

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KIMBERLY GREMO,

Plaintiff,

v.

1:19-cv-13432-NLH-AMD

OPINION

BAYER CORPORATION, BAYER
HEALTHCARE LLC, BAYER
HEALTHCARE PHARMACEUTICALS,
INC., GE HEALTHCARE, INC.,
GENERAL ELECTRIC COMPANY,
MALLINCKRODT, INC.,
MALLINCKRODT LLC, GUERBERT
LLC, LIEBEL-FLARSHEIM COMPANY
LLC, AMERISOURCE BERGEN
CORPORATION, AMERISOURCE
BERGEN DRUG CORPORATION,

Defendants.

APPEARANCES :

DEREK BRASLOW
KETTERER BROWNE & ANDERSON
11130 SUNRISE VALLEY DRIVE, SUITE 140
RESTON, VA 20190

T. MATTHEW LECKMAN, *pro hac vice*
LITTLEPAGE BOOTH LECKMAN
1912 W. MAIN ST.
HOUSTON, TX 77098
On behalf of Plaintiff

JENNIFER GREENBLATT, *pro hac vice*
EDWARD DUMOULIN, *pro hac vice*
GOLDMAN ISMAIL TOMASELLI BRENNAN & BAUM LLP
564 W. RANDOLPH ST., STE. 400
CHICAGO, IL 60661

WILFRED P. CORONATO
MCCARTER & ENGLISH LLP
FOUR GATEWAY CENTER 100 MULBERRY ST.

NEWARK, NJ 07102

On behalf of Defendants Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc.

STEPHEN G. TRAFLET
DEBRA M. ALBANESE
TRAFLET & FABIAN
264 SOUTH STREET
MORRISTOWN, NJ 07960

MICHAEL L. O'DONNELL, *pro hac vice*
JEREMY A. MOSELEY, *pro hac vice*
WHEELER TRIGG O'DONNELL LLP
370 SEVENTEENTH STREET, #4500
DENVER, COLORADO 80202

On behalf of Defendants GE Healthcare Inc. and General Electric Company

ERIN (LOUCKS) LEFFLER
SHOOK, HARDY & BACON L.L.P.
TWO COMMERCE SQUARE
2001 MARKET STREET, SUITE 3000
PHILADELPHIA, PA 19103

DEVIN K. ROSS, *pro hac vice*
ROBERT T. ADAMS, *pro hac vice*
SHOOK, HARDY & BACON L.L.P.
2555 GRAND BOULEVARD
KANSAS CITY, MO 64108

On behalf of Defendants Mallinckrodt, Inc., Mallinckrodt LLC, Amerisource Bergen Corporation, and Amerisource Bergen Drug Corporation

JAMIE L. KENDALL
BRAD M. WELSH
ALEXANDRA H. SCHULZ
KENDALL LAW PC
308 E. LANCASTER AVENUE, SUITE 315
WYNNEWOOD, PENNSYLVANIA 19096

BRIAN W. SHAFFER
MORGAN LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PENNSYLVANIA 19103-2921

On behalf of Defendants Guerbet LLC and Liebel-Flarsheim Company, LLC

HILLMAN, District Judge

This matter concerns FDA-approved gadolinium-based contrast agents ("GBCAs") administered intravenously by medical professionals to enhance the quality of magnetic resonance imaging ("MRI"). The MRIs are used to diagnose serious conditions, such as cancer, strokes and aneurysms. Plaintiff, Kimberly Gremo, claims that Defendants' GBCAs caused her "gadolinium toxicity, or Gadolinium Deposition Disease (GDD), as characterized by a multitude of symptoms," including "skin issues including rashes," "teeth issues including darkened teeth and spots," "brain fog and memory loss," and "loss of smell."

Plaintiff has filed suit against Defendants Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals, Inc. (collectively "Bayer"), GE Healthcare, Inc., General Electric Company (collectively "GE"), Mallinckrodt, Inc., Mallinckrodt LLC (collectively "Mallinckrodt"), Guerbert LLC ("Guerbert"), Liebel-Flarsheim Company LLC ("Liebel-Flarsheim"), Amerisource Bergen Corporation, and Amerisource Bergen Drug Corporation (collectively "AmerisourceBergen"), as "manufacturers" or "sellers" of the GBCAs to which Plaintiff was exposed: Magnevist (manufactured and sold by Bayer), Omniscan (manufactured and sold by GE), and OptiMARK (manufactured and sold by Guerbet,

Mallinckrodt, Liebel-Flarsheim, and AmerisourceBergen¹).

In her amended complaint,² Plaintiff has asserted two counts for Defendants' alleged violations of New Jersey's Product Liability Act (PLA), N.J.S.A. 2A:58C-2: failure to warn (Count I) and defective design (Count II). Plaintiff has also asserted a breach of express warranty claim against Defendants pursuant to N.J.S.A. 12A:2-313 (Count III).

Defendants have moved to dismiss all of Plaintiff's claims against them for numerous reasons. Plaintiff has opposed Defendants' motions. For the reasons expressed below, Defendants' motions will be denied.

I. JURISDICTION

Defendants removed Plaintiff's complaint from state court to this Court pursuant to 28 U.S.C. § 1331.

¹ According to Plaintiff's amended complaint, Defendant Mallinckrodt Inc. developed, invented, manufactured, tested, marketed, advertised, and sold a linear GBCA named OptiMARK before it sold its contrast media portfolio, including OptiMARK, to Guerbert LLC in 2015. Defendant Guerbert LLC manufactured, tested, marketed, advertised and sold OptiMARK before it removed OptiMARK from the United States market in 2018. In August 2016, OptiMARK's product label indicated that it was manufactured and distributed by Defendant Liebel-Flarsheim Company LLC. Defendant AmerisourceBergen has been engaged in the distribution, supply, marketing, and sale of OptiMARK in the State of New Jersey.

² Defendants moved to dismiss Plaintiff's original complaint. In response, Plaintiff filed an amended complaint. The motions to dismiss Plaintiff's original complaint are therefore moot. Pending are Defendants' motions to dismiss Plaintiff's amended complaint.

As the Court found in denying Plaintiff's motion to remand under the well-pleaded complaint rule (see Docket No. 108), even though the three counts in Plaintiff's complaint assert claims based on state law, on the face of Plaintiff's complaint, over which she is the "master," she has also raised claims arising under the laws of the United States, as well as claims that necessarily depend on resolution of a substantial question of federal law, to both of which § 1331 applies.³ See Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal., 463 U.S. 1, 22, 28 (1983) ("[T]he party who brings the suit is master to decide what law he will rely upon," but "it is an independent corollary of the well-pleaded complaint rule that a plaintiff may not defeat removal by omitting to plead necessary

³ For example, Plaintiff pleads: "Upon information and belief, the Defendants have or may have failed to comply with all federal standards and requirements applicable to the sale of GBCAs including, but not limited to, violations of various sections and subsections of the United States Code and the Code of Federal Regulations." (Pl. Compl., Docket No. 1 at 38, ¶ 126.) Plaintiff further claims that "notwithstanding the overwhelming evidence of causal association between GBCAs and NSF [renal impairment called nephrogenic systemic fibrosis], the FDA [Food and Drug Administration] and the GBCA industry have cast the issue of retention as separate from the medical community's experience with NSF, coming short of acknowledging any untoward health effects from gadolinium retention in non-renal patients," and "to date, the FDA and the GBCA industry have refused to acknowledge that GBCAs can cause NSF in renal patients but also can cause, in non-renal patients, a variety of NSF-like injuries and symptoms along a continuum, ranging from minor to severe." (Id. at 36, ¶¶ 120-21.)

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