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

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

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

REPLY OF DEFENDANTS BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER ESSURE INC. AND BAYER HEALTHCARE LLC IN SUPPORT OF THEIR OMNIBUS MOTION FOR JUDGMENT ON THE PLEADINGS UNDER FED. R. CIV. P. 12(C)

I. INTRODUCTION

Defendants filed an Omnibus Motion for Judgment on the Pleadings Under Fed. R. Civ. P. 12(c), which demonstrated that the claims set forth in Plaintiffs' Amended Complaints (hereinafter "Complaints" or "Amended Complaints") are preempted under federal law or otherwise should be dismissed as a matter of law.[1] Plaintiffs spend the majority of their 115-page Response arguing that they are magically cloaked in immunity from the application of *Riegel v. Medtronic Inc.*, 552

[1] All citations to the Complaints are to the First Amended Complaint in *McLaughlin v. Bayer Corp., et al.*, 2:14-cv-07315-JP. *See* footnote 2 to Memorandum of Law in Support of Motion for Judgment on the Pleadings (hereinafter "Motion").

U.S. 312 (2008) and *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001) and any case, including those from this Circuit, which holds as preempted claims which are the same or very similar to those alleged by Plaintiffs. *See, e.g.*, *Williams v. Cyberonics*, 388 Fed. Appx. 169, (3rd Cir. 2010) (citing *Horn v. Thoratec, Inc*., 376 F.3d 163, 165-66 (3d Cir. 2004)).

In arguing that *Riegel* does not apply to the Essure system ("Essure"), Plaintiffs make the astonishing argument that this Court should hold that Essure's PMA approval is invalid. This argument flies in the face of the holding of *Riegel*. Simply stated, if the preemption provision of the MDA means anything at all, it means that courts cannot overrule FDA approval of a device. Moreover, this argument ignores the fact that FDA has not taken any step to recall Essure or to invalidate its approval. Just the opposite has occurred. FDA has examined Essure's safety and validated it. FDA's own website shows a valid PMA in place for Essure. Indeed, since Essure's original approval in 2002, FDA has approved dozens of supplements to the PMA. Finally, Plaintiffs' own actions demonstrate that they themselves know that only FDA can take the action they seek. If that were not the case, why would Plaintiffs' counsel file a citizen petition with FDA asking them to invalidate the PMA—especially if, under Plaintiffs' reasoning, it had somehow automatically been invalidated? As set forth in section II, below, Plaintiffs' "invalidity" argument is factually and legally specious.

Plaintiffs then argue that even if the PMA is still valid they can proceed on their claims of negligent entrustment, breach of express warranty, fraudulent and negligent misrepresentation, Unfair Trade Practices And Consumer Protection Law ("UTPCPL") violation and "negligent pharmacovigilance" because Plaintiffs claim those counts are not preempted and are valid under state law. Response at 4. Plaintiffs are wrong. Those claims are preempted or otherwise without legal merit, as set forth in Section IV, below. Notwithstanding their admission that if the PMA for

Essure is valid only those four claims survive, Plaintiffs then argue that virtually all of their other claims are parallel state claims which survive preemption. Once again, they are wrong. As set forth below in Section IV, below, those claims are preempted and/or not cognizable as a matter of state law.

Defendants cite to dozens of cases in their Motion which support both express and implied preemption of Plaintiffs' thirteen claims. Rather than distinguishing these cases, Plaintiffs disregard most of them as if they were never decided. Moreover, they try to re-cast or disguise the language of their own pleading in an effort to avoid preemption, ignore the fact that they previously raised all of their claims in a citizen petition filed with FDA—a fact which is never mentioned—and attempt to gloss over the fact that Plaintiffs do not identify any specific violation of federal law which supports their claim for damages as required to defeat preemption under *Riegel*. Rather, they simply repeat a series of factual allegations and the text of federal regulations and claim that there has been a "violation." Plaintiffs apparently believe that if they repeat these arguments enough, they must be correct.

Moreover, although Plaintiffs cite a number of supposed facts, and repeat lengthy citations to federal regulations, the Complaints and Response fail to allege, let alone support, the connection between these alleged facts, the regulations and Plaintiffs' alleged injuries. Simply alleging isolated facts and citing regulations does not create any plausible allegation of proximate cause. For example, Plaintiff Walsh, who alleges to have received Essure in 2008, relies in her Complaint on events occurring years after that date, while Plaintiff Strimel, who received her Essure in 2013, is apparently relying on events which supposedly occurred over ten years before that date. Thus, Plaintiffs ignore not only *Riegel* and *Buckman,* but also the teachings of the Supreme Court in *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) and *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544,

570 (2007) (hereinafter "*Iqbal/Twombly*")—which is why it is not surprising that Plaintiffs give short shrift to these two cases in their Response.[2]

Defendants address the specific Counts of Plaintiffs' Complaints in Section IV, below. To assist the Court in its consideration of each of Plaintiffs' 13 counts, a chart is attached as Exhibit 1 hereto, which identifies the pages of Defendants' Motion, Plaintiffs' Response, and this Reply where each count is discussed.

II. ESSURE IS A MEDICAL DEVICE WITH PREMARKET APPROVAL (PMA) SUBJECT TO EXPRESS AND IMPLIED PREEMPTION UNDER *RIEGEL* AND *BUCKMAN*

Plaintiffs' central and lead argument is that Essure is not subject to preemption analysis because the "CPMA is invalid" and that this Court "may deny Defendants' preemption motion without even determining whether Plaintiff has alleged 'parallel claims'." Response at 3, 32-37. This argument is utterly without basis.

Essure was initially approved by FDA through the PMA process in November 2002. http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020014a.pdf. There is no dispute that there are dozens of FDA-approved supplements to the PMA dating up to December 11, 2014. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p020014 (last updated by FDA on June 24, 2015 and viewed on June 25, 2015). There is also no dispute that each time a supplement was reviewed by FDA, Essure was reviewed as a whole for safety and effectiveness and compliance with the PMA and applicable regulations. FDA has also approved Essure's Instructions For Use, Patient Labeling and Summary of Safety and Effectiveness, all of which remain posted on the FDA website. Motion at 7-8. It is also undisputed that FDA can

[2] Plaintiffs also say they are not subject to preemption because of a "presumption against preemption." However, as detailed in Section III below, they fail to mention that the Supreme Court in *Buckman* refused to apply any such presumption to the express preemption provision of the MDA, 531 U.S. at 352, and in applying the express preemption provision to PMA-approved devices, the *Riegel* Court never mentioned it.

withdraw its approval order at any time, but has never done so for Essure. *Riegel*, 552 U.S. at 319-20. In order to withdraw approval, however, FDA must follow administrative procedures which guarantee due process to the PMA holder—it cannot simply "invalidate" a PMA. 21 CFR §814.46(b)(2)(c) - 2(e).

Essure was independently reviewed recently by FDA for safety and effectiveness. The very same injury claims asserted by Plaintiffs in these cases were either made by them or others to FDA when this review occurred, and the documents attached to the Complaints as Exhibits were presumably available to FDA at that time. After reviewing all the available data, FDA has not concluded that the data requires a recall or additional warnings on the device, and has certainly not concluded that the PMA for Essure should be withdrawn as Plaintiffs argue should occur here. *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015). Further, earlier this year Plaintiffs raised their claims directly with FDA in a citizen petition which was dismissed only a few months ago.[3] Plaintiffs do not address their submissions to FDA in their Response. This is because these filings by Plaintiffs demonstrate FDA's exclusive development and oversight of its complex regulatory system for review of Class III PMA approved medical devices, including Essure.

In the recent case of *Millman v. Medtronic*, a Court within the Third Circuit explained the holding of *Riegel* as follows:

> The Court explained that the MDA preemption clause establishes a two-step procedure for determining if state law claims are preempted. First, a court must determine whether "the Federal

[3] http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0001 (viewed on June 29, 2015) (citizen petition); http://www.regulations.gov/#!documentDetail;D=FDA-2015-P-0569-0005 (viewed on June 29, 2015) (dismissal by FDA and referral as trade complaint). FDA has announced that it will hold an Advisory Committee Meeting related to these complaints on September 24, 2015.

> Government has established requirements applicable to" the particular medical device. *Id.* at 321. If it has, the court then must determine whether the state law claims raised by the plaintiffs would impose "requirements with respect to the device that are 'different from, or in addition to'" the federal requirements and that relate to either (i) "safety or effectiveness" or (ii) "any other matter included in a requirement applicable to the device [under the MDA, 21 U.S.C.] § 360k(a)." *Id.* at 321–23. If both conditions are satisfied, then the claim is preempted. *(footnote omitted)*

No. 14-cv-1465, 2015 WL 778779, at *4 (D.N.J. Feb. 24, 2015). *See also Otis-Wisher v. Medtronic, Inc.*, No. 14-3491, 2015 WL 3557011 (2d Cir. June 9, 2015). Almost every court which has discussed *Riegel* since the Court's pronouncement on express preemption under the MDA has held that PMA approval by FDA means that federal requirements attach to medical devices and the first prong of *Riegel* is therefore met. *See, e.g., Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 775 (D. Minn. 2009); *Colombini v. West Chester County Health Care Corp.*, 24 Misc. 3d 1222(A), 2009 WL 2170230 (N.Y.S. 2009). This is because the PMA process itself is a form of "federal safety review" which establishes specific federal requirements for an approved medical device such as Essure. *Horowitz,* 613 F. Supp. 2d at 279.

In order to evade *Riegel* and its progeny, Plaintiffs claim that the PMA is "invalid" and therefore, there are no "established requirements" for Essure. Plaintiffs can point to no document which says the Essure PMA is invalid. That is because none exists. In fact, Plaintiffs do not even attempt to explain why FDA's own website says the Essure PMA was and is approved. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015); http://www.accessdata.fda.gov/cdrh_docs/pdf2/p020014a.pdf (2002 Approval). A

simple internet search of Essure and PMA will pull up these and numerous other links to FDA's website regarding Essure's federally-approved status. Moreover, Plaintiffs do not explain why they asked FDA in their citizen petition filed in 2015 to "invalidate" the PMA if indeed it was already "invalid."

Although Plaintiffs point to language in the initial PMA approval for Essure that states that "failure to comply with the conditions of approval invalidates this approval order," they do not point to any violation found by FDA let alone one which would "invalidate" the PMA, or any document or statement by FDA which says the Essure's PMA is "invalid." The two cases Plaintiffs cite for the proposition that a court can find a PMA "invalid" (Response at 33) were decided under *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 477 (1996), well before *Riegel* which held that PMA does establish federal requirements for the approved device. Both cases also involved products that had already been recalled from the market. In *Woods v. Gliatech*, 218 F. Supp. 2d 802 (W.D. Va., 2002), the "FDA had formally determined that Gliatech committed misconduct during the approval of the PMA" and "Gliatech pled guilty because it failed to notify FDA of adverse events, adulterated a medical device and submitted a materially false and misleading report." *Id.* at 21. Similarly, in *In re St. Jude Med. Inc.*, 2004 WL 45503, at *52-54 (D. Minn. Jan. 5, 2004), FDA advised the manufacturer that the recall was "an alternative to a Food and Drug Administration legal action to remove the defective products from the market." Essure, in contrast, remains on the market with full FDA approval. These cases have no application here.

Beyond that, the supposed factual basis for Plaintiffs' claim of regulatory violations is totally specious. Throughout their Response, Plaintiffs assert that Defendants were "cited" or "violated" federal regulations. The alleged support for this is attached to their Complaints. The documents attached to the Amended Complaints as Exhibits "A-G" range from what appears to be

an FDA website page to reports from the State of California.[4] Contrary to Plaintiffs' contention in their Response, these document do not recite violations of federal law. First, Plaintiffs admit that the California documents, Exhibits C and D, are not attached to show any state violation—and that is all they could be used to demonstrate. Response at 107. These state-created documents relating to state regulations are completely irrelevant even by Plaintiffs' own admission. Further, Exhibits F and G are FDA Form 483 inspection reports in which "observations" are noted.[5] Contrary to Plaintiffs' contention, these reports of observation *do not* establish any federal violation as a matter of law. As discussed in Defendants' Motion, these reports cannot be construed as anything more than observations, and they are not to be construed as federal violations:

> The FDA Form 483 *does not constitute a final Agency determination* of whether any condition is in violation of the FD&C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. *The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.*

http://www.fda.gov/ICECI/Inspections/ucm256377.htm (emphasis added, and last visited June 18, 2015). *See also In re SFBC Int'l, Inc. Sec. & Derivative Litig.*, 495 F. Supp. 2d 477, 481 n.2 (D.N.J. 2007) (Form 483 constitutes a list of "objectionable" conditions requiring no mandatory action by manufacturing facilities); *Sekisui Am. Corp. v. Hart*, 15 F. Supp. 3d 359, 364 (S.D.N.Y. 2014) (FDA rules prohibit inspectors from referring to Form 483 observations as violations

[4] Exhibit A is a picture, and Exhibit B appears to be an FDA web page which cannot be deciphered except to show receipt dates. Nowhere in any of these documents is any federal violation stated nor can these documents be construed to support such an allegation. Moreover, nowhere is there any attempt to tie these documents to any alleged injury of these Plaintiffs.

[5] Exhibit E to the Amended Complaints is a June 26, 2013, "Establishment Inspection Report" in which the inspector noted that he "was not issuing a FDA [Form] 483" as a result of the inspection. So Exhibit E is not even what Plaintiffs purport it to be in their Amended Complaints or Response.

because the agency considers the "circumstances, facts and evidence" of a case, not solely Form 483 observations, before deciding whether a facility has violated FDA regulations). In none of the cases in which Form 483 Observations were made concerning Conceptus can Plaintiffs point to any such "further action" on the part of FDA regarding Essure.

Further, a review of the Complaints' Exhibits themselves demonstrates that Plaintiffs consistently misstate their contents. Here is a comparison of Plaintiffs' allegations and the actual documents they rely upon.

Plaintiffs state: Defendants used non-conforming materials and rejected materials.

> Plaintiffs repeatedly allege that Defendants used non-conforming materials in manufacturing Essure, used rejected materials or manufactured goods out of specification. ("Defendants were cited on numerous occasions by the FDA for not only using non-conforming product, rejected material and product which did not conform to specifications," Response at 109.) Plaintiffs are presumably relying on a *single 2003* Form 483 for these allegations. Complaints Exh. G. However, that document only notes that proper paperwork was not completed during the *rejection* of non-conforming materials—not that non-conforming or rejected materials found their way into devices which were finished, let alone placed into commerce. There is no observation of any non-conforming material actually being used, let alone in a device received by Plaintiffs. Moreover, nowhere do Plaintiffs explain how this documentation error (assuming one existed) from 2003 is in any way related to Plaintiffs' alleged injuries, especially since none of the Plaintiffs received Essure for at least another five years.

Plaintiffs state: Defendants failed to adopt "corrective and preventative actions" as required.

> In support of this contention, Plaintiffs cite to a 2011 Form 483 which contains a statement that "Corrective and Preventative action activities and/or results have not been documented." Complaints Exh. F at 3. The Form 483 does not say that such actions were not taken, only that they were not, in the eyes of the inspector, properly documented. This is at most a documentation error, and nowhere have Plaintiffs even attempted to explain its relevance to their claims. That same Form 483 also notes that the observation was corrected and verified that day.

Plaintiffs state: Defendants failed to disclose the "complaint spreadsheet".

> Plaintiffs cannot even point to an "observation" by FDA where Defendants' purported failure to provide such "complaint spreadsheet" to FDA is described as an "observation" let alone a violation. This is hardly surprising given that complaints are not reportable events. FDA regulations require the maintenance of a complaint handling system which

Defendants had in place. 21 C.F.R. § 820.198(a). Those same regulations, however, make plain that a "complaint" does not equate to a reportable adverse event. *See* 21 C.F.R. § 820.198(a)(3) (specifying that a manufacturer must evaluate complaints to determine whether they are reportable under 21 C.F.R. § 803). As shown on page 2 of Complaints Exh. E (which is an Inspection Report and not even a Form 483), Conceptus provided a copy of the Excel file to the FDA inspector as requested. So assuming Plaintiffs are referring to the Excel file when they refer to a "complaint spreadsheet," Defendants maintained one and provided it to FDA as requested, and had no legal obligation to provide it before that request. Thus, there is not a shred of support for Plaintiffs' insinuation of any impropriety about how complaints were handled.

Plaintiffs state: Defendants failed to report perforations.

Once again, this allegation purports to stem from the January 2011 Form 483.[6] Complaints Exh. F. First, as discussed above, these are only observations, and not violations. Second, what Plaintiffs fail to tell the Court is that perforations are already a warned-about event in the Essure labeling, and have been from the time the device was approved. The Summary of Safety and Effectiveness, 2002 Patient Labeling and 2002 Physician Labeling all list perforations as a possible adverse event.[7] Thus, Plaintiffs' contentions that somehow information about perforations was withheld is simply false—it was always in the warnings provided to doctors and patients and is still listed in the FDA website. Indeed, when FDA reviewed the safety profile of Essure, it again noted that perforations were observed in the clinical trials and that perforations were known risks of the device. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015).

Plaintiffs state: Defendants' risk analysis was incomplete.

Again, this relates to the same 2011 Form 483 discussed above, which observes that the "Design Failure Modes Effects Analysis" does not specifically include as a potential failure mode the location of the Essure coil in the peritoneal cavity. Complaints Exh. F at 2. Plaintiffs have not cited any evidence that FDA found this to be a violation of any regulation or took any took action on this point, because there is none. Finally, like all of Plaintiffs' references to the isolated Forms 483s relating to Essure, there is no attempt to correlate this supposed problem to any of the Plaintiffs' injuries.

[6] This allegation, and the others, are demonstrably false, but demonstrating their falsity would require reference to FDA and Conceptus correspondence outside of the present record. For the purposes of this Motion, Defendants will only rely on the materials attached to the Complaints and/or subject to judicial notice under Fed. R. Evid. 201.

[7] Summary of Safety and Effectiveness, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014b.pdf; 2002 Patient Labeling, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014d.pdf; 2002 Physician Labeling, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf

Plaintiffs state: Defendants manufactured Essure at an unlicensed facility.

> Plaintiffs cite a California state inspection report for this (Complaints Exh. D) and somehow argue that it is a violation of FDA manufacturing regulations. They cite to no document showing a citation by FDA, because there is none. FDA has never cited Defendants for violation of its manufacturing regulations. Beyond that, once again, Plaintiffs have failed to show how this 2008 State of California citation is in any way related to any injury Plaintiffs allege.

Plaintiffs state: Defendants were cited for not using "pre and post sterile cages."

> The documents Plaintiffs cite say nothing of the kind. In reality, there was an observation made in a California state inspection document from 2008 which noted that since moving facilities, Conceptus had continued to use a description of procedures from the old facility which made reference to pre and post sterile cages when none were used in the new facility. Complaints Exh. D at 4, 6. There was no "citation" for failing to use such items (whatever they are—and Plaintiffs have never described them). Plaintiffs have never cited any regulation, guidance or law which would require "pre and post sterile cages" nor do any of the Plaintiffs allege any injury from infections or non-sterile devices.

For these reasons, Plaintiffs' lead argument is frivolous. Plaintiffs are blatantly misrepresenting crucial facts that are clearly and readily established through the public domain, distorting and misrepresenting documents upon which they rely, and misstating the legal effect of those documents in a futile attempt to avoid *Riegel*.[8]

[8] Plaintiffs also raise another frivolous argument hoping to avoid preemption. Plaintiffs argue that Essure is a drug and not a device. Response at 17 n. 14. In support of this contention, Plaintiffs refer to Exhibit H to their Amended Complaints. *Id*. (citing Complaint at 64). Plaintiffs claim that Defendants' prior single reference to Essure as a "drug" as opposed to a medical device "is important because the express preemption principles and case law discussed above do not apply to combination products or to drugs (§ 360k by its terms applies only to devices)." *Id*. First, there is no Exhibit H to Plaintiffs' Amended Complaints. *See* Answer at 64. Second, Essure is a medical device as conclusively determined by FDA and judicial notice of this fact is appropriate. *See 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). Defendants do not decide whether a product is or is not a medical device, FDA does and it did. *See id*. Further, Defendants have submitted their requests to FDA for supplemental approval of Essure for over a decade and under the device regulations. The FDA summary page for Essure shows Essure classified as a PMA device. *See* http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452270.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015). Moreover, and telling of the frivolous nature of this argument, Plaintiffs claim violations of the *device regulations*, and not *drug regulations* in their Amended Complaint.

III. THE PRESUMPTION AGAINST PREEMPTION DOES NOT APPLY UNDER *RIEGEL* AND *BUCKMAN*

Plaintiffs also argue that this Court should not apply *Riegel* and *Buckman* to preempt their claims because Plaintiffs are entitled to a "presumption" that preemption does not apply. Response at 10-12. In support of their argument, Plaintiffs do not cite to a single case which involves a Class III medical device. There is ample reason for this. In *Buckman*, the Supreme Court refused to apply any presumption against preemption in interpreting the express preemption clause of the MDA, § 360k(a). *Buckman*, 531 U.S. at 347, 352. Specifically, the *Buckman* Court stated that, "[t]o the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. Further, the *Riegel* Court, seven years after *Buckman*, held that the express preemption clause applies to PMA-approved devices such as Essure. 552 U.S. at 330. The *Riegel* Court applied the express preemption clause of the MDA without any discussion of the presumption against preemption relied upon by Plaintiffs. In fact, the *Riegel* majority implicitly rejected the discussion of the presumption by Justice Ginsburg in her dissent. *See* 552 U.S. at 334. Consequently, there is no legal basis for Plaintiffs' contention that their claims are not subject to preemption analysis under *Riegel* and *Buckman* on the basis that a "presumption" against preemption applies.[9]

[9] Plaintiffs also suggest that express preemption under *Riegel* does not apply with the same force to post-approval submissions. Response at 20, 25-26. However, this proposition does not fly either. First, post approval submissions are reviewed by FDA with the same vigor as the original PMA submission. *Riegel*, 552 U.S. at 319 (citing §360e(d)(6) and 21 C.F.R. § 814.39(c)). Further, courts which have been faced with this argument have rejected it, interpreting *Riegel* to mean that preemption applies equally to both PMA and PMA supplements. *See, e.g.*, *Nimtz v. Cepin*, No. 08-cv-1294, 2011 WL 831182, *3 (S.D. Cal. Mar. 3, 2011).

IV. PLAINTIFFS' CLAIMS ARE PREEMPTED AND OTHERWISE LEGALLY FLAWED

Plaintiffs' lengthy Response is at times very confusing; it is both internally inconsistent and in conflict with both the Complaints and applicable law. Rather than discussing seriatim why each of Plaintiffs' arguments are incorrect because they are without factual and legal support, Defendants address below why this Court should dismiss with prejudice each of Plaintiffs' enumerated counts in their Complaints.

The preemption afforded by the MDA is broad. "[W]hen Sections 337(a) and 360k(a) – as construed in *Buckman* and *Riegel*, respectively – are read together, nearly all types of claims concerning FDA-approved medical devices are preempted." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1161 (D. Minn. 2009). 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, Inc., Sprint Fidelis Leads Prods. Liab. Litig*, 623 F.3d 1200, 1204 (8th Cir. 2010) (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*, 625 F. Supp. 2d at 777. Here, despite filing a 115-page brief, Plaintiffs are not able to thread the needle between *Riegel* and *Buckman*.[10]

[10] Plaintiffs repeatedly cite to cases like *Wyeth v. Levine*, 555 U.S. 555 (2009) and *Desiano v. Warner-Lambert & Co*, 467 F.3d 85 (2d Cir. 2006), which involve the preemption of claims concerning prescription pharmaceuticals, not Class III medical devices. The statutes and regulations governing prescription pharmaceuticals are vastly different than those governing Class III medical devices, and lack an express preemption provision like § 306k. Accordingly, those cases are simply inapposite here.

A. Plaintiffs' Fraud-Based Claims are Preempted under *Buckman*; Plaintiffs' Attempt to Disguise them as Fraud on the Plaintiff Claims or Warranty Claims in Their Response Must be Rejected. [11]

As explained in the Motion, four counts (VI- UTPCPL, VII- Fraudulent Concealment, VIII- Fraud Misrepresentation and IX- Negligent Misrepresentation) in Plaintiffs' Amended Complaints are fraud based—that is, based upon alleged intentional misrepresentations or omissions to FDA. Motion at 17-18, 36-38. As acknowledged by Plaintiffs' counsel in the hearing before this Court, these claims must be dismissed under *Buckman*:

> THE COURT: For example, illustration. Let's assume that one of the—one or more of the claims in the complaint are obviously based, according to what's said in the complaint, on intentional misrepresentation—or misrepresentations to the feds, implied exemption. You wouldn't even expect that case to go forward. It fits right within *Buckman*.
>
> MR. PARAFINCZUK: Right.

Transcript of April 9, 2015 Hearing, Exhibit A to Motion at p. 9. However, rather than agree that these claims should be dismissed in their Response, Plaintiffs now attempt to disguise them with new names with the hope that they can argue now they are not preempted on that basis. These arguments should be rejected for six independent reasons.

First, Plaintiffs' contention that their causes of action are not claims of fraud *on the FDA* but rather, fraud *on "the Plaintiffs,"* Response at 48, 52-54, must be rejected. Second, their attempt to characterize them as "warranty" claims, *id*. at 52-53, is an equally unavailing last-ditch attempt to recast claims into something they are not. Third, they try to say that the fraud claims do not relate to PMA *approval*, but to the *post-approval* period and for that reason are not subject to preemption under *Buckman*, *id.*, but the cases do not support that distinction. Fourth, all of

[11] Although Plaintiffs' fraud-based claims appear in Counts VI through IX of the AC, Defendants address them first as the legal discussion of preemption applicable to these four counts similarly applies to the other remaining counts.

Plaintiffs' allegations are based on supposed violations of federal law and regulation, attempt to impose obligations on Defendants beyond those imposed by FDA, and are hence preempted under *Riegel*. Fifth, these claims are impliedly preempted by *Buckman.* Sixth, these claims fail under *Iqbal/Twombly* and applicable state law.

First, despite Plaintiffs' attempts to avoid it, their fraud based claims rest on alleged statements or omissions to FDA. Plaintiffs base their fraud claims on the following alleged conduct of Defendants during the ongoing PMA "process":

(1) failure to report adverse events ***to the FDA***;
(2) failure to provide a "complaint spreadsheet" ***to the FDA;***
(3) concealment of "non-conforming product" ***from the FDA*** and public making Essure "adulterated,"
(4) alteration of medical records during the clinical studies, the results which were submitted ***to the FDA***; and
(5) various other "concealed" items or issues which were not disclosed ***to the FDA***.

See Complaints at ¶¶ 196, 205, 206, 207, 217 and 230 (emphasis added).

Each of these allegations attempts to assert fraudulent conduct on the part of Defendants with regard to material presented to or omissions from materials that allegedly should have been presented *to FDA.* Yet, Plaintiffs somehow argue that these claims are really a fraud on "Plaintiffs." Response at 53-54, 56-57. This argument is nothing more than a transparent attempt to avoid the term "fraud on the FDA" used by the *Buckman* Court to describe the state law claims it held as preempted.

Second, in an attempt to overcome *Buckman*'s clear preemption application under 21 U.S.C. § 337(a), Plaintiffs now assert that these allegations were not intended to plead a fraud on the FDA claim, but rather, are part of their express warranty claim. Response at 47-48, 52-53. They now argue preemption does not apply because these claims are based on a device manufacturer's "duty not to deceive" in its advertisements. *Id.* at 48. Plaintiffs' Response directly

contravenes their prior position presented to this Court that if their claims are based on misrepresentations allegedly made to FDA (which they clearly are), then they fit within *Buckman* and cannot proceed. Interestingly, Plaintiffs ignore their prior representations to the Court.

Plaintiffs now contend that these allegations concerning the conduct of Defendants both pre- and post-approval were only included "to show how Defendants breached certain warranties" and not as a separate cause of action. Response at 25, 27. They further contend that their claims only pertain to *general* federal standards, and not device or PMA-specific requirements and hence are not applicable to Essure. This position directly contradicts paragraphs 206 and 208 of their Complaints in which they purport to allege numerous *specific* violations of the PMA and federal CGMPs regulations which they also allege apply to Essure.[12] Complaints at ¶¶ 206 and 208.

In essence, Plaintiffs are trying to amend their Complaints via their Response to avoid the preemption trap they themselves created. They cannot do so. Any effort by Plaintiffs to disguise their claims to avoid preemption should be rejected. Plaintiffs are not permitted to use argument to retroactively alter the clear and plain reading of their allegations in the Complaint in order to overcome preemption. *See Bell v. City of Philadelphia*, 275 Fed. Appx. 157, 160 (3d Cir. 2008) (a plaintiff "may not amend his complaint through arguments in his brief in opposition" to a dispositive motion); *Glover v. Udren*, No. 08-990, 2014 WL 4348078, at *3 (W.D. Pa., Sept. 2, 2014); *see also Pennsylvania ex. rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988).

Further, Plaintiffs do not deny that each of these fraud-based claims was presented to FDA as part of their citizen petition. Although the petition was dismissed prior to Defendants being able to respond, FDA referred the allegations as a "trade complaint" to its investigatory arm and

[12] The CGMPs-based allegations are also purported bases for Plaintiffs' claim for negligent manufacturing in Count XI, *see* Complaint at ¶¶ 268(a) through (z). Count XI is addressed below in Section IV, H.

these same complaints of fraud are presumably currently under review by FDA. There can be no greater conflict with the enforcement scheme of FDA than for Plaintiffs to ask FDA to investigate their fraud allegations and "invalidate" the Essure PMA while simultaneously asking this Court to permit Plaintiffs to pursue these claims under state common law at the same time. *Buckman*, 531 U.S. at 349, 354.

Third, Plaintiffs argue that *Buckman* is inapplicable to their claims because they claim its holding was limited to allegations solely premised on violations of federal law during the PMA approval process and not to events occurring after approval. Response at 20, 25-26. Of course, they cite no case which so holds, and, indeed, there is no logical or policy reason for the limitation urged by Plaintiffs. Regardless of how Plaintiffs attempt to characterize their claims now, any allegations that are *functionally* a state law claim that a manufacturer defrauded FDA are impliedly preempted. *Buckman* at 352-53. As such, Plaintiffs' attempt to distinguish and do away with *Buckman* is unavailing.[13]

Fourth, regardless of how Plaintiffs attempt to improperly construe their claims in their Response, the claims related to any alleged fraud or misrepresentations by Defendants are based solely on alleged violations of federal law and the PMA. *See, e.g.*, Complaints at ¶¶ 205, 206. Indeed, each of the allegations in Counts VI through IX repeat or reference the litany of federal statutes and/or regulations which Plaintiffs claim Defendants violated. *See id.* For the reasons more fully discussed below in Section IV, D, with regard to the failure to warn claim and FDA's control over what is published regarding a device, to the extent that Plaintiffs' misrepresentation

[13] To this end, Plaintiffs' reliance on *Cipollone v. Liggett Group*, 505 U.S. 504 (1992), for the proposition that Plaintiffs' misrepresentation claims based on a duty not to deceive are not preempted is misplaced. Response at 48-50. The *Cipollone* decision did not involve a medical device, the MDA, or the FDCA, but rather addressed preemption under the Public Health Cigarette Smoking Act of 1969 and was decided years before either *Riegel* or *Buckman*. *See* 505 U.S. 504.

and unfair trade practices are founded upon Defendants' alleged inadequate labeling, advertisements, warnings, and selling an "adulterated product," *see e.g.*, Complaints at ¶ 194, then those claims are expressly preempted because they seek to impose requirements beyond those approved by FDA. *Riegel*, 552 U.S. at 323 (MDA preempts states from imposing additional or different medical device requirements with regard to the sufficiency of warnings in labeling and literature); *see also Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206 (W.D. Okla. 2013) (citing cases). Plaintiffs cannot simply recite the magic words that Defendants violated both Pennsylvania and federal law in order to avoid preemption. *Wolicki-Gables v. Arrow Int'l Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). Adding the word "negligent" before each of their claims does not save them.

Plaintiffs' repeated arguments that they are only pursuing general federal violations and thus *Riegel* and *Buckman* do not apply misstates and confuses the preemption legal analysis. It is irrelevant whether they are challenging Defendants' alleged conduct under device-specific PMA requirements or the CGMPs regulations (which are integrated into the Essure PMA anyway) – their claims are preempted under both. *See Riegel*, 552 U.S. at 327-28 ; *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1339 (10th Cir. 2015) (under *Riegel*, "'*any* [state] requirement . . . which relates to the safety or effectiveness of the device' should be read **literally**: any state requirement, *whether device specific or generally applicable*, is preempted when it differs from or adds to federal requirements")(emphasis added); *Williams v. Cyberonics*, 654 F. Supp. 2d 301, 306 (E.D. Pa. 2009), *aff'd*, 388 Fed. Appx. 169 (3d Cir. 2010). Plaintiffs flatly ignore *Riegel*'s holding on this point. Further, Plaintiffs on this point and throughout their Response fail to distinguish preemption cases relating to approval under § 510(k) versus §360k(a) under the MDA, which are two different types of FDA approval/review, the former being much less rigorous. *See Lohr*, 518

U.S. at 478, and *Riegel*, 552 U.S. at 327-28; *see also Gomez v. St. Jude Med. Diag. Div., Inc.*, 442 F.3d 919, 929-31 (5th Cir 2006). Plaintiffs heavily rely on *Lohr*, but do not acknowledge that it addressed an entirely distinct form of approval by FDA, much less rigorous than the PMA process.

Fifth, Plaintiffs' claims are also impliedly preempted under *Buckman.* Defendants' duties to adequately and truthfully report to FDA in conformance with the PMA as a clearly alleged element of their misrepresentation claims exist solely by virtue of the federal law and finds no independent source in Pennsylvania law. *Killen v. Stryker Spine*, Civ. No. 11-1508, 2012 WL 4482371, at *15 (W.D. Pa. Aug. 21, 2012) (fraud and negligent misrepresentation claims based on the regulations governing labeling of devices and written information about the device provided by the manufacturer were impliedly preempted). Plaintiffs have not demonstrated any valid argument for this Court to reject *Buckman* and its progeny's clear application to their claims sounding in fraud and unfair trade practices. *See also Millman*, 2015 WL 778779, at *6 (finding preemption applied to consumer fraud and common law fraud where "they are all theories of liability relating to the safety or effectiveness of the device and seek to impose additional requirements . . . .").

Plaintiffs' contorted efforts in arguing that they only employed the allegations of Defendants' alleged fraudulent submissions and reporting to FDA relating to clinical test results as adjunct to their other causes of action demonstrates either Plaintiffs' reckless pleading (which should be stricken), or more likely the case, is an attempt to confuse the issues under *Buckman*. Indeed, Plaintiffs' citations to *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553 (E.D. Pa. 2008); *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678 (E.D. Pa. 2006); and *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), are inapposite as each of those cases are distinguishable on their face. *Knipe* and *Perry* involved the mislabeling or off-label use of a

prescription drug and FDA's preamble on labeling and *Desiano*'s holding—in connection with a prescription drug, not a medical device—found that the FDCA did not preempt a Michigan statute which eliminated immunity for a manufacturer of an FDA approved drug if that manufacturer misrepresented or withheld material information that would have altered FDA's approval decision. To argue that these cases are controlling or even persuasive as to their interpretation of *Buckman* is specious and would ignore the constitutional reasons for conflict preemption in the arena of Class III, FDA-approved and regulated prescription medical devices.

Sixth, notwithstanding the preemption of Plaintiffs' claims in Counts VI, VII, VIII and IX, Plaintiffs have failed woefully to plead these claims in accordance with *Iqbal/Twombly* and Rule 9. *See, e.g.*, Response at 52-53 (listing the representations upon which Plaintiffs claim to rely). Even if the fraud and misrepresentation claims are construed as part and parcel of the warranty claim, Plaintiffs are still obligated to plead fraud with specificity in each of those counts, including Count V for breach of express warranty. They have not done so. Plaintiffs' claims in Counts VI, VII, VIII, and IX premised on fraud do not satisfy Rule 9(b) because they fail to state with particularity which alleged misrepresentation Plaintiffs (or their doctors) relied upon. Fed. R. Civ. P. 9(b); *Frederico v. Home Depot*, 507 F. 3d 188, 200 (3d Cir. 2007).

Rather than stating the who, when, where, how and why of their fraud claims, as required by Rule 9, Plaintiffs rest on pure legal conclusions. *See* Complaints at ¶¶ 194-197, 208-209, 217, 219-221, 230-232; *see also Caplinger*, 784 F.3d at 1340, n.1. Nowhere in their Amended Complaints or their Response do Plaintiffs set out "with particularity the circumstances constituting fraud or mistake" in accordance with Fed. R. Civ. P. 9(b), any facts regarding the nature of Plaintiffs' reliance or specific representations Defendants made relating to reliance. Plaintiffs simply fail to allege facts indicating the date, time, and place of the alleged fraud, or,

alternatively, to inject any precision or measure of substantiation into their fraud allegations that would "place the defendant on notice of the 'precise misconduct with which [it is] charged.'" *Frederico*, 507 F.3d at 200; *citing Lum v. Bank of America*, 361 F.3d 217, 223-24 (3d Cir. 2004). Indeed, some of their conclusory allegations are ludicrous on their face. For example, Plaintiffs allege in connection with their warranty claim that Plaintiffs *specifically negotiated* the terms of the warranties with Defendants. Amended Complaints at ¶ 179, *see also* Response at 44. Such an allegation borders on sanctionable. It is especially telling, since Plaintiffs nowhere allege the date, time or place of any contract, and do not bother to recite any of its terms or attach any alleged written contract.

Additionally, Plaintiffs' fraudulent concealment, misrepresentation, and unfair trade practices claims are not cognizable under Pennsylvania law because Plaintiffs are barred from asserting a non-negligence cause of action against the manufacturer of a pharmaceutical device. The Pennsylvania Supreme Court has determined that "negligence is the sole theory upon which a plaintiff may recover against a prescription drug manufacturer for a failure to warn." *Kline v. Pfizer*, No. 08-3238, 2009 WL 32477, at *4 (E.D. Pa. Jan. 6, 2009) (citing *Hahn v. Richter*, 543 Pa. 558, 673 A.2d 888, 891 (1996)). Pennsylvania courts have extended the rationale of *Hahn* to medical devices. *See* Section IV, G, below; Motion at 39-40; *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747-48 (W.D. Pa. 2004); *Creazzo v. Medtronic Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2005) (citing *Hahn*, 673 A.2d at 890-91); *see also Runner v. Bard, Inc.*, No. 14-5259, 2015 WL 3513424, at *6 (E.D. Pa., June 3, 2015) (noting that federal district courts applying Pennsylvania law have applied comment k to medical device cases in dismissing claims for strict liability, manufacturing defect failure to warn, misrepresentation and fraudulent concealment). Plaintiffs' claims at root rest on their contention that Defendants failed to warn of Essure's alleged defective

nature. The very basis of Plaintiffs' claims is that Defendants knew of issues with the proper placement of Essure, breakage, and migration (which Defendants vehemently deny), yet fraudulently concealed that information by failing to warn of the associated dangers. Consequently, unless brought as "negligent failure to warn", Plaintiffs' claims fail as a matter of Pennsylvania law.

Specifically as to Plaintiffs' UTPCPL claim, Plaintiffs attempt to skirt the application of the learned intermediary rule by once again arguing their claim is really based on an express warranty theory and by arguing that the case of *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434 (2014), overrules the learned intermediary doctrine as applied to medical device manufacturers. Response at 55-56. Their interpretation of Pennsylvania law is simply incorrect. The *Lance* decision did not overrule the long-standing rule that a pharmaceutical manufacturer's duty to warn is directed to physicians. *See Lance*, 624 Pa. at 270, 85 A.3d at 457 ("we need not consider the wisdom of modification or exceptions to the [learned intermediary] doctrine"); *see also Gurley v. Janssen Pharms., Inc.*, 113 A.3d 283, 292-93 (Pa. Super. Ct. 2015) (applying the learned intermediary doctrine). Plaintiffs also argue that this Court should reject settled Pennsylvania law and instead adopt the minority view of New Jersey and West Virginia that "direct to consumer" advertising somehow obviates the learned intermediary doctrine. Response at 55-56 (*citing Perez v. Wyeth Labs, Inc.*, 161 NJ 1, 734 A.2d 1245 (1999); *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 647 S.E.2d 899 (2007)). This Court should reject any invitation by Plaintiffs to make wholesale changes to well-settled Pennsylvania law. There is simply no basis on which to conclude that Pennsylvania would discard its own law and adopt *Perez*, especially since *Perez* was decided well over ten years ago during which period Pennsylvania has made no move to adopt its reasoning or holding.

Based on the learned intermediary doctrine, Plaintiffs cannot establish the chain of causation and reliance required to state a claim under the UTPCPL. *See also Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 410-11 (E.D. Pa. 2012). Moreover, regardless of the application of the learned intermediary doctrine, Plaintiffs' UTPCPL claim still fails because they have failed to plead any facts demonstrating when, where, and how Plaintiffs were "directly" targeted by any advertisements or warranties in order to plausibly establish reliance. *See Cole v. NIBCO, Inc.*, No. 3:13-cv-07871, 2015 WL 2414740 (D.N.J. May 20, 2015); *see also Militello v. Allstate Prop. & Cas. Ins. Co.*, No. 14-cv-00240, 2014 WL 2892386, at *4 (M.D. Pa. June 26, 2014).

Finally, the UTPCPL allows for a private cause of action to be brought only by "any person who purchases or leases goods or services primarily for personal, family or household purposes" and suffers a loss as set forth in the statute. *See* 73 P.S. § 201-9.2; *see also Katz v. Aetna Cas. & Sur. Co.*, 972 F.2d 53, 55 (3d Cir. 1992) (UTPCPL "unambiguously permits only persons who have purchased or leased goods or services to sue"). Because Essure is a prescription medical device that is not sold to patients, Plaintiffs cannot be the "purchaser" of the device, and therefore do not have standing to bring a claim pursuant to the UTPCPL.[14]

[14] While Defendants are aware of no Pennsylvania caselaw addressing whether a patient-plaintiff who was the ultimate recipient of a prescription medical device is a "purchaser" or "consumer" under the UTPCPL, courts in other jurisdictions applying similar laws have repeatedly held that medical devices such as Essure are not part of consumer transactions. *See, e.g., Otis-Wisher*, 2015 WL 3557011, at *2 (affirming dismissal of plaintiff's claim pursuant to Vermont Consumer Protection Act, which defines a "consumer" as a "person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services…for his or her use or benefit or the use or benefit of a member of his or her household," because plaintiff did not purchase, for her personal use, the subject medical device that was prescribed by her doctor); *Smith v. Smith & Nephew, Inc.*, 5 F. Supp. 3d 930, 932 (S.D. Ohio 2014) (medical device not part of consumer transaction under Ohio Consumer Sales Practices Act); *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 798 n.2 (N.D. Ohio 2012) (no consumer transaction between plaintiff and manufacturer of medical device); *Hogan v. Maryland State Dental Ass'n*, 155 Md. App. 556, 563-64, 843 A.2d 902, 906 (Md. Ct. Spec. App. 2004) (consumer goods, defined under the Maryland Consumer Protection Act as goods "which are primarily for personal, household, family, or agricultural purposes," do not include dental fillings which are not purchased by consumers as a good).

For all of the foregoing reasons, and those set forth more fully in Defendants' Motion, Plaintiffs' claims in Counts VI, VII, VIII and IX are either preempted or fail as a matter of Pennsylvania law. Therefore, they should be dismissed with prejudice.

B. Plaintiffs' Claim for Negligent Training (Count I) Must be Dismissed.

In their Motion, Defendants explain that Count I of the Amended Complaints should be dismissed with prejudice as preempted. In support, Defendants cite to the Essure PMA and PMA supplements to demonstrate that FDA reviewed and approved the training of physicians—including the placement procedure in which a hysteroscope is used. Motion at 23-28.[15] Indeed, the Physician Labeling for Essure approved in 2002 begins with this boxed warning:

> Caution: Federal law restricts this device to sale by or on the order of a physician. *This device should only be used by physicians who are knowledgeable hysteroscopists, have read and understood the information in this Instructions for Use and in the Physician Training Manual, and have successfully completed the Essure training program.* Completion of the Essure Training Program includes preceptoring in Essure placement until competency is established, which is typically expected to be achieved in 5 cases.

http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf (emphasis supplied) (last updated by FDA on June 24, 2015 and viewed on June 25, 2015). A similar warning is at the top of the 2013 Instructions for Use. http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf (last updated by FDA on June 24, 2015 and viewed June 25, 2015).

Plaintiffs acknowledge that Defendants trained the physicians who placed Essure, Complaints at 67, but argue that Defendants should have performed *additional* training, including a screening process for determining which physicians can use Essure. *Id*. at ¶¶ 123-34. To suggest

[15] There is no question that Essure meets the first prong of *Riegel* in that it is a PMA-approved device. Plaintiffs also maintain that, in order to satisfy the first prong of *Riegel*, Defendants must do more than show that Essure is PMA-approved. However, such a position is wholly inconsistent with *Riegel*, 552 U.S. at 323, and its progeny's clearly established jurisprudence on this issue.

that Defendants should have trained the physicians differently by adding requirements on the method of physician selection or approval or to impose on Defendants an obligation to ensure that they are somehow highly qualified to use a hysteroscope in conjunction with Essure is beyond the training approved by FDA and a blatant attempt to impose different or additional safety-related duties which FDA did not. Further, it would mean that the warning approved by FDA and which cannot unilaterally be changed by Defendants is inadequate, and such a claim is preempted. *See Riegel*, 552 U.S. at 319 ("the MDA forbids the manufacturer to make, without FDA permission, changes in … labeling" and if the manufacturer "wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application").

The Courts examining inadequate training claims in the same context as presented here repeatedly have held they are barred as preempted. *See, e.g., Hinkel v. St. Jude Medical, S.C., Inc*., 869 F. Supp. 2d 739, 746 (E.D. La. 2012) (*citing Poole v. Hologic, Inc*., No. 10-314, 2010 WL 3021528 (W.D. La. Jul. 29, 2010)). Plaintiffs contend that "in several of the cases cited by Defendants, a claim for negligent training was never even alleged by the plaintiff" including *Gomez v. St. Jude Med. Diag. Div.*, 442 F. 3d 919, 931 (5th Cir. 2006). Plaintiffs are just plain wrong. In *Gomez*, the Fifth Circuit Court of Appeals held that a plaintiff's claims that the device company's training materials submitted to FDA were inadequate would "displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [the manufacturer]." *Id.* The court in *Gomez* found as significant, FDA's independent review of the Instruction for Use ("IFU") for physicians during the PMA process. *Id*. Here, the IFU for Essure was approved by FDA and a warning was approved relating to the knowledge of the physician related to equipment used to place the device in the patient. *See* 2002 Essure Instructions for Use,

http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf (last updated by FDA on June 24, 2015 and viewed on June 25, 2015); 2013 Essure Instructions for Use http://www.hcp.essure-us.com/assets/pdf/Link%20Essure%20IFU.pdf (last updated June 24, 2015 and viewed on June 25, 2015).

FDA also approved labeling changes resulting from the study required under the PMA order relating to placement rates among newly trained physicians—obviously geared to the evaluation of the training of physicians among other things. *See* Summary http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015) (the study "was conducted to evaluate bilateral placement rate (insert placement in both the right and the left Fallopian tubes at first attempt) for newly trained physicians in the U.S. Data from this study were used to evaluate the training procedures and to update labeling"). Accordingly, any state law claim, if one exists, would add to or be in addition to the requirements of federal law and therefore, is not parallel under *Riegel*. 552 U.S. at 329. And, such a requirement would interfere with FDA's exclusive role in overseeing the regulation of medical devices. *See Gomez*, 442 F. 3d at 931.

Moreover, no tort for "negligent training" exists under these facts under Pennsylvania law. To successfully plead such a claim, there must be an agency or master-servant relationship between the party alleged to be negligent and the party who was supposed to have been trained. *Sedor v. Community Med. Ctr.*, 16 Pa. D&C 5th 193, 2010 WL 5647132, at *8 (Lackawanna Cty. July 19, 2010). Plaintiffs have failed to allege any facts regarding any such relationship between Defendants and the physicians who allegedly placed Essure and, therefore, this claim fails for this additional reason.

C. Plaintiffs' Negligent Entrustment Claim (Count II) Must be Dismissed.

In their Response, Plaintiffs now argue that there are no federal requirements which pertain to its negligent entrustment claim, so the first prong of *Riegel* has not been met and that case does not apply. Response at 37. This argument ignores the holding of *Riegel* and cannot stand. The *Riegel* Court held that when FDA approves a PMA, it imposes "requirements" under the MDA by virtue of that approval. *Riegel*, 552 U.S. at 322-23 (premarket approval imposes "requirements" under *Lohr*). *See also Horn v. Thoratec*, 376 F. 3d 163, 168 (3d Cir. 2004). Here, FDA approved Essure as a Class III device under its PMA process. This is not in dispute. Accordingly, Essure meets the first prong of *Riegel*. *See id*. *See also* Section III, above. As noted above, FDA approved an express warning about the use of hysteroscopes by physicians placing the Essure device. Further, FDA approved the training prescribed for physicians placing Essure. If this Court were to rule that there is a private cause of action arising from the purchase and sale or use of a hysteroscope in conjunction with the placement of Essure, such a ruling would create an irreversible conflict with the exclusive enforcement powers of FDA over the regulation of medical devices. *Buckman*, 531 U.S. at 348.

Similarly, Plaintiffs argue that, as the hysteroscope is not part of Essure's "CPMA" this claim is not preempted.[16] This argument too ignores *Riegel*—the PMA imposes requirements applicable to Essure including how it is used—not to mention that the hysteroscope is part of the IFU and warnings approved by FDA. 552 U.S. at 322-23.

Finally, Plaintiffs argue that *Riegel* does not apply because their claim relates to the hysteroscope under 21 C.F.R. § 808.1(d)(1) and not Essure. This argument, however, is nothing more than a red herring, as it ignores the Supreme Court's holding that this regulation "fails to

[16] Plaintiffs continue to describe Essure's PMA as a "CPMA." There is simply no basis for so doing.

alter" the preemption analysis and "add[s] nothing…but confusion." *Riegel*, 552 U.S. at 329-30 (rejecting the argument that claims of negligence, strict liability and breach of implied warranty could be exempted from preemption pursuant to section 808.1(d)(1)). Since *Riegel*, courts have uniformly followed suit and have refused to acknowledge that 21 C.F.R. § 808.1(d)(1) excludes plaintiffs' claims from preemption, including the claims of breach of express warranty and unfair trade practices for which Plaintiffs seek preemption immunity now. *See, e.g., Covert v. Stryker Corp.*, No. 1:08-cv-447, 2009 WL 2424559, at *7, 22 (M.D. N.C. Aug. 5, 2009) (plaintiff's express warranty and unfair trade practices claims are subject to express preemption under § 360k(a), as "state-law requirements of general import, which regulate a medical device only incidentally, are subject to federal pre-emption in the same way as those state-law requirements which specifically target the device in question"); *Riley*, 625 F. Supp. 2d at 789 (rejecting that 21 C.F.R. § 808.1(d)(1) exempts claim of breach of implied warranty from preemption); *Horowitz*, 613 F. Supp. 2d at 284-85 (same); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (same); *In re Medtronic, Inc., Sprint Fidelis Lead Prods. Liab. State Court Litig.*, Nos. 27-07-22476, et al., 2009 WL 3417867 * 36-37 (D. Minn. Oct. 20, 2009) (same).[17] Plaintiffs also argue that this regulation saves their breach of express warranty and UTPCPL claims. It does not save those claims, either, for these same reasons.

Defendants' Motion explained that there is no parallel state cause of action for negligent entrustment arising under the facts as pled, Motion at 27-28, and Plaintiffs do not cite to a single

[17] To the extent Plaintiffs rely on the decision in *Hofts v. Howmedica*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), in support of their position as it relates to 21 C.F.R. § 808.1(d)(1), the *Hofts* decision is nothing more than an outlier in which the *Riegel* Court's holding was ignored. *See, e.g., Bass v. Stryker Corp.*, 669 F.3d 501, 516, n.3 (5th Cir. 2012) (noting that although the *Hofts* court relied in part on 21 C.F.R. § 808.1(d)(1) to conclude that implied warranty claims were not preempted, "[t]he Supreme Court rejected a similar argument in *Riegel*"); *Horowitz*, 613 F. Supp. 2d at 285 ("The *Hofts* court ignores…that *Riegel* explicitly rejected that the regulation alters the outcome of the case, reasoning that such an interpretation would effectively swallow the preemption rule.").

case which creates a state tort claim under facts like those presented here.[18] It is Plaintiffs' burden and not that of Defendants to demonstrate that there is a parallel state law claim which is identical to the alleged applicable federal requirement. *Riley*, 625 F. Supp. 2d at 776. Plaintiffs filed a 115-page Response, but did not cite a single case that supports the extension of Pennsylvania law to create a tort cause of action for negligent entrustment under the facts alleged. Merely referring to the Restatement (Second) of Torts does not establish any basis for this claim. Negligent entrustment has been applied to cases involving automobiles or firearms entrusted to felons, drunks or minors. *See* Motion at 27-28. Defendants have been unable to locate any case, from any jurisdiction, extending this tort to facts like those presented here; involving sophisticated instruments allegedly provided to skilled, licensed physicians.[19] This Court should decline Plaintiffs' invitation to extend the tort to these facts where, to this point, it has been limited to a very discrete set of facts—especially when Plaintiffs offer no cases which support their invitation. Moreover, the absence of applicable state tort law is another reason why this claim must fail as expressly preempted. *Riegel*, 552 U.S. at 329.

[18] Plaintiffs also claim that the negligent entrustment arises through contracts with third parties. Amended Complaint at ¶ 135. Plaintiffs do not state how they have standing to make such a claim nor do they attach or refer to any applicable contracts.

[19] Likewise, to the extent that Plaintiffs are attempting to make a claim for "negligent sale" of Essure to medical professionals who Defendants purportedly knew or should have known were not competent to perform the placement of Essure, Defendants have found no indication that any jurisdiction has recognized this legal theory to date either. To the contrary, in recent medical device litigation in New Jersey, each judge that considered plaintiffs' theory that defendants negligently sold their spinal devices to licensed physicians who were not certified to perform such procedures refused to allow the claims to proceed because they were "unrecognized at law, and one which offers no possible basis for relief." *See, e.g., Sica v. Kaul, et al*., Docket No. ESX-L-7421-12 (Jan. 29, 2013 Order and Decision) (attached hereto as Exhibit 2); *see also Zetterberg v. Kaul*, et al., Docket No. ESX-L-5451-12 (Apr. 12, 2013 Order and Decision) (attached hereto as Exhibit 3).

D. Plaintiffs' Failure to Warn Claim (Count XII) Must be Dismissed.

Plaintiffs admit that their failure to warn claim is predicated on Defendants' alleged failure to disclose adverse events to FDA and Defendants' supposed duty to alter or strengthen the warnings for Essure after it received PMA approval. Response at 63-64. Plaintiffs repeatedly argue that if Defendants had reported all adverse events and/or properly updated and strengthened its warnings and labels, it would be in compliance with both state and federal law. *Id.* at 27, 30-31, 63. On its face, Plaintiffs' claim is expressly preempted because they have not identified a parallel state-law duty to report adverse events to FDA, and it is impliedly preempted under *Buckman* because the duty to submit adverse-events to FDA, "exists[s] solely by virtue of the FDCA disclosure requirements" and the violation of the corresponding federal regulations is a "critical element" of their claim. *Buckman*, 531 U.S. at 353.

As to the warnings issues, Plaintiffs have not alleged or argued that Defendants failed to provide any of the warnings mandated by FDA through the PMA process. Thus, if Plaintiffs were to prevail on their state law claim that Defendants were required to give additional warnings, Defendants would be required under state law to have provided warnings about Essure that are "different from, or in addition to" those required by federal law. This is precisely the type of failure to warn claim that is expressly preempted by 21 U.S.C. § 360k(a).[20] *See* Motion at 43-44; *Sprint Fidelis*, 623 F.3d at 1205, *aff'g*, 592 F. Supp. 2d 1147 (D. Minn. 2009); *accord Kinetic Co. v. Medtronic, Inc.*, No. 08-CV-6062, 2011 WL 1485601, at *3 (D. Minn. Apr. 19, 2011); *see also Wolicki-Gables*, 634 F.3d at 1301-02; *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 490 (7th

[20] Such a claim also runs headlong into 21 U.S.C. § 360e(d)(6)(A)(i) and 21 C.F.R. § 814.39(c), which prohibit the manufacturer of a Class III medical device with PMA from changing the device's labeling, and thus from issuing an additional warning to consumers or their physicians, without FDA approval. *See Riegel*, 552 U.S. at 319 ("[T]he MDA forbids the manufacturer to make, without FDA permission, changes in . . . labeling" and if the manufacturer "wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application."); *see also PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011).

Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn*, 376 F.3d at 176-77.

Seeking to avoid this result and ignoring contradicting Supreme Court precedent, Plaintiffs cite to and discuss at length the United States Court of Appeals for the Ninth Circuit's *en banc* decision in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224 (9th Cir. 2013), *cert. denied*, 134 S. Ct. 2839 (2014), in support of the argument that because Plaintiffs have pled that Defendants have not complied with federal law and have violated federal law, including the conditions of a PMA and the FDCA's CGMPs, Defendants should not be afforded protection under § 360k(a)'s express preemption clause or under *Buckman*'s implied preemption analysis. Response at 15-16, 28; *Stengel*, 704 F.3d 1224 (construing *Lohr* and subsequent cases). Plaintiffs baldly and incorrectly contend, without citing any authority, that the *Stengel* ruling and the Solicitor General's *amicus curiae* brief to the Supreme Court provide "standing authority" in this Court that the MDA does not preempt Plaintiffs' state law failure to warn claims based on Defendants' alleged conduct after the PMA approval was issued for Essure. *See* Response at 28-30, 63. Because Plaintiffs have purportedly only alleged general violations of federal law post-PMA approval, versus violations of device and PMA-specific federal requirements which Plaintiffs acknowledge would warrant preemption, they contend that preemption does not apply per *Stengel*. *Id.* at 31.

Throughout its discussion of *Stengel*, Plaintiffs' Response mischaracterizes the jurisprudence on the MDA's preemption provision with statements like "it is clear" that preemption does not apply and that Congress and the government have "clearly" made their positions known against preemption. This is simply not supported by any binding authority and is directly controverted by Supreme Court precedent and the reasoning of cases like *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015).

In *Stengel*, the Ninth Circuit held that the sole claim presented—a negligent failure to warn claim under *Arizona law*—which "rests on a state-law duty that parallels a federal-law duty under the MDA" was not preempted where the plaintiffs alleged that the manufacturer violated a specific continuing duty to monitor the medical device, submit reports to and warn FDA after it had received premarket approval. 704 F.3d at 1232-33. Given that *Stengel* is one of the few cases that has found against preemption under the MDA, it is not surprising that Plaintiffs have, in large measure, rested their arguments on that opinion, although those arguments are misplaced and Defendants submit that *Stengel* is wrongly decided.

The Ninth Circuit's rationale with regards to *Buckman*, pertinent here, contradicts years of jurisprudence finding that claims alleging violation of disclosure requirements to FDA are preempted, regardless of whether the disclosures at issue are pre- or post-PMA approval. *See, e.g.*, *Marsh v. Genetech, Inc.*, 693 F.3d 546, 553-54 (6th Cir. 2012) (under *Buckman*, courts should not determine adequacy of post-marketing disclosures to FDA); *Sprint Fidelis*, 623 F.3d at 1205 (*Buckman* preempts allegations that the defendant "failed to provide the FDA with sufficient information and did not timely file adverse events reports, as required by federal regulations"). *See also Erickson v. Boston Scientific Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011) (no distinction between PMA submissions and PMA supplements). As to *Riegel*, the Ninth Circuit respectfully was too quick to find parallel claims and in doing so created a backdoor for failure to warn claims, at least in the Ninth Circuit, when *Riegel* expressly held that similar failure to warn claims for PMA devices were preempted by the MDA. 552 U.S. at 329; *Stengel*, 704 F.3d at 1231-32 (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 765 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546, 549 (7th Cir. 2010), *cert. denied*, 132 S. Ct. 498 (2011)).[21]

[21] However, Judge Watford in his concurring opinion in *Stengel* did note that the Stengels, who framed their claim "as they must do in order to avoid preemption," would likely face a causation hurdle, as do Plaintiffs here.

Plaintiffs would have this Court interpret *Stengel* as broadly rejecting preemption as the law of the land, in the face of controlling Supreme Court precedent in *Lohr*, *Riegel* and *Buckman* and Third Circuit precedent, which is binding on this Court. *See Williams*, 388 F. Appx. at 169; *Horn*, 376 F.3d at 163; *Millman*, 2015 WL 778779, at *5. Moreover, Courts post-*Stengel* have not hesitated to dismiss "failure to warn" claims like those asserted here. *See, e.g.*, *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 109 (D. Conn. 2014) (dismissing the plaintiff's failure to warn claim, after analyzing *Stengel).*

Contrary to Plaintiffs' argument that *Stengel* is the "guidepost" for this Court's ruling in this matter, although decisions of other circuits are persuasive authority, they are not binding on this Court. This Court is bound by rulings of the Supreme Court and the Third Circuit, but not by rulings in the Ninth Circuit. *United States v. Maury*, 695 F.3d 227, 229 n.27 (3d Cir. 2012); *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) ("[u]nder the established federal legal system the decisions of one circuit are not binding on other circuits"); *Velazquez v. Marquez*, 546 F. Appx. 854, 859 (11th Cir. 2013). Furthermore, the Amicus Curiae Brief of the Solicitor General submitted in *Stengel* is owed no deference by this Court. *See Comm'r v. Schleier*, 515 U.S. 323, 334 n.7 (1995). This is especially true when the current position of FDA plainly contradicts years of jurisdiction upholding federal preemption of tort claims involving PMA devices. *See also* U.S. Br. Supporting Respondent at 8, *Riegel*, 552 U.S. 312 (2008) (No. 06-179) (regarding FDA's prior litigating position as articulated in *Riegel* and as advocated by Defendants herein); *see also Caplinger,* 784 F.3d at 1346. In fact, the Court of Appeals for the Tenth Circuit recently rejected with vigor the Solicitor General's position and declined to follow it. *Caplinger,* 784 F.3d at 1346.

Moreover, Plaintiffs have not provided any valid legal authority or argument, for that matter, that this Court should defer to FDA's current position over its previous positions, *cf.* U.S. Br., *Riegel*, 552 U.S. 312; U.S. Br., *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008), leaving aside the body of case law interpreting the Supreme Court's holdings in *Riegel*, *Buckman* and *Lohr* which this Court would have to maneuver around in order to accept the current Solicitor General's position. There is simply no support in Congress' clear and express language in the MDA, the federal regulations, or in any of the Supreme Court's holdings for the positions articulated by Plaintiffs in order to avoid preemption.

Plaintiffs acknowledge that their failure to warn claims are based on Defendants' alleged failure to report adverse events to FDA, which in turn they allege were never reported to the public database and the physicians, and never reflected in updated warnings.[22] Response at 63-64; Complaint at ¶¶ 276-286. As noted above in Section II, those claims are without factual basis. Plaintiffs' claim in Count XII does not allege that Defendants failed to provide any of the warnings approved through the PMA process. Rather, they allege that by reason of state law Defendants were required to give additional warnings, which is precisely the type of state requirement that is "different from or in addition to" the federal requirements and therefore preempted.

To escape express preemption based upon a parallel state claim, Plaintiffs must plead the existence of an "identical" state law requirement. *Lohr*, 518 U.S. at 495; *Otis*, 2015 WL 3557011, at *1 ("[T]he Supreme Court instructs that a state law claim must be identical to an existing federal requirement for such a claim to survive § 360k preemption."). Plaintiffs have not identified a

[22] The alleged "unreported events" are presumably the "perforations" mentioned throughout the Response. Perforations are, of course, already listed in the Physician Labeling and Patient Labeling as having been reported in the clinical trials and as possible adverse events from use of Essure. *See* 2002 Physician Labeling, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014c.pdf; 2002 Patient Labeling, http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014d.pdf.

single case identifying a Pennsylvania duty to file reports with a federal agency that parallels the duty imposed by 21 C.F.R. § 803.50. *See* Response at 22-31, 63-71, 86-87. Instead, Plaintiffs rely on the Fifth Circuit's assumptions about Mississippi law in *Hughes* and the Ninth Circuit's interpretation of Arizona law in *Stengel*. The opinion cited by Plaintiffs and the Pennsylvania case law relied on identify only a manufacturer's duty to warn the physicians in accordance with the learned intermediary doctrine. Response at 63-64, 67. None of those cases recognize a state law duty to report to FDA. *See, e.g.*, *Lance*, 85 A.3d at 434; *Rowland v. Novartis Pharm. Corp.*, 34 F. Supp. 3d 556 (W.D. Pa. 2014). Indeed, Plaintiffs have not cited any cases in support of the notion that Defendants have an independent duty to warn FDA under Pennsylvania state law. Plaintiffs are plainly attempting to add to FDA's requirements for Essure and enforce FDA's regulations themselves, where FDA has found zero violations by Defendants.[23]

Plaintiffs' argument also fails as a matter of logic. A post-sale duty to warn *consumers* or their *physicians* is not identical or genuinely equivalent to a federal duty to submit reports to *FDA*, given that doctors are warned of the risks associated with a medical device through a devices' labeling and not through adverse reporting to FDA. *See* 21 U.S.C. § 360i(a)(1) (requiring the manufacturer to report to the "*Secretary*") (emphasis added); 21 C.F.R. §803.50(a) (manufacturer "must report to *us*") (emphasis added). Adverse event reports to FDA are not required to be reported to the public, and reporting adverse events to FDA is simply not the same as amending the label of a device. For those reasons, a state law duty to warn doctors and patients is not

[23] In contrast, in *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014), relied upon by Plaintiffs, the complaint alleged not only that the defendant failed to comply with FDA reporting requirements, but that FDA later ordered the publication of two "Dear Doctor" letters and a Class I Recall of the device at issue, relating to the precise risk of the harm allegedly suffered by the plaintiff. FDA has never required Dear Doctor letters for Essure, nor has Essure ever been recalled. Instead, FDA continues to note that Essure has a favorable risk/benefit profile. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm (last updated by FDA on June 24, 2015 and viewed on June 25, 2015) (noting that FDA will continue to monitor Essure to ensure that its benefits continue to outweigh its risks).

"identical," *Lohr*, 518 U.S. at 495, or even "genuinely equivalent," *Wolicki-Gables*, 634 F.3d at 1300 – thus is not parallel – to the federal duty to submit adverse events through MDRs to FDA.[24]

Lacking a parallel Pennsylvania duty, Plaintiffs attempt to force their failure to warn claim into the existing state law framework by implying that filing adverse-event reports and updating the device's warnings due to those events is the equivalent of warning Plaintiffs and their physicians because FDA publishes those reports in the MAUDE database. *See* Response at 64.[25] But, courts have recognized that the "state law duty to warn [the patient] or her physician" is not the same as the federal duty to submit adverse event reports to FDA. *McClelland v. Medtronic, Inc.*, No. 6:11-CV-1444-ORL-36, 2012 WL 5077401, at *6 (M.D. Fla. Sept. 27, 2012); *accord Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013). There are several reasons for this. First, FDA is not obligated to publish such reports. 21 C.F.R. § 803.9(a); *Pinsonneault*, 953 F. Supp. 2d at 1016. Second, unlike the device labeling, MDRs are not necessarily made public and are not by themselves sufficient grounds for a labeling change, which requires FDA approval after submission of sufficient scientific data demonstrating an adverse reaction for which there is reasonable evidence of a causal association. *See* 21 C.F.R. § 814.39(d)(2)(i); 21 U.S.C. § 360e(d)(6)(B) (requiring FDA approval of changes to PMA); *see also Riegel*, 552 U.S. at 319 (discussing that FDA *forbids* a manufacturer from changing its labeling without permission). Because MDRs are inherently anecdotal and do not constitute proof

[24] Under the learned intermediary doctrine, which remains valid in Pennsylvania, any duty to warn of risk associated with a prescription medical device is a duty to warn physicians, not their patients. *See Lance*, 85 A.3d at 438; *Daniel v. Wyeth Pharms., Inc.*, 15 A.3d 909, 924 (Pa. Super. Ct. 2011); *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971).

[25] In *Riegel*, the Supreme Court acknowledged that following pre-market approval, a manufacturer must "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, § 803.50(a). The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." 552 U.S. at 319-20 (citations omitted). Any reports submitted by a manufacturer to FDA, including MDRs, "may" be disclosed to the public and the submission of a MDR "is not necessarily an admission that the device . . . caused or contributed to the reportable event." *See* 21 C.F.R. §§ 803.9(a), 803.16.

that a device caused or contributed to an injury, they are not by themselves sufficient grounds for a labeling change. FDA emphasizes that data derived from the adverse-event reports "is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across device." *See* Manufacturer and User Facility Device Experience Database, http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/reportingadverseevents/ucm127891.htm (last updated May 7, 2015 and viewed June 25, 2015). *See also* 21 C.F.R. § 803.16; *Pauley v. Bayer Corp*, No. 2681 EDA 2005, 2009 WL 1654592, at *8 n.2, *9 (Pa. Super. Ct. Aug. 18, 2009) ("the contents of the [adverse event reports] themselves, were properly excluded," because they are "anecdotal, not scientific"). Therefore, because the filing of MDRs with FDA does not change a device's PMA approved labeling, and as a result does not alter the warnings given to doctors, the federal duty to submit MDRs to FDA is not identical to any state-law-duty to warn doctors or patients, making Plaintiffs' claim preempted under § 360k(a). *See Sprint Fidelis*, 623 F.3d at 1205-08.

Even if Plaintiffs' failure to warn claim is not expressly preempted, it is impliedly preempted. *See, e.g.*, *Sprint Fidelis*, 623 F.3d at 1205-06 (claims of failure to provide information relating to adverse events and failure to file averse event reports are "simply an attempt by private parties to enforce MDA . . . foreclosed by . . . *Buckman*"); *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d 979, 989 (E.D. Miss. 2014). Plaintiffs assert continually that Defendants have not cited or interpreted the controlling cases correctly, but it is Plaintiffs who have failed to recognize contrary circuit court opinions and misplaced their arguments on *Stengel*. Further, Plaintiffs' failure to warn claim fails even under the Ninth Circuit's erroneous approach in *Stengel*. *Stengel* involved a situation in which the adverse events concerned a type of risk that was *not known* at the time the PMA was issued and the device label approved. *See* 704 F.3d at 1227. Here, by contrast,

the device label already warns of the risks of pain, difficulty with placement, perforation, expulsion and breakage, which Plaintiffs now claim were insufficient or should have been updated following the adverse events reports. Their own arguments demonstrate why implied preemption applies.

Plaintiffs contend that simply because Defendants supposedly violated federal law, then they must also be subject to state law liability. Response at 70. That unfounded assertion ignores the application of express preemption under § 360k(a) and also the fact that the Supreme Court has expressly *rejected* the "proposition that any violation of the FDCA will support a state-law claim." *Lohr*, 518 U.S. at 495. By emphasizing that their claims are premised on the litany of FDCA sections and regulations cited in Count XII, Plaintiffs demonstrate that their claim falls squarely within implied preemption's prohibition on claims where "the existence of these federal enactments is a critical element in [the] case." *Buckman*, 531 U.S. at 353; *see also Stengel*, 704 F.3d at 1235 (Watford, J., concurring) ("Central to the Court's reasoning in *Buckman* was that the state law claim asserted there 'exist[ed] solely by virtue' of the federal enactments[.]" (quoting *Buckman*, 531 U.S. at 353)). Insofar as Plaintiffs could not possibly base any claim on a purported failure to file adverse event reports if 21 U.S.C. § 360i and 21 C.F.R. § 803.50 did not exist, Plaintiffs' use of a state law failure to warn claim provides no more cover for their attempt to privately enforce the FDCA than the *Buckman* plaintiffs' use of common law fraud. *See Buckman*, 531 U.S. at 343. Plaintiffs "cannot make an end run around" the absence of a private right of action under the FDCA "by recasting violations of the FDCA as violations of state common law." *Sprint Fidelis*, 592 F. Supp. 2d at 1161; *see also PLIVA*, 131 S. Ct. at 2578. Despite being styled as a state law tort claim, Plaintiffs' failure to warn claim is simply an attempt to privately enforce the MDA and is therefore "foreclosed by § 337(a) as construed in *Buckman*." *Sprint Fidelis*, 623 F.3d at 1205-06; *see also Marsh*, 693 F.3d at 552-53; *Pinsonneault*, 953 F. Supp. 2d at 1017;

Littlebear v. Advanced Bionics, LLC, 896 F. Supp. 2d 1085, 1092 (N.D. Okla. 2012); *Purchase v. Advanced Bionics, LLC*, 896 F. Supp. 2d 694, 696 (W.D. Tenn. 2011). Consequently, even if Plaintiffs had stated a failure to warn claim that survived express preemption under § 360k(a), which it does not, their failure to warn claim fails as a matter of law pursuant to *Buckman* and § 337(a).

Plaintiffs have also not alleged any well-pled facts providing a link between the purported reporting failures and any of their alleged injuries, which is what Judge Watford in his *Stengel* concurrence emphasized as the "causation hurdle" that Plaintiffs face. Plaintiffs must demonstrate that *if* Defendants had properly reported the adverse events to FDA, that information would have reached the doctors and would have prevented their injuries. *Stengel*, 704 F.3d at 1234 (Watford, J., concurring); *Sprint Fidelis*, 623 F.3d at 1206-07; *Wolicki-Gables*, 634 F.3d at 1301. Plaintiffs only vaguely argue that if they had been aware of the adverse events, they would have never had the insert implanted. Response at 65. Nowhere do Plaintiffs address the fact that the Instructions for Use, Physician Labeling and Patient Labeling all warn of the possibility of the perforations Plaintiffs claim were "hidden." Plaintiffs' Complaints do not contain any factual elaboration regarding any link, much less a plausible one, between the alleged adverse events reports and their purported injuries and *Iqbal/Twombly* bar reliance on speculative possibilities to sustain a claim. As such, Plaintiffs' failure to warn claim fails. *See Shuker v. Smith & Nephew PLC*, No. 13-6158, 2015 WL 1475368 (E.D. Pa. Mar. 31, 2015) (dismissing failure to warn claim because plaintiffs' allegation that had events been reported FDA would have taken action was entirely speculative); *see also Horowitz*, 613 F. Supp. 2d at 282 ("[I]n order to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's federal violations and

plaintiff's injury."); *Covert*, 2009 WL 2424559, at *15 (claim dismissed where plaintiff only alleged conclusory link to plaintiff's alleged injury).

E. Plaintiffs' Pharmacovigilance – Negligent Distribution/Advertising/ Overpromotion/Reporting Claims and Negligence-Risk Management Claims (Counts III and IV) Must be Dismissed.

As explained in the Motion, Counts III and IV of the Amended Complaints are preempted. Motion at 28-32. Defendants cited via hyperlink to various documents on the FDA website that demonstrate that FDA has imposed obligations related to each of the allegations in Counts III and IV and reviewed them for compliance and therefore, any state law remedy would by necessity add to or be an addition to existing federal requirements. Motion at 29. Plaintiffs do not even address these documents or what FDA said or did with respect to Essure for the past thirteen years. Although Plaintiffs acknowledge that some FDA requirements they reference are part of the PMA, Response at 86, they appear to argue that some of the cited regulations are not sufficiently "specific" to warrant preemption. This is despite the fact that these regulations applicable to Essure employ the same words they argue should be changed by state law, e.g., "distribution," "advertising," "reporting" and discuss post market surveillance as a requirement of the PMA.[26] And, despite arguing that there are no specific regulations pertaining to this claim, Plaintiffs cite no controlling case that distinguishes between "general" and "specific" regulations which apply to Essure, particularly where such regulations pertain to the safety and effectiveness of the medical device and are part of the PMA. *See* discussion *supra*, at 19 – 20.

Plaintiffs' argument on *Riegel* also misses the mark. *Riegel* held that any alleged parallel claim must be identical or virtually identical to the federal requirement and ***not*** impose a

[26] In fact, Plaintiffs cite to the requirements, post approval, related to the "CPMA" and Essure. Response at 8 n.11. They cite to these "express provisions" as mandatory. Yet, as applied to Counts III and IV, they ignore these provisions arguing that there are no specific regulations which apply to Essure. This contradiction is further evidence of Plaintiffs' transparent effort to avoid preemption at all costs without regard to the facts or law.

requirement which relates to safety and effectiveness. *Riegel*, 552 U.S. at 321-22. *See also Lohr*, 518 U.S. at 496-97 (state law claim must be "equal to, or substantially identical to" federal requirement to avoid preemption). Here, Plaintiffs argue that there should have been better post-market surveillance. While they fail to state what this better surveillance actually would be, they appear to assert that such surveillance would relate to issues of adverse event reporting which are clearly covered in the PMA, and subject to detailed federal regulations. *See* discussion *supra*, Section IV, D. Any proposed revisions to the post-market surveillance of Essure, including and especially related to adverse event reporting, would add to and be different from what federal law already imposes. *Id*. Such state law requirements are preempted. *See Riegel*, 552 U.S. at 321-22.

In their Response, Plaintiffs discuss the recent United States District Court case from this Circuit cited by Defendants in their Motion: *Scanlon v. Medtronic Sofamor Danek USA, Inc.*, No. CV 13-224-SLR, 2014 WL 3737501 (D. Del. Jul. 28, 2014). Plaintiffs acknowledge as they must that *Scanlon* holds that federal law governs marketing and promotion of medical devices and that the court found claims like Plaintiffs assert here preempted. Response at 85. However, their attempt to distinguish their claims from those asserted in *Scanlon* falls short. Plaintiffs argue that *Scanlon* does not apply because Plaintiffs have "plead a parallel claim based on violations of both federal regulations and the CPMA." *Id*. However, in the next paragraph they argue that there are no federal requirements concerning marketing and promotion. *Id.* How can Plaintiffs argue in one paragraph that that Defendants have violated federal requirements to avoid preemption under *Riegel* and in the next paragraph argue that there are no applicable federal requirements? This inconsistent argument is typical of Plaintiffs' Response. Plaintiffs simply have not set forth any sound basis for distinguishing *Scanlon*, a court within this Circuit which found preempted the same allegations made by Plaintiffs here.

Plaintiffs go on to discuss the allegations of a federal violation necessary to avoid preemption. However, as they do in their Complaints, they repeatedly just cite to regulations and say they were violated without any supporting factual basis. This is not enough to avoid preemption. *See, e.g.*, *Sprint Fidelis*, 592 F. Supp. 2d at 1157. Further, as noted in Section II, above, not a single purported federal "violation" alleged by Plaintiffs is actually supported by the documents to which they cite and that are appended to the Complaints.

Further, Plaintiffs do not state any recognized Pennsylvania cause of action which parallels the federal requirements at issue. Rather, Plaintiffs cite to Section 402A as the applicable state law. As stated below in Section IV, G, in more detail, strict liability is inapplicable here. Finally, to the extent that Plaintiffs are trying to make a claim based solely on alleged federal violations (and Defendants submit there are no such violations), there is no independent cause of action for alleged violations of the FDCA. *See, e.g.*, *Covert*, 2009 WL 2424559, at *7.

F. Plaintiffs' Express Warranty Claim (Count V) Must be Dismissed.

In light of Plaintiffs' attempt in their Response to employ their fraud claims as a basis for their express warranty claim, Count V should be dismissed as preempted and inadequately pled for the same reasons as discussed above in connection with Plaintiffs' fraud and misrepresentation claims. But Count V should be dismissed for two additional reasons. First, and most importantly, Plaintiffs' claim as pled fits within the holdings of cases which have found similar claims to be preempted. Motion at 34. These cases have held that because the alleged "warranties" were either part of a submission to FDA which was approved as part of the PMA or related to the safety and effectiveness of the device, they would be in conflict with federal requirements under *Riegel* and *Buckman*. As such, because this claim seeks to enforce safety requirements that are different from or in addition to those imposed by FDA, it is preempted. *See Riegel*, 552 U.S. at 325; Motion at

41. Second, even if this claim is not preempted, it is insufficiently pled as a matter of law under *Iqbal/Twombly*. *See also Shuker*, 2015 WL 1475368, at *47-48 (dismissing warranty claim for failure to plead plausible facts).

The alleged warranties cited by Plaintiffs go to the safety and effectiveness of Essure and/or are taken directly from PMA-approved documents. *See* Complaints at ¶¶ 94-120, 180-81. For Plaintiffs to succeed on this claim a jury would need to find "that the [device] was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the MDA, which has preempted safety and effectiveness determinations for a device." *Williams*, 388 F. Appx. at 171; *Gavin*, 2013 WL 3791612, at *15-16; *Caplinger*, 921 F. Supp. 2d at 1222; *Lawrence v. Medtronic, Inc.*, No. 27-cv-131197, 2013 WL 4008821, at *5 (D. Minn. Aug. 7, 2013); *Smith v. DePuy Orthopaedics*, No. 11-4139 (JAP), 2013 WL 1108555 (D.N.J. Mar. 18, 2013) (where the express warranty claim was preempted as per *Williams*); *Millman*, 2015 WL 778779, at * 6. But such a conclusion by a jury would necessarily conflict with FDA's conclusive determination in granting PMA status that "there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" *Riegel*, 552 U.S. at 318.

Plaintiff's express warranty claim should also be preempted because it is based on FDA approved statements, such as those in the Patient Labeling approved by FDA in 2002 which contains four pages of detailed warnings and precautions including warnings about perforations or expulsion of the device. *See* http://www.accessdata.fda.gov/cdrh_docs/pdf2/P020014d.pdf.

If they were not preempted "such [] claim[s] would impose requirements different from, or in addition to, the federal requirements, potentially resulting in the imposition of liability on a manufacturer who has fully complied with federal law." *Horowitz*, 613 F. Supp. 2d at 285. *See also Kubicki v. Medtronic*, No. 12-00734, 2013 WL 1739580 (D.C. Cir. Mar. 21, 2013). And, as

is the case here, where FDA has reviewed available post marketing surveillance and determined that Defendants have complied with federal law, alleging a breach of a safety and effectiveness warranty is the same as questioning the PMA approval by FDA for the device's safety and effectiveness. That is exactly the type of claim envisioned in *Riegel* and *Buckman* to be preempted. *See Williams*, 654 F. Supp. 2d at 306; *Millman*, 2015 WL 778779, at *6.

Indeed, Plaintiffs try to argue against the safety and effectiveness of Essure in connection with each alleged warranty cited in paragraphs 103-119 of the Amended Complaints. In doing so, they ask the Court to "disrupt the federal scheme" by requiring that the devices "be safer, but hence less effective, than the model the FDA has approved." *Riegel*, 552 U.S. at 325. Given the undeniably broad reach of the language in § 360k(a) as affirmed by *Riegel*, the express warranty claim regarding safety and effectiveness is preempted.

Finally, even if this Court were to find that Plaintiffs' express warranty claim is not preempted, it is improperly pled and should be dismissed with prejudice. In order for a claim to survive, it must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. Plaintiffs cannot rely upon the pure legal conclusion that a particular statement "violates" the "CPMA" or a federal regulation. *See, e.g., Covert*, 2009 WL 2424559, at *15 (dismissing alleged "parallel claims" because plaintiff's allegations "hardly cross the line from conclusory to factual" and where plaintiff offered "little more than a formulaic recitation of the elements of a parallel claim, coupled with vague citations to generic allegations of wrongdoing by [defendant] without any identifiable tie between the two"). Even though Plaintiffs cite to specific statements from several alleged sources, Plaintiffs have not pled any specific facts as to how these statements ended up as the basis for an alleged and unspecified bargain between the parties. There are no allegations as to the source of the statements, when the statements were made, in what

manner the statements were made, the Defendants' alleged intended recipient, when Plaintiffs became aware of the statements or their understanding as to the same.

In order for a breach of express warranty claim to be properly pled under Pennsylvania law, a plaintiff must show that "some form of promise or affirmative statement was made," and "a mere recitation of the elements of a cause of action, absent any factual support, specification of a particular promise that became the basis of the bargain, or a showing that the promise was directed at the consumer, is insufficient to withstand dismissal." *McPhee v. DePuy*, 989 F. Supp. 2d 451, 466 (W.D. Pa. 2012) (citing *Gross*, 858 F. Supp. 2d at 502). A promise only "becomes the basis of the bargain if the plaintiff can prove 'that she read, heard, saw, or knew of the advertisement containing the affirmation of fact or promise.'" *Starks v. Coloplast*, No. 13-3872, 2014 WL 617130, at *6 (E.D. Pa. Feb. 18, 2014). Because express warranties are expressly negotiated, "to create an express warranty, the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004), *aff'd*, 885 A.2d 982 (Pa. 2005).

While Plaintiffs have quoted statements from "the website" (¶ 103), "advertisements" (¶ 104), a "fact sheet" (¶ 105), "agents" (¶¶ 106-107), "marketing" (¶¶ 108-110), a "brochure" (¶¶ 111-114), a "booklet" (¶ 115), "data warranties" (¶ 116), a "PMA Supplement" (¶ 117), and "SEC Filings" (¶¶ 118-119), they are missing the other half of the basis of the bargain – stating which Plaintiffs saw which statements, when, and where, and how each particular Plaintiff relied on the statements. It is not plausible that each Plaintiff relied on each and every one of the statements listed in this section of the Complaints because they have not alleged how these statements targeted at others were seen by Plaintiffs. These statements apparently span years of time, before and after the various Plaintiffs had Essure placed. Further, as discussed in Defendants'

Motion, there is no question that certain of these alleged "statements" came from materials submitted to FDA and/or relate to materials submitted to FDA. Motion at 34.

Under Pennsylvania law, a warranty is an "affirmation of fact" or promise made by a seller to a buyer which relates to the goods sold and which becomes a part of the basis of the bargain. *See* 13 Pa. Cons. Stat. Ann. § 2313(a). The Essure Physician Labeling expressly restricts the sale of Essure to a physician or an order by a physician, so it is factually implausible for a contract to exist between Defendants and Plaintiffs. This privity of contract, an essential element of an express warranty claim founded on contract, is entirely lacking. *See Dougherty v. C.R. Bard, Inc.*, No. 11-6048, 2012 WL 2940727, at *9 n.15 (E.D. Pa., July 18, 2012); *Kester v. Zimmer Holdings, Inc.*, No. 10-CV-00523, 2010 WL 2696467, at *3-4 (W.D. Pa. June 16, 2010); *Killen*, 2012 WL 4482371, at *14. Moreover, the allegations in Plaintiffs' Complaints simply do not support this claim.

First, several of the alleged warranties quoted by Plaintiffs in the Amended Complaints are clearly directed at doctors and not at users of the device, such as: "the Essure training program is a comprehensive course designed to provide the information and skills necessary to select appropriate patients, perform competent procedures and manage technical issues related to the placement of Essure micro-inserts for permanent birth control." ¶103(i). An express warranty must be directed at the consumer, and specifically at Plaintiffs. *Starks*, 2014 WL 617130, at *7; *see also Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 752 (W.D. Pa. 2004).

Second, it is highly implausible that the statements listed under the sections entitled Warranties by Agents, the PMA Supplement and SEC Filings (¶¶ 106-107, ¶ 117, ¶¶ 118-119) were "specifically negotiated and expressly communicated to Plaintiffs by Defendants" as Plaintiffs claim, because the audience for these statements and publications is not potential

consumers of Essure, and the statements are not easily publicly accessible or accessible at all (e.g., PMA supplements, SEC filings).

Third, even though Plaintiffs provide alleged quotes from each of the materials they cite, Defendants are still unsure from which particular website, advertisements, fact sheets, marketing, brochure, booklet, and data warranties Plaintiffs are citing. Given that Essure was approved in 2002, it is essential and required under the law that Plaintiffs identify which iteration of each of the materials the Plaintiff allegedly relied on in order to put Defendants on notice regarding from where the material derived.

Plaintiffs' amalgamation of various quotes to support their breach of express warranty claim purportedly from Essure's marketing materials and other publicly-available information is not enough to create a plausible claim on its face. Therefore, Count V is improperly plead and should be dismissed under *Iqbal/Twombly*. Indeed, within the last few days, Judge Dalzell dismissed a breach of express warranty claim in a medical device case after concluding that the plaintiff's vague allegations about "warranties" being made part of a bargain, and his failure to allege the way in which these alleged statements were a material part of the bargain struck, were fatal to his claim. *Runner*, 2015 WL 3513424, at *5; *accord Horsmon v. Zimmer Holdings, Inc.*, No. 11-1050, 2011 WL 5509420 (W.D. PA. Nov. 10, 2011); *Killen*, 2012 WL 4482371, at *14. The same flaws are fatal to Plaintiffs' claim here.

G. Plaintiffs' Strict Liability and Negligent Design Claims (Counts X and XIII) Must be Dismissed.

Plaintiffs' claims in strict liability and negligent design are preempted under *Riegel*. 552 U.S. at 321, 330. As opposed to dismissing these claims under Third Circuit precedent, *Williams*, 388 F. Appx. at 169; *Horn*, 376 F.3d at 176 (preempted claims of defective manufacturing, defective design); *Millman*, 2015 WL 778779, at *6 (preempted claims of strict liability, negligent

design/manufacture), Plaintiffs spend 11 pages of their Response arguing that such claims, except for one part of one claim,[27] should survive preemption. The surviving claims, Plaintiffs contend, are based upon a manufacturing defect and a failure to warn. Response at 88. Plaintiffs' Response does not alter the conclusion that these claims should be dismissed in their entirety.

At the outset, Plaintiffs contend that *Williams* and *Riegel* are not applicable. They argue that these cases are inapplicable because the plaintiff in those cases did not plead a federal violation whereas here, Plaintiffs allege that they have. This attempt to distinguish the instant case from *Riegel, Williams, Horn* and *Millman* is without merit. In each of those cases, the courts held that strict liability claims, whether for design, manufacturing or failure to warn, are the precise type of claim that the express preemption clause of the MDA in § 360k(a) was intended to preempt. *See, e.g., Horn*, 376 F.3d at 177 ("Because these state common law claims and duties are in severe tension with § 360k(a) in that they are either in addition to, or different from, the federal requirements established by the FDA in approving the HeartMate, they are necessarily preempted by federally imposed PMA requirements under § 360k(a).")

Plaintiffs then make a concerted and lengthy attempt to convince this Court that a cause of action for strict liability exists under Pennsylvania law for medical devices. Plaintiffs do not cite to any binding authority for such proposition and completely disregard the long line of courts in this District which have held otherwise. *See, e.g., Runner*, 2015 WL 3513424, at *4; *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 749 (E.D. Pa. 2007); Motion at 39-40. This Court should

[27] Plaintiffs "withdraw" the strict liability count to the extent it is based upon a design defect. Response at 88. However, under Fed. R. Civ. P. 41(a), Plaintiffs cannot withdraw this claim without approval of Defendants—which would be given if with prejudice—or an Order of this Court, neither of which has occurred. As Plaintiffs have taken the position as to their "negligent design" claim that they are withdrawing such a claim without prejudice, *see* Notice of Withdrawal of Claim of Negligent Design, *McLaughlin v. Bayer, et al.*, No. 2:14-cv-07315, Docket No. 54, Defendants respectfully request that the Court dismiss with prejudice both Plaintiffs' strict liability claim for alleged design defect in Count X and Plaintiffs' negligent design claim in Count XIII, for failure to respond to Defendants' Motion.

follow *Soufflas* and the other cases in this District and dismiss any claim for strict liability. Even assuming there were a viable claim for strict liability in Pennsylvania, which there is not, Plaintiffs have not alleged any specific defect which caused Plaintiffs' injury. *Soufflas*, 474 F. Supp. 2d at 749.

H. Plaintiffs' Negligent Manufacturing Claim (Count XI) Must be Dismissed.

Plaintiffs' manufacturing based claims, whether in negligence or strict liability, are preempted. In response to the Defendants' Motion, Plaintiffs not only make a futile attempt to escape *Riegel*, they also completely misconstrue its holding in the opening section of their Response. Plaintiffs argue that "*Riegel* and its progeny limit preemption to manufacturers who comply with federal law, but deny it to those who violate federal law." Response at 17. They then go on to argue: "Again, the CGMPs are general requirements which apply to all devices and are not subject to preemption as they fail to meet the first prong of *Riegel*. This is the position of the Federal Government, the C.F.R., the Supreme Court, and the *Bentzley* court." Response at 77. Thus, Plaintiffs argue that in essence they have a cause of action if they simply plead a violation of federal law—there can be no other plausible reading. *See, e.g.*, Response at 17. However, Plaintiffs have not plausibly pled any violation of federal law. Even if they had done so, they cannot simply allege that Defendants violated federal law without pleading the violation of a substantially identical state law which does not add to or differ from the federal requirements or they would be impliedly preempted under *Buckman. Covert*, 2009 WL 2424559, at *7-8. *See Riegel*, 552 U.S. at 324. Plaintiffs' argument, similar to their argument alleging that the "CPMA" is "invalid", would torture the Supreme Court's holdings, including those of *Riegel* and *Lohr*. Under Plaintiffs' argument, they would conveniently avoid having to state any federal law which was violated or even a parallel state claim. Plaintiffs also believe that they are immune on this

same basis from implied preemption under *Buckman*. *See, e.g.*, Response at 18. This is just nonsense—and would be in direct conflict with other statements in their Response. *See, e.g.*, Response at 71. ("Again, *Buckman* only stands for the proposition that a plaintiff cannot bring suit *solely* on a violation of the FDCA, but that a defendant may still be liable under state law.").

Assuming that Plaintiffs are also trying to argue that they have stated a state cause of action for negligent manufacturing which is based upon allegations of actual violations of federal manufacturing requirements, their argument likewise fails. Plaintiffs argue that their manufacturing claim is based on Section 402A. Response at 102. If so, for the same reasons stated above and in Defendants' Motion, there is no applicable state law claim under Section 402A. *See, e.g., Soufflas*, 474 F. Supp. 2d at 749-50.

Similar claims have been found to be preempted by those courts which have addressed them. Indeed, as discussed at length in *Sprint Fidelis*, 592 F. Supp. 2d at 1157-59, proposed state law theories which would add to or be different from what FDA has required are preempted. Plaintiffs again try to distinguish these cases claiming they are not like their case because Plaintiffs have "plead violations of federal regulations." Response at 104. This argument is unavailing. The cases cited by Defendants base their holdings on the fact that such state law claims are not truly parallel to any alleged federal violation. They conclude that to impose such state law remedies would add to or be different from them. The same holds true here.

Third, Plaintiffs fail to allege any state cause of action sufficient to avoid dismissal under *Iqbal/Twombly*. Plaintiffs argue that her "injuries were caused by the 'manufacturing of Essure inconsistent with the CPMA and Federal law, manufacturing an 'adulterated' and 'misbranded' product.'" Response at 102, 105. Plaintiffs allege that "Defendants breached these duties [not specified] by not complying with FDA specifications, regulations, and/or its CPMA." *Id*. at 105.

Such generalized statements cannot support a claim sufficient to avoid preemption. *See, e.g.*, *Covert*, 2009 WL 2424559, at *15 (dismissing alleged "parallel claims" because plaintiff's allegations "hardly cross the line from conclusory to factual" and where plaintiff offered "little more than a formulaic recitation of the elements of a 'parallel' claim, coupled with vague citations to generic allegations of wrongdoing by [defendant] without any identifiable tie between the two."). Simply incanting a violation by using the words "adulterated" and "misbranded" are legal conclusions and insufficient to state a claim. *See, e.g., Sprint Fidelis*, 592 F. Supp. 2d at 1157. Moreover, in their Motion, Defendants challenged the fact that Plaintiffs had sufficiently pled any causal event: Plaintiffs failed to "allege that Defendants manufactured and placed into commerce, a device which did not comply with manufacturing requirements that were part of the PMA." Motion at 48. Plaintiffs do not even address this failure in their Response. See Response at 104-05. Accordingly, Plaintiffs' claim for negligent manufacturing should be dismissed with prejudice.

I. Plaintiffs' Negligent Design Claim (Count XIII) Must be Dismissed.

In their Motion, Defendants presented several legal bases for dismissal of Count XIII of the Amended Complaints. Plaintiffs have not responded to any of Defendants' arguments. Instead, Plaintiffs filed a notice of dismissal of their negligent design claim, *without prejudice*. *See McLaughlin v. Bayer, et al.*, No. 2:14-cv-07315, Docket No. 54. This negligence claim is identical to the strict liability design claim Plaintiffs state that they withdraw as part of their Response. Response at 88. Defendants agree that these claims should be dismissed from this case, but only with prejudice as they are preempted as a matter of law. Accordingly, as this negligent design claim, as well as any strict liability claim for design in Count X, is preempted as a matter of law, Defendants respectfully request that such claim be dismissed with prejudice.

V. CONCLUSION

Riegel holds that PMA-approved devices such as Essure are devices subject to the express preemption clause in § 360(k)a of the Medical Device Amendments to the Food Drug and Cosmetic Act. Further, the Supreme Court in *Buckman* held that a state law challenge to the regulatory scheme enacted by Congress and administered by FDA is impliedly preempted because this type of "litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme." *Buckman*, 551 U.S. at 353.

For these reasons, those more fully articulated above and in Defendants' Motion, Plaintiffs' claims are clearly preempted under *Riegel* and *Buckman.* To the extent that this Court finds any of the claims to be not preempted, Plaintiffs' claims fail to state a non-preempted claim under *Iqbal/Twombly* or fail to state a claim under Pennsylvania law. Accordingly, Defendants respectfully request that the Court dismiss Plaintiffs' Amended Complaints in their entirety, and dismiss these actions with prejudice.

Dated: June 30, 2015

Respectfully submitted,

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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 Reply of Defendants Bayer Corporation, Bayer HealthCare Pharmaceuticals Inc., Bayer Essure Inc. and Bayer HealthCare LLC in Support of Their Omnibus Motion for Judgment on the Pleadings Under Fed. R. Civ. P. 12(c) was electronically filed with the Court on June 30, 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

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