

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL)) MDL No. 16-2740
PRODUCTS LIABILITY)
LITIGATION) SECTION: “H” (5)
)
This document relates to:)
Cases listed on Exhibit A)

ORDER AND REASONS

Before the Court is Defendants’ Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started After December 11, 2015 (Doc. 9268). For the following reasons, the Motion is **GRANTED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more.

The instant Motion relates to nearly 200 cases. Defendants’ Motion is rooted in the fact that in December 2015, the Taxotere label was updated to specifically warn of the risk of permanent alopecia. Defendants ask the Court to grant summary judgment against these hundreds of Plaintiffs because they were treated with Taxotere after this label change. Defendants argue that

¹ Docetaxel is the generic version of Taxotere.

these Plaintiffs cannot prove an essential element of their failure to warn claims. Alternatively, Defendants argue that their claims are preempted.

LEGAL STANDARD

Summary judgment is warranted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.”² A genuine issue of fact exists only “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”³ Rule 56 of the Federal Rules of Civil Procedure “mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.”⁴ “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.”⁵

LAW AND ANALYSIS

Defendants first argue that the Plaintiffs at issue cannot create a genuine dispute of material fact on an essential element of their claims. Specifically, Defendants aver that Plaintiffs cannot demonstrate that the Taxotere label, after the December 2015 update, was inadequate. Instead, Defendants contend that the updated Taxotere label was adequate as a matter of law. Indeed, the label made several references to permanent hair loss, which is the very injury of which Plaintiffs allege they were not warned. These

² Fed. R. Civ. P. 56.

³ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

⁴ *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

⁵ *Anderson*, 477 U.S. at 249–50 (internal citations omitted).

references were in three sections of the Taxotere label: the “Adverse Reactions” section, the “Patient Counseling Information” section, and the “Patient Leaflet.”

In response, Plaintiffs do not dispute that the December 2015 label addressed the risk of permanent hair loss in these three sections. Plaintiffs argue, however, that the label was nonetheless inadequate because there was no mention of permanent alopecia in the “Warnings and Precautions” section of the label. Notably, Plaintiffs ask the Court to ignore certain testimony from one of their experts, Dr. David Kessler. Dr. Kessler has repeatedly testified (in cases of individual Plaintiffs who received Taxotere before December 2015) that the risk of permanent alopecia should be addressed in either the “Warnings and Precautions” section or the “Adverse Reactions” section of the label. According to Plaintiffs, however, this testimony from Dr. Kessler was case specific and did not contemplate MDL Plaintiffs who were treated after December 2015. Plaintiffs further aver that because none of the roughly 200 Plaintiffs before the Court have been selected as bellwether Plaintiffs, no expert has opined on the adequacy of the label after December 2015.

“It is axiomatic that an essential element of a failure to warn claim is a defendant’s failure to adequately warn about the alleged risks associated with its product.”⁶ In prescription drug cases like this one, the learned intermediary doctrine modifies the adequacy analysis. Under this doctrine, “adequacy in the context of prescription drugs is a function of whether the doctor, rather than the patient, would reasonably understand the risks.”⁷

⁶ *In re Foxamax (Alendronate Sodium) Prods. Liab. Litig.*, No. 12-cv-492, 08-08, 2014 WL 2738224, at *8 (D.N.J. June 17, 2014).

⁷ *Meridia Prods. Liab. Litig. v. Abbott Labs*, 447 F. 3d 861, 867 (6th Cir. 2006).

In the MDL context, transferee courts have issued omnibus orders finding a drug label adequate as a matter of law.⁸ For example, in *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, an MDL court held that a drug label was adequate where it was accurate, clear, consistent, and “as a whole convey[ed] an unmistakable meaning as to the consequences of ingesting [the drug].”⁹ Considering the evidence in the instant cases before this Court, the Court finds that the Taxotere label after December 2015 was adequate as a matter of law.

As Defendants note, the Taxotere label at issue here clearly and consistently explained that the drug carried a risk of permanent hair loss. In the “Adverse Reactions” section of the drug, the label stated that “[c]ases of permanent alopecia have been reported.”¹⁰ In the “Patient Counseling Information” section, the label instructed doctors to “[e]xplain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, excessive tearing, infusion site reactions, and hair loss (cases of permanent hair loss have been reported) are associated with docetaxel administration.”¹¹ Lastly, the “Patient Leaflet,” which is intended for patients, provided a list of the most common side effects of Taxotere, and this list included the following item: “hair loss: in most cases normal hair growth should return. In some cases (frequency not known) permanent hair loss has been observed.”¹² Because the label clearly

⁸ *Id.* (affirming district court’s order in MDL that found drug label adequately warned of drug’s risk of high blood pressure as a matter of law); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 881 F. Supp. 2d 1333, 1343 (N.D. Ala. 2012) (holding drug label, after certain updates, adequately warned of risk of neuropsychiatric injuries as a matter of law).

⁹ 2014 WL 2738224, at *11 (D.N.J. June 17, 2014).

¹⁰ Doc. 9268-2 at 9.

¹¹ *Id.*

¹² *Id.* at 10.

and consistently warned of the precise injury Plaintiffs suffered, the Court finds that the label was adequate.¹³

To defeat summary judgment, Plaintiffs would need to show expert evidence creating an issue of fact on the adequacy of Taxotere's warning.¹⁴ Plaintiffs have failed to do so. Plaintiffs aver that the language about permanent hair loss should have been included in the "Warnings and Precautions" section of the label, but Plaintiffs present no evidence to support this notion. Indeed, Plaintiffs' own expert, Dr. Kessler, testified as follows:

My opinion is that it should have been clearly and – the company should have clearly and prominently warned. I think, in the end, there are different sections of the label. I'm happy to discuss that. There is a warning section. It's called Section 5. There is an adverse event section called Section 6. I think in either section, as long as it was clearly and prominently warned of permanent hair loss, that's what I care about.¹⁵

¹³ *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 290 (6th Cir. 2015) ("[P]rescription medicine warnings are adequate when . . . information regarding 'the precise malady incurred' was communicated in the prescribing information.") (quoting *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009)); *Kling v. Key Pharm., Inc.*, 35 F.3d 556 (Table), at *3 (4th Cir. 1994) (upholding district court ruling that label was adequate as a matter of law where "[t]he precise harm alleged to be suffered by [plaintiff], a seizure, was clearly listed as a potential side effect of taking [the drug]"). *See also Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003) (upholding district court ruling that updated label was adequate as a matter of law where plaintiff's injuries were specifically listed as adverse side effects).

¹⁴ *See Colville v. Pharmacia & Upjohn Co., LLC*, 565 F. Supp. 2d 1314, 1321 (N.D. Fla. 2008) (finding warning adequate as a matter of law and explaining that plaintiff lacked expert evidence on the issue); *Benedict v. Zimmer, Inc.*, 405 F. Supp. 2d 1026, 1033 (N.D. Iowa 2005) ("[T]o show the device was defective because of inadequate instructions or warnings requires expert testimony."). *See also Ziliak*, 324 F.3d at 521. In *Ziliak*, the Seventh Circuit affirmed the district court's grant of summary judgment on the adequacy of a drug label. *Id.* The district court had found that the plaintiff's expert had not sufficiently established his expertise. *Id.* at 520. The court wrote, however, that even if his expert testimony was considered, he failed to create an issue of fact on the adequacy of the warning but instead advocated for a label that was consistent with the language in the label. *Id.* The Seventh Circuit agreed. *Id.* at 521.

¹⁵ Doc. 9268-2 at 14 (quoting transcript).

Unsurprisingly, Plaintiffs now back away from this opinion. They aver that it is case specific and should not be considered along with the instant Motion. However, Plaintiffs have come forward with no other evidence. They claim that no expert has opined on post-2015 cases because there are no bellwether Plaintiffs who received treatment after December 2015.

The Court will not allow Plaintiffs to shield these nearly 200 cases from dismissal under this logic. For months now, the parties and this Court have discussed the filing of this “fencepost” (or omnibus) motion. The parties agreed on the briefing schedule. Most striking, however, is that Plaintiffs’ expert testimony regarding placement of the alopecia warning is solely in the possession of the Plaintiffs. Plaintiffs had ample time and opportunity to identify and present expert evidence supporting their argument that permanent hair loss should have been addressed in the “Warnings and Precautions” section of the label. Yet Plaintiffs failed to do so. Accordingly, summary judgment is appropriate.

Because the Court is granting summary judgment due to Plaintiffs’ lack of evidence on the adequacy of the Taxotere label, the Court sees no need to address Defendants’ preemption argument.

CONCLUSION

For the foregoing reasons, Defendants’ Motion for Summary Judgment on the Claims of Plaintiffs Whose Taxotere Treatment Started After December 11, 2015 (Doc. 9268) is **GRANTED**. The failure to warn claims of the Plaintiffs listed on Exhibit 1 of the Motion are **DISMISSED WITH PREJUDICE**. Any other claims these Plaintiffs have remain pending. Liaison counsel should

provide the Court with a list of any cases that have no claims remaining and should be dismissed as a result of this ruling;

IT IS FURTHER ORDERED that the remaining argument in the Motion for Summary Judgment (Doc. 6186) is **DISMISSED AS MOOT**.

New Orleans, Louisiana this 27th day of May, 2020.

A handwritten signature in black ink, appearing to read "Jane Triche Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

EXHIBIT 1

Last Name	MDL Docket No.	First Treatment Date
PETRIE	2:18-cv-13643	12/15/2015
ROLAND	2:17-cv-16041	12/16/2015
HENRY	2:17-cv-12780	12/17/2015
JACKSON BIREE	2:19-cv-13256	12/18/2015
PAPAJOHN	2:17-cv-16380	12/21/2015
WHITE	2:18-cv-11593	12/21/2015
FLOWERS	2:18-cv-12439	12/22/2015
CHAVEZ	2:17-cv-07497	12/28/2015
MATSUMURA	2:17-cv-09533	12/28/2015
CHASE	2:18-cv-12941	12/29/2015
BERNHARD	2:19-cv-13649	12/30/2015
COZZA	2:18-cv-03442	12/30/2015
SCOTT	2:16-cv-15472	01/5/2016
SCRUGGS	2:18-cv-08227	01/5/2016
ALLBRITTON	2:18-cv-06530	01/6/2016
BEERMAN	2:18-cv-01879	01/7/2016
MCGAHEY	2:19-cv-11467	01/7/2016
WRIGHT	2:17-cv-14420	01/7/2016
JONES	2:18-cv-12850	01/8/2016
WATKINS	2:18-cv-06462	01/8/2016
FEEHERTY	2:19-cv-09670	01/11/2016
VELASQUEZ	2:18-cv-07208	01/12/2016
REECE	2:18-cv-13515	01/15/2016
TICEY	2:17-cv-15859	01/18/2016
HIGHT	2:18-cv-01854	01/21/2016
RANKINS	2:17-cv-14999	01/25/2016
NANNEY	2:19-cv-09538	01/27/2016

Last Name	MDL Docket No.	First Treatment Date
SKELTON	2:18-cv-04810	01/27/2016
LEWIS	2:18-cv-00401	01/28/2016
PERRY	2:18-cv-03417	01/28/2016
ALLEN	2:18-cv-05776	01/29/2016
KING	2:18-cv-12856	02/??/2016
MARTIN	2:17-cv-16355	02/??/2016
RANDALL	2:18-cv-12883	02/??/2016
ROBSON	2:18-cv-06695	02/??/2016
MITCHELL	2:18-cv-10906	02/2/2016
USHER WILLIAMS	2:17-cv-11194	02/4/2016
PIERRE CANEL	2:18-cv-02818	02/5/2016
MILLER	2:18-cv-11729	02/12/2016
WOZNY	2:18-cv-07202	02/15/2016
CADIERE	2:18-cv-06171	02/17/2016
PETTIS	2:19-cv-09443	02/18/2016
CUNNINGHAM	2:19-cv-11930	02/23/2016
MASSIE	2:18-cv-10110	02/23/2016
GROVES	2:17-cv-15595	02/25/2016
IEROKOMOS	2:18-cv-14249	02/26/2016
JONES	2:18-cv-01662	02/26/2016
ROBINSON	2:17-cv-13918	02/28/2016
COWAN	2:17-cv-12540	02/29/2016
MCGAUGHEY	2:17-cv-15967	03/??/2016
JOHNSON	2:17-cv-11214	03/6/2016
BAFFO	2:18-cv-11311	03/7/2016
BLUMLO	2:16-cv-17972	03/8/2016
CONE	2:19-cv-01898	03/9/2016

Last Name	MDL Docket No.	First Treatment Date
TOLAN	2:18-cv-03946	03/10/2016
WEST	2:19-cv-14084	03/14/2016
STOOPS	2:17-cv-13921	03/15/2016
MAJOR	2:19-cv-12303	03/17/2016
CHAGAS	2:20-cv-00022	03/23/2016
SCHULTZ	2:18-cv-00498	03/25/2016
FLOYD MOTTER	2:18-cv-02109	03/28/2016
HUGHES	2:19-cv-01903	03/31/2016
GILMORE	2:19-cv-01900	04/5/2016
DYER	2:19-cv-00730	04/6/2016
LENCREROT	2:19-cv-00365	04/6/2016
FREEMAN	2:18-cv-05554	04/8/2016
NEWMAN PARKER	2:18-cv-10882	04/12/2016
HEGENBART	2:18-cv-09084	04/14/2016
BENIGNO	2:18-cv-10566	04/19/2016
LOPES	2:17-cv-14143	04/19/2016
WILLIAMS	2:18-cv-13268	04/21/2016
CURLEYMORABITO	2:18-cv-05986	04/22/2016
HOLMES	2:18-cv-06700	05/1/2016
MINOR	2:19-cv-00037	05/??/2016
BAILEY	2:17-cv-13942	05/2/2016
JONES	2:18-cv-14329	05/3/2016
CAULKER	2:17-cv-17150	05/6/2016
PROCTOR	2:17-cv-16662	05/6/2016
WEST	2:19-cv-11271	05/6/2016
MCMULLEN	2:17-cv-17056	05/11/2016
DENBY	2:18-cv-07609	05/12/2016

Last Name	MDL Docket No.	First Treatment Date
SINGER	2:19-cv-12536	05/13/2016
CASTLE	2:19-cv-10055	05/19/2016
WOMACK	2:17-cv-15744	05/23/2016
BERRY	2:18-cv-06173	05/24/2016
ROBERTSON	2:18-cv-06092	05/26/2016
WARREN	2:18-cv-13070	05/26/2016
SHADLE	2:18-cv-03292	05/27/2016
JOHNSON	2:17-cv-12544	05/31/2016
HORNE	2:18-cv-04434	06/2/2016
PRZEKURAT	2:18-cv-12913	06/2/2016
BLACKMON	2:19-cv-09973	06/3/2016
ROCHA	2:18-cv-11723	06/9/2016
SMITH	2:18-cv-05556	06/9/2016
JONES	2:18-cv-04465	06/14/2016
WILLIAMS	2:19-cv-11947	06/14/2016
WEEKS	2:17-cv-15119	06/15/2016
HUTCHINSON	2:18-cv-11496	06/16/2016
IRVING	2:18-cv-07846	06/22/2016
SIMPSON	2:17-cv-15575	06/22/2016
MCCULLUM	2:18-cv-06177	06/27/2016
ADKINS	2:18-cv-12307	07/8/2016
MARTIN	2:18-cv-13104	07/11/2016
WILLIAMS	2:18-cv-02391	07/13/2016
WINGATE	2:18-cv-10321	07/13/2016
WHITEHEAD	2:19-cv-12878	07/20/2016
RHEA	2:17-cv-15421	07/21/2016
MATTHEWS	2:17-cv-17055	07/25/2016

Last Name	MDL Docket No.	First Treatment Date
SMITH	2:19-cv-12040	07/28/2016
SANTIAGO	2:17-cv-09131	07/29/2016
DAVIS	2:17-cv-16280	08/??/2016
GHOLAR	2:18-cv-00502	08/??/2016
ARROYO	2:19-cv-07567	08/2/2016
KINSLER	2:19-cv-10627	08/2/2016
NICHOLS	2:17-cv-15204	08/4/2016
FERNANDEZ	2:18-cv-08114	08/11/2016
SMITH	2:18-cv-13890	08/11/2016
BURNS	2:19-cv-11973	08/12/2016
KIMBRELL	2:18-cv-12329	08/17/2016
PRZESTRZELSKI	2:19-cv-01176	08/18/2016
MILTON	2:18-cv-05997	08/19/2016
CREWS	2:17-cv-10525	08/25/2016
GOODMAN	2:18-cv-07244	08/26/2016
ANDRES	2:18-cv-06189	08/29/2016
KNIGHT	2:17-cv-17052	08/31/2016
WEAVER	2:17-cv-15513	08/31/2016
ADAMS	2:17-cv-16210	09/??/2016
KIRBY	2:18-cv-10313	09/13/2016
GILMORE	2:18-cv-05273	09/14/2016
BROWN	2:19-cv-11980	09/20/2016
GREEN	2:17-cv-13902	09/21/2016
BACH	2:19-cv-12357	09/22/2016
MORGAN	2:18-cv-11822	09/22/2016
GLENN	2:18-cv-13020	09/28/2016
MCMILLAN	2:18-cv-10481	09/29/2016

Last Name	MDL Docket No.	First Treatment Date
BROWN	2:19-cv-12433	10/??/2016
CASTILLE	2:18-cv-03431	10/??/2016
COX	2:18-cv-12902	10/??/2016
PARSONS	2:19-cv-02174	10/3/2016
SYLVE	2:17-cv-14650	10/11/2016
HAYES	2:18-cv-08308	10/12/2016
HENDRICKS	2:18-cv-07248	10/13/2016
SHAW	2:18-cv-05780	10/17/2016
RAGSDALE	2:19-cv-11266	10/24/2016
BLACK	2:18-cv-02782	11/??/2016
SKILLOM	2:19-cv-11936	11/1/2016
WELLS	2:18-cv-13440	11/??/2016
HOFF	2:19-cv-12700	11/8/2016
DUVALL	2:18-cv-04715	11/11/2016
EIDEL	2:17-cv-06024	11/17/2016
BAREFIELD	2:19-cv-13433	11/18/2016
MILLICAN	2:18-cv-14040	11/18/2016
SPADA	2:19-cv-12775	11/29/2016
GOLDSBORO	2:18-cv-12441	12/2/2016
DAVIS	2:19-cv-12251	12/8/2016
SAMPSON	2:17-cv-15773	12/8/2016
HARRIS	2:19-cv-00504	12/9/2016
PASTORKOVICH	2:18-cv-13186	12/15/2016
ZUPKO	2:18-cv-13465	12/19/2016
ROLLE	2:18-cv-12914	01/2/2017
BARKER	2:17-cv-13272	01/3/2017
TOLBERT	2:18-cv-04463	01/9/2017

Last Name	MDL Docket No.	First Treatment Date
MCINTOSH	2:18-cv-13176	01/13/2017
REEVES	2:19-cv-12711	01/19/2017
SMITH	2:19-cv-03290	01/24/2017
WILLIAMS	2:18-cv-12464	02/7/2017
MOODY BEAUMONT	2:17-cv-15956	02/21/2017
MCNELLEY	2:18-cv-03612	02/24/2017
WILKINS	2:19-cv-10869	03/9/2017
HALL	2:18-cv-08717	03/10/2017
ALSTON	2:18-cv-06527	03/14/2017
DENNIS	2:18-cv-06154	03/14/2017
BRYANT	2:19-cv-01292	03/22/2017
MUGLESTON	2:19-cv-02205	03/27/2017
TUTT	2:19-cv-01715	03/27/2017
FRANKLIN	2:19-cv-01947	03/29/2017
LANDERS	2:18-cv-08358	03/29/2017
BALAAM	2:18-cv-08761	04/6/2017
NELSON	2:18-cv-08400	04/18/2017
SHELTON	2:19-cv-09977	04/18/2017
GREEN	2:18-cv-06174	05/4/2017
ALLEN	2:19-cv-13477	06/29/2017
CARTER	2:18-cv-07047	06/29/2017
MONNIN	2:18-cv-08006	07/7/2017
MACDONALD	2:18-cv-05994	07/11/2017
WAGGONER	2:19-cv-11423	07/14/2017
RIGO	2:17-cv-09889	12/13/2017
VIDAL	2:19-cv-12539	12/26/2017
SMITH	2:19-cv-11532	01/23/2018

Last Name	MDL Docket No.	First Treatment Date
DORSEY	2:20-cv-00241	07/31/2018
MCCOY	2:18-cv-10424	12/??/2015
VAN DEN VRIJOEF	2:19-cv-01365	12/??/2015