UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 22-cv-22913-BLOOM/Torres

MARIETTE WATERS,

Plaintiff,

v.

CELEBRITY CRUISES, INC.
a Foreign Corporation.

Defendant.
_____/

ORDER ON PLAINTIFF'S DAUBERT MOTION TO EXCLUDE CERTAIN OPINIONS OF DEFENDANT'S HIV EXPERT

THIS CAUSE is before the Court upon Plaintiff Mariette Waters' ("Plaintiff") Motion to Exclude Certain Opinions of Defendant's HIV Expert, Jeffrey Klausner, MD, ("Motion"), ECF No. [53]. Defendant filed a Response ("Response"), ECF No. [67], and Plaintiff filed a Reply, ("Reply"), ECF No. [73]. The Court has reviewed the Motion, the supporting and opposing submissions, the record, and is otherwise fully advised. For the reasons that follow, Plaintiff's Motion is granted.

I. BACKGROUND

The Court assumes the parties' familiarity with the underlying facts. Plaintiff seeks to preclude certain testimony and opinions of the Defendant's HIV expert, Dr. Jeffrey Klausner, MD. Plaintiff seeks to preclude statements that the specific model of HIV rapid test used to test the blood donors in this case (the MedMira Multiplo HBc/HIV/HCV test) has received approval by any regulatory body in any country in the world. Additionally, Plaintiff seeks to preclude Dr. Klausner from testifying that the study he conducted in Peru, regarding a different type of HIV

rapid test, has bearing on the sensitivity or reliability of the subject test used by Defendant in this matter.

II. LEGAL STANDARD

Daubert Analysis

Federal Rule of Evidence 702 governs the admissibility of expert testimony. When a party proffers the testimony of an expert under Rule 702, the party offering the expert testimony bears the burden of laying the proper foundation, and that party must demonstrate admissibility by a preponderance of the evidence. *See Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291-92 (11th Cir. 2005); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999). To determine whether expert testimony or any report prepared by an expert may be admitted, the Court engages in a three-part inquiry, which includes whether: (1) the expert is qualified to testify competently regarding the matters the expert intends to address; (2) the methodology by which the expert reaches his or her conclusions is sufficiently reliable; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. *See City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). The Court of Appeals for the Eleventh Circuit refers to each of these requirements as the "qualifications," "reliability," and "helpfulness" prongs. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004). While some overlap exists among these requirements, the court must individually analyze each concept. *See id.*

Under *Daubert*, a district court must take on the role of gatekeeper, but this role "is not intended to supplant the adversary system or the role of the jury." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1341 (11th Cir. 2003) (citations and quotation marks omitted).

Consistent with this function, the district court must "ensure that speculative, unreliable expert testimony does not reach the jury." *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002). "[I]t is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." *Quiet Tech.*, 326 F.3d at 1341 (citations and quotation marks omitted). Thus, the district court cannot exclude an expert based on a belief that the expert lacks personal credibility. *Rink*, 400 F.3d at 1293 n.7. On the contrary, "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Quiet Tech.*, 326 F.3d at 1341 (quoting *Daubert*, 509 U.S. at 596). "Thus, '[o]n cross-examination, the opposing counsel is given the opportunity to ferret out the opinion's weaknesses to ensure the jury properly evaluates the testimony's weight and credibility.'" *Vision I Homeowners Ass'n, Inc. v. Aspen Specialty Ins. Co.*, 674 F. Supp. 2d 1321, 1325 (S.D. Fla. 2009) (quoting *Jones v. Otis Elevator Co.*, 861 F.2d 655, 662 (11th Cir. 1988)). Ultimately, "a district court enjoys 'considerable leeway' in making" evidentiary determinations such as these. *Cook ex rel. Est. of Tessier v. Sheriff of Monroe Cnty., Fla.*, 402 F.3d 1092, 1103 (11th Cir. 2005) (quoting *Frazier*, 387 F.3d at 1258).

III. DISCUSSION

Plaintiff seeks to preclude: (1) testimony from Defendant's HIV expert, Dr. Jeffrey Klausner, MD, that the HIV rapid test, "the MedMira Multiplo HBc/HIV/HCV test, has been approved by any regulatory body in any country in the world;" and (2) testimony from Dr. Klausner "that the study he conducted in Peru ("Peru Study") regarding a different type of HIV rapid test has any bearing on the reliability or sensitivity of the subject rapid test." ECF No. [53] at 3, 6.

A. Testimony that the HIV rapid test has been approved

Plaintiff asserts that Dr. Klausner testified that he believed the particular model HIV rapid test Defendant used on the blood donors, the MedMira Multiple HBc/HIV/HCV test ("Subject Test"), had regulatory approval in Canada and the European Union through the regulatory bodies in those countries. ECF No. [53] at 3. Regarding approval in the European Union, Dr. Klausner testified that he thought he saw the relevant marking on the Subject Test box. However, when presented with the box during deposition, the box did not have the relevant marking. *Id*. at 4. Dr. Klausner then conceded it was his belief that the Subject Test had approval in the European Union, but he did not know, and had no opinion on European regulatory approval. *Id*. Regarding regulatory approval in Canada, Dr. Klausner testified that he believed he saw documents indicating approval for the Subject Test by Health Canada, the regulatory body for Canada. *Id*. When asked whether he had any basis, or could point to any data, document, or evidence that the Subject Test had that approval, Dr. Klausner replied, no. *Id*. at 5.

Plaintiff argues that *Daubert* requires an expert to have a "sufficient basis" for its testimonial evidence. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993); *See also* Fed. R. Evid. 702(b). Here, Plaintiff argues that the expert has *no* basis, warranting preclusion of his testimony on this topic at trial.

Defendant responds that Dr. Klausner has no intention of offering his opinion that the Subject Test has any regulatory approval. ECF No. [67] at 9. However, Defendant asks this Court to permit Dr. Klausner to testify that the Subject Test shares an underlying technology with a different product made by the same manufacturer, MedMira, which does have some amount of FDA approval. *Id*.

The Court finds the record, including the deposition, supports precluding testimony from

Dr. Klausner that the Subject Test has any approval from any regulatory body from any country in the world. Plaintiff's first motion is granted.

B. Testimony related to the Peru Study

Plaintiff argues that Dr. Klausner's opinions based upon his findings from the Peru Study are neither reliable nor helpful and fails under *Daubert* as there is no basis to impute the findings from that study to the Subject Test. ECF No. [53] at 8. Plaintiff argues that the tests are materially different. The Peru Study was based upon the MedMira Multiplo TP/HIV rapid test ("Multiplo") which tests for HIV and syphilis. *Id*. at 6. The Subject Test used aboard Defendant's vessel and in its medical center tests for HIV, Hepatitis B, and Hepatitis C. *Id*. Dr. Klausner confirmed that Multiplo was not used by Defendant and stated he expected the tests to be similar because they are made by the same manufacturer. *Id.* Plaintiff argues this is an insufficient basis for an expert opinion and would likely mislead the jury. *Id*. at 7; *See* Fed. R. Evid. 702. Plaintiff argues that this testimony is based on "no data," is not the product of reliable principles, and any principles from this opinion have not been reliably applied to the facts in this matter. Fed. R. Evid. 702; *See also* ECF No. [53] at 7.

For support, Plaintiff cites to a case from outside this circuit, *Pessman v. Trek Bicycle Corp*., 18-CV-50243 2021 WL 5769530 (N.D. Ill. Dec. 6, 2021). In *Pessman*, an expert's testimony was stricken under *Daubert* for attempting to impute the defects of one model of bicycle to a different model made by the same manufacturer. *Id*. at *5. There, the court held that the expert failed to explain how his conclusion came about from scientific methodology, and that expert opinions must still be supported by "appropriate validation." *Id*.

Defendant responds with a review of Dr. Klausner's qualifications, noting that Plaintiff bypassed this part of the analysis and that his experience is relevant. ECF No. [67] at 4. Defendant

offers that Dr. Klausner graduated with Honors from Cornell Medical School and holds a Master of Public Health in International Health and Infectious Disease Epidemiology from the Harvard School of Public Health. *Id*. He has two professorships at the Keck School of Medicine, University of Southern California, and prior at the David Geffen School of Medicine and Public Health at the University of California Los Angeles. *Id*. at 5. He has served in various positions at the San Francisco Department of Health, and the United States Centers for Disease Control. *Id*. Dr. Klausner is currently the subject matter expert in HIV at the U.S. Centers for Disease Control and World Health Organization. *Id*. Additionally, he has co-authored over 650 peer reviewed research papers on infectious diseases with a focus on HIV/AIDS. *Id*. Defendant asserts that Dr. Klausner is qualified.

In Dr. Klausner's expert report, he opines that the Multiplo test used in the Peru Study "demonstrated excellent performance in detecting HIV antibodies." ECF No. [64-3, Klausner Report]. Defendant reasons that the Multiplo Test is manufactured by MedMira, a Canadian biotechnology company which also manufactures the Subject Test; both are rapid tests that detect HIV antibodies. *Id*. Defendant points out that MedMira holds the patent on Rapid Vertical Flow Technology ("RVF") and produces products for healthcare providers to rapid test certain infectious diseases like HIV, hepatitis, and syphilis. *Id*. RVF is MedMira's "core engine" for its rapid testing solutions, including a third test Defendant introduces, the MedMira Reveal G2 Rapid HIV-1 Antibody Test ("Reveal Test"). *Id*. The Reveal Test received FDA approval on June 23, 2004. *Id*. RVF is the common technology between the Subject Test, the Multiplo Test used in the Peru Study, and the Reveal Test. Defendant argues that this commonality is sufficient to demonstrate that the regulatory approvals or field studies related to Multiplo, or Reveal are relevant and sufficient to demonstrate the performance of other MedMira HIV rapid antibody testing, including

the Subject Test. ECF No. [67] at 8.

Defendant asserts that various opinions offered by Dr. Klausner support a determination that the different MedMira tests are similar. First, "Dr. Klausner testified that MedMira products use the same HIV antibody detection technology — RVF technology — which received FDA approval." *Id*. at 7. Dr. Klausner also testified that the "MedMira rapid tests are similar, because within the MedMira portfolio of tests, there would be increased similarity between antigens used and the mechanisms of antibody detection." *Id*. Additionally, there "would be greater similarity between MedMira's manufactured HIV antibody tests than there would be between different manufacturers' products." *Id*.; *See also* ECF No. [72-1 Klausner Depo] at p. 27.

Defendant also contends that Plaintiff's HIV expert "had no basis to dispute that the RVF technology used and approved by the FDA to test HIV antibodies in the Reveal Test is the same technology used in the Subject Test." ECF [67] at 7. Therefore, Defendant argues that there is "sufficient evidence of similarities among the MedMira HIV antibody rapid tests that warrant the use of Dr. Klausner's Peru Study in demonstrating the performance of MedMira HIV rapid antibody testing technology." *Id*.

Defendant also argues that Plaintiff's reliance on *Pessman* is misplaced. In *Pessman* the expert relied on information due to a product recall and speculation that issues spread to other models within that manufacturer's portfolio of products. *Id*. at 7; *Pessman*, 2021 WL 5769530, at *5. Defendant also argues that Plaintiff's arguments go towards the weight the jury should give to the expert opinion, not to admissibility. ECF No. [67] at 8. Defendant reasons that *Castro v. Carnival Corp*., 21-20373-cv, 2022 WL 3048255, at *6 (S.D. Fla. July 11, 2022) applies here, which held that the "Supreme Court has recognized that a district court has 'broad latitude' to allow an expert whose testimony is based on 'professional studies or personal experience.'"

(citations omitted). Additionally, Defendant seeks support in *Loudermill v. Dow Chem. Co.*, 863 F.2d 566 (8th Cir. 1988) to argue that Dr. Klausner's testimony is admissible as the opposing party should "examine the factual basis for the opinion on cross-examination." *Id*. at 570. Further, it is only when "an expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *Castro*, 2022 WL 3048255, at *5 (quotations omitted). Defendant concludes that Dr. Klausner's expert opinion is admissible, and Plaintiff will be able to challenge his opinions on-cross examination. ECF No. [67] at 9.

Plaintiff replies that Defendant attempts to fabricate a basis to admit the expert testimony based on shared use of the RVF technology to assert a substantial similarity between the Multiplo Test used in the Peru Study and the Subject Test used by Defendant. ECF No. [73] at 2. Plaintiff argues that this is "without any support from Dr. Klausner" and flawed. *Id*. Plaintiff argues that Dr. Klausner never mentioned RVF technology in his deposition nor opined that similarity was based upon shared use of RVF. *Id*. at 3. Plaintiff argues that this sole, asserted commonality between the tests is irrelevant, cannot establish reliability, and that imputing the results of one test to another is improper. *Id.* at 3.

The Court finds that Dr. Klausner's testimony is neither reliable not helpful to the trier of fact. As such, he is precluded from testifying that findings from the Peru Study regarding the Multiplo test have any bearing on the reliability of the Subject Test used by Defendant. The "reliability," and "helpfulness" prongs under the Eleventh Circuit's *Frazier* test have not been satisfied. *U.S. v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004).

To satisfy the reliability prong requires "ensuring that an expert's testimony. . . rests on a reliable foundation." *Id*. at 1260 (citing *Daubert*, 509 U.S. at 597). Further, to assess the reliability of scientific, expert opinion requires an assessment of "'whether the reasoning or methodology

underlying the testimony is scientifically valid and. . . whether that reasoning or methodology properly can be applied to the facts in issue.'" *Id*. (citing *Daubert*, 509 U.S. at 592-93). The reliability of the Peru Study is not at issue. Rather, the *application* of that study to the facts here is what is at issue.

Imputing findings from the Peru Study to the Subject Test requires as assessment of the RVF Technology. The RVF technology may be a connecting feature between these three MedMira tests, and others manufactured by MedMira, but Defendant has not argued that RVF is the actual technology that is responsible for the detection of HIV antibodies. Instead, the Rapid Vertical Flow technology delivers blood specimens to the elements within the rapid HIV tests that detect antibodies with increased speed. Moreover, Dr. Klausner did not testify that the shared RVF technology is a sufficient basis to impute the safety of one test to another within the MedMira portfolio. Dr. Klausner did not discuss the RVF technology at all in his deposition ECF No. [72-1] or in his prepared expert statement, ECF No. [64-3]. As that was not Dr. Klausner's testimony, the argument is not properly an expert opinion under Fed R. Evid. 701, 702, or 703.

Moreover, Dr. Klausner's expert testimony that he expects MedMira HIV antibody detection qualities to be more like each other than to HIV tests made by different manufacturers is insufficient to satisfy the prong of reliability. It is not scientifically reliable to impute the findings from a well-funded study conducted by, as Dr. Klausner stated in his deposition, outstanding scientists working in an excellent clinical research infrastructure to a different HIV test because of an expectation of similarity.

Consistent with a district court's gatekeeping function under *Daubert*, the district court must "ensure that speculative, unreliable expert testimony does not reach the jury." *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1256 (11th Cir. 2002). Defendant's expert has only

offered speculation that the Subject Test and Multiplo test have similarities. Therefore, the expert testimony fails the reliability and helpfulness prongs under *Daubert*.

Dr. Klausner is precluded from testifying that the study he conducted in Peru regarding a different type of HIV rapid test has bearing on the reliability or sensitivity of the Subject Test.

IV. CONCLUSION

Accordingly, it is **ORDERED AND ADJUDGED** as follows:

a. Plaintiff's Daubert Motion to Exclude, **ECF No. [53],** is **GRANTED**.

DONE AND ORDERED in Chambers at Miami, Florida, on January 29, 2024.

BETH BLOOM
UNITED STATES DISTRICT JUDGE

cc: counsel of record