SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-0680-18T4

ARCELIA SANDOBAL GOMEZ, a/k/a ARCELIA SANDOBAL and ARCELIA SANDOVAL,

Plaintiff-Appellant,

v.

BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER ESSURE, INC., and BAYER HEALTHCARE PHARMACEUTICALS, INC.,

Defendants-Respondents,

and

BAYER A.G., ROBERT WOOD JOHNSON UNIVERSITY HOSPITAL, AMBULATORY SURGICAL PAVILION AT ROBERT WOOD JOHNSON, and ROBERT M. SCHAEFER, M.D.,

Defendants.

_____

Argued November 18, 2019 – Decided January 14, 2020

Before Judges Sabatino, Sumners and Geiger.

On appeal from the Superior Court of New Jersey, Law Division, Middlesex County, Docket No. L-4930-17.

Neal M. Unger argued the cause for appellant (Neil M. Unger, PC, attorneys; Neal M. Unger, of counsel and on the briefs; Ronald L. Lueddeke, Jr., on the briefs).

Erika L. Maley (Sidley Austin LLP) of the Washington, DC Bar, admitted pro hac vice, argued the cause for respondents (DLA Piper, LLP, and Erika L. Maley, attorneys; Jonathan F. Cohn (Sidley Austin LLP) of the Washington, DC Bar, admitted pro hac vice, Brian J. Pendleton, Jr., and Christopher M. Strongosky, of counsel and on the brief; Kristin A. Pacio, on the brief).

PER CURIAM

Plaintiff Arcelia Sandobal Gomez appeals from the Law Division's dismissal of all her claims for damages related to the implantation of a tubal birth control device known as Essure. For the following reasons, we affirm.

I.

Essure is a permanently implanted birth control device that is not intended to be removed. Unlike other marketed permanently implanted birth control devices, insertion of Essure does not require a surgical incision. During the implantation procedure, the doctor places flexible metallic coil inserts through the vagina and cervix and into the fallopian tubes. The implanted Essure

stimulates growth during the three months after implantation. The tissue build-up is meant to create a physical barrier that permanently prevents sperm from reaching the woman's eggs.

Essure was designed and initially manufactured by Conceptus, Inc. It was subsequently manufactured, marketed, promoted, sold, and distributed by the following "Bayer" organizations: (1) Bayer Essure, Inc., the device's manufacturer; (2) Bayer Healthcare, LLC; (3) Bayer Healthcare Pharmaceuticals, Inc.; (4) Bayer Corp., the American parent company of Bayer Essure, Bayer Healthcare, and Bayer Healthcare Pharmaceuticals; and (5) Bayer A.G., the German parent company of Bayer Corp. (collectively the Bayer defendants). The Bayer defendants provided hysteroscopic equipment, manufactured by a third-party, for use in implanting Essure. The Bayer defendants also provided training to physicians in how to implant Essure using the hysteroscopic equipment it supplied.

A. The Statutory and Regulatory Framework

Before 1976, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). This led to inconsistent and inadequate state regulation of complex medical devices. Id. at 315-16. Congress recognized that federal oversight was

needed to prevent Americans from being "put at risk from the use of unsafe and ineffective medical devices." S. Rep. 94-33, at 2 (1975).

To address these concerns, Congress enacted the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360c to 360m (2018), to the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 to 399i. The MDA was aimed at both protecting the public and ensuring that "innovations in medical device technology [were] not stifled by unnecessary restrictions." H.R. Rep. 94-853, at 12 (1976). To effectuate those dual goals, Congress "swept back some state obligations and imposed a regime of detailed federal oversight" administered by the Food and Drug Administration (FDA). Riegel, 552 U.S. at 316. A key goal was to avoid the undue burden imposed by inconsistent state regulation. H.R. Rep. 94-853, at 45. This led to the twofold approach implemented by Congress—combining a comprehensive "system of federal regulation over the introduction of new [medical] devices" to broad preemption of state law that imposes "any different or additional state safety or effectiveness requirements." Shuker v. Smith & Nephew, PLC, 885 F.3d 760, 765 (3d Cir. 2018) (citing 21 U.S.C. §§ 360c to 360f, 360k).

The MDA contains an express preemption clause, which preempts any state "requirement" affecting a medical device "(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). However, states are not precluded "from providing a damages remedy for claims premised on a violation of FDA regulations," if "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)). Nevertheless, all enforcement actions under the MDA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). This section impliedly preempts suits by private parties "for noncompliance with the medical device provisions." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 n.4 (2001).

The MDA "classifies medical devices in three categories based on the risk that they pose to the public." Lohr, 518 U.S. a 476. Class III devices are subject to "the most federal oversight," Shuker, 885 F.3d at 765 (quoting Riegel, 552 U.S. at 316-17), because they "presen[t] a potential unreasonable risk of illness or injury," Buckman, 531 U.S. at 344 (alteration in original) (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)(II)). "Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable

assurance' that the device is both safe and effective." Lohr, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)). This includes

> "a detailed description of the proposed conditions of use of the device," 21 U.S.C. § 360c(a)(3)(D)(i); a sample label delineating the intended uses, 21 U.S.C. § 360e(c)(1)(F); and "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective[.]" 21 U.S.C. § 360e(c)(1)(A).
>
> [Cornett v. Johnson & Johnson, 414 N.J. Super. 365, 386 (App. Div. 2010), aff'd in part and modified in part, 211 N.J. 362 (2012).]

The FDA may condition PMA "on adherence to performance standards, restrictions upon sale or distribution, or compliance with other requirements. The agency is also free to impose device-specific restrictions by regulation." Riegel, 552 U.S. at 319 (citations omitted).

There are two paths to approval of Class III devices. Relevant here is premarket approval (PMA) of devices that are so innovative there are no other "substantially equivalent" devices. Cornett v. Johnson & Johnson, 211 N.J. 362, 389 (2012), abrogated on other grounds, McCarrell v. Hoffmann-La Roche, Inc., 227 N.J. 569 (2017). Obtaining PMA is rigorous.

> To obtain pre-market approval, a device manufacturer must submit to the FDA full

> reports of all investigations relating to the device's safety or effectiveness; a "full statement of the components, ingredients, and properties and of the principle or principles of operation" of the device; a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; references to any performance standards applicable to the device; samples of the device and any component parts; examples of the proposed labeling for the device; and other information[.]
>
> [Walker v. Medtronic, Inc., 670 F.3d 569, 572-73 (4th Cir. 2012) (quoting 21 U.S.C. § 360e(c)(1)).]

A device's labeling includes the Instructions for Use provided to physicians and the Patient Information Booklet provided to patients.

When determining whether to grant PMA, the FDA "weig[hs] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." Riegel, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). The FDA will "grant[] [PMA] only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" Ibid. (quoting 21 U.S.C. § 360e(d)). The FDA may "approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." Ibid.

PMA has important legal effects. It "incorporates an FDA finding that a device is safe and effective under the conditions of use included on the label and that the label is not false or misleading." Cornett, 211 N.J. at 381 (citing 21 U.S.C. § 360e(d)(1)(A)). PMA also imposes federal safety requirements that preempt different or additional state requirements. Riegel, 552 U.S. at 321 (quoting 21 U.S.C. § 360k(a)(1)).

Once a device receives PMA, the manufacturer is prohibited, without FDA approval, from making "changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319. This prohibition includes adding warnings to the label, "until it submits the proposed change as part of a supplemental PMA application and obtains FDA approval." Cornett, 211 N.J. at 381 (citing 21 U.S.C. § 360e(d)(6)). Absent such FDA approval, the approved device must "be made with almost no deviations from the specifications in its approval application." Riegel, 552 U.S. at 323.

"After approval, the devices are subject to additional reporting requirements." Cornett, 211 N.J. at 381 (citing U.S.C. § 360i(a)(1), (3)).

> These include the obligation to: 1) inform the FDA of new clinical investigations or scientific studies concerning the device about which the manufacturer know or reasonably should know, 21 C.F.R. §

> 814.84(b)(2); and 2) report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, 21 C.F.R. § 803.50(a).
>
> [Id. at 381-82 (citing Riegel, 552 U.S. at 319-20).]

The FDA may withdraw the device's PMA "based on newly reported data," however, it "must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Riegel, 552 U.S. at 319-20 (citing 21 U.S.C. §§ 360e(e)(1), 360h(e)).

B. Premarket Approval of Essure

The FDA granted Essure PMA in 2002. After Essure's approval, and before the device was implanted in plaintiff, two pertinent PMA supplements regarding the device's labeling were approved by the FDA:

> 2012: patient and physician labeling updated to include results of 5-year follow-up of subjects in Phase II and pivotal trials and information on pregnancies that have occurred in the commercial setting (that is, outside of clinical trials).
>
> 2013: patient labeling updated to include risks of chronic pain and device migration.
>
> [FDA, Regulatory History: Essure Permanent Birth Control, https://www.fda.gov/medical-devices/essure-permanent-birth-control/regulatory-history (last updated May 15, 2019) (last visited January 2, 2020).]

C. Implantation of Essure and Alleged Resulting Problems

On October 29, 2014, Robert M. Schaefer, M.D., implanted the Essure device in plaintiff at the Ambulatory Surgical Pavilion at Robert Wood Johnson (the Surgical Center). Plaintiff claims after implantation she "experience[d] adverse reactions and side effects including . . . intermittent and severe abdominal pain and chronic and abnormal vaginal bleeding" following implantation. Plaintiff states she underwent approximately six months of diagnostic testing and the removal of uterine polyps during the period from July 2015 until January 2016. Plaintiff ultimately underwent a hysterectomy on January 13, 2016, to remove the Essure.

D. The Litigation

On August 17, 2017, plaintiff filed a nine-count complaint alleging the following causes of action: medical malpractice (counts one and two); negligence (count three); breach of express and implied warranties (count four); gross negligence (count five); strict liability (count six); failure to warn (count seven); fraud and misrepresentation (count eight); and violation of the Consumer Fraud Act (CFA), N.J.S.A. 56:8-1 to -20 (count nine).

Plaintiff alleged the following parties committed medical malpractice: Dr. Schaefer, the Surgical Center, and Robert Wood Johnson University

Hospital (the Hospital), the owner/operator of the Surgical Center. Dr. Schaefer and the Hospital filed unopposed motions to dismiss the medical malpractice claims with prejudice for failure to file an affidavit of merit.[1] The motions were granted on March 29, 2018. Plaintiff does not appeal from those orders. On April 26, 2018, a stipulation of dismissal with prejudice was entered as to the Surgical Center. As a result, counts one and two were dismissed in their entirety and only the products liability and related claims asserted against the Bayer defendants (counts three through nine) remained.

The Bayer defendants moved to dismiss plaintiff's claims with prejudice as preempted by federal law and for failure to state a claim upon which relief may be granted. On August 31, 2018, the court granted the motion dismissing all claims against the Bayer defendants with prejudice.

In its written statement of reasons, the motion court stated plaintiff's claims were preempted. Noting that Essure received PMA, the court determined the FDA had established requirements applicable to the device. It further determined that "[p]laintiff's claims require a finding that issues relating to

[1] A plaintiff who files suit against a physician or a hospital for medical malpractice must provide the defendant with the affidavit of an appropriate expert stating that the action has merit. N.J.S.A. 2A:53A-27. The affidavit must be provided within the time limitations imposed by the statute. Ibid. Failure to do so is "deemed a failure to state a cause of action." N.J.S.A. 2A:53A-29.

factors such as warnings should have been different from the federal requirements." It further found that plaintiff failed "to show her claims fall within [the] narrow exception to this preemption rule."

The motion court also concluded that the New Jersey Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11,

> limits the types of theories that are permissible in a products liability case such as design defects and manufacturing defects. As a result, certain claims do not fall within the PLA and are thus not permissible. These include claims made by [p]laintiff for negligent training and failure to report adverse events. As to the issue of the failure to report adverse events, this [c]ourt acknowledges that courts across the country are split. However, this [c]ourt is guided by the New Jersey Supreme Court decision of Cornett v. Johnson & Johnson, 211 N.J. 362 (2012)[,] which ruled in part that such claims are impliedly preempted. As to the claim for manufacturing defect, this [c]ourt finds that [p]laintiff has not sufficiently labeled what the violation is as it relates to federal manufacturing defects. The [c]ourt needs more than a flat allegation to understand what the actual defective manufacture is here as alleged by [p]laintiff. As a result, this [c]ourt finds that [p]laintiff has not labeled the defect and how it caused [p]laintiff's injuries, which would be necessary to state a claim and possibly proceed past a preemption analysis.

Since plaintiff's claims for medical malpractice were previously dismissed, the dismissal of her claims against the Bayer defendants was a final adjudication. This appeal followed.

Plaintiff raises the following points on appeal:

I. THERE IS A STRONG PRESUMPTION AGAINST PREEMPTION UNDER NEW JERSEY AND FEDERAL LAW.

II. THERE ARE VERY FEW MEDICAL DEVICE PRODUCT LIABILITY ACTIONS NATIONWIDE THAT FIND COMPLETE PREEMPTION OF A PLAINTIFF'S CLAIMS.

III. PLAINTIFF'S CLAIMS ARE NOT PREEMPTED.

A. Plaintiff's Manufacturing Defect And Design Defect Claims Are Not Preempted.

B. Plaintiff's Breach Of Express Warranty Claims Are Not Preempted.

C. Plaintiff's Fraudulent And Negligent Misrepresentation And Breach Of Implied Warranty Claims Are Contained Within The Product Liability Act And Are Not Preempted.

D. Plaintiff's Failure To Warn Claims Are Not Preempted.

E. Plaintiff's Negligent Training Claims Are Not Preempted.

IV. PLAINTIFF HAS PLED VALID CLAIMS FOR RELIEF.

A. Plaintiff[] Has Sufficiently Pled Facts To Show Causation And Reliance.

B. Plaintiff Has Met The Pleading Requirements Of [Rule] 4:5-8.

V. DEFENDANTS FAIL TO HOLD A VALID PREMARKET APPROVAL UNDER THE MEDICAL DEVICES AMENDMENTS TO THE FOOD, DRUG & COSMETIC ACT AND THEREFORE PLAINTIFF'S STATE LAW CLAIMS ARE NOT PREEMPTED.

The primary issue presented on appeal is whether the MDA's express preemption clause, 21 U.S.C. § 360k, bars plaintiff's state-law claims for damages allegedly caused by a medical device given PMA by the FDA. The secondary issue is whether plaintiff sufficiently pleaded any non-preempted claims to avoid dismissal.

II.

"In considering a motion to dismiss under Rule 4:6-2(e), courts search the allegations of the pleading in depth and with liberality to determine whether a cause of action is '"suggested' by the facts." Rezem Family Assocs., LP v. Borough of Millstone, 423 N.J. Super. 103, 113 (App. Div. 2011) (quoting Printing Mart-Morristown v. Sharp Elecs. Corp., 116 N.J. 739, 746 (1989)). The court should "ascertain whether the fundament of a cause of action may be gleaned even from an obscure statement of claim, opportunity being given to amend if necessary." Ibid. (quoting Di Cristofaro v. Laurel Grove Mem'l Park,

43 N.J. Super. 244, 252 (App. Div. 1957)). "For this purpose, 'all facts alleged in the complaint and legitimate inferences drawn therefrom are deemed admitted.'" Rieder v. State, Dep't of Transp., 221 N.J. Super. 547, 552 (App. Div. 1987) (quoting Smith v. City of Newark, 136 N.J. Super. 107, 112 (App. Div. 1975)).

"On appeal, we engage in a de novo review from a trial court's decision to grant or deny a motion to dismiss filed pursuant to Rule 4:6-2(e)." Smith v. Datla, 451 N.J. Super. 82, 88 (App. Div. 2017) (citing Rezem, 423 N.J. Super. at 114). "We owe no deference to the trial court's conclusions." Rezem, 423 N.J. Super. at 114. We will uphold the dismissal if "the factual allegations are palpably insufficient to support a claim upon which relief can be granted." Rieder, 221 N.J. Super. at 552.

III.

In Reigel, the Court described the following two-part analysis for determining whether a plaintiff's state law claims for harm caused by a PMA device are preempted: "First, a court must determine whether the FDA has imposed requirements for the device. Second, a court must determine whether the common law claims are based on state requirements different from or in addition to the federal requirements for the device." Cornett, 211 N.J. at 384

(citing Riegel, 552 U.S. at 321-22). "[T]o escape preemption, the state claim premised on a violation of FDA regulations must be based on state common law duties parallel to but not in addition to federal requirements." Id. at 385 (citing Riegel, 552 U.S. at 330).

A plaintiffs' state-law claims for harm caused by a PMA device may also be "impliedly pre-empted by" federal law. Buckman, 531 U.S. at 348. "[S]tate law claims brought by individuals based on intentional misrepresentation to the FDA during or after the PMA process are barred." Cornett, 211 N.J. at 385 (citing Buckman, 531 U.S. at 349 n.4). "[O]nly the federal government is authorized to sue for failure to comply with the MDA provisions, including providing false or misleading information." Ibid. (citing Buckman, 531 U.S. at 349 n.4). "Thus, regardless of how a plaintiff styles a state claim, if the claim depends on the alleged violation of a federal requirement, it is functionally equivalent to a claim grounded solely on the federal violation, and is impliedly preempted." Cornett, 211 N.J. at 385 (citing Buckman, 531 U.S. at 352-53).

IV.

With those concepts in mind, we turn to New Jersey law regarding claims for harm caused by an allegedly defective product. Such claims are generally governed by the PLA. When our Legislature enacted the PLA, it "established

'one unified, statutorily defined theory of recovery for harm caused by a product, and that theory is, for the most part, identical to strict liability.'" Dean v. Barrett Homes, Inc., 204 N.J. 286, 294 (2010) (quoting In re Lead Paint Litig., 191 N.J. 405, 436 (2007)). The PLA is, thus, "remedial legislation," enacted to "establish clear rules" in claims "for damages for harm caused by products, including certain principles under which liability is imposed." McDarby v. Merck & Co., 401 N.J. Super. 10, 97 (App. Div. 2008) (quoting Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47-48 (1996)).

"A product liability action is defined as 'any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty.'" Sinclair v. Merck & Co., 195 N.J. 51, 62 (2008) (quoting N.J.S.A. 2A:58C-1(b)(3)). The PLA provides the following basis for liability:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

[N.J.S.A. 2A:58C-2.]

In other words, a "prerequisite" for recovery under the PLA "is the existence of a defective condition." Zaza, 144 N.J. at 49.

V.

A. Plaintiff's Claims For Negligence, Breach Of Implied Warranty, Fraud And Misrepresentation, And Violations Of The CFA

We first address plaintiff's claims for negligence (count three); breach of implied warranties (count four); gross negligence (count five); fraud and misrepresentation (count eight); and violation of the CFA (count nine). Plaintiff argues those claims are not preempted by the MDA. We need not reach the issue of whether those claims are preempted because, with the exception of plaintiff's claim for negligent training, here, as in Cornett, "the PLA subsumed those claims." Cornett, 414 N.J. Super. at 404.

"With the sole exception of its accommodation for breach of express warranty, the PLA displaces all other causes of action 'for harm caused by a product, irrespective of the theory underlying the claim[.]'" Ibid. (alteration in original) (quoting N.J.S.A. 2A:58C-1(b)(3)). Put simply, the PLA "encompass[es] virtually all possible causes of action relating to harms caused by consumer and other products." Sinclair, 195 N.J. at 65 (quoting Lead Paint,

191 N.J. at 436-37). Consequently, breach of implied warranty is no longer "a viable separate claim" for harm caused by a product. Cornett, 414 N.J. Super. at 404 (quoting Tirrell v. Navistar Int'l, Inc., 248 N.J. Super. 390, 398 (App. Div. 1991)). A separate claim for negligence is similarly precluded. Tirrell, 248 N.J. Super. at 398. Plaintiffs are likewise barred from asserting "separate causes of action under the PLA and the CFA." McDarby, 401 N.J. Super. at 98. See also Sinclair, 195 N.J. at 66 ("The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product."). As such, except for plaintiff's negligent training claim, counts three, four, five, eight, and nine were properly dismissed, irrespective of any preemption analysis, because the claims are precluded by the PLA.

B. Plaintiff's Claims For Breach Of Express Warranty, Failure To Warn, Negligent Training, And Manufacturing Defect

1. Breach of Express Warranty and Failure to Warn

We next address plaintiff's claims for breach of express warranties (count four) and failure to warn (count seven). Plaintiff again argues her claims are not preempted by the MDA. We affirm the dismissal of those claims because plaintiff has not pleaded her claims with sufficient specificity to survive a preemption analysis.

If a plaintiff's state-law claim concerns the labelling of, or information provided with, a PMA device, the possibility of preemption of that PLA claim arises. Cornett, 211 N.J. at 387 (citing Kemp v. Medtronic, Inc., 231 F.3d 216, 236-37 (6th Cir. 2000)). PMA demonstrates the manufacturer established the safety and effectiveness of the device for its approved uses. Ibid. The PMA encompasses the device's label and instructions. Ibid. "The totality of the approval represents a specific federal requirement." Ibid. (citing Kemp, 231 F.3d at 228).

Our Legislature acknowledged the primacy of federal regulation of medical devices when it included a "rebuttable presumption of the adequacy of labels and instructions in the PLA." Ibid. (citing N.J.S.A. 2A:58C-4).[2] Accordingly, "a plaintiff asserting a failure to warn claim based on an inadequate label or instructions" for a PMA device "has stricter pleading requirements." Id. at 388. The "plaintiff must plead specific facts alleging 'deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects,' or 'manipulation of the post-market regulatory process.'" Ibid. (first quoting Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 626 (2007); then quoting McDarby,

[2] N.J.S.A. 2A:58C-4 states: "If the warning or instruction given in connection with a . . . device . . . has been approved . . . by the [FDA] under the [FDCA,] a rebuttable presumption shall arise that the warning or instruction is adequate."

401 N.J. Super. at 63). The heightened pleading requirement "serves to permit a determination whether a failure to warn claim is preempted by the MDA or is a permissible parallel state claim." Ibid.

Cornett is instructive. In Cornett, the Court decided whether the state-law claims asserted in forty-eight consolidated complaints constituted permissible parallel claims or were preempted by Section 360k of the MDA. 211 N.J. at 368, 370. The named plaintiff, Billie Cornett, who suffered from coronary artery disease and diabetes, had a Cypher® stent, a PMA device, implanted to treat his heart condition. Id. at 368-70. Five months after the stent was implanted, a blood clot formed near the site of the stent; Cornett suffered a subacute stent thrombosis resulting in his death eleven days later. Id. at 368.

Cornett's widow and others filed suit against the defendants for the injuries allegedly caused by Cypher® stents. Id. at 368, 370. The defendants moved to dismiss the plaintiffs' claims as preempted by the MDA. Id. at 370. The plaintiffs were given leave to file an amended complaint that asserted the following nine causes of action: (1) strict liability for defective design; (2) strict liability for defective manufacture; (3) strict liability for failure to warn; (4) breach of implied warranty; (5) breach of express warranty; (6) consumer fraud; (7) punitive damages; (8) wrongful death; and (9) loss of consortium. Ibid.

The Court granted the defendants' motion to dismiss the amended complaint as fully preempted by federal law. Cornett, 211 N.J. at 371. "[T]he claimed express warranty was the patient information card and guide that the FDA had specifically approved as part of [the Cypher® stent] label." Cornett, 414 N.J. at 383. Thus, a claim that the card and guide "failed to conform with the materials expressly approved by the FDA . . . would be patently false.'" Id. at 383-84 (alteration in original). Therefore, the motion court concluded the plaintiffs' claim for breach of express warranty was "'nothing more than a defective labeling/failure to warn claim, which is preempted' for a device approved under the FDA's [PMA] regime." Id. at 384. It held the plaintiffs alleged their claims were parallel to federal requirements merely to invoke the exception to preemption but failed to set forth facts or legal authority that demonstrated their claims were actually equivalent to the federal requirements. Ibid. The motion court dismissed the plaintiffs' wrongful death, loss of consortium and survivorship claims as "derivative of the strict liability and breach of warranty claims it found expressly preempted." Id. at 405.

On appeal, we held the following claims were not preempted by federal law: (1) manufacturing defect; (2) failure to warn, "to the extent that plaintiffs based it on allegations of failure to satisfy federal requirements on disclosure;"

and (3) breach of express warranty, "to the extent that plaintiffs based it on voluntary statements." Id. at 405. We determined "reversal of the Rule 4:6-2(e) dismissal of th[o]se predicate claims compel[led] reinstatement of [the] derivative claims for wrongful death, loss of consortium, and survivorship." Id. at 406. We held the dismissal of the remaining claims – defective design, breach of implied warranty, consumer fraud, and punitive damages – "was proper as either federally preempted or precluded by the PLA itself." Ibid.

After the Court granted certification, the defendants withdrew their challenge to the failure to dismiss the manufacturing defect claim. Cornett, 211 N.J. at 369 n.1. Accordingly, the Court did not decide the issue of whether the plaintiffs' manufacturing defect claim was preempted; the opinion was limited to whether the plaintiffs' failure to warn and breach of express warranty claims were preempted by the MDA. Id. at 372 (citing Cornell v. Johnson & Johnson, 205 N.J. 317 (2011)).

The Court engaged in the following analysis of the plaintiffs' failure to warn claim:

> [T]he failure to warn claim relates to the duration of post-implantation anti-platelet therapy and the lack of comparative studies of the Cypher® stent and alternative devices. This claim is nothing more than a challenge to the adequacy of the information required by the FDA during the PMA process and label approved

by the [FDA, which] falls within the PLA rebuttable presumption and the Riegel express preemption rule. We affirm its dismissal.

Moreover, to the extent [the] claim is based solely on a contention that defendants obtained [PMA] only after submitting fraudulent representations to or withholding material information from the FDA, this claim falls squarely within the Buckman implied preemption rule. We affirm its dismissal. So, too, plaintiffs' failure to warn claim is preempted and dismissed to the extent that it can be established solely by evidence of fraud on the [FDA].

. . . .

On the other hand, to the extent [the] plaintiffs' . . . claim is based on other allegations of wrong-doing apart from [the] defendants' failure to comply with FDA disclosure requirements, it is not preempted. [The plaintiffs alleged the] defendants withheld information from the general public and the medical community about the limitations . . . or safe use of the device, including information that instructions for post-implantation therapy were not part of the PMA process, and misrepresented to the general public and medical community that the Cypher® stent was non-thrombogenic. As stated, this claim overcomes the PLA rebuttable presumption of adequacy. [Perez v. Wyeth Labs., Inc., 161 N.J. 1, 25 (1999).] Such a claim falls within a traditional area of state concern and regulation because fraud on the FDA is not an element of the claim and it can be proved by evidence other than by evidence of fraud on the FDA.

[Id. at 389-90 (footnotes omitted).]

The Court determined the amended complaint, "read indulgently and in its entirety," presented a "colorable" failure to warn claim that was not impliedly preempted. Id. at 391. Nevertheless, the Court warned its decision came "at an early stage in the proceedings" as the motion to dismiss was filed soon after the plaintiffs filed their amended master complaint. Ibid. The Court instructed the trial court that it "should not hesitate to grant" summary judgment, "if appropriate." Consequently,

> [i]f discovery reveals that the failure to warn claim is nothing more than a private action to enforce FDA statutes and regulations, or that plaintiffs' claim is no more than a challenge to the approval of the device or label, or that proof of fraud on the FDA is an element of the[] claim, or that defendants' off-label promotional activities fall within the MDA safe harbor . . . ."
>
> [Ibid.]

Here, the following statement in plaintiff's complaint comprises her entire failure to warn claim:

> The Bayer defendants manufactured, distributed into the stream of commerce, and/or marketed the defective Essure device that was not reasonably fit, suitable or safe for its intended purpose because Essure failed to contain adequate warnings or instructions, was designed in a defective manner, and such other defects as continuing discovery and investigation may reveal.

Plaintiff has not satisfied the heightened pleading requirement applicable to her failure to warn claim. Accordingly, the motion court properly dismissed plaintiff's failure to warn claim.

The MDA also preempts an express warranty claim based on the information contained in FDA approved product labels and packaging inserts. Id. at 392. "Like other state requirements that exceed federal requirements for a PMA device, a state claim that allows liability for statements in the FDA-approved label and other documentation is preempted." Cornett, 414 N.J. Super at 403 (citing Riley v. Cordis Corp., 625 F. Supp. 2d 769, 787-88 (D. Minn. 2009)). The Supreme Court engaged in the following analysis of the plaintiffs' breach of express warranty claim:

> Following Riegel, generalized state common law theories of liability, such as alleged in the [plaintiffs' complaint], are precisely the types of claims preempted by the MDA.
>
> . . . .
>
> [T]o succeed on the breach of express warranty claim, [the] plaintiffs must show . . . the label provides inaccurate or insufficient information in spite of FDA approval following the rigorous PMA process. Success on this state law claim would inevitably impose greater requirements than those already established by the MDA. This claim is, therefore, preempted.

> On the other hand, to the extent [the] plaintiffs allege [the] defendants . . . deviated from the labeling and instructions for use through voluntary statements . . . in the course of its marketing efforts, this claim is not preempted.
>
> [Cornett, 211 N.J. at 392-93.]

The Court held the only aspects of the plaintiffs' breach of express warranty claim that was not preempted were the "voluntary statements" by the defendants that were "not approved . . . or mandated by the FDA about the use or effectiveness of the product for on-label or off-label uses," "because federal law requires any warranty statement to be truthful and accurate." Id. at 392 (citing Cornett, 414 N.J. Super. at 404). When so "limited, an express warranty claim based on state law does not impose additional requirements or obligations on [medical device manufacturers] and is not preempted." Ibid. (citing Cornett, 414 N.J. Super. at 404).

Here, plaintiff's breach of express warranty claim is limited to the following allegations:

> 43. [Bayer] expressly . . . warranted to the general public, and to [plaintiff] in particular, that the . . . Essure device was safe, merchantable, and fit for the use for which it was intended.
>
> 44. [Bayer] breached the aforesaid warranties in that the Essure device was unsafe, not of merchantable quality,

> and/or unfit for the purposes and use for which it was intended.
>
> 45. Plaintiff, relied upon the warranties made by [Bayer].

Once again, plaintiff did not plead her claim with sufficient specificity to survive the motion to dismiss.

2. Negligent Training

We next address the dismissal of plaintiff's negligent training claim. We find the Eastern District of Pennsylvania's decision in McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804 (E.D. Pa. 2016), to be persuasive authority. In McLaughlin, the plaintiffs alleged Bayer was liable for negligent training because it failed to (1) "abide by the FDA training guidelines," i.e., the plaintiffs alleged Bayer provided "training [that was] different from that of the 'Physician Training Manual[]'" approved by the FDA; (2) properly supervise the plaintiffs' procedures; (3) provide the plaintiffs' implanting physicians with adequate training on the use of the hysteroscopic equipment; and (4) "advise implanting physicians of the adverse events and non-conforming product." Id. at 816 (alteration in original). The plaintiffs asserted Bayer's negligent training caused their damages "insofar as the Essure device migrated from [their] fallopian tubes and caused various complications." Ibid.

The McLaughlin court engaged in the following analysis:

> [A]t least to the extent that the claim alleges that Bayer failed to abide by FDA-approved training [requirements], the negligent training claim does not seek to impose training requirements different from those in the federal requirements and, thus, is not expressly preempted on that basis but, rather, asserts a permissible parallel claim. . . .
>
> . . . .
>
> Reading the [c]omplaint in the light most favorable to [the plaintiffs], it alleges that Bayer, by training [the plaintiffs' implanting] physicians, assumed a duty to do so non-negligently; that Bayer breached that duty by failing to follow the FDA-imposed training guidelines; and that [the plaintiffs'] injuries, all of which are alleged to have arisen from the migration of the Essure device from [their] fallopian tubes, were caused by Bayer's training deficiencies. However, the [c]omplaint does not allege how Bayer's training departed from the FDA-approved guidelines, much less any facts that give rise to a recognizable theory as to how any departure from the training guidelines may have caused each [p]laintiff's Essure device to migrate from her fallopian tubes.
>
> [Id. at 816-17 (footnotes and citations omitted).]

As a result, the McLaughlin court dismissed the plaintiffs' negligent training claims for failure to state a claim upon which relief can be granted because their "bald allegations of both negligence and causation d[id] nothing more than posit a 'sheer possibility that [Bayer] has acted unlawfully,' without setting forth a

plausible claim of negligent training." Id. at 817-18 (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

Here, plaintiff's entire negligent training allegation is contained in paragraph forty of the complaint:

> [Bayer] negligently failed to properly and/or adequately train implanting health care providers on how to use the Essure device and hysteroscopic equipment provided for the procedure, failed to ensure that ECTs were performed, failed to properly screen physicians who were not competent or qualified to use said Essure device and hysteroscopic equipment and created an unreasonably dangerous plan of distribution at the expense of Plaintiff's health and well-being.

Because plaintiff's negligent training claim is so insufficiently pleaded, we are prevented from determining whether it is based upon any non-preempted claim for relief. Id. at 818. Plaintiff does not allege Bayer's training departed from the FDA-approved guidelines, much less how it departed from the guidelines. Nor does she posit any theory as to how the allegedly negligent training caused plaintiff's injury. For these reasons, the negligent training claim was properly dismissed.

3. Manufacturing Defect

Lastly, even when read indulgently, plaintiff's complaint claim for "strict liability," which we construe as a manufacturing defect claim, did not assert

sufficient facts or a cognizable theory of liability to survive defendants' motion to dismiss.

Manufacturers of PMA devices are:

> required to follow the design controls process as enumerated in 21 C.F.R. § 820.30. In addition to design controls, the manufacturer must also comply with manufacturing controls outlined at 21 C.F.R. § 814.20(b)(4) and § 820. These controls require the manufacturer to submit to the FDA a complete description of the methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and where appropriate, installation of the device.
>
> [Cornett, 414 N.J. Super. at 386.]

A plaintiff's manufacturing defect claim that alleges the PMA device was "adulterated due to failure to comply with federal regulations" is "not preempted because a jury could find the defendants breached their duty of care to the plaintiff and that the product was unreasonably dangerous without imposing different or additional requirements." Id. at 398 (citing Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 836-37 (S.D. Ind. 2009)).

Plaintiff's complaint states:

> 55. The Essure devices manufactured, sold, promoted and/or distributed by [Bayer] were, at the time they left [the] control of [Bayer], defective products, unreasonably dangerous for use, which were not fit, suitable and/or safe for their intended use of

> contraception in otherwise healthy women resulting in the injuries and damages to plaintiffs as stated above.
>
> 56. Plaintiff used the Essure device in the way [Bayer] intended it to be used and in a manner which was reasonably foreseeable by [Bayer].
>
> 57. Plaintiff's injuries and reliance upon [Bayer's] misrepresentations and expertise were reasonably foreseeable by [Bayer].
>
> 58. [Bayer] failed to warn Plaintiff of the risks inherent in the insertion and function of the Essure device.
>
> 59. Plaintiffs therefore rely upon the doctrine of strict liability in tort against [Bayer].
>
> 60. [Bayer is] strictly liable for plaintiff['s] injuries and loss pursuant to [the PLA].
>
> 61. As the direct result of [Bayer's] conduct, [p]laintiff suffered severe and permanent injuries. As a consequence thereof, she has suffered great pain, disability and mental anguish, and because of the permanency of said injuries she will continue to suffer in the future; moreover, she has suffered other injuries to [p]laintiff's danger and detriment.

As with her negligent training claim, plaintiff fails to adequately state a manufacturing defect claim. Plaintiff does not allege Bayer's manufacturing process departed from the FDA-approved process, much less how it departed from the approved process. In that regard, noticeably absent from the complaint and plaintiff's opposing papers are any facts or allegations that the Essure

implanted deviated from the design approved by the FDA. Nor does she posit any theory as to how the allegedly defective manufacturing process caused her injury. During oral argument before this court, plaintiff conceded that she had no additional facts she could plead in support of her claims if she were permitted to file an amended complaint. Given these circumstances, plaintiff's manufacturing defect claim, comprised of mere bald assertions, was properly dismissed.

VI.

In sum, the dismissal of plaintiff's complaint with prejudice is affirmed. Plaintiff's claims for negligence (other than negligent training), breach of implied warranties, fraud and misrepresentation, strict liability, and violations of the CFA, are subsumed by the PLA. Cornett, 414 N.J. Super. at 404. Plaintiff's claims for negligent training, breach of express warranties, and failure to warn were properly dismissed due to plaintiff's failure to satisfy the "stricter pleading requirements" applicable to claims for harm allegedly caused by PMA devices. Cornett, 211 N.J. at 388. Plaintiff's claim for manufacturing defect amounts to nothing more than an insufficient, factually unsupported, conclusory allegation. During oral argument before this court, plaintiff acknowledged that no additional facts would be added if she were permitted to file an amended

complaint. The motion court properly concluded that even when read indulgently, plaintiff has not sufficiently pleaded her claims to allow the court to conduct a proper preemption analysis or to otherwise survive dismissal. Dismissal of the complaint for "failure to state a claim upon which relief can be granted" was appropriate. R. 4:6-2(e).

We are mindful of the large number of reported problems experienced by women who had Essure birth control devices implanted. We are also aware of the non-binding cases in other jurisdictions which reach a different conclusion and which are not subject to New Jersey precedent. Our Supreme Court has spoken on the subject of federal preemption and the stricter pleading requirements pertaining to claims involving PMA devices, and we follow its guidance here.

Affirmed.