improper Testimony of Dr. Robert Makuch. D.I. 182. The crux of Dr. Makuch's opinion is "that certain claims made by CareDx are 1) not supported by certain peer-reviewed publications and/or 2) scientifically inaccurate, false, and/or misrepresentations of the data based on the claims made, the analyses performed, and/or the presentation of the data without sufficient context." D.I. 207, Ex. 1 ¶ 16. CareDx moves to exclude the opinions set forth in paragraphs 70, 99–102, and 106 of Dr. Makuch's Opening Report and paragraphs 9, 19–20, 24, 26–29, 31, 34, 36, 39, 54, 62–64, and 72–73 of Dr. Makuch's Reply Report. D.I. 182.

Federal Rule of Evidence 702 provides that

> [a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

CareDx argues that Dr. Makuch's testimony should be excluded under Rule 702 because (1) "Dr. Makuch has no expertise that qualifies him to opine as an expert on the impact of CareDx's statements upon consumers," D.I. 183 at 6, and (2) "[his] opinions regarding consumer reactions are unreliable and lack any objective factual basis," D.I. 183 at 8. Both arguments ultimately turn on CareDx's characterization of Dr. Makuch's opinions as "opinions regarding the allegedly misleading effect that CareDx statements would have upon transplant clinicians reviewing CareDx marketing materials." D.I. 183 at 1. Natera disputes this characterization and argues that Dr. Makuch does not opine on consumer confusion but rather "shows that the CareDx advertisements . . . contain numerous statements that are 'not supported' or are 'directly contradicted' by clinical data, or otherwise simply are 'not true.'" D.I. 206 at 1. I agree with Natera.

The substance of Dr. Makuch's reports confirms that what Dr. Makuch meant by "misleading" was that the CareDx advertisements contained statements

that are unsupported or directly contradicted by the underlying research. *See e.g.*, D.I. 207, Ex. 2 ¶ 34 ("CareDx's advertising materials stating that AlloSure has high specificity for rejection detection and/or could detect, determine, diagnose, or rule out Active Rejection, which is defined to include TCMR, are not supported by Bloom or other peer-reviewed publications I have reviewed and were directly contradicted by the 2019 Huang publication. Thus, CareDx's claims that AlloSure (a) can reliably rule out TCMR, (b) has high specificity for TCMR, and/or (c) can distinguish between TCMR and no rejection are false and/or misleading representations of the published data."); *see also* D.I. 207, Ex. 1 ¶¶ 70, 81, 99, 101–02, 106; Ex. 2 ¶¶ 9, 19, 24, 26–29, 34, 36.

Dr. Makuch further confirmed at his deposition that his opinion is that CareDx's advertisements were misleading because they contained claims that were either unsupported or directly contradicted by peer-reviewed research. *See e.g.*, D.I. 207, Ex. 4 at 165 ("I don't see any information to support that claim. I'm not going to be talking about the medical aspects of it. I'm here to provide you my insight as a quantitative scientist and expert in reviewing information such as this that I don't see the peer-reviewed support for this claim. And in fact, I see information to lead me to believe it's not true."); 189 (Q: "[W]hat in here are you alleging is misleading? A: I allege that the figure with the 1 percent cutoff in bold print, that that figure is misleading and actually false. Q: And how do you know

that this is not in the 1 percent threshold according to what you're saying? . . . A: What I'm saying is that the figure itself is incorrect.").

CareDx argues that Dr. Makuch is unqualified. D.I. 183 at 6–7. But Dr. Makuch's opinions involve interpreting medical data and biostatistics; and Dr. Makuch is a biostatistician with 42 years of experience and expertise in the areas of identification and evaluation of clinical outcomes. D.I. 207, Ex. 1 ¶ 2. He is a professor in the Department of Biostatistics at Yale University's School of Medicine, has authored or co-authored over 200 peer-reviewed scientific publications (mostly relating to clinical studies), and was the Section Head of Biostatistics and Data Management at the National Institutes of Health's National Cancer Institute prior to joining the Yale faculty. D.I. 207, Ex. 1 ¶¶ 3, 6, 11. Given "Rule 702's liberal policy of admissibility" regarding the qualification of experts, Dr. Makuch has undoubtedly satisfied this requirement. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994).

Lastly, CareDx argues that "[Dr. Makuch's] opinions regarding how relevant consumers would respond to CareDx's allegedly false or misleading statements are based on no data and involve no application of any recognized method of analysis" and thus should be excluded as unreliable. D.I. 183 at 9. But, again, Dr. Makuch is not asserting that he knows how consumers would respond to CareDx's statements but rather is opining that the statements in question are inherently

misleading because they are unsupported or contradicted by scientific evidence. Throughout his reports, Dr. Makuch relies on peer-reviewed publications and publicly available data to support his opinion that CareDx's advertising claims are unsupported or contradicted. *See* D.I. 207, Ex. 1 ¶¶ 70–102, Ex. 2 ¶¶ 9–68. CareDx does not challenge the reliability of the data or clinical studies that Dr. Makuch relies on. Accordingly, I will not exclude Dr. Makuch's opinions as unreliable under Rule 702.

NOW THEREFORE, at Wilmington this Seventh day of May in 2021, **IT IS HEREBY ORDERED** that CareDx's Motion to Exclude Improper Testimony of Dr. Robert Makuch (D.I. 182) is **DENIED**.

UNITED STATES DISTRICT JUDGE