*GRANTED

Michael C. Zogby (NJ ID 030312002)
Jessica L. Brennan (NJ ID 024232007)
DRINKER BIDDLE & REATH LLP
michael.zogby@dbr.com
jessica.brennan@dbr.com
600 Campus Drive
Florham Park, NJ 07932-1047
(973) 549-7000
Attorneys for Defendants Mentor Worldwide LLC, Ethicon Inc., and Johnson & Johnson

RENEE CASHEN and RICHARD CASHEN, Plaintiffs, v. JOHNSON & JOHNSON; ETHICON, INC.; and MENTOR WORLDWIDE LLC, Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY DOCKET NO. MID-L-002442-18 CIVIL ACTION **ORDER DISMISSING PLAINTIFFS' AMENDED COMPLAINT**

THIS MATTER, having been opened to the Court by Drinker Biddle & Reath LLP, attorneys for the Defendants Mentor Worldwide LLC, Ethicon, Inc., and Johnson & Johnson ("Defendants"), for entry of an Order dismissing Plaintiffs' amended complaint with prejudice pursuant to Rule 4:6-2(e), and the Court having considered the submissions of the parties and oral argument, if any, and for good cause shown;

IT IS on this 24th day of December, 2018

ORDERED as follows:

1. Defendants' Motion to Dismiss Plaintiffs' Amended Complaint pursuant to Rule 4:6-2(e) is hereby is granted.

2. Plaintiffs' amended complaint is hereby dismissed with prejudice.

FURTHER ORDERED that a copy of this Order be served on all parties of record within seven (7) days of its posting to eCourts.

/s/ Andrea Carter

, J.S.C.

This motion was:

_X__ opposed

____ unopposed

* **SEE STATEMENT OF REASONS ATTACHED HERETO**

STATEMENT OF REASONS

CASHEN V. JOHNSON & JOHNSON, ET AL.

Docket No.:	L-2442-18	DED:	---
Case Init.:	04/23/18	Trial Date:	---
		Arb. Date:	---

			Date Filed
1	Movant:	Defendants Mentor Worldwide, LLC; Ethicon, Inc.; and Johnson & Johnson	09/12/18
2	Opposition:	Plaintiffs Renee Cashen & Richard Cashen	10/01/18
3	Reply:	Defendants Mentor Worldwide, LLC; Ethicon, Inc.; and Johnson & Johnson	10/08/18
4	Surreply (withdrawn):	Plaintiffs Renee Cashen & Richard Cashen	11/07/18
		Return Date:	12/24/18

DISMISS COMPLAINT

I. POSTURE

Plaintiffs Renee and Richard Cashen, husband and wife, filed their Complaint on April 27, 2018 against Defendants for injuries allegedly caused by MemoryGel Breast Implants. On July 13, 2018, Plaintiffs amended their Complaint adding claims against Defendants for negligence, failure to warn, strict products liability, negligent misrepresentation, fraudulent misrepresentation, fraudulent concealment, violation of the Ohio Consumers Sales Practices Act ("OSPCA"), strict liability under the Ohio Products Liability Act ("OPLA"), breach of express warranty, and loss of consortium.

Defendants filed the instant Motion to Dismiss Plaintiffs' Amended Complaint in its entirety on September 12, 2018. Defendants' Motion was adjourned due to scheduling conflicts. Plaintiffs filed opposition and Defendants filed a reply. Plaintiffs also filed, and later withdrew, a Motion for Leave to File a Surreply in Response to Defendants' Motion to Dismiss.

Oral argument on the instant Motion was held on November 14, 2018. At the beginning of arguments, Plaintiffs' counsel withdrew Count 1 (Negligence), Count 2 (Strict Products Liability: Failure to Warn), Count 3 (Strict Products Liability), and Count 4 (Negligent Representation) of the Complaint.

Therefore, this Opinion analyzes only the remaining claims, i.e., Count 5 (Fraudulent Misrepresentation), Count 6 (Fraudulent Concealment), Count 7 (Violation of the Ohio Consumer Protection Law a.k.a. "OPLA"), Count 8 (Strict Liability in Violation of the OPLA), Count 9 (Breach of Express Warranty), and Count 10 (Loss of Consortium).

II. FACTUAL BACKGROUND

Plaintiffs' Complaint arises from injuries allegedly sustained by Renee Cashen as a result of bilateral breast implantation surgery on February 7, 2008 in which MemoryGel SILTEX Round Moderate Implants ("the implants" or "the product") were implanted. The implants were manufactured by Mentor Worldwide, LLC ("Mentor"). Mentor is a stand-alone business unit that reports to Ethicon, Inc. ("Ethicon"). Mentor and Ethicon are wholly-owned subsidiaries of Defendant Johnson & Johnson.

In 2016 Plaintiff Renee Cashen noticed an irregular lump under her right armpit and thereafter obtained a biopsy. In a consultation about the biopsy results, Plaintiff was diagnosed with anaplastic large cell lymphoma ("ALCL"). Several weeks later, Plaintiff was informed by her doctor that ALCL was associated with breast implants manufactured by Defendant Mentor. On May 26, 2016, Plaintiff underwent surgery in which six infected lymph nodes were removed. In July of 2017, Plaintiff began chemotherapy treatments.

III. MOVANTS

Defendants argue that summary judgment in their favor is appropriate because (A) Plaintiffs' claims fail under Ohio substantive law and (B) Plaintiffs' claims are preempted by federal law. Preliminarily, the parties appear to agree that the applicable state laws governing this action are those of Ohio because that is where Plaintiffs' injuries arise.

A. State Law

i. Counts 5 & 6 (Fraudulent Misrepresentation & Fraudulent Concealment)

Defendants argue that Plaintiffs' claims of fraudulent misrepresentation & fraudulent concealment fail under Ohio law. [Br. at 8]. Movants assert that all common law product liability claims are abrogated under the Ohio Products Liability Act ("OPLA"). [Brief ("Br.") at 8]. Therefore, Defendants assert that because Counts 5 & 6 of the Amended Complaint are common law claims, they were required to be pled under the OPLA and should therefore be dismissed. [Br. at 9].

ii. Count 7 (Consumer Protection)

Defendants argue that Plaintiffs' Count 7, alleging Defendants' violation of the Ohio Consumer Sales Practices Act ("OCSPA"), also fails under Ohio law because the OPLA preempts OCSPA claims rooted in products liability and the OCSPA does not apply to personal injury claims or prescription medical devices. [Br. at 10-11].

iii. Count 8 (Design & Manufacturing Defect - Strict Liability)

Defendants argue that Plaintiffs' claim under a theory of design defect is barred under the OPLA because Ohio law bars design defect claims for "ethical medical devices" with which the manufacturer provides an adequate warning. [Br. at 12]. Insofar as Count 8 alleges a manufacturing

defect, Defendants argue that the claim is insufficiently pled in that it lacks adequate specificity. [Br. at 12-13].

iv. Count 9 (Breach of Express Warranty)

Defendants argue that Plaintiffs' breach of express warranty claim, like the common law claims, is abrogated by the OPLA. [Br. at 13]. Defendants also assert that (1) under Ohio law, Plaintiffs were required to allege that they provided pre-suit notice to Defendants; and (2) Count 9 was insufficiently pled. [Br. at 13-14]. Further, Defendants argue that their statements do not amount to an express warranty and are merely "non-actionable puffery." [Br. at 15]. Defendants also assert that even if an express warranty did exist it was not part of "the basis of the bargain" and therefore the claim fails. [Br. At 16-17].

B. Federal Law

In addition to Defendants' state law arguments, Movants also assert that Plaintiffs' claims are preempted by federal law under the Medical Device Amendments of 1976 ("MDA"). [Br. at 17]. Defendants argue that the MDA expressly and impliedly preempts claims relating to medical devices that have obtained Pre-Market Approval ("PMA") from the Food & Drug Administration ("FDA"). [Br. at 18]. Therefore, there is a "narrow gap" for plaintiffs pursuing claims against an FDA-approved medical device which Defendants assert is not applicable in this case. [Br. at 22].

C. Pleading Requirements

Defendants assert that Plaintiffs' claims do not satisfy the applicable pleading requirements and therefore must be dismissed. [Br. at 37]. Specifically, Defendants argue that Plaintiffs' claims are not supported by the facts alleged, because Defendants are referred to collectively and not been specifically identified, and the fraud-based claims lack the requisite particularity. [Br. at 42].

D. Loss of Consortium

Lastly, Defendants assert that Plaintiffs' Loss of Consortium claim must also fail because they are derivative of Counts 1 - 9 which fail. [Br. at 44].

IV. OPPOSITION

Plaintiffs oppose the instant Motion and contend that Defendants' arguments are unfounded at this stage. [Opposition ("Opp.") at 5]. Specifically, Plaintiffs urge the Court to deny Defendants' Motion in light of New Jersey's liberal Standard of Review and Plaintiffs' well-pleaded allegations. [Opp. at 5].

A. Federal Preemption & State Law Abrogation

Plaintiffs contend that the MDA's preemption provisions do not apply to Plaintiffs' claims because they "run parallel to the federal requirements and do not conflict." [Opp. at 18]. Therefore, Plaintiffs argue that the claims are not expressly preempted by the federal law. Plaintiffs also argue that their claims are not impliedly preempted under state law because, contrary to Defendants' characterization, Plaintiffs' misrepresentation claims emanate from alleged violations of traditional state tort duties which pre-date the MDA. [Opp. at 19].

i. Count 5 & 6 (Fraudulent Misrepresentation & Fraudulent Concealment)

Plaintiffs contend that their claims of fraud and misrepresentation "are not abrogated by the OPLA because they implicate a more general duty not to deceive rather than the duty to warn." [Opp. at 23]. Similarly, relating to federal preemption, Plaintiffs argue that the general duty not to deceive does not impose different or additional requirements from those in the MDA. [Opp. at 24].

ii. Count 7 (Violation of OCSPA)

Plaintiffs contend that the OPLA does not preempt the OCPSA because Plaintiffs' damages are based not only on personal injury, but also economic harm associated with the cost of the

product, the cost of removing the product, and other economic losses that stem from the product. [Opp. at 26].

iii. Count 8 (Strict Liability - OPLA)

Plaintiffs contend that their claim in Count 8, alleging violation of the OPLA for the product's design, manufacture, and warnings, can be sustained because Plaintiffs' Complaint contains well-pleaded allegations. [Opp. at 30]. With regard to design defect, Plaintiffs argue that their Complaint alleges that the product was unreasonably unsafe. [Opp. at 30-31]. With regard to manufacturing defect, Plaintiffs argue that they have met their burden in establishing a viable claim that the product deviated in a material way from the design specifications. [Opp. at 32]. With regard to Plaintiffs' failure to warn allegation, Plaintiffs assert that Defendants failed to adequately warn of the risks associated with the product in violation of the OPLA. [Opp. at 32-35].

iv. Count 9 (Breach of Express Warranty)

Plaintiffs contend that their claims under the theory of breach of express warranty are viable because the OPLA provides for liability when a product does not conform to representations by the manufacturer. [Opp. at 37]. Plaintiffs also assert, in contradiction to Defendants' claim that the pre-suit notice was not satisfied, that they have met all the conditions precedent necessary under the UCC. [Opp. at 37-38]. Plaintiffs further contend that Count 9 has been sufficiently plead under Ohio law. [Opp. at 38]. Additionally, Plaintiffs assert that it is premature for the Court to analyze whether Defendants' advertisements constitute "non-actionable puffery" and that Plaintiff relied upon the advertisements prior to selecting the product. [Opp. at 40-41].

Plaintiffs argue that federal law does not expressly preempt Plaintiffs' Count 9 because the claims are not based on the FDA-approved label but rather voluntary warranties not reviewed by the FDA contained in advertisements. [Opp. at 41]. Plaintiffs also assert that the claim is not

impliedly preempted because the claims are based on fraud to the consumer rather than fraud to the FDA. [Opp. at 42].

B. Loss of Consortium

Plaintiffs likewise argue that because Plaintiff Renee Cashen's claims survive dismissal, so too must Plaintiff Richard Cashen's Loss of Consortium claim contained in Count 10. [Opp. at 43].

C. Request for Leave to File Amended Complaint

Plaintiffs request an opportunity to file a Second Amended Complaint, should the Court find that Plaintiffs' Complaint is deficient, to bring the Complaint in conformance with the Court's request. [Opp. at 43].

D. Request for Discovery

Lastly, Plaintiffs urge the Court to provide Plaintiffs with an opportunity to carry out some level of discovery. [Opp. at 44]. Plaintiffs argue that they "cannot be expected to plead their claims with greater specificity without discovery to gain access to internal company documents, including communications with the Federal Government and FDA." [Opp. at 44].

IV. REPLY

Preliminarily, Defendants note that Plaintiffs failed to respond to Defendants' arguments surrounding Counts 1 - 4 and therefore argue that these claims should be deemed conceded. [Rep. at 1-2]. Defendants also assert that the remaining claims are abrogated under Ohio law and preempted under Federal law. [Rep. at 2]. Defendants also urge this Court to reject Plaintiffs' requests for discovery and to amend their Complaint because NJ caselaw does not permit this practice. [Rep. at 14-15].

VI. APPLICABLE LAW

A. Standard of Review - Motion to Dismiss

R. 4:6-2(e) requires a motion to dismiss for failure to state a claim be reviewed under the liberal standard enunciated in Printing Mart-Morristown v. Sharp Elecs. Corp., 116 N.J. 739 (1989). The complaint must be searched in depth and with liberality to determine if a cause of action can be gleaned even from an obscure statement, particularly if further discovery is taken. Ibid. Every reasonable inference is therefore accorded the plaintiff and the motion is granted only in rare instances and ordinarily without prejudice. Ibid.

At this preliminary stage of the litigation the Court is not concerned with the ability of plaintiffs to prove the allegation contained in the complaint. Ibid. A motion to dismiss for failure to state a claim must be granted only if "even a generous reading of the allegation does not reveal a legal basis for recovery." Camden County Energy Recovery Assoc. v. NJDEP, 320 N.J. Super. 59, 64-65 (App. Div. 1999), aff'd 170 N.J. 246 (2001). "[I]f a generous reading of the allegations merely *suggests* a cause of action, the complaint will withstand the motion [to dismiss]." F.G. v. MacDonell, 150 N.J. 550, 556 (1997). A complaint should not be dismissed under R. 4:6-2(e) where a cause of action is suggested by the facts and a theory of actionability may be articulated by amendment of the complaint. Pressler, Current N.J. Court Rules, Comment 4.11 on R. 4:6-2 (2014) (citing Printing Mart-Morristown, 116 N.J. at 746).

B. The Medical Device Amendments of 1976

All medical devices sold in the United States are regulated by the Food and Drug Administration ("FDA") "which draws its regulatory authority in this area from the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). Aaron v. Medtronic, Inc. 209 F. Supp. 3d 994 (S.D. Ohio 2016) (citing 21 U.S.C. § 360c *et seq.*). The MDA

classifies medical devices into three groups, Class I to Class III, that correlate with increasing levels of scrutiny by the FDA. 21 U.S.C. § 360c.

Class III medical devices, like the implant that is the basis for Plaintiffs' causes of actions, "'present a potential unreasonable risk of illness or injury' and therefore incur the FDA's strictest regulation." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001) (citing 21 U.S.C. § 360c(a)(1)(C)). "Class III devices must complete a thorough review process," known as premarket approval ("PMA"), "with the FDA before they may be marketed." Ibid. "To obtain PMA, a manufacturer must submit a detailed PMA application that contains, among other things, specimens for the proposed labeling of the device." Riegel v. Medtronic, Inc., 451 F.3d 104, 109 (2d Cir. 2006), aff'd, 552 U.S. 312, 128 S. Ct. 999 (2008) (internal quotations omitted). "The FDA spends an average of 1,200 hours reviewing each application and grants premarket approval only if it finds there is a reasonable assurance of the device's safety and effectiveness." Riegel, 552 U.S. at 318. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319.

Federal Preemption

i. Express Preemption

Congress adopted the Medical Device Amendments ("MDA") of 1976 with the intent to impose a "regime of detailed federal oversight." Riegel v. Medtronic, 552 U.S. 312, 316 (2008); 21 U.S.C. § 360c, *et seq*. Contained within these amendments was an express pre-emption provision that states:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from preemption. 21 U.S.C. § 360k(b).

The Riegel Court articulated a two-step process for Courts when analyzing whether a state law claim is preempted under the MDA. 522 U.S. at 322. First, the Court must determine whether the FDA established requirements applicable to the device at issue. Ibid. Riegel concluded that the first prong of the preemption test is automatically satisfied where a medical device has received premarket approval" from the FDA. Clements v. Sanofi-Aventis, U.S., 111 F. Supp. 3d 586, 597 (D.N.J. 2015) (citing Riegel, 552 U.S. at 321)).

If the first prong of the analysis is satisfied, the Court must then determine whether the plaintiff's common-law claim, which relates to the safety or effectiveness of the device, relies upon a state law requirement that is different from or in addition to federal requirements. Riegel, 552 at 323.

The Riegel Court held that

> state requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Id. at 330.

ii. Implied Preemption

In addition to the MDA's express preemption provision, 21 U.S.C. § 337(a) impliedly preempts plaintiffs' state law claims based upon fraud on the FDA. Buckman Co. v. Plaintiffs'

Legal Comm., 531 U.S. 341, 348 (2001). The Buckman Court, however, noted that claims which are not based upon fraud on the FDA, but rather based upon state law that predates the MDA, are not subject to this implied preemption. Id. at 353.

iii. The "Narrow Gap" Doctrine

While the preemptions provisions preempt most common-law tort duties, the statute "does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements. Riegel, 552 U.S. at 330 (citing Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996)).

D. State Abrogation

i. Ohio Products Liability Act

The Ohio Products Liability Act ("OPLA") is codified in Ohio Revised Code §§ 2307 *et seq*. Section 2307.71(B) provides: "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." While Ohio courts generally agree that this language abrogates most common law claims, there have been "differing conclusions as to whether the OPLA abrogates claims sounding in fraud and misrepresentation." Hogue v. Pfizer, Inc., 893 F.Supp.2d 914, 918 (S.D. Ohio 2012).

However, the courts appear to largely agree that while the OPLA does abrogate fraud claims based on a duty to warn, it "does not abrogate fraud claims which are based on a general duty not to actively deceive." Ibid. (citing Glassner v. R.J. Reynolds Tobacco Co., 223 F.3d 343, 348-49 (6th Cir. 2000). In applying this distinction, the Hogue Court found that the substance of the plaintiff's claims were "unmistakably failure to warn" and therefore were abrogated under the OPLA. Id. at 919.

ii. Ohio Consumer Sales Practices Act

The Ohio Consumer Sales Practices Act ("OCSPA") is codified in Ohio Revised Code §§ 1345.01 *et seq.* Where OCSPA claims are "primarily rooted in product liability claims," Ohio Courts have held that the OPLA preempts claims under the OCSPA. Mitchell v. Proctor & Gamble, 2010 U.S. Dist. LEXIS 17956 (S.D. Ohio); Bouthard v. American Home Prods. Corp., 2002 U.S. Dist. LEXIS 22996 (N.D. Ohio); Blake v. Interneuron Pharmaceuticals, 1998 U.S. Dist. LEXIS 23667 (S.D. Ohio). Courts have held that injuries abrogated under the OPLA include prescription and over-the-counter pharmaceuticals. Schnell v. American Home Prods. Corp., 2000 U.S. Dist. LEXIS 22996, *4-5 (N.D. Ohio); Mitchell, 2010 U.S. Dist. LEXIS 17956 at *12.

E. Pleading Requirements under R. 4:5-2

R. 4:5-2, setting forth the general rules of pleadings for relief, provides:

> Except as may be more specifically provided by these rules in respect of specific actions, a pleading which sets forth a claim for relief, whether an original claim, counterclaim, cross-claim or third-party claim, shall contain a statement of the facts on which the claim is based, showing that the pleader is entitled to relief, and a demand for judgment for the relief to which the pleader claims entitlement

Pursuant to this rule, NJ Courts have held that "pleadings reciting mere conclusions without facts and reliance on subsequent discovery do not justify a lawsuit." Glass v. Suburban Restoration Co., Inc., 317 N.J. Super. 574, 582 (App. Div. 1998). While the Court Rules "require that all pleadings be construed liberally in the interest of justice, N.J. Ct. R. 4:5-7, a party's pleadings must nonetheless fairly apprise an adverse party of the claims and issues to be raised at trial." Milltz v. Borroughts-Shelving, Div. of Lear Siegler, Inc., 203 N.J. Super. 451, 458 (App. Div. 1985).

R. 4:5-8(a) provides that

> In all allegations of misrepresentation, fraud, mistake, breach of trust, willful default or undue influence, particulars of the wrong, with dates and items if

> necessary, shall be stated insofar as practicable. Malice, intent, knowledge, and other condition of mind of a person may be alleged generally.

"It is well settled that one who asserts fraud must allege with specificity the representation, its falsity, materiality, the [declarant's] knowledge or ignorance, and reliance." Palko v. Palko, 73 N.J. 395 (1997).

NJ Courts have found allegations surrounding fraud claims to be adequate where the following five elements have been met in the plaintiffs' allegations: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages." State, Dep't of Treasury, Div. of Inv. Ex rel. McCormac v. Qwest Communications Intern., Inc., 387 N.J. Super. 469, 485 (App. Div. 2005).

VII. ANALYSIS

The central issue for the purposes of the instant Motion is whether Plaintiffs' claims are preempted under federal law or abrogated under state law.

Express preemption applies where a claim under state law is different or in addition to the federal requirements. Implied preemption applies where a claimant seeks to "polic[e] fraud against federal agencies." Preliminarily, the Court finds that the first step of the Riegel analysis is clearly satisfied because Plaintiffs' claims are based upon injuries alleged to have been sustained as a result of the use of a Class III Medical Device that has gone through the PMA process.

Therefore, the Court will first analyze whether the remaining Counts 5 through 10 are preempted under the Riegel and Buckman guidance. Second, the Court will analyze whether the remaining claims are abrogated under Ohio law. While the Court is interpreting Ohio law, the standard of review for Defendants' Motion to Dismiss is that of NJ. This standard, as previously described, is articulated under R. 4:6-2.

A. Counts 5 & 6 (Fraudulent Misrepresentation & Fraudulent Concealment)

i. Federal Preemption

Plaintiffs assert that Counts 5 & 6, alleging fraudulent misrepresentation and fraudulent concealment, are not preempted under the MDA. Specifically, with regard to express preemption, Plaintiffs argue that these allegations are based upon a common law fraud claim which pre-dates Mentor's PMA and does not conflict with the PMA requirements. Further, Plaintiffs assert that these claims are not based upon a theory of fraud on the FDA but rather fraud on Plaintiffs and the general public.

Defendants contend that these claims are expressly preempted because they impose requirements concerning the safety and effectiveness of the product that are different from or in addition to the requirements imposed by the FDA.

The Court is finds that Plaintiffs' claims under Counts 5 & 6 are preempted by federal law. With the first step of the Riegel analysis satisfied, the focus of express preemption is whether Plaintiffs' fraud claim, relating to the safety or effectiveness of the device, relies upon a state law requirement that is different from or in addition to federal requirements.

Inherent in the FDA's approval of the product is its finding that the product and its label have met the federal requirements as a Class III medical device. Therefore, it stands that any claims of fraudulent misrepresentation and fraudulent concealment seek to either (1) impose different or additional requirements to those that the FDA has already determined to have been satisfied or (2) stand in the place of the FDA and enforce federal requirements. The former would make the claims expressly preempted while the latter would be impliedly preempted.

This Court has determined that the claims contained within Counts 5 & 6 fundamentally seek to impose different requirements from those the FDA has already determined to have been

met. Plaintiffs argue that these claims are not based upon the safety or effectiveness of the implants. [Opp. at 24]. This, however, is in contrast to Plaintiffs' allegations contained within their Amended Complaint.

Indeed, Count 5 alleges that "Defendants fraudulently misrepresented information regarding their product including, but not limited to, its propensity to cause *serious physical harm*." [Amended Complaint ("Am. Comp.") ¶ 200 (emphasis added)]. Count 6 states that "Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the *safety* of MemoryGel Breast Implants." [Am. Comp. ¶ 210 (emphasis added)].

Accordingly, the Court finds Counts 5 & 6 to be preempted by federal law and are therefore dismissed. In the interest of diligence, however, the Court also provides an abrogation analysis of Plaintiffs' claims contained within Counts 5 & 6 below.

ii. Abrogation Under Ohio Law

Defendants assert that Plaintiffs' claims of fraudulent misrepresentation and fraudulent concealment are abrogated under a plain reading of the OPLA because they are based upon a theory of omission and concealment. [Rep. at 3]. Plaintiffs contend that claims of fraud and misrepresentation are not abrogated because they implicate a more general duty not to deceive rather than the duty to warn. [Opp. at 23].

This Court is persuaded by Defendants' arguments highlighting the statutory text. Ohio Revised Code § 2308.71(B) states that "Sections 2307.71 to 2307.80 of the Revised Code are intended to abrogate all common law product liability claims or causes of action." Further, § 2307.71 defines the term "product liability claim" as

> a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person,

> emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> > (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> > (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> > (c) Any failure of that product to conform to any relevant representation or warranty.

Ohio Rev. Code § 2307.71(A)(13)(b).

Ohio Courts have consistently interpreted claims of fraudulent misrepresentation and fraudulent concealment to fall within, and thus be abrogated by, the OPLA. See Hogue v. Pfizer, Inc., 893 F. Supp. 2d 914, 919 (S.D. Ohio 2012) (explaining that "claims of fraud based upon fraudulent misrepresentation and concealment are preempted to the extent that they are predicated on a duty to issue additional or clearer warnings through advertising" and therefore the plaintiff's fraud claims were abrogated by the OPLA); see also Johnson v. Eli Lilly & Co., 2015 U.S. Dist. LEXIS 30537, *5 (S.D. Ohio 2015) (finding the plaintiff's fraudulent misrepresentation claim to be based upon a failure to warn and was thus abrogated by the OPLA).

In turning to Plaintiffs' Amended Complaint, the Court finds Plaintiffs' allegations contained within Counts 5 & 6 to be based on a failure to warn theory. More specifically, Plaintiffs allege in Count 5 that Defendants "owed a duty to provide accurate and complete information regarding their product" and that they "breached their duties to Plaintiff by providing false, incomplete and misleading information regarding their product." [Am. Comp ¶¶ 199, 202]. In Count 6, Plaintiffs allege that "[prior] to Plaintiff's user of [the implants] and during the period in which Plaintiffs actually used [the implants], Defendants fraudulently suppressed material information regarding the safety and efficacy of the [implants]" and "fraudulently concealed the safety information about the use of the [implants]."

Plaintiffs rely on Hutchens v. Abbot Laboratories, Inc., 2016 WL 5661582 (N.D. Ohio 2016) [Lexis citation unavailable] to support their argument "that the OPLA does not abrogate common law fraud claims." [Opp. at 23]. The Hutchens Court analyzed whether the plaintiff's failure to warn claim against Defendants who manufactured a Category D drug was abrogated by the OPLA. Hutchens, 2016 WL 5661582, *12. However, the Hutchens case is distinguishable from the facts of this case because a central issue in that case was whether to apply the abrogation amendment, which was adopted in 2005, to a birth defect injury that may have accrued while the plaintiff *in utero* prior to the amendment. Hutchens, 2016 WL 5661582, *10.

In contrast to Hutchens, the Hogue Court found that where a fraud claim is based upon a theory of omission and concealment would be abrogated under the OPLA. While Plaintiffs attempt to construct an argument that avoids abrogation, by arguing its claims are based upon a general duty not to deceive, Plaintiffs' allegations are clearly based upon omission and concealment. [See Am. Comp. ¶ 210 ("Plaintiff relied upon the Defendants' false and fraudulent misrepresentations and *concealments* regarding the safety of [the implants]."); see also Am. Comp. ¶ 212 ("Defendants furthered this fraudulent *concealment* through continued and systematic failure to disclose information to Plaintiff and the public) (emphasis added)].

Furthermore, assuming for the sake of argument that this Court could find that Count 6 is not abrogated by the OPLA, the claim would therefore have to be based on Defendants' statements about the products which were already approved by the FDA. Therefore, even if Count 6 were not found to be abrogated, it would certainly be preempted under federal law. Accordingly, Counts 5 & 6 are dismissed.

ii. Count 7 (Violation of the Ohio Consumer Sales Practices Act)

a. Federal Preemption

Plaintiffs assert that Count 7, alleging violation of the Ohio Consumer Sales Practices Act ("OCSPA"), is not preempted under the MDA. Defendants argue that Count 7 is preempted by federal law because Plaintiffs seek to impose requirements concerning the safety and effectiveness of the product that are different from, or in addition to, the requirements imposed by the FDA. Plaintiffs contend that the duty allegedly breached by Defendants is a general duty and is therefore not preempted.

As explained more fully below, the Court finds that regardless of whether Count 7 is preempted under federal law, it clearly falls within the umbrella of the OPLA rather than the OCSPA and is appropriately dismissed.

b. Abrogation under Ohio Law

Defendants assert that Plaintiffs' claim of violation of the OCSPA is abrogated under the OPLA because the OPLA preempts claims under the OCSPA which are primarily rooted in product liability claims. Plaintiffs argue that this claim is not abrogated because it is based on alleged economic harm. Defendants contend that the phrase "economic loss" is defined by statute as "damage to the product in question" rather than physical injury. Defendants also contend that Plaintiffs' claim fails because the product was a prescription medical device rather than a consumer good for the purposes of the OCSPA.

Ohio courts have consistently held that "medical devices are not 'consumer goods' under the OCSPA" and therefore are "not a part of consumer transaction within the definition of the OCSPA." Smith v. Smith & Nephew, Inc. 5 F. Supp. 3d 930, 932 (S.D. Ohio 2014); Reeves v. PharmaJet, Inc., 846 F. Supp. 2d 791 (N.D. Ohio 2012); Williams v. Boston Sci. Corp., 2013 U.S. Dist. LEXIS 43427 (N.D. Ohio 2013).

Accordingly, this Court finds the OPLA abrogates the claim contained within Count 7.

iii. Count 8 (Violation of the Ohio Products Liability Act)

a. Federal Preemption

Plaintiffs assert that Count 8, alleging violation of the Ohio Products Liability Act ("OPLA") for defects in design, manufacturing, and failure to warn, is not preempted under the MDA. Defendants argue that these claims, which are premised on theories that the product was defective, are expressly preempted under the MDA because Plaintiffs are seeking to impose requirements that are different from, or in addition to, those imposed by the FDA. Plaintiffs contend that the state law requirements are no different than the federal duties and thus qualify as parallel claims.

The Court is persuaded by Defendants' arguments and thus finds that Count 8 is preempted by federal law. In obtaining premarket approval, Mentor's implant has satisfied the FDA's strictest requirements for medical devices when it obtained PMA.

By definition, claims that the implant was defectively designed is expressly preempted by the MDA because any alternative design would violate the product's PMA. "[T]o prevail on this claim, Plaintiffs would need to establish that the [device] should have been designed in a manner *different* than that approved by the FDA. However, the Supreme Court's decision in Riegel - which held that § 360k(a) preempts 'claims of strict liability and negligence in the design of a device - squarely forecloses any such claim which would necessarily 'establish design requirements different from, or in addition to, federal requirements for [the device]." Aaron v. Medtronic, 209 F. Supp. 3d 994, 1007 (S.D. Ohio 2016) (internal punctuation omitted).

Similarly, the Court finds Plaintiffs' manufacturing defect claim is preempted by federal law. Count 8, contained within ¶¶ 223-252 of Plaintiffs' Amended Complaint, sets forth a plethora of allegations against Defendants under the OPLA. However, these generic allegations lack the

requisite specificity to survive the instant Motion in light of caselaw interpreting the MDA. "Generalized common law theories of liabilities . . . are precisely the type of claims the MDA sought to preempt." Williams v. Cyberonics, Inc., 388 F. App'x 169, 171 (3d Cir. 2010).

Further, the Court finds Plaintiffs' failure to warn claim contained within Count 8 to be without merit because the FDA has already approved the implant's warnings. Therefore, a claim based upon the product's warning would inherently seek to impose different requirements than those imposed by the FDA. For these reasons, the Court finds the claims contained with Count 8 to be expressly preempted by the MDA. Therefore, the Court will not analyze the merits of Count 8 against Ohio law.

iv. Count 9 (Breach of Express Warranty)

a. Federal Preemption

Plaintiffs assert that Count 9, alleging breach of express warranty, is not preempted by federal law. Defendants argue that this claim is expressly preempted because it seeks to impose requirements that are different from, or in addition to, those imposed by the FDA. Plaintiffs contend that this claim is based on Defendants' voluntary statements that were not reviewed by the FDA and therefore the claim is not expressly preempted. Likewise, Plaintiffs assert that the claim is not impliedly preempted because it does not involve fraud on the FDA.

For Plaintiffs to prevail on a Breach of Express Warranty claim against Defendants, "a jury would need to find that [the product] was not safe and effective as labeled." Aaron v. Medtronic, 209 F. Supp. 3d 994, 1008 (S.D. Ohio 2016). This, however, "would conflict with the FDA's conclusive determination in granting premarket approval that 'there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" Ibid. (quoting Riegel, 552 U.S. at 318). Accordingly, this

Court finds Count 8 to be expressly preempted by federal law and appropriately dismissed. Therefore, the Court does not engage in an Ohio-abrogation analysis.

v. Count 10 (Loss of Consortium)

Because all remaining claims of Plaintiffs' Amended Complaint warrant dismissal, Plaintiffs' Loss of Consortium claim must fail. Therefore, the Amended Complaint is dismissed in its entirety.