IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

HELEN MCLAUGHLIN,

Plaintiff,

vs. Case No. 2:14-cv-07315-JP

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

RUTH RUBLE,

Plaintiff,

vs. Case No. 2:14-cv-07316-ER

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

MELDA STRIMEL,

Plaintiff,

vs. Case No. 2:14-cv-07317-LFR

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

SUSAN STELZER,

Plaintiff,

vs. Case No. 2:14-cv-07318-ER

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

HEATHER WALSH,

Plaintiff,

vs. Case No. 2:14-cv-00384-GP

BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC. and BAYER A.G.

Defendants.
_____/

PLAINTIFF'S RESPONSE TO OMNIBUS MOTION FOR JUDGMENT ON THE PLEADINGS UNDER FED. R. CIV. P. 12(c) OF DEFENDANTS BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS INC., AND BAYER ESSURE INC. [D.E.49]

NOW COMES the PLAINTIFF, MELDA STRIMEL, ("Strimel" or "Plaintiff"), by and through undersigned counsel, and files her response to Omnibus Motion for Judgment on the Pleadings Under Fed. R. Civ. P. 12(c) of Defendants Bayer Corporation, Bayer Healthcare LLC, Bayer Healthcare Pharmaceuticals Inc., Bayer Essure Inc., and [D.E. 49] and incorporated memorandum of law, and states as follows:

INTRODUCTION

Strimel has brought this lawsuit for serious injuries caused by Defendants' wrongful conduct alleging state law claims for: (1) Negligent Training; (2) Negligent Entrustment; (3) Negligence-Pharmacovigilance; (4) Negligence-Risk Management; (5) Breach of Express Warranty; (6) PA Unfair Trade Practices and Consumer Protection ("UTPCPL"); (7) Fraudulent Concealment; (8) Fraudulent Misrepresentation; (9) Negligent Misrepresentation; (10) Strict Liability; (11) Negligence-Manufacturing; and (12) Negligence-Failure to Warn.

Defendants have moved for judgment on the pleadings on all of Plaintiff's claims in Plaintiff's First Amended Complaint ("Complaint") based primarily on the issue of preemption. However, Plaintiff's claims either (1) fall outside the scope of the Medical Device Act ("MDA") or (2) amount to "parallel claims." Plaintiff's claims are not preempted because (1) Congress has not explicitly preempted all state law; (2) Congress has not impliedly occupied the entire field; and (3) PA state law is complementary, not obstructive of federal law. This is especially true in tort cases involving injury as the United States Supreme Court, Third Circuit Court of Appeals, and Eastern District of PA courts have all held there is a strong presumption against preemption and that courts should not reach to find the same.

In fact, this Court may deny Defendants' preemption motion without even determining whether Plaintiff has alleged "parallel claims." Pursuant to Food and Drug Administration ("FDA"), the conditional premarket approval ("CPMA") for Essure is no longer valid as Defendants violated the conditions of the CPMA which, without discretion, invalidates the CPMA.[1] Accordingly, preemption is a non-issue for all of Plaintiff's claims as a medical device manufacturer must have a valid CPMA in order to benefit from the preemption defense.

[1] CPMA order reads: "Failure to comply with conditions of approval invalidates this approval order."

Without a CPMA there is no valid federal regulation that applies specifically to Essure. Therefore, there is no preemption under *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 316 (2008).

Assuming arguendo, that Defendants had a valid CPMA, Plaintiff's claims for Negligent Entrustment, Breach of Express Warranty, Fraudulent and Negligent Misrepresentation, UTPCPL, and Negligence-Pharmacovigilance all fall outside the scope of preemption.

First, Plaintiff's claim for Negligent Entrustment is not subject to the CPMA as it centers on equipment used to place Essure, hysteroscopes, which is not a part of Essure's CPMA. Moreover, the C.F.R. expressly excludes "other products" such as hysteroscopes, from preemption.[2]

Second, it is well settled law, pursuant to the United States Supreme Court, Third Circuit Court of Appeals, and Eastern District of PA courts that causes of action for breach of express warranties are not subject to preemption as they are considered contract liability warranties. In addition to the well settled precedent of binding courts, other courts around the United States and the FDA agree with this position.[3] Moreover, the Code of Federal Regulations ("C.F.R.") also expressly excludes express warranties from preemption.[4] Because Plaintiff's claims for Fraudulent Misrepresentation, Negligent Misrepresentation, and UTPCPL are also based on the very same contract liability warranties, the same reasoning holds true. Similar to warranty claims, the C.F.R. also expressly excludes state unfair trade practice claims from preemption.[5]

Third, Plaintiff's claim for Negligence-Pharmacovigilance also falls outside the scope of

[2] 21 C.F.R. 808.1 (d) (1) : (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.

[3] Defendants' CPMA expressly states; "CDRH does not evaluate information related to contract liability warranties."

[4] 21 C.F.R. 808.1 (d) (1) : (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.

[5] *Id.*

preemption as Defendants' unreasonably dangerous advertising and promotion scheme of Essure had no type of approval, conditional or otherwise, by the FDA. In addition, this advertising and promotional scheme also violated federal law, as Defendants were precluded from either marketing or selling an "adulterated" or "misbranded" product. As such, the Pharmacovigilance claim also amounts to a parallel claim as discussed *infra*.

In short, per the FDA, Defendants' CPMA is invalid and Defendants are not afforded the protection they seek. Moreover, even if Defendants had a valid CPMA, Plaintiff's claims for Negligent Entrustment, Breach of Express Warranty, Fraudulent and Negligent Misrepresentation, UTPCPL, and Negligence-Pharmacovigilance all fall outside the scope of preemption.

Assuming arguendo, (1) Defendants had a valid CPMA and (2) the above mentioned claims were subject to preemption, the claims would still survive Defendants' motion, along with the remaining claims, as they are all based on violations of federal law and are parallel claims.

The United States Supreme Court in *Riegel* recognized that MDA §360k(a) enacted a two-step test[6] in determining whether state law claims are expressly preempted.

- [T]he Federal Government [must have] established requirements applicable to" a specific medical device. *Riegel*, 552 U.S. at 321. If no federal requirements exist, the inquiry ends—there can be no express preemption without an applicable federal requirement.

- The Court must next ask whether the Plaintiffs' claims impose requirements on the defendant that are "different from, or in addition to" the federal ones. *Id*. at 322. State-law requirements that do not differ from, or add to, the federal requirements applicable to a device are termed "parallel" requirements and are not preempted. 552 U.S. at 316

Plaintiff's claims are not preempted unless both of the MDA §360k(a) requirements are

[6] All emphasis is supplied in this motion.

satisfied. The Supreme Court and Eastern District of PA courts have held that "§ 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." *Riegel*, 552 U.S. at 330; *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 at 432 (E.D. Pa. Feb. 3, 2004); *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443 (E.D. Pa. Nov. 28, 2011).

Lastly, Defendants argue that Plaintiff's claims are without basis under state law and fail to meet the pleading standard under *Iqbal*/*Twombly*. As discussed *infra*, this "last-ditch" effort to dismiss Plaintiff's claims also fails.

It is beneficial to note a few of Plaintiff's positions upfront: (1) All of Plaintiff's claims are grounded in traditional state tort law premised on violations of several federal laws and requirements;[7] (2) Not one of Plaintiff's causes of action is a "fraud upon the FDA"[8] claim which occurred during the premarket approval process as contemplated in *Buckman Co. v. Pl.'s Legal Comm.*, 531 U.S. 341 (2001); (3) Plaintiff is not attempting to enforce any federal regulations; (4) Plaintiff is not seeking to impose more requirements than what the CPMA required; and (5) Plaintiff is not suggesting that Defendants should have done anything that would have required them to violate federal law.

In short, Defendants are clearly not entitled to the PMA protection they seek. Their violations and wrongful conduct are not only alleged and well documented with particularity throughout the extensive allegations of Plaintiff's Complaint, but also have been memorialized in writing by the FDA and sharply rebuked by several OBGYN doctors across the United

[7] Including not only just "Current good manufacturing practices" ("CGMP") but also other federal statutes and the CPMA itself.

[8] Plaintiff's fraud claims are based on fraud on the Plaintiff. Moreover, the paragraphs which mention Defendants' alteration of medical records of its own trial participants during the clinical trials is alleged to show how certain warranties of Defendants are false and how Defendants defrauded the Plaintiff.

States.[9]

BACKGROUND

I. SUMMARY OF RELEVANT ALLEGATIONS

Plaintiff's Complaint alleges in extraordinary detail and particularity, Defendants' wrongful conduct, upon which Plaintiff's actions are predicated. In 2002, Defendants received their CPMA, a very narrow and limited FDA approval for permission to sell Essure. Essure is a medical device intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically, causing the blockage. Essure consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. The hysteroscopic equipment needed to place Essure was manufactured by a third party, is not a part of Defendants' CPMA, and is not a part of Essure. However, because the hysteroscopic equipment is extremely expensive, Defendants provided it to Plaintiff's implanting physician who was unable to use it safely. This type of equipment can be life threatening if not in the hands of an expert hysteroscopist as it results in misplacement, perforations, migrations, and in some cases death (of both the newborn and mother). [10] The micro-inserts or coils are alleged to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

Subsequent to receiving its CPMA, Defendants then embarked on a false and deceptive marketing and distribution scheme to promote the sale of Essure and increase revenue. During this process, Defendants violated several federal laws including the C.F.R. rendering Essure an "adulterated," "misbranded," and "restricted" medical device. Pursuant to federal law, Essure could not have been marketed or sold to Plaintiff. Defendants also forced the implanting

[9] http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=FDA-2015-P-0569
[10] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=4531887

physician to purchase two Essure devices per month, thereby compelling the implanting physician to "push" Essure onto Plaintiff. This type of distribution plan was aimed solely at capturing the market with reckless disregard for the safety of the public and Plaintiff. Unfortunately, besides Plaintiff's significant injuries, there have been five deaths associated with Essure and thousands of other serious injuries.

As a result of Defendants' fraudulent and wrongful actions, Plaintiff and her implanting physician were deprived of material information known by Defendants, while Defendants continued to market, distribute, and sell Essure. Plaintiff also relied on contractual warranties not approved by the FDA or a part of the FDA's CPMA before having Essure implanted.

Defendants' distributing and advertising scheme was undertaken in conscious disregard of the health and safety of hundreds of thousands of women and in violation of federal law, the PMA, and parallel state law. Thousands of vulnerable and unsuspecting patients, including Plaintiff, have been seriously and permanently injured as a result of Defendants' actions.

II. SUMMARY OF RELEVANT FEDERAL LAW AND REGULATIONS

The premarket approval for devices can either be "approved," "conditionally approved," or "not approved." Essure was "conditionally approved" or in other words, had only CPMA as it was conditioned upon subsequent compliance with certain express conditions.[11] Defendants' failure to comply with the conditions of approval invalidated the CPMA.

[11] -Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA.
-Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury.
-Report Due Dates- six month, one year, eighteenth month, and two year reports.
-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.
-Warranties are truthful, accurate, and not misleading…Warranties are consistent with applicable Federal and State law.
-Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.
-Successful bilateral placement of Essure is documented for newly trained physicians.

The C.F.R. also delineates certain federal law regarding medical devices. All Class II and III, and most of Class I, devices are subject to the FDA's good manufacturing practice requirements ("CGMP"). *See* 21 U.S.C. § 360j(f); *see also* 21 C.F.R. §§ 820 *et seq.* The CGMP requirements, which are not device-specific regulations, control the "manufacture, packing, storage, and installation .... [of medical devices,] to assure that [they] ... will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act." ("FDCA") 21 C.F.R. § 820.1. The CGMP requirements order every device manufacturer to, among other things, (1) maintain a quality assurance program; (2) establish environmental controls at the manufacturing site; (3) formulate "adequate written cleaning procedures and schedules to meet manufacturing process specifications"; (4) maintain written manufacturing specifications and processing procedures; (5) establish controls regarding labeling; (6) adopt written procedures for "finished device inspection to assure that device specifications [have been] met"; and (7) maintain detailed records. 21 C.F.R. §§ 820.1 -.184.

In addition to the CPMA and CGMP's, other federal statutes relevant to Plaintiff's case include: 21 C.F.R. 814, 21 C.F.R. 814.80, 21 C.F.R. 803.1(a), 21 C.F.R. 803.10, 21 C.F.R. 803.50(a), 21 C.F.R. 803.53, 21 C.F.R. 806.10, (a) 21 C.F.R. 814.84(a), 21 C.F.R. 822, 21 U.S.C. 352(q)(1), 21 U.S.C. 331(a), 21 U.S.C. 351(a) (h), and 21 U.S.C. 352 (q) (r).

The specific violations that the FDA found and documented are cited in great detail throughout Plaintiff's Complaint. A few examples are that Defendants violated federal law by: failing to report adverse reactions (perforations and coils breaking into pieces); failing to put the FDA on notice of over 16,000 complaints, using non-conforming material, not tracking the non-conforming material, and providing warranties which were false and misleading.

LEGAL STANDARDS

I. MOTION FOR JUDGMENT ON THE PLEADINGS FED. R. CIV. P. 12(h)(2)

A motion for judgment on the pleadings after a defendant has answered the complaint is subject to the same standards under Rule 12(b)(6). *Turbe v Government of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted pursuant to Fed.R.Civ.P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. *Evancho v. Fisher*, 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Under the liberal federal pleading rules, it is not necessary to plead evidence, and it is not necessary to plead all the facts that serve as a basis for the claim. *Bogosian v. Gulf Oil Corp.*, 562 F.2d 434, 446 (3d Cir. 1977). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Baldwin County Welcome Ctr. v. Brown*, 466 U.S. 147, 149–50 n.3 (1984)(quotation and citation omitted). A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim." *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007).

II. THRERE IS A STRONG PRESUMPTION AGAINST PREEMPTION

Pursuant to the United States Supreme Court, there is a well-established "basic presumption against pre-emption" because preemption upsets the balance of power between the federal government and the states as independent sovereigns. *Bates v. Dow Agrosciences, LLC*,

544 U.S. 431, 449 (2005). This presumption holds "even in the event of an express preemption clause," *id.* (citation omitted), and is particularly strong in tort cases like this one because the states have historically enjoyed broad powers to protect the "lives, limbs, health, comfort, and quiet of all persons." *Slaughter House Cases*, 83 U.S. 36 (1873); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)(applying the presumption against preemption in a medical device case).

In fact, parties seeking to invalidate a state law based on preemption bear the considerable burden of overcoming the starting presumption that Congress does not intend to supplement state law. *De Buono v. NYSA-ILA Med. & Clincial Servs. Fund,* 520 U.S. 806, 814 (1997). The Supreme Court has cautioned that courts should be "reluctant" to find pre-emption when "interpreting a federal statute pertaining to a subject traditionally governed by state law." *CSX Trans. Inc. v. Easterwood,* 507 U.S. 658 (1993).

The Supreme Court also recently held that the presumption against preemption applies to both express and implied preemption and a "case for federal pre-emption is particularly weak where Congress has indicated its awareness of operation of state law in field of federal interest and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." *Wyeth v. Levine*, 555 U.S. 555 (2009).

The Third Circuit Court of Appeals opined that there is a strong presumption against preemption in state-tort like actions arising from the use of a product as they touch upon areas traditionally left to the police powers of the state. *Indian Brand Farms, Inc. v. Novartis Crop Protection, Inc.,* 617 F.3d 207 (3d Cir. 2010); *Fellner v. Tri–Union Seafoods, L.L.C.,* 539 F.3d 237, 248 (3d Cir. 2008). "That issues of health and safety have traditionally fallen within the province of state regulation is beyond refute." *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233 (3d Cir.

2009). Moreover, even where courts are faced with two equally plausible readings of statutory text, [courts] have a duty to accept the reading that disfavors preemption.'" *Id.* at 240.

Similar to the Supreme Court and the Third Circuit Court of Appeals, The Honorable Stewart R. Dalzell of the Eastern District of PA recently held that: "Courts should therefore not reach to find that FDA regulations preempt state law." *Perry v. Novartis Pharma, Corp.* 456 F. Supp. 2d 678 (E.D. Pa. Oct. 16, 2006); *In Re Budeprion XL Marketing & Sales Litigation*, 2010 WL 2135625 (E.D. Pa. May 26, 2010)(holding the presumption against preemption applies in a products liability case as it falls within the realm of historic police powers). The *Perry* Court also opined that in regard to injury cases similar to the Plaintiff's case here:

> the bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent." *Perry*, 456 F. Supp. 2d at 684.

III. OVERVIEW OF THE *RIEGEL* DECISION AND EXPRESS PREEMPTION

Federal pre-emption of state law can occur in three instances: where Congress explicitly pre-empts state law; where pre-emption is implied because Congress has occupied the entire field; and where pre-emption is implied because there is an actual conflict between federal and state law. *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293 (1988). It is imperative to note that the presumption against preemption applies to both express and implied preemption. *Wyeth*, 555 U.S. 555.

The MDA includes an express, but limited, preemption provision for claims against manufacturers of Class III medical devices:

> [N]o 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 United States Supreme Court has twice addressed the limited scope of this preemption provision. First, in 1996, the United States Supreme Court held that lawsuits brought under state law against medical device manufacturers who submit "premarket notification" to the FDA are not preempted by § 360k(a) when liability is premised on theories that the device was defective and unreasonably dangerous and that the manufacturer failed to use reasonable care in the device's design, manufacture, assembly, and sale. *Lohr*, 518 U.S. at 481, 494-95.

Second, in 2008, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain the full federal "premarket approval" are preempted by section § 360k(a) when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices. *Riegel*, 552 U.S. at 330. Importantly, neither case held that state lawsuits premised on violations of federal law are preempted under § 360k(a). In fact, *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law.

The United States Supreme Court limited its holding to claims that the device at issue "violated state tort law notwithstanding compliance with the relevant federal requirements." *Riegel*, 552 U.S. at 330. The United States Supreme Court opined that claims will proceed when they are based on violations of federal law:

> § 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. *Riegel*, 552 U.S. at 330.

Lohr expressly recognized that common law remedies were not preempted so long as the actions were based on violations of federal regulations:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law. *Lohr* 518 U.S. at 494-495.

Riegel and *Lohr* thus confirm that state law claims based on violations of federal law are not expressly preempted by section § 360k(a). *Lohr*, 518 U.S. at 495. The *Riegel* Court also favorably cited *Lohr*, similarly recognizing that the state law claims can be maintained for violations of FDA regulations. In other words, the *Riegel* court did not hold that common law claims are expressly preempted merely because they are related to medical devices approved under the PMA process. The *Riegel* court recognized that common law actions are preempted only to the extent they are based on device-specific requirements that differ from PMA approval; and indicated that common law claims are not preempted by general CGMP regulations as they are outside the purview of § 360k(a).[12]

The holding in *Riegel* is supported by 21 C.F.R. 808.1(d)(10): "Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." Moreover, the regulations promulgated by the FDA expressly state that § 360k(a) "does not

[12] The *Riegel* Court noted that a majority in *Lohr* interpreted 360k(a)(1) "substantially informed" by FDA regulation, 21 C.F.R. 808.1(d), that says state requirements are preempted only when FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device…"*Lohr*, 518 at 495. General manufacturing and labeling requirements applicable across the board to all manufacturers were deemed not specific to the 510(k) device in *Lohr*. *Id.* at 501. Yet the court in *Lohr* concluded that state law claims predicated on violations of federal law were not preempted. *Id.* The holding in *Riegel* thus clarified that even specific requirements imposed on a PMA class III device do not preempt a common law action focused on violations of those regulations. *Riegel*, 128 S. Ct. at 1011.

preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." *Lohr*, 518 U.S. at 496-97; 21 CFR § 808.1(d)(2); see also § 808.5(b)(1)(i)16.

A. PA District Courts and Circuit Courts uphold no express preemption.

The Supreme Court in *Riegel* and *Lohr*, most circuit and district courts throughout the country, the C.F.R., and Eastern District of PA courts have held that preemption does not apply when plaintiffs' claims are based on violations of federal law, including the CGMPs. *Bentzley*, 827 F. Supp. 2d 443; *Davenport*, 302 F. Supp. 2d 419 at 432 (holding claims based on the theory that a class III device did not satisfy PMA/FDA standards were not preempted.); *Shuker v. Smith & Nephew, PLC*, 2015 WL 1475368 (E.D. Pa. March 31, 2015)(holding 360k(a) protects a manufacturer to the extent that it complied with federal law, but does not extend protection from liability where the claim is based on violation of federal law); *McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451 (W.D. PA. 2012)(holding that "an allegation that the medical device did not adhere to the FDA-approved standards or regulations" would amount to a parallel claim); *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770–71 (5th Cir. 2011) (holding a nonpreempted claim was adequately plead regarding a manufacturer's failure to accurately report serious injuries and malfunctions of its device as required under federal law); *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232–33 (9th Cir. 2013) (holding a failure to perform federal-law duty to warn the FDA of adverse events involving its device was not preempted); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 798 (8th Cir. 2001) ("a claim of failure to comply with FDA regulations is not preempted by [§ 360k of] the MDA ... since such a state claim imposes no requirement 'different from, or in addition to' any federal requirement."); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 583 (5th Cir. 2001) ("tort suits based on a manufacturer's failure to follow the

FDA's regulations and procedures are not preempted."); *Mitchell v. Collagen, Corp,* 126 F.3d at 913 n. 6 (7th Cir. 1997)("To the extent that the [Plaintiff's] complaint may be read as alleging that [the manufacturer] was negligent in adherence to standards of the FDA in the PMA, the negligence claim would not be preempted."); *Howard v. Sulzer Orthopedics, Inc.,* 382 Fed. Appx. 436, 440–41 (6th Cir. 2010); *Bausch v. Stryker Corp.,* 630 F.3d 546, 555–56 (7th Cir. 2010); *Bass v. Stryker, Corp.*, 669 F.3d 501, at 509–10 (5th Cir. 2012); FDA Regulation 21 C.F.R. 808.1(6)(ii) ("Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices.")

In *Shuker v. Smith & Nephew, PLC,* the court held: "Section 360k(a) thus protects a manufacturer of a PMA-approved medical device from civil liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law.'" 2015 WL 1475368 at 7. The *Bentzley* court also weighed in on the subject, citing to *Lohr* and recognizing that preemption does not apply to violations of federal law, including violations of the CGMPs. The Court stated:

> "the Lohrs theory of recovery was based on Medtronic's alleged violations of FDA 'good manufacturing practices' regulations…21 C.F.R. 820.1-820.250…MDA did not preempt the…allegations because they 'may include claims that Medtronic has…violated FDA regulations." *Bentzley*, 827 F. Supp. 2d at 453

Ultimately, the *Bentzley* court found that plaintiffs failed to allege that their claims were based on violations of any federal requirements and, therefore, dismissed the negligence claims.[13] *Id.* at 454.

Similarly, the *Davenport* court also cited to *Lohr* recognizing the same:

> As previously noted, the *Lohr* Court emphasized that "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-

[13] C.f. Plaintiff's Complaint alleging in detail the specific federal regulations Defendants violated.

> law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495, 116 S. Ct. 2240.... In the present case, Davenport's strict product liability and negligent manufacturing claims are based on the theory that the Activa systems implanted in him did not satisfy PMA/FDA standards. These claims do not impose requirements "*different from or in addition to*" PMA/FDA requirements, which is a requirement for preemption under *Lohr* and Section 360k of the MDA. As such, the strict product liability and negligent manufacture claims are not preempted pursuant to the MDA. *Davenport*, 302 F. Supp. 2d at 433.

In other words, *Riegel* and its progeny limit preemption to manufacturers who comply with federal law, but deny it to those who violate federal law. *Riegel*, 552 U.S. at 330. It remains clear that the shield of preemption drops when the manufacturer violates federal law, including conditions of a CMPA, CGMP's, and other federal laws.

Throughout their motion, Defendants misconstrue Plaintiff's claims. Plaintiff does not claim that Defendants should have done anything differently from what the FDA approved. Rather, Plaintiff alleges that (1) Defendants' warranties, representations, and unfair trade practices were never considered or approved by the FDA and (2) Plaintiff's remaining claims are parallel claims premised on violations of its CPMA and federal law. Defendant relies on several cases, most of which are not binding on this Court, arguing that express preemption applies. However, the cases Defendants rely on are distinguishable, as discussed *infra*, as they either (1) do not contain causes of action outside the scope of preemption or (2) fail to adequately allege that their claims are premised on specific federal regulations. Here, Plaintiff has plead not only the specific federal violations on which her claims are based, but also how Defendants violated each regulation.[14]

In short, Defendants argue that Plaintiff's claims are expressly preempted, as state law imposes requirements that are "different from, or in addition to" the federal laws. Defendants'

[14] Para. 64 of Strimel Complaint- Plaintiffs also assert that Defendants categorize Essure as a "drug" as opposed to a medical device. This distinction is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices).

reliance on this argument is misplaced. It is well-established that Plaintiff's state law claims are substantially similar to those allowed in *Riegel* and *Lohr*, and that Defendants violated both state and federal law. Plaintiff has presented a more than plausible claim that such state law claims are not preempted. This conclusion is only strengthened by the strong presumption against preemption.

IV. OVERVIEW OF THE *BUCKMAN* DECISION AND IMPLIED PREEMPTION

Implied preemption can be found where Congress has occupied the entire field or where there is an actual conflict between federal and state law. *Schneidewind*, 485 U.S. 293. Again, the presumption against preemption applies to implied preemption. *Wyeth,* 555 U.S. 555.

It is clear that Congress did not signal its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices given that neither the MDA nor any other federal law speaks to redress for plaintiffs. First, "Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Id.* citing to *Maryland v. Louisiana,* 451 U.S. 725 (1981). It has long fallen within the province of states to safeguard the health and safety of their citizens. *See Medtronic Inc,* 815 at 475. Consonant with the "historic primacy of state regulation" of these matters, *see Medtronic*, 518 U.S. at 485, the power of states to govern in this field is considerable and undisputed. *See Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as 'to the protection of the lives, limbs, health, comfort, and quiet of all persons.'"); *Thorpe v. Rutland & Burlington R. Co.,* 27 Vt. 140, 149 (1854). Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as "a critical component of the States' traditional ability to protect the health and safety of their

citizens." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 544 (1992) (Blackmun, J., concurring in part and dissenting in part).

Moreover, where the FDCA provides no remedy for an injured consumer, the bar to a finding of preemption is raised even higher. *Id.* Thus, where a finding of preemption will foreclose a remedy that was traditionally available and for which federal law provides no substitute, courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent. *Id.* citing to *Lohr* ("It is, to say the least, 'difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.'") (quoting *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238, 251 (1984); *Bates*, 554 U.S. 449 (opining: "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.").

Second, in terms of conflict preemption the Honorable Stewart R. Dalzell of the Eastern District of PA recently opined that (1) "Such a conclusion is not to be found lightly" and (2) therefore courts should not "reach to find that FDA regulations preempt state law claims." *Perry*, 456 F.Supp. 2d at 684.

Moreover, in *Medtronic v. Lohr*, the United States Supreme Court held that:

> The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. *Medtronic, Inc.*, 518 U.S. at 501-502.

Because the *Lohr* Court found that failure to warn claims did not interfere with FDA regulations, the claims were not impliedly preempted. Subsequently, in *Wyeth v. Levine*, the Supreme Court similarly held that the FDA has long maintained that state law complements FDA regulations. 555 U.S. at 578-79.

In addition to the United States Supreme Court, the Third Circuit Court of Appeals in *Farina v. Nokia, Inc.*, has also recognized the holding in *Wyeth* when it compared the roles of the FDA and the Federal Communications Commission ("FCC"). 625 F.3d 97 (3d Cir. 2010) The *Farina* court opined that, unlike the FCC, the FDA "itself had traditionally regarded state law as a complement to federal regulations." *Id.* at 129. The Third Circuit Court of Appeals has also held that violations of federal law can be redressed through state common-law claims when analyzing preemption in different fields as well.[15]

The United States Supreme Court has found implied preemption in a limited scenario where (1) a newly-fashioned and sole "fraud on the FDA claim" was asserted; (2) the fraud alleged occurred during the premarket approval; (3) plaintiff's only claim was assigning liability solely on the basis of this fraud; (4) plaintiff's claim was brought against a regulatory consultant; and (5) the claim did not rely on traditional state tort law but rather a theory that exists solely by virtue of the FDCA. *Buckman*, 531 U.S. at 348. In *Buckman*, patients claimed they suffered injuries from implantation of orthopedic bone screws into their spines. *Id.* The patients settled their claims against the device manufacturer and proceeded on a suit solely against a regulatory consultant they alleged made fraudulent representations to the FDA in the course of the FDA

[15] *Delaware & Hudson Ry. Co., Inc. v. Knoedler Mfrs., Inc.* 781 F. 3d 656 (3d Cir. 2015)(holding no preemption regarding the Locomotive Inspection Act); *Silkwood v. Kerr–McGee Corp.*, 464 U.S. 238, 258 (1984) (concluding that a state-law remedy based on a violation of the Atomic Energy Act was not preempted); *see also Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 367 (3d Cir.1999) (noting that "[f]ederal preemption of the standards of care can coexist with state and territorial tort remedies" and holding that state law remedies for a violation of the Federal Aviation Act were not preempted.

preapproval process. *Id.* The United States Supreme Court held that the FDCA impliedly preempted the patients' sole cause of action for "fraud on the FDA." *Buckman*, 531 U.S. at 348.

However, as ignored by Defendants, the *Buckman* court specifically distinguished such "fraud-on-the-agency" claims, (i.e., claims not related to a field of law that states traditionally occupied), from claims based on state law tort principles such as in *Silkwood*, 464 U.S. 238(state tort action against federally licensed nuclear plant), and *Lohr*. (state tort action against device manufacturer) *Buckman*, 531 U.S. at 352-53.[16]

The *Buckman* court also acknowledged that claims that "parallel" FDA regulations would be allowable and suggested that had plaintiffs relied on traditional tort law, the claims may not have been preempted. *Id.* at 352-53. If it were the Supreme Court's intent in *Buckman* to abolish all state law claims premised on violations of the FDCA, not only would the Court have stated so with no uncertain terms, but also there would have been no need for the Supreme Court to reexamine the issue subsequently in *Riegel*. Not only does *Riegel* contemplate parallel claims alleging FDCA violations that survive preemption, but also there is no mention to *Buckman* in the *Riegel* opinion.

In short, it is clear that there is no field preemption as Congress did not clearly signal its intent to deprive States of any role in protecting consumers from the dangers of medical devices and there is no conflict preemption as Plaintiff's claims are grounded in traditional state tort law, not solely by the virtue of the FDCA.

[16] Subsequent to *Buckman*, in *Bates v. Dow Agrosciences*, the Supreme Court dealt with an identical preemption provision found in the Federal Insecticide, Fungcide, and Rodenticide Act (FIFR Act) which reads: "a state shall not impose or continue in effect any requirements for labeling or packaging in in addition to or different from federal regulatory requirements. 544 U.S. 431 (2005). Here, the court held that "the preemption provision did not preclude the plaintiff's common law tort claims and explained "a requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 554 U.S. at 445.

A. PA District Courts and Circuit Courts uphold no implied preemption.

In an effort to persuade this Court that implied preemption applies here, Defendants attempt to re-plead Plaintiff's Complaint to contain one sole claim for fraud on the FDA during the premarket approval process and expand *Buckman* beyond its limits. However, Defendants' argument has been rejected by several courts.

In fact this isn't the first time an Eastern District of PA court has dealt with this exact issue. In *Knipe v. SmithKline Beecham,* the Honorable Ronald L. Buckwalter addressed this issue three times and consistently held that *Buckman* is limited to fraud that occurred during the premarket approval process:

> As the Court previously explained, the United States Supreme Court has defined fraud on the FDA claims as violations of the FDA disclosure requirements, which are "various provisions aimed at detecting, deterring and punishing false statements made *during the approval process."* *citing to Buckman,* 531 U.S. at 349, 121 S. Ct. 1012 (emphasis added).
>
> Had Plaintiffs argued that GSK improperly secured approval for a pediatric indication for Paxil by hiding data from the FDA, the Court would deem the claim preempted. In this case, however, the gist of Plaintiffs' argument does not contend that GSK committed any fraud on the FDA during its efforts to secure approval for a pediatric indication for Paxil. Rather, Plaintiffs present a pure state law claim that (1) after initial FDA approval, GSK learned of dangers associated with an off-label use of its drag; (2) GSK failed to warn either the public or the medical community of the dangers associated with that drug; and (3) this failure to warn resulted in Jake Garrison's injuries…To the extent Plaintiff has alleged that Defendant did not timely produce its pediatric data to the FDA prior to seeking approval for a pediatric indication, such claims were made only in connection with rebutting Defendant's claim that the FDA explicitly rejected a pediatric warning; they do not allege fraud on the FDA. In short, and contrary to Defendant's arguments, Plaintiffs' claims do not exist by virtue of the FDCA disclosure requirements, but rather are premised entirely on state tort theories. *Knipe v. SmithKline Beecham,* 583 F. Supp. 2d 553, 597-98 (E.D. Pa. 2008)

As noted above, several other courts have rejected Defendants' argument. *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation,* 2004 WL 45503, at *11 (D. Minn. Jan. 5, 2004)(Citing *Buckman,* defendant argues that plaintiffs' consumer fraud and

deceptive trade practices claims are really "fraud on the FDA claims" in disguise, and are therefore preempted…Instead, the Court finds this case more analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F. Supp. 2d 565 (D.N.J. 2001). In *Dawson*, the court rejected defendant's preemption argument, noting: Plaintiffs' Complaint here does not allege a claim of "fraud on the FDA," but rather alleges that Defendants deceived the public, including Plaintiffs…*Buckman* thus clarified that traditional state tort law claims (even those which parallel FDCA requirements) are not necessarily preempted by the FDCA and are not necessarily the same as "fraud on the FDA" type claims.) *Id.*; *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 784 (D. Minn. 2009)(neither *Riegel* nor *Buckman* would preempt a properly pled claim based on violation of federal law); *Cornett*, 414 N.J. Super. 365, 402 (N.J. App. Div. 2010)(claims that device manufacturer illegally promoted its device would not be preempted by *Riegel* or *Buckman); In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 899 (D. Minn. 2006) *(Buckman* did not preempt plaintiff's state tort law claims against Medtronic and further holding: "States may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries."); *Bausch*, 630 F.3d at 557 *(Buckman* did not preempt plaintiffs' claims against manufacturer that failed to comply with FDA regulations…and "the pleading of FDCA violations rarely warrants *Buckman* preemption so long as the allegations are grounded in traditional state tort law."); *Phillips v. Stryker Corp.*, 2010 WL 2270683 (E.D. Tenn. June 3, 2010) *(Buckman* did not preempt plaintiff's ability to establish a "parallel claim" as mandated by *Riegel); Elmore v. Smith & Nephew, Inc.*, 2013 WL 1707956, at *4 (N.D. Il. 2013) (Plaintiffs' claims were not impliedly preempted because they were based on common-law duties of care that exist independently of the FDA regulations); *Stengel*, 704 F.3d at 1233.

In fact, even where a Plaintiff incorporates that there was fraud in the premarket approval process the claim is still not impliedly preempted. In *U.S. ex rel. Krahling v. Merck & Co., Inc.*, 44 F. Supp. 3d 581, 603 (E.D. Pa. Sept. 5, 2014), the court found *Buckman* unavailing where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, thereby finding no preemption. The court noted that in the wake of *Buckman*, courts have held that where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, a state tort claim is not preempted. *Id.* Similarly in *Desiano v. Warner–Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), the Second Circuit held that because Plaintiff's state law causes of action merely required some proof of fraud on the FDA during the PMA process, but such proof was not conclusive, the Supreme Court's holding in *Buckman* was inapplicable. Following *Buckman,* courts have distinguished preempted claims from viable ones in the following manner:

> The plaintiff must be suing for conduct that violates the FDCA ... but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA. *Riley*, 627 F. Supp. 2d at 777. *see Lefaivre v. KV Pharm. Co.*, No. 4:09 CV00588, 2010 WL 59125, at *3 (E.D. Mo. Jan. 5, 2010).

I. Defendants' arguments

Throughout their motion, Defendants make the same arguments regarding implied preemption attempting to apply *Buckman* to each claim. In effort to avoid repetition, Plaintiff responds with the following:

Ostensibly, Defendants recognize that Plaintiff has pled viable parallel claims based upon Defendants' violations of federal law, and alternatively argue that such parallel claims are "impliedly preempted" under the Supreme Court's ruling in *Buckman.* Defendants' argument fails to explain why the Court, in 2008, would go through the trouble of creating the parallel

claim exception in *Riegel*, which was, according to Defendants, prohibited by its earlier 2001 *Buckman* decision. The practical effect of this *non sequitur* argument, of course, is to immunize Defendants against any possible civil liability for violating either federal or state law.

However, Plaintiff's case is wholly distinguishable from *Buckman.* First, Plaintiff's claims are grounded in traditional state tort law and not solely by virtue of the FDCA. Additionally, Plaintiff's sole cause of action is not "fraud on the FDA" which occurred during the premarket approval process. In fact, nowhere in the Complaint is she alleging such a claim. The sole allegation that amounts to such an inference was incorporated not as a cause of action but to show how Defendants breached certain warranties. For example, one of the warranties given to Plaintiff was the there was "no pain" associated with Essure. In order to prove that Defendants breached this warranty, Plaintiff plead that Defendants altered records of its trial participants to reflect less pain, proving that Defendants were aware that Essure caused pain before it warranted to Plaintiff the direct opposite.

The court in *U.S. ex rel. Krahling,* 44 F. Supp 3d at 603, found *Buckman* unavailing where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, thereby finding no preemption. The court noted that in the wake of *Buckman*, courts have held that where a plaintiff's claim incorporates, but does not rely upon a fraud on the FDA, a state tort claim is not preempted.

Similarly in *Desiano*, the Second Circuit held that because Plaintiff's state law causes of action merely required *some* proof of fraud on the FDA but such proof was not conclusive, the Supreme Court's holding in *Buckman* was inapplicable. 467 F.3d 85.

Additionally, Plaintiff's allegations that Defendants failed to disclose adverse events and used nonconforming products did not occur during the premarket approval process as was

the case in *Buckman.* Unlike in *Buckman,* the allegations at issue occur outside the context of this regulatory process. Plaintiff's allegations are that Defendants violated the CPMA and federal law after the CPMA was awarded to Defendants. Lastly, Plaintiff is not bringing this claim against a regulatory consultant.

In *Knipe v. SmithKline Beecham,* the Honorable Ronald L. Buckwalter held that *Buckman* is limited to fraud that occurred during the premarket approval process:

> As the Court previously explained, the United States Supreme Court has defined fraud on the FDA claims as violations of the FDA disclosure requirements, which are "various provisions aimed at detecting, deterring and punishing false statements made *during the approval process*." *Citing Buckman,* 531 U.S. at 349, 121 S. Ct. 1012 (emphasis added).
>
> Had Plaintiffs argued that GSK improperly secured approval for a pediatric indication for Paxil by hiding data from the FDA, the Court would deem the claim preempted. In this case, however, the gist of Plaintiffs' argument does not contend that GSK committed any fraud on the FDA during its efforts to secure approval for a pediatric indication for Paxil. Rather, Plaintiffs present a pure state law claim that (1) after initial FDA approval, GSK learned of dangers associated with an off-label use of its drag; (2) GSK failed to warn either the public or the medical community of the dangers associated with that drug; and (3) this failure to warn resulted in Jake Garrison's injuries…To the extent Plaintiff has alleged that Defendant did not timely produce its pediatric data to the FDA prior to seeking approval for a pediatric indication, such claims were made only in connection with rebutting Defendant's claim that the FDA explicitly rejected a pediatric warning;they do not allege fraud on the FDA. In short, and contrary to Defendant's arguments, Plaintiffs' claims do not exist by virtue of the FDCA disclosure requirements, but rather are premised entirely on state tort theories. 583 F. Supp. 2d at 597-98.

As noted above, several other courts and Circuits agree with the *Knipe* Court.

Here, Plaintiff has alleged that Defendants conduct violated both federal law and PA state tort law, as discussed in depth *infra*. Plaintiff is not alleging that Defendants secured approval by hiding data from the FDA. Again, the one allegation that concerns Defendants altering of medical records during was plead to show Defendants breached certain warranties. Accordingly, although Plaintiff's claims are premised on alleged violations of federal law, they

nonetheless exist independently as state law causes of action. As the *Knipe* Court has already held, these claims are not impliedly preempted by *Buckman.*

Next, Defendants have failed to show how it would be impossible to comply with both state and federal law or how state law would stand as an obstacle to the accomplishment of the full purposes of objective of Congress. That is because neither exists. Accordingly, there is no implied preemption here. In fact, how can it be obstructive and conflicting when the FDA, in both the C.F.R. and the CPMA, expressly excludes certain claims from preemption?[17]

It is certainly possible for Defendants to comply with both state and federal law, as noted by the *Lohr* and *Riegel* courts. It is just that Defendants chose not to comply with either. For example, Defendants could have reported all adverse events or used conforming product, thereby satisfying PA state and federal law. Moreover, PA state law is not obstructive to the accomplishments of the full purposes of the objectives of Congress. In fact, state law "is no more of a threat to federal requirements than would be a state-law duty" to comply with a local fire prevention code. *Medtronic, Inc.*, 518 U.S. 471. Lastly, the Third Circuit Court of Appeals has opined that the FDA itself regards state law as a complement to federal regulations. *Farina,* 625 F.3d at 129. Accordingly, when viewing this case with the strong presumption against preemption, PA state law is not obstructive, but complementary.

[17] 21 C.F.R. 808.1 (d) (1) : (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.
"Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices." 21 C.F.R. § 808.1(d)(6)(ii).
21 C.F.R. 808.1(d)(10): "Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States

V. THE GOVERNMENT'S POSITION ON PREEMPTION

After *Buckman* and upon invitation from the United States Supreme Court, the issue as to whether a state law failure to warn claim was either (1) expressly preempted under 360k(a) or (2) impliedly preempted under *Buckman* was also presented to the Federal Government and the FDA in *Stengel v. Medtronic, Inc.* The failure to warn claim was premised on a device manufacturer's failure to report adverse events to the FDA as the MDA generally requires manufacturers to do. In short, the Solicitor General opined that it was not:

> Section 360(k)a does not preempt respondents' straightforward claim that petition should have brought new safety information to physicians' attention … because such a claim implicates no preemptive device-specific federal requirement.
>
> As for implied preemption, such a claim does not implicate *Buckman*; rather, it closely resembles the claim against the brand-name prescription drug manufacturer that *Wyeth* held was not impliedly preempted. U.S. Amicus Br. at 7 *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).

Recently, the Supreme Court denied certiorari in *Stengel*, a case decided in the 9th Circuit Court of Appeals *en banc*, which unanimously held that the MDA did not preempt consumers' state law failure-to-warn claim. The Solicitor General submitted an amicus brief that outlined the government's (and also, the FDA's position) that only device-specific federal requirements have any preemptive force and "by contrast FDA's general manufacturing and labeling regulations do not have preemptive force."[18] As recommended by the Solicitor General, the petition was then denied. *See Stengel*, 704 F.3d 1224.

In light of that recent denial, *Stengel* is now the standing authority on preemption and the views of the Solicitor General are a guidepost to courts facing this complex issue. In a unique situation, this Court has the distinct advantage of knowing the position of the government

[18] U.S. Amicus Br. at 9, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013), attached hereto as Ex. "A."

with respect to this complex issue.

As stated above, the first step to *Riegel's* two-part test is whether "[T]he Federal Government has established requirements applicable to" a particular medical device. *Riegel*, 552 U.S. at 321. The Solicitor General's opinion was that most circuits are making the mistake of simply skipping over this first step by concluding that any federal device-specific requirement, regardless of whether a plaintiff's state-based claim impinges on it, imposes across-the-board preemption:

> The courts of appeals, in every case since *Riegel* involving a device subject to premarket approval, have tacitly dispensed with the first step of a proper Section 360k(a) preemption analysis—i.e., asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement. That practice in the circuits may reflect an erroneous assumption that the existence of *any* device-specific federal requirement has across-the-board preemptive effect, even on a state requirement addressed to a different subject. U.S. Amicus Br. at 15, *Stengel*,704 F.3d at 1226.

In addition, "[t]o have preemptive force under Section 360k(a), a federal requirement ordinarily must be not only device specific, but also relevant to the asserted state claim." *Id.* Based on the above analysis, this Court must ask whether the FDA has established device-specific requirements, on the same subject as Plaintiff's state tort claims, and whether those state claims actually conflict with the federal law. *Id.* It is vital to note that such federal requirements must be something other than requirements or regulations that only generally apply to all devices ("CGMP").

In the context of PMA approved devices, only the initial PMA would have preemptive force as it alone is specific to any particular device.[19] Thus, any claim alleging state tort claims despite compliance with the PMA would be preempted under *Riegel*. Plaintiff, in this case,

[19] *See Riegel*, 552 U.S. at 322-323.

similar to plaintiff in *Stengel*, is attacking the conduct of the manufacturer after PMA approval and therefore, bringing traditional state tort claims that cannot conflict with the device-specific regulations set forth by the PMA.

Defendants' position that all claims against PMA approved devices should be either expressly or impliedly preempted is illogical, as stated by the Solicitor General:

> [I]f a state requirement were preempted absent a specific federal requirement that reflects FDA's weighing of competing considerations on the same subject and specific to the device (or type of device), the MDA would have the ironic effect of providing less public protection from unsafe and ineffective medical devices than pre-MDA law. U.S. Amicus Br. at 11, *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).

When viewed in comparison to the ruling in *Stengel*, Defendants' position that the "federal law specifically *forbids* manufacturers from issuing additional warnings…" cannot be correct, as the Supreme Court and the government established that a manufacturer can always provide additional warnings to protect the public against newly recognized dangers. The Solicitor General recognized that a device manufacturer requires FDA approval for label changes but prior to receiving that approval stressed that a "manufacturer may place into effect '[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction,' 'that add or strengthen an instruction that is intended to enhance the safe use of the device,' or 'that delete misleading, false, or unsupported indications.'" Defendants had the ability and were required to notify the FDA of "changes being effected" (CBE) to their device's labeling. *See* 21 C.F.R. 314.70(c)(6)(iii)(A) and (C).

Similar to *Stengel*, Plaintiff raises the same issues surrounding Defendants' conduct after Defendants gained CPMA approval. Plaintiff's claims are based upon Defendants' violations of general manufacturing regulations that all device manufacturers must adhere to. Simply because a device manufacturer has their device approved under the PMA process, rather than the 510(k)

process or another method, does not allow that manufacturer to violate blanket manufacturing regulations without any possibility of recourse for the public. It was certainly not the intent of Congress in enacting the MDA to eliminate the public's protection from unsafe devices and it is clear that the Supreme Court will recognize this fact. In closing, the Government opined "..an overly expansive reading of *Buckman* would extinguish the very parallel claims that Section 360k(a) preserves-a result that both *Buckman* itself…and *Riegel* disclaim."

In short, the FDA's position is that a failure to warn claim based on failing to report adverse events is not expressly preempted because it does not entail a device-specific regulation and it is not impliedly preempted because it is seeking to enforce traditional tort law, not the FDCA itself, which resembles *Wyeth* more than *Buckman*.

ARGUMENT

First, after accepting Plaintiff's allegations as true and taking judicial notice of Defendants' CPMA, there is no valid federal requirements as Defendants' CPMA is invalid. This Court should not "reach to find" preemption due to Defendants' failure to comply with the conditions of its CPMA. Accordingly, without a valid CPMA there is no federal requirement specific to Essure.

Second, even if the CPMA were valid, as fully discussed *infra*, there are no specific federal requirements applicable to Essure as it relates to Plaintiff's claims for: Negligent Entrustment; Breach of Express Warranty; Fraudulent and Negligent Misrepresentation; UTPCPL; and Negligence-Pharmacovigilance. The FDA never granted Defendants permission or approved (1) Defendants' entrustment of hysteroscopic equipment to physicians; (2) Defendants' warranties and misrepresentations to Plaintiff; and (3) Defendants' promotion/distribution/advertising scheme for Essure.

In fact, Plaintiff's claims for Negligent Entrustment, Breach of Warranty, and UTPCPL

are also excluded from preemption under 21 C.F.R. 808.1(d)(1). Moreover, the FDA expressly excludes warranty and misrepresentation claims from preemption in Essure's CPMA. Even assuming there were some federal regulations specific to each claim and that the C.F.R. did not expressly exclude these claims from preemption, the claims are still not preempted as all are based on the violations of federal law which amount to parallel claims.

Lastly, *assuming arguendo* that the CPMA is valid, Plaintiff's remaining defective product claims (Negligent Training, Negligence-Risk Management, Fraudulent Concealment, Strict Liability, Negligence-Manufacturing, Negligence-Failure to Warn) amount to parallel claims as fully discussed *infra.* Accordingly, there is no preemption.

I. DEFENDANTS' FAIL TO HOLD A VALID CPMA

Before analyzing this argument in terms of preemption, it is important to keep in mind four points: (1) Plaintiff's allegations are accepted as true; (2) Courts should not reach to find preemption, especially in injury cases where the preemption bar is set even higher; (3) Plaintiff is not seeking relief from the Court to have the CPMA declared invalid; and (4) The FDA's own order leaves no room for discretion that should Defendants fail to comply with any of the conditions of approval, the CPMA is invalid.[20]

First, this allegation is not subject to a preemption analysis as Plaintiff has not brought a cause of action to invalidate the CPMA. The CPMA itself has already done so.

Second, accepting Plaintiff's allegations as true, there are no valid federal requirements specific to Essure as Defendants CPMA is invalid. *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 n. 4 (W.D. Va. Aug. 27, 2002) (holding that defendant's failure to comply with the CPMA conditions invalidated the FDA's approval); *In re: St. Jude Medical, Inc. Silzone Heart Valves*

[20] Moreover, the FDA requires almost no deviations from the specifications in its orders as the approval order provides the reasonable assurance of safety and effectiveness. *Riegel v. Medtronic, Inc.*, 552 U.S. 312 at 323 (2008).

Products Liability Litigation, MDL No. 01-1396, 2004 WL 45503 at *16 (denying summary judgment on preemption and finding persuasive plaintiff's argument that the subject medical device no longer had FDA approval based on its failure to comply with conditions.) Although both cases are pre-*Riegel*, the holdings regarding the validity of CPMA orders still hold true as *Riegel* did not touch upon this issue. In fact, the Supreme Court in *Riegel* acknowledged that a medical device may have conditional premarket approval or CPMA:

> After completing its review, the FDA may grant or deny premarket approval. § 360e(d). It may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. The agency is also free to impose device-specific restrictions by regulation. § 360j(e)(1). *Riegel* 552 U.S. at 319

Essure's CPMA is invalid and Defendants no longer have a valid FDA approval specific to Essure. In fact, this allegation is supported by the FDA as its own CPMA order leaves no room for discretion stating: "Failure to comply with conditions of approval invalidates this approval order." The CPMA order does not read: "failure to comply may invalidate the order." After accepting Plaintiff's allegations as true and taking notice of the CPMA, the CPMA is invalid and therefore Plaintiff's claims are not preempted.

I. Defendants' argument

Defendants' first claim that there is no such thing as CPMA and argue that Plaintiff cites to no case law or statute to support such an allegation. However, in *Woods*, the court stated: "assuming the conditional PMA constitutes a preemptive requirement, the court finds that Gliatech's failure to comply with the PMA conditions invalidated the FDA's approval." 218 F. Supp. 2d at 802 n. 4. In *Kemp v. Medtronic, Inc.*, the court recognized that "If the FDA approves a PMA, it does so subject to conditions described in a document entitled 'Conditions of Approval.'" 231 F.3d 216, 223 (6th Cir. 2000). Further, *In re: St. Jude Medical, Inc. Silzone*

Heart Valves Products Liability Litigation, the court, in denying summary judgment, noted that it found plaintiff's argument persuasive that the subject medical device no longer had FDA approval based on its failure to comply with conditions. 2004 WL 45503 at *16. Lastly, the Supreme Court in *Riegel* acknowledged that a medical device may have conditional premarket approval or CPMA:

> After completing its review, the FDA may grant or deny premarket approval. § 360e(d). It may also condition approval on adherence to performance standards, 21 CFR § 861.1(b)(3), restrictions upon sale or distribution, or compliance with other requirements, § 814.82. The agency is also free to impose device-specific restrictions by regulation. § 360j(e)(1). *Riegel*, 552 U.S. at 319

As stated by the Supreme Court in *Riegel*, the FDA could have granted PMA, denied PMA, or provided a CPMA. As such, it is clear from several courts, including the *Riegel* court, that CPMA may be granted to a particular medical advice and that the term is not something Plaintiff "cut out of whole cloth" as alleged by Defendants.

In addition to the case law recognizing "conditional PMA," the C.F.R. also recognizes the same: 21 C.F.R. § 814.82(a) states:

> FDA may impose postapproval requirements in a PMA approval order....
>
> Postapproval requirements may include….
>
> (2) continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted…
>
> (7) Submission to FDA at intervals specified in the approval order of periodic reports…
>
> (9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device. 21 C.F.R. § 814.82(a).

It is important to recognize that the C.F.R. provides that the FDA "may" impose post approval requirements and that it is not required to do so, as recognized by the Supreme Court in *Riegel.*

In addition to the specific post-approval conditions that the FDA may place on a medical device, the C.F.R also mandates a more general post-approval requirement which applies to all devices: "A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device," 21 C.F.R. § 814.80. The C.F.R. also explains that additional post-approval conditions may be required as they "provide reasonable assurance…of the safety and effectiveness of the device."

Lastly, a cursory glance at the CPMA itself confirms that Essure's premarket approval was "conditioned" upon subsequent conditions directed to Defendants, the failure of which "invalidated" the order:

- "Failure to comply with the conditions of approval invalidates this approval order."
- "Continued approval of this PMA is contingent upon the submission of postapproval reports."

Even the "Summary of Safety and Effectiveness Data" reads:

- "As a condition to this approval, Conceptus agreed …to a 5-year follow up on all patients from the…pivotal studies."

In short, to state that "CPMA" was "made out of whole cloth" by Plaintiff and is not supported by any case law or statutes is a misrepresentation as (1) prior courts, including *Riegel*, have recognized this; (2) the C.F.R. supports this position; and (3) a simple reading of the order on Essure clearly mandates that the approval of the device is conditioned upon Defendants complying with specific post-approval conditions.

Defendants then argue that the FDA has never withdrawn the CPMA, yet offer no

evidence for this Court to take judicial notice of to support this contention. The only evidence Defendants request that this Court take judicial notice of, the CPMA, actually supports Plaintiff's allegation that Defendants' CPMA is invalid. *Assuming arguendo*, that Defendants presented the Court with a statement from the FDA that its CPMA is still valid, and this Court took judicial notice of the same, Defendants cannot ignore the contradictory position the FDA has already expressly taken in the CPMA. If you fail to comply with any of the post-approval conditions, the CPMA is invalid. This type of contradictory position would not even survive summary judgment as it creates an issue of fact as to whether the CMPA is valid.

Lastly, Defendants also briefly argue that even if their CPMA were invalid, Plaintiff's claims would be impliedly preempted under *Buckman*. First, whether or not the CPMA is valid or not is not subject to a preemption analysis as it is an allegation, not a cause of action. Plaintiff is not requesting that the Court invalidate the CPMA. The CPMA has already done so. Moreover, Plaintiff is not alleging that Defendants committed fraud on the FDA during the preapproval process. Plaintiff is alleging that Defendants failed to comply with postapproval conditions thereby rendering the CPMA invalid. The *Knipe* court has already opined on this exact argument limiting the *Buckman* holding to fraud that occurred during the premarket approval process. *Knipe*, 583 F. Supp. 2d at 597-98. Accordingly, *Buckman* is inapplicable to Plaintiff's allegation that the CPMA is invalid as Plaintiff is not bringing a claim for "Fraud on the FDA" during the preapproval process.

II. PLAINTIFF'S NEGLIGENT ENTRUSTMENT, BREACH OF EXPRESS WARRANTY, FRAUDULENT AND NEGLIGENT MISREPRESENTATION, UTPCPL, AND NEGLIGENCE- PHARMACOVIGILANCE CLAIMS ARE OUTSIDE THE SCOPE OF PREEMPTION.

A. Negligent Entrustment

The FDA never approved Defendants' third party contract with the implanting physician, entrusting him with very specialized hysteroscopic equipment. In fact, the FDA expressly excludes "other products" from preemption. Federal Statute: 21 C.F.R. 808.1(d)(1) reads:

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products (hysteroscopes) in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices (UTPCPL) in which the requirements are not limited to devices.

In short, there is no specific federal requirement applicable to Defendants' entrustment of hysteroscopic equipment. Accordingly, Defendants' argument cannot satisfy the first prong of *Riegel*.

The hysteroscopic equipment necessary to place Essure was (1) manufactured by a third party; (2) is not a part of Defendants' CPMA; and (3) is not a part of Essure or the Essure delivery system. However, because the hysteroscopic equipment is both necessary to place Essure and extremely expensive, Defendants provided it to the Plaintiff's implanting physician who was unable to use it safely which caused Plaintiff's injuries. This contract was independent of Essure's CPMA. As such, Defendants' entrustment of hysteroscopic equipment is not afforded any protection via Essure's CPMA.

The specialized hysteroscopic equipment is so difficult to use that even expert OBGYN's have difficulty using the same. Defendants acknowledge this in Essure's Physician Training Manual: "Essure should be used only by physicians who are knowledgeable hysteroscopists." This type of equipment can be life threatening if not in the hands of an expert hysteroscopist.

For example, a female patient with no known medical conditions recently died during the placement of Essure when the physician utilizing Essure and the hysteroscope perforated the patient's uterus resulting in blood entering the abdomen and the patient suddenly coding.[21] There are four other deaths associated with Essure which was inserted with a hysteroscope.

In short, Plaintiff's claim for Negligent Entrustment is not subject to a preemption defense as it (1) centers around equipment used to place Essure, hysteroscopes, which is not a part of Essure's CPMA; and (2) is expressly excluded by 21 C.F.R. 808.1 (d) (1).

I. Defendants' arguments

Defendants contend that this claim would require a jury to demand more from Defendants than what is required by the CPMA. This argument misses the point. Plaintiff is not alleging that Defendant should do more or less than what the FDA approved as it relates to the Essure system, the only product which had CPMA.

Plaintiff is alleging that before Defendants enter into independent contracts to provide implanting physicians with equipment that is not a part of the medical device which was approved, they have a duty to make sure that the implanting physician is competent to use such equipment. Defendants should not just hand out dangerous medical equipment to unqualified physicians in order to sell its product. In short, a jury could find that Defendants breached the duty of care it owed to Plaintiff when it provided hysteroscopes to unqualified physicians in order to sell Essure. This is a pure negligent entrustment claim, outside the realm of Defendants' CPMA.

The FDA never approved this independent contract, nor did the FDA have any knowledge of this contract. Defendants provided these hysteroscopes to unqualified physicians so that it could flood the market with Essure. Simply because the FDA granted the Essure system CPMA,

[21] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=4531887

it does not follow that Defendants can raise a preemption defense for other equipment that Defendants provided to physicians.

Further, Defendants cite to *Riegel*, but fail to do a proper *Riegel* analysis. There is no specific federal requirement that applies to a third party contract where Defendants provide physicians with equipment, which was not a part of the CPMA. If this requirement existed, Defendants would have provided it to the Court and asked the Court to take judicial notice of the same.

Defendants also cite to no case law, statute, or any other authority which stands for the proposition that separate contracts entered into with physicians regarding equipment which was never approved by the FDA in any way is afforded preemption status.

Defendants argue that the Restatement of Torts Section 408 requires entrustment of an instrumentality to a person that the defendant knows to be incompetent or unable to use it safely. However, Defendants misapprehend the law. Under the Restatement of Torts Section 308:

> Permitting Improper Persons to Use Things or Engage in Activities: "It is negligence to permit a third person to use a thing or to engage in an activity which is under the control of the actor, if the actor knows or should know that such person intends or is likely to use the thing or to conduct himself in the activity in such a manner as to create an unreasonable risk of harm to others. *See also Christiansen v. Silfies,* 446 Pa. Super. 464 (Pa. Super. Ct. 1995).

Therefore, the proper inquiry as to Defendants' state of mind is whether the defendant knew or should have known that the person was likely to use the thing or to conduct himself or herself in a manner that creates an unreasonable risk of harm to others. *Id.* According to the Restatement, Plaintiff's allegations are properly plead: "The implanting physician was not an expert hysteroscopist nor competent to use such equipment. Defendants were aware of this dangerous condition but provided the physician with the equipment in order to sell its product."[22]

[22] Para. 139 of Strimel Complaint.

Further, Defendants argue that they had no duty to investigate doctors to determine whether they were sophisticated enough to use such specialized equipment. However, Defendant cites to no case law or statute supporting this conclusory position.

Lastly, Defendants contend that negligent entrustment does not apply to the facts at issue here. However, Defendants again cite to no case law or statute to support their position that a claim for negligent entrustment cannot be brought under these facts. Defendants' reasoning as to why there is no "cognizable state law claim here at all" is that Defendants "have found no case where it has been applied to the entrusting of a medical device or equipment to a physician." The two cases Defendants do cite merely state that "the theory of negligent entrustment, while accepted in Pennsylvania, appears to be confined to specific and narrow situations"[23] and that "its most frequent application"[24] is where the entrustee is a member of a class which is notoriously likely to misuse the product.

There is no law that confines negligent entrustment claims to only vehicles, fireworks, and guns, or certain classes of people, as Defendants imply. Here, accepting Plaintiff's allegations as true, Plaintiff has plead a proper claim for negligent entrustment.

B. Beach of Express Warranty

A warranty is a promise voluntarily made – the "requirement[s] imposed by an express warranty claim are not imposed under State law, but rather imposed by the warrantor." *Cipollone*, 505 U.S. at 525 (finding breach of express warranty not preempted). Because warranty claims do not concern the breach of a promise pertaining to safety or effectiveness required by the FDA, but rather a voluntary contractual promise made by the defendant, separate and apart from any FDA requirements, determination of warranty claims do not

[23] *Kuhns v. Brugger*, 390 Pa. 331, 347-8, 135 A.2d 395, 347-8, 404-5 (1997).
[24] *Hosler v. Reich*, No. CV-19-1991, 1992 WL 676630 *47 (Ct. Com. Pl., Snyder Cnty. Oct. 13, 1992).

"require a finder of fact to challenge or usurp the FDA's conclusions of safety and effectiveness." *Cline v. Advanced Neuromodulation Sys*., 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012).[25]

The FDA never reviewed or approved Defendants' warranties made by Defendants to Plaintiff regarding Essure. The Supreme Court, Third Circuit Court of Appeals, courts within the Eastern District of PA, and several other courts throughout the U.S. all opine that breach of express warranty claims are not subject to preemption. In addition, Federal Statute, 21 C.F.R. 808.1(d)(1) and Defendants' CPMA both expressly exclude any warranty and misrepresentation claims from preemption. As such, under the Supreme Court's, Third Circuit's, and several Eastern District of PA District Courts' reasoning, the C.F.R., and Essure's very own CPMA, Plaintiff's breach of warranty claim is not preempted.

First, the Supreme Court, the Third Circuit Court of Appeals, and most courts, including Eastern District of PA courts, opine that an adequately plead claim for breach of express warranty is not preempted. *Cipollone,* 505 U.S. at 525; *Michael,* 46 F.3d at 1316, abrogated on other grounds; *Bentzley,* 827 F. Supp. 2d 443.[26]

In *Michael v. Shiley*, the Third Circuit Court of Appeals held that breach of express warranty claims are not preempted by the MDA because they arise out of representations made by a party and not from independent operation of law. 46 F.3d at 1325.

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[25] *See also Mitchell*, 126 F. 3d at 915 ("A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the [premarket approval], and therefore we cannot say that such a cause of action is preempted"); *Alton*, 2013 U.S. Dist. LEXIS 127190, at *93-*94 (warranty claim premised solely on Medtronic's voluntary statements to public and medical community regarding the safety and efficacy of off-label uses of Infuse, which statements are not subject to FDA regulation and thus not preempted); *Riley*, 625 F. Supp. 2d at 788 (§ 360k does not preempt a warranty claim based on voluntary statements and "Any other result would turn FDA approval of [FDA-required] statements into a free pass to deceive consumers. . .").

[26] *Davenport*, 302 F. Supp. 2d at 433; *Starks v. Coloplast Corp.*, No. 13–3872, 2014 WL 617130, at *6 (E.D. Pa. Feb.18, 2014); *McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 465 (W.D. Pa. 2012); *Killen v. Stryker Spine*, 2012 WL 4498865 (W.D. Pa. 2012)**;** *Rosci*, 447 Pa. Super. 403; *Byrnes v. Small*, 2015 WL 1243219, at *10 (M.D. Fla. Mar. 18, 2015); *Wright v. Medtronic, Inc.*, WL 328596, at * 15 (W.D. Mich. Jan. 23, 2015); *Mitchell v. Collagen Corp*., 126 F.3d 902 (7th Cir. 1997); *Alton v. Medtronic, Inc.*, 2013 WL 478631, at *30 (D. Or. 2013).

Likewise, in *Rosci v. Acromed, Inc.*, the PA Superior Court agreed with the *Michael* court's reasoning holding:

> We agree with the reasoning of the *Shiley* Court because the judicial enforcement of an express warranty, even where the warranty terms have previously been submitted for approval by the FDA pursuant to the provisions of the MDAs, cannot result in an order or opinion imposing a requirement under state law that is "different from, or in addition to ... any requirement applicable under this chapter to the device." 21 U.S.C. § 360k. Rather, the purpose of such litigation would be to seek enforcement of the express terms already approved by the FDA. Thus, the express warranty claim of appellants is not preempted by the MDAs. 447 Pa. Super. at 442.

The reasoning behind the courts' holdings is that "express warranties arise from representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law." *Michael,* 46 F.3d 1316, abrogated on other grounds. (citing 13 Pa. Cons. Stat. Section 2313); *Hofts,* 597 F. Supp. 2d 830. Moreover, The parties to a contract, not the state, define the substantive obligations of the contract and any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties. *Id.*

Accordingly, it follows that preemption does not apply to express warranty claims as they do not subject the device manufacturer to any state requirements, let alone any requirements that impose standards above and beyond those imposed by the FDCA. In *Hofts v. Howmedica Osteonics Corp.*, the court held that even statements approved by the FDA would survive preemption, as plaintiff was not claiming that the statements were defective, but rather that defendants did not live up to the FDA approved promises. 597 F. Supp. 2d at 839. The court opined that defendants were confusing the warranty claim with a claim for defective labeling, noting that plaintiffs were not alleging the FDA-approved label was defective. *Id.* The *Rosci* court agreed with this. Here, although Defendants have failed to show how any of the

alleged warranties were approved by the FDA, assuming they did, even those approved warranties still survive as Plaintiff is not in any way alleging that the label was defective in this claim.

FDA federal regulations also clearly state that warranty claims are not preempted because they are state laws of general applicability, not specifically developed with respect to medical devices. *See* 21 C.F.R. § 808.1(d)(1): "Exemptions from Federal Preemption of State and Local Medical Device Requirements" (such claims are "not 'requirements applicable to a device' within the meaning of section [360k(a)]"). Thus, express preemption does not apply.

> 21 C.F.R. 808.1 (d) (1) : (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness), or to unfair trade practices in which the requirements are not limited to devices.

Lastly, it should also be noted that Defendants' CPMA order expressly excludes warranties: "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

In sum, Plaintiff's warranty claims are not subject to preemption as they arise out of representations made by a party and not from independent operation of law.

I. Defendants' arguments

Defendants argue that there are no specific facts regarding what the warranties were, when they were made, how they were made, who they were negotiaited with, and how the breaches caused injury. However, Plaintiff did allege (1) the specific warranaites, verbatim;[27] (2) that they were made prior to implantation;[28] (3) the means by which they

[27] Paras. 102-118 of Strimel Complaint.

were communicated;[29] (4) that they were "specifically negotiated and expressly communicated to Plaintiff by Defendants";[30] and (5) that the breaches caused injury because Plaintiff relied on them and they were false.[31] Further, Plaintiff alleged how each warranty is false as plead underneath each warranty in Plaintiff's Complaint.

Defendants also assert that "most if not all of these claims relate to the product labeling/instructions for physicians approved by the FDA." Where is the evidence that supports that any of the warranties were apprvoed by the FDA? Defendants do not present this Court with any evidence for it to take judicial notice that the FDA approved these specific warranties. In fact, the CMPA says the direct opposite acknowledging that the FDA "does not evaluate information related to contractual liability warranties…" Moreover, even warranties submitted to the FDA for approval, are not regarded as a requirement imposed under state law but rather imposed by the warrantor and the purpose of such litigation would be to seek enforcement of express terms already approved by the FDA. *Rosci*, 447 Pa. Super. At 967, citing *Michael v. Shiley, Inc., supra,* 46 F.3d at 1326.

Defendants argue that the warranty claims are preempted because the warranties involve the safety and effectiveness of Essure and would therefore require a finding that Essure was not safe and effective. However, warranty claims do not relate to the breach of a promise pertaining to safety or effectiveness required by the FDA, but rather a voluntary contractual promise made by the defendant. In *Michael v. Shiley*, the Third Circuit Court of Appeals held that breach of express warranty claims are not preempted by the MDA because they arise out of representations made by a party and not from independent operation of law.

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[28] Para. 101 of Strimel Complaint.
[29] Paras. 101-118 of Strimel Complaint.
[30] Para. 178 of Strimel Complaint.
[31] Para. 182 of Strimel Complaint.

In other words, the parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. *Michael,* 46 F.3d 1316, abrogated on other grounds. (citing 13 Pa. Cons. Stat. Section 2313).

The cases cited by Defendants to support this position are either not binding on this Court or are inapplicable. Regarding the Supreme Court and Third Circuit cases cited by Defendant, both are inapplicable and Defendants reasoning and reliance on the same is misapplied.

In *Riegel v. Medtronic, Inc.*, a breach of express warranty claim was not at issue with the Supreme Court. 552 U.S. 312 (2008). In fact, the Riegels brought a breach of express warranty claim in the district court which was not dismissed based on preemption. *Riegel v. Medtronic, Inc.*, 2003 WL 25556778 (N.D. NY 2003).

In *Williams v. Cyberonics, Inc.*, the court affirmed the district court's decision preempting plaintiff's warranty claim. 388 Fed. Appx. 169. However, Plaintiff's express warranty claim was found to be preempted on summary judgment because it was actually restricted to a breach of implied warranty and plaintiff failed to show that an express warranty was given:

> Plaintiffs generally plead a "breach of warranty" without specifying whether they claim a breach of an express warranty or an implied warranty. To the extent that they do plead a warranty breach, they fail to set forth any facts demonstrating that Cyberonics made an express guarantee. Therefore, Plaintiffs' claim is restricted to one of breach of implied warranty. *Williams*, 654 F. Supp. 2d at 306.

As such, this case did not involve a breach of express warranty claim.

Unlike *Williams*, Plaintiff has plead a breach of express warranty claim. Eastern District of PA District Courts, on several occasions, have held breach of express warranty claims are not preempted when properly plead even post-*Williams*. *See Bentzley,* 827 F.

Supp. 2d 443; *Starks*, 2014 WL 617130 at 6.

More importantly, the Supreme Court, upon certiorari from the Third Circuit, reviewed whether a breach of express warranty claim would be preempted in *Cipollone v. Liggett Group, Inc.*. Here, the Court found that breach of express warranty claims are not preempted. The Court reasoned:

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirements" imposed by an express warranty claim are not "imposed under State law," but rather imposed *by the warrantor*. ... In short, a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement ... *imposed under State law*" within the meaning of § 5(b). *Cipollone*, 505 U.S. at 525

The Third Circuit Court of Appeals and Eastern District of PA District Courts have followed the same reasoning in regard to defective product claims under 360k(a).

Lastly, Defendants claim that Plaintiff has failed to plead facts supporting a plausible inference that an express warranty was created. Once again, the cases Defendants rely on to support this contention are inapplicable. *Shuker*, 2015 WL 1475368 at 12 (holding plaintiff inadequately plead warranty claim where the content of the warranty was not described, the source of the warranty was not identified, nor how plaintiff became aware of the warranty); *Starks*, 2014 WL 617130, at *7 (holding plaintiff inadequately plead warranty claim where he did not plead any details regarding the content of the warranty, how it was made or that it was the basis of the bargain); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243 at *5 (D. N.J. Mar. 5, 2009)(holding plaintiff's warranty claim inadequately plead where he failed to allege what was promised or by whom the promise was made); *Kester v. Zimmer Holdings, Inc.*, 2010 WL 2696467 at *11(W.D. Pa. June 16, 2010)(holding plaintiff's breach of warranty claim inadequately plead where plaintiff's complaint was merely a "formulaic

recitation of th elements…devoid of any factual support.")

Contrary to the cases relied on by Defendant, Plaintiff has plead her breach of express warranty claim with the requisite factual support including (1) the specific warranties, verbatim;[32] (2) that they were made prior to implantation;[33] (3) the means by which they were communicated;[34] (4) that they were "specifically negotiated and expressly communicated to Plaintiff by Defendants";[35] and (5) that the breaches caused injury because Plaintiff relied on them and they were false.[36] In fact, Plaintiff even alleged how each warranty is false underneath each warranty. Plaintiff's allegations go beyond a mere recitation of the elements and put Defendants on requisite notice. Accordingly, this Court should follow the Supreme Court's and Third Circuit's prior finding that claims for breach of express warranty are not preempted.

C. Negligent/Fraudulent Misrepresentations and UTPCPL Claims

Similarly, Plaintiff's claims for fraudulent and negligent misrepresentation and UTPCPL are not preempted because these claims are based on the same warranties as in Plaintiff's breach of express warranty claim. As such, the same reasoning as above holds true. Again, the MDA only preempts state law claims which seek to impose a requirement on a medical device manufacturer that is "different from, or in addition to, any requirement applicable under this chapter to the device…which relates to the safety or effectiveness of the device…" 21 U.S.C. Section 360k (emphasis added). Plaintiff's misrepresentation and UTPCPL claims do not impose requirements on Defendants related to the safety and efficacy of Essure. As the United States Supreme Court has held in both *Lohr* and *Cipollone,* misrepresentation claims, including

[32] Paras. 102-118 of Strimel Complaint.
[33] Para. 101 of Strimel Complaint.
[34] Para. 101-118 of Strimel Complaint.
[35] Para. 178 of Strimel Complaint.
[36] Para. 182 of Strimel Complaint.

those based on allegedly false statements made in advertisements, are not pre-empted because they are predicated on the duty not to deceive.

Similar to a breach of warranty claim, these claims are based on voluntary contractual representations made by Defendants directly to Plaintiff, separate and apart from any FDA requirements. The FDA never granted Defendants permission or approved the representations and Plaintiff's claims arise out of Defendants' common law obligation not to deceive Plaintiff.

First, the Supreme Court's holding in *Cipollone* is instructive on this issue. 505 U.S. 504. In that case, the Supreme Court considered whether the plaintiffs' fraud and misrepresentation claims against a cigarette manufacturer for representations it made regarding the hazards of smoking were preempted by federal law. *Id.* at 509-10. The plaintiff alleged that the defendant cigarette manufacturers' misrepresentations included advertisements that were meant to "neutralize" the warning labels that were federally mandated to be place on each packet of cigarettes. *Id.* The defendant asserted that the plaintiff's claims were preempted by Section 5(b) of the Federal Cigarette Labeling and Advertising Act, which read "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are [lawfully] labeled." *Id.* The Supreme Court held that the plaintiff's fraudulent-misrepresentation claims were not pre-empted because such claims were not predicated on a duty "based on smoking and health," but rather the state law duty not to make "false statements of material fact or to conceal such facts." *Id.* at 528-292. The court stated:

> State law prohibitions on false statements of material fact do not create 'diverse, nonuniform, and confusing' standards. Unlike state-law obligations concerning the warning necessary to render a product 'reasonably safe,' state-law proscriptions on intentional fraud rely only on a single, uniform standard: falsity. Thus, we conclude that the phrase 'based on smoking and health' fairly but narrowly construed does not encompass the more general duty not to make

> fraudulent statements. Accordingly, petitioner's claim based on allegedly fraudulent statements made in respondents' advertisements is not pre-empted by §5(b) of the 1969 Act. *Id.* at 529.

The Court in *Lohr* also noted:

> A plurality of this Court concluded in *Cipollone* that a similar analysis was required under the Public Health Cigarette Smoking Act of 1969….We held that the petitioner's fraudulent misrepresentation claims, including those based on allegedly false statements made in advertisements, were not pre-empted because they were "predicated not on a duty 'based on smoking and health' but rather on a more general obligation—the duty not to deceive." *Id.*, at 528–529, 112 S.Ct., at 2623–2624. The general common-law duty "not to make fraudulent statements" was not within the specific category of requirements or prohibitions based on smoking and health imposed under state law "with respect to the advertising or promotion" of cigarettes that were pre-empted by the 1969 statute. *Medtronic, Inc.*, 518 U.S. at 529.

Similarly, in *Michael v. Shiley*, the Third Circuit Court of Appeals, citing to *Cipollone*, held that plaintiff's claims for fraudulent misrepresentation based on defendant's advertising and promotional efforts not directly regulated by the FDA were not preempted by the MDA. 47 F.3d at 1329-31. The court noted that while the FDA regulated the information the defendant put on its labels, it did not directly regulate all advertising and promotional efforts. *Id.* at 1331. Therefore, the court held that the plaintiff's claims that the defendant, through its efforts to advertise and promote its heart valve, "knowingly misrepresented the extent of the valve problem and knowingly overstated the reduction in serious side effects achieved by the Shiley valve" were not preempted by the MDA. *Id.* at 1329-30. Furthermore, the court, again citing *Cipollone* noted "that Congress offered no sign that it wished to insulate…manufacturers from longstanding rules governing fraud." *Id.* at 1331. *See also In re Orthopaedic Bone Screw Products Liability Litigation*, 1996 WL 221784 (E.D. Pa. 1996) ("Claims arising from Defendant's alleged fraudulent promotion of its devises…are not preempted by 21 U.S.C. § 360k(a)[of the MDA]").

Regarding Plaintiff's UTPCPL claim, it should first be noted that the PA Supreme Court has opined that UTPCPL should "be construed liberally to effect its object of preventing unfair or deceptive practices." *Commonwealth v. Monumental Props.*, 459 Pa. 450, 460 (1974). *See also Wallace v. Pastore*, 742 A. 2d 1090, 1093 (Pa. Super. Ct. 1999) (citing *Monumental Properties* and applying the UTPCPL liberally in a private action context).

With this in mind, the FDA has expressly excluded state unfair trade practices from preemption. 21 C.F.R. § 801.1(d).

> Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates … to unfair trade practices in which the requirements are not limited to devices.

In addition to the express, codified exclusion from preemption, several courts have analyzed whether state unfair trade practice claims are preempted. *Hofts v. Howmedica Osteonics, Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009)(holding that "in light of the FDA's regulations specifically permitting claims for breaches of state deceptive practices statutes" the court denies defendant's argument on preemption); *In Re: Medtronic Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d at 898 (analyzing whether consumer protection statutes are preempted and concluding that there was no preemption); *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*, 2004 WL 45503, at *11 (holding state unfair trade practices not preempted). In *In re Medtronic, Inc. Implantable Defibrillators Litigation* the court held:

> These claims are premised on Defendants' purportedly misleading statements regarding the safety of its devices. Again, Defendants do not claim the FDA regulates its advertising and promotional materials concerning the devices. Thus, to the extent the PMA does not address these materials, a jury verdict based on these statutes would not conflict with the PMA, and plaintiffs' claims are not preempted. *Mitchell*, 126 F.3d at 915. Alternatively, to the extent these materials departed from the PMA specifications, they also survive preemption. *Id.* Finally,

> like state requirements under the UCC, the FDA implementing regulations specifically exclude state unfair trade practices claims from preemption. 21 C.F.R. § 801.1(d); … For all these reasons, plaintiffs' claims based on the various states' consumer protection statutes are not subject to MDA preemption…Plaintiffs' claims either contain parallel requirements, or involve areas not covered by the PMA. Their claims do not impose any requirements different from or in addition to those contained in their PMA. Thus, none of plaintiffs' claims are expressly preempted. 465 F. Supp. 2d at 889

Similarly the court *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation* held:

> Like state law requirements under the U.C.C., the applicable regulation expressly states that claims under state unfair trade practices are not preempted. 21 C.F.R. § 808(d). Citing *Buckman*, defendant argues that plaintiffs' consumer fraud and deceptive trade practices claims are really "fraud on the FDA claims" in disguise, and are therefore preempted…Instead, the Court finds this case more analogous to *Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA*, 145 F.Supp.2d 565 (D.N.J.2001). In that case, the Court rejected defendant's preemption argument, noting: Plaintiffs' Complaint here does not allege a claim of "fraud on the FDA," but rather alleges that Defendants deceived the public, including Plaintiffs. 2004 WL 45503, at *11

Assuming arguendo that Plaintiff's claims were centered on statements controlled and approved by the FDA, Defendants argument still fails as Plaintiff's misrepresentation and UTPCPL claims are also parallel claims based on violations of federal law as detailed in the Complaint. As such, pursuant to the United States Supreme Court and Third Circuit Court of Appeals, claims based on misrepresentations, such as Plaintiff's claims for Negligent Misrepresentation, Fraudulent Misrepresentation, and UTPCPL survive preemption.

I. Defendants' arguments

Defendants contend that Plaintiff's claims for UTPCPL and Negligent Misrepresentation "appear to fall within the fraud on the FDA claims" which are preempted under *Buckman*. Plaintiff refers this Court to Plaintiff's argument under Sections IV and V above for the analysis

as to why Defendants' argument fails. Interestingly, Defendants almost concede this point as their motion states that this "appears to fall" within *Buckman.* In short, this exact argument has been attempted on several courts, including the *Knipe* Court in the Eastern District of PA, to no avail.

Second, Defendants argue that much of the material Plaintiff claims was deceptive was submitted to the FDA for review and approval. Defendants allege that the warranties referenced under "PMA Supplement" "Essure Booklet Warranties" and "Brochure Warranties" were "submitted to and approved by the FDA." However, notwithstanding the fact that the CPMA expressly states that it is has not evaluated any warranties, Defendants have failed to provide the Court with any evidence to show that the warranties listed below were approved by the FDA. These warranties are not a part of Essure's instructions or product label. They are warranties provided in advertising brochures and booklets.

For example, Plaintiff has plead that the following representations were made to her in a brochure, which was never evaluated by the FDA, regarding Essure:

- "Worry free"
- "The Essure inserts stay secure, forming a long protective barrier against pregnancy. They also remain visible outside your tubes, so your doctor can confirm that they're properly in place."
- "Surgery Free"
- "Anesthesia-free"
- "Step Two: "pregnancy cannot occur"; Step Three: The Confirmation."
- "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures."
- In January 2014, Defendants warranted that over 750,000 procedures had been performed.

These warranties were never approved by the FDA. Defendants' website it references to in the instant motion does not provide evidence of approval by the FDA or even evaluation of these warranties. This same argument holds true for Defendants arguments on the "Booklet Warranties" and the "PMA Supplement." Moreover, regarding Defendants' "PMA Supplement" argument, the warranty was not made in the PMA supplement. The PMA supplement was mentioned because it proves that Defendants' representation was false.

Accordingly, Defendants argument that the warranties above were approved by the FDA is a misnomer. Moreover, the courts in *Rosci* and *Hofts*, both held that even statements approved by the FDA would survive preemption, as plaintiff is not claiming that the statements were defective, but rather that defendants did not live up to the FDA approved promises. 447 Pa. Super. 403; 597 F. Supp. 2d at 839

Next, Defendants contend that Plaintiff does not state that these "Facts and Warranties" violate any specific federal law and that Plaintiff is suggesting that Essure's labeling is insufficient.

Plaintiff's misrepresentation claims and UTPCPL are based on warranties which are based on voluntary contractual representations made by Defendants, separate and apart from any FDA requirements. Again, as described in full detail above, the Supreme Court in *Lohr* held that fraudulent misrepresentation claims were not preempted because they are based on the duty not to deceive. Similarly, in *Michael v. Shiley*, the Third Circuit Court of Appeals, citing to *Cipollone*, held that plaintiff's claims for fraudulent misrepresentation based on defendant's advertising and promotional efforts not directly regulated by the FDA were not preempted by the MDA. 47 F.3d at 1329-31.

Moreover, the FDA has expressly excluded state unfair trade practices from preemption under 21 C.F.R. § 801.1(d) and several courts have held that a state's unfair trade practice claim was not preempted. *In Re: Medtronic Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886 at 898; *In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation*, 2004 WL 45503, at *11; In *In re Medtronic, Inc. Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886. The courts reasoned that because the claims are premised on misleading statements and the FDA does not regulate advertising they are not preempted. Accordingly, Plaintiff is not required to allege that the warranties violated federal law. Notwithstanding this, Plaintiff does allege that the misrepresentations violate both Federal law and the CPMA in great detail throughout her Complaint.

Contrary to Defendants' allegation, these claims are not based on Essure's FDA approved labeling. Nowhere in Plaintiff's Complaint does Plaintiff allege this. Plaintiff is not alleging that Defendants should have done anything that violated Federal Law. Plaintiff is alleging that Defendants should not have represented to Plaintiff false and misleading statements.

Defendants then cite to *Farina v. Nokia, Inc.* arguing that "allowing juries to perform their own risk-analysis and second guess the agency's conclusion would disrupt the expert balancing underlying the federal scheme." 625 F.3d 97. In *Farina*, the court was analyzing preemption in relation to the FCC and FCA. *Id.* However, in *Farina* the court noted the differences between its case involving the FCC and a case involving the FDA, as the FDA has seen state law as a complement to federal regulations, not an obstacle. *Id.* Similarly, as noted above in Section IV, the Supreme Court in *Lohr* also found state law was no threat to the federal law. Moreover, these claims do not obstruct or conflict with federal law because federal law

actually expressly precludes them from preemption in the C.F.R.

Lastly, Defendants contend that UTPCPL claims are preempted because a manufacturer does not have a duty to disclose information directly to the consumer because of the learned intermediary rule. In support of this position Defendants cite to *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405 (E.D. Pa. 2012) and *Kester*, 2010 WL 2696467.

However, (1) neither case analyzed whether UTPCPL claims based on "warranties" communicated directly to the patient, as opposed to "warnings," were also precluded because of the learned intermediary rule; (2) both cases accepted the intermediary was appropriately "learned;" and (3) both cases were prior to the PA Supreme Court's recent holding in *Lance v. Wyeth*.

The PA Supreme Court just recently acknowledged that the underpinnings of the learned intermediary doctrine have come into question in light of prescription product manufactures new practices of direct-to-consumer advertising. i.e. "warranties" directly communicated to patients. *Lance v. Wyeth*, 624 Pa. 231 (2015). The Supreme Court then cited to *State ex rel. Johnson & Johnson Corp. v. Karl*, acknowledging that courts have rejected the learned intermediary doctrine based on such factors such as "direct-to-consumer" advertising. 220 W.Va. 463, 647 S.E. 2d 899, 913–14 (2007). The PA Supreme Court also cited to Vicki L. MacDougall, *The Impact of the Restatement (Third) of Torts: Products Liability (1998) on Product Liability Law*, 62 CONSUMER FIN. L.Q. REP. 105, 114 (2008) acknowledging that "direct-to-consumer advertising has injected itself into the doctor/patient relationship and has eroded the policy justifications for the learned intermediary doctrine." *Id.* at Cmt 34; See also *Perez v. Wyeth Laboratories, Inc.* 161 N.J. 1 (1999)("Learned intermediary" doctrine, under which manufacturer generally discharges its duty to warn ultimate user of prescription drugs by

supplying physician with information about drug's dangerous propensities, does not apply to direct marketing of prescription drugs to consumers.); *Centocor, Inc. v. Hamilton,* 310 S.W. 3d 476, 508 (Tex. App. 2010)(adopting an exception to the learned intermediary doctrine where this "direct-to-consumer" advertising.); See also *Hill v. Searle Labratories,* 884 F.2d 1064 (8th Cir. 1989)(holding that contraceptive devices are not subject to the learned intermediary doctrine as unlike other products, the patient makes an independent decision as to whether she desires a prescription for birth control, and if so, which method she prefers, with only limited input from the prescribing physician). Accordingly, our highest state Court has recognized the distinction between general "warnings" which would be subject to the learned intermediary doctrine as compared to direct-to-consumer "warranties." *Lance,* 624 Pa. 231.

More importantly, the PA Supreme Court then held that where a plaintiff has:

> …staked her claim on the premise that (manufacturers) knew or should have known of information that it did not convey to prescribing physicians…the prescribing physician, as an intermediary, is not likely to be appropriately "learned." *Lance,* 85 A.3d at 457.

Accordingly, the PA Supreme Court held that in such situations the learned intermediary doctrine does not apply. *Id.*

Here, Plaintiff has both (1) based her UTPCPL claim, in part, on "direct-to-consumer" false and misleading advertising and (2) also staked her UTPCPL claim on the premise that Defendants knew of information it did not convey to Plaintiff's implanting physician. First, Plaintiff alleges that her "loss was caused by justifiable reliance on deceptive conduct, specifically the "Facts and Warranties" outlined in the preceding paragraphs, Defendant's failing to disclose adverse events and concealing the same, and marketing and selling a "misbranded" and "adulterated" product"[37] and that "The conduct was deceptive as the warranties were false and misleading and the failure to disclose and concealment violated both Federal law and

[37] Para. 193 of Strimel Complaint.

Defendants' CPMA and it sold a 'misbranded' and 'adulterated' product."[38] Plaintiff goes on to allege that: "As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading."[39] These Facts and Warranties were made "by Defendants…through Defendants' website and advertising."[40] This is the direct-to-consumer advertising contemplated in *Lance*.

Even if this Court were to choose not to consider any modifications or exceptions to the learned intermediary doctrine, the intermediary in this case was not "learned" under the holding in *Lance*, as Plaintiff has alleged that Defendants had information it did not convey to the implanting physician. For example, Plaintiff has alleged that Defendants were "failing to disclose adverse events and concealing the same;[41] Not reporting … complaints in which their product migrated;[42] Defendants also breached their duty by failing to disclose to Plaintiff and her implanting physician the fact that it altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process;[43] Specifically, Defendants were: "not reporting complaints in which their product migrated from the fallopian tube in to the peritoneal cavity … the firm did not consider these complaints in their risk analysis … and failed to document CAPA activities for a supplier corrective action."[44] Plaintiff goes into great detail referencing several violations it received from the FDA for failing to disclose thousands of adverse events. In fact, the implanting physician cannot be appropriately "learned" when "the implanting physician who implanted the device was not

[38] Para 194 of Strimel Complaint.
[39] Para. 195 (e) of Strimel Complaint.
[40] Para. 101 of Strimel Complaint.
[41] Para. 193 of Strimel Complaint.
[42] Para. 195 (m) of Strimel Complaint.
[43] Para. 149 (w) of Strimel Complaint.
[44] Para. 163 of Strimel Complaint.

trained by Defendants pursuant to FDA guidelines."[45]

Moreover, the *Rosci* court in an earlier decision also held that:

> (1) Under the learned intermediary doctrine, as it is applied in Pennsylvania, a manufacturer will be held liable … where it fails to exercise reasonable care to inform … the prescribing physician.
>
> (2) The learned intermediary doctrine, however, while applicable to implied warranties, has never been applied to bar an action by an injured consumer based upon breach of an express warranty since such a claim is unrelated to the issue of the warnings given to the prescribing physician and instead is based solely upon the express affirmation of fact made by the manufacturer. *Rosci,* 447 Pa. Super 403.

Even under *Rosci*, Defendants should be liable under the learned intermediary doctrine because they clearly failed to exercise reasonable care to inform the FDA and implanting physician of the facts which make Essure dangerous as alleged above and in great detail in Plaintiff's Complaint. i.e. Defendants failing to report adverse events, using non-confirming product, using non-sterile cages, failing to advise the physician of altering medical records etc.

Moreover, the rationale outlined in *Rosci* in terms of a breach of express warranty claim is consistent with the court's acknowledgement in *Lance* that the learned intermediary can be rejected based on factors such as "direct-to-consumer" advertising and warranties. The reason why the learned intermediary doctrine has never been applied to breach of express warranty claims is that such claims are unrelated to the issue of the warnings given to the prescribing physician and instead is based solely upon the express affirmation of fact made by the manufacturer, or in other words warranties. *Id.* This logic is consistent with the Supreme Court's later acknowledgment in *Lance* that the learned intermediary doctrine can be rejected when a claim is based on direct-to-consumer advertising. i.e. "warranties" as opposed to "warnings."

[45] Para 102(h) of Strimel Complaint.

In short, Plaintiff's UTPCPL claim is valid because (1) the implanting physician was not appropriately "learned" under either the PA Supreme Court's recent holding in *Lance* or the *Rosci* court, and even if he were (2) the basis of Plaintiff's claim is centered on express "direct-to-consumer" advertisements or warranties, unrelated to the issue of the warnings given to the prescribing physician.

Defendant also argues that Plaintiff's misrepresentations and UTPCPL claims are impliedly preempted pursuant to *Buckman.* Plaintiff refers this Court to her argument above under Section IV and V above for the analysis as to why Defendants' argument fails. In short, this exact argument has been attempted on several courts, including the *Knipe* court in the Eastern District of PA, several times to no avail. Plaintiff's claims are based on Defendants' misrepresentations "to Plaintiff and her Implanting physician." Moreover, it is inconceivable how any cause of action for misrepresentations made to private individuals, outside the realm of the FDA, can be preempted by applying the holding in *Buckman.*

D. Negligence-Pharmacovigilance

To the extent that this claim is centered around promotion, advertising, and distribution, the claims falls outside the scope of preemption for the same reasoning as outlined above regarding Plaintiff's warranty and misrepresentation claims. To the extent that this claim is centered on reporting adverse events, Plaintiff refers this Court to Plaintiff's argument outlined in Plaintiff's "Failure to Warn" analysis below in Section III "A."

Plaintiff alleges, *inter alia*, that:

- Defendants had a duty to <u>distribute, advertise, promote, and report</u> adverse events regarding Essure in a reasonably safe manner and to comply with the following Federal regulations and post-approval conditions contained in the CPMA.

- Defendants … breached this duty by requiring the implanting physician to purchase two (2) Essure "kits" per month regardless of whether they used them or not and by contracting with third parties from the hysteroscopic manufacturers to promote Essure who were not competent to perform the same.

- Defendants also breached this duty by promoting Essure through representatives of hysteroscopic equipment companies who were not qualified to do the same.

- As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

- Defendants' warranties were not consistent with applicable Federal and State law.

In short, there are no federal requirements specific to Essure relating to Defendants' promotion, distribution, and advertising of Essure. The FDA never granted Defendants permission or approved Defendants' promotion, distribution, or advertising of Essure.

Accordingly, to the extent that this claim centers on Defendants' promotion and distribution of Essure through (1) contracts it had with implanting physicians and (2) third parties who were not qualified to do the same, it is not preempted as the FDA issued no specific federal requirement regarding these actions. Similarly, to the extent that this claim centers on Defendants' warranties in its advertising, the claim is not preempted for the same reasoning Plaintiff's Breach of Warranty claim is not preempted. In other words, Defendants promotion, distributing, and advertising of Essure through false representations is not preempted because it had no approval by the FDA and therefore fails to meet the first prong under *Riegel*.

Further, the Honorable Louis C. Bechtle has held that a defendant's promotional activities are not preempted. *In re Orthopaedic Bone Screw Products Liability Litigation*, 1996 WL 221784. Here, the court reasoned that because the FDA had not promulgated specific requirements regarding advertising and promotion of the device at issue the claim did not

impose a requirement that 'is different from, or in addition to' a FDA requirement and 'which relates to the safety or effectiveness of the device or to any ... requirement applicable to the device under this chapter."'*Id.* at 1330 (quoting 21 U.S.C. § 360k).

Lastly, Defendants fail to provide this Court with any evidence for it to take judicial notice of which supports the position that any of these activities were approved by the FDA in any way. However, even assuming there was, to the extent that this claim may be based on a requirement specific to Essure, the claim is still not preempted because they amount to parallel claims as they are also based on violations of federal law, as discussed in Section III "J" *infra*.

III. PLAINTIFF'S REMAINING COUNTS AMOUNT TO PARALLEL CLAIMS

Defendants argue that Plaintiff's state law claims are preempted because each is expressly preempted by the MDA. But Defendants admit that Plaintiff may avoid preemption by successfully enunciating state-based causes of action consistent with federal duties imposed under the MDA.

The Supreme Court in *Riegel* recognized that MDA § 360k(a) enacted a two-step test in determining whether state law claim are expressly preempted.

- "[T]he Federal Government [must have] established requirements applicable to" a specific medical device. *Riegel*, 552 U.S. at 321. If no federal requirements exist, the inquiry ends—there can be no express preemption without an applicable federal requirement.

- The Court must next ask whether the Plaintiffs' claims impose requirements on the defendant that are "different from, or in addition to" the federal ones. *Id*. at 322. State-law requirements that do not differ from, or add to, the federal requirements applicable to a device are termed "parallel" requirements and are not preempted. *Id*. at 330.

Plaintiff's claims are not preempted unless both of the MDA § 360k(a) requirements are satisfied. With this in mind, assuming there exists a device-specific regulations for each claim, Plaintiff's claims below are not preempted as they are all based on violations of federal law.

Multiple violations of FDA regulations were alleged by Plaintiff, not in an effort to enforce these provisions, but solely to prove they are parallel claims. Plaintiff's claims are seeking monetary compensation for injuries. Just because a jury may award damages on a state tort action, does not deem the state tort claim an "enforcement" action as common law actions do not have the ability to do so. Accordingly, even if the CPMA is valid and there are established federal requirements specifically applicable to Essure, there would still be no basis for express preemption.

Plaintiff's state-law claims are not based on requirements "different from, or in addition to" the requirements of federal law. Plaintiff's state-law claims seek only to impose liability for misconduct that happens to violate federal law and FDA regulations (thus avoiding expressed preemption), while independently basing such claims on PA law (thus avoiding implied preemption). Such claims are deemed valid "parallel claims," as explained by the Supreme Court in *Lohr*:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely *provides another reason* for manufacturers to comply with identical existing "requirements" under federal law. *Medtronic, Inc.*, 518 U.S. at 45 (emphasis added).

Parallel claims need not be "identical," just as train tracks are "parallel" but never truly identical, although they arrive at the same destination. Several circuit courts and courts within the Eastern District of PA have followed suit holding that state-law parallel claims, such as

Plaintiff's claims, avoid preemption for precisely the same reason. For example, the Ninth Circuit, in an unanimous *en banc* decision held that 360k(a) of the MDA did not preempt plaintiffs' parallel state-law claim, noting that: "[o]ur sister circuits have uniformly held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty 'parallels' the federal-law duty under the MDA." *Stengel,* 704 F.3d at 1227-28; *Medtronic, Inc. v. Stengel*, 2014 WL 2807193 (June 23, 2014).

A. Negligence-Failure to Warn and Fraudulent Concealment

Considering several of Plaintiff's claims involve, in part, a failure to warn, Plaintiff begins her analysis of parallel claims with her "Failure to Warn" analysis and incorporates it into her analysis of her other claims. Moreover, Plaintiff's "Fraudulent Concealment" claim would not be subject to preemption for the same reasoning in this section. As such, Plaintiff adopts the following reasoning for the same. Here, Plaintiff's failure to warn claim is based primarily on Defendants failure to advise the FDA of thousands of adverse events, which in turn were never reported to the public database or the implanting physician.

In PA, there exists (1) a general duty of care on product manufacturers; (2) a cause of action for failure to warn; and (3) a contemplation that a warning to a third party, such as the FDA, can satisfy a manufacturer's duty to warn. *Sherk v. Daisy-Heddon, a Div. of Victor Comptometer Corp.*, 498 Pa. 594, (1982); *Gurley v. Janssem Pharmaceuticals*, 2015 WL 1135894, (2015); § 388 cmt. n of the Restatement.[46]

Moreover, the law of negligence in PA establishes a duty of care on the part of manufacturers to warn, which can be viewed on a continuum from the requirements of: a

[46] *See Diggs v. M&J Painting & Wallcovering, Inc.*, 1996 WL 1038814; *Phillips v. A.P. Green Refractories Co.*, 428 Pa. Super. 167, 630 A.2d 874 (1993); *Gower v Savage Arms, Inc.*, 166 F. Supp. 2d 240, 96 A.L.R. 5th 647 (E.D. Penn. July 31, 2001); *Dauphin Deposit Bank and Trust Co. v. Toyota Motor, Corp.*, 408 Pa. Super. 256 (1991).

warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of its relative risks. *Lance,* 85 A. 3rd 434; *Rowland v. Pharmaceuticals, Corp.*, 34 F. Supp. 3d 556 (W.D. Pa. July 28, 2014)(holding the duty to warn requires a manufacturer to research and investigate risks associated with its product.) In other words, under PA law, manufacturers have a duty to warn third parties and PA law contemplates that a warning to a third party, such as the FDA, can satisfy this duty. Moreover, the duty to warn is continuous.

Defendants' failure to warn claim is based on PA state law, imposing a continuing duty to warn, which parallels federal regulations and the CPMA regarding disclosing adverse events to the FDA. Both laws are in place for the health and wellbeing of the public and are complementary rather than obstructive. In fact, the FDA has stated that the duties to advise and warn are in place because "These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." The FDA publishes adverse events in a public, searchable database called the Manufacturer and User Facility Device Experience (MAUDE), where physicians and the general public have access to view adverse events. However, by violating federal law and not disclosing the adverse events, Defendants did not use reasonable care in informing the medical community of Essure's true known risks.

As alleged in her Complaint, had Plaintiff become aware of the thousands of adverse events that were not reported, including coils migrating out of the fallopian tubes and perforations of organs, Plaintiff would never have had Essure implanted in her.

The United States Supreme Court has held on two prior occasions that failure to warn claims are not preempted. In *Lohr,* the Court held that:

> Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. 518 U.S. at 501-502.

Moreover, because the *Lohr* Court found that failure to warn claims did not interfere with FDA regulations, the claims were not impliedly preempted. Subsequently, in *Wyeth v. Levine*, the Supreme Court similarly held:

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.
>
> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law…complements FDA regulation. 555 U.S. at 578-79

Accordingly, in both the medical device and drug fields, the Supreme Court has made it clear that failure to warn claims are outside the scope of preemption. They do not interfere with federal regulations because the FDA regards state law as a complement to the federal regulations, not an obstacle, and as stated in *Lohr* "escape preemption."

In addition to the United States Supreme Court, the Third Circuit Court of Appeals in *Farina v. Nokia, Inc.*, has also recognized the holding in *Wyeth* when it compared the roles of the FDA and the FCC. The *Farina* court noted that, unlike the FCC, the FDA "itself had traditionally regarded state law as a complement to federal regulations." 625 F.3d at 129.

In the context of the FDCA, several Eastern District of PA district courts have also held that failure to warn claims are not preempted. *Perry*, 456 F. Supp. 2d at 687; *Knipe*, 583 F. Supp. 2d 553 (holding that "state law failure to warn claims were not preempted by the FDCA).

As it applies to failure to warn cases in the scope of the MDA, the majority of circuit courts with opinions on this subject have also held that failure to warn claims are not preempted under the MDA. *Hughes*, 631 F.3d at 770-71 (holding that a manufacturer violated its duty to warn under state law by failing to accurately report serious injuries as required by federal law); *Stengel*, 704 F.3d at 1232-33, *cert. denied*, (holding that a claim for negligence alleging that a manufacturer breached its federal law duty to warn the FDA of adverse events was not preempted where state law recognized a claim for failure to warn third parties such as FDA); *Bausch*, 630 F. 3d 546; *McClellan v. I-Flow Corp.*, 776 F.3d 1035 (9th Cir 2015). In fact, the Solicitor General opined that there are "no clear circuit conflicts" on whether a failure to warn claim was either expressly or impliedly preempted. U.S. Amicus Br at 7 *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013).

Similarly, several district courts in extremely thorough opinions, evaluating both express and implied preemption, have followed suit finding that claims for failure to warn in the context of the MDA are not preempted. *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 1443944, (D. Hawaii Jan. 9, 2015)(holding that claim for negligence-failure to warn was not preempted where plaintiff alleged that defendant failed to disclose required information to the FDA); *Waltenburg v. St. Jude Medical, Inc.*, 33 F. Supp. 3d 818 (W.D. Ken. July 21, 2014); *Rosen v. St. Jude Medical, Inc.*, 41 F. Supp. 3d 170 (N.D. NY Aug. 28, 2014)(holding that failure to warn claims are neither expressly or impliedly preempted.); *Killen v. Stryker Spine*, 2012 WL 4498865 (W.D. Pa. Sept. 28, 2012)(holding failure to warn claim not preempted where plaintiff alleged defendant was negligent in its record keeping and did not disclose manufacturing flaws that

increased the risk of injury to patients and that this activity violated the manufacturers duty to establish and maintain procedures for implementing corrective and preventative action).

Lastly, the Federal Government, through the Solicitor General, has opined that Failure to Warn claims within the context of the MDA are not expressly preempted because the disclosure requirements are not device-specific and not impliedly preempted because they are grounded in state law, not solely by virtue of the FDCA.

Stengel is an instructive example. There, the plaintiff was rendered a paraplegic by an implanted Medtronic class III medical device and claimed that Medtronic had violated a state-law duty of care by failing to report to the FDA risks discovered after the date of the FDA's premarket approval of the device. *See Stengel*, 704 F.3d at 1226. The Ninth Circuit found that not only did Medtronic's failure to inform the FDA of known risks violate the MDA's requirements but also parallel state law requirements on manufacturers to act with reasonable care and to warn others of potential dangers. *Id.* at 1233. Specifically, Arizona law recognized a failure to warn claim and contemplated that a warning to a third party, such as the FDA, can satisfy a manufacturer's duty "if, given the nature of the warning and the relationship of the third party, there is 'reasonable assurance that the information will reach those whose safety depends on their having it." *Id.* at 1233 (*quoting* Restatement (Second) of Torts § 388 cmt. n.)

Here, as noted above, PA law is no different as it too recognizes a general duty of care for product manufacturers,[47] a cause of action for failure to warn,[48] and § 388 cmt. n of the Restatement.[49] *i.e.* a contemplation that a warning to a third party, such as the FDA, can satisfy a manufacturer's duty to warn.

[47] *Sherk v. Daisy-Heddon, a Div. of Victor Comptometer Corp.*, 498 Pa. 594, 450 A.2d 615, (1982).
[48] *Gurley v. Janssem Pharmaceuticals*, 2015 WL 1135894, 2015 Pa. Super 49 (2015).
[49] *See Diggs v. M&J Painting & Wallcovering, Inc.*, 1996 WL 1038814; *Phillips v. A.P. Green Refractories Co.*, 428 Pa. Super. 167, 630 A.2d 874 (1993); *Gower v Savage Arms, Inc.*, 166 F. Supp. 2d 240, 96 A.L.R. 5th 647 (E.D. Penn. July 31, 2001); *Dauphin Deposit Bank and Trust Co. v. Toyota Motor, Corp.*, 408 Pa. Super. 256 (1991).

As such, PA law parallels federal regulations to report the adverse events to the FDA as alleged in great detail in Plaintiff's Complaint. Plaintiff is not attempting to enforce these regulations. In fact, the FDA enforces these through the issuing of Form 483s and Notices of Violations. Plaintiff has plead the violations to show parallel claims as contemplated by the Supreme Court in *Riegel*. For just a few examples:

Reporting procedures

- FDA requirement in CPMA order- "Within 10 days after Defendant receives knowledge of any adverse reaction to report the matter to the FDA.

- FDA requirement in CPMA order- "Report to the FDA under the MDR whenever it receives information from any source that reasonably suggests that the device may have caused or contributed to a serious injury."

- 21 C.F.R. 803.1(a)- This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

- 21 C.F.R. 803.10- (a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers…

- 21 C.F.R. 803.50(a)- (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:(1) May have caused or contributed to a death or serious injury; or(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur…

- 21 C.F.R. 803.53- You must submit a 5-day report to us, on Form 3500A or an electronic equivalent approved under 803.14, no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health…

Several Eastern District of PA District courts have held that claims do not impose requirements different from or in addition to PMA/FDA requirements where plaintiffs' claims are based on violations of PMA/FDA standards. *Davenport*, 302 F. Supp. 2d at 432; *Bentzley*, 827 F. Supp. 2d 443; *Killen,* 2012 WL 4498865. i.e. a parallel claim exists. Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are based on violations of the same as alleged in great detail:

Reporting procedures

- On January 6, 2011, the FDA issued a violation to Defendant for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." … These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes. Defendants were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.[50]

- Defendants failed to notice the FDA of their internal excel file containing 16,047 entries of complaints.[51]

- Defendant did not disclose to the FDA complaints where its product migrated outside of the fallopian tube.[52]

- Not reporting to the FDA incidents of bowel perforation, Essure coils breaking into pieces and migrating out of the fallopian tubes.[53]

- Failing to disclose 16, 047 complaints to the FDA as MDR's (Medical Device reports which are suspected from device malfunction or associated with injury).[54]

[50] Para. 282(n) of Strimel Complaint.
[51] Para. 282(e) of Strimel Complaint.
[52] Para. 292 (k) of Strimel Complaint.
[53] Para. 20 of Strimel Complaint.

- Failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two year report schedules.[55]

- Defendants failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury concealing the injuries. Again, Defendants failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in Form 483.[56]

- failed to report known hazards to the FDA.[57]

- Not reporting … complaints in which their product migrated.[58]

- Failing to document CAPA activities for a supplier corrective action.[59]

In sum, each of the above breaches by Defendant was plead with great particularity and supported by the actual FDA violation notice as an exhibit. In sum, Defendants' alleged misconduct – *i.e.* failing to exercise due care by not warning of thousands of adverse events, violates federal law, as well as parallel PA state-law regarding the same. *Burman*, 420 Pa. Super. 209; *Gurley,*, 2015 WL 1135894; *See Diggs*, 1996 WL 1038814; *Lance,* 85 A. 3rd 434; *Rowland*, 34 F. Supp. 3d 556.

Moreover, this claim is not impliedly preempted under *Buckman* as noted in detail above. Again, *Buckman* only stands for the proposition that a plaintiff cannot bring suit based *solely* on a violation of the FDCA, but that a defendant may still be liable under state law.

In fact, as noted above, the *Knipe* Court in the Eastern District of PA addressed this issue three times and consistently held that *Buckman* is limited to fraud that occurred during the premarket approval process:

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[54] Para. 282(e) of Strimel Complaint.
[55] Para. 20(l) of Strimel Complaint.
[56] Para. 282(c) of Strimel Complaint.
[57] Para. 17 of Strimel Complaint.
[58] Para. 282(k) of Strimel Complaint.
[59] Para. 282(m) of Strimel Complaint.

> As the Court previously explained, the United States Supreme Court has defined fraud on the FDA claims as violations of the FDA disclosure requirements, which are "various provisions aimed at detecting, deterring and punishing false statements made *during the approval process." Buckman,* 531 U.S. at 349, 121 S.Ct. 1012 (emphasis added).
>
> Had Plaintiffs argued that GSK improperly secured approval for a pediatric indication for Paxil by hiding data from the FDA, the Court would deem the claim preempted. In this case, however, the gist of Plaintiffs' argument does not contend that GSK committed any fraud on the FDA during its efforts to secure approval for a pediatric indication for Paxil. Rather, Plaintiffs present a pure state law claim that (1) after initial FDA approval, GSK learned of dangers associated with an off-label use of its drag; (2) GSK failed to warn either the public or the medical community of the dangers associated with that drug; and (3) this failure to warn resulted in Jake Garrison's injuries…To the extent Plaintiff has alleged that Defendant did not timely produce its pediatric data to the FDA prior to seeking approval for a pediatric indication, such claims were made only in connection with rebutting Defendant's claim that the FDA explicitly rejected a pediatric warning; they do not allege fraud on the FDA. In short, and contrary to Defendant's arguments, Plaintiffs' claims do not exist by virtue of the FDCA disclosure requirements, but rather are premised entirely on state tort theories. 583 F.Supp. 2d 553, 583, 597-98.

In short, Plaintiff's failure to warn claim is not preempted. This is especially true considering (1) Plaintiff's claims need not be identical, merely parallel federal requirements; (2) Defendants failure to cite to any binding law; (3) the Supreme Court's holding in *Lohr* that failure to warn claims are not preempted and are no threat to state law; (4) the Federal Government's position that such claims are not expressly or impliedly preempted; and (5) this Court should not "reach" to find preemption. Thus, § 360k(a) does not preempt Plaintiff's failure to warn claims.

I. Defendants' arguments

Defendants assert that (1) the gravamen of each claim is that Defendants should have made different or additional statements about Essure than what was submitted to, and approved by the FDA; (2) Plaintiff does note allege that Defendants failed to provide any of the warnings required by the FDA; and (3) that Plaintiff is asserting that Defendants were required to have

given additional warnings beyond those required by the FDA. In support of these claims, Defendants fail to cite to any binding case law on this Court.

Plaintiff is not alleging that Defendants should have done anything that violated federal law. What Plaintiff is alleging is that Defendants failed to warn of thousands of adverse events which was required by the CPMA and federal regulations and that this claim parallels PA state law requiring Defendants to do the same. (Consistent with *Stengal*, *Hughes,* and *Lohr*)

Contrary to Defendants' statement, Plaintiff has alleged that Defendants failed to provide warnings required by the FDA, the CMPA, and federal law. Plaintiff is not asserting that Defendants should have violated any Federal law, only that Defendants failed to comply with the conditions of the of the CPMA and federal regulations requiring Defendants to disclose the adverse events such that the medical community could be privy to the same.

Like the plaintiffs in *Stengel*, *Hughes*, *Lohr*, and countless other district courts noted above, Plaintiff is asserting a negligence claim based on Defendants violation of state-law duty to warn. Under the precedent set by those decisions, Plaintiff's failure to warn claims can only be found to be preempted to the extent that it purports to impose liability despite Defendants' compliance with FDA regulations. As such, to the extent that Plaintiff's claim is based on Defendants' violation of the applicable reporting requirements, the claim is not preempted. This conclusion is strengthened by the Third Circuit's holdings that (1) there is a strong presumption against preemption; (2) where courts are faced with two equally plausible readings of statutory text, courts have a duty to accept the reading that disfavors preemption; and (3) and that courts should not reach to find preemption.

As in *Stengel*, *Hughes*, *Lohr,* and the other countless district courts noted *supra*, Plaintiff asserts a negligence claim based on a manufacturer's violation of a state-law duty.

Plaintiff alleges that after the FDA's approval of Essure in 2002, Defendants knew of, but failed to report adverse events to involving Essure to the FDA. In fact, Plaintiff has plead the same in great detail which is also memorialized in several FDA findings which were also attached to the Complaint. That failure violated both federal law and state law. Thus, the Plaintiff's claims based on Defendants' failure to report adverse events to the FDA are parallel claims that escape preemption under § 360k(a).

B. Negligence-Risk Management

Here, Plaintiff alleges that Defendants had a duty to have in place a risk management procedure to ensure (1) that adverse reports were being reported to the FDA;[60] (2) that non-conforming product could be tracked appropriately; and (3) that adverse reports were considered in its risk analysis.

In PA, Defendants have a duty, in any situation, not to place others at risk as it pertains to those risks which are reasonably foreseeable. *Burman v. Golay and Co., Inc.*, 420 Pa. Super. 209, 616 A.2d 657 (1992). Moreover, the law of negligence establishes a duty of care on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of its relative risks. *Lance*, 85 A. 3rd 434; *Rowland*, 34 F. Supp. 3d 556(holding the duty to warn requires a manufacturer to research and investigate risks associated with its product, updating its accompanying warnings as necessary.) Lastly, products sold without adequate warnings of risks are considered defective under PA law. *Mazur v Merck & Co., Inc.*, 964 F.2d 1348 (3d Cir. 1992). In other words, under PA state law, manufacturers have a continuing duty to not place others at risk or sell defective products.

[60] Plaintiff refers this Court to Section "A" "Failure to Warn" for a complete analysis as to this portion of the claim.

As such, PA law parallels federal regulations not to put people at risk or sell defective or adulterated/misbranded product, as alleged in great detail in this claim. For just a few examples:

Controlling defective product

- 21 C.F.R. 820.90-(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.. Disposition of nonconforming product shall be documented…

- 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

- 21 U.S.C. 351(a) (h)- A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with …an applicable condition prescribed by an order.

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

Procedures for tracking product

- 21 C.F.R. 820.65- establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

- 21 C.F.R. 820.65- Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

- 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and

maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

Procedures for maintaining design control

- 21 C.F.R. 820.30 - Each manufacturer of any class III …device… shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

Several Eastern District of PA District courts have held that claims do not impose requirements different from or in addition to PMA/FDA requirements where plaintiffs' claims are based on violations of PMA/FDA standards. *Davenport*, 302 F. Supp. 2d at 432; *Bentzley*, 827 F. Supp. 2d 443; *Killen*, 2012 WL 4498865. i.e. a parallel claim exists. Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are based on violations of the same as alleged in great detail:

Controlling defective product

- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

- As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

- erroneously using non-conforming material in the manufacturing of Essure.

Procedures for tracking product

- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).

Procedures for maintaining design control

- On January 6, 2011, Defendants were cited for their risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity. See Exhibit "F." Form 483/Violation form issued by Timothy Grome on January 6, 2011.

- On January 6, 2011, Defendants were cited for not documenting Corrective and Preventive Action Activities. Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

- Defendants excluded the risk assessment for safety of loose coils in its Risk Management Plan and stated that Defendants had violated the FD&C Act.

- Not considering these complaints in their risk analysis for the design of Essure;

In sum, each of the above breaches was plead with great particularity and supported by the actual FDA violation notice as an exhibit. In sum, Defendants' alleged misconduct – *i.e.* failing to exercise due care by placing Plaintiff at risk and by selling an "adulterated/ misbranded/restricted product," violates federal law, as well as parallel PA state-law regarding not placing Plaintiff at risk and not selling her a defective product. *Burman v. Golay and Co.*, Pa. Super. at 616 A.2d 657; *Gurley*, 2015 WL 1135894 2015; *See Diggs*, 1996 WL 1038814.

This is especially true considering (1) Plaintiff's claims need not be identical, merely parallel some federal requirement; (2) Defendants failure to cite to any binding law; and (3) the fact that courts should not "reach" to find preemption. Thus, § 360k(a) does not preempt Plaintiff's Negligence-Risk Management claim.

I. Defendants' arguments

Defendants again argue that *Riegel* and *Buckman* preclude this claim. Defendants argue

that both cases hold that a claim for failing to have a proper risk management procedure in place is preempted. It is important to first note that plaintiffs in both *Riegel* and *Buckman* never asserted this claim.

Defendants also claim that its risk management procedure was exclusively regulated by the FDA. However, even assuming these risk management procedures were specific to Essure, Plaintiff's allegations are based on the violations of the federal statutes which amount to a parallel claim.

Defendants also claim that complaint handling procedures and reporting requirements are expressly regulated by the FDA under 21 C.F.R. 820.19 and 803.1. Again, the CGMPs are general requirements which apply to all devices and are not subject to preemption as they fail to meet the first prong of *Riegel*. This is the position of the Federal Government, the C.F.R., the Supreme Court,[61] and the *Bentzley* court.

The Supreme Court in both *Riegel* and *Lohr* addressed the issue of whether violations of CGMP's implicated implied preemption and found it not a concern:

> [T]he Lohrs' common-law claims are not pre-empted by the federal labeling and manufacturing requirements. The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

[61] … federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr*. The federal requirements, we said, were not requirements specific to the device in question—they reflected "entirely generic concerns about device regulation generally." 128 S. Ct. at 1007.

> Similarly, the general state common-law requirements in this suit were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the MDA. *Medtronic, Inc.*, 518 U.S. at 501-02.

Justice Breyer concurred stating "I can find no actual conflict between any federal requirement and any of the liability-creating premises of the plaintiffs' state-law tort suit, nor, for the reasons discussed above, can I find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field." *Id.* at 508.

The *Riegel* court subsequently confirmed the lack of preemption as to the general manufacturing and labeling requirements:

> Informed by the regulation, we concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in *Lohr*. The federal requirements, we said, were not requirements specific to the device in question—they reflected "entirely generic concerns about device regulation generally." 552 U.S. 1006

Several Eastern District of PA District courts have also held that preemption does not apply when plaintiff's claims are based on violations the CGMPs. *Bentzley*, 2011 U.S. Dist. Lexis 136570. Other circuit and district courts agree with the Supreme Court and Eastern

District courts. *See also Howard,* 382 Fed. Appx. At 440–41 (holding plaintiff's negligence claims that tracked violations of the federal Good Manufacturing Practices survived preemption challenge); *Bausch,* 630 F.3d at 555–56; *Gelber,* 788 F.Supp.2d at 159; *Bass,* 669 F.3d at 512–13; *Hofts,* 597 F. Supp. 2d 830; *Rosen,* 41 F. Supp. 3d 170.

The Seventh Circuit in *Bausch* provided sound reasoning for binding CGMPs on manufacturers. Id. at 555. Specifically,

> Section 360k makes preemption a defense if a state seeks to impose on a manufacturer `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). We emphasize the phrase `any requirement.' And federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements `under this chapter.' 21 C.F.R. § 820.1. `The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.' 21 C.F.R. § 820.1(c). *Bausch,* 630 F.3d at 555.

The Court concluded that requiring concrete, product-specific requirements would leave injured patients without any remedy for a wide range of harmful violations of federal law. *Id.* ("The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices.") *Id*. Other courts follow the reasoning of the Seventh Circuit finding that the CGMPs are binding regulations imposed on manufacturers. See also, *Howard v. Sulzer Orthopedics, Inc*., 382 F.App'x 436, 440 (6th Cir. 2010) (finding plaintiff identified specific GMP that he thought had been violated, and rejecting defendant's argument that the relevant GMP is categorically unenforceable).

In one of the most recent opinions on this subject, the court in *Rosen v. St. Jude Medical, Inc.* conducted a very thorough analysis on "device-specific" vs. "general requirements." *Rosen,*

41 F. Supp. 3d 170. In this case, after analyzing the different positions taken by different courts, the court reasoned that "allegations that the defendants violated either the PMA or CGMPs, so long as they are supported by sufficient factual evidence of the violation and demonstrate a causal connection" is all that is required to avoid preemption under § 360k(a) and *Riegel* and satisfy *Twombley*. *Id.* at 182.

If this were not enough, the CGMP's are expressly excluded from preemption under 21 C.F.R. 808.1(d)(10): Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. The Federal Government's position as reflected in the Solicitor General's brief reflects the same.

Next, Defendants argue that Plaintiff is attempting to enforce federal regulations. In support of this claim, Defendants cite to *Buckman* claiming that private litigants cannot enforce the MDA. However, Plaintiff is not attempting to enforce the MDA. The FDA regulatory violations were alleged by Plaintiff, not in an effort to enforce these provisions, but solely to prove parallel claims. The *Riegel* court, subsequent to *Buckman*, held that plaintiffs were able to allege violations of federal law holding: "§ 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." *Riegel*, 552 U.S. at 330. As such, Defendants application of *Buckman* is misapplied and expressly refuted by the Supreme Court's subsequent finding in *Riegel.*

Defendants then cite to several cases alleging that any allegation that Defendants violated federal regulations by not reporting adverse information regarding Essure is preempted. Notably, Defendants fail to cite to any binding law on this Court to support this position. For a

full analysis on this subject, Plaintiff refers the Court to Plaintiff's analysis regarding her Failure to Warn claim in Section III "A."

Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are based on violations of the same as alleged in great detail and therefore are not preempted.

J. Negligence-Pharmacovigilance (Promotion, Distribution, Advertising, Reporting)

As discussed *supra*, this claim is outside the scope of preemption as Defendants' promotion, distribution, advertising, and reporting activities for Essure had no type of approval, conditional or otherwise, by the FDA. However, even assuming there is an Essure specific requirement as it relates to this claim, preemption is still not applicable as Plaintiff's claims parallel federal requirements and therefore fail to meet the second prong of *Riegel*.

Here, Plaintiff alleged that Defendants had a duty to (1) promote; (2) distribute; (3) advertise; and (4) report adverse events[62] regarding Essure in a reasonably safe manner.

In PA, Defendants have a general duty, in any situation, not to place others at risk as it pertains to those risks which are reasonably foreseeable. *Burman,* 420 Pa. Super. 209. More specifically, PA law recognizes a duty of reasonable care with respect to marketing, promotion, and distribution. *Lance,* 85 A. 3rd 434; *Widdoss v Haufman,* 2003 WL 22512092 (Pa. Com. Pl. 2003). PA law also recognizes that "one engaged in the business of selling chattels who, by advertising…or otherwise, makes to the public a misrepresentation of a material fact…is subject to liability…even though it is not made fraudulently or negligently, and the consumer has not bought the chattel from or entered into any contractual relation with the seller. Restatement (Second) of Torts 402B. In other words, under PA state law, product manufacturers have a duty

[62] Plaintiff refers this Court to Section III "A" "Failure to Warn" for a complete analysis as to this portion of the claim.

of reasonable care with respect to marketing, promotion, distribution, and advertising.

As such, PA law parallels federal regulations to exercise reasonable care with respect to marketing, promotion, distribution, and advertising, as alleged in great detail in this claim. For just a few examples:

Promotion

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

- FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

Distribution

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

- 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

- 21 U.S.C. 351(a) (h)- A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with …an applicable condition prescribed by an order.

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any

particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title

- FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

- 21 C.F.R. 803.1(a)- This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports.

- 21 C.F.R. 820.90-(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

Advertising

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

- FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

Several Eastern District of PA District courts have held that claims do not impose requirements different from or in addition to PMA/FDA requirements where plaintiffs' claims are based on violations of PMA/FDA standards. *Davenport*, 302 F. Supp. 2d at 432; *Bentzley*,

827 F. Supp. 2d 443; *Killen,* 2012 WL 4498865. i.e. a parallel claim exists. Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are based on violations of the same as alleged in great detail:

Promotion

- As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

Distribution

- erroneously using non-conforming material in the manufacturing of Essure.
- failing to use pre-sterile and post-sterile cages.
- manufacturing Essure at an unlicensed facility.
- manufacturing Essure for three years without a license to do so.
- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went).
- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

Advertising

- As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.

In sum, each of the above breaches was plead with great particularity and supported by the actual FDA violation notice as an exhibit. In sum, Defendants' alleged misconduct – *i.e.* failing to exercise due care in its promoting, distributing, advertising, and reporting of Essure, violates federal law, as well as parallel PA state-law. *Burman,* 420 Pa. Super. 209; *Lance,* 85 A. 3rd 434; *Widdoss,* 2003 WL 22512092. This is especially true considering (1) Plaintiff's claims need not be identical, merely parallel federal requirements and (2) court's should not "reach" to

find preemption. Thus, § 360k(a) does not preempt Plaintiff's Negligence Pharmacovigilance claim.

I. Defendants' argument

Defendants argue that this claim is preempted based on *Riegel* and *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, No. CV 13-224-SLR, 2014 WL 3737501 *6 (D. Del. Jul. 28, 2014).

However, the *Riegel* Court held plaintiffs' claims were preempted "insofar as the claim was not premised on the theory that Medtronic had violated federal law." *Riegel*, 552 U.S. 312. The *Riegel* court never contemplated whether plaintiffs' claims were parallel claims as plaintiffs made no such contention in their briefs. *Id.* at 330. The *Riegel* court was certain to conclude that claims are not preempted to the extent that they were based on violations of FDA regulations. *Id.* at 330. Here, Plaintiff's claim is premised on the theory that Defendants violated federal law as described above.

In *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, the court did hold that FDCA governs both marketing and promotion of medical devices and found that plaintiff's claims were preempted. *Scanlon*, No. CV 13-224-SLR, 2014 WL 3737501 *6. However, Plaintiff's case is different in that Plaintiff has (1) premised her claim on warranties not approved or regulated by the FDA and (2) plead a parallel claim based on violations of both federal regulations and the CPMA. As such, Plaintiff's claim is not preempted.

Defendants then cite to the CPMA in an effort to convince this Court that the FDA has approved its distribution, advertising, and promoting scheme. However, nowhere in the CPMA or any other evidence that Defendants requested that this Court consider memorialize that the FDA has approved or issued an Essure specific requirement as it relates to Defendants' distribution, advertising, or promoting scheme. In fact, the CPMA actually reads:

> "FDA has also determined that, to ensure the safe and effective use of the

> device…insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act."
>
> "CDRH does not evaluate information related to contractual warranties, however you should be aware that such warranty statements must be truthful, accurate, and not misleading, and must be consistent with Federal and State laws."

Assuming that this is the Essure specific regulation, (1) it only relates to distribution and (2) the claim is still not preempted as Plaintiff alleges that Defendants violated this FDA/PMA standard as noted in detail above by distributing a "misbranded," "adulterated," and "restricted" device.

Moreover, there is no federal requirement specific to Essure regulating its promotion or advertising. Accordingly, to the extent that Plaintiff's claim is based on Defendants' promoting and advertising of Essure, Defendants fail to show how this was exclusively regulated by the FDA or had any type of approval from the FDA.

More recently, in *Stengel v. Medtronic, Inc.*, the court held that claims that were based on a device manufacturer's failure to monitor its product after premarket approval and to discover and report to the FDA any complaints of adverse health consequences which it had become aware of were not preempted. *Stengel*, 704 F.3d at 1232-33. Similarly, in the state of PA, the court in *Killen v. Stryker Spine*, recently ruled that plaintiff had plead a parallel claim where she alleged that defendant (1) was negligent in its record keeping and did not disclose manufacturing flaws that increased the risk of injury to patients and that this activity violated the manufacturers duty to establish and maintain procedures for implementing corrective and preventative action; and (2) was negligent in failing to give proper warnings concerning defects in the device. 2012 WL 4498865. This is exactly the case here. In fact, Plaintiff's Complaint is plead with greater specificity.

Lastly, Defendants argue that "There is no discussion of who created this scheme, who perpetrated this alleged scheme, or how this alleged scheme caused any injury to any plaintiff."

However, contrary to this argument, Plaintiff has alleged the following:

- Defendants…created an unreasonably dangerous distribution plan.
- Defendant's distribution plan … included (1) negligently distributing Essure in violation of FDA orders and Federal regulations; (2) marketing and selling an "adulterated" and "misbranded" product; (3) promoting Essure through representatives of the hysteroscopic equipment manufacturers, who were not adequately trained nor had sufficient knowledge regarding Essure; (4) failing to report and actively concealing adverse events which occurred as a result of Essure; (5) erroneously using non-conforming material and failing to keep track of the same in the manufacturing of Essure; (6) failing to use pre-sterile and post-sterile cages; (7) manufacturing Essure at an unlicensed facility and (8) manufacturing Essure for three years without a license to do so.
- As a result of Defendants' negligence…Plaintiff sustained…injuries.
- Plaintiff would never had Essure implanted in her had she known of the above.

Accordingly, Defendants fail to meet their high burden of rendering Plaintiff's claim preempted as (1) the CPMA in invalid; (2) there is no Essure-specific federal regulation as it relates to this claim; and even if there were a valid CPMA and Essure-specific regulation pertaining to any part of this claim; (3) plaintiff has plead a viable parallel claim based on violations of FDA/PMA regulations.

K. Strict Liability

Here, Plaintiff has alleged that Defendants (1) manufactured and (2) failed to warn of a defective and unreasonably dangerous product. (the product was "adulterated" and "misbranded" per Federal Law)[63]

PA recognizes three different types of defective conditions that can give rise to a strict liability claim: (1) design defect; (2) manufacturing defect; and (3) failure-to-warn defect. *Phillips v. A-Best Products Co.*, 665 A.2d 1167, 1170 (Pa. 1995). To the extent that Plaintiff's claim involves a strict liability-design defect claim, Plaintiff hereby withdraws the same.

[63] Para. 243 of Strimel Complaint.

Under PA state law, under the theory of strict liability, those who sell a product are held responsible for damage caused by the reasonable use of the product. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (2014). Moreover, manufacturers have a duty to make and market the product … free from "a defective condition unreasonably dangerous to the consumer. *Id.* No product is expressly exempt from strict liability and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect. Restatement (Second) of Torts § 402A comment. *Id*. To demonstrate a breach of duty in a strict liability matter, a plaintiff must prove that a seller (manufacturer or distributor) placed on the market a product in a "defective condition." *Id.*

The PA Supreme Court has adopted Section 402A of the Restatement (Second) of Torts as the law of strict products liability in PA. *Webb v. Zern*, 220 A.2d 853, 854 (Pa. 1966). Section 402A states:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such product and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it was sold.

In other words, those who sell a product have a duty not to manufacture, sell, or market any product in a defective condition.

As such, PA law parallels federal regulations not to manufacture, sell or market a product in a defective condition, as alleged in great detail in Plaintiff's Complaint. For just a few examples:

- 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the

causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.

- 21 U.S.C. 351(a) (h)- A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with …an applicable condition prescribed by an order.

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title.

- FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device

- 21 C.F.R. 820.65- establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.

- 21 C.F.R. 820.70(e)(h) (a) *General.* Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

- 21 C.F.R. 820.90-(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

Several Eastern District of PA District courts have held that claims do not impose requirements different from or in addition to PMA/FDA requirements where plaintiffs' claims are based on violations of PMA/FDA standards. *Davenport*, 302 F. Supp. 2d at 432; *Bentzley*, 827 F. Supp. 2d 443; *Killen*, 2012 WL 4498865. i.e. a parallel claim exists. In fact, in *Killen v.*

Stryker Spine, the court held that plaintiff plead a parallel strict liability-manufacturing claim *Id.*

More importantly, the C.F.R. also supports the position that strict liability claims are not subject to preemption: "Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices." 21 C.F.R. § 808.1(d)(6)(ii). Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are not only excluded by the C.F.R. but are also based on violations of the same as alleged in great detail:

- erroneously using non-conforming material in the manufacturing of Essure.
- failing to use pre-sterile and post-sterile cages.
- manufacturing Essure at an unlicensed facility.
- manufacturing Essure for three years without a license to do so.
- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)
- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.
- Designing, manufacturing, assembling, marketing, and selling an "adulterated" and "misbranded" product, per Federal law.
- As outlined in "Facts and Warranties" *infra*, Defendants' warranties were not truthful, accurate, and not misleading.
- Defendants' warranties were not consistent with applicable Federal and State law.

In sum, each of the above breaches was plead with great particularity and supported by the actual FDA violation notice as an exhibit. Defendants' alleged misconduct – *i.e.* manufacturing, selling, or marketing a defective product, violates federal law, as well as parallel PA state-law

regarding the same. *Tincher*, 104 A.3d 328.

This is especially true considering (1) Plaintiff's claims need not be identical, merely parallel federal requirements; (2) Defendants failure to cite to any binding law as it relates to strict liability claims based on violations of federal regulations; (3) the PA Supreme Court's presumption that strict liability claims apply to all products and (4) courts should not "reach" to find preemption. Thus, § 360k(a) does not preempt Plaintiff's Strict Liability claims.

I. Defendants' arguments

Defendants argue that all strict liability claims fail as (1) they are preempted by *Riegel* and *Williams* and (2) they fail as a matter of law because of comment *k* of Section 402A of the Restatement (Second) of Torts. To support this position Defendants cite to primarily four cases, *Riegel*, 552 U.S. 312 , *Williams*, 388 Fed. App'x 169, *Mazur*, 964 F.2d 1348, and *Hahn v. Richter*, 543 Pa. 558 (Pa. 1996) and then several other cases which Defendants argue extend their holdings from drugs to medical devices, such as Essure.

First, the *Riegel* Court held that plaintiff's claim for strict liability was preempted because plaintiff's claim was not premised on violations of FDA regulations. *Riegel*, 552 U.S. at 329. In other words, the *Riegel* Court did not hold all claims for strict liability are preempted, rather only those not based on violations of FDA regulations. *Id.* The *Riegel* holding was followed in *Williams v. Cyberonics, Inc.* (holding consumers strict liability claim was preempted absent any evidence it did not adhere to FDA regulations.) *Williams*, 388 Fed. Appx. 169. Here, Plaintiff has premised her strict liability claim on violations of the FDA in great detail. Accordingly, Defendants reliance on *Riegel* and *Williams* is misapplied. Moreover, Plaintiff's claims are similar to those in *Killen* where the court held that plaintiff had sufficiently plead a parallel strict liability-manufacturing claim where he alleged that the device at issue was "not properly heat treated" and was made not made in the proper facility. *Killen*, 2012 WL 4498865.

Presumably, Defendants recognize this and then argue that even if the claim is not preempted it fails as a matter of law because Section 402A of the Restatement (Second) of Torts does not apply to any of the three forms of strict liability claims centered on a medical device. The PA Supreme Court has adopted Section 402A of the Restatement (Second) of Torts as the law of strict products liability in PA. *Webb,* 220 A.2d at 854. Section 402A states:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (c) the seller is engaged in the business of selling such product and
>
> (d) it is expected to and does reach the user or consumer without substantial change in the condition in which it was sold.

Defendants rely on Comment k to Section 402A for the argument that PA law bars the application of all claims for strict liability to medical device manufacturers. Comment k states, in relevant part:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected.... Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of the physician.... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known and apparently reasonable risk. *Restatement (Second) of Torts* § 402A cmt. k; *Mazur*, 964 F.2d at footnote 5 (3d Cir. 1992).

First, several Eastern District of PA District courts have most recently held that comment k's exemption from strict liability does not extend to claims for strict liability-manufacturing defects. *Doughtery*, 2012 WL 2940727. Subsequently, the Western District also agreed with

the *Doughtery* court, holding that a plaintiff's claim for strict liability-manufacturing defect was neither preempted nor precluded under comment k. *Killen,* 2012 WL 4498865. Accordingly, Plaintiff's claim for strict liability as it pertains to negligent manufacturing survives.

As it relates to Plaintiff's remaining strict liability-failure to warn claim, Plaintiff recognizes that the PA Supreme Court has interpreted the language in Comment k to preclude plaintiffs from bringing strict liability- failure to warn claims against drug manufacturers. *Hahn*, 673 A.2d at 891.

However, the product in *Hahn* was never contested as being improperly prepared or marketed. A close inspection of the actual language contained within the comment reveals that Comment k does not work as an absolute bar to strict liability but is conditioned upon the product being both properly prepared and marketed.

In fact, the PA Supreme Court agrees and has held that Comment k contains exceptions which cannot be ignored. Specifically, in a prescription products case, the court in *Coyle v. Richardson-Merrell, Inc.*, expressly recognized the exceptions or conditions in Comment k: "Comment k to Section 402A provides an explicit exception that is relevant in the present case." 526 Pa. 208, 213 (1991).

Furthermore, ignoring the PA Supreme Court's recognition of the exceptions in Comment k would undermine the explicit purpose of strict products liability law. Comment k contemplates products that necessarily pose some risk to consumers, but protects manufacturers of these products from strict liability claims where the potential public benefit outweighs these risks. However, the comment only affords manufacturers this protection where the product is "properly prepared, and accompanied by proper directions and warning."

In addition to the PA Supreme Court, several other courts have recognized the conditions and reasoned that Comment k does not act as an absolute bar to strict liability against manufacturers of unavoidably unsafe products. See e.g. *Bearden v. Wyeth*, 482 F. Supp. 2d 614, 618 (E.D. Pa. 2006) (noting that Arkansas law recognizes comment k caveats); *Killen*, 2012 WL 4482371; *Perez v. Wyeth Labs., Inc*., 734 A.2d 1245, 1250 (N.J. 1999) (New Jersey recognizes the "properly prepared" and "accompanied by proper directions and warning" caveats); Frumer & Friedman, Products Liability, § 12.01[4] (2003); see also *Parkinson v. Guidant Corp*., 315 F. Supp. 2d 741, 748 (W.D. Pa. 2004). Rather, the comment holds manufacturers of unavoidably unsafe products strictly liable when their products have not been properly prepared (i.e. manufacturing or design defect) or lack adequate warnings (i.e. failure-to-warn). To interpret Comment k as barring any and all strict liability claims against medical device manufacturers is to ignore the plain language of the comment and insulate these manufacturers from liability at the expense of patient-consumer safety.

Ignoring the conditions contained in Comment k also forces the public to take medical device manufacturers at their word that they are providing patients and their doctors with adequate warnings and that the manufacturers have properly designed and manufactured their products. This undermines the principles of products liability law and forces patient-consumers to bear all the risks associated with these "unavoidably unsafe products" while allowing the manufacturers to reap all the rewards.

PA adopted strict liability in the products liability context "in response to changing societal concerns over the relationship between the consumer and the seller of a product." *Berkbile v. Brantly Helicopter Corp*., 337 A.2d 893, 898 (Pa. 1975). "The

increasing complexity of the manufacturing and distributional process placed upon the injured plaintiff a nearly impossible burden of proving negligence where, for policy reasons, it was felt that a seller should be responsible for injuries caused by defects in his products." *Id*. (discussing PA's decision to adopt § 402A). The PA Supreme Court reasoned that no societal interest was served by permitting manufacturers to place a defective article in the stream of commerce and then avoid responsibility for damages caused by that defect. *Id.*

For these reasons, other jurisdictions have also rejected the contention that Comment k acts as an absolute bar to drug and device manufacturer strict liability. *See* e.g. *West v. Searle & Co.*, 806 S.W.2d 608, 612 (Ark. 1991) ("In reading the comment it is obvious that the drafters did not intend to grant all manufacturers of prescriptive drugs a blanket exception to strict liability"); *Perez*, 734 A.2d at 1250 (Under New Jersey law, Comment k is not an absolute bar and whether or not strict liability is excluded in prescription drug cases requires a case-by-case review); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969); *Toner v. Lederle Laboratories, a Div. of Am. Cyanamid Co*., 732 P.2d 297, 305 (Idaho 1987) (Idaho recognizes that Comment k is not an absolute bar to strict liability against drug manufacturers); *Hawkinson v. A.H. Robins Co., Inc.*, 595 F. Supp. 1290, 1308 (D. Colo. 1984) (Colorado law applies strict liability to drug manufacturers and in order to avoid liability a manufacturer must show that the product was properly prepared and accompanied by adequate warnings).

In short, (1) several courts, including the *Bearden* court, have held that strict liability-manufacturing defect claims are not exempt from strict liability under Comment k; (2) in regards to Plaintiff's strict liability-failure to warn claim, the PA Supreme Court has recognized the exceptions under Comment k if it is alleged that the device was not "properly prepared or

marketed"; and (3) if there is a doubt as to either, there is presumption under the PA Supreme Court's recent holding in *Tincher* that strict liability will apply to either claim.

Regarding the first case cited by Defendants, *Mazur v. Merck & Co.*, the court held that a strict liability claim- failure to warn claim regarding a drug fails because Comment k of the Restatement renders the drugs "unavoidably unsafe." 964 F.2d 1348. However, Defendants fail to provide the Court with the full context of comment k.

Viewing the comment in its entirety is critical because the *Mazur* court never found the drug to be "improperly prepared." Comment k and the *Mazur* court acknowledge the qualification: that if the product is properly prepared and marketed then the manufacturer is not subject to strict liability. In fact, not only does comment k state the drug must be "properly prepared," but it also reiterates that in order for the drug to be exempt from strict liability it must meet the "qualification that (Defendants) properly prepared and marketed" the product. Here, Plaintiff's strict liability claim is plead with great detail that Essure was not properly prepared or marketed. Plaintiff even attaches the FDA violations memorializing that it was not properly prepared or marketed.

Accordingly, accepting Plaintiff's allegations as true, Plaintiff's allegations are consistent with *Mazur's* recognition that comment k does not apply as the Essure medical device was not properly prepared or marketed. (an express condition to comment k) In fact, pursuant to FDA regulations Essure was "misbranded" and "adulterated."

In addition to the qualifier in comment k, the PA Supreme Court has held that:

> Even where the Supreme Court has adopted section of the Restatement as law of Pennsylvania, language of Restatement is not to be considered controlling in manner of statute…with the court having power and obligation to refuse to apply rule when facts of case demonstrate that rule outruns reason…
>
> Court always retains right and duty to test reason behind common-law rule in determining applicability of rule to facts before it, and in face of contrary arguments as to why rule should not apply in given case, it is not sufficient to say

merely that rule as stated contains no exceptions. *Coyle by Coyle*, 526 Pa. at 212.

With this mind, there is no blanket holding that comment k applies to all strict liability claims. Moreover, the rule clearly outruns reason in this limited case because Plaintiff has plead with great specificity that the Essure device was not properly prepared and marketed. Lastly, the *Mazur* holding was solely dealing with a strict liability-failure to warn claim.

Next, Defendants cite to *Hahn. v. Richter,* 543 Pa. 558. However, the *Hahn* court actually recognizes that the qualifier in comment k applies. i.e. that the product must be properly prepared and marketed in order for it to be exempt from strict liability. Moreover, notwithstanding the fact that the court did not find the product to be improperly prepared or marketed, the *Hahn* court's holding that plaintiff's strict liability claim failed was limited only to a strict liability claim of failure to warn. *Id.* at 563.

Here, as discussed above, Essure was not properly prepared or marketed which also happens to be in violation of FDA regulations. Moreover, Plaintiff has plead a claim of strict liability-manufacturing claim asserting "Defendants manufactured…a defective and unreasonably dangerous product."[64] As such, *Hahn* is also inapplicable to the case at issue because (1) *Hahn* did not deal with a "misbranded" and "adulterated" product and (2) *Hahn*'s holding is only applicable to strict liability-failure to warn claims.

Unlike the other cases Defendants cite to which all predate the ruling in *Doughtery*, Plaintiff has plead in great detail that the product was not properly prepared or marketed, which is a condition precedent to applying comment k. Accordingly, after accepting Plaintiff's allegations as true, comment k does not apply.

A jury could find that Defendants' deviation from the FDA's manufacturing or marketing requirements was unreasonably dangerous without imposing different or additional

[64] Para. 243 of Strimel Complaint.

requirements to the federal requirements. The only state law requirements implicit in Plaintiff's tort claims are parallel to the FDA's federal requirements under *Riegel,* so that Plaintiff's state tort claims are not preempted under § 360k(a).

In short, (1) the only cases cited by Defendants, *Riegel* and *Williams* do not hold that preemption bars strict liability claims (rather only to the extent they are not based on violations of federal law); (2) the cases cited by Defendant all pre-date the *Daughtery* decision and are therefore limited to strict liability-failure to warn cases; and (3) the cases cited by Defendants also do not deal with a product that was improperly prepared or marketed per the FDA as alleged in Plaintiff's Complaint. Lastly, if there is any doubt as to whether Plaintiff's strict liability claims fail as a matter of law the claims should survive under the *Tincher* presumption.

L. Negligent Training

Plaintiff's claim for Negligent Training is based on three arguments, any one of which, escapes preemption. Plaintiff alleges that Defendants failed to:

- abide by the FDA training guidelines;
- train the implanting physicians in hysteroscopy with the hysteroscopic equipment it was providing to the implanting physicians; and
- disclose all known adverse events to the implanting physician[65].

Plaintiff alleges that Defendants failed to abide by the FDA training guidelines for Essure. i.e. a federal requirement specific to Essure. Moreover, contrary to Defendants' position, Plaintiff is not alleging in any way that Defendants should have had different "instructions," "directions for use," or "training guidelines" as these instructions were approved by the FDA. Nor is Plaintiff seeking to impose "specialized training" as it relates to Essure.

Plaintiff is alleging that Defendants (1) violated an "independent duty" when Defendants

[65] Plaintiff refers this Court to Plaintiff's argument outlined in Plaintiff's "Failure to Warn" analysis above in Section III "A."

"failed to abide by FDA training guidelines;" (2) failed to train the implanting physician, who was not an expert hysteroscopist, on how to use the hysteroscope before providing the same to him; and (3) failed to disclose all known adverse events to the implanting physician.

In *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790, 801(W.D. Louisana 2008), the court held that "to the extent that…Defendants failed to abide by the training requirements imposed by the FDA" plaintiff's failure to train claim would not be preempted.

I. Failure to train physician pursuant to the FDA-approved guidelines.

Defendants have failed to comply with the FDA-approved training guidelines. Plaintiff alleges this very fact in her Complaint at Paragraphs 123-124. For example, the FDA-approved "Instructions for Use" supplied to the Court by Defendant state: "This device should only be used by physicians who are knowledgeable hysteroscopists"… and who … "have successfully completed the Essure training program." Defendants violated this FDA requirement by providing Essure to the implanting physician who was not a knowledgeable hysteroscopist[66] and where it failed to abide by the FDA-approved training guidelines,[67] thereby violating the requirements of the FDA. Similarly, Defendants had a duty under PA state law to not permit a third party to use a thing ... which is under the control of the actor if the actor knows or should know that such person intends or is likely to use the thing...in such a manner as to create an unreasonable risk of harm." Restatement (Second) of Torts §308 (1965). In short, this law parallels the federal requirement that the device should only be used by knowledgeable hysteroscopists. Further, the OBGYN's must have successfully completed the Essure training program, which Plaintiff alleges was not completed.

II. Failure to train implanting physicians in hysteroscopy.

Second, the training of the implanting physician with a hysteroscope is not a part of the

[66] Para. 25 of Strimel Complaint.
[67] Para. 66 of Strimel Complaint.

CPMA and therefore is not preempted. It has nothing to do with the CPMA and is not a part of the Essure device. This portion of Plaintiff's Negligent Training claim is outside the scope of preemption for the same reasons Plaintiff's claim for Negligent Entrustment is excluded from preemption. In other words, the training of the implanting physician with this equipment had no type of approval, conditional or otherwise, by the FDA.

III. Defendants' arguments

Defendants attempt to address this portion of the claim by arguing that the hysteroscope is mentioned in Essure's "Summary of Safety and Effectiveness," and therefore somehow obtained some type of protection. Plaintiff agrees that a hysteroscope is mentioned in this document. However, Essure's "Summary of Safety and Effectiveness" does not explain how the implanting physicians obtain this equipment, how to use the hysteroscope, what kind of hysteroscope should be used, or any warning regarding the same. More importantly, the hysterscope and the training that is needed to properly use the same, is not a subject of the CMPA for Essure nor is it considered a part of Essure system.[68] Accordingly, to the extent that Plaintiff's claim for negligent training revolves around Defendants failure to train the implanting physician with the hysteroscopes it was providing, the claim is not subject to preemption.

The four cases cited by Defendants relate to claims where plaintiffs were challenging the adequacy of FDA-approved labels and warnings as it relates to the device that held PMA. In fact, in several of the cases cited by Defendants, a claim for negligent training was never even alleged by the plaintiff. *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919 (5th Cir. 2006)(dismissing the negligent training claim because plaintiff's alleged the "training material the FDA required and approved through the PMA process were inadequate"; *Hinkel v St. Jude Med., S.C.*, 869 F. Supp. 2d 739, 745 (E.D. La 2012)(the court never addressed a failure to train

[68] The Essure System according to the CPMA is (1) Essure micro-insert; (2) a disposable delivery system; and (3) a disposable split introducer.

claim); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009)(court never addressed a failure to train claim); *Mattingly v. Hubbard*, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008)(court held that negligent failure to train claim was preempted as it would impose an additional requirement as it relates to that "specific device").

Unlike the cases cited by Defendant, Plaintiff's claim is not seeking to impose any additional requirements specific to Essure or challenging the adequacy of any training by the FDA. Instead, Plaintiff's claim is based on (1) violations of FDA-approved material; (2) claims outside the scope of preemption as they are not related to the Essure system; and (3) violations of federal law, all of which escape preemption.

M. Negligence-Manufacturing

Here, Plaintiff has alleged that her injuries were caused by the "manufacturing of Essure inconsistent with the CPMA and Federal law, manufacturing an "adulterated" and "misbranded" product."[69]

Under PA state law, manufacturers have a duty not to sell a product in a defective condition. Restatement (Second) of Torts § 402A. The defective condition may arise not only from harmful ingredients… but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is [manufactured] or packed." Restatement (Second) of Torts § 402A, comment h. Moreover, manufacturers have a duty to ensure that its product comports with its intended design and is safe for normal handling or use, otherwise it is defective.

As such, PA law parallels federal regulations not to manufacture or sell a defective/adulterated/misbranded product, as alleged in great detail in this claim. For just a few examples:

[69] Para. 269 of Strimel Complaint.

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device.

- 21 U.S.C. 351(a) (h)- A drug or device shall deemed to be adulterated…if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with …an applicable condition prescribed by an order.

- FDA requirement in CPMA order- A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in a CPMA approval order for the device. 21 C.F.R. Section 814.80.

- 21 C.F.R. 814.80-A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval specified in the PMA approval order for the device

- 21 C.F.R. 820.90-(a) *Control of nonconforming product.* Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

- 21 C.F.R. 820.90-(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

Several Eastern District of PA District courts have held that claims do not impose requirements different from or in addition to PMA/FDA requirements where plaintiffs' claims are based on violations of PMA/FDA standards. *Davenport*, 302 F. Supp. 2d at 432; *Bentzley*, 827 F. Supp. 2d 443; *Killen*, 2012 WL 4498865. i.e. a parallel claim exists. Accordingly, Plaintiff's claims do not impose requirements different from or in addition to the PMA/FDA requirements as they are based on violations of the same as alleged in great detail:

- On January 6, 2011, … Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

- erroneously using non-conforming material in the manufacturing of Essure

- failing to use pre-sterile and post-sterile cages

- manufacturing Essure at an unlicensed facility

- manufacturing Essure for three years without a license to do so.

- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

- Designing, manufacturing, assembling, marketing, and selling an "adulterated" and "misbranded" product, per Federal law;

In sum, each of the above breaches was plead with great particularity and supported by the actual FDA violation notice as an exhibit. Defendants' alleged misconduct – *i.e.* manufacturing a product in a defective condition, violates federal law, as well as parallel PA state-law regarding the same. Restatement (Second) of Torts § 402A.

This is especially true considering (1) Plaintiff's claims need not be identical, merely

parallel federal requirements; (2) Defendants failure to cite to any binding law which outright precludes manufacturing claims; and (3) courts should not "reach" to find preemption. Thus, § 360k(a) does not preempt Plaintiff's Negligent Manufacturing claim.

I. Defendants' arguments

First, Defendants state that Plaintiff did "not ever allege that Defendants manufactured and placed into commerce, a device which did not comply with manufacturing requirements that were part of the PMA." Defendants also cite to the *Riegel*, 552 U.S. at 328, *Wolicki-Gables*, 643 F.3d at 1302 and *In re Medtronic Sprint Fidelis*, 623 F. 3d at 1207 to support this position. All three cases are inapplicable here, as in each case the plaintiff failed to plead violations of federal regulations. Moreover, contrary to Defendants' assertion, Plaintiff has alleged that Defendants manufactured Essure which did not comply with the CPMA or manufacturing regulations: "Plaintiff's injuries were caused by the manufacturing of Essure inconsistent with the CPMA and Federal law."[70] Moreover, Plaintiff has alleged that "Defendants breached these duties by not complying with FDA specifications, regulations, an/or its CPMA."[71] Plaintiff then goes into great detail outlining the specific federal regulations and how Defendants violated the same.

In *Hofts v. Howmedica Osteonics, Corp.*, the court found that plaintiffs' manufacturing claim was not preempted where plaintiff alleged that (1) the class III medical device "was defectively manufactured and not in compliance with Current Good Manufacturing Practice requirements approved by the FDA and had an impurity, imperfection, and/or another product defect allowed to be created, contained or placed within the product in defendants manufacturing process" and (2) that this "impurity, imperfection, and/or another product defect was a deviation from design and quality manufacturing standards for the [device] approved by

[70] Para. 269 of Strimel Complaint.
[71] Para. 271 of Strimel Complaint.

the FDA." 597 F. Supp. at 836. The court reasoned that "Unlike the claims the Supreme Court considered in *Riegel*, [plaintiff] bases his tort claims on his allegations that [defendant] failed in its obligation to meet the FDA's requirements, not that [defendant] failed to exceed those requirements or to meet different requirements." *Id.*

Notably, Plaintiff does not have access to the confidential design specifications at this early stage of litigation. As was noted in *Burgos v. Satiety, Inc.*:

> Plaintiffs alleging state-law parallel claims based on a violation of a manufacturer's agreement with the FDA often suffer from a unique disadvantage: the agreements that would provide the necessary factual specificity are confidential, and available only to the defendants and the FDA… '[A] plaintiff's pleading burden should be commensurate with the amount of information available to them. Other courts have similarly observed that it would be an injustice to penalize a plaintiff for alleging, through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury. 2011 WL 1327684 (E.D.N.Y. 2011) (*citing In re Medtronic, Inc., Spring Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (Melloy, J., concurring in part and dissenting in part)). 2011 WL 1327684 (E.D. NY 2011)

In *Burgos*, the plaintiff's complaint alleged that an approved medical device was "manufactured in violation of the terms, conditions, standards and specifications of the [IDE] secured by [the defendant]." *Id.* The court held that the plaintiff has "alleged as many facts as she can at this point," which included a reference to the incident report filed following the implantation of the device. *Id.* The court concluded that the plaintiff had stated a claim that the defendant did not manufacture the device in conformity with its requirements, and that the plaintiff was entitled to limited discovery which would permit her to make a more factually-based claim that the defendant's manufacturing process did not comply with FDA standards. *Id.*

Similarly, in *Bausch v. Stryker Corp.*, the Seventh Circuit noted that "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law," and that "formal discovery is necessary

before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." 630 F.3d at 555. The court rejected the defendant's contention that the plaintiff must cite to violations of the concrete, device-specific requirements contained within the confidential contract between the manufacturer and the FDA in order to survive a preemption challenge. *Id.* Instead, the court allowed the plaintiff to amend her complaint in order to allege violations of general FDA regulations for IDE devices, Quality System Regulations, and Current Good Manufacturing Practices adopted by the FDA. *Id. See, e.g. Howard,* 382 Fed. Appx. at 440 (plaintiff's negligence claims that tracked violations of the federal Good Manufacturing Practices survived preemption challenge). Here, even without the confidential specifications for Essure, Plaintiff has still plead a viable parallel cause of action based on the CGMP's. (which are not subject to preemption) As such, Plaintiff's manufacturing claim survives preemption.

Next, Defendants focus on two of Plaintiff's Exhibits she attached to her Complaint and argue (1) they have no bearing on a violation of a federal regulation; (2) they are hearsay; (3) Plaintiff does not have a private right of action to enforce CA law; (4) any claim is time bared; and (5) there is no allegation that the anything manufactured at the CA facility was problematic or that the devices made there are the subject of Plaintiff's claims. Notwithstanding the fact that Plaintiff's manufacturing claim is not based solely on these two documents, Defendants positions are irrelevant and a non-sequitur.

First, it is important to note that these exhibits were cited and attached to the Complaint not for the purposes of proving that Defendants were violating CA law. In fact, nowhere in Plaintiff's Complaint does she allege that Defendants violated CA law. The exhibits were cited to simply prove that Defendants were violating federal law. For example, federal law requires

Defendants to manufacture the device in a sanitary condition, and the attached exhibits are proof that Defendants were manufacturing the device in unsanitary conditions. Accordingly, the exhibits do have bearing on a violation of federal law.

Evidentiary issues with the exhibits are a non-issue at this stage. The fact of the matter is that the allegations in Plaintiff's Complaint and exhibits attached thereto must be accepted as true. If Defendants' logic was accepted than the Court could not consider anything in the Complaint because it is all hearsay. Notwithstanding this, the exhibits are Self-Authenticating Domestic Public Documents that are Sealed and Signed under FRE 902 and also fall under the Public Records exception of FRE 803(8).

Defendants assert that any claim based on these two exhibits is "likely time barred" because they occurred between 2005-2008. Defendants cite to no law or authority to support this vague position. Regardless, as Plaintiff plead in her Complaint: "Plaintiff did not have knowledge of facts that would lead a reasonable, prudent person to make inquiry to discover Defendants' tortious conduct until her hysterectomy on or about January 30, 2014. Under appropriate application of the Discovery Rule, Plaintiff's suit was filed well within the applicable statutory limitations period[72]… In addition, Defendants' fraudulent concealment of the relevant facts as described *infra* toll any relevant statutes of limitations."[73]

Lastly, Defendants claim that there is not a single allegation that anything manufactured in the facility referenced in these exhibits was problematic or that any devices made there are the subject of Plaintiff's claims. First, as noted above, Plaintiff's manufacturing claim is not solely based on this facility and the two documents that reference it. For example, Plaintiff also alleges that

[72] Para. 90 of Strimel Complaint.
[73] Para 91 of Strimel Complaint.

- On January 6, 2011, … Specifically, the FDA found that there were failures in Defendants' Design. The FDA also found that Defendants' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that Defendants' engineers learned of this and it was not documented.

- On July 7, 2003, Defendants were cited for not analyzing to identify existing and potential causes of non-conforming product and other quality problems. Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, which is used to track the data. (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

- On July 7, 2003, Defendants were cited for not following procedures used to control products which did not confirm to specifications.

As such, Defendants were cited on numerous occasions by the FDA for not only using non-conforming product, rejected material, and product which did not conform to specifications, but also for failing to track the same. Moreover, as Plaintiff plead in the Complaint Plaintiff's "injuries were caused by the manufacturing of Essure inconsistent with the CPMA and Federal law, manufacturing an "adulterated" and "misbranded" product, and by engaging in the following negligent and reckless conduct."

Defendants then cite to a string of cases where courts have found "manufacturing claims" expressly preempted. However, the cases were preempted because plaintiffs failed to premise their manufacturing claim on violations of federal law.[74] Moreover, manufacturing defect claims are not subject to the "particularity" pleading requirements of Rule 9.

[74] *Williams*, 388 Fed. App'x at 171(holding that plaintiff's strict liability-manufacturing claims were not preempted if premised on a violation of FDA regulations, citing to *Riegel*); *See also Gross v. Stryker*, 858 F. Supp. 2d at 495(holding that an adequately pleaded claim that a device was not manufactured in accordance with the PMA was not preempted); *see also In re Medtronic Inc.*, 592 F. Supp. 2d at 1158, *aff'd In re Medtronic*, 623 F.3d 1200 (holding that plaintiffs' claims were preempted as "plaintiffs have not identified any specific requirements…that were purportedly violated"); *Bradley v. Baxter Healthcare Corp.*, Civ. No. 1:12-cv-00312-MR.-DLH, (W.D.N.C. Oct. 18, 2013)(holding "[A]lthough a plaintiff may maintain a suit based on violations of FDA regulations, the complaint fails to set forth a single allegation supporting such a claim.); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (holding that plaintiff failed to set forth any failure to comply with any FDA regulation); *Horowitz*, 613 F. Supp. 2d at 283 (holding "Plaintiff's negligence/recklessness claim cannot withstand preemption as it is not premised on a federal violation.

By way of comparison, in *Lohr*, the Supreme Court reversed dismissal of similar claims, even though "the precise contours of their theory of recovery have not yet been defined," because it was clear that the plaintiffs allegations "may include claims that Medtronic has, to the extent that they exist, violated FDA regulations." 518 U.S. at 495, 116 S. Ct. 2240. As alleged in her Complaint, Plaintiff has asserted sufficient parallel claims based on Defendants failure to meet its obligation to the FDA.

IV. PLAINTIFF'S CLAIMS DO NOT FAIL AS A MATTER OF LAW

First, Defendants allege that Plaintiff's claims for Fraud and Fraudulent Concealment fail to meet the requirements of Rule 9. Defendants then argue that Plaintiff's claims are not "plausible" because (1) "Plaintiffs repeatedly fail to allege any specific violations of federal law" and (2) Plaintiffs allegations "are just plain wrong."

A. Plaintiff has met the Rule 9 Requirement as to her claims for Fraud

Defendants contend that Plaintiff has failed to allege any specificity as to (1) how, when, and where the alleged misrepresentations were made; (2) to whom they were made; and (3) how they are fraudulent.

Rule 9(b) requires that a plaintiff plead the circumstances of the alleged fraud with enough particularity to put the defendants on notice of the precise misconduct with which they are charged. *Lum v. Bank of Am.*, 361 F.3d 217, 223–24 (3d Cir. 2004) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F. 2d 786, 791 (3d Cir. 1984)).

The Third Circuit Court of Appeals has noted that while "allegations of date, place or time fulfill these functions, ... nothing in the rule requires them. Plaintiffs are free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud." *Id.* at 791. In the alternative, a plaintiff may satisfy the pleading

restrictions of Fed.R.Civ.P. 9(b) by pleading with a degree of precision or some measure of substantiation into the fraud allegation. *Frederico v. Home Depot*, 507 F. 3d 188, 200 (3d Cir. 2007).[75]

Moreover, courts must be mindful that Rule 9(b) exists to prevent defendants from being forced to defend against shapeless allegations of nefarious behavior. *In re Budeprion XL Marketing & Sales Litigation*, 2010 WL 2135625 (E.D. Pa. May 26, 2010). It should not be read to include a checklist of necessities to avoid a motion to dismiss or read so narrowly as to make pleading fraud impossible. *Id.* In *re Budeprion XL Marketing & Sales Litigation*, the Court held that plaintiffs met the duty under Rule 9 where plaintiffs plead the factual circumstances of the alleged fraud. (where plaintiffs alleged that Defendants' misrepresentations and material omissions failed to adequately inform them of problems with generic medication that Defendants marketed and as a result, plaintiffs spent money on medication they would not have purchased had they been properly informed by Defendants) *Id.*

Here, contrary to Defendants representation, Plaintiff did allege (1) the specific warranaites, verbatim;[76] (2) that they were made prior to implantation;[77] (3) the means by which they were communicated;[78] (4) that Plaintiff justfiably relied on the misrepresentations";[79] and (5) how each warranty is false, as plead underneath each warranty in Plaintiff's Complaint.[80] In fact, for most misrepresentations plaintiff even includes the exact date Defendants were cited for their fraudulent concealment, who cited them, and attach the actual violation. In addition, Plaintiff also plead (1) why the misrepresenations were made to her- "Defendants intentionally

[75] The Court of Appeals for the Third Circuit has further recognized that Fed.R.Civ.P. 9(b) may be relaxed when the relevant factual information is peculiarly within the defendant's knowledge or control." *See EP Medsystems, Inc. v. EchoCath, Inc.*, 235 F.3d 865, 882 (3d Cir.2000) (internal citations omitted).
[76] Paras. 102-118 of Strimel Complaint.
[77] Para. 101 of Strimel Complaint.
[78] Para. 101-118 of Strimel Complaint.
[79] Para. 221 of Strimel Complaint.
[80] Subparts to Paras. 102-118 of Strimel Complaint.

made the statements so that Plaintiff would be induced to have Essure implanted in her"[81] and (2) similar to the Plaintiff in *re Budeprion XL Marketing & Sales Litigation*, that she "would have never had Essure implanted had she been aware of the falsity of the representations specifically delineated in the preceding paragraphs which violate both Federal law and the CPMA."[82] Accordingly, Plaintiff has not only plead (1) how, when, and where the alleged misrepresentations were made; (2) to whom they were made; and (3) how they are fraudulent, but she also adequately plead the factual circumstances of the alleged fraud, either of which satisfies Rule 9.

B. Plaintiff's claims

Defendants argue under *Iqbal*/*Twombley* that Plaintiff's claims are not "plausible" because (1) "Plaintiffs repeatedly fail to allege any specific violations of federal law" and (2) Plaintiffs allegations "are just plain wrong."

First, Plaintiff alleged specific violations of federal law throughout her Complaint. Not only does Plaintiff allege the specific violations by Defendants but Plaintiff also alleges the conduct by Defendants which violates federal law in great detail.[83] Plaintiff also pleads how the damages are caused by Defendants. For example, Plaintiff has plead that "Had Plaintiff known that Defendants were concealing adverse reactions, not using conforming material approved by the FDA (and failing to track the nonconforming material), not using sterile cages, operating out of an unlicensed facility, and manufacturing medical devices without a license to do the same, she never would have had Essure implanted" and "Had Defendants disclosed such information as was required by its CPMA and Federal law to Plaintiff or Implanting Physician, Plaintiff would never had Essure implanted in her."

[81] Para. 220 of Strimel Complaint.
[82] Para. 221 of Strimel Complaint.
[83] E.g. Paras.148-149 of Strimel Complaint.

Regarding Defendants' assertion that Plaintiff's allegations are incorrect, the ultimate truth of the allegations is for a jury to decide. Defendants assert that there is "no such term as condition premarket approval….plaintiffs conveniently fail to cite to any law or document which so states-because there is none." As noted above, several courts have used this exact this term;[84] our Supreme Court in *Riegel* and the C.F.R. expressly acknowledge that a premarket approval may be conditional;[85] and the Defendants' own CPMA speaks for itself.[86] As noted in *Riegel* and in the C.F.R., had the FDA decided to grant Essure PMA with no conditions, it could have. However, here the FDA decided to condition the approval on certain postapproval conditions. As such, it is a fact that Essure had CPMA.

Defendants argue that there were no conditions precedent to the FDA's conditional approval of Essure. Plaintiff is not alleging that Defendants failed to comply with conditions precedent to its CPMA or that it shouldn't have been awarded CPMA. Plaintiff is alleging that by failing to comply with the postapproval conditions to the CPMA the CPMA is invalid, as per the FDA's order. Defendants contend that Essure's CPMA has never been found to be invalid. However, pursuant to the FDA's very own order in the CPMA, the CPMA is invalid. In fact, this order leaves no room for discretion as noted above: "Failure to comply with conditions of approval invalidates this approval order."

Defendants also allege that any claim that is based, in part, on the allegation that Defendants actively concealed 16,047 entries for complaints should be dismissed. First, Defendants cite to no law to support this contention. Second, that is just one allegation of

[84] *Woods*, 218 F.Supp. 2d at n. 4.
[85] *Riegel*, 552 U.S. at 319. (holding the FDA may grant or deny premarket approval. § 360e(d). It may also condition approval on adherence to performance standards; C.F.R. § 814.82(a) states: FDA may impose postapproval requirements in a PMA approval order.
[86] "Failure to comply with the conditions of approval invalidates this approval order." And "Continued approval of this PMA is contingent upon the submission of postapproval reports."

several others that Plaintiff bases several of her claims on. Third, at this point Plaintiff's allegations must be accepted as true. Whether or not any of the 16,047 complaints amounted to a mandatory reportable event would be a proper subject for expert witnesses. Lastly, the 16,047 complaints were concealed from the FDA because the MAUDE database reflects less than 5,000 events.

Moreover, Defendant is ignoring the several other express findings that Defendants failed to report adverse events. As such, the argument that all claims should fail because Defendants disagree with one allegation in Plaintiff's Complaint is unsupported by any law and unwarranted.

Lastly, Defendants re-argue that Plaintiff may not assert a claim based on a duty to file timely reports with the FDA and cite to *In re Medtronic, Inc., Sprint Fidelis Leads Product Liability Litigation.* As already discussed above, the Supreme Court, the *Knipe* court in the Eastern District of PA, the Solicitor General, and several other circuit and district courts disagree.[87]

CONCLUSION

Considering Plaintiff's well plead Complaint, the strong presumption against preemption in tort cases, and the positions of the United States Supreme Court and Federal Government through the Solicitor General's Amicus Brief, Defendants' Omnibus Motion for Judgment on the Pleadings Under Fed. R. Civ. P. 12(c) should be denied.

[87] *See Medtronic, Inc.*, 518 U.S. 471; *Perry*, 456 F. Supp. 2d at 687; *Knipe*, 583 F. Supp. 2d 553 (holding that "state law failure to warn claims were not preempted by the FDCA); *Hughes*, 631 F.3d at 770-71; *Stengel*, 704 F.3d at 1232-33, *cert. denied*; *Bausch*, 630 F. 3d 546; *McClellan*, 776 F.3d 1035; *Beavers-Gabriel*, 2015 WL 1443944; *Waltenburg*, 33 F. Supp. 3d 818; *Rosen*, 41 F. Supp. 3d 170; *Killen*, 2012 WL 4498865.

Respectfully submitted,

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CERTIFICATE OF SERVICE

WE HEREBY CERTIFY that on June 1, 2015, we served this document via CM/ECF to the Clerk of the Court which will also deliver an electronic copy to the following parties on the service list:

For Bayer Corp., Bayer Healthcare, LLC
Bayer Essure, Inc., Bayer Healthcare
Pharmaceuticals, Inc.

Al Bixler
Eckert Seamans
Two Liberty Place 22nd Floor
Philadelphia, PA 19102

No. 12-1351

In the Supreme Court of the United States

MEDTRONIC, INC., PETITIONER

v.

RICHARD STENGEL AND MARY LOU STENGEL

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

DONALD B. VERRILLI, JR.
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EXHIBIT A

QUESTIONS PRESENTED

Petitioner manufactures a medical device subject to premarket approval by the Food and Drug Administration (FDA) under the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq*. A patient using the device was paralyzed by an adverse event allegedly caused by the device. That patient and his wife (respondents in this Court) allege that after the device was approved by FDA, petitioner learned about adverse events associated with the device; that petitioner failed to make reports of those adverse events to the FDA as the MDA generally requires manufacturers to do; that such reports would have prompted changes to the device's approved labeling; and that those changes would have given physicians information that would have prevented or mitigated the patient's injury.

Respondents sued petitioner on various theories, the gravamen of which is that petitioner breached its duty under Arizona law to use reasonable care in warning of risks associated with its product. The questions presented are as follows:

1. Whether respondents' claim is expressly preempted by the MDA, 21 U.S.C. 360k(a).

2. Whether respondents' claim is impliedly preempted under the rationale of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

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In the Supreme Court of the United States

No. 12-1351

MEDTRONIC, INC., PETITIONER

v.

RICHARD STENGEL AND MARY LOU STENGEL

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, "impose[] a regime of detailed federal oversight" administered by the Food and Drug Administration (FDA) for medical devices. *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 316 (2008). Depending on the nature of the device and the risks it presents, that oversight ranges from "general federal regulations governing the labeling and manufacture of all medical devices," *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 497 (1996), to "a rigorous regime of premarket approval for [certain] devices," *Riegel*, 552 U.S. at 317.

FDA may grant premarket approval for a device only if it finds, among other things, that (a) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (b) the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). After premarket approval, a manufacturer generally must receive FDA's approval of a supplemental application before making any change to the device itself that would affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. 814.39(a). The same process that applies to an original PMA application generally applies to such a supplemental application. See 21 U.S.C. 360e(d)(6)(B); 21 C.F.R. 814.39(c).

Most changes to the labeling of a device after premarket approval likewise require FDA's prior approval, 21 C.F.R. 814.39(a)(2), but certain changes do not, 21 C.F.R. 814.39(d)(1). In particular, prior to receiving FDA approval, a manufacturer may place into effect "[l]abeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction," "that add or strengthen an instruction that is intended to enhance the safe use of the device," or "that delete misleading, false, or unsupported indications." 21 C.F.R. 814.39(d)(2)(i)-(iii). Those standards, and the associated process for a manufacturer to notify FDA of "changes being effected" (CBE) to a device's labeling, mirror the CBE provisions applicable to the labeling of brand-name prescription drugs addressed by this Court in *Wyeth* v. *Levine*, 555 U.S. 555, 568-569 (2009) (discussing 21 C.F.R. 314.70(c)(6)(iii)(A) and (C)).

"[P]remarket approval is specific to individual devices," *Riegel*, 552 U.S. at 323, but such devices are also subject to the more general provisions of the MDA and

FDA's regulations, such as those discussed above that govern revision of the labeling of a device subject to premarket approval. In addition, a manufacturer is required to collect and report to FDA within certain timeframes information on certain adverse events associated with its device. See 21 U.S.C. 360i(a); 21 C.F.R. Pt. 803.

b. The MDA's express preemption provision states:

> [N]o 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 [the FDCA] 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 [the FDCA].

21 U.S.C. 360k(a). FDA may exempt state requirements from preemption under appropriate circumstances. 21 U.S.C. 360k(b). This Court has described Section 360k as "authorizing the FDA to determine the scope of [preemption under] the [MDA]." *Wyeth*, 555 U.S. at 576; but see *Riegel*, 552 U.S. at 326 (suggesting FDA's view may merit "mere *Skidmore* deference").

In implementing Section 360k, FDA has long recognized that Congress did not wish "State and local regulation of medical devices [to] be reduced or eliminated before compensating FDA regulations [are in] effect[]." 43 Fed. Reg. 18,663 (May 2, 1978). FDA's regulations implementing Section 360k accordingly provide that such "requirements are preempted only when [FDA] has established specific counterpart regulations or there are

other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d).

Even when preemptive federal requirements exist, a state requirement is preempted only if it is "different from, or in addition to," federal requirements. 21 U.S.C. 360k(a)(1). Through that qualification, Section 360k(a) permits a State to "provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr*, 518 U.S. at 495. *Riegel* confirmed the availability of such "parallel claims." 552 U.S. at 330.

2. Petitioner manufactured the SynchroMed EL Infusion System, a medical device with FDA premarket approval that delivers analgesics through a catheter into the space surrounding the spinal cord. According to respondents' complaint (Doc. 1 Ex. A) (Compl.), in 2000, surgeons implanted the device in respondent Richard Stengel. Compl. ¶ 5. A granuloma, or inflammatory mass, developed at the tip of the catheter, eventually leading to Mr. Stengel's collapse and hospitalization in 2005. *Id.* ¶ 6. Surgeons removed the device and most of the granuloma, but respondent was rendered permanently paraplegic. *Id.* ¶¶ 7-9. We are informed by respondents' counsel that Mr. Stengel has since died from his injuries.

According to respondents' substitute proposed amended complaint (Doc. 22 Att. 1) (Proposed Compl.), at the time FDA granted premarket approval, the agency was not aware that the device could cause granulomas. Proposed Compl. ¶ 13. The proposed complaint further alleges, however, that after premarket approval petitioner became aware of adverse events that should have been reported to FDA and that should have led petitioner to revise its label to warn physicians as early

as 2002 about the risk of granuloma formation. *Id.* ¶¶ 13-18, 21. Petitioner eventually warned physicians in 2008, but, the proposed complaint continues, if petitioner had delivered those warnings sooner, Mr. Stengel's injuries could have been avoided. *Id.* ¶¶ 19, 24.

3. Respondents sued petitioner in Arizona state court on various theories, the gravamen of which is that petitioner breached its duty under Arizona law to use reasonable care in warning of risks associated with its product. Petitioner removed the case to federal court based on diversity of citizenship, and it moved to dismiss respondents' claim as expressly preempted by Section 360k(a) or impliedly preempted under the rationale of *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). The district court dismissed the claim as expressly preempted and denied respondents' motion for leave to amend, concluding that the claim in the proposed complaint would be impliedly preempted under *Buckman*. Pet. App. 52a-58a.

4. A divided panel of the court of appeals affirmed, Pet. App. 26a-51a, but on rehearing the en banc court unanimously reversed, *id.* at 1a-21a. The principal en banc opinion held that the proposed complaint escaped express preemption "insofar as the state-law duty parallels a federal duty under the MDA." *Id.* at 19a. In particular, the court noted that respondents allege that "[petitioner] failed to perform its duty under federal law" to "monitor the [device] after pre-market approval and to discover and report to the FDA any [adverse events]," and that "because [petitioner] failed to comply with its duty under federal law, it breached its duty to use reasonable care under Arizona negligence law." *Id.* at 18a-19a (internal quotation marks omitted). The court pointed to general Arizona tort law regarding the duty of a

manufacturer to provide adequate warnings, *id.* at 19a, and explained that "Arizona law contemplates [that this duty can be discharged via] a warning to a third party such as the FDA," *id.* at 20a.

As for implied preemption, the principal en banc opinion emphasized that the plaintiffs in *Buckman* "alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred" in the agency process that cleared the device in question for marketing. Pet. App. 12a. The court of appeals noted that this Court held that claim impliedly preempted in *Buckman* because it would interfere with the "somewhat delicate balance of statutory objectives" the FDA pursues in policing such fraud, and because "the fraud claims [in *Buckman*] exist[ed] solely by virtue of the FDCA" rather than "traditional state tort law." *Id.* 12a-13a (quoting *Buckman*, 531 U.S. at 348, 352-353). By contrast, the court of appeals reasoned, respondents' claim is not impliedly preempted because it is "independent of the FDA[] * * * process that was at issue in *Buckman*." *Id.* at 20a.

Judge Watford filed a concurring opinion joined by a majority of the en banc court. Pet. App. 22a-25a. He observed that "[t]he most direct way to state [respondents' failure-to-warn] claim would be to allege that under Arizona law [petitioner] owed a post-sale duty to warn doctors when it learned of adverse events." *Id.* at 22a. Judge Watford recognized that the CBE regulation permitted petitioner to do so, but he believed that the mandatory state duty would be preempted by Section 360k(a) because it is different from the merely permissive FDA regulation. *Ibid.* He thus understood respondents to have assumed "a causation hurdle that would not otherwise exist," *viz.*, "that [petitioner]

breached its duty of reasonable care under Arizona negligence law by failing to report adverse events *to the FDA*," and that if petitioner had made proper reports, "that information would have reached Mr. Stengel's doctors in time to prevent his injuries." *Id.* at 22a-23a. Judge Watford rejected petitioner's contention that this reformulation implicated *Buckman*; "[petitioner's] failure to report was more than a mere misrepresentation to the FDA [as in *Buckman*] because it simultaneously misled the device's * * * users, to whom [petitioner] owed an independent duty under state law." *Id.* at 24a.

DISCUSSION

Respondents' failure-to-warn claim is neither expressly nor impliedly preempted, but for reasons that differ from those given by the court below. Section 360k(a) does not preempt respondents' straightforward claim that petitioner should have brought new safety information to physicians' attention through a CBE revision to the device's labeling, because such a claim implicates no preemptive device-specific federal requirement. As for implied preemption, such a claim does not implicate *Buckman*; rather, it closely resembles the claim against the brand-name prescription drug manufacturer that *Wyeth* held was not impliedly preempted.

The court of appeals' misimpression that Section 360k(a) would preempt such a straightforward claim led it to analyze the express and implied preemption questions in the context of unnecessarily tortuous theories of causation. That misstep creates a host of problems for review in this Court at this time. Most prominently, the correct analysis of the express preemption question would not be available to this Court because it would result in a more favorable judgment for respondents than they obtained below, and they have not cross-

petitioned for certiorari. And the implied preemption question the court of appeals analyzed is largely academic because it arises only under the peculiar theory of causation that the court of appeals embraced out of a misperceived need to navigate around Section 360k(a). Even setting those problems aside, there are no clear circuit conflicts on the questions presented. Especially given the case's interlocutory posture, the Court should deny the petition.

I. The Court Of Appeals' Conclusion That Respondents' Failure-To-Warn Claim Is Not Expressly Preempted Does Not Warrant This Court's Review In The Present Posture Of This Case

The court of appeals' conclusion that respondents' failure-to-warn claim is not expressly preempted is correct, but for a different and more basic reason than the court identified: the federal requirements relevant to respondents' claim are not device-specific, and therefore they do not have preemptive effect under Section 360k(a). This case, however, is not in a suitable posture for correcting that error.

A. Respondents' failure-to-warn claim escapes express preemption for reasons the parties and lower courts apparently overlooked

1. The analytical framework for the express preemption question here comes from this Court's decisions in *Lohr* and *Riegel*, and from the FDA's MDA preemption regulation, 21 C.F.R. 808.1.

a. In *Lohr*, the Court held that federal "requirement[s]" are "applicable to the device" within the meaning of Section 360k(a)(1) only when they are "'applicable to the device' in question," 518 U.S. at 500, and, in accordance with FDA regulations, only when they are

"'specific counterpart regulations' or 'specific' to a 'particular device,'" *ibid.* (quoting 21 C.F.R. 808.1(d)). Federal requirements therefore can have preemptive force under Section 360k(a) when "the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." *Id.* at 501. Federal requirements ordinarily do not have a preemptive effect under Section 360k(a), however, when they "reflect * * * entirely generic concerns about device regulation generally." *Ibid.*

Thus, as we have previously argued to this Court, FDA's regulations addressing particular medical devices (such as hearing aids, 21 C.F.R. 801.420 and .421) preempt counterpart state requirements that are different from, or in addition to, those device-specific federal requirements, while by contrast FDA's general manufacturing and labeling regulations do not have preemptive force. See U.S. Amicus Br. at 12, *Buckman*, *supra*, No. 98-1768 (U.S. *Buckman* Br.) (citing *Lohr*, 518 U.S. at 501). As we explained in our amicus brief in *Buckman*, which supported the defendant on its *implied* preemption defense, the plaintiffs' claim there—that they would not have been injured but for the defendant's fraud on the FDA when obtaining clearance for the device—was not *expressly* preempted: Because the FDA requirement regarding the submission of information "is stated in general terms, and it applies to all devices that must undergo the [relevant] clearance process," it was "not the kind of federal requirement that can have a preemptive effect under [Section 360k(a)]." *Ibid.*

Riegel reaffirmed that distinction between "manufacturing and labeling requirements applicable across the board to almost all medical devices" and "requirements specific to the device in question." 552 U.S. at 322. The Court held that "[p]remarket approval * * * imposes 'requirements' under the MDA," explaining that "[u]nlike general labeling duties, premarket approval is specific to individual devices." *Id.* at 322-323. On the understanding that the *Riegel* plaintiffs' "claims * * * assert[ed] that [the] device violated state tort law notwithstanding compliance with the relevant federal requirements" established by the device's premarket approval, the Court concluded those claims were expressly preempted. *Id.* at 330.

b. To have preemptive force under Section 360k(a), a federal requirement ordinarily must be not only device-specific, but also relevant to the asserted state claim. "[I]n most cases a state law will be pre-empted only *to the extent* that the FDA has promulgated a *relevant* federal 'requirement.'" *Lohr*, 518 U.S. at 496 (emphases added). As FDA explained in promulgating its preemption regulation shortly after Congress enacted the MDA, "the scope of preemption is limited to instances where there are specific FDA requirements"; for example, where FDA had regulated hearing-aid labeling and conditions for sale, "only [state or local] requirements relating to labeling and conditions for sale were preempted, not all [s]tate or local requirements regulating all facets of hearing-aid distribution." 43 Fed. Reg. 18,662 (May 2, 1978). Accordingly, FDA has provided by regulation that "[s]tate or local requirements are preempted only when [FDA] has established specific counterpart regulations or there are other specific re-

quirements applicable to a particular device under the [FDCA]." 21 C.F.R. 808.1(d).[1]

c. That framework reflects sound policy. The "overarching concern" of Section 360k is "that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Lohr*, 518 U.S. at 500. If a state requirement were preempted absent a specific federal requirement that reflects FDA's weighing of competing considerations on the same subject and specific to the device (or type of device), the MDA would have the ironic effect of "provid[ing] less public protection from unsafe and ineffective medical devices" than pre-MDA law. 43 Fed. Reg. at 18,663. At best, FDA would be put in the straitjacket of federalizing *all* requirements for a given device once it chose to adopt *any* requirement. But a regulator often "take[s] one step at a time, addressing itself to the phase of the problem which seems most acute." *Massachusetts* v. *EPA*, 549 U.S. 497, 524 (2007) (citation omitted). Moreover, as this Court recognized in the analogous context of prescription drug labeling, "[s]tate tort suits" can be an important complement to the FDCA's regulatory framework because they "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly," and "also serve a distinct compensatory function that may motivate injured per-

[1] The references in 21 C.F.R. 808.1(d) to "specific counterpart regulations or * * * other specific requirements" recognize that FDA establishes preemptive requirements both by promulgating "regulations" (as in the hearing-aid context) and through other agency action carrying the force of law (as in granting premarket approval). See 42 Fed. Reg. 30,384 (June 14, 1977) (explaining that a federal requirement is an FDA "*regulatory* or *administrative* action involving the application of a particular requirement of the [FDCA] to a particular device") (emphases added).

sons to come forward with information." *Wyeth*, 555 U.S. at 579.[2]

2. The foregoing principles refute petitioner's contention that Section 360k(a) expressly preempts respondent's failure-to-warn claim. Under *Riegel*, FDA's premarket approval of petitioner's device established preemptive requirements with respect to the design, manufacturing, and labeling of the device. Those would preempt any claim alleging in substance that FDA should have conditioned its approval on adopting some other design, manufacturing specification, or labeling. Such were the nature of the claims at issue in *Riegel* (see U.S. Amicus Br. at 13-14, *Riegel*, *supra*, No. 06-179), and those claims were therefore preempted.

But here, respondents attack petitioner's conduct *after* its device received premarket approval (and after FDA approved any relevant supplemental application). That conduct, as alleged in the proposed complaint, would have been governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents' failure-to-warn claim—whether styled as arising from petitioner's failure to make adverse event reports to FDA or from its failure to make a CBE revision to the device's labeling—is not expressly preempted.

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[2] Of course, an "express pre-emption provision[] does *not* bar the ordinary working of conflict pre-emption principles." *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869 (2000). In some situations, a state requirement may be impliedly preempted because it threatens to frustrate the general operation of the federal program.

Indeed, the nature of the labeling change respondents contend petitioner should have made underscores the conclusion that no device-specific federal requirement appears to be implicated here. That change apparently would have been one to "strengthen a * * * warning" or "add * * * information about an adverse reaction," 21 C.F.R. 814.39(d)(2)(i), and it would have been based on new safety information. Cf. *Wyeth*, 555 U.S. at 568-570 (discussing the "newly acquired information" available to the manufacturer there). The change therefore could have been placed into effect under the device CBE regulation prior to FDA approval, belying any claim on petitioner's part that FDA had specifically required it to maintain its existing labeling in the face of that new safety information.

B. The court of appeals' reasoning for why respondents' failure-to-warn claim escapes express preemption may also be correct

1. The court of appeals reasoned that, although Section 360k(a)'s conditions for express preemption were in its view otherwise met, respondents' failure-to-warn claim was saved from express preemption because the requirements of Arizona law respecting warnings about a product communicated through an intermediary are parallel to federal requirements regarding reporting adverse events to FDA. See Pet. App. 18a-20a.

That may reflect a reasonable result, if one accepts the mistaken premise that general federal requirements ordinarily *do* have preemptive effect under Section 360k(a). Both the FDCA (as implemented by FDA) and Arizona law (as the court of appeals understood it) require petitioner to deliver warnings regarding its device through an appropriate channel, *viz.*, the device's FDA-mediated labeling. That parallelism is reinforced by the

FDCA's command that either inadequate warnings (21 U.S.C. 352(f)(2)) or a failure to submit required adverse event reports to FDA (21 U.S.C. 352(r)(2), 360i(a)) will render a device misbranded, and therefore "prohibited [from] introduction or delivery for introduction into interstate commerce" (21 U.S.C. 331 and (a)). Cf. *Mutual Pharm. Co.* v. *Bartlett*, 133 S. Ct. 2466, 2477 n.4 (2013) (noting but "not address[ing] state design-defect claims that parallel the federal misbranding statute").

If respondents' claim indeed parallels a federal misbranding claim, it is not expressly preempted. But subtleties may exist in squaring the broad and generalized requirements on both the state and federal sides of that parallelism. Here, the respective requirements may be conceived as analogous responses to somewhat different problems: The state requirement may be primarily concerned with warnings to traditional intermediaries (such as physicians using a specialized device), while the federal requirement exists to provide *FDA* with information bearing on the execution of its regulatory responsibilities. If those different objectives mean manufacturers do not face "*genuinely* equivalent" obligations, *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (construing an express preemption provision similar to Section 360k(a)), then the state requirement would be preempted as "different from, or in addition to" the federal requirement. However that subtle question of parallelism is resolved, though, respondent has (for the reasons given above, pp. 8-13, *supra*) stated a claim that is not expressly preempted.

2. Petitioner asserts that the court of appeals erred because, in petitioner's view, (1) "[Section] 360k(a) expressly preempts state-law claims regarding medical devices that have received premarket approval, unless

they are based on state-law duties that 'parallel' federal requirements," but (2) that "parallel-duty exception is limited to device-specific federal duties, and does not extend to the generally applicable federal reporting duty on which respondents' negligence claim is based." Reply Br. 10 (citation omitted); see Pet. 29-32. As explained above, pp. 10-12, *supra*, that misreads this Court's precedents and gets things backwards where general federal requirements are concerned. Such general requirements do not have preemptive force at all under Section 360k(a) because they "reflect important but entirely generic concerns about device regulation generally." *Lohr*, 518 U.S. at 501.

C. The circuits take a consistent, albeit incorrect, approach to express preemption of claims involving medical devices subject to premarket approval, but this case is not an appropriate vehicle for announcing the correct approach

1. The courts of appeals, in every case since *Riegel* involving a device subject to premarket approval, have tacitly dispensed with the first step of a proper Section 360k(a) preemption analysis—*i.e.*, asking whether FDA has established device-specific requirements on the same subject as the relevant state requirement. That practice in the circuits may reflect an erroneous assumption that the existence of *any* device-specific federal requirement has across-the-board preemptive effect, even on a state requirement addressed to a different subject. See, *e.g.*, *Hughes* v. *Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir. 2011) ("[W]e ask if the FDA has established requirements applicable to the * * * device."). But that would be contrary to *Lohr*'s reasoning and FDA's consistent interpretation in its regulations and briefs to this Court.

Alternatively, that judicial practice may reflect a mistaken belief that the act of premarket approval itself establishes device-specific requirements on all possible subjects, thus preempting additional or different state requirements whatever their subject. See, *e.g.*, *Bausch* v. *Stryker Corp.*, 630 F.3d 546, 563 (7th Cir. 2010) ("Section 360k provides immunity for manufacturers of [devices with premarket approval] to the extent that they comply with federal law."), cert. denied, 132 S. Ct. 498 (2011). That oversimplification would lead to correct results in cases, like *Riegel*, where a plaintiff's claim does indeed concern a subject specifically addressed by the FDA's premarket approval (for example, the safety and effectiveness of a device's design and labeling given the information submitted to FDA at the time of premarket approval). But that approach fails where a plaintiff's claim concerns a subject not addressed in device-specific terms by FDA's premarket approval of the device—here, a manufacturer's duties *after* premarket approval upon learning of new information bearing on the safety of its device.[3]

2. Petitioner contends (Pet. 17-21) that the circuits diverge in their application of Section 360k(a) in cases involving a device subject to premarket approval. No clear conflict exists. The courts in question all begin with the premise that in such cases, Section 360k(a) preempts *all* state requirements with respect to the device that are not parallel to some federal requirement. We disagree with that premise because it leads to express preemption of state requirements on subjects

[3] FDA can impose device-specific postmarketing requirements on a device as a condition of premarket approval, see 21 C.F.R. 814.82, but petitioner does not contend its device was subject to any such requirement of relevance here.

addressed only by general federal requirements. But accepting it as correct, the petition then presents the question of the proper analysis where the state requirement is parallel to a federal requirement, but the federal requirement is not device-specific.

Most courts (including, implicitly, the Ninth Circuit below) have held that a state requirement is saved from express preemption if it parallels a federal requirement of any kind, be it device-specific or general. See *Bass* v. *Stryker Corp.*, 669 F.3d 501, 511-513 (5th Cir. 2012); *Bausch*, 630 F.3d at 554-556; *Howard* v. *Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436, 440 (6th Cir. 2010). Other courts have found claims preempted where the counterpart to the state requirement would have been a general federal requirement. See *Wolicki-Gables* v. *Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-1302 (11th Cir. 2011); *In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206-1207 (8th Cir. 2010) (*Sprint Fidelis*). Although passing language in those decisions is consistent with petitioner's position that a state requirement cannot escape preemption by being parallel to a general federal requirement, the cases provide no explanation for why that would be so, and they appear ultimately to rest on deficiencies in the plaintiffs' pleadings. See *Wolicki-Gables*, 634 F.3d at 1301-1302 (discussing conclusory allegations of complaint); *Sprint Fidelis*, 623 F.3d at 1207 ("[*A*]*s pleaded and argued*, the manufacturing defect claims are not parallel.").

3. In all events, the procedural posture of this case makes it an inappropriate vehicle for resolving any conflict, either among lower courts or between the decision below and *Lohr* and *Riegel*. The circuit conflict petitioner posits is essentially academic because it concerns how extensive a preemptive effect Section 360k(a) gives to

general federal requirements, yet such requirements should ordinarily have *no* such preemptive effect under Section 360k(a). As explained below, it is doubtful that this Court could properly announce the latter holding in this case.

Under the court of appeals' judgment, respondents' claim escapes preemption only by "facing a causation hurdle that would not otherwise exist," namely, that Mr. Stengel's injury resulted from petitioner's "fail[ure] to report adverse events *to the FDA*," rather than from petitioner's failure to warn physicians directly. Pet. App. 22a-23a (Watford, J., concurring). The concurring judges (who represented a majority of the en banc court) stated that a claim predicated "on an alleged state law duty to warn doctors directly"—via a CBE revision of the device's labeling—"would have been expressly preempted." *Id.* at 22a. Although the proposed complaint alleges such a claim, respondents have not filed a cross-petition for a writ of certiorari challenging the holding of the court of appeals rejecting that claim. Yet a correct application of Section 360k(a) would not only sustain the court of appeals' holding favoring respondents, *but also reverse its holding unfavorable to respondents*.

That is problematic. As a leading treatise explains, this Court has held repeatedly that "[i]f the *rationale* of an argument would give the satisfied party [*i.e.*, respondents] more than the judgment below, even though the party is not asking for more," that argument "is not open to the respondent who fails to file a cross-petition." Stephen M. Shapiro et al., *Supreme Court Practice* ch. 6.35, at 493 (10th ed. 2013) (collecting cases). Because the Court apparently could not consider all possible approaches to the express preemption question—

including what we submit is the *correct* approach—it should deny review of that question in this case.

II. The Court Of Appeals' Conclusion That Respondents' Failure-To-Warn Claim Is Not Impliedly Preempted Does Not Warrant Review At This Time

Petitioner also contends that respondents' failure-to-warn claim is impliedly preempted under *Buckman*. The parties and court of appeals proceeded on the assumption that, "to avoid express preemption," respondents were obliged to assume "a causation hurdle that would not otherwise exist"—that petitioner should have reported adverse events to FDA, which in turn would have warned physicians. Pet. App. 22a-23a (Watford, J., concurring). That "causation hurdle" refers (at least in part) to the agency decisionmaking process, and therefore may implicate *Buckman*. But as explained above, pp. 8-13, *supra*, that assumption about express preemption is mistaken. Freed of that error, the proposed complaint's more natural theory of causation is that petitioner should have invoked the CBE provision to update its device's labeling in light of new safety information. Such a claim would not implicate *Buckman*, and would not appear to be otherwise impliedly preempted. Respondents' continued pursuit of an unnecessarily complex causation theory might impel this Court to confront difficult questions about *Buckman*'s reach, but in the case's interlocutory posture immediate review is unnecessary.

A. Tort claims based on a manufacturer's failure to update its product's labeling to account for new safety information ordinarily are not impliedly preempted

Respondents may properly proceed on the theory that petitioner should have invoked the CBE process to update its device's labeling to reflect new information

bearing on the safety of the device. Such a claim would mirror the failure-to-warn claim against the prescription drug manufacturer that this Court held was not impliedly preempted in *Wyeth*. There, as here, the plaintiff contended that the manufacturer could have appropriately invoked the CBE process for drugs (which is similar in relevant respects to the CBE process for devices) to communicate warnings without FDA's prior approval. 555 U.S. at 568-572. The Court agreed, and for that reason rejected the manufacturer's impossibility-preemption defense. *Ibid.* The Court acknowledged that "FDA retains authority to reject labeling changes made pursuant to the CBE regulation"—which is true for both drugs and devices—"[b]ut absent clear evidence that the FDA would not have approved a change * * * , [the Court would] not conclude that [the FDCA made compliance with state law] impossible for [the manufacturer]." *Id.* at 571.

The same analysis applies here because the proposed complaint alleges that Mr. Stengel's injuries could have been avoided if petitioner had revised its device's labeling based on new safety information of the sort that permits labeling revision through the CBE process. Indeed, it may be true in practice that *any* tort claim predicated on a failure to report adverse events to FDA can be cast—with no worse prospect of ultimate recovery and in far simpler terms—as a claim that the manufacturer should have discharged its state-law warning duties by invoking the CBE process to revise its labeling to reflect its new knowledge about adverse events. If so, the court of appeals' decision on implied preemption is of only academic interest because it analyzed a causation theory that a plaintiff should have no reason to advance. Moreover, *Buckman* is not implicated on a straightfor-

ward causation theory here any more than it was implicated in *Wyeth*, and petitioner has not argued otherwise.

B. No clear circuit conflict exists on implied preemption, and any tension between the decision below and *Buckman* arises from the court of appeals' unnecessary reliance on a tortuous theory of causation

Petitioner contends that the decision below misapplies *Buckman* and exacerbates a circuit split over implied preemption involving medical devices. Pet. 13-17, 22-29. No clear split exists. Although the decision below may raise difficult questions about *Buckman*'s precise scope, those are essentially the product of lower courts' misplaced focus on an attenuated theory of causation.

1. In *Buckman*, the plaintiffs allegedly suffered injuries from devices that had been cleared for sale by FDA through the defendant's efforts. Those efforts, the plaintiffs claimed, involved a fraud on the FDA, and "[h]ad [those fraudulent] representations not been made, the FDA would not have [cleared] the devices, and plaintiffs would not have been injured." 531 U.S. at 344.

This Court held those claims preempted, relying on several considerations. First, the putative state-law claims sought to police fraud on a federal agency by entities it regulates, a matter of exclusively federal character on which FDA possessed ample direct authority. *Buckman*, 531 U.S. at 347-350. Relatedly, state tort law "would exert an extraneous pull" (*id.* at 353) on the relationship between FDA and those it regulates. *Id.* at 350-351. Moreover, enforcement of the FDCA is by statute vested exclusively in the United States. *Id.* at 349 n.4, 352 (citing 21 U.S.C. 337(a)). Finally, the claims did not "rely[] on traditional state tort law" but rather a theory that "exist[s] solely by virtue of the FDCA." *Id.* at 353.

2. The decision below implicates some of the concerns recognized in *Buckman* because the court of appeals relied on a causation theory in which a decision by FDA is an essential element. Allowing respondents' claim to proceed could influence the relationship between FDA and manufacturers like petitioner. Moreover, the court of appeals' causation theory inevitably asks the finder of fact to speculate about the answers to questions of device regulation committed to FDA's discretion. And, absent the FDCA, the FDA would not exist as an intermediary for warnings.

But respondents' claim differs from the claim in *Buckman* in that the underlying state-law duty to warn here apparently exists even absent the FDCA; in that sense, respondents seek to enforce traditional tort law, not the FDCA itself. A claim against a device manufacturer is viable if the plaintiff is "suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by [Section] 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis*, 623 F.3d at 1204 (citation omitted). Indeed, an overly expansive reading of *Buckman* would extinguish the very parallel claims that Section 360k(a) preserves—a result that both *Buckman* itself, 531 U.S. at 352-353, and *Riegel*, 552 U.S. at 330, disclaim.

3. Petitioner contends that the circuits are divided on whether claims like respondents'—if pursued under the causation theory on which the Ninth Circuit relied—are impliedly preempted under *Buckman*'s rationale. Pet. 13-17. No clear conflict exists. Consistent with the decision below, the Fifth Circuit has held similar claims not impliedly preempted. *Hughes*, 631 F.3d at 775-776.

Petitioner contends that the Eighth Circuit in *Sprint Fidelis*, 623 F.3d at 1205-1206, and the Sixth Circuit in *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421, 423-424, cert. denied, 546 U.S. 935 (2005), held to the contrary. But the *Buckman*-preempted claims in those cases appear to have been materially different from respondents' claim. In neither of those cases did the plaintiffs allege that the manufacturer's conduct violated an independent state-law duty; their theory instead apparently was that they were entitled to recover based simply on the manufacturer's alleged violation of federal requirements. See Br. in Opp. 15 (discussing district court's order in *Cupek*); Am. Master Consol. Compl. for Individuals, *In re Medtronic, Inc.*, No. 08-1905 Doc. 250-1 (D. Minn. Feb. 27, 2009) (*Sprint Fidelis* complaint lacking allegations that the manufacturer's failure to timely report adverse events violated any common law duty (¶¶ 161-168), despite asserting other counts premised on "parallel common law" duties (¶¶ 127, 143, 154, 183, 191) or violations of Minnesota state law (¶¶ 238-264)). So understood, those claims are unquestionably the type that *Buckman* forbids, but they are distinct from the Arizona-law claim respondents make here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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