**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| HELEN MCLAUGHLIN,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07315-JP<br><br>The Hon. John R. Padova |
| RUTH RUBLE,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07316-ER |
| MELDA STRIMEL,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07317-LFR |

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| SUSAN STELZER,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07318-ER |
| HEATHER WALSH,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:15-cv-00384-GP |

**O R D E R**

AND NOW, this ____ day of _____, 2015, upon consideration of the 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. and any Response thereto, it is hereby ORDERED that said Motion is GRANTED.

IT IS FURTHER ORDERED that plaintiffs' Complaints are dismissed with prejudice.

BY THE COURT:

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Padova, J.

M1364632

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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|---|---|---|
| HELEN MCLAUGHLIN,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07315-JP<br><br>The Hon. John R. Padova |
| RUTH RUBLE,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07316-ER |
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| SUSAN STELZER,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07318-ER |
| HEATHER WALSH,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:15-cv-00384-GP |

**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.**

For the reasons set forth in the attached Memorandum of Law, defendants Bayer Corporation, Bayer HealthCare LLC, Bayer HealthCare Pharmaceuticals Inc. and Bayer Essure Inc. move to dismiss plaintiffs' Complaints with prejudice under Federal Rule of Civil Procedure 12(c).

**ECKERT SEAMANS CHERIN & MELLOTT, LLC**

Dated: April 29, 2015

By: */s/ Albert G. Bixler*
Albert G. Bixler
Leslie A. Hayes
Mark C. Levy
Heather R. Olson
Pa. I.D. Nos. 45639, 35975, 42234, & 92073

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*Attorneys for Defendants Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer Essure Inc., and Bayer HealthCare LLC*

M1364638

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| HELEN MCLAUGHLIN,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07315-JP<br><br>The Hon. John R. Padova |
| RUTH RUBLE,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07316-ER |
| MELDA STRIMEL,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07317-LFR |

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| SUSAN STELZER,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:14-cv-07318-ER |
| HEATHER WALSH,<br>Plaintiff,<br><br>v.<br><br>BAYER, CORP., BAYER HEALTHCARE LLC., BAYER ESSURE, INC., BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER A.G.,<br>Defendants. | : | Civil Action No. 2:15-cv-00384-GP |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' OMNIBUS MOTION FOR JUDGMENT ON THE PLEADINGS UNDER FED. R. CIV. P. 12(c)**

Defendants Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer Essure Inc. and Bayer HealthCare LLC (collectively "Defendants" ),[1] by and through their undersigned counsel, respectfully submit this Memorandum of Law in support of their Omnibus Motion for Judgment on the Pleadings under Fed. R. Civ. P. 12(c) requesting that Plaintiffs' First Amended Complaints (ECF Nos. 34, 32, 31, 32, 29), hereinafter "Complaints" or "Compl.")[2] be dismissed with prejudice.

## I. INTRODUCTION

In this matter, Plaintiffs claim that they were injured by a Class III prescription medical device—the Essure® System for Permanent Birth Control ("Essure")—whose design, manufacture, and labeling were approved by the Food and Drug Administration ("FDA") through the agency's Premarket Approval ("PMA") process. *See* Compl. at ¶¶ 46, 48, 49. FDA approved Essure under the stringent PMA process in 2002. Dozens of PMA supplements have been submitted, revised and approved from 2002 to 2014 addressing among other things, physician training and post-approval studies. These supplements were reviewed and approved by FDA under the same stringent review process. Plaintiffs and others have several times challenged Essure's safety and efficacy with FDA directly, as recently as this year. However, FDA has held steadfast in its opinion that Essure is safe and effective. In fact, contrary to Plaintiffs' direct assertions in this litigation, Essure remains a PMA-approved Class III medical device available for

[1] Defendant Bayer AG has not yet been served with original process of the Summons and Complaint in any of the five cases involving Essure filed at Civ. A. Nos. 14-cv-07315, 14-cv-07316; 14-cv-07317; 14-cv-07318; and 15-cv-00384. These five matters have been consolidated for purposes of discovery and motion practice before this Honorable Court. (*See* ECF No. 36, Order Dated March 13, 2015).

The use of the term "Defendants" collectively in no way implies that Defendants agree with Plaintiffs' allegation that there has been any disregard of the corporate entities or that any entity is "sham." *See McLaughlin* Complaint at pp. 2-3, ¶ 8. To the contrary, Defendants expressly deny this allegation and believe any suggestion that there is any "sham" should be stricken. *See* Fed. R. Civ. P. 12(h).

[2] All citations to the Complaints are to the First Amended Complaint in *McLaughlin v. Bayer Corp., et al*. 2:14-cv-07315-JP. For purposes of this Motion, Defendants believe that all five complaints are sufficiently similar (or identical) that there is no need for separate citations. All citations to the Answers are to the Answer and Additional Defenses of Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Essure, Inc., Bayer Healthcare LLC and Bayer Corporation in Plaintiff's First Amended Complaint. *McLaughlin v. Bayer Corp., et al*., 2:14-cv-07315 – JP.

commercial distribution in the United States. *See* Answer at ¶ 15. For the reasons addressed herein, Defendants respectfully request that this Court dismiss these actions in their entirety, with prejudice, because: (1) Plaintiffs' claims are expressly preempted by 21 U.S.C. § 360k(a) (*Riegel*); (2) Plaintiffs' claims for violations of FDA regulations are impliedly preempted and barred by 21 U.S.C. § 337(a) (*Buckman*); and (3) Plaintiffs' claims are also without basis under applicable state law and lack even the basic requirements for an adequately pleaded Complaint under *Iqbal/Twombly*.

## II. PROCEDURAL HISTORY

These cases were removed to this Court from the Court of Common Pleas of Philadelphia County, Pennsylvania, on December 30, 2014 (*Helen McLaughlin, Ruth Ruble, Melda Strimel* and *Susan Stelzer*) and January 26, 2015 (*Heather Walsh*). Each is brought by a single plaintiff, alleging personal injury to herself. After certain Defendants filed answers to the original complaints, Plaintiffs in four cases filed their First Amended Complaints on February 20, 2015, February 23, 2015 and February 24, 2015; the First Amended Complaint in the fifth case was filed on March 30, 2015. On March 13, 2015, the five cases were consolidated for purposes of pretrial discovery and motion practice before this Court. On April 9, 2015, the Court directed that the preemption issues would be resolved under Fed. R. Civ. P. 12 prior to any discovery taking place in the five cases. Accordingly, the Court ordered Defendants to file their dispositive motion based on federal preemption by April 29, 2015. As of April 14, 2015, Defendants have answered all five of the close to 130-page amended complaints. As such, the pleadings in all five cases are closed and the matters are ripe for Defendants' Motion.

## III. STATEMENT OF FACTS

### A. Statutory and Regulatory Background

The Medical Device Amendments ("MDA"), 21 U.S.C. § 360c, *et seq*., were enacted by Congress in 1976 and gave the FDA comprehensive and exclusive jurisdiction to regulate the sale of all medical "devices intended for human use." 21 U.S.C. § 360c(a)(1). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (providing overview of MDA). The MDA created in FDA a "regime of detailed federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); Pub. L. No. 94-295, 90 Stat. 539 (1976). Through passage of the MDA, Congress's intent was to ensure that safe and effective medical devices would be available to treat consumers in need of lifesaving care. So, Congress created a regulatory framework designed both to foster innovation in the arena of medical devices while ensuring the safety of those devices through regulation. The MDA "provide[s] for the safety and effectiveness of medical device[s]" (90 Stat. 539), while simultaneously "encourag[ing] the[] research and development" of "sophisticated, critically important" devices. S. Rep. No. 94-33, at 2 (1975), reprinted in 1976 U.S.C.C.A.N. 1070, 1071; *see also* H.R. Rep. No. 94-853, at 12 (1976) (MDA "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research").

The MDA established processes for classification of and performance standards for medical devices. 21 U.S.C. § 360c-m. Under the MDA, three different types of devices receive different levels of FDA scrutiny. 21 U.S.C. § 360c. Devices that "support[ing] or sustain[ing] human life" (21 U.S.C. § 360c(a)(1)(C)(ii)) or "presents a potential unreasonable risk of illness or injury" are designated "Class III." 21 U.S.C. § 360c(a)(1). A Class III device must receive FDA's premarket approval before it may be brought to market, and "incur[s] the FDA's strictest

regulation." *Buckman Co. v. Plaintiff's Legal Comm.,* 531 U.S. 341, 343 (2001). There is no dispute that Essure is a Class III medical device. *See* Compl. at ¶ 46, 49.

There are two available review processes which FDA employs to approve a Class III device – (1) premarket approval ("PMA"); and (2) premarket notification, commonly known as the "§ 510(k) process." The PMA process is the most exacting form of FDA review for devices and the FDA spends an average of 1,200 hours reviewing each application. *Riegel*, 552 U.S. at 318; *Lohr*, 518 U.S. at 494-501. "[I]n 2005, approximately ninety-nine percent of such devices went through the § 510(k) process and ***only one percent*** went through the PMA process." *Riegel*, 451 F.3d at 112 (emphasis added). In reviewing PMA applications, FDA must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). For these reasons, obtaining "[p]remarket approval is a 'rigorous' process." *Id.* at 317 (internal citations omitted); *see also Lohr,* 518 U.S. at 477*; Horn v. Thoratec Corp.,* 376 F.3d 163 (3d Cir. 2004). FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id*. (quoting 21 U.S.C. §360e(d)). To obtain FDA's PMA approval, a manufacturer:

> [M]ust submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

*Riegel v. Medtronic, Inc*., 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e, *aff'd*, 552 U.S. 312 (2008)). If the agency is not satisfied with the manufacturer's submission, it can demand

more and may also refer the application to a panel of outside experts. *See Riegel*, 552 U.S. at 318 (citing 21 U.S.C. § 360eI(1)(G)); 21 C.F.R. § 814.44(a)).

FDA closely and rigorously scrutinizes PMA applications, '"weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)). As part of the PMA process, FDA must review a device's proposed labeling to "evaluate[s] safety and effectiveness under the conditions of use set forth on the label," and "determine that the proposed labeling is neither false nor misleading." *Id.* (quoting § 360e(d)(1)(A)). If FDA decides a device's design, manufacturing methods, or labeling should be revised, it can require revisions before approval. *See id.* at 319 (citing 21 C.F.R. § 814.44I). After completing its review, FDA may grant or deny approval. *See* 21 U.S.C. § 360e(d).

FDA's regulatory role does not end at PMA approval. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel*, 525 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). A manufacturer wishing to make such changes must submit a PMA Supplement and may not implement the proposed changes without FDA approval. *See id*. The PMA Supplement is subject to the same rigorous standards of review as an initial PMA application. *Id.* and 21 C.F.R. § 814.39(c). The MDA also imposes post-approval reporting obligations on manufacturers. FDA regulations require manufacturers "to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of . . . and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or

contribute to death or serious injury if it recurred." *Id.* (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)).

Congress did not provide plaintiffs with a federal cause of action under the FDCA, either expressly or impliedly. Recognizing the "undu[e] burden[]" imposed by differing state regulations, Congress also adopted a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 94-853, at 45 (1976). Therefore, Congress incorporated an express-preemption clause – a "general prohibition on non-Federal regulation" (*id.*) – providing that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable … to the device" under federal law. 21 U.S.C. § 360k(a).

Further, Congress has specified that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Although "citizens may report wrongdoing and petition the agency to take action," there is no private right of action to enforce the FDCA. *Buckman*, 531 U.S. 341, 349 and n.4. Consistent with its exclusive enforcement power under the FDCA, FDA has the authority to investigate violations of the FDCA and "has at its disposal a variety of enforcement options that allow it to make a measured response" to any wrongdoing. *Id.* at 349. Those enforcement options include "injunctive relief, 21 U.S.C. § 332, and civil penalty, 21 U.S.C. § 333(f)(1)(A); seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a)." *Id.*

Accordingly, Congress both precluded actions by private plaintiffs to enforce the FDCA (*Buckman*) and preempted state law claims that attempt to impose different or additional requirements on Class III PMA devices (*Riegel*). [3]

[3] This Court should not be swayed by concern that the application of federal preemption would effectively leave Plaintiffs without any recourse. The *Riegel* majority rejected this sentiment shared by the *Riegel* dissent stating, "[i]t

### B. FDA's Premarket Approval of the Essure Medical Device

#### 1. The 2002 PMA Approval

It is a matter of public record that Essure is a Class III device that was approved through the PMA process. *See also* Compl. At ¶¶ 46 and 48-51. Conceptus, Inc. originally obtained the PMA for Essure in 2002, after which the stock of Conceptus, Inc. was acquired by a subsidiary of Defendant Bayer HealthCare, LLC in 2013. *Id.* at ¶¶ 43-45. The Essure device's design, construction, manufacturing, warnings, instructions for use, labeling and testing were all reviewed and approved by FDA pursuant to the PMA process. S*ee* U.S. Food & Drug Admin., *Premarket Approval Order for the Essure® System*, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014A.pdf (last visited April 13, 2015).[4] That PMA process also reviewed the training to be provided to physicians before and after the 2002 approval. http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014b.pdf (last viewed April 25, 2015) (summary of safety and effectiveness of Essure);

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is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available—the text of the statute—suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50…to all innovations*." Riegel*, 552 U.S. at 326.

[4] This web page is part of the FDA's public database of premarket approvals, which is accessible at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. This Court may take judicial notice of the fact of Essure's PMA because the FDA's public website is a database maintained by the FDA in the normal course of its business and reflects final agency action. FED. R. EVID. 201; *see, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) (affirming judicial notice of PMA approval); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012) (taking judicial notice of FDA approval documents). Further, courts across the country have taken judicial notice of public FDA records – in the form of both approval letters and webpages – without converting a motion to dismiss into one for summary judgment. *See, e.g., Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 794 n. 1 (N.D. Ohio 2012); *Desabio v. Howmedica Osteonics Corp.*, 817 F. Supp. 2d 197, 201 n.3 (W.D.N.Y. 2011); *In re Wellbutrin SR/Zyban Antitrust Litg.*, 281 F. Supp. 2d 751, 754 n. 2 (E.D. Pa. 2003); *see also Tillman v. Smith & Nephew, Inc.*, No. 12 C 4977, 2012 WL 6681698, at *1-2 (N.D. Ill. Nov. 1, 2012) (taking judicial notice of PMA approval letter from the federal Department of Health and Human Services); *Ali v. Allergan USA, Inc.*, No. 1:12-CV-115 (GBL/TRJ), 2012 WL 3692396, at *1 (E.D. Va. Aug. 23, 2012) (same); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522 (S.D. Tex. 2009), *aff'd*, 631 F.3d 777 (5th Cir. 2011) (taking judicial notice of PMA approval letter from the FDA); *Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1088-89 (C.D. Cal. Dec. 12, 2011) (taking judicial notice of supplemental PMA and PDP approvals relating to four different cardiac pacemakers on defendant's preemption-based motion for judgment on the pleadings); *Tierney v. AGA Med. Corp.*, No. 4:11CV3098, 2011 WL 7400469, at *1 n.9 (D. Neb. Nov. 18, 2011) (taking judicial notice of PMA approval information available on the FDA's website).

http://www.fda.gov/ohrms/dockets/ac/02/briefing/3881b1_03.pdf (last viewed April 25, 2015) (Instructions for Use); http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhfoiaelectronicreadingroom/ucm413804.pdf (last viewed April 25, 20015) (Post approval study submitted June 13, 2008 used to determine the effectiveness of physician training, awareness, training materials, and labeling.) The PMA approval order was issued for the Essure device on November 4, 2002, and remains in effect today. It has never been suspended or revoked.

**2. Over Thirty PMA Supplements for Essure Have Been Filed and Approved by FDA.**

Since Essure was issued its Premarket Approval in 2002, thirty-seven supplements have been submitted to the FDA and summaries for each of those supplements are publicly available on the FDA's website.[5] *See* Compl. At ¶ 63 (only identifying 36 supplements). Each of these supplements are subject to the same rigorous standards of review as the initial PMA application and were granted FDA approval. *See Riegel*, 552 U.S. at 319; and 21 C.F.R. § 814.39(c)(2)(ii). The most recent supplement was filed by Bayer HealthCare LLC on July 7, 2014 and approved by FDA on December 11, 2014.[6]

**3. FDA's Recent Retrospective Review of Essure Concluded that it is Safe and Effective.**

A retrospective review of the Essure device was completed by FDA and was last updated in June 2014. This information is publicly available and is easily accessible on FDA's website: fda.gov.[7]

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[5] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4960 (last visited April 13, 2015).

[6] *See* FDA' Summary for PMA Supplement Number S042, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=1810 (last visited April 13, 2015).

[7] *See* "FDA's Review of Reported Problems" http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm (last visited April 15, 2015).

http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm (last reviewed April 27, 2015). In this review, FDA notes that it relies on a "variety of postmarket surveillance data sources to monitor the safety and effectiveness of medical devices." *See id.* FDA conducted an extensive review of Essure and the experiences of patients who were implanted with the device since its initial approval in 2002, including, *inter alia*, reports of adverse events by the Defendants and reports of problems from other sources, including patients and physicians as well as web-based testimonials. *Id.* From this "reported" data, FDA discusses some of the most frequent problems which were noted by the post-market materials available for review. *Id*. Specifically, FDA talks about the following issues: migration or malposition of the device or device components and device breakage, perforations and pregnancy rates/occurrences. *Id*. Telling of the lack of substance to Plaintiffs' claims that such issues were "concealed" or not "reported," these are the same issues raised by the Plaintiffs in this litigation. *See* Complaint at e.g., ¶¶ 88 (pregnancy); 90 (breakage); 92 (perforations); and 183 (malposition or migration). The most frequently documented adverse events of physical problems included pain, hemorrhage, headache, menstrual irregularities, fatigue, depression, weight fluctuations and patient device incompatibility (e.g., possible nickel allergy). These documented reports reviewed by FDA similarly parallel the claims made by the Plaintiffs in this litigation. *See, e.g.*, Complaint at ¶¶ 87-90, 142. Despite Plaintiffs' claims that these adverse events were not disclosed by Defendants, they were available for FDA review and comment.

FDA also reviewed a five-year study conducted by Conceptus, Inc. and required by FDA as part of the product's 2002 approval. *Id.* FDA found that, although "there is evidence of complications, as there are with all medical devices, overall results from this study did not demonstrate any new safety problems or an increased incidence of problems already known." *Id.*

As a result, based on the scientific evidence, FDA found that the Essure device remains a "highly effective means of sterilization when providers and patients follow the appropriate instructions for use, [while] no form of birth control is 100 percent effective … [t]he FDA will continue to monitor the safety of Essure to make certain that its benefits of providing women with a non-incisional sterilization choice continue to outweigh its risks." *Id.* Thus, FDA's own analysis of the safety and effectiveness of Essure as of 2014 shows that Plaintiffs' claims were not hidden, concealed or unreported. Rather, these reports were part of submissions to FDA which were reviewed on several occasions by the agency after approval of Essure.

**4. Plaintiffs' Counsel Filed a Citizen Petition with FDA Seeking its Intervention on the Very Same Issues Raised in the First Amended Complaint**

On February 20, 2015, after they filed their Complaints, Plaintiffs' counsel in these cases filed with FDA a thirty-two page citizen petition under, *inter alia*, 21 C.F.R. § 10.30. *See* http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0001 (last visited April 27, 2015). In their citizen petition, counsel for Plaintiffs in these actions ask FDA to adjudicate the ***same*** issues raised in their First Amended Complaints. *See id.* at 1-8. Specifically, Plaintiffs' counsel asks FDA to issue various orders, including a declaration that the PMA has been violated and is therefore invalid, because Plaintiffs' counsel alleges that the Defendants (1) perpetrated fraud on the FDA with respect to clinical trials data provided in support of the Essure PMA; (2) violated the terms of the PMA; and (3) violated various federal laws. *Id.* at 1-2. As the purported justification for those actions, the citizen petition recites virtually the same facts and law which are set forth in the First Amended Complaint. *See id.* at 1-8. Defendants dispute vigorously the validity of Plaintiffs' allegations in the citizen petition, but FDA dismissed the citizen petition on March 26, 2015 before Defendants responded. FDA found the citizen petition to be a "trade complaint," and referred the complaint to the Office of Compliance at the FDA branch which oversees medical

devices, the Center for Devices and Radiological Health ("CDRH"). http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0005 (last viewed April 27, 2015). The Office of Compliance within CDRH reviews issues ranging from medical device approval requirements, surveillance, quality, research, labeling, manufacturing, advertising, and promotion to inspections. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm115809.htm (last visited April 29, 2015). Accordingly, under *Buckman* as discussed below, the claims raised in the petition—which are essentially identical to those raised in these cases—are now within the province of FDA's compliance arm for review and, hence, Defendants believe they are all impliedly preempted for that reason alone. *See, e.g.*, 21 U.S.C. § 337(a).

## IV. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(h)(2), a defense of failure to state a claim upon which relief can be granted may also be made by a motion for judgment on the pleadings after the defendant has answered the complaint. *See also Turbe v. Government of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). In that situation, the same standards under Rule 12(b)(6) are applied. *Turbe*, 938 F.2d at 428 (citations omitted); *see also Dahlhammer v. Citibank (South Dakota) N.A.*, No. 05-CV-1749, 2006 WL 3484352 *3 (M.D. Pa. Nov. 30, 2006).

A defendant moving to dismiss under Fed. R. Civ. P. 12(b)(6) bears the burden of proving that a plaintiff has failed to state a claim for relief, *see* Fed. R. Civ. P. 12(b)(6); *see also, e.g.*, *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). According to the Supreme Court, a complaint must state a claim to relief that is "plausible on its face" as determined by a judge's "judicial experience and common sense." *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Plausibility requires "more than a sheer

possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. Furthermore, the plausibility of a claim depends on the amount of factual material that the plaintiff includes in the complaint; district courts "*are not bound to accept as true a legal conclusion couched as a factual allegation*." *Twombly*, 550 U. S. at 555 (emphasis added). Plaintiffs cannot merely offer a "formulaic recitation of the elements" or an "unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555; *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). These standards apply to every type of civil litigation in the federal courts, except for fraud, which has its own heightened standard of pleading. *See* Fed. R. Civ. P. 9(b).

Courts routinely have decided the issues of express and implied preemption of state law claims against medical device manufacturers under Rule 12. *See, e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 508 n.1 (5th Cir. 2012); *Desai v. Sorin* CRM USA, Inc., Civ. No. 12-2995, 2013 WL 163298, at *9 (D.N.J. Jan. 15, 2013); *Hayes v. Howmedica Osteonics Corp*., Civ. No. 08-6104, 2009 WL 6841859, at *6-8 (D.N.J. Dec. 16, 2009*); Delaney v. Stryker Orthopaedics*, Civ. No. 08-03210 (D.M.C.), 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009). *Gross v. Styker Corp.*, 858 F. Supp. 2d 466, 503-504 (W.D. Pa. 2012) (granting a Rule 12(b)(6) motion on PMA preemption and denying plaintiff's request to defer ruling pending discovery) *Lewkut v. Stryker Corp*., 724 F. Supp. 2d 648, 653 n.1, 655 (S.D. Tex. 2010) (relying on publicly available FDA documents in granting a PMA preemption motion to dismiss and declining to treat the motion as one for summary judgment).

## V. ARGUMENT

As discussed above, Plaintiffs have presented, formally and informally, all of their claims to FDA. After reviewing all available safety data as late as 2014, FDA confirmed that Essure is

safe and effective. This includes the alleged adverse events cited by Plaintiffs. Plaintiffs' counsel then filed a citizen petition with FDA in February 2015 reciting the same claims raised in the present lawsuits. *See* http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0001 (last visited April 27, 2015), at 1-2. (Plaintiff's 2/20/15 Citizen Petition). Notwithstanding FDA's review and rejection of Plaintiffs' claims, Plaintiffs have filed lengthy Amended Complaints in this Court seeking damages for personal injury allegedly suffered by five individual plaintiffs who claim to have had the Essure device placed by their treating physicians for permanent birth control. Plaintiffs' Complaints assert thirteen counts ranging from strict liability, "negligent risk management," to breach of warranty. As set forth below, these claims are expressly and impliedly preempted under federal law. They are also for the most part not cognizable under state law even if not preempted. Further, despite the length of the Complaints, the relentless repetition of allegations and the plaintiffs' histrionics, to the extent that any claims are not preempted, they are not "plausible" under *Iqbal* and *Twombly*. For all of these reasons, the Complaints should be dismissed with prejudice.

### A. The Supreme Court's Decision in *Riegel* and Other Jurisprudence Applying the MDA's Express Preemption Clause

Under the Supremacy Clause of the Constitution, "the Laws of the United States . . . shall be the supreme Law of the Land … the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST. art. VI, cl. 2. The doctrine of preemption arises out of the Supremacy Clause. *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 238 (3d Cir. 2009) (citing *Hillsborough County, Fla. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)). Courts have recognized three different `forms of preemption: express preemption, field preemption and conflict preemption. *Bruesewitz*, 561 F.3d at 238-39. The instant lawsuits presents the strongest example of preemption, when a "federal enactment expressly preempts state law [based on] language so

requiring." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001); *see also Lohr*, 518 U.S. at 484.

The MDA contains an express preemption clause:

> … no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The United States Supreme Court has held that this preemption clause bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by FDA. *Riegel*, 552 U.S. at 320-330. *See also Shuker v. Smith & Nephew PLC*, Civ. A. No. 13-6158, 2015 WL 1475368 (E.D. Pa. Mar. 31, 2015).

In *Riegel*, the medical device at issue was an Evergreen Balloon Catheter marketed by Medtronic. *Riegel* at 320. That catheter was a Class III device that received premarket approval from FDA in 1994. *Id.* Riegel alleged that the Evergreen Balloon Catheter was designed, labeled and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries. *Id.* Specifically, Riegel alleged claims for strict liability, negligence, breach of implied warranty, breach of express warranty and loss of consortium. *Id.*

The district court held that the MDA preempted Riegel's claims of strict liability, breach of implied warranty and negligence in design, testing, inspection, distribution, labeling, marketing and sale of the Evergreen Balloon Catheter. *Id.* at 320. It also held that the MDA preempted a

negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law. *Id.* at 321. Finally, it held that the MDA preempted a claim for loss of consortium to the extent it was derivative of the preempted claims. *Id.* The United States Court of Appeals for the Second Circuit affirmed. *Id.*

The Supreme Court set forth a two-step analysis to use in determining whether the MDA expressly preempts a plaintiff's claims. *Id.* at 321-22. First, the court must determine "whether the Federal Government has established requirements applicable to [the subject device]." *Id.* at 321. If so, then the court must determine "whether the [plaintiff's] common-law claims are based upon [State] requirements with respect to the device that are 'different from or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 322. With respect to the first prong, the Court held that the PMA process, constitutes a federal "requirement" specific to an individual device as defined in the MDA. *Id.* at 322. Analyzing the second prong, the Court held that a state's common law "tort duties," including "the duties underlying negligence, strict-liability, and implied-warranty claims" do qualify as "requirements," which in turn means that state common-law claims based upon those duties are preempted by the MDA. *Id.* at 324, 327 (quotations omitted). The Court explained that state tort judgments, which are premised on establishing a legal duty, "require[] a manufacturer's [device] to be safer than the model the FDA has approved [and] disrupt[] the federal scheme." *Id.* at 325. *Riegel* explicitly rejected the proposition that, to be preempted, a common-law duty "must apply ***only*** to the relevant device," or even "only to medical devices and not to all products and all actions in general*."* *Id.* at 327-29. (emphasis in original). The *Riegel* Court specifically found:

> [I]n the context of [the MDA] excluding common-law duties from the scope of preemption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal

> scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.

*Riegel*, 552 U.S. at 324-25.

Since the Supreme Court's decision in *Riegel*, the Third Circuit, its district courts and other courts across the country have broadly interpreted Section 360k(a) and determined that *Riegel*'s express preemption applies to a wide-ranging set of state law claims challenging the safety and effectiveness of PMA devices, or relating to the manufacturing, design, advertising, promotional materials, and labeling of PMA devices. *See e.g., Williams v. Cyberonics, Inc*., 388 Fed. App'x 169, 171 (3d Cir. 2010) (affirming grant of summary judgment on strict liability, manufacturing defect and breach of warranty claims); *Millman v. Medtronic*, No. 14-cv-1465 2015 WL 778779 (D.N.J. Feb. 24, 2015) (finding express preemption to preclude plaintiff's claims for fraud, failure to warn, strict liability, breach of warranty, negligent design/manufacture, negligence and breach of contract); *Desai v. Sorin CRM USA, Inc.*, Civ. No. 12-2995, 2013 WL 163298, at *6-7 (D.N.J. Jan. 15, 2013) (motion to dismiss granted against all claims in case involving cardiac defibrillator); *Smith v. DePuy Orthopedics, Inc.*, Civ. No. 11-4139 (JAP), 2013 WL 1108555, at *12 (D.N.J. Mar. 18, 2013) (summary judgment granted against all claims); *McPhee v DePuy Orthopedics, Inc.*, Civ. No. 3:11-287, 2013 WL 5462762, at *6-7 (W.D. Pa. Sept. 30, 2013) (motion to dismiss granted against all claims in case involving knee implant and holding that plaintiffs failed to plead a parallel claim); *Bentzley v. Medtronic, Inc*., 827 F. Supp. 2d 443 (E.D. Pa. 2011) (plaintiff's strict liability, negligence, and implied warranty claims based on alleged design and manufacturing

defects were preempted); *Gross v. Stryker*, 858 F. Supp. 2d 466, 490 (W.D. Pa. 2012) (stating that breach of implied warranty is a state claim "that imposes requirements that are different [from], or in addition to, specific federal requirements"); *Delaney v. Stryker Orthopaedics*, No. Civ. A. 08-03210 DMC, 2009 WL 564243 (D.N.J. March 5, 2009) (dismissing claims for failure to warn, defective design, negligence and breach of implied warranties).[8]

### B. The Supreme Court's Decision in *Buckman* Applying Implied Preemption

In *Buckman*, the plaintiffs filed a claim alleging a violation of state tort law against a consulting company affiliated with the manufacturer of orthopedic bone screws, which were classified as Class III medical devices that had been approved through the § 5l0(k) process. *Id*. at 343, 346 (quoting *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 159 F.3d 817, 820 (3d Cir. 1998)). Specifically, the plaintiffs claimed that the defendant, "made fraudulent representations to the FDA in the course of obtaining approval to market the screws. *Id*. at 343. Additionally, the plaintiffs claimed that the fraudulent representations caused their

[8] *See also Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 682 (W.D. Ky. 2013) (fraud claim preempted by MDA); *Anderson v. Boston Scientific Corp.*, No. 1:12-CV-00762, 2013 WL 632379 (S.D. Ohio Feb. 20, 2013) (MDA preempted product liability claim sounding in negligence); *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 911 (S.D. Ohio 2012) (dismissing claims for negligent and fraudulent misrepresentation as preempted by the MDA); *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-08 (8th Cir. 2010) (affirming district court's dismissal based on preemption of design defect, manufacturing defect, breach of express warranty, and failure to warn and related claims); *Funk v. Stryker Corp.*, 673 F. Supp. 2d 522 (S.D. Tex. Dec. 1, 2009), *aff'd*, 631 F.3d 777 (5th Cir. 2011) (dismissing claims for strict liability, negligence and for violation of the Texas Deceptive Trade Practices Act as preempted by the MDA); *Covert v. Stryker Corp.*, No. 1:08-CV-447, 2009 WL 2424559, at *1 n.2 (M.D.N.C. Aug. 5, 2009) (granting motion to dismiss all claims, including express warranty and consumer fraud); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2009 WL 1210633 (N.D. Ill. Apr. 30, 2009) (granting motion to dismiss all claims); *Dorsey v. Allergan, Inc*., No. 3:08-0731, 2009 WL 703290 (M.D. Tenn. Mar. 11, 2009) (granting summary judgment on plaintiff's single strict-liability claim); *Horowitz v. Stryker Corp*., 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (granting motion to dismiss all claims, including consumer fraud claims); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. Jan. 5, 2009) (granting motion to dismiss all claims, including claims based on manufacturing defect, failure to warn, design defect, negligence per se, breach of warranty, loss of consortium, and other derivative claims); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174 (N.D. Ill. 2008) (granting summary judgment on all claims); *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090 (D. Minn. 2008); *Blunt v. Medtronic, Inc*., 760 N.W.2d 396, 315 Wis. 2d 612 (Wis. 2009) (affirming summary judgment on all claims); *Parker v. Stryker Corp*., 584 F. Supp. 2d 1298 (D. Colo. 2008) (granting motion to dismiss all claims); *Mullin v. Guidant Corp*., 970 A.2d 733, 114 Conn. App. 279 (Conn. Ct. App. 2009) (affirming summary judgment on all claims); *In re Medtronic Sprint Fidelis Leads State Court Litig.*, Nos. 27-07-224476, et al. 2009 WL 3417867 (D. Minn. Oct. 20, 2009) (motion to dismiss granted against all claims, including consumer fraud and express warranty).

alleged injuries. *Id.* Thus, "[h]ad the representations not been made, the FDA would not have approved the devices, and the plaintiffs would not have been injured. *Id.* The Court considered whether the plaintiffs' fraud-on-the-FDA claims were preempted by the FDCA. *Id.*

The Supreme Court reasoned that the "presumption against preemption," *Buckman, 531 U.S. at 348,* that generally arises in cases dealing with matters of health and safety did not exist in *Buckman* because the claims asserted . . . "involved the relationship between a federal agency and the entity it regulates. *Id.* at 347. Such relationships are "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* The Court noted that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the . . . [FDA,] . . . and this authority is used by the . . . [FDA] to achieve a somewhat delicate balance of statutory objectives." Id. at 348 As a result of this federal scheme and the FDA's authority, the . . . [FDA] . . . can be skewed by allowing fraud- on-the-FDA claims under state tort law." *Id.*

The Court noted that allowing state fraud-on-the-FDA claims would "dramatically increase the burdens facing potential applicants," who would be subject to liability under both the FDCA and each individual state's laws. *Id.* at 350. As a result of allowing such claims, potential applicants may be discouraged from seeking § 510(k) approval[9] of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer to unpredictable civil liability. *Id.* The Court also expressed concern that, should state law fraud-on-the-FDA claims be allowed, it could result in applicants submitting a "deluge of information" to the FDA because of "fear that their disclosures to the FDA, although deemed

[9] *But see* Joyce B. Margarce & Michelle R. Schieffele, "*Is the Preemption Defense for PMA-Approved Medical Devices in Jeopardy?*" 75 DEF. COUNS. J. 12, 15 (2008) (noting that while the PMA process indicates that a medical device has been approved by the FDA, the §510(k) process is a clearance process not an approval process).

appropriate by the . . . [FDA could] . . . later be judged insufficient in state court." *Id.* at 351. The § 510(k) process could be slowed as a result of the increased information. *Id*. at 353.

Additionally, the Court distinguished the claims at issue in *Buckman* from the claims addressed in its earlier *Lohr v. Medtronic* decision because in *Buckman* the claims "exist[ed] solely by virtue of the FDCA disclosure requirements," while the claims in *Lehr* "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." *Id.* at 353. The Court held that "[s]tate-fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives," and therefore the plaintiff's claims were preempted through implied conflict preemption. *Id.* at 348, 350.

Further, the U.S. Supreme Court held in *Buckman* that there is no "doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions" of federal law. 531 U.S. at 349 n.4. As the Third Circuit recognized, "[a]llowing juries to perform their own risk-utility analysis and second guess the [agency's] conclusion would disrupt the expert balancing underlying the federal scheme." *Farina v. Nokia, Inc.*, 625 F.3d 97, 126 (3rd Cir. 2010) (citing *Buckman*, 531 U.S. at 350-51)). Thus, under *Buckman*, claims asserting non-compliance with the FDCA, or asserting that there had been fraud or misrepresentation committed against the FDA, are impliedly preempted.

"[W]hen Sections 337(a) and 360k(a) – as construed in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2008)] and *Riegel*, respectively – are read together, nearly all types of claims concerning FDA-approved medical devices are preempted." *In re Sprint Fidelis Leads*, 592 F. Supp. 2d at 1161. In order to avoid dismissal, a "plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly

preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA [because] such a claim would be impliedly preempted under *Buckman*)." *In re Medtronic Sprint Fidelis*, 623 F.3d at 1204 (internal quotation marks omitted). In other words, "[f]or a state-law claim to survive 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 v. Cordis Corp*., 625 F. Supp. 2d 769, 777 (D. Minn. 2009). Here, Plaintiffs cannot escape express and implied preemption—they are preempted by one or the other.

### C. The Application of Express Preemption (*Riegel*) and Implied Preemption (*Buckman*) to Plaintiffs' State Law Claims

Applying the framework set out in *Riegel* for analyzing preemption under the MDA, the Court first must address, based on the allegations in the First Amended Complaint, (1) whether the Federal Government has established requirements applicable to the Essure system; and (2) whether Plaintiff's state law claims are based on requirements imposed by Pennsylvania law with respect to the Essure system that are "different from or in addition to" the Federal requirements and relate to safety and effectiveness. *Riegel*, 552 U.S. 321-23. The answer to both of these inquiries is yes, and dismissal of the Plaintiff's claims based on federal preemption is appropriate. Similarly, the plaintiff must not be suing *because* the conduct violates the FDCA because such a claim would be impliedly preempted under *Buckman*. *See, e.g., In re Medtronic Sprint Fidelis*, 623 F.3d at 1204.

It is a matter of public record that Essure is a Class III medical device which was subjected to the PMA regulatory process. On November 4, 2002, FDA notified Conceptus, Inc. that it had been granted PMA of the Essure system. (PMA Approval P020014). Further, FDA published a list, which included the Essure system, of approved PMAs in the Federal Register in order "to inform the public of the availability of safety and effectiveness summaries of approved PMAs

through the Internet and the agency's Division of Dockets Management." *See* 68 Fed. Reg. 62812-13 (2003) ("Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications").

Claims involving a device with a Class III PMA, such as the Essure device, automatically satisfy the first prong of *Riegel*'s two-part test. *See Riegel*, 552 U.S. at 322-23. As the Supreme Court noted, "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323; *see also Horn v. Thoratec Corp.*, 376 F.3d 163, 170-2 (3d Cir. 2004) (holding that premarket approval imposes federal requirements on a device and noting that the FDA's position that a PMA order from the agency "specifically approves as a matter of law those features set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA"). The Supreme Court in *Riegel* unequivocally held that devices which are subject to PMA approval by the FDA are considered to be subject to Federal Government regulation for purpose of preemption analysis under the MDA. *Riegel*, 552 U.S. 322-23.

Accordingly, the Federal Government has established requirements applicable to the Essure device for purposes of § 360k(a) and Plaintiffs' claims undeniably satisfy the first condition of *Riegel*'s test for express preemption.

By passing the MDA, Congress ceded exclusive regulatory authority over medical devices to FDA because it determined that satisfaction of FDA's PMA requirements is adequate, as a matter of law, to safeguard the American public in its use of medical devices. Congress further expressly preempted certain state-law regulations and common-law claims that relate "to the safety

or effectiveness of the device or to any other matter included in" a federal requirement. 21 U.S.C. §360(a); *see also Riegel*, 552 U.S. 330.

Under *Riegel*, the MDA expressly preempts the type of state-law claims asserted by the Plaintiffs against the Class III Essure insert. *Riegel*, 552 U.S. at 321-23, 324-25, and 330 (claims for strict products liability, negligence, breach of warranty, failure to warn, manufacturing-and-design-defect, and negligence per se all preempted). The *Riegel* Court reasoned that private lawsuits based on state law have the same – if not greater – potential to interfere with FDA's regulatory regime than state legislative or agency action. *Id.* at 324-25 (citing *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 521-22 (1992)).

Plaintiffs' state law claims challenging the design and manufacturing process, alleging a failure to warn, fraud, breach of warranty, and the Defendants' supposed negligence (such as in training, risk management and adverse event reporting) by their very nature require application of principles that are entirely distinct from the enactments of FDA and thus impose requirements that are "different from" those imposed by FDA. Plaintiffs' claims would require a jury to contradict FDA's decisions and find, among other things, that the Essure device: (1) was accompanied by inadequate instructions and training for implantation, use, maintenance instructions, or warnings,[10] (2) was defectively designed, (3) was defectively manufactured, (4) was improperly distributed, (5) was distributed with improper training to the implanting physicians, and (6) was distributed to be used with implanting equipment which the implanting physicians were not qualified to use. Such findings would require *different* or *additional* marketing and distribution materials, instructions, training, or warnings, a *different* design, or a *different* manufacturing process than the

[10]To the extent that any of Plaintiff's claims are premised on a theory that the Defendants failed to warn or report to the FDA, "concealed" information from FDA, were "deceitful" with FDA or committed fraud in their reporting obligations to the FDA, such claims are impliedly preempted under *Buckman*, as discussed in further detail below in Section V. D.

ones expressly approved and required by the FDA. In effect, Plaintiffs' claims would encourage, and in fact require, "judges and juries to second-guess the balancing of benefits and risks of a specific device to their intended patient population – the central role of FDA – sometimes on behalf of a single individual or group of individuals." *Horn*, 376 F.3d at 178 (quoting the FDA's *Amicus Curiae* Letter Br. At 25-26).

Further, many of Plaintiffs' claims, including those based upon alleged fraud, misrepresentation, concealment or deceit, are impliedly preempted under *Buckman* as they are but an attempt by Plaintiffs to privately enforce the FDCA. *Buckman*, 531 U.S. at 341.

**1. Plaintiffs' negligent training and negligent entrustment claims are preempted (Counts I and II).**

Plaintiffs allege in Count I of their Complaints that Defendants had a legal duty to provide "training" to implanting physicians of Essure and in Count II to provide specific oversight over the implanting physician. Plaintiffs further allege that Defendants breached their duties because, among other reasons, they "failed to supervise the procedure" and failed to train the Plaintiffs' physicians on how to use hysterocopic equipment used by the Plaintiffs' physicians to place the Essure medical device. Complaint at ¶ 125.[11]

Plaintiffs admit that Defendants did train the "implanting physician … on how to properly insert the micro-inserts using the disposable delivery system…" Complaint at ¶¶ 67, 94. Plaintiffs do not allege that Defendants violated any specific federal regulations or the PMA itself as required under *Riegel*. *See id.* at ¶ 94 (alleging that "Defendants failed to abide by FDA-approved

[11] As part of the training of physicians placing the Essure device in their patients, FDA approved instructions that explicitly required the use of a medical instrument (not manufactured by Defendants) used to facilitate the placement of the Essure medical device safely and effectively: namely, an hysteroscope. A hysteroscope is a telescope-like instrument, which is used to view the inside of the uterus. http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhfoiaelectronicreadingroom/ucm413834.pdf. The use of the hysteroscope with regard to Essure is described by FDA, among other places, in its Summary of the Safety and Effectiveness of Essure. http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014b.pdf.

training guidelines…" without more). Rather, they seek to impose their own requirements (such as "supervision" or "specialized training") upon Defendants which FDA chose not to. *See* Complaint at ¶¶ 121-131. Plaintiffs do not dispute that the PMA for Essure covers training. *Id*. at ¶ 67. Indeed, the standard FDA "Conditions of Approval" accompanying the Essure PMA order recognize that instructions, directions for use, warnings and maintenance procedures are described in the approved labeling. *See Riegel v. Medtronic*, 451 F.3d 104, 111 (2d Cir. 2006), *aff'd* 552 U.S. 312 (quoting from "Adverse Reaction and Device Defect Reporting" section of PMA Conditions of Approval). Moreover, the PMA also required a Post Marketing Study on the training of physicians. That study was submitted as a PMA Supplement and approved by FDA. See, e.g., http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014b.pdf (last viewed April 25, 2015) (summary of safety and effectiveness of Essure); http://www.fda.gov/ohrms/dockets/ac/02/briefing/3881b1_03.pdf (last viewed April 25, 2015) (Instructions for Use); http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhfoiaelectronicreadingroom/ucm413804.pdf (last viewed April 25, 20015) (Post approval study submitted June 13, 2008 used to determine the effectiveness of physician training, awareness, training materials, and labeling.)

As the U.S. Supreme Court explained in *Riegel*, Congress enacted § 360k(a) to preempt any state-law claim that would impose a requirement "different from, or in addition to" those imposed by the FDA. *Id*. at 321-28. The PMA process and the resulting instructions for use, labeling and summary of safety and effectiveness—all FDA approved—specify how physicians are to be trained. This evaluation by FDA of the safety and effectiveness of Essure is not a function for a judge or jury. *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)) (FDA

‘“weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.’”). Accordingly, even assuming there is some state law which required Defendants to train Plaintiffs’ physicians,[12] which there is not, such law would violate the express preemption clause set forth in the MDA.

To survive preemption, Plaintiffs must allege what has been referred to as a “parallel state claim.” *Riegel* at 324, 327 Here, Plaintiffs cannot establish that there is any applicable state law cause of action for negligent training of Plaintiffs’ physicians. Plaintiffs do not allege, and they cannot allege, that their physicians were employees or agents of Defendants. In Pennsylvania, only a “master-servant” relationship may give rise to vicarious liability for negligence. *I.H. ex rel. Litz v. County of Lehigh*, 610 F.3d 797, 802 (3d. Cir. 2010) (citing *Smalich v. Westfall*, 269 A.2d 476, 481 (1970)). The rationale behind any tort involving the “master-servant” relationship is the premise that an employer has the right to exercise control over the physical activities of a servant within the time of service. *Id*. “In a master-servant relationship, ‘a master not only controls the results of the work but also may direct the manner in which such work shall be done.’” *Id*. In “determining whether a master-servant relationship exists, ‘[a]ctual control of the manner of work is not essential; rather, it is the right to control which is determinative.’” *Id*. (citing *Drexel v. Union Prescription Ctrs., Inc.*, 582 F.2d 781, 785 (3d. Cir. 1978). Defendants had no right to control the actions of the physicians responsible for placing Essure into Plaintiffs, nor was he or she an employee or agent of the Defendants. Because an entity cannot be held vicariously liable for the actions of an individual who was not the entity’s agent and that the entity did not have a

[12] Defendants have not found any state law which blindly imposes a duty on the manufacturer of a medical device to “train” the implanting physician and Plaintiffs do not cite to any specific law on this point. Thus, as federal regulations are the only applicable law, Plaintiffs’ claims for negligent training must be dismissed on implied preemption grounds as well.

right to control over, Defendants did not owe a duty, through the physicians, to the Plaintiffs. Therefore, these claims should be dismissed for this reason as well.

Indeed, courts across the country have held that incidental claims implicating training materials approved through the PMA process are preempted. *See, e.g., Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (preempting plaintiff's state-law claims that the manufacturer's "labeling, warning, information, and training were inadequate or incomplete"); *Hinkel v. St. Jude Med., S.C.*, 869 F. Supp. 2d 739, 747-48 (E.D. La. 2012) ("A jury hearing a breach of express warranty claim would thus be required to determine whether [the defendant's] representations regarding the [medical device] – including the FDA-approved label, warnings, and instructions for use – were false. Such a determination would clearly undermine the federal regulatory scheme."); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1291 (M.D. Fla. 2009) *aff'd*, 634 F.3d 1296 (11th Cir. 2011) (preempting plaintiff's negligence claim against device manufacturer's sales representative for alleged failure to train and educate); *Mattingly v. Hubbard*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008) (holding that plaintiff's claim for negligent failure to train "would nonetheless impose an additional substantive requirement for a specific device"). Any state-law claims implicating the Defendants' Instructions for Use ("IFU"), http://www.fda.gov/ohrms/dockets/ac/02/briefing/3881b1_03.pdf and Patient Information Booklet ("PIB"), http://www.fda.gov/ohrms/dockets/ac/02/briefing/3881b1_04.pdf (last viewed April 25, 2015), for the device are also expressly preempted because to hold otherwise would require Defendants to use different or additional instructions, training, instructions and warnings than that approved by the FDA in the PMA process.[13]

[13] *Cf. Gomez*, 442 F.3d at 931 ("To permit a jury to decide [plaintiff's] claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would

Plaintiffs also allege in Count II that Defendants "negligently entrusted" Plaintiffs' "implanting physicians" with equipment used by the physician in placing the Essure device consistent with the PMA. Plaintiffs first blindly allege that each of the Plaintiffs' physicians were each unqualified to use a hysteroscope generally, notwithstanding their professional degrees and licenses. Complaint at ¶ 140. Then, Plaintiffs allege that Defendants had a duty to investigate the competency of each physician to use the hysteroscope to insert the Essure device. *Id*. at ¶ 141.

First, as discussed above, *Riegel* does not require that Defendants do more than that required by FDA as to training and related protocols for physicians who use the Essure device. *Riegel*, 525 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). In fact, the labeling approved by FDA cannot be changed by Defendants without approval of FDA. Simply, Defendants had to follow the PMA and could not do more than was approved by the regulatory body which approved Essure. *Id.* What Plaintiffs ask a jury to demand of Defendants is more than what the PMA requires, so any suggestions such as those made by Plaintiffs in this Count would add to and not parallel existing federal requirements. Accordingly, Plaintiffs have not stated a parallel state cause of action under *Riegel*. *See id.*

Further, the tort of negligent entrustment is simply inapplicable here. Under the Restatement (Second) of Torts § 408, the tort requires entrustment of an instrumentality to a person defendant knows to be incompetent or unable to use it safely. Defendants had no duty to investigate licensed physicians to determine whether they were good doctors or sophisticated doctors, and the doctors here each had an independent duty to their patients arising from their professional licensing**.** It is important to note that "[t]he theory of negligent entrustment, while accepted in Pennsylvania, appears to be confined to specific and narrow fact situations." *Hosler v.*

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displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [defendant].").

*Reich*, No. CV-19-1991, 1992 WL 676630 *47 (Ct. Com. Pl., Snyder Cnty. Oct. 13, 1992). Specifically, "its most frequent application [is] where the third person is a member of a class which is notoriously likely to misuse the thing which the actor permits him to use." For example, "it is negligent to place loaded firearms or poisons within reach of young children or feeble-minded adults." *Kuhns v. Brugger*, 390 Pa. 331, 347-8, 135 A.2d 395, 347-8, 404-5 (1957). Pennsylvania has limited its application of the negligent entrustment theory of liability to a very limited number of scenarios and we have found no case where it has been applied to the entrusting of a medical device or equipment to a physician. It is certainly not the case that the doctors here were in the same category as young children or known drunk drivers. Thus, there is no cognizable state law claim here at all. If there is no applicable state law, and the only applicable law is that of FDA, then Plaintiffs' claims are impliedly preempted under *Buckman,* 531 U.S. at 353.

**2. Plaintiffs' pharmacovigilance-negligent distribution/advertising/over-promotion/reporting claims and negligent risk management claims are preempted (Counts III and IV).**

Plaintiffs allege in Count IV that Defendants breached a duty to have a "reasonable risk management procedure." This unspecified procedure, Plaintiffs allege, should have addressed adverse event reports to FDA, tracking of "non-conforming product', and consideration of the adverse events in its "risk analysis." Complaint at ¶ 162. However, to the extent that "risk management" or "pharmacogilance" for Essure exists, it is plainly and comprehensively and exclusively regulated by FDA.[14] For example, risk management of the device is implicated when FDA requires reporting of events involving safety and efficacy and this is specifically recited in

[14] FDA regulations provide a detailed framework for the collection and reporting of adverse event information. *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm (last visited April 27, 2015). Pharmacovigilance is part of risk management and both are part of evaluation of adverse event reporting. *See* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf (last viewed April 29, 2015) (*pharmacovigilance* means all scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events).

the PMA approval order. *See* "Approval Order" http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4960 (last visited April 27, 2015). In fact, when FDA approved Essure under the PMA process, it expressly evaluated the risk/benefits of approving it for commercial distributions. http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014b.pdf *See also Riegel*, 451 F.3d at 109 (citing 21 U.S.C. § 360e), *aff'd*, 552 U.S. 312 (2008)). Further, in its recent retrospective analysis, FDA reviewed the available post-marketing surveillance. http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm (last visited April 27, 2015). And, as discussed in more detail below, complaint handling procedures and reporting requirements are expressly regulated by FDA and imposed upon Defendants as part of the Essure approval. *See* 21 C.F.R. § 820.198, 21 C.F.R. § 803.1, *et seq*.

Any state law relating to "risk management", assuming one existed, would add to and not parallel the FDA's detailed regime of event reporting and processing and the exhaustive review the FDA has undertaken of Essure's safety in the PMA and during its post-approval reviews. Accordingly, any such claim is expressly preempted. *Riegel*, 451 F. 3d at 109.

Further, Plaintiffs do not cite to any state law creating the tort of "negligent risk management." This is because there is no such tort. As such, there is no parallel state law—only federal law—and claims alleging violation of that federal law alternatively would be impliedly preempted**.** In the end, Plaintiffs' "claims are simply an attempt by [a] private part[y] to enforce the MDA, claims foreclosed by § 337(a) as construed in *Buckman." In re Medtronic Sprint Fidelis*, 623 F.3d 1200. Plaintiffs cannot evade § 337(a) by bringing a state-law cause of action to enforce the federal regulatory clothed as a negligence claim. Section 337(a)

constrains '"[a] state's ability to use a federal statute violation as a basis for state tort liability and negligence per se depends on the intent of Congress, and not merely on the intent of the state.'" *Kemp v. Medtronic,* 231 F. 3d 216, 236 (6th Cir. 2000). Such claims are preempted under *Buckman* and § 337(a).

For example, any claim premised on an allegation that Defendants violated federal regulations by not reporting or not reporting timely, negative information about Essure is both expressly and impliedly preempted. *McClelland v. Medtronic, Inc.,* 944 F. Supp. 2d 1193, *1200 (M.D. Fla. 2013) (failure to file reports with FDA expressly preempted); *Sprint Fidelis Leads,* 623 F.3d 1200, 1205-06 (8th Cir. 2010) (untimely reports to FDA impliedly preempted). Similarly, the alleged failure to submit adverse events to FDA would be an impermissible attempt to enforce exclusively federal requirements with no counterpart in state law and would be impliedly preempted. *See, e.g., In re Medtronic Sprint Fidelis,* 623 F. 3d at 1205 (claim that manufacturer was negligent for "not timely fil[ing] adverse event reports, as required by federal regulations" was "simply an attempt by private parties to enforce the MDA"); *Littlebear v. Advanced Bionics, LLC,* 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012). ("All claims predicated on the failure to comply with adverse event reporting requirements are impliedly pre-empted."); *McClelland,* 2012 WL 5077401, at *7 ("[C]laims based upon FDCA disclosure requirements are impliedly preempted."); *Purchase v. Advanced Bionics, LLC,* 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011) ("[P]rivate rights of action to enforce FDA administrative and reporting requirements are prohibited by 21 U.S. C. § 337(a)."); *accord Cupek v. Medtronic, Inc.,* 405 F.3d 421 (6th Cir. 2005) 424-25 (claim that manufacturer failed to comply with federal reporting requirements "is a disguised fraud on the FDA claim" preempted by *Buckman ).* As *Buckman* teaches, "the relationship between a federal agency and the entity it regulates is inherently

federal in character because it originates from, is governed by, and terminates according to federal law." 531 U.S. at 347; *see also Dawson v. Medtronic, Inc.,* 2013 WL 4048850, at *7 (D.S.C. 2013) ("[T]hese [reporting] regulations relate to information that manufacturers are required to provide to the FDA, and Plaintiff cannot usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations."). Any tort claim based on an alleged failure to submit adverse-event reports to the FDA "would not be relying on traditional state tort law which had predated" the FDCA *(Buckman,* 531 U.S. at 353), because no duty to submit reports to the FDA would exist absent the FDA and the FDCA. Since "the existence of these federal enactments" is therefore "a critical element" of any such claim, such claims are impliedly preempted. *Id.*

In Count III, Plaintiffs broadly allege a series of claims based upon the same allegations as their negligent risk management claim in Count IV. The only difference between Count III and Count IV appears to be that Plaintiffs allege that there was some sort of "distribution scheme" on the part of Defendants which was negligent—relating to the Plaintiffs' physicians' use of the hysteroscope discussed above. This "negligent distribution" allegedly involves an undefined "unreasonably dangerous distribution scheme." Complaint at ¶¶ 151-53. This "negligent distribution," "advertising," "promotion", and "reporting plan," Plaintiffs claim, was aimed at "capturing the market" with disregard for safety. *Id.* at ¶ 151. There is no discussion of who created this alleged scheme, who perpetrated this alleged scheme, or how this alleged scheme caused any injury to any plaintiff. [15]

[15] To the extent this claim alleges a scheme which was in "reckless disregard of the safety of the public and Plaintiff," Complaint at ¶ 151, Plaintiffs should have to meet the heightened standard of Fed. R. Civ. P. 9(b), which they clearly do not. Further, there is nothing alleged which amounts to "reckless" behavior, let alone negligent actions. *See id.* at ¶¶ 151-53. And, further, such claims should be preempted under *Buckman*.

As discussed above, FDA approved the Essure device under the stringent standards for PMA approval. The use of the hysteroscope was part of the instructions for use and the training approved by FDA. The conditions of any "pharmacovigilence, distribution, advertising, promotion or reporting" are within the four walls of the PMA approval and FDA regulations. *Riegel v. Medtronic, Inc*., 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360eI), *aff'd*, 552 U.S. 312 (2008)). "Approval Order" *See also* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4960 (last visited April 27, 2015). Defendants are not permitted to deviate from the PMA without express permission of FDA. *Riegel*, 525 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Accordingly, any suggestion that Defendants should have done more than what was required under the PMA would be expressly preempted under *Riegel*. 552 U.S. at 324-25. *See also Scanlon v. Medtronic Sofamor Danek USA Inc.*, No. CV 13-224-SLR, 2014 WL 3737501 *6 (D. Del. Jul. 28, 2014) ("[t]he FDCA governs both marketing and promotion of medical devices….", and therefore, claims preempted). Further, Plaintiffs have raised these issues with FDA, and FDA has not found anything warranting any change to the PMA, let alone the issuance of a warning, a recall or a hearing on whether the PMA approval should be withdrawn. *See, e.g.*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4960 (last visited April 27, 2015). "Approval Order."

**3. Plaintiffs' breach of express warranty claim is preempted (Count V).**

Plaintiffs allege in Count V that there were warranties which were "expressly communicated to Plaintiff[s] by Defendants or its agents in such a manner that Plaintiff[s] understood and accepted them." Complaint at ¶ 179. The warranties, Plaintiffs allege, were

"specifically negotiated." *Id.* at ¶ 182.[16] However, there are no specific facts alleged in Count V regarding what many of the alleged warranties were, when they were made, and how they were made. Further, there are no specific facts alleged regarding how any of the alleged warranties were "specifically negotiated" and with whom and no specific allegations regarding how the alleged breach of the warranties caused any of Plaintiffs' alleged injuries. *See id*.

When read in light of the alleged "Facts and Warranties" referred to by Plaintiffs, *see* Complaint at ¶¶ 180, 94-120, these claims are specious. Plaintiffs assert that the alleged "warranties" came from an alleged "website," "advertisement," "Fact Sheet," "agent," "marketing," "brochure," "booklet," "data," or a "PMA Supplement," or "SEC filings." *Id.* at ¶¶ 103-120. While Plaintiffs allege that they saw the alleged warranties before Essure was placed, they do not say how and when they saw these alleged warranties. *See id*. at ¶ 102. Further, most if not all of these claims relate directly to the product labeling/instructions for physicians approved by FDA. *See, e.g., id*. at ¶¶ 94-102. For example, Plaintiffs refer to unspecified "data warranties" pertaining to the use of hysteroscopes, *see id.* at ¶ 116, "Essure Booklet Warranties" which appear to be, by Plaintiffs' admission, approved PMA labeling, *see id*. at ¶ 115, or even alleged representations made in what is referred to as the "PMA Supplement." There is no doubt that the PMA Supplement has to be a submission made by Defendants to FDA. It is not an express warranty made to Plaintiffs. By way of example, these claims do not relate to an express warranty by Defendants to Plaintiffs to pay for unreimbursed medical costs in the event of a device malfunction—which would be an express warranty to the patient—but rather, statements, most of which were made to FDA or to the Plaintiffs' physicians.

[16] How this can possibly be the case is anyone's guess since many of these "warranties" were allegedly made years before or after the Plaintiffs had Essure placed and/or are statements made in securities filings, or other circumstances that cannot have formed a part of any specific contractual understanding between Defendants and Plaintiffs or their physicians.

Moreover, while there is no allegation of how these warranties were made to Plaintiffs other than they were "on the internet and in the implanting physician's office," *id* at ¶ 102, each of the alleged "warranties" involves the safety and effectiveness of Essure. And, they involve information which was presented to and reviewed by FDA on multiple occasions without any negative finding. For example, Plaintiffs claim that these "warranties" relate to the (1) number of pregnancies in clinical trials (¶ 103), "effectiveness" of Essure (¶¶ 103, 105), design of Essure (¶¶ 106, 111, 117), placement of Essure (¶¶ 110, 111), and the failure to report adverse events (¶¶ 111, 115, 119). Each of the alleged warranties applies to materials submitted to FDA over years and evaluated by FDA to determine whether Essure is safe and effective.

*See* http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm (last visited April 27, 2015). Such claims are expressly preempted. Indeed, Plaintiffs' claims in Count V would in essence require a finding that Essure was not safe and effective—a finding that would contradict the FDA's conclusive determination during the PMA process that there is "a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. §360e(d)). *Millman v. Medtronic*, 2015 *13 (D.N.J. February 24, 2015) (following *Fidelis Leads*, 592 F. Supp. at 1164; *Timberlake v. Synthes Spine Inc.* 2011 WL 711075, (S.D. Tex. Feb. 18, 2011)). *See also* Bass v. Stryker Corp., 669 F. 3d 501, 515-16 (5th Cir. 2012)); *Williams v. Cyberonics, Inc*., 388 Fed. App'x 169, 171 (3d Cir. 2010) (breach of warranty claim preempted as well as other generalized common law claims); *Kitchen v. Biomet, Inc.*, 2014 U.S. Dist. LEXIS 21672, *14 (E.D. Ky. February 21, 2014); *Smith v. DePuy Orthopaedics, Inc.*, 2013 WL 1108555, *29 (D. N.J. March 18, 2013).

Plaintiffs suggestion that this Court's analysis under ***Riegel*** should change because FDA stated in the Approval Order that it did not evaluate contract liability warranties is without merit. Specifically, Plaintiffs cite in the text of Count V to *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443 (E.D. Pa. 2011) for the proposition that its claims in Count V are not preempted on this basis. Complaint at ¶ 177. *Benzley* appears to follow several cases in this district. *See, e.g.*, *Huber v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 WL5451072 (D. N. J. Dec. 15, 2009), at *3-4. However, the *Bentzley* decision cannot be reconciled with that of *Millman*, 2015 WL 778779, *6 (D.N.J. Feb. 24, 2015), or the courts of other jurisdictions which found such claims to violate the holdings of *Riegel*. *See, e.g.*, *In re Medtronic Sprint Fidelis*, 623 F. 3d at 1208.[17] For these reasons, Defendants believe Plaintiffs' express warranty claims are preempted.[18]

Finally, because Plaintiffs have failed to plead facts supporting a plausible inference that an express warranty was created, their claims in Count V also should be dismissed with prejudice pursuant to Rule 12(b)(6). *Iqbal*, 556 U.S. at 662. Other courts in this jurisdiction and elsewhere have dismissed similarly implausible claims under Rule 12. *See, e.g.*, *Shuker v. Smith & Nephew PLC*, No. Civ. A. 13-6158, 2015 WL 1475368 (E.D. Pa. Mar. 31, 2015) (failing to identify source of warranty, how it was made or how plaintiff became aware of it) ; *Starks v. Coloplast Corp.*, No. Civ. A. 13-3872, 2014 WL 617130, *7 (E.D. Pa. Feb. 18, 2014) (dismissing a breach of express warranty claim where the plaintiff failed to "plead any details regarding the content of any express warranty, how it was made, that it became the basis of the bargain, or that it was directed to [plaintiff]"); *Delaney v. Stryker Orthopaedics*, No. Civ. A. 08-03210 DMC, 2009

[17] Further, we note that the *Bentzley* court did not determine whether the express warranty claims there could be disposed of as a matter of law. 827 F. Supp. 2d at 454 n.15.

[18] Plaintiffs' claims in Count V should be dismissed for other reasons as well. Plaintiffs use the words "concealed" (¶¶ 104, 116, 117), "altered the records" (¶¶ 105, 115), and "fake" or "fictitious" (¶ 109) in almost every paragraph associated with the alleged "warranties." To the extent Plaintiffs' claims in Count V are a disguised "fraud on the FDA" claim as asserted elsewhere in the Complaints, they are impliedly preempted under *Buckman.*

WL 564243, *6 (D. N.J. Mar. 5, 2009) (failure to plead the grounds upon which express warranty is based); *Kester v. Zimmer Holdings, Inc.*, No. 10-CV-00523, 2010 WL 2696467 *10-11 (W.D. Pa. June 16, 2010) (dismissing a breach of express warranty claim based on the allegation that defendants "expressly warranted that [their devices] were safe and well accepted by users").[19]

**4. Plaintiffs' Pennsylvania Unfair Trade Practices and Consumer Protection and negligent misrepresentation claims are preempted (Counts VI and IX).**

Counts VI and IX appear to fall within the "fraud on the FDA" claims which this Court discussed as likely preempted, and Plaintiffs' counsel appear to agree are preempted under *Buckman*. *See* Transcript of April 9, 2015 Hearing, Exhibit A at 9. While Plaintiffs do not use the word "fraud" and the claims are couched in language of other state law claims, the factual basis for each of these claims appears to be Defendants' alleged affirmative misrepresentations and omissions set forth in the fraud counts (VII and VIII). Accordingly, to the extent the gravamen of these claims are fraud based, Defendants submit that they should be dismissed under *Buckman* for the reasons set forth in Section V. D. below.

Additionally, much of the material which Plaintiffs claim was "deceptive" in Counts VI and IX was submitted to FDA for review and approval. For example, as discussed above, Plaintiffs' allegations make reference to materials such as an unspecified "PMA Supplement" and "Essure Booklet Warranties" and "Brochure Warranties." These documents were submitted to and approved by FDA and are part of its labeling. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=4960 (last viewed April 27, 2015). Plaintiffs now claim that these documents are somehow deceptive because they lack certain

[19] Plaintiffs also fail to state under *Twombly* how each of the alleged breach of express warranties caused Plaintiffs' injury. *Twombly*, 550 U.S. at 570.

information. Complaint at ¶¶ 94-175. As discussed above, *Riegel* teaches that state law claims which attempt to add to the requirements of the PMA or applicable regulations are expressly preempted. 552 U.S. at 324-25. Here, Plaintiffs do not state that these "Facts and Warranties" violate any specific federal law as required by *Riegel*. Rather, Plaintiffs suggest that what FDA did approve was, according to Plaintiffs, insufficient. Such a suggestion flies in the face of the approval by FDA of the PMA and challenges the decision of FDA in a way that would require additional labeling. *Riegel*, 525 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). As the Third Circuit recognized, "[a]llowing juries to perform their own risk-utility analysis and second guess the [agency's] conclusion would disrupt the expert balancing underlying the federal scheme." *Farina v. Nokia, Inc.*, 625 F.3d 97, 126 (3d Cir. 2010) (citing *Buckman*, 531 U.S. at 350-51)). Accordingly, any challenge to these materials on the basis of state statutory or common laws, assuming they are applicable to these facts, are expressly or impliedly preempted. *Id. See also Scanlon*, 2014 U.S. Dist. LEXIS at *16 (fraud, negligent misrepresentation and failure to file adverse event reports preempted).

The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), which appears to be the statute to which Plaintiffs refer in Count VI, prohibits "unfair methods of competition" and "unfair or deceptive acts or practices." 73 Pa. Cons. Stat. Ann § 201-3 (West 2012). In *Kee v. Zimmer, Inc.*, the court held that a consumer does not have a cause of action under the UTPCPL against the manufacturer of prescription medical devices because such manufacturers do not have a duty to disclose information directly to consumers due to Pennsylvania's adoption of the learned intermediary rule . 871 F. Supp. 2d 405, *408 (E. D. Pa. 2012). This is so because a claim under the UTPCPL requires proof of causation and reliance, and the "learned intermediary doctrine breaks the chain in terms of reliance, [because] the patient

cannot obtain prescription drugs without the physician no matter what [the patient] believe[s] about them." *Id*. In other words, "a private right of action under the UTPCPL requires proof of justifiable reliance and causation, and such requirements cannot be present when the defendant is a pharmaceutical company that did not sell its product directly to the patient." *Kester*, 2010 WL 2686467, at *14. The *Kee* court held that the same reasoning extends to manufacturers of prescription medical devices. 871 F. Supp. 2d at *410-11 dismissing UTPCPL claim against prescription medical device manufacturer). Therefore, the learned intermediary doctrine breaks the chain of causation and reliance with respect to Plaintiff's UTPCPL claim. *See id*. Accordingly, Plaintiffs claims under the UTPCPL must be dismissed on this basis as well.

**5. Plaintiffs' strict liability and negligent design claims are preempted (Counts X and XIII).**

Plaintiffs' strict liability (count X) and negligent design claim (Count XIII) are also preempted. Notably, Plaintiffs do not allege that the design of the Essure device they received was anything other than the design approved by FDA through the PMA process. Thus, to prevail on their state-law strict liability and negligent design claims, Plaintiffs necessarily would have to prove that the Essure device should have employed a design different from that approved by FDA. *Riegel* squarely forecloses any such claim. *See* 552 U.S. at 320 (MDA preempts "claims of strict liability . . . and negligence in the design" of a device). A strict liability claim or negligent design claim is the very type of generalized common law liability foreclosed under the law of this Circuit. *Williams v. Cyberonics, Inc*., 388 Fed. App'x 169, 171 (3d Cir. 2010) (affirming grant of summary judgment on strict liability, manufacturing defect and breach of warranty claims). Indeed, a state-law claim that would require a medical device to have a design different from that approved by the FDA through the PMA process is a frontal "attack[] on the risk/benefit analysis that led the FDA to approve" the device. *In re Medtronic Sprint Fidelis*, 623 F.3d at 1206; *accord Kemp v.*

*Medtronic, Inc*., 231 F.3d 216, 219 (6th Cir. 2000) (affirming dismissal of "strict products liability claims for defective design . . . as well as . . . claims for negligent design"). Accordingly, "this is the exact type of claim that is expressly preempted under § 360k(a)." *Gomez: v. St. Jude Med. Daig Div. Inc*., 442 F.3d 919, 930 (5th Cir. 2006). ("To permit a jury to second-guess the [device] design . . . would risk interference with the federally- approved design standards and criteria."); *Walker v. Medtronic Inc.*, 670 F. 3d 569, 580 (4th Cir. 2012) ("A common law tort claim that presupposes a Class-III device should have been designed in a manner other than that contemplated by its premarket approval is . . . expressly preempted by the MDA as interpreted by *Riegel*. "); *Wolicki-Gables*, 634 F.3d at 1301-02 (affirming district court's determination that "state commonlaw claims" – including claims of strict liability for . . . court defect and . . . liability for negligent design" – "were preempted");

Moreover, Plaintiffs' strict liability claims fail as a matter of well-settled Pennsylvania law. Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts which imposes strict liability on manufacturers of products sold "in a defective condition unreasonably dangerous to the user or consumer." *Mazur v. Merck & Co.*, 964 F.2d 1348, 1353 (3d Cir. 1992). Despite § 402A's general imposition of strict liability for unreasonably dangerous products, *comment k of* § 402A denies application of strict liability to products considered "unavoidably unsafe." These products include "prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 889-90 (Pa. 1996). In *Hahn*, the Pennsylvania Supreme Court made clear that *§ 402A* is inapplicable to prescription drugs. *Id.* The reasoning behind comment k is that some products, such as prescription drugs, present a unique set of risks and benefits that may be harmful to one person and beneficial to another. *Taylor v. Danek*

*Medical, Inc.*, No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998) While the Pennsylvania Supreme Court has not ruled on the application of comment k to medical devices, this court has followed other federal courts in predicting, based on its reasoning in *Hahn*, that the Pennsylvania Supreme Court would extend § 402A's comment k to exclude prescription ***medical devices*** from strict liability. *See, e.g., Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420, at *2 (W.D. Pa. Nov. 10, 2011) (Bissoon, J.) predicting that Pennsylvania Supreme Court would apply comment k to prescription medical devices): *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 750 (E.D. Pa. 2007) (Robreno J.) (same); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004) (Kelly, J.) (same); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (Diamond, J.) (same); *Murray v. Synthes (U.S.A.), Inc.*, No. 95-7796, 1999 WL 672937, at *6-8 (E.D. Pa. Aug. 23, 1999) (Hutton, J.) (same); *Burton v. Danek Med., Inc.*, No. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999) (Kelly, J.) (same); *Taylor v. Danek Med., Inc.*, No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998) (Broderick, J.) (same); *Kee v. Zinner, Inc.*, 871 F. Supp. 2d 405, 408 (E.D. Pa. 2012). Accordingly, Plaintiffs' strict liability claims must be dismissed for this additional independent reason. Based upon the same reasoning, this Court has ruled that a claim for failure to warn is also not cognizable under Pennsylvania law. *See, e.g., Soufflas*, 474 F. Supp. 2d at 750.

**6. Plaintiffs' negligent manufacturing claims are preempted (Count XI).**

Plaintiffs' negligent manufacturing claims under Count XI are also expressly preempted. In order to state a claim under *Riegel*, Plaintiffs would have to prove that the devices they received were manufactured in a different manner from that approved by FDA. *See, e.g., Riegel*, 552 U.S. at 328; *Wolicki-Gables*, 643 F. 3d at 1302; *In re Medtronic Sprint Fidelis*, 623 F.3d at 1207. Despite Plaintiffs' repeated use of the words "manufacturing" or "non-conforming product", *see*,

*e.g.*, Complaint at ¶¶ 269 (g), (h), (i), (j), (q), I, or (s), they do not ever allege that Defendants manufactured and placed into commerce, a device which did not comply with the manufacturing requirements that were part of the PMA approval or the PMA Supplements that dealt with manufacturing. Plaintiffs attach to their Complaints as Exhibits "C" and "D" several documents which they claim support the alleged negligent manufacturing claims. The documents attached are not even FDA documents, but rather, supposedly from the California Department of Public Health. These documents are not relevant to whether there has been a stated violation of federal regulations or parallel state law. Indeed, any argument that California imposed different manufacturing requirements than FDA runs headlong into *Riegel.* The reliance on these documents is misplaced for a number of other reasons as well. First, the report is issued by the California Department of Health under California law. Complaint, Exhibit "C". It has no bearing on any alleged *federal* violation. Second, the report is pure hearsay without foundation and a simple reading of the report shows that Defendants not only cooperated with the inspection, but also that the State confirmed that Defendants had properly responded to FDA on any related observations.[20] *Id.* Third, the issues noted were, in fact, addressed by the State of California, so they were not in any way concealed. Plaintiffs cannot cite to any law which provides them a private right of action to enforce these aspects of California law. Fourth, this allegedly occurred between 2005 and 2008 and any claim based on it is likely time-barred as a matter of law. Finally, there is not a single allegation that anything manufactured at the facility referenced in Exhibits C and D was problematic or that any devices were made there that are the subject of Plaintiffs'

[20] . Plaintiffs repeatedly state that "Form 483's" are issued after an inspection if an FDA inspector has observed conditions that violate the "F, D, & C" which Plaintiffs state renders Essure "adulterated." *See, e.g.*, notes 8 -11. However, this is plain wrong. As stated by FDA, the observations in a 483 have no binding effect on whether there is an actual violation of regulations or statutes. A form FDA 483 is not a final Agency determination of whether any condition is in violation of the MDA or any of its relevant regulations. *Inspections, Compliance, Enforcement, and Criminal Investigations: FDA Form 483 Frequently Asked Questions*, http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited April 24, 2015).

claims.[21] Accordingly, there is no basis for these claims and they must be dismissed for this reason as well.

Many courts have found similarly nebulous "manufacturing claims" expressly preempted, including courts in this Circuit. *See, e.g., Williams v. Cyberonics, Inc.*, 388 Fed. App'x 169, 171 (3d Cir. 2010) (affirming grant of summary judgment on strict liability, manufacturing defect and breach of warranty claims). *See also Gross v. Stryker*, 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012) (holding that "[a]llowing a plaintiff to plead non-specific [Good Manufacturing Practices ("GMP")] regulations as a basis for a parallel claim is inconsistent with the Supreme Court's reasoning in *Riegel*"); *see also In re Medtronic Inc.*, 592 F. Supp. 2d at 1157, *aff'd In re Medtronic*, 623 F.3d 1200 (holding that general allegations of failure to comply with FDA GMP are too vague to escape preemption, and are a "frontal assault" on the FDA's risk/benefit conclusion); *Bradley v. Baxter Healthcare Corp.*, Civ. No. 1:12-cv-00312-MR.-DLH, (W.D.N.C. Oct. 18, 2013), *adopted without separate opinion*, 2013 WL 5952060 (W.D.N.C. Nov. 6, 2013) (granting motion to dismiss and holding that a general allegation of violating "good manufacturing practices" was insufficient to state a parallel claim); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (holding that GMPs were too "vague and open-ended" to constitute a non-preempted parallel violation claim because they "would necessarily result in the imposition of standards that are 'different from or in addition to' those imposed by the MDA"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (holding that reliance on GMPs "are simply too generic, standing alone" to support a parallel claim).

**7. Plaintiffs' failure-to-warn claims are preempted (Count XII).**

[21] This is true of most of Plaintiffs' complaints. They are filled with overblown rhetoric, and citations to isolated facts, but lack any connection between those alleged facts—assuming they have any validity—and Plaintiffs or their alleged injuries. Further, this Count again alleges the same facts as do the fraud related counts. Compare Complaint at 206 and 269. For that reason, these claims should be dismissed under *Buckman* as well.

Plaintiffs' failure-to-warn claims under Count XII or any other legal theory based on a contention that Essure should be labeled differently are preempted. Regardless of the how these claims are phrased, to the extent Plaintiffs contend that Defendants failed to inform them or their doctors about risks allegedly associated with Essure, each of their claims "is, 'at bottom, a failure to warn claim.'" *See, e.g., Millman v. Medtronic,* No. C14-CV-1465, 2015 WL 778779, *5-6 (D. N.J. Feb. 24, 2015); *Hayes v. Howmedica Osteonics Corp.,* No. 08-6104, 2009 WL 6841859 at *6 (D. N. J. Dec. 15, 2009); *Delaney v. Stryker Orthopaedics,* No. Civ. A. 08-03210 DMC, 2009 WL 564243 at *3 (D. N.J. Mar. 5, 2009). *See also Timberlake v. Synthes Spine, Inc.*, No. Civ. A. V-08-04, 2011 WL 711075, at *7 (S.D. Tex. Feb. 11, 2011); *see also, e.g., Caplinger v. Medtronic*, 921 F. Supp. 2d 1206, 1219-24 (W.D. Okla. Feb. 6, 2013). 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, FDA. [22]

Significantly, Plaintiffs do not allege that Defendants failed to provide any of the warnings required by FDA through the PMA process. Instead, Plaintiffs assert that, to comply with state law, Defendants were required to have given additional warnings, beyond those required by FDA when it granted premarket approval to the Essure device. But, any claim based on a state-law requirement that Bayer provide different or additional warnings runs straight into § 360k(a). As the U.S. Supreme Court has explained, § 360k(a) "[s]urely would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings." *Riegel,* 552 U.S. at 329; *see also id*. at 320 (affirming dismissal of "claims of strict liability ... and negligence in the labeling of the [device]"); accord *Wolicki-Gables*, 634 F.3d at 1301-02; *In re Medtronic Sprint Fidelis,* 623 F.3d at 1205; *McMullen v. Medtronic, Inc*.,

[22] *See e.g.*, Compl. ¶¶ 279, 280.

421 F. 3d 482, 489-90 (7th Cir. 2005); *Blankenship v. Medtronic, Inc.*, No. 4:13-CV-1087 CEJ, 2014 WL 1226491, at *6; *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1177 (C.D. Ca. 2013); *Caplinger*, 921 F. Supp. 2d at 1221, 1223.[23]

[23] In fact, federal law specifically forbids manufacturers from issuing additional warnings beyond those prescribed by the FDA. "Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in . . . labeling … that would affect safety or effectiveness." *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. §360e(d)(6)(A)(i)). "If the applicant wishes to make such a change, it must submit, and the FDA must approve, and application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application." *Id.* (citing 21 U.S.C. §360(e)(D)(6); 21 C.F.R. § 814.39(c)). Thus, any claim that rests on a state-law duty to issue different or additional warnings necessarily fails because '[u]nder the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013).

### D. *Buckman* Impliedly Preempts Plaintiffs' Fraud on the FDA Claims (Counts VII and VIII)

Plaintiffs allege that Defendants engaged in conduct which was aimed at concealing information from FDA in Counts VII (fraudulent concealment) and VIII (fraud misrepresentation) as well as allegations incorporated into every other count.[24] This alleged concealment appears to involve a number of areas of reporting to FDA. First, Plaintiffs allege that Defendants failed to report various product complaints or adverse events. *See, e.g.*, Complaint at ¶¶ 206 (b), (c), (d), I, (g), (h), (i), (j), (k), (l), (n), (o), (p)-(u). Second, as discussed above, Plaintiffs allege that Defendants concealed "non-conforming product." *See id.* at ¶¶ 205-207. Third, Plaintiffs allege that Defendants altered medical records to reflect less pain than was actually reported during clinical studies which "were required to go through the PMA process." *Id.* at 206(u). Plaintiffs also allege that Defendants "concealed" various items or issues from FDA: "the risk assessment for safety of loose coils in its Risk Management Plan;" failing to use "pre-sterile and post-sterile cages;" not considering the "complaints" that the "product migrated;" and manufacturing "without a license" as well as other "observations" (not conclusions) noted in its attached Exhibits.

Each of these claims at Counts VII and VIII and similar ones elsewhere in the Amended Complaints involve misrepresentations or omissions which allegedly were intentionally made during Defendants' interactions with FDA as part of the PMA process or afterwards. This is precisely the type of allegations addressed by the Supreme Court in *Buckman*, which held that the such claims were impliedly preempted.

[24] While Plaintiffs also contend that Defendants concealed this same information from the Plaintiffs and their physicians, they cite to no law requiring such disclosures to patients or physicians. As there is no legal requirement other than those imposed upon the device by FDA, any suggestion that Defendants should have disclosed information to the patient or physician would be a change to the PMA requiring approval by FDA. As such, Plaintiffs claims are preempted for these reasons as well. *Riegel*, 552 U.S. at 329.

In light of the regulatory framework established by FDA, Plaintiff's state law fraud claims conflict with, and are therefore, impliedly preempted by federal law. *Buckman*, 531 U.S. at 348. This conflict is based on the fact that the federal statutory scheme "amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.*

Here, Plaintiffs evidently agreed with this Court that, if their claims are based on misrepresentations allegedly made to FDA, these claims fit within *Buckman* and cannot proceed. Transcript of April 9, 2015 Hearing, Exhibit A at 9. Whether it is the concealment of allegedly "non-conforming product", the failure to disclose adverse events, or even the submission of allegedly fraudulent clinical trials data, Plaintiffs' claims are that Defendants actively concealed information from FDA during pre- and post-approval interactions with the agency. Complaint at Counts VII and VIII (and certainly Counts VI and IX and others as well). These claims fit squarely within the four corners of what *Buckman* preempts and therefore, they must be dismissed with prejudice. Indeed, Plaintiffs' own citizen petition filed after these Complaints contains a repetition of these allegations – demon demonstrating that Plaintiffs believed that the evaluation of these claims was within the province of FDA and not this Court.

Alternatively, these counts should be dismissed for failure to meet the requirements of Rule 9. There is simply no specificity in these Complaints as to how, when and where the alleged misrepresentations were made, to whom they were made, and how some of these representations are fraudulent. A complaint that merely alleges entitlement to relief, without alleging facts that show entitlement, must be dismissed. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 211 (3d Cir.

2009). Courts need not accept "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements . . . ." *Iqbal*, 556 U.S. at 678. "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*. at 679. Lack of compliance with Rule 9(b)'s pleading requirements is treated as a failure to state a claim under Rule 12(b)(6). *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 783 (4th Cir. 1999). In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. The purpose of the heightened pleading standard is to require the plaintiff to state the circumstances of the alleged fraud with sufficient particularity to "place the defendant[] on notice of the precise misconduct with which [it] [is] charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." *Seville Indus. Mach. Corp. v. Southmost Mach. Corp*., 742 F.2d 786, 791 (3d Cir. 1984); *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007).

To satisfy the heightened standard of Rule 9(b), a "plaintiff must plead or allege the date, time and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d at 200. In general, the complaint alleging fraud must describe the "who, what, when, where and how of the events at issue." *In re Rockefeller Ctr. Props. Secs. Litig*., 311 F.3d 198, 217 (3d Cir. 2002). Rule 9(b) is meant to prevent "fishing expeditions" as well as "spurious charges of immoral and fraudulent behavior." *United States ex rel. Bledsoe v. Cmty. Health Sys*., 501 F.3d 493, 510 (6th Cir. 2007).

Here, the pleading alleges only bare bones conclusions which are inherently implausible. First, Plaintiffs simply and repeatedly recite twenty-six paragraphs of regulations. Complaint at 205. Then, without any support, Plaintiffs allege that Defendants violated these regulations without stating which allegation relates to which regulation. *Id*. at 206. Further, Plaintiffs do not

state sufficient facts to put Defendants on notice of any fraud. For example, Plaintiffs cite as the first basis for their claim that Defendants did not timely file reports with FDA. To support this, Plaintiffs attach Exhibit "B." When one reviews Exhibit "B," it reveals on its face that Defendants DID submit the very reports which Plaintiffs submit they did not submit "timely." Even if filing the alleged reports several days past what appears to be the due date were a violation of federal law, FDA accepted these reports over ten years ago and did not complain. To submit that these facts constitute fraud makes a mockery of federal pleading. Accordingly, because Plaintiffs have not alleged sufficient facts under Rule 9, these claims should be dismissed with prejudice for this reason as well. *See, e.g.*, *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, *1039 ( D. Az. 2014); *Brady v. Medtronic, Inc*., No. 13-CV-62199-RNS, 2014 WL 1377830 *7-8 (S.D. Fla. Apr. 8, 2014);

**E. Plaintiffs' Claims are not "Plausible" under *Iqbal* and *Twombly***

Finally, in addition to preemption, and the other grounds addressed above, Plaintiffs' Amended Complaints must be dismissed for failing to plead claims that are "plausible." The Court itself described "plausibility problem[s]" if the Complaint failed to adequately allege cognizable claims. Transcript of April 9, 2015 Hearing, Exhibit A at 8. Although Plaintiffs' counsel stated that they do not suffer from such a "plausibility problem," Defendants submit that they do.

According to the Supreme Court, a complaint must state a claim to relief that is "plausible on its face" as determined by a judge's "judicial experience and common sense." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Plausibility requires "more than a sheer possibility that the defendant acted unlawfully." *Iqbal*, 556 U.S. at 678. Furthermore, the plausibility of a claim depends on the amount of factual

material that the plaintiff includes in the complaint; district courts "*are not bound to accept as true a legal conclusion couched as a factual allegation*." *Twombly*, 550 U. S. at 555 (emphasis added). Plaintiffs cannot merely offer a "formulaic recitation of the elements" or an "unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555; *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007); *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009).

Here, Plaintiffs repeatedly fail to allege any specific violations of federal law. Because there are none which form a basis for their claims, they recite bare assertions of violations, repeatedly quoting sections of federal regulations without any reference to Essure. This, without more, does not stand up under *Iqbal* and *Twombly*. 556 U.S. at 678; 550 U.S. at 555. Further, Plaintiffs do not state any specific allegation of how any damage they claim is tied to the alleged violations of state law. *See, e.g.*, Compl. At ¶ 126 ("This breach caused Plaintiff's damages.") Rather, they make nothing but conclusory and bare allegations that their injuries were caused by Defendants' unspecified conduct.

In an apparent attempt to paper over this problem, Plaintiffs have substituted length and repetition for substantive pleading. Plaintiffs' Complaints – almost 300 paragraphs long (not counting dozens of subparts) – are extremely hard to comprehend and purposefully confusing. Plaintiffs' claims are a deliberate attempt to obfuscate the facts and law in order to circumvent federal preemption grounds which preclude them. And, moreover, some of Plaintiffs' allegations are just plain wrong.

Defendants will use as examples for this Court, several repeated allegations—each of which is patently incorrect and demonstrates in part why Plaintiffs' claims should be dismissed for additional reasons under *Iqbal* and *Twombly*.[25]

First, Plaintiffs repeatedly state that some or all of their claims are based upon violations by the Defendants of the "Conditional Premarket Approval" or "CPMA" that FDA gave to Essure. *See, e.g.*, Compl. at ¶¶ 15, 24, 65. Plaintiffs further allege that Essure was "conditionally approved" as opposed to "outright PMA (premarket approval), the 'gold standard.'" *Id.* at ¶ 56 (parentheses added). Plaintiffs' allegations show a complete misunderstanding of the facts, FDA terminology and the law. ***Essure was granted what Plaintiffs refer to as the "gold standard" as it was approved under the PMA process.*** ***(****See* "Approval Order"). There is no such term as "conditional premarket approval' and Plaintiffs have not cited to any statute or regulation which uses or defines it. So, contrary to Plaintiffs' allegations to the contrary, Essure was approved under the most stringent standard for a medical device and it was not granted some lower level "conditional approval."

Second, these improperly pleaded facts lead to yet another gross error by Plaintiffs. Plaintiffs allege that Defendants supposedly violated the alleged conditions of approval and that as a result, the PMA is invalid as a matter of law and as a result Essure cannot be sold in the United States. (*See e.g.*, Complaint at ¶¶ 16, 57, 58.) However, there were no conditions precedent to the FDA approval of Essure under its standards for approval. So, while Defendants strongly dispute that there is any violation of any standard, there is simply no basis for Plaintiffs' contention that the Essure PMA has been rendered "invalid." *Id.* at ¶ 57. Essure's PMA has never been found to be invalid by FDA—indeed, Defendants have never even received a warning letter from FDA.

[25] All of Plaintiffs' allegations are wrong, but the error in the following example can be shown without reference to documents outside the limited record of this Motion.

Answer at ¶ 19. And, Plaintiffs conveniently fail to cite to any law or document which so states—because there is none. Accordingly, not only are these claims preempted under *Buckman*, each and every allegation made by Plaintiffs that has an "invalid" PMA are false—and should be stricken as a matter of law. [26]

Third, Plaintiffs claim that Bayer had to "submit a PMA amendment" to notify FDA that it was the new owner of the Essure PMA, and failed to do so. *See, e.g.,* Compl. At ¶¶ 62-63. Plaintiffs, of course, cite to no law for this proposition. Contrary to Plaintiffs' allegations that the PMA is allegedly invalid because Bayer HealthCare LLC did not properly notify the FDA of its acquisition of Conceptus, Inc., *see* Compl. At ¶¶ 62-63, 65. FDA's website confirms that FDA was properly notified that Bayer HealthCare, LLC acquired Conceptus on June 5, 2013[27] and the same was acknowledged by the FDA in a letter dated August 7, 2013. *See* Defendants' Answer, at ¶ 63.[28] Again, Plaintiffs suggestion of some regulatory responsibility and attendant failure by Defendants is just plain false.

Fourth, as a repeated basis for almost all of their claims, Plaintiffs suggest Defendants have breached "federal law" because they "fraudulently concealed" from FDA "16,047 entries of complaints" from consumers. Complaint at ¶ 206(e) (citing to Exhibit E). This, Plaintiffs contend, is based upon a "concealment" memorialized by an FDA inspector during a plant visit

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[26] *See* Fed. R. Civ. P. 12(h).

[27] *See* http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/ucm371014.htm#review (last visited April 13, 2015).

[28] Furthermore, ownership of a PMA may be transferred at any time before or after FDA approval. If a PMA has already been approved, as is the case here, the new owner need only report that the transfer of PMA ownership will not result in a change or modification that would require a submission of a PMA supplement or affect the conditions of approval applicable to the PMA. *See* 21 C.F.R. § 814.39. Because Plaintiffs' claims are based in part of the Defendants' alleged improper notification to the FDA of the change in ownership, the Court may properly consider the publicly available information regarding this issue in evaluating the sufficiency of the claims. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (holding a court may consider "documents incorporated into the court by reference" in evaluating a motion to dismiss).

and observations made in a "Form 483" noting "observations."[29] *Id.* First, there was no concealment whatsoever. The document attached by Plaintiffs to their Complaints on its face reveals that, during the inspection and at the request of the inspector, FDA was provided by Defendants with a CD-ROM which contained "16, 047 entries for complaints." *Id.* Further, the documents clearly note that the inspector's review was simply part of his routine examination of Defendants' complaint handling procedures. Complaint, Exhibit E at 2. There is no indication that these complaints were "concealed", let alone is there any "observation" that Defendants violated federal law. Further, Plaintiffs' allegations fail to recognize is that there is no obligation to submit "complaints" to FDA—in fact, such a suggestion directly affronts FDA's regulations. *See* 21 C.F.R. § 820.198. Defendants review complaints to see if they are required to be reported to FDA—there is no requirement to blindly submit them to FDA as this would defeat the very purpose of the regulation. *See* 21 C.F.R. § 803. In addition, not only are the observations noted by Plaintiffs multiple hearsay, a Form FDA 483 is not a final Agency determination of whether any condition is in violation of the MDA or any of its relevant regulations. *Inspections, Compliance, Enforcement, and Criminal Investigations: FDA Form 483 Frequently Asked Questions*, http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited April 24, 2015). Not only are these claims preempted, Plaintiffs' reliance on this alleged "concealment" is baseless and any claim based upon this alleged federal violation (and there is none) should be dismissed. [30]

[29] According to the FDA's official website, an FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgement [sic] may constitute violations of the Food Drug and Cosmetic Act and related Acts. FDA, **[**8]** *Inspections, Compliance, Enforcement, and Criminal Investigations: FDA Form 483 Frequently Asked Questions*, http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited April 24, 2015).

[30] This argument applies with equal force to Plaintiffs' claims regarding alleged "non-conforming material" and "failing to use pre-sterile and post-sterile cages." *See* Complaints at Exhibits C and D. Both reports cited to are pure hearsay and do not contain any conclusion that any federal law was violated.

Fifth, Plaintiffs also repeatedly allege that a basis for federal noncompliance is Defendants' untimely filing of various reports post approval. *See, e.g.*, Complaint at ¶ 206(a). Plaintiffs, however, may not assert a claim based on Defendant's alleged breach of a duty to file timely reports with the FDA. *See In re Medtronic Sprint Fidelis*, 623 F.3d at 1205-06. Plaintiff's attempt to recast a claim for violation of the FDCA as a state-law negligence claim is impliedly barred by § 337(a) and *Buckman*. Beyond that, a simple review of Exhibit "B" to Plaintiffs' Complaints demonstrates that Defendants submitted the reports and in some cases, FDA notes indicate that they were received perhaps a few days late. This does not mean that Defendants submitted the reports late, and it does not mean that they were untimely. FDA accepted these reports over ten years ago and have never suggested that these reports were untimely, let alone that the submission of these reports was in any way a violation of federal law or the PMA. Accordingly, these allegations too are not only preempted, they are baseless.

Having already amended their complaints once (or in the case of Ms. Walsh, twice) in order to try to plead a plausible entitlement to relief, Plaintiffs' failure to do so demonstrates the futility of any further amendment. While the Court has discretion to permit an amendment, *Foman v. Davis*, 371 U.S. 178, 182 (1962), futility is one of the grounds justifying denial of leave to amend. *Phillips v. County of Allegheny*, 515 F.3d 224, 245 (3d Cir. 2008). Allowing an amendment would be futile if "the complaint, as amended, would fail to state a claim upon which relief could be granted." *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). "In assessing futility, the District Court applies the same standard of legal sufficiency as applies under Rule 12(b)(6)." *Id.*

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http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited April 24, 2015) (483s are not conclusions as to a violation of any law, but rather observations to which the party inspected responds).

Here, even if Plaintiffs could come up with the facts that they to date have failed to plead, their claims based on purported violations of the Essure PMA approval, federal regulations and federal law are preempted either under *Riegel* or *Buckman* for the reasons stated above. Thus, as a matter of law, repleading would be futile. The Court should therefore dismiss the Plaintiffs' actions with prejudice. *See Smith v. DePuy Orthopaedics, Inc.*, No. Civ. A. 11-4139 JAP, 2013 U.S. WL 1108555 (D.N.J. Mar. 18, 2013) (finding that any motion to amend would be futile where claims based on a Class III medical device are all preempted), *aff'd*, 552 Fed. App'x. 192 (3d Cir. 2014).

## VI. CONCLUSION

For all of the foregoing reasons and authorities, Defendants respectfully submit that all of the Plaintiffs' claims in the five consolidated matters are preempted by the MDA's express preemption clause, 21 U.S.C. § 360k(a), as interpreted by the Supreme Court in *Riegel*. Further, Plaintiffs' claims are impliedly preempted under *Buckman*. Finally, there are independent bases for dismissal of Plaintiffs' claims including the failure of Plaintiffs to state plausible claims under *Iqbal* and *Twombly*. As such, all of Plaintiffs' claims fail as a matter of law, and Defendants respectfully request that this Court dismiss the five First Amended Complaints in their entirety with prejudice and grant Defendants such other further relief as the Court deems appropriate.

Dated: April 29, 2015

Respectfully submitted,

**ECKERT SEAMANS CHERIN & MELLOTT, LLC**

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**CERTIFICATE OF SERVICE**

I, ALBERT G. BIXLER, attorney for Defendants, Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer Essure Inc., and Bayer HealthCare LLC, in the above-captioned action, certify that a true and correct copy of the foregoing 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. was electronically filed with the Court on April 29, 2015, and that all counsel of record received service of same via the Court's Electronic Filing System.

*/s/ Albert G. Bixler*
Albert G. Bixler