UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CONNIE DE SOUZA,	:	
	:	
Plaintiff,	:	NO. 3:03-CV-2247 (MRK)
	:	
v.	:	
	:	
TAP PHARMACEUTICALS, INC.	:	
	:	
Defendant.	:	

ORDER

Pending before the Court is Defendant TAP Pharmaceuticals, Inc.'s Motion for Summary Judgment [doc. #37]. For the reasons that follow, Defendant's motion is DENIED. The Court notes that it has not yet ruled on Defendant's request to strike the expert testimony of Dr. Larry Bernstein and Dr. Suzanne Parisian under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and therefore, as Defendant's counsel agreed at oral argument, their testimony is admissible for purposes of the present summary judgment motion.

Familiarity with the case's underlying facts is assumed. Summary judgment is inappropriate unless a lack of dispute as to genuine issues of material fact entitles the moving party to judgment as a matter of law. Fed. R. Civ. P. 56(c); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The moving party must demonstrate that no such genuine material dispute exists. *Carlton v. Mystic Transp., Inc.*, 202 F.3d 129, 133 (2d Cir. 2000). Moreover, "in determining whether a genuine issue has been raised, the inferences to be drawn from the underlying facts revealed in the affidavits, exhibits, interrogatory answers, and depositions must be viewed in the light most favorable to the party opposing the motion." *Tomka v. Seiler*, 66 F.3d 1295, 1304 (2d Cir. 1995). Here, the Court

would be permitted to grant summary judgment only if no reasonable jury could conclude that Defendant's package-insert warning was inadequate.

While the Court notes that Plaintiff would appear to face an uphill battle on her claim, several factors lead the Court to conclude that summary judgment at this time would be inappropriate. First, "[g]enerally, whether a warning is adequate is an issue of fact to be determined at trial." *Erony v. Alza Corp.*, 913 F. Supp. 195, 199 (S.D.N.Y. 1995); *see LaMontagne v. E.I. Du Pont De Nemours & Co., Inc.*, 41 F.3d 846, 860 (2d Cir. 1994) (finding that summary judgment as to a warning's adequacy is inappropriate unless "'the mind of a fair and reasonable person could reach only one conclusion'" (quoting *Sharp v. Wyatt Inc.*, 31 Conn. App. 824, 835 (1993))). Second, the package-insert's warning of "Ophthalmologic disorders" – a term that under the COSTART manual ranges from "dry eye" to blindness – is extremely broad, covering over sixty conditions. *See* Local Rule 65(A)(1) Statement [doc. #37] Ex. A-1. A jury might conclude that use of such an all-embracing term was inadequate to warn of the adverse effect that Plaintiff suffered in this case. Third, Plaintiff's expert Dr. Suzanne Parisian is prepared to opine before the jury that the warning did not "adequately warn a prescribing physician of the potential risk" of the adverse reactions that Plaintiff claims to have experienced. *See* Local Rule 56(A)(2) Statement [doc. #46] Ex. K at 5. Fourth, Dr. Parisian also cites reports and articles suggesting that severe reactions, including "permanent loss of eyesight," were known to be possible side effects of Lupron. *See, e.g.*, *id.* at 7. While Defendant challenges Dr. Parisian's right to give the jury such opinions, at least for purposes of the present motion, Dr. Parisian's proposed testimony raises a genuine issue of material fact. Fifth, Dr. Edward Watson, Plaintiff's physician, testified that he was unaware that retinal hemorrhages were a possible adverse effect of the use of Lupron. *See id.* Ex. J at 18. Finally, cases in which summary judgment

has been granted as to a warning's adequacy are distinguishable, either because they involve warnings far more specific than the one at issue here, because the injured patient's physician was aware of the risk of the specific adverse effect that plaintiff suffered, or both. *See, e.g.*, *Goodson v. Searle Laboratories*, 471 F. Supp. 546, 546-48 (D. Conn. 1978) (finding a warning adequate as a matter of law where the package insert had warned of the specific adverse effect that plaintiff experienced and where plaintiff's treating physician was aware of the possible adverse effect); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 30-31 (Tenn. 1994) (holding package-insert warnings adequate as a matter of law because defendant gave "extensive information" to plaintiff's physician about the adverse effect plaintiff suffered); *cf. Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) (reversing a grant of summary judgment for defendant because the FDA-approved package insert contained an "equivocal" warning and because "[t]he mere mention of a possible injury . . . is not necessarily adequate"); *Erony*, 913 F. Supp. at 200 (denying summary judgment where the package-insert warning was incomplete and where the treating physician did not understand the insert to warn of the specific adverse condition that caused the plaintiff's injuries).

This non-exhaustive list suffices to persuade the Court that there remain factual disputes that should be decided by a jury. Therefore, Defendant's Motion for Summary Judgment [doc. #37] is DENIED. The Court will issue a schedule for filing the parties' Joint Trial Memorandum and for holding a hearing on the *Daubert* motions.

IT IS SO ORDERED,

/s/ Mark R. Kravitz
United States District Judge

Dated at New Haven, Connecticut, on January 3, 2006.