IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TIMOTHY MOORE and JEAN MOORE, Plaintiffs,	**CIVIL ACTION**
v.	
COMBE INC., Defendant.	**NO. 22-320**

MEMORANDUM OPINION

This is a products liability action by Plaintiffs Timothy and Jean Moore against Defendant Combe Inc., the manufacturer of the Just For Men brand of hair dye products. The Moores allege that Combe knew or should have known that its products can cause vitiligo and/or skin depigmentation, but that they failed to adequately warn users of this risk. Presently pending is Combe's motion to exclude the testimony of the Plaintiffs' expert witness, Dr. Lila Laux, pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). For the reasons that follow, the motion will be denied.

I. FACTUAL BACKGROUND

As noted, this is a failure-to-warn lawsuit. In brief, the Moores allege that Just For Men Control GX Grey Reducing Shampoo ("Control GX") contains a chemical known as p-phenylenediamine ("PPD"), and that there are known health risks when this chemical comes into contact with skin. One of these risks is vitiligo—a condition leading to widespread skin depigmentation. Mr. Moore used Control GX beginning in 2017, and in the years that followed he began to suffer from vitiligo. He did not learn of the association between PPD and vitiligo until 2020, and he alleges that Combe's packaging, inserts, and marketing material failed to adequately convey the risk of its products.

During discovery, the Moores offered Lila Laux, Ph.D., as an expert witness on the

subject of human factors engineering. In her report, Dr. Laux opined that that Just For Men products failed to provide sufficient warning of the risk of vitiligo. Specifically, she explained that an effective safety warning "needs to be explicit, legible, prominently located and conspicuous enough to attract the potential user's attention," and she stated that the warning label on the Control GX product "do not meet these criteria." Dr. Laux further opined that if Combe had made a warning regarding the potential for vitiligo and other skin conditions more prominent and conspicuous on the packaging, "Mr. Moore would not have bought and therefore not used the product."

II. LEGAL STANDARDS

Daubert and its progeny established a "gatekeeping" role for trial courts to ensure that expert testimony "both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. As codified in Federal Rule of Evidence 702, the standard 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. In short, *Daubert* "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003)).

In this case, the Defendants challenge both the fit and reliability of Dr. Laux's testimony. The issue of "fit" goes to whether an expert's testimony assists the trier of fact. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994). "[A]dmissibility depends in part on 'the

proffered connection between the scientific research or test result to be presented and particular disputed factual issues in the case.'" *Id.* (quoting *United States v. Downing*, 753 F.2d 1224, 1237 (3d Cir. 1985)). "Reliability," meanwhile, goes to the reliability of an expert's methods. Courts consider factors including whether a particular methodology is scientifically valid, whether it "has been subjected to peer review and publication, the frequency by which the methodology leads to erroneous results, the existence and maintenance of standards controlling the technique's operation, and whether the methodology has been generally accepted in the scientific community." *Id.* at 742. In all cases, the proponent of expert testimony has the burden of establishing its admissibility by a preponderance of the evidence. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (citing *Daubert*, 509 U.S. at 593 n.10).

III. DISCUSSION

A. Fit

At the outset, Combe challenges the relevance of Dr. Laux's opinions regarding the adequacy of the Control GX warning labels to the facts of this case. Specifically, it notes that Timothy Moore acknowledged in his deposition that he never read the existing warnings on the product's packaging, label, or insert prior to using Control GX. As a result, it argues, Dr. Laux's opinions regarding the adequacy of those warnings are irrelevant to this case and should be excluded.

But as the Moores point out, Combe previously made this same argument in its motion for summary judgment, where it was rejected. As the Court's order on that motion observed, Mr. Moore did not merely testify that he had failed to read the Control GX warning label. Rather, he described the warning label as borderline illegible, explaining that its text was so small that he could not read it "without two pairs of glasses," and adding that it was only possible to do so at

the deposition because Combe's attorneys "bl[e]w it up on the screen." Based on this testimony, the Court identified a genuine issue of material fact concerning the adequacy of the Control GX warning label. And that factual dispute is precisely the issue addressed by Dr. Laux. As she wrote in her report, effective warning labels must be "explicit, legible, prominently located and conspicuous," and she opined that the labels used by Combe failed to meet those criteria. The question of fit presents "a relatively low obstacle to clear," and there is "a strong preference for admitting any evidence that may assist the trier of fact." *Crockett v. Luitpold Pharma., Inc.*, 2023 WL 2187638, at *2 (E.D. Pa. Feb. 23, 2023) (citations and internal quotation marks omitted). Dr. Laux's expert opinions concerning a central question in this case easily satisfy that threshold.

Resisting this outcome, Combe points to two cases—neither precedential—that reject expert testimony in failure-to-warn cases where the plaintiff acknowledged not reading the product's warning labels. Those decisions are inapposite. The first, *Gebhardt v. Mentor Corp.*, involved a medical device installed by a physician who did not read the warning label because he "was familiar with the risks and benefits of the device based on personal experience, review of medical literature, and his interview with the device's inventor." 15 F. App'x 540, 542 (9th Cir. 2001). Here, in contrast, Mr. Moore was not "a learned intermediary on the risks of the device," *id.* at 543, and he testified at his deposition that "I would just never think that a shampoo would have warnings that would be this severe." The second decision, *Atanassova v. Gen. Motors LLC*, is superficially more analogous, as it excluded the testimony of two expert witnesses (one of whom was Dr. Laux) who opined on the adequacy of a warning in a car's owner manual. 2021 WL 683246, at *6-8 (D.S.C. Feb. 22, 2021). But in that same decision, the court granted summary judgment on the failure-to-warn claim, reasoning that "a different warning label would

not have made a difference in this case." *Id.* at *3. Here, in contrast, a genuine issue of material fact exists on this point, making Dr. Laux's testimony highly relevant.

B. Reliability

In addition to attacking the relevance of Dr. Laux's testimony, Combe also challenges the reliability of her methods, arguing that she offered "no discernible methodology" for reaching the conclusion that the Control GX warning labels were inadequate, or that differently designed warnings would have changed Mr. Moore's purchase decisions. As a result, it argues, these conclusions are nothing more than unsupported *ipse dixit*.

But contrary to Combe's characterization of her testimony, Dr. Laux did offer a basis for her expert opinions. In both her report and deposition, she described a more than 30-year career in the field of human factors engineering, during which she conducted research, reviewed the relevant literature, consulted with corporate clients, and evaluated the adequacy of other warning labels. Relying on this specialized experience, she described the process for "developing and evaluating optimal warnings and instructions" as consisting of three steps:

> 1. Evaluat[e] the user population and identifying where consumers may experience difficulties or make errors in decision-making due to human limitations in the ability to adequately evaluate the risks and consequences associated with use of a product.
>
> 2. Evaluat[e] product associated factors that affect or shape the consumer's ability to make an optimal decision.
>
> 3. Evaluat[e] the interface and expected interactions of the consumer with the product and identifying where the human consumer must make decisions and how the interaction between the characteristics of the consumer and the product interface influence consumer safety behavior.

And after considering the Control GX warning label in light of this process, she ultimately concluded that it was "inadequate to provide the user population with the information they need." While a jury will ultimately decide the credibility of this testimony and the

persuasiveness of her opinion, "[t]he evidentiary requirement of reliability is lower than the merits standard of correctness." *Paoli*, 35 F.3d at 744; *see also In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) ("[T]he standard for determining reliability is not that high, even given the evidentiary gauntlet facing the proponent of expert testimony under Rule 702.") (internal quotation marks and citation omitted). Dr. Laux's testimony satisfies this threshold.

Attempting to show otherwise, Combe first argues that Dr. Laux never actually looked at a Control GX box, tube, or insert, instead basing her opinions on "blurred photographs" of the product's warnings labels. But Combe does not claim that these photographs—copies of which are included in the expert report—failed to accurately and fairly portray the Control GX warning labels, and the Court's own examination of them confirms that they are legible. Even assuming that "consider[ing] the warnings as they actually appear on the product" might have led to a more informed opinion, as Combe suggests, this merely concerns the credibility of Dr. Laux's testimony, not its reliability.

Second, Combe argues that Dr. Laux did not compare the Control GX warning labels against those used on other hair dye products, which it claims makes "her methodology [] inherently questionable and . . . unreliable." But that is not what Third Circuit precedent requires: such a comparison would be inconsistent with "the appropriate level of flexibility required by Rule 702." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 248 (3d Cir. 2008). That case involved the adequacy of an automobile owner's manual, and the trial court excluded testimony from the plaintiff's expert for "failing to compare the language of the 2002 service manual with the language provided by other automobile manufacturers." *Id.* The Third Circuit reversed, holding that the expert "did not have to compare the language of the 2002 service manual with the language provided by other manufacturers in order to render a reliable opinion that Ford's

service manual failed to provide adequate instructions or warnings." *Id.* at 248-49. So too here.

Finally, Combe objects to Dr. Laux's repeated references to American National Standards Institute ("ANSI") standard Z535.4, a voluntary standard that provides guidance to manufacturers on the design of product safety labels. But again, the question under *Daubert* is not whether an expert's opinions are correct, but whether they are reliable. *Paoli*, 35 F.3d at 742. Combe does not offer any explanation for why the relevant ANSI standard, voluntary or not, is an unreliable consideration when evaluating the adequacy of warning labels—indeed, its own expert witness, Riana Shah, previously served as a member of the ANSI subcommittee that developed them. And Dr. Laux's testimony makes clear that her opinion was not solely based on Control GX's compliance with ANSI Z535.4, and that consideration of this industry standard was just one factor that went into her analysis. Whether or not that analysis is correct is ultimately a question for the jury. But a relevant industry standard need not be binding to be reliable, and Combe offers no other explanation for why Dr. Laux's consideration of it was inappropriate.

An appropriate order follows.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.