Nos. 125020, 125021

IN THE
SUPREME COURT OF ILLINOIS

NICHOLE HAMBY ET AL., *Plaintiffs-Appellees* v. **BAYER CORPORATION ET AL.,** *Defendants-Appellants,* and **DOES 1–10,** *Defendants.*	On Appeal from the Appellate Court of Illinois, Fifth District, No. 5-18-0279 There on Interlocutory Appeal from the Circuit Court of the Third Judicial Circuit, Madison County, Illinois, No. 16-L-1617 The Hon. William A. Mudge Judge Presiding
CHRISTINE RIOS ET AL. *Plaintiffs-Appellees* v. **BAYER CORPORATION ET AL.,** *Defendants-Appellants,* and **DOES 1–10,** *Defendants.*	On Appeal from the Appellate Court of Illinois, Fifth District, No. 5-18-0278 There on Interlocutory Appeal from the Circuit Court of the Third Judicial Circuit, Madison County, Illinois, No. 16-L-1046 The Hon. Denis R. Ruth Judge Presiding

BRIEF AND ARGUMENT OF DEFENDANTS-APPELLANTS BAYER CORPORATION ET AL.

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NATURE OF THE CASE

The court below should have resolved these cases with a straightforward application of *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1781 (2017). Other courts, addressing similar or identical facts, have relied on that decision and correctly held that there is no personal jurisdiction over claims by out-of-state plaintiffs against out-of-state defendants concerning out-of-state injuries. This Court should do the same. In these consolidated cases, 181 Plaintiffs from 33 states have sued Bayer over alleged injuries related to their use of Essure, an FDA-approved permanent contraceptive device. Of those Plaintiffs, 160 do not allege that they reside in or experienced any injuries in Illinois ("non-Illinois Plaintiffs"). Further, none of the Bayer Defendants (collectively, "Bayer") is a citizen of Illinois or otherwise subject to general jurisdiction here. And as set forth below, Bayer is not subject to specific personal jurisdiction in Illinois for the claims of the 160 out-of-state Plaintiffs, who have failed to identify a link between "the forum and the *specific claims at issue*," as the Due Process Clause requires. Misapplying *Bristol-Myers*, the Fifth District Appellate Court affirmed the Madison County Circuit Court's decisions denying Bayer's motions to dismiss for lack of personal jurisdiction. Bayer sought this Court's review based on the weighty constitutional issues presented and the conflict the Appellate Court's decisions created with decisions of federal courts and the supreme courts of other states. This Court granted Bayer's petitions for leave to appeal and consolidated these cases. Consistent with the decisions of other courts across the country, this Court should reverse the decisions below and remand with instructions for the Circuit Court to dismiss the claims of the non-Illinois Plaintiffs.

INTRODUCTION

In these consolidated cases, the Fifth District Appellate Court erred in holding that the Madison County Circuit Court has specific personal jurisdiction over claims brought by out-of-state Plaintiffs against out-of-state Defendants for injuries suffered out of state. The court based this ruling on its finding that Bayer's *nationwide* marketing, research, and training activity—which took place in dozens of states across the country, including Illinois—was sufficient to create specific jurisdiction. But under established U.S. Supreme Court precedent, Plaintiffs have not shown the constitutionally required substantial connection between Bayer's limited Illinois contacts and the "specific claims" of the non-Illinois Plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1781; *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). The nexus between Illinois contacts and "specific claims" is constitutionally inadequate, and the decision below should be reversed for three reasons.

First, the decision conflicts with the U.S. Supreme Court's ruling in *Bristol-Myers*, which held that each plaintiff must demonstrate a constitutionally "adequate link" between "the forum and the *specific claims* at issue," meaning that each individual plaintiff's suit "must arise out of or relate to the defendant's contacts with the *forum*." 137 S. Ct. at 1780 (emphasis added). Following *Bristol-Myers*, numerous courts have rejected arguments for personal jurisdiction that are virtually identical to the Plaintiffs' arguments here. These cases—many of which involved identical allegations concerning the Essure device—correctly held that the alleged in-state contacts are "too attenuated" from the non-resident plaintiffs' "specific claims" to support personal jurisdiction. *See infra* pp. 14–17.

Here, the non-Illinois Plaintiffs do not allege that they received their Essure devices or viewed marketing in Illinois; they argue only that Bayer's nationwide

research, marketing, and training activities, some of which took place in Illinois among numerous other states, give Illinois courts specific jurisdiction over any Essure claim brought by any Essure user anywhere in the world. This expansive view of *specific* personal jurisdiction would subject Bayer to "a loose and spurious form of general jurisdiction" virtually anywhere it does business. *Bristol-Myers*, 137 S. Ct. at 1781. But there is simply no link, much less a constitutionally adequate one, between the out-of-state Plaintiffs' claims and this forum.

Second, the decisions below erroneously concluded that the non-Illinois Plaintiffs' claims against Bayer "aro[s]e from" Bayer's nationwide testing, development, and marketing of Essure, without requiring any causal connection between the activities that took place in Illinois and the specific injuries that the non-Illinois Plaintiffs allege. *See* A14, A24–25. Courts nationwide—including in Illinois—have made clear that, for specific jurisdiction to obtain, the defendant's in-state conduct must be the *legal cause* of the plaintiff's alleged injuries.

Plaintiffs plainly fail to meet these standards. For instance, the non-Illinois Plaintiffs bring claims for manufacturing defects, but the devices were not manufactured in Illinois, and Plaintiffs did not obtain the devices or experience injuries in Illinois. Plaintiffs likewise assert a variety of misrepresentation and warranty claims, but they never allege that they viewed any of these statements in Illinois, or even that the statements they relied upon were written in Illinois. The out-of-state Plaintiffs here similarly do *not* allege that they participated in a clinical trial in Illinois, or that their doctors were trained in Illinois. Bayer's research, marketing, and training activities in Illinois thus did not give rise to these Plaintiffs' claims. Rather, their alleged injuries

arose from the marketing they actually viewed and the training of their own physicians—all of which occurred somewhere other than Illinois. The alleged links to Illinois that the circuit court found sufficient are so highly attenuated from Plaintiffs' claims that they would not distinguish Illinois from dozens of other states across the country where Bayer sold, marketed, or studied Essure. Indeed, Essure plaintiffs in several other states—including plaintiffs represented by the same plaintiffs' counsel—have already relied on identical allegations to argue that specific jurisdiction exists over non-residents' claims in *those* states. *See infra* note 3.

At most, Plaintiffs have speculated that, *but for* Bayer's limited in-state activities, Essure would not have been approved and the non-Illinois Plaintiffs would never have undergone the procedure. Illinois courts and courts nationwide have rightly rejected this approach to specific personal jurisdiction as "vastly overinclusive." *GCIU-Employer Ret. Fund v. Goldfarb Corp.*, 565 F.3d 1018, 1025 (7th Cir. 2009); *accord, e.g.*, *Keller v. Henderson*, 359 Ill. App. 3d 605, 615–16 (2d Dist. 2005); *Harlow v. Children's Hosp.*, 432 F.3d 50, 61 (1st Cir. 2005). If but-for causation were all that is required, then a near-limitless array of facts could give rise to *specific* personal jurisdiction in potentially every state in the Union. This Court should reject the non-Illinois Plaintiffs' attenuated theory of specific personal jurisdiction.

Finally, jurisdiction is unreasonable here, particularly given that it appears that all but five of the non-Illinois Plaintiffs filed duplicate claims in California, the state in which Essure was developed and initially manufactured. Moreover, each non-Illinois Plaintiff could pursue her claim against Bayer in her home state, or in any other state where Bayer is subject to general jurisdiction—states that have a closer connection to,

and a greater interest in, the specific claims at issue in the Amended Complaints. This Court should reject Plaintiffs' efforts to make Illinois a magnet for nationwide mass tort suits that have nothing to do with the State.

ISSUE PRESENTED FOR REVIEW

Whether the Fifth District Appellate Court erred in holding that the Madison County Circuit Court has personal jurisdiction over claims brought by non-Illinois plaintiffs against non-Illinois defendants for personal injuries allegedly suffered outside of Illinois, based on allegations that certain clinical trial, marketing, and training activities for the product occurred in numerous states, including Illinois, even though those activities are not the basis of the non-Illinois Plaintiffs' claims.

JURISDICTION

The circuit court denied Bayer's Motions to Dismiss for lack of personal jurisdiction on April 18, 2018. A27, A36. The Appellate Court, Fifth District, granted Bayer's petitions for leave to file interlocutory appeals on June 28, 2018, and affirmed the Circuit Court's decisions May 29, 2019. A16, A27. This Court granted Bayer's petitions for leave to appeal on September 25, 2019, and ordered the *Hamby* and *Rios* cases consolidated. A1, A3. Therefore, this Court has appellate jurisdiction under Supreme Court Rule 315(a).

STATEMENT OF THE FACTS

This appeal arises from two complaints asserting virtually identical allegations concerning Essure, a Class III medical device with pre-market approval from the FDA that is indicated for use as a form of permanent female contraception. In the *Hamby* complaint, the Plaintiffs are 86 women from 22 different states; of those 86 women, only eight reside in Illinois, another five allege they obtained Essure in Illinois, and only one

alleges she resides in the forum county. *See Hamby* C190–203 [FAC ¶¶ 229–314].[1] The 95 *Rios* Plaintiffs are similar—they hail from 27 different states, only eight allege that they reside in or obtained Essure in Illinois, and just one resides in the forum county. *See Rios* C580–95 [FAC ¶¶ 238–332]. The remaining 160 Plaintiffs in the two cases all allege that they reside in, obtained their Essure devices in, and experienced injuries in other states (the "non-Illinois Plaintiffs"). *See Hamby* C190–203 [FAC ¶¶ 229–314]; *Rios* C580–95 [FAC ¶¶ 238–332].

Plaintiffs filed their complaints before the Supreme Court decided *Bristol-Myers*, and initially asserted that Bayer was subject to general personal jurisdiction in Illinois because it engages in "substantial and continuous" business activities in Illinois, C2,[2] or alternatively that the court had specific personal jurisdiction over *all* of the Plaintiffs' claims because the non-Illinois Plaintiffs were joined to Illinois residents bringing similar claims, C4.

Following the Supreme Court's rulings in *Bristol-Myers* and *BNSF Railway Co. v. Tyrrell*, 137 S. Ct. 1549 (2017), which rejected both of these theories of jurisdiction, Plaintiffs filed Amended Complaints changing their jurisdictional theory. *Hamby* C144; *Rios* C534. In their Amended Complaints, Plaintiffs abandoned any claim of general personal jurisdiction. Instead, they advanced a new theory, asserting jurisdiction based on alleged clinical trial, marketing, and training activities, which did not have a nexus to their "specific claims." Plaintiffs alleged that locations in Illinois (along with dozens of

[1] The plaintiffs appear to have been split into two cases to avoid federal jurisdiction under 28 U.S.C. § 1332(d)(11).

[2] Except when case- or plaintiff-specific facts are in issue, Bayer cites to the record on appeal from the *Hamby* case.

other states) were used as sites for some of the numerous Essure clinical studies; that Bayer developed a "marketing strategy" for Illinois, which was later "rolled out" across the country; and that Bayer developed a "pilot" physician-accreditation program for Illinois, which was later rolled out across the country. C147–50 [FAC ¶ 11]. Essure plaintiffs in other suits—including some represented by these same Plaintiffs' counsel—have made similar allegations about several other states, including Missouri, Pennsylvania, Indiana, and New Mexico.[3]

Regardless, Plaintiffs do not allege claims arising from the alleged Illinois activities. Instead, the Amended Complaints alleged causes of action for negligence, strict liability, breach of warranty, and fraud, based on four theories of liability: (1) Plaintiffs' Essure devices were defectively manufactured; (2) Plaintiffs relied on false or misleading statements in Essure promotional materials; (3) Plaintiffs were not adequately warned of the risks of the Essure device; and (4) Plaintiffs' physicians were not adequately trained to perform their Essure procedures. The Amended Complaints do

[3] *See* C589–90 ("Defendants engaged in extensive contacts with Missouri during the development of Essure, creating a marketing strategy for Essure, creating the Essure labeling, and in obtaining FDA approval of Essure," including because "for three of th[e] four pre-market clinical studies for Essure, Conceptus used Missouri hospitals and contracted with Missouri physicians to serve as clinical investigators."); C595–96 (alleging personal jurisdiction in New Mexico because "one of the two post-approval studies mandated by the FDA was performed in part in New Mexico" and "Bayer used … safety and efficacy data [collected in New Mexico] to promote and market Essure in New Mexico and across the United States"); *see also* Complaint ¶¶ 117–118, *Leach v. Bayer Corp.*, No. 49D14-1803-CT-012218 (Ind. (Marion Cty.) Super. Ct. filed March 28, 2019) ("Bayer used Indiana to develop, create a marketing strategy for, label, and/or work on the regulatory approval for Essure," and "Indiana was the site of clinical studies regarding Essure."); Complaint ¶¶ 92–93, *Vazquez v. Bayer Corp.*, No. GD-18-002824 (Pa. (Allegheny Cty.) Ct. of Common Pleas filed Feb. 28, 2018) ("Defendants used Pittsburgh, Pennsylvania to develop, create a marketing strategy for, label, and/or work on the regulatory approval for Essure," and "Pennsylvania was the site of clinical studies regarding Essure.").

not allege that Bayer manufactured any Essure devices in Illinois; that any of the non-Illinois Plaintiffs viewed Essure marketing materials in Illinois or viewed materials that Bayer wrote in Illinois; that any of the non-Illinois Plaintiffs received warnings about the risks of the device in Illinois; or that Bayer trained any of the non-Illinois Plaintiffs' physicians in Illinois, whether through the "physician-accreditation program" or otherwise. *Hamby* C241–49; *Rios* C633–41.

In addition to amending their complaint following *Bristol-Myers*, it appears that 155 of the 160 non-Illinois Plaintiffs filed duplicate complaints in Alameda County Superior Court in California. California was the headquarters of Bayer's predecessor, Conceptus, and is the location where Essure was developed and initially manufactured. A coordinated proceeding of thousands of plaintiffs concerning Essure is currently pending there.[4]

Bayer moved to dismiss the claims of the non-Illinois Plaintiffs in the Madison County Circuit Court, on the ground that Illinois's exercise of personal jurisdiction over claims between non-Illinois parties arising out of non-Illinois conduct would violate the Due Process Clause. *Hamby* C241–49; *Rios* C633–41.[5] The circuit court denied Bayer's motion to dismiss, holding that *Bristol-Myers* was distinguishable because in that case, the U.S. Supreme Court had "noted that the out-of-state defendant corporation did not

[4] In nearly all of those refiled cases, Plaintiffs are represented by attorneys who are also counsel of record in this case. Bayer has challenged personal jurisdiction in the California suits only as to a limited category of Plaintiffs who obtained their devices after late 2013 and filed suit in 2018 or later, after defendants had ceased to be citizens of California. None of the non-Illinois plaintiffs in these suits fit those criteria.

[5] Bayer also moved to dismiss all Plaintiffs' claims as preempted by federal law and inadequately pleaded. *Hamby* C251–66; *Rios* C643–58. The circuit court deferred ruling on those aspects of Bayer's motion to dismiss. A35, A43.

create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for [the product]" in the forum state. A32, A40.

The court also relied heavily on a pre-*Bristol-Myers* case, *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 2016 IL App. (1st) 151909 ¶ 75, which held that personal jurisdiction existed over claims challenging the actual conduct of clinical trials that took place in Illinois. *See* A30, A38. Applying *M.M.*, the circuit court reasoned that the claims of all plaintiffs "arise out of or relate to" the clinical trials in Illinois, because they were "necessary for the initial FDA approval" of Essure. A30–32, A38–40. Further, the data from the clinical trials sites in Illinois were "ultimately funneled along, with other cumulative data," and "used to inform the warning label context" of Essure. A33, A41. The court held that the clinical trials in Illinois therefore were sufficient to create specific personal jurisdiction, because "but for Bayer's activities in Illinois, Plaintiffs[] would not have suffered their alleged injuries." A32, A40. Likewise, the court found that the existence of a pilot training program and marketing strategy in Illinois was sufficient to create specific personal jurisdiction because plaintiffs raised claims concerning training and marketing, and alleged that the success of the Illinois pilot programs influenced the nationwide programs. A33, A41.

Bayer petitioned for, and on June 28, 2018 was granted, leave to file an interlocutory appeal in the Fifth District. On May 29, 2019, in a pair of unpublished decisions, the Fifth District affirmed the circuit court's orders and found that Illinois had specific personal jurisdiction over the non-Illinois Plaintiffs' "class-action claims[]."[6]

[6] Although the appellate court's decision refers to the complaints here as class actions, A6 & n.2, A17 & n.2, in fact Plaintiffs never filed a class action complaint. The

A5, A16. Relying, as the circuit court did, on the *M.M.* decision, A12, A23, the appellate court held that there was specific personal jurisdiction in Illinois because "Bayer conducted clinical trials in Illinois, targeted Chicago for developing a marketing campaign, and developed its physician training program in Illinois," and the non-Illinois Plaintiffs' claims "relate[] to the testing, development, and marketing of the Essure product." A13–14, A24–25.

The Fifth District's decisions did not consider whether there was any causal connection between Bayer's in-state conduct and the non-Illinois Plaintiffs' specific claims, much less whether that connection rose to the "legal cause" of injury requirement imposed by Illinois precedents and by other courts nationwide. Nor did the court conduct the claim-by-claim analysis required by *Bristol-Myers*. Instead, it relied heavily on a single line from *Bristol-Myers*' background section—a statement that the company "did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California." A11–13, A22–24. The Court purported to distinguish *Bristol-Myers* on the grounds that "[a]ll of Bayer's conduct cited by the plaintiffs relates to the testing, development, and marketing of the Essure product." A14, A25. The court concluded that it did not matter "whether the plaintiffs themselves were injured in Illinois, visited doctors in Illinois, or had the device implanted in Illinois" because "we must look to the conduct of Bayer that occurred in Illinois." A13, A24. It summarily concluded that Plaintiffs' claims "all arise, at least in part, from Bayer's conduct in

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Amended Complaints here, as in *Bristol-Myers*, involve the individual claims of numerous Plaintiffs from dozens of states.

Illinois." A14, A25. Finally, the Court held that "Illinois has an undeniable interest in resolving a dispute arising, in part, from clinical trials held in Illinois, by Illinois doctors, in Illinois facilities" and, thus, that forcing Bayer to litigate all claims in Illinois would be reasonable. A14–15, A25–26.

Bayer filed petitions for leave to appeal on July 3, 2019. This Court granted Bayer's petitions and consolidated the cases on September 25, 2019. A1–4.

ARGUMENT

Whether the circuit court possesses personal jurisdiction over a defendant is a question of law, which this Court reviews *de novo*. *BAC Home Loans Servicing, LP v. Mitchell*, 2014 IL 116311, ¶ 17. "The plaintiff has the burden of establishing a *prima facie* basis to exercise personal jurisdiction over a nonresident defendant." *Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 2017 IL 121281, ¶ 12.

I. THE FIFTH DISTRICT'S RULING IS CONTRARY TO *BRISTOL-MYERS* AND ITS PROGENY.

The Fifth District's rulings should be reversed, because they are contrary to *Bristol-Myers* and its progeny, which hold that nonresident plaintiffs cannot bring claims against nonresident defendants based on activities that occurred nationwide and that are highly attenuated from the plaintiffs' *specific claims*.

Bristol-Myers makes clear that specific personal jurisdiction requires "a connection between the forum and the *specific claims at issue*." 137 S. Ct. at 1781 (emphasis added). In that case, 678 Plaintiffs from 34 different states sued a pharmaceutical manufacturer in California state court, even though neither the manufacturer nor 592 of the plaintiffs were from California. Applying "settled principles regarding specific jurisdiction," the Court held that the state court's exercise of

jurisdiction over the non-resident plaintiffs' claims violated due process, because those plaintiffs failed to demonstrate an "adequate link between the State and the nonresidents' claims." *Id.* For a constitutionally adequate link to exist, "the *suit* must arise out of or relate to the defendant's contacts with the *forum*." *Id.* at 1780 (alterations omitted). This means that the nexus between the plaintiff's claims and the defendant's conduct must create "a *substantial* connection with the forum State." *Walden*, 134 S. Ct. at 1121. This significant showing cannot be made where "all the conduct giving rise to the nonresidents' claims occurred elsewhere." *Bristol-Myers*, 137 S. Ct. at 1782 (citing *Walden*). Applying these principles, in *Bristol-Myers*, the Court held that there was not a sufficient nexus between the manufacturers' extensive in-state marketing, distribution, and research activities and the specific claims in issue, because "nonresident plaintiffs did not allege that they obtained Plavix through California physicians or from any other California source; nor did they claim that they were injured by Plavix or were treated for their injuries in California." *Id.* at 1778.

The court below held that it is irrelevant "whether the plaintiffs themselves were injured in Illinois, visited doctors in Illinois, or had the device implanted in Illinois," so long as components of Bayer's nationwide testing, development, and marketing activities took place in Illinois. A13, A24. That analysis cannot be squared with *Bristol-Myers*, which made clear that a defendant's "general connections with the forum are not enough" for "specific personal jurisdiction," where the "plaintiffs are not [in-state] residents and do not claim to have suffered harm in that state," and "the conduct giving rise to the nonresidents' claims occurred elsewhere." 137 S. Ct. at 1781–82. The non-Illinois Plaintiffs here "did not allege that they obtained [Essure] through [Illinois] physicians or

from any other [Illinois] source; nor did they claim that they were injured by [Essure] or were treated for their injuries in [Illinois]." *Id.* at 1778. The non-Illinois Plaintiffs, further, do not allege that Bayer manufactured their devices in Illinois, that Bayer exposed them to any Essure marketing materials in or from Illinois, or that Bayer trained their doctors in Illinois. Thus, under *Bristol-Myers*, specific personal jurisdiction over their claims does not exist in Illinois.

Despite this, the Fifth District held that *Bristol-Myers* was "easily distinguishable," because the defendant in that case "did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California," A13, A24 (quoting *Bristol-Myers*, 137 S. Ct. at 1778), whereas Plaintiffs allege here that Bayer "directly targeted and marketed in Illinois, conducted clinical trials in Illinois, contracted with Illinois physicians and facilities, and established a physician accreditation program in Illinois," A14, A25. But the basis of this reasoning is a sentence in the Supreme Court's description of the factual background, not a ruling on the legal standard. As the Court's actual holding in *Bristol-Myers* makes clear, the specific personal jurisdiction analysis does not turn on the overall quantity of the defendant's contacts with the forum, nor the quantity of contacts related to the particular product. Rather, the key question is whether there is a constitutionally sufficient nexus between those forum contacts and "and the specific claims at issue." *See* 137 S. Ct. at 1780–81, 1788; *see Citadel Grp. Ltd. v. Wash. Reg'l Med. Ctr.*, 536 F.3d 757, 761 (7th Cir. 2008) ("In analyzing whether the defendant's contacts are sufficient to establish specific jurisdiction, we do not employ a 'mechanical or quantitative' test.").

For that reason, several courts have expressly rejected the exact same argument that Plaintiffs make here, holding that the sentence in *Bristol-Myers*' background section does not lay out "a blueprint for establishing personal jurisdiction," *Dyson v. Bayer Corp.*, No. 4:17-CV-2584-SNLJ, 2018 WL 534375, at *4 (E.D. Mo. Jan. 24, 2018). For example, a judge from the Eastern District of Missouri, considering virtually identical claims concerning Essure, explained that "[t]he language contained in the background section of *Bristol-Myers Squibb* does not authorize a federal court to exercise broad personal jurisdiction on the mere basis of nationwide contacts—such as the development of a marketing strategy—rather than the defendant's contacts within the forum state itself." *Jordan v. Bayer Corp.*, No. 4:17-CV-00865-AGF, 2018 WL 837700, at *4 (E.D. Mo. Feb. 13, 2018) ("*Jordan II*"). Here, just as in *Bristol-Myers*, plaintiffs who do not reside in Illinois, were not prescribed Essure in Illinois, did not view Essure advertising in Illinois, did not purchase Essure in Illinois, did not undergo the Essure procedure in Illinois, and do not allege to have been injured by Essure in Illinois may not bring their claims in Illinois.

The Fifth District's decision to the contrary is an outlier; the overwhelming majority of courts to reach the question have rejected Plaintiffs' jurisdictional theory under *Bristol-Myers*. In particular, Illinois federal district courts have held that *Bristol-Myers* forecloses specific personal jurisdiction over the claims of non-residents in highly similar cases. For example, in a series of decisions involving the prescription drug Xarelto, Judge David Herndon rejected virtually identical arguments that Illinois courts have personal jurisdiction over claims of non-Illinois Plaintiffs because the defendant "purposefully targeted Illinois as the location for multiple clinical trials which formed the

foundation for defendants' Xarelto Food and Drug Administration application." *Roland v. Janssen Research & Dev., LLC*, No. 3:17-CV-00757-DRH, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017), *appeal voluntarily dismissed sub nom. Luddy v. Janssen Research & Dev.*, LLC, No. 17-cv-3205 (7th Cir. Nov. 21, 2017). The court held that personal jurisdiction was lacking because those Plaintiffs "failed to allege ingestion of Xarelto in Illinois, or [that they] suffered from injuries caused by Xarelto in Illinois." *Id.* at *5; *see also In re Xarelto Cases*, No. 4862, 2018 WL 809633, at *10 (Cal. Super. Ct., Los Angeles Cty., Feb. 6, 2018) (similar); *In re Pradaxa Cases*, Nos. CJC-16-004863 et al., 2019 WL 1177510 (Cal. Super. Ct. Jan. 31, 2019) (similar).[7] As a result, if the decisions below are not reversed, then Illinois cases will reach different results on this constitutional question depending on whether they are heard in federal or state court.

The Fifth District relied on *M.M.*, from the First District, but that decision predates *Bristol-Myers*. A12, A23; *see also* A30–33, A38–A41. It conflicts with *Bristol-Myers* and should not be followed. *See, e.g.*, *Roland*, 2017 WL 4224037, at *5 (rejecting similar *M.M.*-based argument and instead relying on *Bristol-Myers*); *see also* C1483–84

[7] *Accord BeRousse v. Janssen Research & Dev., LLC*, No. 3:17-CV-00716-DRH, 2017 WL 4255075, at *4 (S.D. Ill. Sept. 26, 2017); *Douthit v. Janssen Research & Dev., LLC*, No. 3:17-CV-00752-DRH, 2017 WL 4224031, at *5 (S.D. Ill. Sept. 22, 2017); *Braun v. Janssen Research & Dev., LLC*, No. 17-CV-00756-DRH, 2017 WL 4224034, at *5 (S.D. Ill. Sept. 22, 2017); *Bandy v. Janssen Research & Dev., LLC*, No. 17-CV-00753-DRH, 2017 WL 4224035, at *5 (S.D. Ill. Sept. 22, 2017); *Pirtle v. Janssen Research & Dev., LLC*, No. 3:17-CV-00755-DRH, 2017 WL 4224036, at *5 (S.D. Ill. Sept. 22, 2017); *Woodall v. Janssen Research & Dev., LLC*, No. 3:17-CV-00752-DRH, 2017 WL 4237924, at *5 (S.D. Ill. Sept. 22, 2017). Plaintiffs have voluntarily dismissed their appeals in each of these cases.

(motion in *Roland* relying on *M.M.*). Further, as discussed below, *infra* pp. 25–25, *M.M.* is distinguishable in any event.[8]

In addition, several decisions in the Eastern District of Missouri rejected the same jurisdictional arguments—*i.e.*, that Essure clinical trial sites in Missouri gave rise to personal jurisdiction over non-residents' claims. *Dyson*, 2018 WL 534375, at *2, 5; *accord Jordan II*, 2018 WL 837700, at *4; *McClain v. Bayer Corp.*, No. 4:17-CV-01534-JCH, 2018 WL 3725777, at *2 (E.D. Mo. Feb. 20, 2018); *Schaffer v. Bayer Corp.*, No. 4:17-CV-01973 JAR, 2018 WL 999980, at *4 (E.D. Mo. Feb. 21, 2018); *Johnson v. Bayer Corp.*, No. 4:17-CV-02774-JAR, 2018 WL 999972, at *4 (E.D. Mo. Feb. 21, 2018).

In those decisions, the courts held that "the Missouri clinical trials … are simply too attenuated" from the claims of the nonresident plaintiffs to "serve as an 'adequate link' between Missouri and nonresidents' claims that their individual device injured them in another state." *E.g.*, *Dyson*, 2018 WL 534375, at *5. Further, those decisions rejected as an insufficient basis for personal jurisdiction plaintiffs' allegations that Missouri was "ground zero" for the development of an Essure marketing strategy later rolled out nationwide, holding "[t]hat Missouri happened to be Essure's first marketed area has no bearing on the non-Missouri plaintiffs' claims where those plaintiffs did not see

[8] Below, Plaintiffs suggested that this Court's and the U.S. Supreme Court's decision not to review *M.M.* indicates a *sub silentio* approval of its reasoning. But this Court's denial of review predates *Bristol-Myers*, and it is black-letter law that denials of discretionary review by either court "import[] no expression of opinion upon the merits of a case." *House v. Mayo*, 324 U.S. 42, 48 (1945); *Mattis v. State Univs. Ret. Sys.*, 212 Ill. 2d 58, 75 (2004) ("The denial of a petition for leave to appeal has no precedential effect and in no way amounts to a consideration of the merits of the case.") (alteration omitted).

marketing in Missouri, were not prescribed Essure in Missouri, did not purchase Essure in Missouri, and were not injured by Essure in Missouri." *Id.* at *4.[9]

The Fifth District's error invites the very harm that *Bristol-Myers* and the Due Process Clause intend to prevent: forcing a nonresident defendant to "submit[] to the coercive power of a State" without an adequate connection to "the claims in question." *Bristol-Myers*, 137 S. Ct. at 1780. None of the defendants is an Illinois citizen, nor are the 160 plaintiffs at issue in this appeal. Nonetheless, the Fifth District's order subjects Bayer to personal jurisdiction over their claims—and the claims of any other Essure plaintiff nationwide—in Madison County. Indeed, under the Fifth District's reasoning, it is not necessary for there to be *any* Illinois resident in the case for the court to have jurisdiction. Affirming the orders below will make Madison County a magnet for nationwide products liability litigation, and burden local courts and juries with complex trials that involve neither an Illinois party, nor Illinois conduct, nor any harm suffered in Illinois. The decisions below should be reversed.

II. THE FIFTH DISTRICT ERRONEOUSLY AUTHORIZED THE EXERCISE OF SPECIFIC PERSONAL JURISDICTION OVER CLAIMS WITHOUT ANY SUBSTANTIAL CONNECTION TO ILLINOIS.

The Court should also reverse the decision below because the Fifth District failed to consider whether the tenuous connections between Bayer's limited in-state conduct and the non-Illinois Plaintiffs' specific claims were *substantial* enough to justify the exercise of specific personal jurisdiction. *See Walden*, 134 S. Ct. at 1121; *see also, e.g.*,

[9] Missouri state and federal cases considering similar allegations about other products are in accord. *See, e.g.*, *Siegfried v. Boehringer Ingelheim Pharm., Inc.*, No. 4:16 CV 1942, 2017 WL 2778107 (E.D. Mo. June 27, 2017); *State ex rel. Johnson & Johnson v. Burlison*, No. SC96318 (Mo. July 11, 2017) (recognizing *Bristol-Myers* "is dispositive on the issue" of personal jurisdiction over nonresident plaintiffs' claims).

Brook v. McCormley, 873 F.3d 549, 552 (7th Cir. 2017) ("Specific jurisdiction requires a defendant's contacts with the forum State to be *directly related* to the conduct pertaining to the claims asserted.") (emphasis added). Applying this rule, courts in Illinois and nationwide have required a defendant's in-state conduct to be a *legal cause* of the plaintiff's asserted injuries before it will assert personal jurisdiction over out-of-state defendants. Because the non-Illinois Plaintiffs cannot make such a showing here, the decision below should be reversed and their claims dismissed for lack of personal jurisdiction.

A. Specific Personal Jurisdiction Requires the Forum State Contacts to be the Legal Cause of the Specific Claims Asserted.

Even before *Bristol-Myers*, decisions from Illinois and across the country recognize that specific personal jurisdiction is proper only when the defendant's conduct is both "a cause in fact and legal cause" of the plaintiff's alleged injuries. *Keller*, 359 Ill. App. 3d at 617; *accord Spartan Motors, Inc. v. Lube Power, Inc.*, 337 Ill. App. 3d 556, 561 (2d Dist. 2003). Federal courts in Illinois have reached an identical conclusion, *e.g.*, *Hitz Entm't Corp. v. Mosley*, No. 16 C 1199, 2017 WL 444073, at *5 (N.D. Ill. Feb. 1, 2017); *see also GCIU-Employer Ret. Fund*, 565 F.3d at 1025, as have other federal and state courts around the country. *See, e.g.*, *Beydoun v. Wataniya Rests. Holding, Q.S.C.*, 768 F.3d 499, 507 (6th Cir. 2014); *Harlow*, 432 F.3d at 61; *see also, e.g.*, *Robinson v. Harley-Davidson Motor Co.*, 316 P.3d 287, 300 (Or. 2013) (en banc) (defendant's in-state conduct must make the plaintiff's specific claims "reasonably foreseeable by the defendant"); *Montgomery v. Airbus Helicopters, Inc.*, 414 P.3d 824, 834 (Okla. 2018) (holding that personal jurisdiction requires "direct and specific conduct with this State directly related to the incident giving rise to the injuries").

Similarly, outside of the personal jurisdiction context, this Court has recognized that the term "arising out of" "refers to a causal connection," and requires that the alleged "injuries [] have their origin in, or [be] incidental to" the defendant's conduct. *Brucker v. Mercola*, 227 Ill. 2d 502, 523–24 (2007). Thus, for example, in assessing whether a worker's injuries arose out of his employment, this Court noted that "[a]n injury which cannot fairly be traced to the employment as a *contributing proximate cause* … does not arise out of it." *J. I. Case Co. v. Indus. Comm'n*, 36 Ill. 2d 386, 388 (1966); *see Chicago Hardware Foundry Co. v. Indus. Comm'n*, 393 Ill. 294, 301 (1946) (for an injury to arise out of a workers employment, there must be "apparent to the rational mind a causal connection between the conditions under which the work is required to be performed and the resulting injury."). So too, in assessing whether a plaintiff's alleged injuries arose out of the defendant's in-state conduct, a court must consider whether that conduct is "a cause in fact and legal cause" of the plaintiff's alleged injuries. *Keller*, 359 Ill. App. 3d at 617.

The Fifth District's decision below did not identify any causal link—must less a "substantial connection," *Walden*, 134 S. Ct. at 1121—between Bayer's limited Illinois contacts and the non-Illinois Plaintiffs' specific injuries. Rather, the court below appears to have concluded that *any* type of "relat[ion]" or "connect[ion]" to "the product at issue, *i.e.*, the Essure product" was sufficient. A14, A25. But that standard is manifestly inconsistent with prior decisions of the Illinois Courts of Appeals and the Seventh Circuit, which have held that a causal connection—and more than merely "but for" cause—is necessary. For instance, *Keller* held that the "arises out of or relates to" requirement "establishes a limitation on the degree of permissible attenuation between

the defendant, the forum, and the litigation." 359 Ill. App. at 615. It *rejected* a proposed standard that "the defendant's forum activities must simply provide 'a link in the causal chain which ultimately leads to plaintiff's injury," holding instead that "the cause of action must directly arise out of the contacts between the defendant and the forum." *Id.* at 616. To "directly arise," the Illinois contacts must "meet both a 'cause in fact' and 'legal cause' test," meaning that the "alleged tortious act" must have "significant connections to Illinois." *Id*. at 617. Other decisions of the Illinois Courts of Appeals, the Seventh Circuit, and Illinois federal district courts have adopted the same test. *See Spartan Motors, Inc. v. Lube Power, Inc.*, 337 Ill. App. 3d 556, 561 (2d Dist. 2003); *uBID, Inc. v. GoDaddy Grp., Inc.*, 623 F.3d 421, 430 (7th Cir. 2010); *RAR, Inc. v. Turner Diesel, Ltd.*, 107 F.3d 1272, 1277 (7th Cir. 1997); *Hitz Entm't,* 2017 WL 444073, at *5 ("[A] mere 'but for' causal relationship is insufficient to establish the required nexus between a defendant's contacts and the underlying cause of action."); *cf., e.g., James River Ins. Co. v. Kemper Cas. Ins. Co.*, 585 F.3d 382, 386 (7th Cir. 2009) (Posner, J.) ("'[A]rising from' implies a tighter connection than a mere 'but for' cause creates.").

Decisions from other courts across the country are in accord. For example, in *Harlow*, the First Circuit held that a "'but for' requirement [for specific personal jurisdiction] has in itself no limiting principle; it literally embraces every event that hindsight can logically identify in the causative chain." 432 F.3d at 61. Instead, as the Sixth Circuit held in *Beydoun*, "the plaintiff's cause of action must be *proximately caused* by the defendant's contacts with the forum state." 768 F.3d at 507–08 (emphasis added). And likewise, in *O'Connor v. Sandy Lane Hotel Co.*, the Third Circuit held that "specific jurisdiction requires a closer and more direct causal connection than that provided by the

but-for test," and that the defendant's in-state contacts must be "intimate enough to keep … personal jurisdiction reasonably foreseeable." 496 F.3d 312, 323 (3d Cir. 2007). The highest courts of Oklahoma, New Hampshire, Nevada, and Oregon have likewise rejected a mere but-for standard, and other federal and state high courts have also found that more is required to support the exercise of specific personal jurisdiction. *See Montgomery*, 414 P.3d at 834 ("direct and specific conduct with this State directly related to the incident giving rise to the injuries"); *In re Reddam*, 180 A.3d 683, 691 (N.H. 2018) ("an important, or at least material, element of proof in the plaintiff's case"); *Tricarichi v. Coop. Rabobank, U.A.*, 440 P.3d 645, 652 (Nev. 2019) ("specific and direct relationship"); *Robinson*, 316 P.3d at 300 ("may not be only a but-for cause of the litigation").

These decisions recognize that the "but-for" standard is "vastly overinclusive" and offers "no limiting principle; it literally embraces every event that hindsight can logically identify in the causative chain." *GCIU-Employer Ret. Fund*, 565 F.3d at 1025 (quoting *O'Connor v. Sandy Lane Hotel Co., Ltd.*, 496 F.3d 312, 322 (3d Cir. 2007)); *accord, e.g.*, *Davis v. Baylor Univ.*, 976 S.W.2d 5, 8 (Mo. Ct. App. 1998) (rejecting "but-for" theories of specific personal jurisdiction "as being too lax and permitting a virtually unlimited exercise of jurisdiction."). As Judge Posner hypothesized in *James River*, "Maybe if Columbus hadn't discovered America the federal courts of appeals would not have been created in 1891; but it would be odd to say that the federal appellate judiciary 'arose from' Columbus's voyages." 585 F.3d at 386. So too with Essure, a virtually limitless list of facts encompassing every state in the nation could be considered "but for" causes of Essure's development, approval, and sales, but none of those facts would

provide an adequate basis for exercising specific jurisdiction over otherwise unrelated claims. *See Davis,* 976 S.W.2d at 8-9 ("[A] defendant's birth is a historical but for cause of his subsequent tortious conduct, yet the location of one's birth normally should not determine personal jurisdiction").

Eliminating any meaningful causal requirement for specific personal jurisdiction would also eviscerate the sharp distinctions that the Supreme Court has drawn and reaffirmed "between specific or case-linked jurisdiction and general or all-purpose jurisdiction." *BNSF,* 137 S. Ct. at 1558. The Supreme Court has repeatedly rejected arguments that companies can be subjected to general jurisdiction in any state in which they "engage[] in a substantial, continuous, and systematic course of business." *Daimler AG v. Baumann*, 134 S. Ct. 746, 749 (2014); *see BNSF*, 137 S. Ct. at 1559 ("[I]n-state business, we clarified in *Daimler* and *Goodyear*, does not suffice to permit the assertion of general jurisdiction over claims ... that are unrelated to any activity occurring in [the forum state]"). Yet the Fifth District's approach to specific jurisdiction is so capacious that it is virtually indistinguishable from the "approach to general jurisdiction that *Daimler* rejected"; companies operating nationwide could be sued in nearly any state on nearly any claim. *State ex rel. Norfolk S. Ry. Co. v. Dolan*, 512 S.W.3d 41, 49 (Mo. banc 2017). As the Missouri Supreme Court recognized in rejecting a similar argument, this "turn[s] specific jurisdiction on its head." *Id.* The "substantial connection" requirement cannot be interpreted in so toothless a fashion as to render the distinction between specific and general jurisdiction meaningless. *Walden,* 134 S. Ct. at 1121; *see Nowak v. Tak How Invs., Ltd.*, 94 F.3d 708, 714 (5th Cir. 1996) ("relatedness is the divining rod that separates specific jurisdiction cases from general jurisdiction cases").

B. Bayer's Alleged Conduct in Illinois Lacks a Substantial Connection to the Non-Illinois Plaintiffs' Claims.

Once the proper test is applied, it is clear that specific personal jurisdiction is lacking with respect to the non-Illinois Plaintiffs' claims. For instance, each non-Illinois Plaintiff alleges that Bayer defectively manufactured her device, and that the manufacturing defect caused her injuries. *See, e.g.*, C176–178 [FAC ¶¶ 183–192]. The circuit court, however, expressly found that Bayer did not manufacture any of the Plaintiffs' devices in Illinois (in fact, Bayer manufactured Essure devices in California, and later abroad, *see, e.g.*, C177 [FAC ¶ 186]). The non-Illinois Plaintiffs also do not allege that Bayer provided their devices to them in Illinois, or that they experienced any injuries from the alleged manufacturing defects in Illinois. A28, A36–37. Thus, any Illinois contacts are plainly not the "legal cause" of the non-Illinois Plaintiffs' manufacturing defect claims. *Keller*, 359 Ill. App. 3d at 617.

The same is true of the non-Illinois Plaintiffs' claims that Bayer negligently trained their physicians. *E.g.*, C184 [FAC ¶ 208]. These Plaintiffs do not allege that Bayer trained their physicians in Illinois or that the physicians performed their procedures in Illinois. Indeed, the Amended Complaints are devoid of any allegations about Plaintiffs' individual physicians.

And finally, as to the claims that non-Illinois plaintiffs were injured by misleading marketing materials and inadequate warnings, Plaintiffs do not allege either that Bayer wrote the alleged misrepresentations in Illinois or that Bayer sent the misrepresentations to them in Illinois. Thus, the legal cause of each of these claims clearly occurred elsewhere as well.

The Fifth District based its decision on three factors: (1) clinical trial sites and related contracts with physicians and facilities in Illinois, (2) Bayer's marketing activity in Illinois, and (3) a pilot physician accreditation program in Illinois. But none of these factors has any substantial connection to the non-Illinois Plaintiff's "specific claims."

1. The clinical trials—which spanned numerous states across the country, including Illinois—are not enough for specific personal jurisdiction. None of the non-Illinois Plaintiffs participated in a clinical trial in Illinois or had anything to do with those clinical trials. Further, the Amended Complaint *never* alleges that Essure was wrongfully approved, let alone that it was wrongfully approved due to clinical trial misconduct in Illinois. The most the Amended Complaint does is make conclusory allegations of clinical trial fraud.[10] But the complaint stops there. It alleges no connection—let alone a substantial one—between such purported fraud and any of Plaintiffs' "specific claims." Those claims pertain only to Bayer's manufacture, marketing and warnings of the device, and training of Plaintiffs' physicians—none of which occurred in Illinois.

For that reason, numerous decisions have held that allegations that a defendant "targeted Illinois as the location for multiple clinical trials which formed the foundation for defendants' [product's FDA approval]" are insufficient to support personal

[10] Plaintiffs' decision not to challenge the clinical trials and subsequent approval is no oversight; Plaintiffs *cannot* do so under federal preemption principles. *See* 21 U. S. C. §§ 337(a), 360k(a). FDA approved Essure, it has never withdrawn that approval, and, most significantly, it has never found that the clinical trials were flawed in any way. *See* 21 U.S.C. § 360k; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). To the contrary, FDA has specifically *rejected* allegations that there was misconduct in the clinical trials. C465–72. Accordingly, it is unsurprising that despite its conclusory allegations regarding the clinical trials, the Amended Complaint contains no claims that Bayer wrongfully obtained FDA approval of Essure, much less that it wrongfully obtained approval due to clinical trial misconduct in Illinois.

jurisdiction. *See, e.g.*, *Roland*, 2017 WL 4224037, at *4; *Bandy*, 2017 WL 4224035, at *4–6; *see also Dyson*, 2018 WL 534375, at *5 (rejecting argument that "specific jurisdiction exists because Essure could not have been approved without clinical trials, and some of those clinical trials occurred in Missouri," and finding it "too attenuated" from the plaintiffs' claims); *supra* pp. 14–17.

The Fifth District's reliance on *M.M.* was misplaced. As discussed, this decision from the First District predates and conflicts with *Bristol-Myers*. *See supra* p. 15. In any event, *M.M.* does not even support the ruling below, because the alleged connection between the clinical trial activities in the forum state and the plaintiffs' claims was significantly closer in that case. The plaintiffs in *M.M.* were minors and their mothers, who alleged that the mothers' ingestion of a prescription drug caused birth defects. *See M.M.*, 2016 IL App (1st) 151909, ¶ 9. Plaintiffs sought to establish personal jurisdiction in Illinois based on allegations that GSK concealed data on fetal abnormalities (the precise injury at issue) of clinical trial participants, and thereafter failed to warn that the drug was unsafe for pregnant women, causing the alleged injury. *See id.* ¶¶ 11, 72. Here, by contrast, none of Plaintiffs' claims arises from alleged acts or omissions in clinical trials in Illinois.[11]

Ultimately, Bayer's clinical trial activity in Illinois does not come close to establishing a substantial legal "connection between the forum *and the specific claims at issue*." *Bristol-Myers*, 137 S. Ct. at 1781 (emphasis added); *see also Walden*, 134 S. Ct.

[11] In *M.M.*, the plaintiffs alleged to have been injured by a drug, not a pre-market approved, Class III device like Essure. Therefore, the preemption analysis in *M.M.* was not the same as the preemption analysis in this case, since the express preemption provision of 21 U. S. C. § 360k(a) does not apply to drugs.

at 1121 (due process requires "a *substantial* connection with the forum State") (emphasis added). Clinical studies in Illinois involve an Illinois physician providing Essure to an Illinois patient; they no more demonstrate that the Court has personal jurisdiction over the claims of non-Illinois plaintiffs against Bayer than does any other Illinois physician's provision of Essure to an Illinois patient.

Indeed, as is typical, the Essure clinical trials were "conducted across the country" in "dozens of states." *State ex rel. Bayer Corp. v. Moriarty*, 536 S.W.3d 227, 234 (Mo. banc 2017); *see also, e.g.*, C148–49 [FAC ¶ 11(f)] (noting one trial was conducted in eight states, including Illinois); Aaron V. Kaplan et al., *Medical Device Development: From Prototype to Regulatory Approval*, Circulation (June 29, 2004), https://www.ahajournals.org/doi/pdf/10.1161/01.CIR.0000134695.65733.64 ("[P]ivotal trials may require enrollment of 1000 or more patients at 30 to 50 sites."). It could be alleged that any of these clinical trial sites were part of the FDA approval process, and thus, somehow "connected" to Plaintiffs' claims. Essure plaintiffs in other jurisdictions—including plaintiffs in other states represented by the same plaintiffs' counsel—are likewise arguing that clinical trial activities conducted in *those* states provide specific jurisdiction for identical Essure claims brought by all non-resident plaintiffs in those forums. *See supra* note 3 (citing complaints asserting personal jurisdiction in Missouri, New Mexico, Indiana, and Pennsylvania based on clinical trial sites in those states). Indeed, the same could be alleged of *every* state where a product is sold, because post-market experience with a product also informs the product's warning label and potential regulatory action. A5; *see, e.g.*, 21 C.F.R. § 814.39; C844.

Thus, the implication of the Fifth District's decision would be that courts in dozens of states—perhaps all fifty—have *specific* jurisdiction over the claims of the same nonresident plaintiffs and any other plaintiffs challenging Essure. Basing specific personal jurisdiction on nationwide clinical trial activity would eviscerate *Bristol-Myers*'s ruling that each plaintiff must "identify[] an[] adequate link between the State" and her own "specific claims." *Bristol-Myers*, 137 S. Ct. at 1781. This "loose and spurious" jurisdictional analysis, 137 S. Ct. at 1781, is entirely inconsistent with the Due Process Clause.

2. The Fifth District also erred by holding that Bayer's marketing activities in Illinois created a substantial connection to Plaintiffs' claims because they "relate[] to the … marketing of the Essure product." A14, A25. Any connection between this alleged contact and the non-Illinois Plaintiffs' claims is far too attenuated to support specific jurisdiction, and cannot be distinguished from arguments rejected in *Bristol-Myers*.

Plaintiffs never allege that the non-Illinois Plaintiffs were exposed to any Essure marketing in Illinois. Nor do they allege that Bayer wrote any of the statements that Plaintiffs characterize as warranties or misrepresentations in Illinois. Rather, Plaintiffs allege only that Bayer created some abstract "marketing strategy" in Illinois, and "modeled" other marketing "[b]ased on the success of Defendants' Illinois-based marketing campaign." A7, A18. Thus, it is clear that the alleged Illinois contacts are not the "legal cause" of the non-Illinois Plaintiffs' claims, *Keller*, 359 Ill. App. 3d at 617, and that they are "too attenuated" from their claims to support personal jurisdiction. *Dyson*, 2018 WL 534375, at *4; *see also Jordan II*, 2018 WL 837700, at *1 (same).

Other courts have rejected this precise argument for this reason. *Hinton* recognized that it is "of no consequence" that a particular state "happened to be Essure's first marketed area … where those plaintiffs did not see marketing in Missouri, were not prescribed Essure in Missouri, did not purchase Essure in Missouri, and were not injured by Essure in Missouri." *Hinton v. Bayer Corp.*, No. 4:16-CV-1679 HEA, 2018 WL 3725776, at *4 (E.D. Mo. July 27, 2018). Likewise, in *Dyson*, the plaintiffs argued that specific jurisdiction existed over non-resident plaintiffs' claims in Missouri, because Missouri was "ground zero" and the "test marketing campaign site" for Essure's nationwide "marketing strategy." 2018 WL 534375, at *4. The district court held that the alleged fact "[t]hat Missouri happened to be Essure's first marketed area has no bearing on the non-Missouri plaintiffs' claims where those plaintiffs did not see marketing in Missouri, were not prescribed Essure in Missouri, did not purchase Essure in Missouri, and were not injured by Essure in Missouri." *Id.*; *accord Jordan II*, 2018 WL 837700, at *4. Another judge likewise rejected these same allegations, explaining that "*Bristol–Myers Squibb* does not authorize a federal court to exercise broad personal jurisdiction on the mere basis of nationwide contacts—such as the development of a marketing strategy." *Jordan II*, 2018 WL 837700, at *4.

The result here, in fact, is indistinguishable from the lower court's decision in *Bristol-Myers*, which based jurisdiction on "BMS' nationwide marketing and distribution of Plavix." *Bristol-Myers Squibb Co. v. Superior Court*, 377 P.3d 874, 889 (Cal. 2016); *see Dyson*, 2018 WL 534375, at *4 ("[T]he *BMS* plaintiffs themselves alleged that BMS marketed, advertised, and actively sought to promote Plavix in California specifically."). The U.S. Supreme Court reversed that decision, because "[t]he relevant plaintiffs are not

California residents and do not claim to have suffered harm in that state." *Bristol-Myers*, 137 S. Ct. 1782. The same is true here, and the same result should follow.

3. Finally, the Fifth District's holding that specific personal jurisdiction exists because Bayer "used Illinois as a test-base for its physician training program," A13, A24, is also erroneous. The Accreditation Program is a training program for some physicians. Plaintiffs did not allege that Bayer trained any of the non-Illinois Plaintiffs' physicians in Illinois, or even that Bayer wrote the supposedly deficient materials used in training Plaintiffs' physicians in Illinois, either as part of the Accreditation Program or otherwise. The allegations that Illinois was the site of a "pilot program" for training—just like the allegation that the state was used as a "test marketing campaign site," *Dyson*, 2018 WL 534375, at *4—lacks any constitutionally adequate link to the non-Illinois Plaintiffs' specific claims. As with the alleged marketing and clinical trial activity, the connection (if any) between the Essure Accreditation Program and the non-Illinois Plaintiffs' specific claims is simply far "too attenuated" to support specific personal jurisdiction. *Dyson*, 2018 WL 534375, at *4; *see also Jordan II*, 2018 WL 837700, at *4 (same).

In short, none of Bayer's alleged contacts with Illinois has any constitutionally substantial connection to the specific claims of the non-Illinois Plaintiffs. The Fifth District therefore erred in holding that it has specific jurisdiction over those claims, and its decision should be reversed.

III. EXERCISING JURISDICTION OVER THE NON-ILLINOIS PLAINTIFFS' CLAIMS IS UNREASONABLE.

Finally, even if Plaintiffs had demonstrated sufficient, claims-related contacts with Illinois, asserting jurisdiction would be unreasonable. *See Russell v. SNFA*, 2013 IL

113909, ¶ 87. "The factors to consider when deciding reasonableness include: (1) the burden imposed on the defendant by requiring it to litigate in a foreign forum; (2) the forum state's interest in resolving the dispute; (3) the plaintiff's interest in obtaining relief; and (4) the interests of the other affected forums in the efficient judicial resolution of the dispute and advancement of substantive social policies." *Id.*

The Fifth District held jurisdiction reasonable for two reasons. First, it stated that "Illinois has an undeniable interest in resolving a dispute arising, in part, from clinical trials held in Illinois, by Illinois doctors, in Illinois facilities." A14. But, as explained above, the non-Illinois Plaintiffs' *specific claims* do not "aris[e]" from those clinical trials, but from their experiences with Essure in other states. *Supra* § II.B.1.

Second, the Fifth District expressed concern with "piecemeal litigation" resulting "in additional costs and use of judicial resources" and the possibility of "conflicting rulings." A14–15, A25–26. This is a false dilemma. Essure-related litigation is already proceeding in states where there is or was general jurisdiction over Bayer, in addition to numerous other states where plaintiffs are at home. For the non-Illinois Plaintiffs, it would be no more burdensome to litigate their claims in forums where personal jurisdiction exists than it would be in Illinois. And in fact, after the Supreme Court decided *Bristol-Myers*, 155 of the non-Illinois Plaintiffs—all but five—filed new complaints raising the same allegations in California,[12] where thousands of plaintiffs have joined their cases in a coordinated state court proceeding concerning Essure. C1052–59.

[12] Since Bayer first raised this issue, many of these re-filing Plaintiffs have voluntarily dismissed their California complaints. At last count, 35 of the *Hamby* Plaintiffs and 36 of the *Rios* Plaintiffs have duplicate claims pending in California. Again, Bayer is challenging personal jurisdiction only as to a narrow subset of Plaintiffs in California, *see*

Thus, the result of reversing the Fifth District's decision would just be to funnel these claims into the states with greater interest in their resolution. *See Bristol-Myers*, 137 S. Ct. at 1783–84 (Due Process "does not prevent the California and out-of-state plaintiffs from joining together in a consolidated action in the States that have general jurisdiction over BMS," or prevent "plaintiffs who are residents of a particular State [from] su[ing] together in their home States"). There is no reason to burden Illinois courts and Illinois juries with litigation over events that occurred entirely outside of Illinois and regarding which there will be substantial conflicts of law issues. *See World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 294 (1980).

CONCLUSION

For the foregoing reasons, the Court should reverse the decision of the Fifth District Appellate Court and remand these cases to the Circuit Court of Madison County with directions to dismiss the non-Illinois plaintiffs' claims against Bayer for lack of personal jurisdiction.

DATED: October 30, 2019

Respectfully Submitted,

By: /s/ W. Jason Rankin

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supra p. 8 & note 4; Bayer has not challenged personal jurisdiction in California over the claims of any of the *Rios* or *Hamby* Plaintiffs.

CERTIFICATE OF SERVICE

The undersigned certifies pursuant to section 1-109 of the Code of Civil Procedure that a copy of the foregoing document was served upon the following attorneys of record by electronic mail on this 30th day of October, 2019:

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Nos. 125020, 125021

IN THE
SUPREME COURT OF ILLINOIS

NICHOLE HAMBY ET AL., *Plaintiffs-Appellees* v. **BAYER CORPORATION ET AL.,** *Defendants-Appellants,* and **DOES 1–10,** *Defendants.*	On Appeal from the Appellate Court of Illinois, Fifth District, No. 5-18-0279 There on Interlocutory Appeal from the Circuit Court of the Third Judicial Circuit, Madison County, Illinois, No. 16-L-1617 The Hon. William A. Mudge Judge Presiding
CHRISTINE RIOS ET AL. *Plaintiffs-Appellees* v. **BAYER CORPORATION ET AL.,** *Defendants-Appellants,* and **DOES 1–10,** *Defendants.*	On Appeal from the Appellate Court of Illinois, Fifth District, No. 5-18-0278 There on Interlocutory Appeal from the Circuit Court of the Third Judicial Circuit, Madison County, Illinois, No. 16-L-1046 The Hon. Denis R. Ruth Judge Presiding

CERTIFICATE OF COMPLIANCE PURSUANT TO RULE 341(C)

W. Jason Rankin, being of adult age and under no legal disability, upon his sworn oath, certifies as follows:

I certify that this Brief conforms to the requirements of Rule 341(a) and (b). The length of this Brief, excluding the pages containing the Rule 341(d) cover, the Rule 341(h)(1) statement of points and authorities, the Rule 341(c) certificate of compliance, the certificate of service, and those matters to be appended to the petition under Rule 342(a), is 32 pages.

FURTHER AFFIANT SAYETH NOT

/s/ W. Jason Rankin
W. Jason Rankin

STATE OF ILLINOIS)
)
COUNTY OF MADISON)

SUBSCRIBED AND SWORN to before me on this 30th day of October, 2019, W. Jason Rankin, personally known to me or proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

(SEAL) "OFFICIAL SEAL"
SHERI THOMAS
NOTARY PUBLIC — STATE OF ILLINOIS
MY COMMISSION EXPIRES OCT. 26, 2023

Signature

APPENDIX

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Carolyn Taft Grosboll
SUPREME COURT CLERK

APPENDIX

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September 25, 2019

In re: Nichole Hamby et al., Appellees, v. Bayer Corporation et al., Appellants. Appeal, Appellate Court, Fifth District.
125020

The Supreme Court today ALLOWED the Petition for Leave to Appeal in the above entitled cause.

The Court also ordered that this cause be consolidated with:

125021 Rios v. Bayer Corporation

A list of all counsel on these appeals is enclosed.

We call your attention to Supreme Court Rule 315(h) concerning certain notices which must be filed.

Very truly yours,

Carolyn Taft Grosboll

Clerk of the Supreme Court

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September 25, 2019

In re: Christy Rios et al., Appellees, v. Bayer Corporation et al., Appellants. Appeal, Appellate Court, Fifth District.
125021

The Supreme Court today ALLOWED the Petition for Leave to Appeal in the above entitled cause.

The Court also ordered that this cause be consolidated with:

125020 Hamby v. Bayer Corporation

A list of all counsel on these appeals is enclosed.

We call your attention to Supreme Court Rule 315(h) concerning certain notices which must be filed.

Very truly yours,

Carolyn Taft Grosboll

Clerk of the Supreme Court

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125020

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2019 IL App (5th) 180279-U

NO. 5-18-0279

IN THE

APPELLATE COURT OF ILLINOIS

FIFTH DISTRICT

NICHOLE HAMBY, *et al.*,	)	Appeal from the
	)	Circuit Court of
Plaintiffs-Appellees,	)	Madison County.
	)	
v.	)	No. 16-L-1617
	)	
BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER ESSURE, INC.; and BAYER HEALTHCARE PHARMACEUTICALS, INC.,	)	
	)	
Defendants-Appellants,	)	
	)	
and	)	
	)	
DOES 1-10,	)	Honorable
	)	William A. Mudge,
Defendants.	)	Judge, presiding.

JUSTICE WELCH delivered the judgment of the court.
Presiding Justice Overstreet and Justice Moore concurred in the judgment.

ORDER

¶ 1 *Held*: The order of the circuit court of Madison County is affirmed where Bayer has purposefully availed themselves to Illinois, the plaintiffs have made a *prima facie* showing that exercising specific personal jurisdiction in this case is appropriate, the defendants have failed to rebut that showing, and litigating in Illinois would not be unreasonable.

¶ 2 This is an interlocutory appeal of the circuit court of Madison County's denial of the defendants' (Bayer)[1] motion to dismiss for lack of personal jurisdiction. The class-action claim was filed by 73 nonresident plaintiffs against Bayer for injuries caused by Essure, a permanent contraceptive device manufactured by Bayer.[2] For the reasons that follow, we affirm.

¶ 3 I. BACKGROUND

¶ 4 On November 28, 2016, 86 women—73 of whom were nonresidents of Illinois—filed a complaint in Madison County alleging negligence, strict products liability, breach of express warranty, breach of implied warranty, and fraud against Bayer for injuries received from defective Essure contraceptive devices—which were developed and manufactured by Bayer.

¶ 5 On June 19, 2017, the United States Supreme Court issued its decision in *Bristol-Myers Squibb Co. v. Superior Court of California*, 582 U.S. __, 137 S. Ct. 1773 (2017). On September 5, 2017, Bayer filed a motion to dismiss the case. It argued that under *Bristol-Myers*, Illinois lacked both general and specific jurisdiction. Thereafter, the plaintiffs filed a response in opposition to Bayer's motion to dismiss, and a first amended complaint.

[1]There are multiple defendants in this case; however, all are Bayer corporations and LLCs. Therefore, for clarity and ease of reading, we will refer to all defendants simply as Bayer.

[2]The class-action claim included eight plaintiffs that alleged that they resided in or experienced injuries in Illinois and are not part of this appeal.

¶ 6 In the first amended complaint, the plaintiffs alleged that the trial court could exercise specific personal jurisdiction in this case against Bayer because of the numerous ways in which it purposefully availed itself to this forum, including:

> "at all relevant times [Bayer has] engaged in substantial business activities in the State of Illinois. At all relevant times [Bayer] transacted, solicited, and conducted business in Illinois through their employees, agents, and/or sales representatives. In addition, *** [Bayer] committed tortious acts within the state—specifically making fraudulent and negligent misrepresentations, failing to properly train physicians, failing to warn [the] Plaintiffs and their implanting physicians about the dangers of Essure, negligently conducting clinical trials, negligently developing a marketing strategy, and negligently developing the Essure Accreditation Program.
>
> *** [Bayer] used Illinois to develop, label, or work on the regulatory approval, for Essure®. In addition, [Bayer] created the Essure Accreditation Program and the marketing strategy for Essure in Illinois. All of the Plaintiffs' claims arise out of or relate to [Bayer's] contacts with Illinois.
>
> ***
>
> a. [Bayer] engaged in extensive contacts with Illinois during the development of Essure®, creating a marketing strategy for Essure®, creating the physician training program for Essure® that all Essure®-implanting physicians must take, creating the Essure® labeling, and in obtaining FDA approval of Essure®.
>
> b. Illinois was the site of one of the clinical studies that allowed Conceptus—[Bayer's] predecessor-in-interest—to clear Essure® for marketing with the FDA and thereafter continue marketing the product with inadequate labeling because of a failure to follow-up during post-marketing testing.
>
> c. Illinois was the site of a [Bayer] Essure® consumer marketing campaign, including radio, print, and direct mail advertisements. Based on the success of [Bayer's] Illinois-based marketing campaign, [Bayer] rolled out additional consumer campaigns across the country, modeled from the Illinois campaign.

> d. Illinois was also the site of [Bayer's] pilot program for the Essure® Accreditation Program, which every physician who implants Essure® must go through. [Bayer was] negligent in creating the Essure® Accreditation Program in Illinois, which was then implemented across the country thereby negligently training all [the] Plaintiffs' implanting physicians.
>
> e. Conceptus was required to conduct ***four*** pre-approval clinical studies for Essure's initial pre-market approval ('PMA') submission to the FDA. *** Conceptus conducted at least one of those four pre-market clinical studies for Essure in part, in Illinois, using Illinois hospitals and Illinois physicians to serve as clinical investigators ***. ***
>
> f. To conduct the Pivotal Phase III Study, [Bayer] contracted with Dr. Rafael [F]. Valle at Northwestern University ***, to serve as a principal investigator. The purpose of the Pivotal Trial was to demonstrate the safety and the effectiveness of the Essure® device in providing permanent contraception. Chicago, Illinois is one of only eight principal sites in the United States to perform the Pivotal Trial. That Pivotal Trial took place between May 2000 and February 2001 in Illinois, and was one of two pre-market clinical trials Conceptus was required to perform before Essure® could obtain FDA approval." (Emphasis in original.)

¶ 7 The plaintiffs alleged that Bayer breached its obligation to update warnings and report adverse events; that Essure had quality problems and manufacturing defects; and that Bayer engaged in false and misleading sales and marketing tactics. The causes of action raised by the plaintiffs in the first amended complaint were negligence, strict products liability, breach of express warranty, breach of implied warranty, and fraud.

¶ 8 On December 15, 2017, Bayer filed a motion to dismiss the first amended complaint, arguing that Illinois lacked specific personal jurisdiction over it because the plaintiffs were not citizens of Illinois, and they did not undergo the Essure procedure in

Illinois. In response to the motion to dismiss, the plaintiffs argued that it would be appropriate for the trial court to exercise specific personal jurisdiction over Bayer because it conducted the pivotal clinical trials for Essure in Illinois using Illinois physicians; the data collected during these trials was included in the pre-market approval materials and directly related to Essure's regulatory approval; it used Illinois as "a critical test bed" for its nationwide marketing strategy; and it launched its Essure Accreditation Program in Illinois. Bayer filed a reply, once again arguing that Illinois lacked specific personal jurisdiction under the United States Supreme Court's ruling in *Bristol-Myers*.

¶ 9 On April 18, 2018, the trial court issued a written order denying Bayer's motion to dismiss for lack of personal jurisdiction. The court found that the "nonresident Plaintiffs' claims 'directly arose from or [were] related to' Bayer's purposeful activities in Illinois. Thus, the nonresident Plaintiffs' factual allegations establish a *prima facie* showing that Illinois has specific jurisdiction over Bayer." The court also found that it would not be unreasonable to require Bayer to litigate in Illinois. This court granted leave to appeal and has jurisdiction under Illinois Supreme Court Rule 306(a)(3) (eff. Nov. 1, 2017).

¶ 10 II. ANALYSIS

¶ 11 A trial court's finding of jurisdiction based solely on documentary evidence is reviewed *de novo*. *Russell v. SNFA*, 2013 IL 113909, ¶ 28. Initially, it is plaintiffs' burden to make a *prima facie* showing that jurisdiction is appropriate. *Id.* "Any conflicts in the pleadings and affidavits must be resolved in the plaintiff's favor, but the defendant may overcome plaintiff's *prima facie* case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Id.*

¶ 12 A state's power to exercise personal jurisdiction over a nonresident defendant is limited by the due process clause of the fourteenth amendment. *Riemer v. KSL Recreation Corp.*, 348 Ill. App. 3d 26, 34 (2004) (citing *Maunder v. DeHavilland Aircraft of Canada, Ltd.*, 102 Ill. 2d 342, 348 (1984)). "The due process clause [thus] limits a state's exercise of personal jurisdiction over a nonresident defendant to those instances where the defendant had at least 'minimum contacts' with the state." *Commercial Coin Laundry Systems v. Loon Investments, LLC*, 375 Ill. App. 3d 26, 30, (2007). In making this determination, courts must evaluate whether jurisdiction is proper under the long-arm statute, as well as whether it comports with the constitutional requirements of due process. *Higgins v. Richards*, 401 Ill. App. 3d 1120, 1123-24 (2010).

¶ 13 In order for a state court to exercise specific personal jurisdiction over an out-of-state defendant, the suit must arise out of, or relate to, defendant's contact with the forum. *Bristol-Myers Squibb*, 582 U.S. at __, 137 S. Ct. at 1780. The primary focus of a specific jurisdiction inquiry is the conduct of defendants. *Id.* at __, 137 S. Ct. at 1779. With regard to a corporation, courts may exercise specific personal jurisdiction when the claim directly arises from, or is connected to, defendant's purportedly wrongful acts within the forum state such that it is reasonable to require defendant to litigate in the forum. *Sabados v. Planned Parenthood of Greater Indiana*, 378 Ill. App. 3d 243, 248 (2007). To exercise specific personal jurisdiction against an out-of-state corporation: (1) defendant must have certain minimum contacts with the forum that (a) it purposefully directed its activities toward the forum, and (b) the suit must directly arise from or be connected to defendant's purported wrongful conduct within the forum state; and (2) it must be

reasonable to require defendant to litigate within the forum state. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985).

¶ 14 A. Cases Addressing Jurisdiction

¶ 15 In *Bristol-Myers Squibb*, 582 U.S. __, 137 S. Ct. 1773, over 600 plaintiffs, most of which did not reside in California, filed a civil action in state court against a pharmaceutical company, Bristol-Myers Squibb (BMS), for injuries they allegedly suffered from the drug Plavix. *Id.* at __, 137 S. Ct. at 1777. In the complaint, none of the nonresident plaintiffs ever alleged that they "obtained Plavix through California physicians or from any other California source; nor did they claim that they were injured by Plavix or were treated for their injuries in California." *Id.* at ___, 137 S. Ct. at 1778. Additionally, BMS was incorporated in Delaware, headquartered in New York, and maintained substantial business operations in New York and New Jersey. *Id.* at __, 137 S. Ct. at 1777-78. BMS engaged in business activities in California in that it maintained five research and laboratory facilities, employed roughly 310 employees (around 160 at the laboratory and research facilities and 250 as sale representatives), and maintained "a small state-government advocacy office in Sacramento." *Id.* at __, 137 S. Ct. at 1778. Though BMS sold Plavix within the state, "BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California." *Id.* Between 2006 and 2012, BMS generated $900 million in the sale of roughly 187 million pills in the state of California. *Id.* That amount represented just over 1% of the company's sales revenue nationwide. *Id.* In that case, the Supreme Court found that there was no

"connection between the forum and the specific claims at issue." *Id.* at __, 137 S. Ct. at 1781. In making its decision, the Court reasoned that "[t]he relevant plaintiffs are not California residents and do not claim to have suffered harm in that State. In addition, *** all the conduct giving rise to the nonresidents' claims occurred elsewhere. It follows that the California courts cannot claim specific jurisdiction." *Id.* at __, 137 S. Ct. at 1782.

¶ 16 In *M.M. v. GlaxoSmithKline LLC*, 2016 IL App (1st) 151909, eight minor plaintiffs, and their parents, sued GlaxoSmithKline (GSK) for catastrophic birth defects they suffered from *in utero* exposure to the drug Paxil. *Id.* ¶ 1. GSK filed a motion to dismiss the claims of the out-of-state defendants for lack of jurisdiction. *Id.* In finding that plaintiffs had made a *prima facie* showing that Illinois had specific jurisdiction over GSK, the First District found that GSK had purposefully directed its activities at Illinois by "contracting with 17 Illinois physicians in 10 Illinois cities—from Springfield to Chicago to Gurnee—to conduct between 18 and 21 clinical trials of Paxil in Illinois, on Illinois study subjects, every year from 1985 to 2003." *Id.* ¶ 49. The court further stated that:

> "Plaintiffs argue that their claims arose out of these collective failures during the Paxil trials. Plaintiffs claim that their children were born with serious congenital defects as a result of Paxil's warning labels, which inadequately warned the mothers of the association between the drug and birth defects. These labels were informed, in part, by the results of the Illinois clinical trials. Thus, plaintiffs' claims directly arose from defendant GSK's acts and omissions in Illinois." *Id.* ¶ 52.

The court concluded that defendant had failed to overcome plaintiffs' *prima facie* showing and therefore the lower court did not err in denying defendant's motion to dismiss for lack of specific personal jurisdiction. *Id.* ¶ 80.

¶ 17 B. Bayer's Contacts With the Forum

¶ 18 Here, Bayer mistakenly focuses its arguments on appeal on the actions of the plaintiffs, and whether the plaintiffs themselves were injured in Illinois, visited doctors in Illinois, or had the device implanted in Illinois. That is not the correct analysis under the case law. Instead, we must look to the conduct of Bayer that occurred in Illinois and whether the causes of action in the complaint arose from or were connected to its conduct in Illinois.

¶ 19 1. *Purposeful Availment*

¶ 20 Bayer conducted clinical trials in Illinois, targeted Chicago for developing a marketing campaign, and developed its physician training program in Illinois. Bayer contracted with Illinois doctors and facilities to conduct both pre- and post-approval trials for Essure, developed its nationwide marketing strategy in Illinois, and used Illinois as a test-base for its physician training program. Illinois was one of eight states in which phase III of the Pivotal Trial was conducted. The plaintiffs' claims in this case directly arose, at least in part, from these contacts with Illinois.

¶ 21 2. *Claims Arising From Bayer's Purposeful Availment*

¶ 22 Bayer relies on the Supreme Court's reasoning in ***Bristol-Myers Squibb*** in defense of its position that Illinois cannot exercise specific personal jurisdiction over them in these claims. However, in ***Bristol-Myers Squibb***, the Court specifically stated that "BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval

of the product in California." *Bristol-Myers Squibb*, 582 U.S. at __, 137 S. Ct. at 1778. The facts before us are easily distinguishable.

¶ 23 Here, Bayer directly targeted and marketed in Illinois, conducted clinical trials in Illinois, contracted with Illinois physicians and facilities, and established a physician accreditation program in Illinois. Unlike *Bristol-Myers Squibb*, the clinical trials conducted in Illinois were for the product at issue, *i.e.*, the Essure product. All of Bayer's conduct cited by the plaintiffs relates to the testing, development, and marketing of the Essure product. Therefore, the plaintiffs' claims for negligence, strict products liability, breach of express warranty, breach of implied warranty, and fraud for harm suffered as a result of having the Essure device implanted all arise, at least in part, from Bayer's conduct in Illinois.

¶ 24 C. Reasonableness

¶ 25 In order to comply with federal due process requirements, we must also determine whether it is reasonable to require a defendant to litigate in Illinois. In making this determination, courts must consider: (1) the burden on defendant; (2) the forum state's interest in resolving the dispute; (3) plaintiff's interest in obtaining convenient and effective relief; and (4) the interest of several states, including the forum state, in the efficient judicial resolution of the dispute and the advancement of substantive social policies. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980).

¶ 26 Here, Illinois has an undeniable interest in resolving a dispute arising, in part, from clinical trials held in Illinois, by Illinois doctors, in Illinois facilities. Also, regardless of whether the out-of-state plaintiffs' claims are dismissed, this case will move forward in

Illinois as there are also in-state plaintiffs who joined this suit. Though we recognize that there are other forums in which the out-of-state plaintiffs could bring suit, piecemeal litigation would result in additional costs and use of judicial resources, and would run the risk of conflicting rulings. Therefore, considering these facts, we do not find that litigating in Illinois would be unreasonable.

¶ 27 III. CONCLUSION

¶ 28 Therefore, as Bayer has purposefully availed itself to Illinois, the plaintiffs have made a *prima facie* showing that exercising specific personal jurisdiction in this case is appropriate, Bayer has failed to rebut that showing, and litigating in Illinois would not be unreasonable, we find that the trial court did not commit reversible error in denying Bayer's motion to dismiss for lack of jurisdiction.

¶ 29 For the foregoing reasons, the order of the circuit court of Madison County is hereby affirmed.

¶ 30 Affirmed.

2019 IL App (5th) 180278-U

NO. 5-18-0278

IN THE

APPELLATE COURT OF ILLINOIS

FIFTH DISTRICT

CHRISTY RIOS, *et al.*,	)	Appeal from the
	)	Circuit Court of
Plaintiffs-Appellees,	)	Madison County.
	)	
v.	)	No. 16-L-1046
	)	
BAYER CORPORATION; BAYER HEALTHCARE LLC; BAYER ESSURE, INC.; and BAYER HEALTHCARE PHARMACEUTICALS, INC.,	)	
	)	
Defendants-Appellants,	)	
	)	
and	)	
	)	
DOES 1-10,	)	Honorable
	)	Dennis R. Ruth,
Defendants.	)	Judge, presiding.

JUSTICE WELCH delivered the judgment of the court.
Presiding Justice Overstreet and Justice Moore concurred in the judgment.

ORDER

¶ 1 *Held*: The order of the circuit court of Madison County is affirmed where Bayer has purposefully availed themselves to Illinois, the plaintiffs have made a *prima facie* showing that exercising specific personal jurisdiction in this case is appropriate, the defendants have failed to rebut that showing, and litigating in Illinois would not be unreasonable.

¶ 2 This is an interlocutory appeal of the circuit court of Madison County's denial of the defendants' (Bayer)[1] motion to dismiss for lack of personal jurisdiction. The class-action claim was filed by 87 nonresident plaintiffs against Bayer for injuries caused by Essure, a permanent contraceptive device manufactured by Bayer.[2] For the reasons that follow, we affirm.

¶ 3 I. BACKGROUND

¶ 4 On July 25, 2016, 95 women—87 of whom were nonresidents of Illinois—filed a complaint in Madison County alleging strict products liability, negligent failure to warn, negligence in training, negligence in manufacturing, negligence/negligence *per se*, negligent misrepresentation, and breach of express warranty against Bayer for injuries received from defective Essure contraceptive devices—which were developed and manufactured by Bayer. In the original complaint, the plaintiffs alleged jurisdiction over Bayer "because the Bayer Defendants are authorized to do business in the State of Illinois ***."[3]

¶ 5 On June 19, 2017, the United States Supreme Court issued its decision in *Bristol-Myers Squibb Co. v. Superior Court of California*, 582 U.S. __, 137 S. Ct. 1773 (2017). As a result of that decision, the plaintiffs thereafter filed a first amended complaint alleging that specific personal jurisdiction could be asserted in this case against Bayer

[1]There are multiple defendants in this case; however, all are Bayer corporations and LLCs. Therefore, for clarity and ease of reading, we will refer to all defendants simply as Bayer.

[2]The class-action claim included eight plaintiffs that alleged that they resided in or experienced injuries in Illinois and are not part of this appeal.

[3]None of the Bayer defendants named in the complaint are incorporated or headquartered in the state of Illinois; however, all are authorized to do business within the state.

because of the numerous ways in which it purposefully availed itself to this forum, including:

> "at all relevant times [Bayer has] engaged in substantial business activities in the State of Illinois. At all relevant times [Bayer] transacted, solicited, and conducted business in Illinois through their employees, agents, and/or sales representatives. In addition, *** [Bayer] committed tortious acts within the state—specifically making fraudulent and negligent misrepresentations, failing to properly train physicians, failing to warn [the] Plaintiffs and their implanting physicians about the dangers of Essure, negligently conducting clinical trials, negligently developing a marketing strategy, and negligently developing the Essure Accreditation Program.
>
> *** [Bayer] used Illinois to develop, label, or work on the regulatory approval, for Essure®. In addition, [Bayer] created the Essure Accreditation Program and the marketing strategy for Essure in Illinois. All of the Plaintiffs' claims arise out of or relate to [Bayer's] contacts with Illinois.
>
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> a. [Bayer] engaged in extensive contacts with Illinois during the development of Essure®, creating a marketing strategy for Essure®, creating the physician training program for Essure® that all Essure®-implanting physicians must take, creating the Essure® labeling, and in obtaining FDA approval of Essure®.
>
> b. Illinois was the site of one of the clinical studies that allowed Conceptus—[Bayer's] predecessor-in-interest—to clear Essure® for marketing with the FDA and thereafter continue marketing the product with inadequate labeling because of a failure to follow-up during post-marketing testing.
>
> c. Illinois was the site of a [Bayer] Essure® consumer marketing campaign, including radio, print, and direct mail advertisements. Based on the success of [Bayer's] Illinois-based marketing campaign, [Bayer] rolled out additional consumer campaigns across the country, modeled from the Illinois campaign.

> d. Illinois was also the site of [Bayer's] pilot program for the Essure® Accreditation Program, which every physician who implants Essure® must go through. [Bayer was] negligent in creating the Essure® Accreditation Program in Illinois, which was then implemented across the country thereby negligently training all [the] Plaintiffs' implanting physicians.
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> e. Conceptus was required to conduct *four* pre-approval clinical studies for Essure's initial pre-market approval ('PMA') submission to the FDA. *** Conceptus conducted at least one of those four pre-market clinical studies for Essure in part, in Illinois, using Illinois hospitals and Illinois physicians to serve as clinical investigators ***. ***
>
> f. To conduct the Pivotal Phase III Study, [Bayer] contracted with Dr. Rafael [F]. Valle at Northwestern University ***, to serve as a principal investigator. The purpose of the Pivotal Trial was to demonstrate the safety and the effectiveness of the Essure® device in providing permanent contraception. Chicago, Illinois is one of only eight principal sites in the United States to perform the Pivotal Trial. That Pivotal Trial took place between May 2000 and February 2001 in Illinois, and was one of two pre-market clinical trials Conceptus was required to perform before Essure® could obtain FDA approval." (Emphasis in original.)

¶ 6 The plaintiffs alleged that Bayer breached its obligation to update warnings and report adverse events; that Essure had quality problems and manufacturing defects; and that Bayer engaged in false and misleading sales and marketing tactics. The causes of action raised by the plaintiffs in the first amended complaint were negligence, strict products liability, breach of express warranty, breach of implied warranty, and fraud.

¶ 7 On December 15, 2017, Bayer filed a motion to dismiss the first amended complaint, arguing that Illinois lacked specific personal jurisdiction over it because the plaintiffs were not citizens of Illinois, and they did not undergo the Essure procedure in

Illinois. In response to the motion to dismiss, the plaintiffs argued that it would be appropriate for the trial court to exercise specific personal jurisdiction over Bayer because it conducted clinical trials in Illinois using Illinois physicians, and those trials became the framework for Essure's regulatory approval and labeling; it created its nationwide marketing strategy in Illinois; and it launched its Essure Accreditation Program in Illinois. Furthermore, were it not for Bayer's conduct in Illinois, the plaintiffs would not have had Essure implanted.

¶ 8 On April 18, 2018, the trial court issued a written order denying Bayer's motion to dismiss for lack of personal jurisdiction. The court found that "the nonresident Plaintiffs have made a *prima facie* showing that Illinois has specific jurisdiction over Bayer and Bayer has failed to overcome Plaintiffs' *prima facie* case." This court granted leave to appeal and has jurisdiction under Illinois Supreme Court Rule 306(a)(3) (eff. Nov. 1, 2017).

¶ 9 II. ANALYSIS

¶ 10 A trial court's finding of jurisdiction based solely on documentary evidence is reviewed *de novo*. *Russell v. SNFA*, 2013 IL 113909, ¶ 28. Initially, it is plaintiffs' burden to make a *prima facie* showing that jurisdiction is appropriate. *Id.* "Any conflicts in the pleadings and affidavits must be resolved in the plaintiff's favor, but the defendant may overcome plaintiff's *prima facie* case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Id.*

¶ 11 A state's power to exercise personal jurisdiction over a nonresident defendant is limited by the due process clause of the fourteenth amendment. *Riemer v. KSL*

Recreation Corp., 348 Ill. App. 3d 26, 34 (2004) (citing *Maunder v. DeHavilland Aircraft of Canada, Ltd.*, 102 Ill. 2d 342, 348 (1984)). "The due process clause [thus] limits a state's exercise of personal jurisdiction over a nonresident defendant to those instances where the defendant had at least 'minimum contacts' with the state." *Commercial Coin Laundry Systems v. Loon Investments, LLC*, 375 Ill. App. 3d 26, 30, (2007). In making this determination, courts must evaluate whether jurisdiction is proper under the long-arm statute, as well as whether it comports with the constitutional requirements of due process. *Higgins v. Richards*, 401 Ill. App. 3d 1120, 1123-24 (2010).

¶ 12 In order for a state court to exercise specific personal jurisdiction over an out-of-state defendant, the suit must arise out of, or relate to, defendant's contact with the forum. *Bristol-Myers Squibb*, 582 U.S. at __, 137 S. Ct. at 1780. The primary focus of a specific jurisdiction inquiry is the conduct of defendants. *Id.* at __, 137 S. Ct. at 1779. With regard to a corporation, courts may exercise specific personal jurisdiction when the claim directly arises from, or is connected to, defendant's purportedly wrongful acts within the forum state such that it is reasonable to require defendant to litigate in the forum. *Sabados v. Planned Parenthood of Greater Indiana*, 378 Ill. App. 3d 243, 248 (2007). To exercise specific personal jurisdiction against an out-of-state corporation: (1) defendant must have certain minimum contacts with the forum that (a) it purposefully directed its activities toward the forum, and (b) the suit must directly arise from or be connected to defendant's purported wrongful conduct within the forum state; and (2) it must be reasonable to require defendant to litigate within the forum state. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985).

¶ 13 A. Cases Addressing Jurisdiction

¶ 14 In *Bristol-Myers Squibb*, 582 U.S. __, 137 S. Ct. 1773, over 600 plaintiffs, most of which did not reside in California, filed a civil action in state court against a pharmaceutical company, Bristol-Myers Squibb (BMS), for injuries they allegedly suffered from the drug Plavix. *Id.* at __, 137 S. Ct. at 1777. In the complaint, none of the nonresident plaintiffs ever alleged that they "obtained Plavix through California physicians or from any other California source; nor did they claim that they were injured by Plavix or were treated for their injuries in California." *Id.* at ___, 137 S. Ct. at 1778. Additionally, BMS was incorporated in Delaware, headquartered in New York, and maintained substantial business operations in New York and New Jersey. *Id.* at __, 137 S. Ct. at 1777-78. BMS engaged in business activities in California in that it maintained five research and laboratory facilities, employed roughly 310 employees (around 160 at the laboratory and research facilities and 250 as sale representatives), and maintained "a small state-government advocacy office in Sacramento." *Id.* at __, 137 S. Ct. at 1778. Though BMS sold Plavix within the state, "BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California." *Id.* Between 2006 and 2012, BMS generated $900 million in the sale of roughly 187 million pills in the state of California. *Id.* That amount represented just over 1% of the company's sales revenue nationwide. *Id.* In that case, the Supreme Court found that there was no "connection between the forum and the specific claims at issue." *Id.* at __, 137 S. Ct. at 1781. In making its decision, the Court reasoned that "[t]he relevant plaintiffs are not

California residents and do not claim to have suffered harm in that State. In addition, *** all the conduct giving rise to the nonresidents' claims occurred elsewhere. It follows that the California courts cannot claim specific jurisdiction." *Id.* at __, 137 S. Ct. at 1782.

¶ 15 In *M.M. v. GlaxoSmithKline LLC*, 2016 IL App (1st) 151909, eight minor plaintiffs, and their parents, sued GlaxoSmithKline (GSK) for catastrophic birth defects they suffered from *in utero* exposure to the drug Paxil. *Id.* ¶ 1. GSK filed a motion to dismiss the claims of the out-of-state defendants for lack of jurisdiction. *Id.* In finding that plaintiffs had made a *prima facie* showing that Illinois had specific jurisdiction over GSK, the First District found that GSK had purposefully directed its activities at Illinois by "contracting with 17 Illinois physicians in 10 Illinois cities—from Springfield to Chicago to Gurnee—to conduct between 18 and 21 clinical trials of Paxil in Illinois, on Illinois study subjects, every year from 1985 to 2003." *Id.* ¶ 49. The court further stated that:

> "Plaintiffs argue that their claims arose out of these collective failures during the Paxil trials. Plaintiffs claim that their children were born with serious congenital defects as a result of Paxil's warning labels, which inadequately warned the mothers of the association between the drug and birth defects. These labels were informed, in part, by the results of the Illinois clinical trials. Thus, plaintiffs' claims directly arose from defendant GSK's acts and omissions in Illinois." *Id.* ¶ 52.

The court concluded that defendant had failed to overcome plaintiffs' *prima facie* showing and therefore the lower court did not err in denying defendant's motion to dismiss for lack of specific personal jurisdiction. *Id.* ¶ 80.

¶ 16 B. Bayer's Contacts With the Forum

¶ 17 Here, Bayer mistakenly focuses its arguments on appeal on the actions of the plaintiffs, and whether the plaintiffs themselves were injured in Illinois, visited doctors in Illinois, or had the device implanted in Illinois. That is not the correct analysis under the case law. Instead, we must look to the conduct of Bayer that occurred in Illinois and whether the causes of action in the complaint arose from or were connected to its conduct in Illinois.

¶ 18 1. *Purposeful Availment*

¶ 19 Bayer conducted clinical trials in Illinois, targeted Chicago for developing a marketing campaign, and developed its physician training program in Illinois. Bayer contracted with Illinois doctors and facilities to conduct both pre- and post-approval trials for Essure, developed its nationwide marketing strategy in Illinois, and used Illinois as a test-base for its physician training program. Illinois was one of eight states in which phase III of the Pivotal Trial was conducted. The plaintiffs' claims in this case directly arose, at least in part, from these contacts with Illinois.

¶ 20 2. *Claims Arising From Bayer's Purposeful Availment*

¶ 21 Bayer relies on the Supreme Court's reasoning in *Bristol-Myers Squibb* in defense of its position that Illinois cannot exercise specific personal jurisdiction over them in these claims. However, in *Bristol-Myers Squibb*, the Court specifically stated that "BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California." *Bristol-Myers Squibb*, 582 U.S. at __, 137 S. Ct. at 1778. The facts before us are easily distinguishable.

¶ 22 Here, Bayer directly targeted and marketed in Illinois, conducted clinical trials in Illinois, contracted with Illinois physicians and facilities, and established a physician accreditation program in Illinois. Unlike *Bristol-Myers Squibb*, the clinical trials conducted in Illinois were for the product at issue, *i.e.*, the Essure product. All of Bayer's conduct cited by the plaintiffs relates to the testing, development, and marketing of the Essure product. Therefore, the plaintiffs' claims for negligence, strict products liability, breach of implied warranty, breach of express warranty, and fraud for harm suffered as a result of having the Essure device implanted all arise, at least in part, from Bayer's conduct in Illinois.

¶ 23 C. Reasonableness

¶ 24 In order to comply with federal due process requirements, we must also determine whether it is reasonable to require a defendant to litigate in Illinois. In making this determination, courts must consider: (1) the burden on defendant; (2) the forum state's interest in resolving the dispute; (3) plaintiff's interest in obtaining convenient and effective relief; and (4) the interest of several states, including the forum state, in the efficient judicial resolution of the dispute and the advancement of substantive social policies. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980).

¶ 25 Here, Illinois has an undeniable interest in resolving a dispute arising, in part, from clinical trials held in Illinois, by Illinois doctors, in Illinois facilities. Also, regardless of whether the out-of-state plaintiffs' claims are dismissed, this case will move forward in Illinois as there are also in-state plaintiffs who joined this suit. Though we recognize that there are other forums in which the out-of-state plaintiffs could bring suit, piecemeal

litigation would result in additional costs and use of judicial resources, and would run the risk of conflicting rulings. Therefore, considering these facts, we do not find that litigating in Illinois would be unreasonable.

¶ 26 III. CONCLUSION

¶ 27 Therefore, as the defendants have purposefully availed themselves to Illinois, the plaintiffs have made a *prima facie* showing that exercising specific personal jurisdiction in this case is appropriate, the defendants have failed to rebut that showing, and litigating in Illinois would not be unreasonable, we find that the trial court did not commit reversible error in denying Bayer's motion to dismiss for lack of jurisdiction.

¶ 28 For the foregoing reasons, the order of the circuit court of Madison County is hereby affirmed.

¶ 29 Affirmed.

IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY, et al.
Plaintiffs,

vs.

BAYER CORP., et al.
Defendants.

Case No. 16-L-1617

ORDER

This matter comes before the Court on Defendants' 735 ILCS 5/2-619.1 combined Motion to Dismiss for lack of personal jurisdiction. This matter has been fully briefed and argued by both sides. For the reasons set forth below, Defendants' motion is DENIED.

I. LAW

The pertinent inquiry in reviewing a 2-615 motion to dismiss is whether plaintiff has alleged sufficient facts in the complaint which, if proved, would entitle the plaintiff to relief. A Section 2-615 motion is based upon the pleadings rather than underlying facts. Such a motion attacks only defects apparent on the face of the complaint. *Barber-Coleman v. A.K. Midwest Insulation*, 236 Ill.App.3d 1065 (5th Dist. 1992). A court must take all well-pleaded facts as true, and all allegations must be viewed in the light most favorable to the non-movant. *Khan v. Deutsche Bank AG*, 2012 IL 112219. Only those facts apparent from the face of the pleadings, matters subject to judicial notice, and judicial admissions in the record may be considered. *Wilson v. County of Cook*, 2012 IL 112026.

A section 2-619 contemplates two types of motions: a pleading motion or a fact motion. It is a pleading motion if the grounds appear on the face of the complaint under attack; if the grounds rest upon facts supplied by the movant pursuant to section 2-619(a), then it is a fact motion. If a defect does not appear on the face of the complaint the motion must be supported by affidavit. 735 ILCS 5/2-619(a). As such, it is much like a summary judgment proceeding. If a motion challenging pleadings may be determined solely from the face of the pleadings, a 2-619 motion is appropriate; if matters not on the face of the pleadings must be considered to decide the motion, that is if the defect challenged lies in the underlying facts rather than in the pleadings, a summary judgment motion is the proper tool. *Reynolds v. Jimmy John's Enters., LLC*, 2013 IL App (4th) 120139. A 2-619 motion concedes the truth of the factual allegations in the complaint, and a movant cannot submit evidentiary material in

support of the motion that contradicts well-pleaded allegations in the complaint. *Abruzzo v. City of Park Ridge*, 231 Ill.2d 324 (2008).

II. FACTS

This case arises from injuries Plaintiffs suffered as a result of the implantation of Defendants' permanent birth control device, Essure. In the present case, Plaintiff has joined together 87 women from 22 states, including Illinois. Defendants in this case include Bayer Corporation, Bayer Healthacare LLC, Bayer Essure Inc., and Bayer Pharmaceuticals Inc. (together, "Bayer"), which are incorporated and have their principal place of business in states outside of Illinois. However, Bayer is authorized to and does business in the state of Illinois. Bayer has run clinical trials in Illinois on Illinois residents, contracted with Illinois physicians and facilities to run its clinical trials, facilitated its Essure Accreditation Program, a physician training program, in Illinois, and created a marketing strategy in Chicago, Illinois.

In summary, Plaintiffs have claimed in their First Amended Complaint that: Defendants' product, Essure, has quality problems and manufacturing defects; Defendants breached its obligation to provide accurate information, update warnings, and report adverse events and risks of its device; and Defendants engaged in false and misleading sales and marketing tactics; and but for these actions, Plaintiffs would not have used Essure and suffered their alleged injuries. The specific causes of action include: (1) Negligence; (2) Strict Products Liability; (3) Breach of Implied Warranty, (4) Breach of Express Warranty and; (5) Fraud.

Bayer moved to dismiss the nonresident Plaintiffs' claims due to a lack of personal jurisdiction. Bayer argues that Illinois lacks specific jurisdiction because the nonresident Plaintiffs claims did not arise from its Illinois activities because the nonresident Plaintiffs did not: have their devices implanted in Illinois, receive a device manufactured in Illinois, have Illinois doctors implant the device or treat them for an injury relating to the device, participate in Essure clinical trials in Illinois, or were injured by Essure in Illinois.

In response, Plaintiffs point out that, in their First Amended Complaint, they alleged that Bayer facilitated clinical trials in Illinois with the assistance of Illinois physicians. Those clinical trials became the framework for the device's regulatory approval and its labeling. Additionally, Bayer created its marketing strategy for its nationwide marketing campaign and launched its Essure Accreditation Program in Chicago, Illinois. The nonresident Plaintiff's contend that Bayer's clinical trials, its physician training program, and its marketing strategy, all conducted in Illinois, directly relate to all Plaintiffs' claims, regardless of state, because without these clinical trials Plaintiffs would not have had Essure implanted. Plaintiffs maintain that Illinois is the "testing base" for Essure and Plaintiffs have alleged that their injuries arose from acts or omissions during the clinical trials and the resulting inadequate warning label.

III. PERSONAL JURISDICTION

Illinois courts recognize the "minimum contacts" test as the threshold issue in any personal jurisdiction challenge. *Wiles v. Morita Iron Works Co.*, 125 Ill.2d 144, 161 (1988). In order for a state court to exercise specific jurisdiction, the suit must arise out of or relate to the defendant's contacts with the forum. *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773, 1780 (2017). In the context of corporations, specific personal jurisdiction may be asserted when the suit directly arises out of or is connected to the defendant's purportedly wrongful acts within the forum state, such that it is reasonable to require the defendant to litigate in that state. *Sabados v. Planned Parenthood of Greater Indiana*, 378 Ill.App.3d 243, 248 (2011). The Supreme Court has clarified that the placement of a product into the stream of commerce, without more, is not an act of a defendant purposefully directed toward the forum state. *Asahi Metal Industry Co. v. Superior Court*, 480 U.S. 102, 112 (1987). In Illinois, it is the plaintiff's burden to establish a prima facie basis to exercise personal jurisdiction over a nonresident defendant pursuant to the applicable provisions of the Illinois long-arm statutes. *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 2016 IL App (1st) 151909, 61 N.E.3d 1026.

IV. ANALYSIS

The analysis for specific jurisdiction is two-fold: (1) the corporate, nonresident defendant must have minimum contacts with Illinois in that (a) it purposefully directed its activities at that state and (b) plaintiffs' claims arose from or related to those contacts with Illinois (see *Burger King Corp.*, 471 U.S. at 472, (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414.)); and (2) it must be reasonable for Illinois to exercise jurisdiction over the defendant. See *World-Wide Volkswagen Corp.*, 444 U.S. at 286, 292 (1980) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945)). Defendant may "overcome [the] plaintiff's prima facie case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Russell*, 2013 IL 113909, ¶ 28, 370 Ill.Dec. 12, 987 N.E.2d 778. This Court finds that the nonresident Plaintiffs have made a prima facie showing that Illinois has specific jurisdiction over Bayer and Bayer has failed to overcome Plaintiffs' prima facie case.

Bayer relies on *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773 (2017). In *Bristol-Myers*, a group of plaintiffs, 86 California residents and 592 residents from other states, sued Bristol-Myers Squibb Company (BMS) in California State Court, alleging that the pharmaceutical company's drug Plavix had damaged their health. *Id.* at 1775. BMS is incorporated in Delaware and headquartered in New York, but it maintains substantial operations in both New York and New Jersey. *Id.* Although it engages in business activities in California and sells Plavix there, BMS did not create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for Plavix in California. *Id.* BMS did sell Plavix in California by contracting with a California distributing company to sell the drug. *Id.* at1786.

The Supreme Court held that there was no adequate link between the state and the nonresidents' claims because the nonresidents were not prescribed the drug in California,

they did not purchase or ingest the drug in California, they were not injured by the drug in California, nor were they treated for their injuries in California. *Id.* at 1781. Further, it was not sufficient, or even relevant, that BMS conducted research in California on matters unrelated to Plavix. *Id.* The mere fact that *other* plaintiffs were prescribed, obtained, ingested Plavix in California, and allegedly sustained the same injuries as the nonresidents, did not allow the state to assert specific jurisdiction over nonresidents' claims. *Id.* Further, BMS's decision to distribute Plavix nationally did not provide a sufficient basis for personal jurisdiction. *Id.* at 1783. The mere fact that BMS contracted with a California distributor was not enough to establish personal jurisdiction in California. *Id.* Thus, the California State Court did not have personal jurisdiction to hear the nonresidents' claims. *Id.*

Conversely Plaintiffs rely on *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 2016 IL App (1st) 151909, ¶ 75, 61 N.E.3d 1026. Defendant contends that the Court should reject *Meyer,* however, this Court is bound by the *Myers* decision because it is an Illinois appellate case, which has not been reversed by any superior court. In *Meyers,* a group of plaintiffs—twelve non-Illinois and four Illinois residents— allegedly suffered injuries from using defendant's drug, Paxil, and sued defendant, GlaxoSmithKline ("GSK"), in Illinois. *Id.* at 1030. GSK is incorporated in Delaware, maintains its principal place of business in Delaware, and has corporate and administrative headquarters in Pennsylvania and North Carolina. *Id.* GSK moved to dismiss the nonresidents' suit for lack of specific jurisdiction. *Id.* Specifically, GSK argued that Illinois lacked specific jurisdiction over these plaintiffs' claims because none of the events relevant to their claims occurred in Illinois—plaintiffs did not serve as study subjects in Illinois, receive Paxil prescriptions in Illinois, ingest Paxil in Illinois, or were injured by Paxil in Illinois. *Id.*

The court held that plaintiffs made a prima facie showing that Illinois had specific jurisdiction over GSK because GSK had purposeful contacts with Illinois and the plaintiffs' claims "arose from" acts or omissions by GSK during clinical trials for the prescription drug Paxil. *Id.* at 1037-1039.

The court stated that the first prong, "purposeful activities", was met because GSK purposefully availed itself of the state's benefits by contracting with 17 Illinois physicians in Illinois to conduct 18 to 21 clinical trials of Paxil in Illinois on Illinois study subjects every year from 1985 to 2003. *Id.* at 1036. Further the court noted that for 6 years, GSK had employed 71 to 121 employees, marketing Paxil in Illinois. *Id.* at 1037. The court held that the GSK conducted a part of its general business in Illinois, and plaintiffs' claims arose out of those very trials conducted, in part, in Illinois. *Id.* The fact the plaintiffs were not Illinois residents did not destroy the jurisdiction established on the basis of GSK activities in Illinois. *Id.* at 1040. Thus, GSK purposefully availed itself of the privilege of conducting activities in Illinois. *Id.* at 1038.

In addressing the second prong, "claims directly arose from or related to", plaintiffs claimed that their children were born with serious congenital defects as a result of Paxil's warning labels, which inadequately warned the mothers of the association between the drug and birth defects. *Id.* at 1037. These labels were influenced, in part, by the results of the Illinois

clinical trials. *Id.* Thus, plaintiffs' claims directly arose from defendant GSK's acts and omissions in Illinois. *Id.* GSK refuted plaintiffs' claims by asserting that there was nothing unique about the Illinois clinical trials and only 5% of Paxil clinical trials occurred in Illinois. *Id.* at 1041. However, GSK failed to provide any case law that named "uniqueness" as a requirement for establishing jurisdiction. *Id.* In addition, the court emphasized the trial court's question: "[W]hat if [Illinois] had 1/10 of 1 percent [of the total trials], but it was that date that skewed the entire interpretation of the tests?" *Id.* at 1038. In response to this question, the court reasoned that even that small percentage was a meaningful contact because the Illinois data was aggregated with other data to inform the warning label context for Paxil, upon which the nonresident plaintiffs relied in making the decision to take the drug. *Id.* 1038. Lastly, the court rejected GSK's contention that Illinois principal investigators had little or no input in or control over the study design protocol or analysis of the aggregate data collected. *Id.* The court reasoned that the word "little" invites the inference that the physicians had some degree of input into and control over clinical trials. *Id.*

In conclusion, under the "lenient and flexible" standard, the court held that plaintiffs' claims "directly arose from or [were] related to" GSK's Paxil trials in Illinois. *Id.* at 1039. Specifically, the court noted that plaintiffs' injuries arose out of the deficiencies in the clinical trials and the inadequate warning label was "informed, in part, by the results of the Illinois clinical trials." *Id.* 1038-1039. Therefore, plaintiffs made a prima facie showing that the Illinois has specific jurisdiction over defendant GSK, and GSK failed to overcome plaintiffs' prima facie case. *Id.* at 1039.

A. Purposeful Activities

In the present case, Bayer diminishes its purposeful activities in Illinois and claims that specific jurisdiction is lacking because it is being sued by nonresident plaintiffs who were injured outside of Illinois. In *Bristol-Myers* the court noted that the only contact the defendant had with California was contracting with a third party distributor to sell its drug. Unlike *Bristol-Myers*, Bayer is being sued in Illinois, the birth place and accreditation of its device, Essure. Further, in *Myers*, the court found that GSK had purposeful contacts with Illinois because it contracted with 17 principal investigators in Illinois to conduct clinical trials in Illinois pertaining to Plavix. Like in *Myers*, Bayer contracted with Illinois doctors and facilities to conduct pre and post approval clinical trials relating to Essure, it developed its nationwide marketing strategy in Illinois, and it chose Illinois as its test-base city for its physician accreditation program. Bayer contends that its purposeful contacts concerning Essure were not completely conducted in Illinois. However, like in *Meyer*, [Bayer] conducted a part of its general business in Illinois, and Plaintiff's claims arose out of the very trials conducted, in part, in Illinois. *Myers*, 61 N.E.3d at 1041. The fact that the contested Plaintiffs are not Illinois residents does not destroy the jurisdiction established on the basis of Bayer's activities here. *Id.* Therefore, Bayer's claim that the nonresident Plaintiffs may not sue in Illinois is unavailing because Bayer purposefully availed itself of the privilege of conducting its business, relating to Essure, in Illinois.

B. Directly Arose from or Related to

Bayer's main argument relates to this section of analysis. Bayer specifically argues that there is no link between Plaintiffs' claims and its contacts in Illinois. This Court holds that Plaintiffs has pled sufficient facts to satisfy this prong.

In *Bristol-Myers*, the court noted that the out-of-state defendant corporation did not create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for Plavix in California. Conversely, in the present case, Bayer conducted clinical trials, contracted with Illinois physicians and facilities, developed a marketing strategy for, produced the labeling for, worked on the Food and Drug Administration ("FDA") approval, and established a physician accreditation program for Essure in Illinois. Bayer minimizes its purposeful activities in Illinois and how this litigation results from the alleged injuries that arise out of or relate to those activities. In their First Amended Complaint, Plaintiffs have made several claims, including Bayer negligently conducted clinical trials, engaged in false and misleading sales and marketing tactics, failed to warn Plaintiffs and their physicians by not reporting the risks, failed to include the risks and adverse effects on its labeling and failed to update it to meet its new findings, and, but for, Bayer's activities in Illinois, Plaintiffs' would not have suffered their alleged injuries.

1. Clinical Trials in Illinois

Unlike *Bristol-Myers*, where the court held that it was not sufficient, or even relevant, that BMS conducted research in California on matters unrelated to Plavix, here, Illinois was Bayer's testing-base for Essure. Bayer ran clinical trials relating to Essure and it conducted post approval FDA mandated studies—conducted to assess the long-term safety and effectiveness of Essure—in Illinois. In the First Amended Complaint, Plaintiffs allege that the pivotal clinical trials resulted in the misinformation regarding the product's safety and effectiveness. Similarly to the defendant in *Myers*, Bayer argues that Illinois lacks specific jurisdiction over Plaintiffs' claims because none of the events relevant to their claims occurred in Illinois— Plaintiffs did not serve as study subjects in Illinois; receive Essure prescriptions in Illinois; have Essure implanted in Illinois; or were not injured by Essure in Illinois. However, like in *Myers*, Bayer conducted a part of its business relating to Essure in Illinois, which influenced the data, labeling, and marketing, and Plaintiffs claims arose out of those trials conducted, in part, in Illinois.

Defendant suggests that the manufacturing and development of Essure happened elsewhere. However, like in *Myers*, where only 5% of Paxil trials were conducted in Illinois, here, Bayer conducted a substantial number of its Essure clinical trials in Illinois and, others are still underway. Therefore, the clinical trials in Illinois are sufficient to satisfy this prong because those studies influenced the labeling and FDA accreditation of Essure, and continue to do so. Similar to the reasoning in *Myers*, here, every Essure clinical trial conducted in Illinois was necessary for the initial FDA approval and brought about the conduct which Plaintiffs complain about, regardless if Plaintiffs were not the trial subjects. That is because Bayer's

contacts with Illinois were integral to its ability to distribute Essure to *all* Plaintiffs and the Plaintiffs' implanting physicians.

2. Physicians in Illinois

Defendant further contends that specific jurisdiction cannot be attached because the nonresident Plaintiffs were not treated by Illinois doctors. However, similar to *Myers*, the nonresident Plaintiffs were not implanted Essure by Illinois doctors nor were treated by Illinois doctors. This Court finds that Bayer's contacts in Illinois gave rise to Plaintiffs' injuries because Bayer contracted with Illinois doctors and facilities to conduct pre and post approval clinical trials relating to Essure. The Illinois doctors had some degree of input into and control over the Essure clinical trials and the knowledge gathered from those doctors was ultimately funneled along, with other cumulative data, to doctors all across the United States, whether it was the non-Illinois Plaintiffs' doctors or the Illinois Plaintiffs' doctors, to prescribe Essure. Further, Plaintiffs provided evidence that Bayer used Illinois doctors to do pivotal studies in Illinois. The pivotal studies were important to get Essure past the FDA's Premarket Approval ("PMA") process and get the device approved, so it could ultimately be implanted in women in Illinois and across the United States.

3. Accreditation Program in Illinois

In the present case, the Essure Accreditation Program, a physician training program, was created in Illinois. Every single implanting physician was required to undergo training and Plaintiffs have adequately tied their injuries to this Illinois training program, specifically claiming that Bayer failed to train their implanting physicians. Bayer claims Plaintiffs did not rely on any of the accreditation done, but in fact, those pivotal studies is what formed the process by which this device was put on the market and how the labeling was composed. Thus, Bayer's inadequate training, developed exclusively in Illinois, is meaningfully connected to all Plaintiffs' claims.

4. Labeling was a Product of the Illinois Clinical Trials

The labeling for Essure was a product of the numerous and continuing studies in Illinois that influenced the use and warnings for the device. Plaintiffs have alleged that: Bayer breached its duties by failing to include warnings about the adverse reactions, the labeling was false or misleading, and Bayer failed to update the labeling after it became aware of adverse effects and its defects.

In the present case, like in *Meyers*, the Illinois clinical trials were used to inform the warning label context for Essure, upon which the nonresident Plaintiffs relied in making the decision to use Essure. *Id.* 1038. In other words, the labeling, created through these clinical studies in Illinois, and approved by the FDA is what all of these Plaintiffs and their doctors relied upon in order to make a decision to implant this device or to not implant this device. Therefore, the inadequate labeling is related to Plaintiffs' claims.

5. The Marketing Strategy Developed in Illinois

Bayer correctly argues that marketing alone is not sufficient to establish personal jurisdiction and points to *Bristol-Myers.* However, in *Bristol-Myers,* the court held that marketing alone was not sufficient to confirm personal jurisdiction because defendant did not create a marketing strategy in California. Conversely, here, the Plaintiffs are suing in Illinois, where Bayer created its marketing strategy for Essure—the same forum where clinical trials, physician contracting, accreditation of the device, and labeling of the product all took place. Bayer chose Illinois for Essure's marketing campaign and its marketing strategy which rolled out consumer campaigns across the country, modeled from the Illinois campaigns. Further, the nonresident Plaintiffs have claimed that it was this marketing that resulted in identical campaigns across the country, including Plaintiffs' home states. The alleged false and misleading marketing that proved successful in Illinois was ultimately disseminated nationwide. Without the success of the marketing strategy set in Chicago, Illinois, Plaintiffs would not have seen, nor relied upon, the misrepresentation outlined in their First Amended Complaint and suffered the alleged injuries.

In conclusion, the Court holds that nonresident Plaintiffs' claims "directly arose from or [were] related to" Bayer's purposeful activities in Illinois. Thus, the nonresident Plaintiffs' factual allegations establish a prima facie showing that Illinois has specific jurisdiction over Bayer.

V. REASONABLENESS

Finally, to comply with federal due process, the reasonableness of requiring the defendant to litigate in Illinois must be considered. *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778. To determine reasonableness, courts consider (1) the burden on the defendant; (2) the forum state's interest in resolving the dispute; (3) the plaintiff's interest in obtaining convenient and effective relief; and (4) the interest of several States, including the forum State, in the efficient judicial resolution of the dispute and the advancement of substantive social policies. *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778; *World-Wide Volkswagen Corp.,* 444 U.S. at 292.

In *Myers,* it was reasonable to require defendant to litigate in Illinois products liability claims brought against it by out-of-state minors and their mothers for birth defects allegedly caused by company's drug, as required for exercise of personal jurisdiction over company to comply with due process; if plaintiffs sued in each of the states where they resided, that would have resulted in suits in six different states, and Illinois had interest in resolving litigation because it stemmed from clinical trials run in the state *M.M. ex rel. Meyers,* 61 N.E.3d 1026.

Like in *Myers,* here, Illinois has an interest in resolving litigation stemming, in part, from clinical trials held in Illinois, run by Illinois doctors on Illinois subjects. In addition, Bayer has not presented any reason how different forums advances the goals of "efficient judicial resolution of the dispute" and "substantive social policies." *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778. Separating these cases into 22 separate jurisdictions raises

the cost, considerably, to the collective Plaintiffs and the Defendants, while also running the risk of inconsistent verdicts. *M.M. ex rel. Meyers*, 61 N.E.3d at 1042.

Therefore, considering the factors in *Russell*, exercising jurisdiction over Bayer is not unreasonable.

WHEREFORE, for the reasons stated above, Defendant's Motion to Dismiss for lack of personal jurisdiction is DENIED. All other briefed and argued motions remain under advisement.

IT IS SO ORDERED.

Clerk to send copies of this order to the parties/counsel of record.

Entered:

APR 1 8 2018

William A. Mudge
Judge Presiding

IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et al.
Plaintiffs,

vs.

BAYER CORP., et al.
Defendants.

Case No. 16-L-1046

ORDER

This matter comes before the Court on Defendants' 735 ILCS 5/2-619.1 combined Motion to Dismiss for lack of personal jurisdiction. This matter has been fully briefed and argued by both sides. For the reasons set forth below, Defendants' motion is DENIED.

I. FACTS

This case arises from injuries Plaintiffs suffered as a result of the implantation of Defendants' permanent birth control device, Essure. In the present case, Plaintiff has joined together 95 women from 27 states, including Illinois. Defendants in this case include Bayer Corporation, Bayer Healthacare LLC, Bayer Essure Inc., and Bayer Pharmaceuticals Inc. (together, "Bayer"), which are incorporated and have their principal place of business in states outside of Illinois. However, Bayer is authorized to and does business in the state of Illinois. Bayer has run clinical trials in Illinois on Illinois residents, contracted with Illinois physicians and facilities to run its clinical trials, facilitated its Essure Accreditation Program, a physician training program, in Illinois, and created a marketing strategy in Chicago, Illinois.

In summary, Plaintiffs have claimed in their First Amended Complaint that: Defendants' product, Essure, has quality problems and manufacturing defects; Defendants breached its obligation to provide accurate information, update warnings, and report adverse events and risks of its device; and Defendants engaged in false and misleading sales and marketing tactics; and but for these actions, Plaintiffs would not have used Essure and have suffered their alleged injuries. The specific causes of action include: (1) Negligence; (2) Strict Products Liability; (3) Breach of Implied Warranty, (4) Breach of Express Warranty and; (5) Fraud.

Bayer moved to dismiss the nonresident Plaintiffs' claims due to a lack of personal jurisdiction. Bayer argues that Illinois lacks specific jurisdiction because the nonresident Plaintiffs claims did not arise from its Illinois activities because the nonresident Plaintiffs did not: have their devices implanted in Illinois, receive a device manufactured in Illinois, have Illinois doctors implant the device or treat them for an injury relating to the device, participate in Essure clinical trials in Illinois, or were injured by Essure in Illinois.

In response, Plaintiffs pointed out that, in their First Amended Complaint, they alleged that Bayer facilitated clinical trials in Illinois with the assistance of Illinois physicians. Those clinical trials became the framework for the device's regulatory approval and its labeling. Additionally, Bayer created its marketing strategy for its nationwide marketing campaign and launched its Essure Accreditation Program in Chicago, Illinois. The nonresident Plaintiff's contend that Bayer's clinical trials, its physician training program, and its marketing strategy, all conducted in Illinois, directly relate to all Plaintiffs' claims, regardless of state, because without these clinical trials Plaintiffs would not have had Essure implanted. Plaintiffs maintain that Illinois is the "testing base" for Essure and Plaintiffs have alleged that their injuries arose from acts or omissions during the clinical trials and the resulting inadequate warning label.

II. PERSONAL JURISDICTION

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III. ANALYSIS

The analysis for specific jurisdiction is two-fold: (1) the corporate, nonresident defendant must have minimum contacts with Illinois in that (a) it purposefully directed its activities at that state and (b) plaintiffs' claims arose from or related to those contacts with Illinois (see *Burger King Corp.*, 471 U.S. at 472, (citing *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414.)); and (2) it must be reasonable for Illinois to exercise jurisdiction over the defendant. See *World–Wide Volkswagen Corp.*, 444 U.S. at 286, 292 (1980) (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945)). Defendant may "overcome [the] plaintiff's prima facie case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Russell*, 2013 IL 113909, ¶ 28, 370 Ill.Dec. 12, 987 N.E.2d 778. This Court finds that the nonresident Plaintiffs have made a prima facie showing that Illinois has specific jurisdiction over Bayer and Bayer has failed to overcome Plaintiffs' prima facie case.

Bayer relies on *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, 137 S. Ct. 1773 (2017). In *Bristol-Myers*, a group of plaintiffs, 86 California residents and 592

residents from other states, sued Bristol-Myers Squibb Company (BMS) in California State Court, alleging that the pharmaceutical company's drug Plavix had damaged their health. *Id.* at 1775. BMS is incorporated in Delaware and headquartered in New York, but it maintains substantial operations in both New York and New Jersey. *Id.* Although it engages in business activities in California and sells Plavix there, BMS did not create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for Plavix in California. *Id.* BMS did sell Plavix in California by contracting with a California distributing company to sell the drug. *Id.* at1786.

The Supreme Court held that there was no adequate link between the state and the nonresidents' claims because the nonresidents were not prescribed the drug in California, they did not purchase or ingest the drug in California, they were not injured by the drug in California, nor were they treated for their injuries in California. *Id.* at 1781. Further, it was not sufficient, or even relevant, that BMS conducted research in California on matters unrelated to Plavix. *Id.* The mere fact that *other* plaintiffs were prescribed, obtained, ingested Plavix in California, and allegedly sustained the same injuries as the nonresidents, did not allow the state to assert specific jurisdiction over nonresidents' claims. *Id.* Further, BMS's decision to distribute Plavix nationally did not provide a sufficient basis for personal jurisdiction. *Id.* at 1783. The mere fact that BMS contracted with a California distributor was not enough to establish personal jurisdiction in California. *Id.* Thus, the California State Court did not have personal jurisdiction to hear the nonresidents' claims. *Id.*

Conversely Plaintiffs rely on *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 2016 IL App (1st) 151909, ¶ 75, 61 N.E.3d 1026. Defendant contends that the Court should reject *Meyer*, however, this Court is bound by the *Myers* decision because it is an Illinois appellate case, which has not been reversed by any superior court. In *Meyers,* a group of plaintiffs—twelve non-Illinois and four Illinois residents— allegedly suffered injuries from using defendant's drug, Paxil, and sued defendant, GlaxoSmithKline ("GSK"), in Illinois. *Id.* at 1030. GSK is incorporated in Delaware, maintains its principal place of business in Delaware, and has corporate and administrative headquarters in Pennsylvania and North Carolina. *Id.* GSK moved to dismiss the nonresidents' suit for lack of specific jurisdiction. *Id.* Specifically, GSK argued that Illinois lacked specific jurisdiction over these plaintiffs' claims because none of the events relevant to their claims occurred in Illinois—plaintiffs did not serve as study subjects in Illinois, receive Paxil prescriptions in Illinois, ingest Paxil in Illinois, or were injured by Paxil in Illinois. *Id.*

The court held that plaintiffs made a prima facie showing that Illinois had specific jurisdiction over GSK because GSK had purposeful contacts with Illinois and the plaintiffs' claims "arose from" acts or omissions by GSK during clinical trials for the prescription drug Paxil. *Id.* at 1037-1039.

The court stated that the first prong, "purposeful activities", was met because GSK purposefully availed itself of the state's benefits by contracting with 17 Illinois physicians in Illinois to conduct 18 to 21 clinical trials of Paxil in Illinois on Illinois study subjects every year from 1985 to 2003. *Id.* at 1036. Further the court noted that for 6 years, GSK had employed 71 to 121 employees, marketing Paxil in Illinois. *Id.* at 1037. The court held that the GSK conducted a part of its general business in Illinois, and plaintiffs' claims arose of those very trials conducted, in part, in Illinois. *Id.* The fact the plaintiffs were not Illinois residents did not destroy the

jurisdiction established on the basis of GSK activities in Illinois. *Id.* at 1040. Thus, GSK purposefully availed itself of the privilege of conducting activities in Illinois. *Id.* at 1038.

In addressing the second prong, "claims directly arose from or related to", plaintiffs claimed that their children were born with serious congenital defects as a result of Paxil's warning labels, which inadequately warned the mothers of the association between the drug and birth defects. *Id.* at 1037. These labels were influenced, in part, by the results of the Illinois clinical trials. *Id.* Thus, plaintiffs' claims directly arose from defendant GSK's acts and omissions in Illinois. *Id.* GSK refuted plaintiffs' claims by asserting that there was nothing unique about the Illinois clinical trials and only 5% of Paxil clinical trials occurred in Illinois. *Id.* at 1041. However, GSK failed to provide any case law that named "uniqueness" as a requirement for establishing jurisdiction. *Id.* In addition, the court emphasized the trial court's question: "[W]hat if [Illinois] had 1/10 of 1 percent [of the total trials], but it was that date that skewed the entire interpretation of the tests?" *Id.* at 1038. In response to this question, the court reasoned that even that small percentage was a meaningful contact because the Illinois data was aggregated with other data to inform the warning label context for Paxil, upon which the nonresident plaintiffs relied in making the decision to take the drug. *Id.* 1038. Lastly, the court rejected GSK's contention that Illinois principal investigators had little or no input in or control over the study design protocol or analysis of the aggregate data collected. *Id.* The court reasoned that the word "little" invites the inference that the physicians had some degree of input into and control over clinical trials. *Id.*

In conclusion, under the "lenient and flexible" standard, the court held that plaintiffs' claims "directly arose from or [were] related to" GSK's Paxil trials in Illinois. *Id.* at 1039. Specifically, the court noted that plaintiffs' injuries arose out of the deficiencies in the clinical trials and the inadequate warning label was "informed, in part, by the results of the Illinois clinical trials." *Id.* 1038-1039. Therefore, plaintiffs made a prima facie showing that the Illinois has specific jurisdiction over defendant GSK, and GSK failed to overcome plaintiffs' prima facie case. *Id.* at 1039.

A. Purposeful Activities

In the present case, Bayer diminishes its purposeful activities in Illinois and claims that specific jurisdiction is lacking because it is being sued by nonresident plaintiffs who were injured outside of Illinois. In *Bristol-Myers* the court noted that the only contact the defendant had with California was contracting with a third party distributor to sell its drug. Unlike *Bristol-Myers*, Bayer is being sued in Illinois, the birth place and accreditation of its device, Essure. Further, in *Myers*, the court found that GSK had purposeful contacts with Illinois because it contracted with 17 principal investigators in Illinois to conduct clinical trials in Illinois pertaining to Plavix. Like in *Myers*, Bayer contracted with Illinois doctors and facilities to conduct pre and post approval clinical trials relating to Essure, it developed its nationwide marketing strategy in Illinois, and it chose Illinois as its test-base city for its physician accreditation program. Bayer contends that its purposeful contacts concerning Essure were not completely conducted in Illinois. However, like in *Meyer*, [Bayer] conducted, a part, of its general business in Illinois, and Plaintiff's claims arose out of the very trials conducted, in part, in Illinois. *Myers*, 61 N.E.3d at 1041. The fact that the contested Plaintiffs are not Illinois residents does not destroy the jurisdiction established on the basis of Bayer's activities here. *Id.* Therefore, Bayer's claim that the nonresident Plaintiffs

may not sue in Illinois is unavailing because Bayer purposefully availed itself of the privilege of conducting its business, relating to Essure, in Illinois.

B. Directly Arose from or Related to

Bayer's main argument relates to this section of analysis. Bayer specifically argues that there is no link between Plaintiffs' claims and its contacts in Illinois. This Court holds that Plaintiffs has pled sufficient facts to satisfy this prong.

In *Bristol-Myers*, the court noted that the out-of-state defendant corporation did not create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for Plavix in California. Conversely, in the present case, Bayer conducted clinical trials, contracted with Illinois physicians and facilities, developed a marketing strategy for, produced the labeling for, worked on the Food and Drug Administration ("FDA") approval, and established a physician accreditation program for Essure in Illinois. Bayer minimizes its purposeful activities in Illinois and how this litigation results from the alleged injuries that arise out of or relate to those activities. In their First Amended Complaint, Plaintiffs have made several claims, including Bayer negligently conducted clinical trials, engaged in false and misleading sales and marketing tactics, failed to warn Plaintiffs and their physicians by not reporting the risks, failed to include the risks and adverse effects on its labeling and failed to update it to meet its new findings, and, but for, Bayer's activities in Illinois, Plaintiffs' would not have suffered their alleged injuries.

1. Clinical Trials in Illinois

Unlike *Bristol-Myers*, where the court held that it was not sufficient, or even relevant, that BMS conducted research in California on matters unrelated to Plavix, here, Illinois was Bayer's testing-base for Essure. Bayer ran clinical trials relating to Essure and it conducted post approval FDA mandated studies—conducted to assess the long-term safety and effectiveness of Essure—in Illinois. In the First Amended Complaint, Plaintiffs allege that the pivotal clinical trials resulted in the misinformation regarding the product's safety and effectiveness. Similarly to the defendant in *Myers*, Bayer argues that Illinois lacks specific jurisdiction over Plaintiffs' claims because none of the events relevant to their claims occurred in Illinois— Plaintiffs did not serve as study subjects in Illinois; receive Essure prescriptions in Illinois; have Essure implanted in Illinois; or were not injured by Essure in Illinois. However, like in *Myers*, Bayer conducted a part of its business relating to Essure in Illinois, which influenced the data, labeling, and marketing, and Plaintiffs claims arose out of those trials conducted, in part, in Illinois.

Defendant suggests that the manufacturing and development of Essure happened elsewhere. However, like in *Myers,* where only 5% of Paxil trials were conducted in Illinois, here, Bayer conducted a substantial number of its Essure clinical trials in Illinois and, others are still underway. Therefore, the clinical trials in Illinois are sufficient to satisfy this prong because those studies informed the labeling and FDA accreditation of Essure, and continue to do so. Similar to the reasoning in *Myers*, here, every Essure clinical trial conducted in Illinois was necessary for the initial FDA approval and brought about the conduct which Plaintiffs complain about, regardless if Plaintiffs were not the trial subjects. That is because Bayer's contacts with

Illinois were integral to its ability to distribute Essure to *all* Plaintiffs and the Plaintiffs' implanting physicians.

2. Physicians in Illinois

Defendant further contends that specific jurisdiction cannot be attached because the nonresident Plaintiffs were not treated by Illinois doctors. However, similar to *Myers,* the nonresident Plaintiffs were not implanted Essure by Illinois doctors nor were treated by Illinois doctors. This Court finds that Bayer's contacts in Illinois gave rise to Plaintiffs' injuries because Bayer contracted with Illinois doctors and facilities to conduct pre and post approval clinical trials relating to Essure. The Illinois doctors had some degree of input into and control over the Essure clinical trials and the knowledge gathered from those doctors was ultimately funneled along, with other cumulative data, to doctors all across the United States, whether it was the non-Illinois Plaintiffs' doctors or the Illinois Plaintiffs' doctors, to prescribe Essure. Further, Plaintiffs provided evidence that Bayer used Illinois doctors to do pivotal studies in Illinois. The pivotal studies were important to get Essure past the FDA's Premarket Approval ("PMA") process and get the device approved, so it could ultimately be implanted in women in Illinois and across the United States.

3. Accreditation Program in Illinois

In the present case, the Essure Accreditation Program, a physician training program, was created in Illinois. Every single implanting physician was required to undergo training and Plaintiffs have adequately tied their injuries to this Illinois training program, specifically claiming that Bayer failed to train their implanting physicians. Bayer claims Plaintiffs did not rely on any of the accreditation done, but in fact, those pivotal studies is what formed the process by which this device was put on the market and how the labeling was composed. Thus, Bayer's inadequate training, developed exclusively in Illinois, is meaningfully connected to all Plaintiffs' claims.

4. Labeling was a Product of the Illinois Clinical Trials

The labeling for Essure was a product of the numerous and continuing studies in Illinois that informed the use and warnings for the device. Plaintiffs have alleged that: Bayer breached its duties by failing to include warnings about the adverse reactions, the labeling was false or misleading, and Bayer failed to update the labeling after it became aware of adverse effects and its defects.

In the present case, like in *Meyers*, the Illinois clinical trials were used to inform the warning label context for Essure, upon which the nonresident Plaintiffs relied in making the decision to use Essure. *Id.* 1038. In other words, the labeling, created through these clinical studies in Illinois, and approved by the FDA is what all of these Plaintiffs and their doctors relied upon in order to make a decision to implant this device or to not implant this device. Therefore, the inadequate labeling is related to Plaintiffs' claims.

5. The Marketing Strategy Developed in Illinois

Bayer correctly argues that marketing alone is not sufficient to establish personal jurisdiction and points to *Bristol-Myers.* However, in *Bristol-Myers,* the court held that marketing alone was not sufficient to confirm personal jurisdiction because defendant did not create a marketing strategy in California. Conversely, here, the Plaintiffs are suing in Illinois, where Bayer created its marketing strategy for Essure—the same forum where clinical trials, physician contracting, accreditation of the device, and labeling of the product all took place. Bayer chose Illinois for Essure's marketing campaign and its marketing strategy which rolled out consumer campaigns across the country, modeled from the Illinois campaigns. Further, the nonresident Plaintiffs have claimed that it was this marketing that resulted in identical campaigns across the country, including Plaintiffs' home states. The false and misleading marketing that proved successful in Illinois was ultimately disseminated nationwide. Without the success of the marketing strategy set in Chicago, Illinois, Plaintiffs would not have seen, nor relied upon, the misrepresentation outlined in their First Amended Complaint and suffered the alleged injuries.

In conclusion, the Court holds that nonresident Plaintiffs' claims "directly arose from or [were] related to" Bayer's purposeful activities in Illinois. Thus, the nonresident Plaintiffs' factual allegations establish a prima facie showing that Illinois has specific jurisdiction over Bayer.

IV. REASONABLENESS

Finally, to comply with federal due process, the reasonableness of requiring the defendant to litigate in Illinois must be considered. *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778. To determine reasonableness, courts consider (1) the burden on the defendant; (2) the forum state's interest in resolving the dispute; (3) the plaintiff's interest in obtaining convenient and effective relief; and (4) the interest of several States, including the forum State, in the efficient judicial resolution of the dispute and the advancement of substantive social policies. *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778; *World–Wide Volkswagen Corp.*, 444 U.S. at 292.

In *Myers*, it was reasonable to require defendant to litigate in Illinois products liability claims brought against it by out-of-state minors and their mothers for birth defects allegedly caused by company's drug, as required for exercise of personal jurisdiction over company to comply with due process; if plaintiffs sued in each of the states where they resided, that would have resulted in suits in six different states, and Illinois had interest in resolving litigation because it stemmed from clinical trials run in the state *M.M. ex rel. Meyers,* 61 N.E.3d 1026.

Like in *Myers*, here, Illinois has an interest in resolving litigation stemming, in part, from clinical trials held in Illinois, run by Illinois doctors on Illinois subjects. In addition, Bayer has not presented any reason how different forums advances the goals of "efficient judicial resolution of the dispute" and "substantive social policies." *Russell,* 2013 IL 113909, ¶ 87, 370 Ill.Dec. 12, 987 N.E.2d 778. Separating these cases into 27 separate jurisdictions raises the cost, considerably, to the collective Plaintiffs and the Defendants, while also running the risk of inconsistent verdicts. *M.M. ex rel. Meyers*, 61 N.E.3d at 1042.

Therefore, considering the factors in *Russell,* exercising jurisdiction over Bayer is not unreasonable.

WHEREFORE, for the reasons stated above, Defendant's Motion to Dismiss for lack of personal jurisdiction is DENIED. All other briefed and argued motions remain under advisement.

Clerk to send copies of this order to the parties/counsel of record.

Entered: 4/18/18

Dennis R. Ruth
Judge Presiding

EFILED
Case Number 2016L 001617
Transaction ID: 61475431
Date: Dec 15 2017 04:33PM
Mark Von Nida
Clerk of Circuit Court
Third Judicial Circuit, Madison County Illinois

IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY ET AL.,	)	Case No. 16-L-1617
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., BAYER HEALTHCARE PHARMACEUTICALS INC., and DOES 1-10, inclusive,	)	
Defendants.	)	

DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER 735 ILL. COMP. STAT. §§ 5/2-301, 5/2-619.1, 5/2-619(a)(9) AND 5/2-615

For the reasons set forth in their Memorandum of Law, defendants Bayer Corporation, Bayer HealthCare LLC., Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") move to dismiss the Plaintiffs' Complaint with prejudice under Sections 5/2-301, 5/2-619.1, 5/2-619(a)(9), and 5/2-615 of Title 735 of the Illinois Compiled Statutes.

DATED: December 15, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on 15th day of December, 2017, a true and correct copy of the foregoing was served upon the following by enclosing same in an envelope addressed as below, with proper first class postage fully prepaid, and depositing same in the U. S. Mail at Edwardsville, Illinois, at 5 p.m.:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY ET AL.,	)	Case No. 16-L-1617
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., BAYER HEALTHCARE PHARMACEUTICALS INC., and DOES 1-10, inclusive,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER 735 ILL. COMP. STAT. §§ 5/2-301, 5/2-619.1, 5/2-619(a)(9), AND 5/2-615

INTRODUCTION

In *Bristol-Myers Squibb Co. v. Superior Court of California*, 137 S. Ct. 1773, 1782 (2017), the U.S. Supreme Court rejected the precise jurisdictional artifice Plaintiffs attempt to use in this case. The Supreme Court made clear that a court cannot exercise specific jurisdiction over the claims of out-of-state plaintiffs against an out-of-state defendant when "the conduct giving rise to the nonresidents' claims occurred elsewhere." *Id.* at 1782. That holding is "dispositive of the specific personal jurisdiction issue" in this case, where 73 of the 86 Plaintiffs ("non-Illinois Plaintiffs") have *no* connection at all to Illinois and bring claims against non-Illinois defendants for events that occurred elsewhere. *Jordan v. Bayer Corp.*, No. 4:17-CV-865, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017); *see also, e.g.*, *BeRousse v. Janssen Research & Dev.*, LLC, No. 3:17-cv-00716, 2017 WL 4255075, at *4 (S.D. Ill. Sept. 26, 2017) ("Similar to BMS . . . , this Court lacks specific personal jurisdiction over defendants regarding the non-Illinois plaintiffs' claims."), *appeal docketed*, No. 17-3200 (7th Cir. Oct. 24, 2017).

Recognizing that *Bristol-Myers* rejects personal jurisdiction over the non-Illinois Plaintiffs' claims, Plaintiffs have filed an amended complaint that adds a series of jurisdictionally irrelevant claims about Essure's sales, marketing, training, and clinical trial activities. But the newly added allegations of purported "extensive contacts," First Am. Compl. ("FAC") ¶ 11(a), do not identify any connection—let alone a constitutionally "adequate" one—to the "specific claims" of the individual non-Illinois plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1776. The First Amended Complaint does not, for instance, allege that any of the non-Illinois plaintiffs participated in clinical trial activities in Illinois, saw any marketing in Illinois, or purchased their devices in Illinois. These allegations do not distinguish Illinois from any other state across the country where Bayer sold, marketed, or studied Essure; indeed, plaintiffs in other states

(including plaintiffs represented by *the same plaintiffs' counsel*) have relied on identical allegations to argue that specific jurisdiction over non-residents' claims exists in those states as well. *See infra* pages 8-9, 11-12. The First Amended Complaint fails to allege an adequate "connection between the forum and the specific claims at issue," *Bristol-Myers*, 137 S. Ct. at 1776, and there is no personal jurisdiction.

Turning to the merits, Plaintiffs' claims are preempted by federal law and fail to meet Illinois pleading standards, and numerous courts have rejected virtually identical claims. Four federal courts have dismissed all of the claims, and others have dismissed almost all of them. *See, e.g.*, *Burrell v. Bayer Corp.*, No. 1:17-CV-00031, 2017 WL 1955333 (W.D.N.C. May 10, 2017) (dismissing all claims with prejudice); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017) (same); *Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 WL 4007547 (D. Conn. July 26, 2016) (same); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (dismissing all claims); *Richardson v. Bayer HealthCare Pharms. Inc.*, No. 4:15-cv-00443, 2016 WL 4546369 (D. Idaho Aug. 30, 2016) (dismissing almost all claims, after which plaintiff voluntarily dismissed case); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838-39 (E.D. Pa. 2016) (dismissing 10 of 12 claims) ("*McLaughlin I*"); *McLaughlin v. Bayer Corp.*, No. 14-7315, *et al.*, 2017 WL 697047, at *18 (E.D. Pa. Feb. 21, 2017) ("*McLaughlin II*") (further narrowing claims).

Plaintiffs have fared no better in state courts. *See Medali v. Bayer HealthCare LLC*, No. RG15771555 (Cal. Super Ct. Feb. 16, 2016) (demurrer sustained with leave to amend certain claims) (order attached as Exhibit A to concurrently filed Request for Judicial Notice ("RJN")); *Noris v. Bayer Essure, Inc.*, No. BC589882, (Cal. Super. Ct. April 26, 2016) (demurrer sustained with leave to amend two claims) (RJN, Ex. B); *Williams v. Bayer Corp.*, No. 15BA-CVNo.

WD8023802526 (Mo. Ct. App. Dec. 5, 2017) (affirming dismissal with prejudice of most claims) (RJN, Ex. C); *Lance v. Bayer Essure Inc.*, No. RG16809860 (Cal. Super. Ct. Aug. 2, 2016) (demurrer sustained in part with leave to amend certain claims) (RJN, Ex. D); *In re Essure Prods. Cases*, JCCP No. 4887 (Cal. Super. Ct. Apr. 12, 2017) (further narrowing claims) (RJN, Ex. E).

These courts have had no trouble dismissing the claims at issue because, at bottom, Plaintiffs are attempting to second-guess the Food & Drug Administration ("FDA"). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204-08 (8th Cir. 2010); *see also* 21 U.S.C. §§ 360k(a), 337(a). FDA has the exclusive authority to regulate Class III medical devices like Essure, and has decided—numerous times—that Essure is safe and effective. FDA has balanced the benefits and risks of the device and recently confirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," and that "FDA continues to believe that the benefits of the device outweigh its risks." FDA News Release (RJN, Ex. F); FDA Activities (RJN, Ex. M). Plaintiffs' boilerplate allegations also do not suffice under Illinois pleading standards. *See* Ill. Comp. Stat. § 5/2-615. This Court should dismiss the Complaint.

BACKGROUND

A. Statutory And Regulatory Background

Congress has spoken. Federal law grants FDA the exclusive power to regulate medical devices. In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). The legislation "swept back" much of the state regulation that had emerged in patchwork form, and instead "imposed a regime of detailed

federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). As part of this regime, Congress adopted a "general prohibition on non-Federal regulation" to avert the "undu[e] burden[]" of differing state regulations that can stifle innovation and ultimately harm public health. H.R. Rep. No. 94–853, at 45 (1976). Congress preempted all state laws that impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

Instead of state regulation, FDA provides the necessary oversight. Under this regime, "each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). A device intended "for a use in supporting or sustaining human life," or that otherwise "presents a potential unreasonable risk of illness or injury" is deemed a Class III device. 21 U.S.C. §§ 360c(a)(1)(C)(i)-(ii). FDA subjects a small percentage of innovative Class III devices, such as Essure, to the most "rigorous" level of FDA scrutiny. These devices must receive Premarket Approval ("PMA") before they can be marketed or sold. *Riegel*, 552 U.S. at 318; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1152 (Ill. 1999).

To receive such approval, the device manufacturer "must submit what is typically a multivolume application," and the "FDA spends an average of 1,200 hours reviewing each application," ultimately "grant[ing] premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317-18 (quoting 21 U.S.C. § 360e(d)); *see also Weiland*, 721 N.E.2d at 1152 (describing premarket approval process); *Ala. Tissue Ctr. of Univ. of Ala. Health Serv. Found., P.C. v. Sullivan*, 975 F.2d 373,

374-75 (7th Cir. 1992) (describing premarket approval process). A "manufacturer must furnish" numerous materials to FDA, including "detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling." *Leavitt*, 470 F.3d at 74. FDA then heavily scrutinizes these applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)).

As part of this process, FDA reviews a device's proposed labeling, which includes the Instructions for Use ("IFU") (for physicians) and Patient Information Booklet ("PIB") (for patients). The agency "evaluates safety and effectiveness under the conditions of use set forth on the label," and "must determine that the proposed labeling is neither false nor misleading" before granting approval. *Id.* (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). Once a device has been approved, a manufacturer cannot make changes to the labeling without FDA permission, 21 U.S.C. § 360e(d)(6)(A)(i), under "largely the same criteria" as the initial application. *Riegel*, 522 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). The statute likewise "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)). FDA may demand additional information from the manufacturer at any time, *see* 21 U.S.C. § 360e(c)(1)(H), and may require revisions to any component of the application, *see* 21 C.F.R. § 814.44(c). Only upon successfully "running the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996), may a Class III device lawfully be marketed in the United States.

A device manufacturer's obligations under federal law do not end with pre-market approval. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1336 (10th Cir. 2015). By design,

FDA enjoys wide and exclusive enforcement authority. Congress has made clear that actions to enforce the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a), and this judgment forecloses any private right of action under that statute, *see Buckman*, 531 U.S. at 349 n.4. FDA may investigate manufacturers of drugs and devices, and the agency "has at its disposal a variety of enforcement options that allow it to make a measured response" to any violations it uncovers. *Buckman*, 531 U.S. at 349; *see also* 21 U.S.C. §§ 332, 333, 334.

B. Factual Background

FDA has long recognized that Essure is a safe and effective method of permanent female contraception. In 2002, FDA granted Essure PMA, and FDA has never withdrawn or suspended that PMA. *See* FDA, Premarket Approval Order, Essure System (RJN, Ex. G); Summary of Safety and Effectiveness Data for Essure System (RJN, Ex. H); FDA, Regulatory History (RJN, Ex. I). Rather, FDA has granted numerous supplemental approvals, including as recently as December 2016. PMA Supplements (RJN, Ex. J). FDA repeatedly has reviewed and approved Essure's design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling. Premarket Approval Order (RJN, Ex. G at 4); Summary of Safety and Effectiveness (RJN, Ex. H); Professional Labeling (2002) ("2002 IFU") (RJN, Ex. K); Professional Labeling (2013) ("2013 IFU") (RJN, Ex. L). In fact, FDA recently rejected challenges to the device, reconfirming that "FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," and that "FDA continues to believe that the benefits of the device outweigh its risks." FDA News Release (RJN, Ex. F); FDA Activities (RJN, Ex. M).

Plaintiffs, who are 86 unrelated women from 22 different states, allege that they have sustained a wide variety of injuries including device migration, pain, weight gain, heavy

menstrual bleeding, and perforated organs. *See, e.g.*, FAC ¶¶ 229-314. After Bayer moved to dismiss the complaint, Plaintiffs sought leave to file a First Amended Complaint adding additional allegations concerning Essure's sales, marketing, training, and clinical trial activities. *See id.* ¶¶ 9-12. The Court granted leave to file the amended complaint "without prejudice to Defendants raising any arguments in a motion to dismiss or motion to sever and transfer venue as to the claims in the First Amended Complaint."

STANDARD OF REVIEW

Under Illinois law, a complaint must be dismissed "where it is apparent that no set of facts could be proven that would entitle the plaintiff to relief." *Turcios v. DeBruler Co.*, 32 N.E.3d 1117, 1122 (Ill. 2015); *see also Richter v. Prairie Farms Dairy, Inc.*, 53 N.E.3d 1, 7 (Ill. 2016). The Court "must disregard the conclusions that are pleaded and look only to well-pleaded facts to determine whether they are sufficient to state a case of action against the defendant. If not, the motion must be granted, 'regardless of how many conclusions the count may contain and regardless of whether or not they inform the defendant in a general way of the nature of the claim against him.'" *City of Chi. v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1112-13 (Ill. 2004) (quoting *Knox Coll. v. Celotex Corp.*, 430 N.E.2d 976, 985 (Ill. 1981)).

ARGUMENT

I. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR LACK OF PERSONAL JURISDICTION.

Pursuant to 735 Ill. Comp. Stat. § 5/2-301, Bayer is not subject to personal jurisdiction with respect to the claims of the 73 Plaintiffs who are neither citizens of Illinois nor allege that they underwent the Essure procedure in Illinois. Plaintiffs bear the burden to show that personal jurisdiction exists. *See Russell v. SNFA*, 987 N.E.2d 778, 784 (Ill. 2013). To meet this burden, Plaintiffs must plead allegations, which, if taken as true, would establish sufficient contacts to

satisfy the requirements of due process. *Id*. Here, the non-Illinois Plaintiffs do not plead sufficient—or any—facts to show specific jurisdiction over Bayer. *See, e.g.*, *Bristol-Myers*, 137 S. Ct. at 1782; *Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 761 n.19 (2014); *Jordan*, 2017 WL 3006993, at *3-4.

Plaintiffs have abandoned their argument that any of the Bayer Defendants are subject to general jurisdiction in Illinois, *see* FAC ¶¶ 9-10, and their allegations are plainly insufficient to justify such all-purposes jurisdiction over Bayer, *see Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 761 n.19 (2014); *BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549, 1559 (2017). As the Supreme Court has held and repeatedly reaffirmed, a court has general jurisdiction only where a defendant's affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State." *BNSF*, 137 S. Ct. at 1558 (quoting *Daimler*, 134 S. Ct. at 754). Thus, a corporate defendant is subject to general jurisdiction in the states where it is incorporated and has its principal place of business, *id.* at 1558–59, and in in an "exceptional" case, where its "operations" are "so substantial and of such a nature as to render the corporation at home" *id.* at 1558 (giving as an example of an "exceptional case" *Perkins v. Benguet Consol. Mining Co*., 342 U. S. 437 (1952), where "war had forced the defendant corporation's owner to temporarily relocate the enterprise from the Philippines to Ohio"). "[S]imply doing continuous and systematic business in a state is not enough to establish general jurisdiction." *Jinright v. Johnson & Johnson, Inc.*, No. 4:17CV01849, 2017 WL 3731317, at *3 (E.D. Mo. Aug. 30, 2017).[1]

[1] It is not surprising that Plaintiffs have abandoned their argument that any of the Bayer Defendants are subject to general jurisdiction in Illinois. Here, no Defendant is incorporated in Illinois or has its principal place of business in Illinois. *See* Declaration of Keith Abrams, Ex. A, hereto.

Nor is Bayer subject to specific personal jurisdiction with regards to the non-Illinois Plaintiffs' claims. "In order for a state court to exercise specific jurisdiction, 'the *suit*' must 'aris[e] out of or relat[e] to the defendant's contacts with the *forum*.'" *Bristol-Myers*, 173 S. Ct. at 1780 (quoting *Daimler*, 134 S. Ct. at 754) (alterations in original). Here, Plaintiffs allege that specific personal jurisdiction exists because Bayer "engaged in substantial business activities in the State of Illinois." FAC ¶ 9. In particular, Plaintiffs allege that specific jurisdiction exists over the non-Illinois Plaintiffs' claims because of sales and marketing of Essure in Illinois, physician training and accreditation events held in Illinois, and Essure clinical trial activities in Illinois. But these allegations fail as a matter of law because they do not demonstrate a constitutionally "adequate link between the State" and the specific claims of the individual non-Illinois plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, the allegations of marketing and sales activities are no different than the allegations that the U.S. Supreme Court rejected as constitutionally inadequate in *Bristol-Myers*.

In the First Amended Complaint, the non-Illinois Plaintiffs do not allege that "they acquired the Essure device from [an Illinois] source or that they were injured or treated in [Illinois]." *Jordan*, 2017 WL 3006993, at *4. Nor does the First Amended Complaint include any factual allegations that Plaintiffs' Essure devices were developed, manufactured, packaged, or labeled in Illinois. *See id.* In fact, Conceptus—the original developer and manufacturer of Essure—was indisputably located in California and undertook these activities largely in California. *See Jordan*, 2017 WL 3006993, at *4 (noting the same in a nearly identical Essure case). Nor does the First Amended Complaint allege that any of the non-Illinois Plaintiffs' own doctors were trained or accredited in Illinois. In short, "all the conduct giving rise to the [non-Illinois Plaintiffs'] claims occurred elsewhere," *Bristol-Myers*, 137 S. Ct. at 1782, and those

plaintiffs therefore are not entitled to bring their claims in Illinois, *see Jordan*, 2017 WL 3006993, at *4.

The Supreme Court has clearly rejected any argument that this court has personal jurisdiction over the claims of the 73 non-Illinois plaintiffs simply because they are joined with "and allegedly sustained the same injuries as" the Illinois Plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1781. And the defendants' alleged sales, marketing, training, and clinical trial activities in Illinois cannot give rise to personal jurisdiction because there is no "adequate link between the State" and the *specific claims* of any non-Illinois plaintiff. *Bristol-Myers*, 137 S. Ct. at 1781. The Supreme Court's holding is clear: there is no basis—consistent with federal Due Process—to exercise personal jurisdiction over Bayer with respect to the non-Illinois Plaintiffs' claims. *See, e.g.*, *id.* at 1782; *BNSF*, 137 S. Ct. at 1559; *see also Jordan*, 2017 WL 3006993, at *3-4.

A. The Alleged Sales, Marketing, and Training Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs' argument that Essure sales and marketing activities in Illinois give rise to personal jurisdiction for the non-Illinois plaintiffs' claims cannot be distinguished from arguments that *Bristol-Myers* rejected. Plaintiffs allege that Conceptus and Bayer developed sales, marketing, and training in Illinois (along with other states), and that Essure marketing "specifically targeted" doctors in Illinois. *See* FAC ¶ 11. But they do not allege that any of the non-Illinois Plaintiffs in this case underwent the Essure procedure in Illinois, were exposed to marketing about Essure in Illinois, or that their doctors participated in training in Illinois.

Thus, these allegations are no different than those in *Bristol-Myers.* In that case, the California Supreme Court had held that specific jurisdiction existed because "all the plaintiffs' claims arise out of BMS's nationwide marketing and distribution of Plavix," *Bristol-Myers Squibb Co. v. Superior Court*, 377 P.3d 874, 889 (Cal. 2016), and "BMS market[ed] and

advertise[d] Plavix in this state, it employs sales representatives in California, contracted with a California-based pharmaceutical distributor, operates research and laboratory facilities in this state," and "BMS actively and purposefully sought to promote sales of Plavix to California residents, resulting in California sales of nearly $1 billion over six years," *id*. at 886. But the U.S. Supreme Court *reversed* that decision, holding that none of those activities could provide specific jurisdiction because "[t]he relevant plaintiffs are not California residents and do not claim to have suffered harm in that State." *Bristol-Myers*, 137 S. Ct. at 1782.

The Supreme Court held that "[t]he mere fact that other plaintiffs were prescribed, obtained, and ingested [the drug] in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents' claims." 137 S. Ct. at 1781. Rather, "settled principles regarding specific jurisdiction" require each plaintiff to identify "an 'affiliation between the forum and the underlying controversy, principally [an] activity or an occurrence that takes place in the forum state.'" *Id*. at 1781 (alteration in original). Because "[t]he relevant plaintiffs [were] not California residents" and "all the conduct giving rise to the nonresidents' claims occurred elsewhere," specific personal jurisdiction did not exist. *Id*. at 1782.

Here, as in *Bristol-Myers*, the non-Illinois Plaintiffs "were not prescribed [Essure] in [Illinois], did not purchase [Essure] in [Illinois], . . . and were not injured by [Essure] in [Illinois]." *Id*. at 1781. Plaintiffs' argument that Essure sales, marketing, and training in Illinois creates specific jurisdiction over non-Illinois Plaintiffs' claims, *e.g.*, FAC ¶ 11(c), (k), is thus directly contrary to *Bristol-Myers*. Allegations that Bayer or Conceptus "specifically targeted Chicago, Illinois as . . . part of a broader marketing plan to increase sales and revenue," FAC ¶ 11(k), cannot provide specific jurisdiction over the non-Illinois Plaintiffs' claims, because these

Plaintiffs do not allege that they viewed Essure advertising in Illinois. *See Jordan*, 2017 WL 3006993, at *4. Indeed, such allegations could be used to argue specific jurisdiction exists in any state where Bayer or Conceptus marketed Essure—as plaintiffs' counsel is in fact arguing in other states. *Cf.* Resp't App. at A8 ¶ 10(i), *State of Missouri ex rel. Bayer Corp. v. Moriarty*, No. SC96189 (Mo. filed Oct. 4, 2017) (RJN Ex. U) ("The Defendants specifically targeted St. Louis, Missouri, as . . . part of a broader marketing plan to increase sales and revenue.").

The same conclusion applies to Plaintiffs' allegations regarding "Key Opinion Leaders" who allegedly "promote[d] Essure" in Illinois—none of the non-Illinois plaintiffs alleges that she (or her physician) viewed or relied upon statements made by a "Key Opinion Leader" located in Illinois. *See* FAC ¶ 11(l); *cf* RJN Ex. U, at A8–9 ¶ 10(j) (making identical allegations about Key Opinion Leaders in Missouri). And finally, allegations concerning a physician training and accreditation program in Illinois are plainly inadequate to confer personal jurisdiction over the non-Illinois Plaintiffs' individual claims, since there is no allegation that the non-Illinois Plaintiffs' own physicians participated in that program—much less that non-Illinois Plaintiffs' alleged injuries were connected to that program.

The First Amended Complaint thus does not provide the court with specific jurisdiction over the claims of non-Illinois Plaintiffs, because the new allegations provide no "connection between the forum and the specific claims at issue," *Bristol-Myers*, 137 S. Ct. at 1781, and specific jurisdiction over the claims of the non-Illinois plaintiffs therefore does not exist.

B. The Alleged Clinical Trial Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs' allegations regarding Conceptus's clinical trial activities in Illinois are also inadequate as a matter of law. In particular, Plaintiffs cite clinical studies which allegedly involved Illinois patients and doctors (as well as patients and doctors from many other States)

and were part of the process that led to FDA approval, which in turn led to the approved labeling and marketing campaigns for Essure. *See, e.g.*, FAC ¶ 11(e) (acknowledging that the clinical trials involved Illinois only "in part"). But Plaintiffs do not allege that they participated in an Illinois clinical study or that they reviewed and relied on an Illinois clinical study in deciding to use Essure. Their attenuated argument based on clinical trials fails for multiple reasons.

First, to the extent Plaintiffs are arguing that specific jurisdiction exists because clinical trials wrongfully led to Essure's approval, such assertions are both inconsistent with the other allegations in their Complaint and obviously deficient. *See id.* ¶ 11(b), (f), (h) (alleging clinical studies that were conducted, in part, in Illinois led to Essure's approval and "formed the basis" of its FDA-approved labeling); *cf* RJN Ex. U, at A5, A7 ¶ 10(b), (g) (making identical allegations about clinical trial activity in Missouri); Plaintiffs' Notice of Supplemental Authority (ECF No. 65), *Vigil v. Bayer Corp*., No. 1:16-CV-848 (D.N.M. July 12, 2017) (RJN Ex. V) (making identical allegations about clinical trial activity in New Mexico). The Complaint does not allege that the product was wrongfully approved, much less that it was wrongfully approved due to clinical trial misconduct occurring in Illinois.

Moreover, any such theory clearly would be preempted by federal law: FDA approved Essure, it has never withdrawn that approval, and it has never found that the clinical trials were in any way flawed. *See* 21 U.S.C. § 360k; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). To the contrary, FDA has specifically *rejected* allegations that there was any misconduct in the clinical trials, RJN Ex. N, at 8 (Re-Evaluation of Case Reports Summary and Key Findings (Feb. 29, 2016)) (concluding that there was no "evidence of systematic or intentional modification of study subject responses in an effort to falsify (provide a more favorable device profile) the data relied upon by FDA to make the original PMA approval

decision in 2002."). The Plaintiffs' allegations are an effort to second-guess FDA's decision that the clinical trials demonstrated the safety and efficacy of the device and supported its approval, and thus would plainly be preempted. The clinical trials are not and cannot be relevant to the plaintiffs' claims, and they therefore cannot provide a basis for personal jurisdiction.[2]

In addition, *Bristol-Myers* forecloses Plaintiffs' theory that clinical trial activity in Illinois gives rise to personal jurisdiction in all Essure cases even when the Plaintiffs' claims have no connection to Illinois. The U.S. Supreme Court repeatedly emphasized that "[w]hat is needed . . . is a connection between the forum *and the specific claims at issue*." *Bristol-Myers*, 137 S. Ct. at 1781 (emphasis added). Plaintiffs do not come close to establishing such a connection here. Clinical studies in Illinois involve an Illinois physician providing Essure to an Illinois patient; they no more demonstrate that the Court has personal jurisdiction over the claims of non-Illinois plaintiffs against Bayer than does any other Illinois physician's provision of Essure to an Illinois patient. Instead, each non-Illinois plaintiff must show a specific connection between *her claim* and Bayer's activities in Illinois. But here, the non-Illinois plaintiffs do not allege that any non-Illinois Plaintiffs participated in these trials, or that anything that occurred in

[2] In their opposition to Bayer's motion to dismiss the original complaint (at 7), Plaintiffs relied on *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 61 N.E.3d 1026 (Ill. App. Ct. 2016). But in *M.M.*, which predates *Bristol-Myers*, the connection between clinical trial activities in the forum state and the plaintiffs' claims was much closer. The plaintiffs were minors and their mothers who alleged that the mothers' ingestion of a prescription drug caused birth defects. *See M.M.*, 61 N.E.3d at 1029. Plaintiffs sought to establish personal jurisdiction in Illinois based on allegations that GSK concealed data on fetal abnormalities *of clinical trial participants*, and thereafter failed to warn that the drug was unsafe for pregnant women. *See id.* at 1032. Here, none of Plaintiffs' claims arise from alleged acts or omissions in clinical trials in Illinois. Moreover, the express preemption provision governing medical device cases was not at issue in *M.M.*, which involved drugs, and thus the plaintiffs could and did raise claims challenging the FDA-approved labeling. To the extent *M.M.* suggested that personal jurisdiction would exist whenever clinical trials for a product are held in a state, even when these factors are absent, it is no longer good law after *Bristol-Myers* and should not be followed.

the Illinois clinical trials gave rise to their claims. Rather, their theory appears to be simply that specific jurisdiction exists because the product could not have been approved without clinical trials, and the clinical trials "in part" occurred in Illinois and numerous other states. Under this theory, any plaintiff could sue a medical device manufacturer in nearly any state in the country, because clinical trials require many participants and are typically very widespread geographically.

To hold that the clinical trial activities that occurred in Illinois provide personal jurisdiction over the claims of all Plaintiffs involving the Essure device—even if the plaintiffs did not participate in clinical trials in Illinois and their claims do not concern the clinical trials in Illinois—would eviscerate *Bristol-Myers's* ruling that each plaintiff must "identify[] an[] adequate link between the State" and her own specific claims. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, Essure plaintiffs in other jurisdictions—including plaintiffs in other states represented by the same plaintiffs' counsel—are likewise arguing that clinical trial activities conducted in *those* states provide specific jurisdiction for identical Essure claims brought by all non-resident plaintiffs in those forums. *See* RJN Ex. U, at A5–8 (concerning clinical trials in Missouri); *see* also RJN Ex. V ("[O]ne of the two post-approval studies mandated by the FDA was performed in part in New Mexico," and "[h]ad the post-approval study performed in New Mexico been adequate and follow-up been competently performed, the true safety profile of Essure would have been made known to Plaintiffs . . . years earlier").

This attempt to create an end-run around the Supreme Court's decision should be rejected. As in *Bristol-Myers*, Plaintiffs' reasoning "resembles a loose and spurious form of general jurisdiction," 137 S. Ct. at 1781, that is entirety inconsistent with the Due Process Clause. *See also, e.g.*, *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL

4224037, at *4 (S.D. Ill. Sept. 22, 2017) (holding that there was no personal jurisdiction based on allegations that defendant "purposefully targeted Illinois as the location for multiple clinical trials which formed the foundation for defendants' Xarelto Food and Drug Administration application," because the "non-Illinois plaintiffs do not claim injuries from ingesting Xarelto in Illinois, and all conduct giving rise to non-Illinois plaintiffs' claims occurred in other states"); *Bandy v. Janssen Research & Dev., LLC*, No. 17-cv-00753, 2017 WL 4224035, at *4-6 (S.D. Ill. Sept. 22, 2017) (same). The Court therefore should dismiss the claims of the 73 non-Illinois Plaintiffs for lack of personal jurisdiction.

II. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED UNDER THE DOCTRINE OF *FORUM NON CONVENIENS*.

Alternatively, this Court should dismiss the non-Illinois Plaintiffs' claims under the *forum non conveniens* doctrine. *See* Supreme Court Rule 187. *Forum non conveniens* applies where (1) there is an alternative forum where "all parties are amenable to process" and "the parties will not be deprived of all remedies or treated unfairly," and (2) public and private interest factors favor dismissal. *In re Bridgestone/Firestone, Inc.*, 420 F.3d 702, 704 (7th Cir. 2005); *accord Fennell v. Ill. Cent. RR.*, 987 N.E.2d 355, 359-60 (Ill. 2012); *Vinson v. Allstate*, 579 N.E.2d 857, 859 (Ill. 1991). The private interest factors include ease of access to and cost of obtaining witnesses, as well as other practical problems. *See id.* The public interest factors include avoiding court congestion, the interest in having localized controversies decided locally, the interest in having trial in a forum that is at home with the applicable law, the interest in avoiding conflict of laws questions, and the unfairness of burdening Illinois citizens with jury duty to decide claims unrelated to Illinois. *See Fennell*, 987 N.E.2d at 360.

All of these factors are met here. Adequate alternative fora indisputably exist in the non-Illinois Plaintiffs' home states, key evidence and witnesses (including Plaintiffs' doctors) will be

more easily accessible there, and there is no reason to burden this Court or Illinois juries with the claims of 73 non-Illinois Plaintiffs regarding events that took place entirely outside of Illinois and regarding which there will be substantial conflicts of law issues. *See Fennell*, 987 N.E.2d at 361-66 (holding that circuit court abused its discretion in denying *forum non conveniens* motion where "plaintiff [did] not reside in Illinois and the action did not arise [t]here" and "Illinois' only connection with th[e] lawsuit [was] the offices of the parties' counsel," "documents in the possession of defendants' counsel," and an expert witness); *Vinson*, 579 N.E.2d at 859 (holding that circuit court abused discretion where plaintiff was an out-of-state resident at the time of the incident and filing of suit, the incident took place out-of-state, and most witnesses lived out of state); *Kamel v. Hill-Rom Co.*, 108 F.3d 799, 802-05 (7th Cir. 1997) (affirming dismissal under *forum non conveniens* where adequate alternative forum exists, and where private and public interests favor dismissal); *see also McIver v. Am. Med. Sys. Inc.*, No. 5-17-0011, 2017 WL 6327143, at *7-8 (Ill. App. Ct. Dec. 8, 2017) (noting a public "interest in having local controversies decided locally" and holding the district court abused its discretion by not granting *forum non conveniens* motion where "nearly all of the … witnesses" resided in other states and trial would "impos[e] jury duty upon residents of a county with no connection to the litigation").

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW.

As other courts have held in dismissing similar complaints against Essure, federal law preempts claims like Plaintiffs' here, and they should be dismissed with prejudice pursuant to 735 Ill. Comp. Stat. § 5/2-619(a)(9). *See Norman*, 2016 WL 4007547; *De La Paz*, 159 F. Supp. 3d at 1100; *see also Richardson*, 2016 WL 4546369, at *9 (dismissing nine out of ten claims); *McLaughlin*, 2016 WL 1161578, at *25-26 (dismissing ten of 12 claims); *see also supra* pages 2-3 (collecting additional cases). Federal law expressly preempts any state tort claim against medical device manufacturers that would impose safety or effectiveness requirements on a Class

III medical device "different from, or in addition to, any requirement" imposed by FDA. 21 U.S.C. § 360k(a)(1); *Riegel*, 552 U.S. at 321; *Norman*, 2016 WL 4007547, at *2; *De La Paz*, 159 F. Supp. 3d at 1091; *see also Herron v. Smith & Nephew, Inc.*, 7 F. Supp. 3d 1043, 1048 (E.D. Cal. 2014). Claims against Essure are expressly preempted unless Plaintiffs adequately allege (and ultimately prove) a violation of FDA "requirements related to" their devices as well as "a causal nexus between the[ir] alleged injur[ies] and the violation" of federal requirements. *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013); *see also Medali*, No. RG15771555, at 2 (RJN Ex. A); *Noris*, No. BC589882, Tr. at 25:20-25 (RJN Ex. B).

In addition, because FDA has extensive and exclusive authority to enforce its own requirements, federal law impliedly preempts claims based solely on the violation of FDA requirements. *Buckman*, 531 U.S. at 349 n.4; *see* 21 U.S.C. § 337(a) (all actions to enforce the FDCA "shall be by and in the name of the United States"). Plaintiffs cannot second-guess FDA or its decision on how to enforce those requirements. *Riegel*, 552 U.S. at 343; *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014) (explaining that a "claim may be impliedly preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist") (emphasis and internal quotation omitted).

Thus, to survive preemption, state-law claims against Bayer concerning Essure must fit within a "narrow gap": "The 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 (such a claim would be impliedly preempted under *Buckman*)." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010)). To fit within this

narrow gap, each Plaintiff must plead and prove (1) that Bayer violated some federal requirement; (2) that this federal violation also ran afoul of an independent and "parallel" state law requirement; and (3) that the federal violation actually caused her individual injuries. *Id*; *see also Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009) ("to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury"); *Norman*, 2016 WL 4007547, at *2.

Plaintiffs' claims do not fall within this "narrow gap" and are therefore preempted. They raise four meritless theories of liability: (1) their Essure devices were defectively manufactured; (2) Bayer negligently trained physicians in the Essure procedure; (3) Bayer made misrepresentations concerning Essure; and (4) Bayer inadequately warned of the risks of Essure. All of them are preempted.[3]

A. Plaintiffs' Manufacturing Defect Claims Are Preempted.

Plaintiffs bring manufacturing defect claims under negligence and strict liability theories (Counts I and II). *See, e.g.*, FAC ¶¶ 359, 377. As numerous courts have held, federal law preempts these claims because Plaintiffs fail to allege facts plausibly showing that a deviation from Essure's FDA-approved manufacturing process resulted in a defect in their devices that caused their individual alleged injuries. *See, e.g.*, *Burrell*, 2017 WL 1955333, at *6; *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *3; *Richardson*, 2016 4546369, at *5; *McLaughlin II*, 2017 WL 697047, at *18.

[3] To the extent Plaintiffs raise a design-defect claim, *see* FAC ¶¶ 379, 411, it is preempted as well. FDA specifically approved the design of Essure and found it safe and effective, *see* pp. 6–7, *supra*; thus, a design-defect claim "cannot survive preemption, inasmuch as [plaintiff] cannot allege that Bayer departed from" the FDA-approved design. *De La Paz*, 152 F. Supp. 3d at 1095.

As an initial matter, Plaintiffs' manufacturing claims are expressly preempted because they are not based on a failure to follow a "specific federal requirement in the PMA approval." *In re Medtronic*, 623 F.3d at 1206; *Norman*, 2016 WL 4007547, at *3. "In order to avoid preemption on a manufacturing defect claim, [a] plaintiff must allege that her device was not manufactured in conformance with the specification approved by the FDA." *Norman*, 2016 WL 4007457, at *3. Every manufacturing "requirement" Plaintiffs identify is actually a generally applicable FDA Current Good Manufacturing Practice ("CGMP"). *See, e.g.*, FAC ¶¶ 356, 358(h), 359, 362. As the Eighth Circuit explained in *In re Medtronic*, CGMP requirements are merely an "umbrella quality system," that do not create "specific federal requirement[s] in the PMA approval"—and thus "do not save . . . claims from preemption." *In re Medtronic*, 623 F.3d at 1206; *see also Olmstead*, 2017 WL 3498696, at *4 ("[A]llowing a suit to continue on the basis of the CGMPs would necessarily impose 'standards that are 'different from, or in addition to' those imposed by the MDA—precisely the result that the MDA preemption provision seeks to prevent.'"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (CGMPs are too "intentionally vague and open-ended" to save claims from preemption); *Horowitz*, 613 F. Supp. 2d at 284 (CGMPs are "too generic" to save claims from preemption).

In addition, as other courts have held in dismissing Essure claims based on similar allegations, the claims also are preempted and inadequately pled because Plaintiffs fail to allege facts plausibly showing that any deviation from FDA requirements "resulted in a manufacturing defect that caused [their] injuries." *De La Paz*, 159 F. Supp. 3d at 1094. In order to avoid preemption on a manufacturing defect claim, "[a] plaintiff must allege that her device was not manufactured in conformance with the specification approved by the FDA," *Norman*, 2016 WL 4007547, at *3, and that such deviation "resulted in a manufacturing defect that *caused her*

injuries," *De La Paz*, 159 F. Supp. 3d at 1094 (emphasis added). Plaintiffs' conclusory allegation that Bayer (or its predecessor) manufactured Essure at an unlicensed facility, used non-conforming material in the manufacturing of Essure, and failed to adequately document its use, FAC ¶ 358, offer:

- "no description of the 'non-conforming material' used in manufacturing the device, or how the use of that material caused a defect in the product itself," *De La Paz*, 159 F. Supp. 3d at 1095,
- no "explanation of the function of 'pre-sterile and post-sterile cages' in the manufacturing process," *id.*,
- no "explanation for how Bayer's alleged operation without a license led to any manufacturing defect," *id.*,
- no "plausible reason to think that [their] device[s] came from [a] non-conforming batch, or that [they] suffered from any other manufacturing defect," *Norman*, 2016 WL 4007457, at *3,
- no "facts that would make it plausible that the complications [they] suffered . . . were due to any defect in the device," *id.*

Accordingly, as in *Burrell*, *Norman*, and *De La Paz*, Plaintiffs' claims fail. As those courts explained, Plaintiffs "cannot state a claim based *solely*" on an alleged failure to follow various manufacturing regulations, "since any such claim would 'exist solely by virtue of the [MDA],'" and is therefore impliedly preempted under *Buckman*. *De La Paz*, 159 F. Supp. 3d at 1094-95 (quoting *Buckman*, 531 U.S. at 353) (emphasis added).

B. Plaintiffs' Negligent Training Claim Is Preempted.

In Count I, Plaintiffs also claim that Bayer was negligent because it "fail[ed] to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device." FAC ¶ 356(f). FDA specifically approved Essure requirements for physician training. When FDA specifies training requirements for Class III medical devices, the training

requirements must appear in the FDA-approved labeling. 21 U.S.C. § 360j(e). Essure's labeling provides that:

> Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions tor Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

RJN Ex. L, at 1 (2013 IFU).

Here, Plaintiff's negligent training claim alleges state-law duties that are wholly absent from these FDA training requirements. FDA did not place a duty on Bayer to monitor and supervise implanting physicians. *See Glennen v. Allergan, Inc.*, 247 Cal. App. 4th 1, 14 (2016) ("[T]he specific procedures used in the practice of medicine by a professional are not part of the manufacturer regulation process . . . . The PMA process does not obligate . . . manufacturers to follow their products into the surgery room."). Nor was Bayer required to train and certify physicians on the use of hysteroscopic equipment; the FDA-approved labeling makes clear that the onus was on the *physician* to acquire those skills prior to beginning Bayer's Essure training. *See* RJN Ex. L, at 1 (2013 IFU) (Essure should be "used only by physicians who are knowledgeable hysteroscopists"). As the *McLaughlin* court held, "training in the basics of hysteroscopy" is simply not "part of the FDA-mandated training" for Essure. 172 F. Supp. 3d at 817 n.9. Because the FDA-approved training requirements do not include Bayer training in hysteroscopy, the claim seeks to impose a state requirement, which is in addition to FDA's own safety requirements and, therefore is expressly preempted. *Norman*, 2016 WL 4007547, at *5; *De La Paz*, 159 F. Supp. 3d at 1096.

The negligent training claim is also preempted because Plaintiffs fail to "allege . . . any facts that give rise to a recognizable theory as to how any departure from the training guidelines may have caused [Plaintiff's injuries]." *McLaughlin I*, 172 F. Supp. 3d at 817; *see also De La*

Paz, 159 F. Supp. 3d at 1096 (dismissing negligent-training claim); *Frere v. Medtronic, Inc.*, No. EDCV 15-02338-BRO, 2016 WL 1533524, at *10 (C.D. Cal. Apr. 6, 2016) (dismissing similar claim for failure to "allege any facts" showing a "causal connection between the potential deviations and her injuries"). Indeed, Plaintiffs allege *no* facts regarding how their respective doctors were trained, how that training violated FDA requirements, or how the vague and overbroad alleged inadequacies in the training caused Plaintiffs' respective injuries. *See* FAC ¶¶ 205, 208(a)-(d), 356(f).

This Court should dismiss the Plaintiffs' training claim for these reasons. Indeed, numerous courts have done the same with respect to highly similar claims against Essure. *See De La Paz*, 159 F. Supp. 3d at 1096 (dismissing claim because "De La Paz has not alleged that Bayer ever deviated from the approved training as to Essure"); *McLaughlin*, 2016 WL 1161578, at *7; *Noris*, Apr. 26, 2016 Hr'g Tr. at 25:16-17 ("[T]raining is out. I will sustain [Bayer's motion to dismiss] the training without leave [to amend].") (RJN Ex. B); *Norman*, 2016 WL 4007547, at *5 (dismissing claim for negligent training because "Plaintiff fails to allege any facts that could plausibly suggest that her injuries were the result of the alleged negligent training").

C. Plaintiffs' Misrepresentation and Warranty Claims Are Preempted.

Plaintiffs assert claims for negligent misrepresentation, breach of express warranty, and fraudulent misrepresentation (Counts I, III, V) based on allegations that Bayer "disseminated false information" and "[e]ngaged in [f]alse and [m]isleading [s]ales and [m]arketing [t]actics." FAC ¶ 337; *see also id.* ¶¶ 193-218, 338-48, 397-405, 422-28. These claims are preempted, because the alleged misrepresentations track FDA-approved language in the Essure labeling, *see, e.g.*, *Burrell*, 2017 WL 1955333, at *7-8; *De La Paz*, 159 F. Supp. 3d at 1097-99; *Norman*, 2016 WL 4007547, at *3-6; *Williams*, Ex. C, at 8-11:

Alleged Misrepresentation by Bayer	Labeling Statement Approved by the FDA
• Essure was the "[o]nly FDA approved female sterilization procedure to have **zero pregnancies** in the **clinical trials**." FAC ¶ 203(a).	• "In the Essure **clinical studies**, **zero (0) pregnancies** were reported in women who had the Essure inserts for up to 5 years." *See* 2015 PIB at 12 (RJN, Ex. O); 2012 PIB at 12 (RJN, Ex. P) (similar); 2008 IFU at 3 (RJN Ex. Q) (similar).
• Essure is **"[s]urgery-free."** FAC ¶ 203(b). • "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures." FAC ¶ 203(f).	• Essure is "**Non-Surgical**." *See* 2015 PIB at 5 (RJN, Ex. O); 2012 PIB at 5 (RJN, Ex. P). • The "benefits of Essure" include that it is that "No General Anesthesia [is] Required" and that "most women return to normal activity within one to two days." *See* 2015 PIB at 5 (RJN, Ex. O).
• Essure is "**[w]orry free**." FAC ¶ 203(c). • Essure is a "**simple** procedure **performed in your doctor's office" that takes less than 10 minutes.**" FAC ¶ 203(c). • "[C]orrect placement … is performed easily because of the design of the microinsert." FAC ¶ 203(h).	• "Essure may be right for you if . . . You would like to **stop worrying** about getting pregnant" and "prefer a method or procedure that . . . [i]s **simple** and **does not take a lot of time**." 2012 PIB at 4 (RJN, Ex. P); 2015 PIB at 4 (RJN, Ex. O). • "[T]he Essure procedure is usually **performed in your doctor's office**." *See* 2012 PIB at 6 (RJN, Ex. P); *see also* RJN Ex. 2008 PIB at 6 (RJN, Ex. R) (similar). • "The entire process usually takes **less than ten minutes**." *See* 2012 PIB at 9 (RJN, Ex. P).
• "Essure inserts stay secure, forming a long **protective barrier** against pregnancy. They also remain visible outside your tubes, so your doctor can **confirm** that they're properly in place." FAC ¶ 203(d).	• "[Y]our body will form tissue around the Essure inserts. This will develop a **natural barrier** within the fallopian tubes." 2012 PIB at 6 (RJN, Ex. P); *see also* 2008 PIB at 4 (RJN, Ex. R) (similar). • During "Essure Micro-Insert Placement Procedure," "[e]xpanded outer coils of the Essure micro-insert trailing into the uterus indicates **ideal placement**." *See* 2011 IFU at 5 (RJN, Ex. S); 2013 IFU at 8 (RJN, Ex. L) (similar). • "Th[e] **viewable portion** of the micro-insert serves to **verify placement** . . . ." *See* 2008 PIB at 10 (RJN, Ex. R).
• "Essure inserts are made from the same trusted, silicone free material used in **heart stents**." FAC ¶ 203(e).	• "These same materials have been **used for many years** in **cardiac stents** and other medical devices placed in other parts of the

	body." *See* 2012 PIB at 11 (RJN, Ex. P); 2015 PIB at 11 (RJN, Ex. O); 2008 PIB at 4 (RJN, Ex. R) (similar).
• "Essure is the **most effective** birth control available." FAC ¶ 203(g).	• "The Essure procedure is **99.83% effective** based on five-year clinical study data." 2012 PIB at 5 (RJN, Ex. P). • Comparing Essure with both tubal ligation and vasectomy procedures, and **reporting a rate of failure for each that is higher than that of Essure**. 2012 PIB at 15-16 (RJN, Ex. P); *see also* 2008 IFU at 3 (RJN, Ex. Q) (same); 2013 IFU at 5-6 (RJN, Ex. L); 2015 PIB at 15-19 (RJN, Ex. O).
• "[T]he PET fibers are what caus[es] the tissue growth." FAC ¶ 203(i).	• "PET fiber causes tissue in-growth into and around the insert, facilitating insert retention." *See* 2013 IFU at 2 (RJN, Ex. L).

Because these purported "misrepresentations" and "warranties" track FDA-approved statements, Plaintiffs' claims for negligent and fraudulent misrepresentation and for breach of express warranty are expressly preempted.[4] *See* 21 U.S.C. § 360k(a); *see also Williams*, Ex. C, at 8-11 (affirming dismissal of misrepresentation claims based on statements "functionally equivalent to those in the Essure labeling," because prevailing on such claims "would require a finding contrary to that reached by the FDA"); *Norman*, 2016 WL 4007547, at *5-6 (dismissing as preempted Essure plaintiff's claims for breach of warranty and negligent misrepresentation because claims were "so similar to the approved language as to be substantively the same"); *De La Paz*, 159 F. Supp. 3d at 1098 (dismissing as preempted Essure plaintiff's claims for "negligent

[4] Plaintiffs' negligent misrepresentation claim is also inadequately pled. Under Illinois law, negligent misrepresentation requires proof of, among other elements, "a false statement of a material fact" and "action by the other party in reliance on the truth of the statement." *Capiccioni v. Brennan Naperville, Inc.*, 791 N.E.2d 553, 562 (Ill. App. Ct. 2003). Here, Plaintiffs plead *no* plaintiff-specific facts regarding which statements the Plaintiffs reviewed, when they reviewed the statements, and how each of them relied upon the statements. *See* FAC ¶¶ 193-218. The misrepresentation claim should be dismissed for this additional reason. *Norman*, 2016 WL 4007547, at *6 (dismissing a similar claim because plaintiff did "not allege that she read or saw any of the[] statements").

misrepresentation" concerning Essure because "the statements conformed to statements approved by the FDA"); *Burrell*, 2017 WL 1955333, at *8 (dismissing misrepresentation claims based on statements "indistinguishable from FDA-approved labeling statements"); *Richardson*, 2016 WL 4546369, at *9 (holding similar).

Plaintiffs' claims based on such statements are preempted because their success depends on "second-guess[ing] the FDA's judgment, a result that the express preemption provision of the MDA prevents." *Williams*, Ex. C, at 11. Claims that target "marketing that complied with the FDA-approved requirements" must be dismissed, "because success on [such a] claim[] requires a showing that the FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006).

D. Plaintiffs' Failure To Warn Claims Are Preempted.

Plaintiffs base their failure to warn claims on two theories. Like the plaintiffs in *In re Medtronic*, Plaintiffs here "d[o] not allege that [Bayer] modified or failed to include FDA-approved warnings." 623 F.3d at 1205. Instead, they (1) challenge the FDA-approved labeling as false, misleading, and inadequate, and (2) allege that Bayer failed to report adverse events and other information to FDA. Neither type of claim falls within the "gap" between express and implied preemption.

First, Plaintiffs allege that Essure's labeling failed to adequately warn consumers and the medical community of its risks. *See* FAC ¶¶ 135-36, 142, 322-25, 369-72, 421-24, 429-30. Plaintiffs, however, do not allege that the warnings Bayer provided in any way deviated from the FDA-approved language. Courts have routinely held that state-law claims that would require additional warnings or information beyond what FDA required are "precisely the type[s] of state requirements that [are] 'different from or in addition to' the federal requirement[s] and therefore

are preempted." *In re Medtronic*, 623 F.3d at 1205; *Gomez*, 442 F.3d at 929; *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993) (claims challenging the adequacy of "FDA-regulated packaging and labeling" were preempted); *Caplinger*, 784 F.3d at 1345; *Perez*, 711 F.3d at 1118; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011). For this reason, highly similar claims concerning Essure have been consistently dismissed as preempted. *See Norman*, 2016 WL 4007547, at *3.

Plaintiffs allege that Bayer could have unilaterally provided additional warnings, *see, e.g.*, FAC ¶ 135, but these allegations do not save their claims. "Because § 814.39 *permits*, but does not *require*, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation" and is expressly preempted. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489-90 (7th Cir. 2005) (emphasis added); 21 C.F.R. § 814.39(d); *see also In re Medtronic*, 623 F.3d at 1205.

Second, Plaintiffs allege that Bayer failed to report adverse events in a timely and adequate manner to FDA. *See, e.g.*, FAC ¶¶ 324-32, 369, 421. Plaintiffs claim that had Bayer "timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physician, of those adverse events," and that "if Plaintiffs and Plaintiffs' physicians had been adequately warned of these serious and adverse events, they would not have agreed to or used the Essure implant." *Id.* ¶¶ 329, 333.

Burrell, *Norman*, and *De La Paz* dismissed this claim as well. *See Norman*, 2016 WL 4007547; *De La Paz*, 159 F. Supp. 3d 1085; *Burrell*, 2017 WL 1955333, at *5. The claim is impliedly preempted under *Buckman*, because it is "simply an attempt by [a] private part[y] to enforce the MDA." *In re Medtronic*, 623 F.3d at 1205; *see also Norman*, 2016 WL 4007547, at *3-4. In *Buckman*, the Supreme Court made clear that "it is the Federal Government rather than

private litigants who are authorized to file suit for noncompliance" with FDA reporting requirements. 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337). Because Plaintiffs' state law action for such noncompliance would "inevitably conflict with the FDA's responsibility to police fraud consistently," it is impliedly preempted by federal law. *Id.* at 350. Plaintiffs cast their claim as one of Illinois common law, but "a common law claim"—to the extent it exists under state law—"may be *impliedly* preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014) (internal quotes omitted).[5]

This claim also fails because Plaintiffs do not allege a plausible causal nexus between Bayer's supposed failure to report adverse events and their injuries. According to Plaintiffs' allegations, FDA is now in possession of all of the supposedly withheld information. FAC ¶¶ 150-51 (alleging that FDA analyzed various complaints in connection with its 2011 inspection); *id.* ¶¶ 161-62 (alleging that FDA analyzed various complaints in connection with

[5] In *Stengel v. Medtronic Inc.*, the Ninth Circuit held a failure-to-warn claim was not preempted where the plaintiff alleged a failure to provide information to FDA because "Arizona law contemplates a warning to a third party such as the FDA." 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *see also Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (same, "[a]ssuming that a failure to warn [the FDA] claim may be pursued under Mississippi law"). *Stengel* is inapposite because there, unlike in this case, "given the nature of the warning and the relationship of the third party, there [was a] reasonable assurance that the information w[ould] reach" plaintiff's physician and affect his treatment decision had it been disclosed. 704 F.3d at 1233. Here, by contrast, FDA's recent Guidance confirms that the allegedly new information would not have made a difference. *See* FDA Guidance (RJN, Ex. T); *see also* pp. 29–30, *infra*. Moreover, because *Stengel* runs counter to the Supreme Court's holding in *Buckman*, it is wrongly decided, and this court should follow the persuasive decision of the Eighth Circuit, *In re Medtronic*, 623 F.3d at 1205-06. Nor is there an equivalent cause of action for failure to warn third parties in this context under Illinois law. *See Norman*, 2016 WL 4007547, at *4 (distinguishing *Stengel* under Connecticut law); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 200-01 (E.D.N.Y. 2015) (same under New York law).

2013 inspection).[6] Despite having reviewed and considered these allegedly withheld reports and additional medical literature, FDA has never withdrawn its approval of Essure. To the contrary, FDA found "no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure," FDA Activities (RJN, Ex. M), and reaffirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," FDA News Release (RJN, Ex. F).

As *Norman* held, Plaintiffs' attempt to invoke FDA's recent boxed warning and Patient Decision Checklist only further undermines their claims. 2016 WL 4007547, at *4. After holding a public hearing "concerning the safety and efficacy of [] Essure," during which FDA considered the allegedly withheld complaints, *see* FAC ¶ 217, FDA did not require Bayer to change its disclosures on the percentage of patients who may be injured, the number of adverse events, or the rate of unintended pregnancies. Instead, FDA released a "boxed warning" for all "devices of this type," because the agency believes "that some women are not receiving or understanding information regarding the risks and benefits." FDA Guidance at 5-6 (RJN, Ex. T). As *Norman* held, this "new *type* of warning did not change any of the warnings' substance," 2016 WL 4007547, at *4. Rather, the same information was already in Essure's labeling:

[6] Plaintiffs' repeated attempts to highlight the number of complaints received by Bayer relative to the number of MDRs submitted, *see, e.g.*, FAC ¶ 151, also ignore the fact that there is no obligation blindly to report all "complaints" to the agency. *See* 21 C.F.R. § 820.198(d) (providing additional procedures for "[a]ny complaint that represents an event which must be reported to FDA"). Plaintiffs point to no FDA finding that the complaints on these spreadsheets were adverse events that should have been reported to FDA but were not.

Essure Labeling *RJN, Ex. P (2012 PIB)* *RJN, Ex. S (2011 IFU)*	**Boxed Warning** *RJN, Ex. T (2016 FDA Guidance)*
• "To reduce **the risk of uterine perforation**, the procedure should be terminated if excessive force is required to achieve cervical dilation . . . ." (IFU, 2).	• "Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including **perforation of the uterus and/or fallopian tubes**, identification of **inserts in the abdominal or pelvic cavity**, **persistent pain**, and **suspected allergic or hypersensitivity reactions**. If the device needs to be removed to address such an adverse event, **a surgical procedure will be required**." (Guidance, 9).
• "In rare cases, part of an Essure insert may **puncture the fallopian tube.**" (PIB, 7).	
• "Potential adverse events" include "[p]erforation of **internal bodily structures other than the uterus and fallopian tube**." (IFU, 2).	
• "A very small percentage of women in the Essure procedure clinical trials reported recurrent or **persistent pelvic pain.**" (IFU, 2).	
• "Patients who are allergic to nickel may have an **allergic reaction** to the inserts. **Symptoms** include rash, itching and hives." (PIB, 8).	
• "[I]f device removal is required for any reason, it will likely **require surgery**, including an **abdominal incisions** and general anesthesia, and possible hysterectomy." (IFU, 2).	

Thus, Plaintiffs' conclusory assertion that had Bayer "timely and adequately reported the adverse events to the FDA," it would have resulted in additional warnings to physicians is insufficient to allege causation, and the claim is preempted. FAC ¶ 329. As *Burrell*, *Norman*, and *De La Paz* held, it should be dismissed.

IV. PLAINTIFFS FAIL TO PLAUSIBLY PLEAD A CLAIM FOR RELIEF.

Plaintiffs' complaint also fails for the separate reason that, pursuant to 735 Ill. Comp. Stat. § 5/2-615, it does not state any valid cause of action under Illinois law. First, as described above, Plaintiffs assert a claim based on Bayer's alleged failure to report adverse events to FDA, but no such claim has been recognized under Illinois law. *See* n.4, *supra*. In addition, all of the claims fail to make more than conclusory allegations that Bayer's actions caused Plaintiffs' alleged injuries, a necessary element of each cause of action. Plaintiffs' fraud claims also fail

because they do not allege adequate facts to establish that Bayer made false statements or that Plaintiffs and their physicians relied on them—necessary elements of each claim.

A. Plaintiffs Fail To Plead Causation Adequately.

Under Illinois law, "[i]t is a fundamental principle applicable alike to breaches of contract and to torts, [that] in order to found a right of action there must be a wrongful act done and a loss resulting from that wrongful act; the wrongful act must be the act of the defendant, and the injury suffered by the plaintiff must be the natural and not merely a remote consequence of the defendant's act." *Town of Thornton v. Winterhoff*, 92 N.E.2d 163, 166 (Ill. 1950). "Cause in fact can only be established when there is a reasonable certainty that a defendant's acts caused the injury." *Yager v. Ill. Bell Tel. Co.*, 667 N.E.2d 1088, 1093 (Ill. App. Ct. 1996). Plaintiffs fail to make such a showing for any of their claims, and thus, they should be dismissed.

Plaintiffs do not plead facts connecting any alleged wrongful act by Bayer with their injuries. For most of the claims, they state only that, "[a]s a proximate result" of Bayer's actions, "Plaintiffs suffered and will continue to suffer [injuries]." FAC ¶ 399; *see also id.* ¶¶ 392 (similar), 412 (similar), 424 (similar), 439 (similar). Such "[p]leadings which state mere conclusions and characterize acts rather than set forth facts are insufficient to state a cause of action." *Dangeles v. Muhlenfeld*, 548 N.E.2d 45, 48 (Ill. App. Ct. 1989); *see also City of Chi.*, 821 N.E.2d at 1112-13 (quoting *Knox Coll.*, 430 N.E.2d at 985). The Complaint should be dismissed for this additional reason, as multiple courts have held in other Essure cases. *See, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *6.

B. Plaintiffs Fail To Plead Their Misrepresentation Claims Adequately.

Plaintiffs' fraud claims are deficient because they are not pleaded with sufficient particularly. Plaintiffs allege that Bayer "made affirmative representations to Plaintiffs . . . [that] Essure was safe and effective" and "intentionally, willfully, and maliciously concealed and/or

suppressed" material facts regarding Essure from Plaintiffs and their physician. FAC ¶¶ 429-30. Such claims must satisfy heightened pleading standards, which require that Plaintiffs "allege, with specificity and particularity, facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations and to whom they were made." *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584, 591 (Ill. 1996). Plaintiffs must allege with "sufficient particularity the facts that make the defendant's omission or concealment material." *White v. DaimlerChrysler Corp.*, 856 N.E.2d 542, 550 (Ill. App. Ct. 2006).

As in *McLaughlin I*, the Complaint here "makes no effort to inject[] precision by either pleading the date, place or time of the alleged fraud or by using any alternative means to substantiate the allegations." 172 F. Supp. 3d at 829. The Complaint does not specifically allege who was responsible for the supposedly fraudulent utterances or omissions, or when they were made (or not made), or indicate *when*, *where*, and *how* Plaintiff encountered or relied upon the myriad misstatements or omissions alleged. Bayer is thus without notice of the precise misconduct that is allegedly fraudulent. As *McLaughlin I* recognized, this is precisely the sort of prejudice that heightened pleadings standards are designed to avert. *See id*. Because Plaintiffs have not satisfied this burden, these fraud claims should be dismissed.

Finally, Plaintiffs' complaint includes several requests for punitive damages. *E.g.*, FAC ¶¶ 441–49. Under 735 Ill. Comp. Stat. § 5/2.604.1, "no complaint shall be filed containing a prayer for relief seeking punitive damages." Any of Plaintiffs' claims for punitive damages should therefore be struck.

CONCLUSION

For these reasons, the Court should dismiss the complaint as to the non-Illinois Plaintiffs for lack of personal jurisdiction, 735 Ill. Comp. Stat. § 5/2-301, and the complaint as to all

Plaintiffs as being preempted pursuant to 735 Ill. Comp. Stat. § 5/2-619, and for being insufficient in law pursuant to 735 Ill. Comp. Stat. § 5/2-615.

DATED: December 15, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on 15th day of December, 2017, a true and correct copy of the foregoing was served upon the following by enclosing same in an envelope addressed as below, with proper first class postage fully prepaid, and depositing same in the U. S. Mail at Edwardsville, Illinois, at 5 p.m.:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY, et. al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 16-L-1617
	)	
BAYER, CORP., et al.,	)	
	)	
Defendants.	)	

PLAINTIFFS' RESPONSE IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

Defendants' (collectively "Bayer" or "Defendants") attempt at making this case go away should be rejected for several reasons:

1. Bayer's reliance on *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County* (*BMS*) is misplaced. 137 S. Ct. 1773 (2017). *BMS* does not apply to this case. Bayer tirelessly quotes *BMS* throughout its motion to dismiss, all the while ignoring every fact that makes this case materially distinguishable from *BMS*.

2. Bayer's mischaracterization of Plaintiffs' claims as an effort to second guess the FDA is unavailing. Bayer's recitation of federal preemption law is far too narrow. As **all** of the cases Bayer relied upon—as well as many others—have found, preemption does not afford indiscriminate immunity from liability for violations of state law that parallel federal regulations.

3. Plaintiffs' claims are adequately pled to satisfy the Illinois pleading requirements. Plaintiffs have alleged violations of Illinois law which mirror federal laws and regulations. And Plaintiffs have adequately tied those violations to their injuries.

4. Bayer's improperly seeks this Court's dismissal of the nonresident Plaintiffs based on forum non conveniens because FNC is premised on severance of their claims. Further, it is Bayer's burden to prove FNC is warranted, which it does not come close to doing in the roughly one page it devoted to FNC in its Motion.

As Plaintiffs will demonstrate below, Bayer's Motion to Dismiss should be denied in its entirety.

I. BACKGROUND

A. Essure Medical Device

Essure® is a Class III medical device designed as a form of permanent female birth control through bilateral occlusion of the fallopian tubes. Essure® consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. The micro-inserts contain an inner coil made of stainless steel, polyethelene terephthalate (PET) fibers, and an outer coil made of nickel titanium (Nitinol). Physicians implanting Essure® visualize the procedure through hysteroscopic guidance using equipment supplied by Bayer. The hysteroscopic equipment needed to place Essure® was manufactured by a third party and is not a part of Essure®. The micro-inserts or coils are supposed to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

B. Medical Device Statutory Background

In 1976, Congress enacted the Medical Device Amendment (MDA) to extend the coverage of the Food, Drug & Cosmetic Act (FDCA) to medical devices. The MDA "classifies medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). "Class III devices 'presen[t] a potential unreasonable risk of illness or injury' and therefore incur the FDA's strictest regulation." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)(II)). "Before a new Class

III device [like Essure®] may be introduced to the market, the manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)).

The MDA includes an express preemption clause, 21 U.S.C. § 360k(a). This clause preempts any state-law "requirement" with respect to a particular medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." *Id.*

C. **Essure® PMA**

Premarket Approval (PMA) is the process the FDA uses to evaluate the safety and efficacy of Class III medical devices, such as Essure®. Class III medical devices are "generally the highest risk devices." Class III devices are those that "present a potential, unreasonable risk of illness or injury," among other things. In November 2002, the FDA approved Bayer's PMA application for Essure®.

In order to comply with the Essure® PMA, Bayer was required to comply with a number of post-approval conditions as well:

- Submit post-approval reports including "unpublished reports of data from any clinical investigations or nonclinical laboratory studies . . . and reports in the scientific literature concerning the device."
- Report any adverse reaction not addressed in Essure® labeling; or if the reaction was addressed in the label report, if the reaction was occurring with unexpected severity or frequency.
- Report adverse events under the Medical Device Reporting (MDR) Regulation if Essure® may "have caused or contributed to a death or serious injury; or [h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur"; and

- Include in its Annual Report any failures of the device meeting the specifications outlined in the PMA, which would have been correctable by procedures described in the Essure® labeling.

II. ARGUMENT

A. Illinois Courts Have Personal Jurisdiction Over Bayer

1. Standard for Personal Jurisdiction

When a court considers whether it should exercise personal jurisdiction over a nonresident defendant, it is the plaintiff who bears the initial burden to establish a prima facie case for exercising jurisdiction. *Russell v. SNFA,* 2013 IL 113909, ¶ 28, 987 N.E.2d 778, 784 (Ill. 2013). We resolve any conflicts in the pleadings and affidavits in favor of the plaintiff seeking jurisdiction, "but the defendant may overcome [the] plaintiff's prima facie case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Id.*

Personal jurisdiction analysis begins by looking at "the relationship among the defendant, the forum, and the litigation." *Walden*, 134 S. Ct. at 1121. There are two types of personal jurisdiction, specific and general. *Id*. at n.6. A court has specific jurisdiction over an out-of-state defendant when a suit arises out of or relates to the defendant's contact with the forum. *Id*.

Personal jurisdiction is established by the forum-state's laws and constitutional due process. *See Intercon, Inc. v. Bell Atl. Internet Solutions*, 205 F.3d 1244, 1247 (10th Cir. 2000). Illinois's long-arm statute provides that "a court may exercise jurisdiction in any action arising within or without this State against any person who: [i]s a natural person or corporation doing business within." 735 ILCS 5/2-209(b)(4). Additionally, a catch-all provisions allows the Court to "exercise jurisdiction on any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States." 735 ILCS 5/2-209(c). Because of the catch-all provision, Illinois' long-arm statute is now coextensive with constitutional limitations imposed by the Due Process Clause. *Russell*, 2013 IL 113909, ¶ 28.

2. Bayer's Reliance on *BMS* is Misplaced

Throughout its motion, Bayer touts *BMS* as dispositive of personal jurisdiction here. But *BMS* does not govern this case. To have *Hamby* fall within *BMS*, Bayer must ignore the dispositive differences between the facts of *BMS* and these.

BMS involved in-state and out-of-state plaintiffs who sued in California regarding their use of Plavix. 133 S. Ct. at 1778. The holdings of *BMS* can be summarized as follows:

- "The primary focus of our personal jurisdiction inquiry is the *defendant's* relationship to the forum State." *Id.* at 1779 (citing *Walden v. Fiore*, 134 S. Ct. 1115, 1121–23 (2014)) (emphasis supplied).

- "In order for a state court to exercise specific jurisdiction, 'the *suit*' must 'aris[e] out of or relat[e] to the defendant's contacts with the '*forum*.'" *Id.* at 1780 (quoting *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014)) (alterations in original).

- "[T]here must be 'an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation.'" *Id.* (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011)) (alteration in original).

- "When there is no such connection, specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State." *Id.* at 1781 (citing *Goodyear*, 564 U.S. at 931 n.6).

But the Supreme Court observed that **"BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California."** *Id.* That is not the case with Essure. Bayer tries to stretch the *BMS* opinion too far. Bayer goes to great lengths to try to diminish its Illinois clinical trial activity and development of a nationwide marketing and

accreditation campaign, to convince this Court that those activities are the type that *BMS* found insufficient. As Plaintiffs have alleged in their First Amended Complaint, Bayer conducted clinical trials in Illinois and used Illinois as a testing ground for its nationwide marketing campaign and physician training program. The clinical trials conducted in Illinois directly relate to all Plaintiffs' claims, regardless of state, because without these clinical trials Plaintiffs would never have had Essure implanted. *Id*. At least one court agrees with this approach. In *Cortina v. Bristol-Myers Squibb Co.*, a court analyzed this very issue:

> Lastly, the Court notes that the United States Supreme Court recently held in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, that the fact that a defendant had research and laboratory facilities, sales representatives, and sales and marketing operations in a forum state was insufficient to justify the exercise of specific jurisdiction in the absence of an "adequate link between the State and the nonresidents' claims." —— S.Ct. ——, 2017 WL 2621322, at *8 (2017). The present case is distinguishable from *Bristol-Myers*. . . . In this case, Plaintiff alleges that "nearly every pivotal clinical trial necessary for NDA approval involved studying of the Saxagliptin drugs throughout the State of California," and that "but for the pre-NDA development of the Saxagliptin drugs within the State of California, the drugs would not have been sold and marketed throughout the U.S. nor ingested by Plaintiff." ECF No. 27 at 5. This linkage between Defendants' in-state clinical trial activity and Plaintiff's injury is sufficient to satisfy the Ninth Circuit's "but for" test.

No. 17-CV-00247-JST, 2017 WL 2793808, at *4 (N.D. Cal. June 27, 2017). And, as already discussed, the First District has previously followed similar reasoning. *See M.M. ex rel. Meyers*, 61 N.E.3d at 1041. This case is no different.

Bayer developed Essure using Illinois clinical trials, created a marketing strategy for Essure in Illinois, and worked on the regulatory approval of Essure using Illinois investigators and physicians. The conduct about which Plaintiffs complain occurred through Bayer's contacts with Illinois. For example, Plaintiffs cite a whole host of false and misleading marketing tactics, all of which can be tied to the strategy developed in Illinois. *See* FAC ¶¶ 10, 11, 193–218. Plaintiffs go

on to claim that Bayer's contacts with Illinois were integral to its ability to distribute Essure to all Plaintiffs and Plaintiffs' implanting physicians. *See, e.g.*, *id.* at ¶ 321. But for Bayer's conduct in Illinois, Plaintiffs would not have been harmed.

Furthermore, the patient awareness marketing strategy developed in Illinois is much more than just an Illinois woman or physician seeing a commercial or print ad for Essure. The Essure marketing strategy that was eventually rolled out to the entire country was created from of Bayer's Illinois contacts. In *BMS*, the Court noted that the defendant **did not** "create a marketing strategy for Plavix in California." This is not the case here. **Without Illinois**, Bayer's scheme of fraudulent and misleading marketing, as alleged in Plaintiffs' First Amended Complaint, would not have been possible. This distinction matters jurisdictionally. These activities in Illinois establish specific jurisdiction.

Bayer ignores facts significant to personal jurisdiction:

(1) Bayer chose Illinois to conduct these clinical activities,

(2) it developed a nationwide marketing strategy in Illinois, and

(3) it chose Chicago, Illinois as a test-bed city for its physician marketing and accreditation program.

In short, Bayer chose Illinois for Essure. These jurisdictional contacts are much more far reaching than simply having a patient choose Essure in her doctor's office in Illinois, as Bayer would like this Court to believe. After having chosen Illinois testing and developing a marketing plan, Bayer cannot now contend that Illinois courts do not have jurisdiction over claims related to its conduct there.

3. Court has Specific Jurisdiction

In support of Plaintiffs' prima facie showing of this Court's personal jurisdiction over Defendants, Plaintiffs have attached the Affidavit of Cheryl Blume, PhD as Exhibit A. Dr. Blume

has been repeatedly recognized as an expert on drug and medical device safety and regulatory approval by multiple courts. Dr. Blume's opinions demonstrate that Plaintiffs' claims arose out of, or relate to Defendant's clinical trial, marketing, and physician training activities in Illinois. Specific jurisdiction exists because Plaintiffs' claims arise out of Bayer's conduct in Illinois, and Plaintiffs' claims are related to this conduct. Specific jurisdiction is established by the following facts:

- The Defendants conducted the pivotal clinical trials for Essure in Illinois. FAC at ¶¶ 11, 122; *see also* Aff. of Cheryl Blume, attached as Exhibit A;
- Data from the Illinois trials was included in the Essure PMA material and was directly related to its regulatory approval. FAC at ¶ 11, 125; *see also* Ex. A;
- Bayer contracted with Illinois doctors and facilities to help conduct the clinical trials, even selecting Illinois-based physician, Rafael Valle, to respond directly to specific comments from FDA. FAC at ¶¶ 11, 196; *see also* Ex. A;
- Illinois was a critical test bed for the Defendants marketing and advertising for Essure, and that success of that program was utilized to conduct marketing nationwide. FAC at ¶¶ 10, 11, 197, 204; *see also* Ex. A; and
- Bayer launched its Essure Accreditation Program, a physician training program, in Illinois. FAC at ¶¶ 11, 198, 204; *see also* Ex. A.

4. Bayer's Clinical Trial Activity

Bayer ran its clinical trials relating to Essure in Illinois from at least 2000 to 2002. FAC at ¶¶ 11, 12, 125. And in addition to pre-approval clinical trials, Defendants also conducted one of their post-approval FDA mandated studies—conducted to assess the long-term safety and effectiveness of Essure—in Illinois. FAC at ¶ 11. And ultimately out of those trials came the misinformation

regarding the product's safety and effectiveness described in the Complaint. *Id* at ¶¶ 11, 12. Almost the exact same circumstances were considered in *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, and were found to be sufficient for specific personal jurisdiction as to both resident and non-resident plaintiffs. *See* 2016 IL App (1st) 151909, ¶ 71–72, 61 N.E.3d 1026, 1041 (1st Dist. 2016) *appeal denied sub nom. M.M. v. GlaxoSmithKline LLC*, 65 N.E.3d 842 (Ill. 2016), *and cert. denied*, No. 16-1171, 2017 WL 1153625 (U.S. Oct. 2, 2017) ("[P]laintiffs' injuries allegedly arose from acts of omission during the clinical trials and the resulting inadequate warning labels. . . . Defendant GSK has failed to overcome plaintiffs' *prima facie* showing that their claims arose from or related to defendant GSK's Illinois activities.").[1] In fact, Bayer is conducting **three** Essure clinical trials in Illinois **right now**. FAC at ¶ 11(j).

Further, Bayer complains that exercising jurisdiction based on clinical trial activities would subject it to jurisdiction "in nearly any state in the country." Mot. at 15. However, if the Court were to entertain this contention, it would require a bright-line rule setting out some threshold level of activity that would confer jurisdiction.[2] That is not the law. It does not matter how many clinical trials were conducted in Illinois versus other states,[3] but rather the question turns on the

[1] Bayer tries to distance itself from *Meyers* by claiming that it was pre-*BMS* and therefore any holding regarding clinical trials and personal jurisdiction is "no longer good law" post-*BMS*. Resp. at 11. However, this position is directly contrary to Bayer's position in other cases. Indeed, Bayer just finished arguing that *BMS* did **not** change the law, but rather was based on "settled principles regarding specific jurisdiction." *See State ex rel. Bayer Corp. v. Hon. Joan Moriarty*, No. SC96189, Reply Brief of Relators, at 6. According to this version of Bayer's argument, since *BMS* did not change the law, it is irrelevant that *Meyers* was decided pre-*BMS*.

[2] If the meaningfulness of the activity is not considered, the Court would have to decide what percentage of clinical trial activity was enough for personal jurisdiction. For example, surely one-hundred percent of clinical trial activity in a forum state would give rise to personal jurisdiction; but what about seventy-five percent, or forty-five percent?

[3] Bayer's claim that since Essure plaintiffs in other states are also arguing that Bayer's clinical trials confer specific jurisdiction in those states misses the point. Mot. at 13. Personal jurisdiction turns on whether the trials in those states equate to meaningful contacts in relation to Plaintiffs'

meaningfulness of those contacts. *In re Syngenta Mass Tort Actions*, No. 3:16-CV-00255-DRH, 2017 WL 2117728, at *5 (S.D. Ill. May 15, 2017) ("It did not matter that a small percentage of the clinical trial took place in Illinois, a plaintiff only has to prove a *proper* place for personal jurisdiction. And a proper place for personal jurisdiction is when there is a nexus between a defendant's actions and plaintiff's cause of action that does not disrupt the quid pro quo.") (citing *Meyers*, 61 N.E.3d at 1040).

A California court recently issued a decision which supports Plaintiffs' claims. *DellaCamera v. DePuy Orthopaedics, Inc.*, involved plaintiffs from Connecticut and a defendant based in Indiana. No. CJC-10-004649, at 6 (Cal. Sup. Ct. Nov. 1, 2017) (attached as Exhibit B). The court held that defendant's use of two California surgeons in developing the design of the ASR hip implant was sufficient for personal jurisdiction over nonresident defendants. *Id.* at 5. The court reasoned that "the Nonresident Defendants' decision to consult and/or collaborate with two California residents on the design of the product at issue, even making one of them 'lead surgeon designer' for the product, demonstrates that Plaintiffs' claims 'arise out of' the Nonresident Defendants conduct in California." *Id.* at 6.

The same holds true here. Bayer chose to "consult and/or collaborate with" Illinois physicians to evaluate the safety and effectiveness of Essure in the Pivotal Trial. Moreover, **all** Plaintiffs' claims can be tied to the clinical trial activity in Illinois. Plaintiffs do not need to allege that they were clinical trial participants, or had Essure implanted in Illinois to satisfy their *prima facie* burden on personal jurisdiction, as Bayer would have this Court believe. Plaintiffs have alleged

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causes of action, and "not at all on a percentage-based comparison between how much related conduct occurred outside of Illinois." *Meyers*, 61 N.E.3d at 1041. It very well may be that Bayer is subject to personal jurisdiction in multiple states due to its clinical trial activity, if Bayer's contacts with those states are meaningful.

that Bayer negligently conducted clinical trials (FAC ¶ 9), falsified records of clinical trial participants (FAC ¶ 128), misrepresented the number of pregnancies in the clinical trials (FAC ¶ 203), and but for Bayer's actions in its Illinois clinical trial, Plaintiffs never would have had Essure implanted. FAC ¶ 12. These contacts are enough to meet Plaintiffs' burden regarding personal jurisdiction.

5. Bayer's Marketing and Accreditation Activities

Even though its clinical trial activity is enough to bestow personal jurisdiction in Illinois, Bayer also orchestrated a patient awareness marketing campaign and Essure Accreditation Program in Illinois. FAC at ¶¶ 10, 11, 197, 204; *see also* Ex. A. The marketing campaign included radio, print, and direct mail advertisements, scheduled to arrive weekly to the offices of local Chicago physicians. *Id.* In addition, the pilot program for the Essure Accreditation Program—a physician training program—that Conceptus created was carried out in the Chicago area. If the Chicago-area campaign was successful, Conceptus's goal was to roll out additional consumer campaigns in other cities across the U.S. FAC at ¶¶ 11, 198.

Bayer tries to trivialize these programs by suggesting that they do not create personal jurisdiction because the non-Illinois Plaintiffs did not view the materials in Illinois. Mot. at 11–12. But that is not what Plaintiffs allege. In fact, Plaintiffs allege that the success of the patient awareness campaign, forged in Illinois, was the impetus for rolling out the identical campaign across the country, including Plaintiffs' home states. The false and misleading marketing that proved so successful in Illinois was ultimately disseminated nationwide. Without the success of the Illinois patient awareness program, Plaintiffs would not have seen, nor relied upon, the misrepresentations outlined in their First Amended Complaint.

In addition, the FDA *required* Bayer to adhere to training guidelines and requirements. The physician training program Bayer developed to meet this requirement—the Essure Accreditation

Program—was created solely in Illinois. Every single implanting physician was required to undergo training. And Plaintiffs have adequately tied their injuries to this Illinois training program. Plaintiffs specifically pled that Bayer failed to train their implanting physicians, including the failure to ensure their physicians successfully completed five preceptorings, to ensure they understood the Essure training manual, and to ensure they successfully completed simulator training. FAC ¶ 371. Thus, Bayer's inadequate training program, developed exclusively in Illinois, is meaningfully connected to **all** Plaintiffs' claims. Accordingly, these activities in Illinois establish specific jurisdiction.

B. **Plaintiffs' Claims are not Preempted.**

Preemption is not wholesale immunity from liability. It is axiomatic that Congress did not intend to give complete protection from civil liability to medical device manufacturers for violations of federal law that injure patients. As the Supreme Court has repeatedly held, violations of state law claims that parallel federal requirements are not preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). In pleading parallel state law claims, a plaintiff's only burden is to put forth facts that make the claim plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Nevertheless, despite this powerful precedent allowing claims such as Plaintiffs' to proceed, Bayer attempts to persuade this Court that it should enjoy complete insulation from liability. As this Court will see, Bayer's attempt fails.

First, Bayer greatly exaggerates those orders. Bayer Motion at 13. In reality, the orders Bayer relies upon are more favorable to Plaintiffs than they are to Bayer. In fact, the orders cited

did not expressly or impliedly preempt many of the plaintiffs' claims.[4] A close examination of these orders establishes that Plaintiffs' claims are not preempted for several reasons:

- Their claims are due to Bayer's conduct that violated provisions of the Food, Drug, & Cosmetic Act (FDCA), the Medical Device Amendments (MDA), or Essure® Premarket Approval (PMA);
- Their claims are based on parallel state law claims that are not "different from, or in addition to" Essure® federal requirements. *See Riegel*, 552 U.S. at 312; and
- Bayer's conduct in violation of both state and federal law caused their injuries.

Additionally, Bayer also contends that Plaintiffs' claims fail to meet plausibility standards. But as the FAC shows, Plaintiffs have sufficiently alleged that Bayer's conduct was the cause of their injuries. Should the Court find the complaint at all deficient, however, Plaintiffs respectfully ask leave to amend.

1. Anti-Preemption Presumption

There is a "basic presumption against pre-emption." *See Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005). Parties seeking preemption protection must overcome a considerable burden. "The presumption against preemption is heightened 'where federal law is said to bar state action in fields of traditional state regulation.'" *Riegel*, 552 U.S. at 334 (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). "Federal laws containing a preemption clause do not automatically escape the presumption against preemption." *Id.* When a statutory preemption clause is subject to more than one plausible interpretation, courts usually "accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at

[4] Rather than preemption, some of the plaintiffs' claims were dismissed due to perceived deficiency in pleadings. But to the extent that plaintiffs' claims were dismissed, they were almost always allowed leave to amend. Specifically related to *Norman*, the complaint had already been amended a number of times, and therefore the court determined that further amendment would be futile. While Plaintiffs do not agree with this finding, it is inapplicable here as Plaintiffs have only amended their complaint once.

449. This presumption is particularly strong in tort cases like this one because the states have historically enjoyed broad powers to protect the "lives, limbs, health, comfort, and quiet of all persons." *Slaughter House Cases*, 16 Wall 36, 62 (1873).

Accordingly, preemption under the MDA is not unlimited. *Riegel*, 552 U.S. at 330. Rather, state law claims that are not different from or in addition to federal law are not expressly preempted, as such duties "parallel," rather than add to, federal requirements. *Id*. This exception to preemption includes state law claims based on a Class III device's violation of its own premarket approval standards—precisely the case here. *Id.*

2. Overview: Few Preemption Holdings

Bayer maintains that "other courts" have preempted claims like Plaintiffs'. But Bayer exaggerates the reach of preemption. A closer look at the orders Bayer cites establishes that Plaintiffs' claims are ***not*** subject to preemption. For instance, the *McLaughlin* court found:

- Negligent Risk Management: **Not preempted** to the extent Plaintiff seeks to hold Bayer to federal risk management standards; and
- Breach of Express Warranty: **Not preempted** because the claim arose from alleged contracts between the parties; and
- Negligent Misrepresentation: **Not preempted** to the extent that the misrepresentations were inconsistent with FDA materials; and
- Negligent Manufacturing: **Not preempted** to the extent that the manufacturing differed from federal requirements; and
- Negligent Failure to Warn the FDA: **Not preempted** because independent state law exists under Section 388 of the Restatement 2d of Torts.

See generally McLaughlin v. Bayer Corp., 172 F. Supp.3d 804 (E.D. Pa. 2016).[5]

[5] *McLaughlin* held that Pennsylvania did not recognize strict liability claims. *Id.* at 833–34. However, another case out of the Eastern District of Pennsylvania has already disagreed with this

The same pattern holds true for the other orders Bayer relies upon—no court has held blanket preemption applies to claims regarding Essure. *See generally De La Paz*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (claims for negligent training and failure to warn not preempted and leave to amend granted to plead non-preempted claims on express warranty, misrepresentation, and manufacturing defect); *Williams v. Bayer Corp.*, No. 15BA-CV02526 (Mo. Cir. Ct. July 18, 2016) (Bayer RJN, Ex C) (dismissed with no analysis and therefore not helpful to the Court); *Medali v. Bayer HealthCare LLC*, No. RG15771555, slip op. (Cal. Super Ct. Feb. 16, 2016) (Bayer RJN, Ex. A) (denying demurrer on manufacturing defect and failure to warn, granting leave to amend breach of express warranty); *Noris v. Bayer Essure, Inc.*, No. BC589882, Cal. Super. Ct. Apr. 26, 2016) (Bayer RJN, Ex. B) (denying demurrer on manufacturing defect and failure to warn); *Lance v. Bayer Corp.*, RG 16809860 (Cal. Super. Ct. Aug. 2, 2016) (multiple joined cases) (Bayer RJN, Ex. D) (denying preemption demurrer on failure to warn FDA, breach of warranty and misrepresentation; granting leave to amend for manufacturing defect and negligent training); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017) (dismissing the complaint because plaintiff failed to cite parallel state law and based her claims were based *entirely* on federal law).[6]

"The United States Supreme Court has cautioned that in the interest of preventing federal encroachment on the state's authority, a court interpreting a federal statute pertaining to areas traditionally controlled by state law should be reluctant to find preemption." *State ex rel. Proctor*

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holding. *Smith v. Howmedica Osteonic Corp.*, No. 17-1174, 2017 WL 1508992, at *4 (E.D. Pa. Apr. 27, 2017). *Smith* held that the court "predicts that the Pennsylvania Supreme Court would **not** bar strict liability claims." *Id.* at *5 (emphasis supplied).

[6] Bayer also relies upon *Burrell v. Bayer Corp.*, No. 1:17-CV-00031, 2017 WL 1599333 (W.D.N.C. May 10, 2017). However, this case is currently pending on appeal.

v. Messina, 320 S.W.3d 145, 148 (Mo. 2010) (citing *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 667 (1993)). In finding preemption, a court must conclude that it "was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

3. Specific Claims are not Preempted and Are Plausible

Plaintiffs' claims are not preempted. Each claim is all brought under Illinois law, which parallels federal requirements:

Count	Federal Requirement	Illinois Law
Strict Liability	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39(d)	*Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 525, 901 N.E.2d 329, 335 (2008), *opinion modified on denial of reh'g* (Dec. 18, 2008) (strict liability for product defects would further the adoption of strict liability generally).
Negligent Manufacturing	21 C.F.R. § 820.20 *et seq.* Essure® PMA conditions Current Good Manufacturing Practices; 21 U.S.C. § 351(f)	*See Patton v. Country Place Condo. Ass'n*, 4-00-0008, 2000 WL 33728374, at *4 (Ill. App. Ct. 4th Dist. July 7, 2000)
Negligent Failure to Warn	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) Essure® PMA conditions	*Broussard v. Houdaille Indus., Inc.*, 183 Ill. App. 3d 739, 744, 539 N.E.2d 360, 363 (1st Dist. 1989); *Brobbey v. Enter. Leasing Co. of Chicago*, 404 Ill. App. 3d 420, 430, 935 N.E.2d 1084, 1093 (1st Dist. 2010) (discussing RESTATEMENT (SECOND) OF TORTS § 388)).
Negligence/Negligence Per Se	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39(d) 21 C.F.R. § 820.20 *et seq.* Essure® PMA conditions	*Bier v. Leanna Lakeside Prop. Ass'n*, 305 Ill. App. 3d 45, 58–59, 711 N.E.2d 773, 783 (2d Dist. 1999), *as modified on denial of reh'g* (May 19, 1999)

Negligent Misrepresentation/Fraud	Essure® PMA conditions Essure advertising and promotional materials	*Bd. of Educ. of City of Chicago v. A, C & S, Inc.*, 131 Ill. 2d 428, 452, 546 N.E.2d 580, 591 (1989); *Illinois State Bar Ass'n Mut. Ins. Co. v. Cavenagh*, 2012 IL App (1st) 111810, ¶ 38, 983 N.E.2d 468, 481.
Breach of Express Warranty	Preemption Not Applicable - *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525 (1992)	*See Moorman Mfg. Co. v. Nat'l Tank Co.*, 91 Ill. 2d 69, 72, 435 N.E.2d 443, 444 (1982).
Negligent Training	Essure®-specific training guidelines Physicians' Training Manuel	*See Pippin v. Chicago Housing Authority*, 78 Ill. 2d 204, 210, 399 N.E.2d 596, 600 (1979) (citing to RESTATEMENT (SECOND) OF TORTS § 324A).

4. Negligent Failure to Warn Claims

(a) Negligent Failure to Warn Claim Is not Preempted

Bayer asserts that Plaintiffs' failure to warn claim is preempted. Bayer Motion at 19. Insofar as Plaintiffs' failure to warn claims are based on Bayer's negligence in failing update the Essure® label to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction; . . . that add or strengthen an instruction that is intended to enhance the safe use of the device; . . . [or] that delete missing, false, or unsupported indications," they are not preempted because the claims do not require FDA approval prior to the change. *See* 21 C.F.R. § 814.39(d). "At this early stage in the litigation, there was no reason for the Court of Appeals to preclude altogether the [plaintiffs'] . . . labeling claims to the extent that they rest on claims that

Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under federal law." *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996).

A state duty to update warnings in response to new safety information would not be "different from, or in addition to" federal requirements, because federal law itself requires medical devices to carry adequate warnings. 21 U.S.C. §352(f)(2) provides that a device is misbranded "unless its labeling bears . . . adequate warnings against use . . . where its use may be dangerous to health . . . as are necessary for the protection of users" and 21 U.S.C. §331 prohibits the sale of misbranded devices. Indeed, the premarket approval letter for Essure® makes it a condition of approval that "[a] PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Bayer Motion, Ex. G. And FDA's draft guidance establishes that the agency views Essure®'s current warnings as inadequate.

In addition, as FDA explained to the Supreme Court in response to a request for its views in *Stengel*, express preemption under the MDA only exists where FDA has established device-specific federal requirements. *See* Brief for the U.S. as Amicus Curiae, *Medtronic, Inc. v. Stengel*, No. 12-1351, 2014 WL 2111719, at 8–9 (May 2014) (citing *Lohr*, 518 U.S. at 500; 21 C.F.R. 808.1(d)), (copy of brief attached as Ex. G to Aff. of G. Sean Jez). Federal requirements that "reflect . . . entirely generic concerns about device regulation generally," such as general federal labeling and manufacturing requirements, "ordinarily do not have a preemptive effect under Section 360k(a)." *Id.* at 9 (quoting *Lohr*, 518 U.S. at 501); *id.* at 10 (noting that "*Riegel* reaffirmed that distinction between 'manufacturing and labeling requirements applicable across the board to almost all medical devices' and 'requirements specific to the device in question.' 552 U.S. at 322"). "Section 360k(a) does not preempt [Stengel's] straightforward claim that [Medtronic] should have

brought new safety information to physicians' attention through a CBE revision to the device's labeling, because such a claim implicates no preemptive device-specific federal requirement." *Id.* at 7.

The FDA elaborated:

> Under *Riegel*, FDA's premarket approval of petitioner's device established preemptive requirements with respect to the design, manufacturing, and labeling of the device. Those would preempt any claim alleging in substance that FDA should have conditioned its approval on adopting some other design, manufacturing specification, or labeling. Such were the nature of the claims at issue in *Riegel*, and those claims were therefore preempted.
>
> But here, respondents attack petitioner's conduct after its device received premarket approval. . . . That conduct . . . would have been governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents' failure-to-warn claim—whether styled as arising from petitioner's failure to make adverse event reports to FDA or from its failure to make a CBE revision to the device's labeling—is not expressly preempted.

Id. at 12. This FDA position is entitled to judicial deference. *See Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 210 (2011) (deferring to agency position set forth in amicus brief). As the Supreme Court has noted, §360k "authoriz[es] the FDA to determine the scope of the Medical Devices Amendments' preemption clause." *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

The basis of Bayer's preemption argument is that any claim for negligent failure to warn FDA regarding adverse events is impliedly preempted as an attempt by a private party to enforce the MDA. Motion at 21. But many courts have repeatedly rejected that argument, including the Ninth and Fifth Circuit Courts of Appeal; and the four courts analyzing the issue as to Essure® in particular. Specifically, the Northern District of Illinois rejected this exact argument. *Laverty v. Smith & Nephew, Inc.*, No. 15 C 9485, 2016 WL 3444191, at *7 (N.D. Ill. June 23, 2016).

> The Lavertys' claims more closely resemble non-preempted claims approved by the Ninth and Fifth Circuits. In *Stengel*, the Ninth Circuit declined to find preemption where the plaintiffs asserted a failure-to-warn claim under Arizona law based on the failure to comply with post-approval requirements established by the

> FDA. The court explained that the plaintiffs' failure-to-warn claim was not preempted, because "Arizona law contemplates a warning to a third party such as the FDA." *Stengel*, 704 F.3d at 1233. Accordingly, the claim rested "on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*." *Id.* Similarly, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 764, 776 (5th Cir.2011), the Fifth Circuit found that the MDA neither expressly nor impliedly preempted plaintiffs' failure-to-warn claim under Mississippi law based on post-approval failure to abide by disclosure requirements set by the FDA. As explained above, Illinois has long recognized negligence and strict liability torts arising out of a failure to warn, placing a duty on a product manufacturer not to communicate directly with an end user, but to engage in "reasonable conduct for the benefit" of the end user. Here, that reasonable conduct includes fully and correctly complying with FDA disclosure requirements. The Lavertys' claims are not impliedly preempted.

Id.

In addition, as previously discussed, multiple courts have found no preemption of a failure to warn claim premised on Bayer's failure to report Essure adverse events to the FDA—which is precisely Plaintiffs' claim. *McLaughlin*, 172 F. Supp. 3d at 838 (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) and *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 768 (5th Cir. 2011)); *De La Paz*, 159 F. Supp. 3d at 1097; *Medali*, No. RG15771555 (Bayer RJN, Ex. A); *Noris*, No. BC589882 (Bayer RJN, Ex. B at 20:16–20:18); *Lance v. Bayer Corp*., RG 16809860 (Cal. Super. Ct. Aug. 2, 2016) (multiple joined cases) (Bayer RJN, Ex. D). The Court should follow this precedent. Put plainly, the great weight of authority is against preemption and Bayer.

(b) Negligent Failure to Warn Claim Is Plausible

In arguing for preemption, Bayer also asserts that Plaintiffs have failed to plausibly allege a causal nexus between Bayer's failure to report and their injuries. Bayer is incorrect. Plaintiffs have alleged a multitude of failures by Bayer to warn the FDA of adverse events and alleged that those failures caused their injuries. FAC at ¶¶ 133–173. Further, as mentioned above, at the pleading stage those allegations are assumed true and all inferences are made in Plaintiffs' favor. Accordingly, Plaintiffs have pled a plausible failure to warn claim.

For instance, Plaintiffs allege that from January 2008 to June 2013, Bayer failed to disclose over 32,000 complaints to the FDA as required under the MDA and Essure's® PMA. *E.g.,* FAC at ¶¶ 150, 161–167, 171. The FDA had no warning of these adverse events until well after Plaintiffs were implanted with the Essure® coils. *Id*. And, after receiving Bayer's previously unreported adverse events, the FDA ultimately strengthened the warning for Essure®, including the addition of its strongest warning—a black-box warning. *Id*. at ¶ 4, 219–228

A black-box warning "appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks."[7] "If a problem may lead to death or serious injury, FDA may expect [the manufacturer] to highlight the warning by placing it in a box."[8] Even though some of the contents of the boxed warning are reflected in previous labeling of Essure®, the very fact that the FDA wanted to place a black box warning at all shows that the FDA agreed that the prior warnings were not strong enough.

In addition to the boxed warning, the FDA proposed a patient checklist to accompany all Essure® implantations. The patient checklist demonstrates that Bayer negligently failed to warn the FDA about all of the known risks associated with Essure®, including the injuries suffered by Plaintiffs. Further, the FDA determined that these risks were significant enough to include in the materials presented directly to a patient. During the September 2015 advisory committee meeting, patients, physicians, and researchers testified regarding problems with Essure®—and they were just the tip of the iceberg. Finally, the patient checklist reinforces the allegation that Bayer

[7] FDA Consumer Health Information, *A Guide to Drug Safety Terms at FDA*, available at http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107976.pdf

[8] FDA, *Guidance on Medical Device Patient Labeling*, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm070782.htm

continued to negligently fail to warn the FDA about these risks the women who are suffering have come forward, a duty that it should have fulfilled.

Bayer implies that the causal connection is broken because the FDA released a statement that Essure® "remained an appropriate option." Bayer Memo. at 22. However, that means only that the FDA decided not to recall it from the market. The finding has *nothing* to do with whether Essure®'s warnings were sufficient. In fact, the FDA's addition of a black-boxed warning and a patient checklist furnishes compelling evidence that the warnings *were not* sufficient. Had the FDA found that Bayer was adequately warning patients, there would be no need for a patient checklist.

Due to Bayer's negligence in warning the FDA of these adverse events, Plaintiffs' physicians were not able to adequately convey the risks and warnings associated with Essure® to Plaintiffs. FAC at ¶¶ 150, 161–167, 171–173. Had Plaintiffs, or their implanting physicians, known of these warnings through adequate reporting of adverse events, the physicians would not have recommended the implant of Essure®, and Plaintiffs would not have had the device implanted. *Id* at ¶¶ 315–319. Instead Plaintiffs suffered: chronic pelvic pain, weight gain, heaving bleeding with clotting, painful intercourse, hair loss, and depression. Had they known that these were possible risks of Essure® they would not have agreed to the procedure. *Id*.

Accordingly, Plaintiffs have adequately pled negligent failure to warn in their complaint: Bayer had a duty to warn the FDA of adverse events associated with Essure® and Bayer breached that duty, thereby failing to warn Plaintiffs' implanting physicians and causing their injuries. If the Court should find otherwise, Plaintiffs respectfully request leave to amend in order to provide additional facts in support of their claims.

5. Negligent Misrepresentation and Warranty Claims

(a) Negligent Misrepresentation and Warranty Claims Are not Preempted

A warranty is a promise voluntarily made—the "requirement[s] imposed by an express warranty claim are not imposed under State law, but rather imposed by the warrantor." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525 (1992) (holding breach of express warranty not preempted). Many courts have found that express warranties exist outside the FDCA, founded in traditional state law. *See, e.g.*, *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166 (C.D. Cal 2013); *Beavers–Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021 (D. Haw. 2014); *Schouest v. Medtronic, Inc.*, 13 F.Supp.3d 692 (S.D. Tex. 2014); *Arvizu v. Medtronic, Inc.*, 41 F.Supp.3d 783 (D. Ariz. 2014). Warranty claims are not common-law tort actions, but exist by virtue of positive legislative enactments of state law. *See* 810 ILCS §§ 5/2-314–15. Because warranty claims do not concern the breach of a promise pertaining to safety or effectiveness required by the FDA, but rather a voluntary contractual promise made by the defendant, separate and apart from any FDA requirements, a determination of warranty claims does not "require a finder of fact to challenge or usurp the FDA's conclusions of safety and effectiveness." *Cline v. Advanced Neuromodulation Sys.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012).

Bayer claims that Plaintiffs' claims of false and misleading advertising and promotional materials are the "same as" language FDA approved. However, as is clear from Bayer's Motion, the language is not the same. Further, any exercise in comparing and contrasting the false advertising materials with FDA-approved language is not proper at the pleadings stage.

Nevertheless, if the Court were inclined to compare the language in the marketing materials with FDA language, Bayer's motion still fails. By cherry-picking certain representations and warranties, Bayer tries to persuade this Court that all representations and warranties were contained in the label. This is not so. For example, Bayer touted Essure® as the most effective form of permanent birth control, and yet nowhere in the Essure® labeling does it state that Bayer

actually conducted a clinical trial comparing different forms of permanent birth control. In fact, Dr. Patricia Carney, Bayer Healthcare's Director of Medical Affairs for Women's Healthcare, admitted this at the September 2015 FDA Advisory Committee Meeting: "[T]here are no head-to-head prospective clinical trials of Essure versus tubal ligation." Aff. of G. Sean Jez, Ex. E (Advisory Committee Meeting Transcript) at 50. And yet, when Plaintiffs were implanted with Essure®, Bayer was claiming that it was the most effective form of permanent birth control.

Further, Bayer made representations and warranties about Essure® that it never reported to the FDA. They warranted that implanting physicians must complete hands-on training. FAC at ¶ 208, 356. In reality, the "training" was conducted by a Bayer sales representative with no medical education. *Id*. Saying that Essure was a "gentle procedure," for example, is not "the same" as the FDA-approved language that the "majority of women . . . experienced mild to moderate pain during and immediately following the procedure." In fact, there were many negligent misrepresentations and warranties that Bayer made to physicians and patients that do not mirror the FDA-approved Essure® language:

BAYER MISREPRESENTATION/WARRANTY	**FDA-APPROVED LANGUAGE**
Bayer warranted that "[s]ince Essure does not contain hormones, it should not cause weight gain." FAC at ¶ 203.	**FDA-approved language does not mention weight gain:** No language in Instructions for Use (Bayer Motion, Exs. K, L, P, R); No language in Summary of Safety and Effectiveness Data (Bayer Motion, Ex. H); Language from 2015 Patient Guide does not mention weight gain (Bayer Motion, Ex. O).
Bayer declared that the "Essure procedure is the most effective form of permanent birth control available." FAC at ¶ 203(g); Aff. of	**FDA-approved language does not say most effective:**

G. Sean Jez, Exhibit F (Patient Brochure); Aff. of G. Sean Jez, Exhibit D (Essure® Physicians' Website "Essure Technology")	"While the one and two-year effectiveness rates for Essure compare quite favorably to the effectiveness rate for other methods [. . .] longer term data on Essure are not available and may not compare favorably." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 20. "Long-term nature of the tissue response to Essure device is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 months, the nature of the cellular/fibrotic response and the ability of the response and the device to maintain occlusion are not known." Bayer Motion, Ex. K (Instructions for Use 2002) at 4; Ex. S (Instructions for Use 2011), at 1; FAC at ¶ 127.
Bayer warranted that to be trained in Essure®, the physician "must either already possess operative hysteroscopy skills or be willing to train in hysteroscopy. FAC at ¶ 115. Further it warranted that its training program was "comprehensive." *Id*. at 208. Physicians performing Essure® procedures must have achieved "Signed Off" training status for the procedure. FAC at ¶ 208; Aff. of G. Sean Jez, Exhibit C (Essure® FAQ Training Website); Aff. of G. Sean Jez B (Essure® Website "Learning Library Overview")	**Bayer's program was not comprehensive and was inadequate. Further, Bayer "signed-off" on implanting physicians who were not trained in operative hysteroscopy, like Plaintiffs' implanting physicians.** FAC at ¶ 208. Further, **Sales consultant or sales representative—who possessed no actual medical training—would train physicians.** FAC at ¶ 208.
Bayer represented that the "mechanism of action is the body's natural healing response" and the PET fibers "on the inner core of the micro-insert elicit a benign tissue healing response and acts as a scaffolding into which tissue growth occurs, completely occluding the fallopian tubes in three months' time. The tissue response has been found to be reliable and localized to the micro-insert." FAC at ¶	**FDA-approved language does not mention "natural healing" or that "tissue response has been found to be reliable and localized":** "Long-term nature of the tissue response is not known." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 5; Bayer Motion, Ex. K (Instructions for Use 2002) at 4; Ex. S (Instructions for Use 2011), at 1; FAC ¶ 127.

203; Aff. of G. Sean Jez, Exhibit D (Essure® Physicians' Website "Essure Technology")	
CONTRAINDICATIONS . . . known hypersensitivity to nickel confirmed by skin test." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 1.	**Regarding nickel hypersensitivity and/or allergic reaction: "**And studies have also demonstrated that there's no correlation between skin-testing results and allergic reactions to Essure." Aff. of G. Sean Jez, Ex. E (Advisory Committee Meeting Transcript) at 33 (Testimony from Dr. Edio Zampaglione on behalf of Bayer HealthCare).

For these reasons, the *McLaughlin* court properly rejected Bayer's preemption arguments concerning Plaintiffs' warranty and misrepresentation claims. The court noted that 21 U.S.C. §352(q) expressly prohibits the use of false or misleading advertising and concluded that Plaintiffs' could state viable, non-preempted warranty and misrepresentation claims based on false and misleading statements in Bayer's unapproved advertising and other promotional materials. *McLaughlin*, 2016 WL 1161578 at *11, *15. This Court should come to the same conclusion.

Even statements the FDA approved can survive preemption if plaintiffs do not claim the statements were defective. Rather, they should allege that defendants did not live up to the FDA-approved promises. *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009). That court opined that defendants were confusing the warranty claim with a claim for defective labeling, and noted that plaintiffs were not alleging the FDA-approved label was defective. *Id.* That is the case here. Even the FDA-approved warranties still survive, as Plaintiffs are not alleging that the label was defective—but that Essure® simply did not live up to its claims.

FDA regulations also clearly state that warranty claims are not preempted because they are state laws of general applicability, not specifically developed with respect to medical devices. *See* 21 C.F.R. § 808.1(d)(1): "Exemptions from Federal Preemption of State and Local Medical Device

Requirements" (such claims are "not 'requirements applicable to a device' within the meaning of section [360k(a)]"). Thus, express preemption does not apply. And, the FDA expressly declined to approve Bayer's warranties, stating in the Essure® PMA: "CDRH [The Center for Devices and Radiological Health] does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

But Plaintiffs' misrepresentation claims do not impose requirements on Bayer related to the safety and efficacy of Essure. As the Supreme Court has held in *Cipollone*, misrepresentation claims, including those based on allegedly false statements made in advertisements, are not preempted because they are predicated on the duty not to deceive. 505 U.S. at 525.

(b) Negligent Misrepresentation and Warranty Claims Are Plausible

Plaintiffs have also adequately alleged that Bayer's misrepresentations and breach of warranty caused their injuries. For instance, Bayer misrepresented that Essure® was more effective than other permanent birth control. *See, e.g.*, FAC at ¶¶ 7, 203. Had Plaintiffs or their implanting physicians known of the misrepresentation, Plaintiffs would not have had the Essure® coils implanted. *Id*. at ¶¶ 204, 315–319. Similarly, Bayer's failure to follow through on its promise to adequately train Plaintiffs' implanting physicians also caused or worsened their injuries. *See infra* (section on negligent training).

6. Negligent Training Claim

(a) Negligent Training Claim Is not Preempted

As noted above, and contrary to Bayer's contention, the cases Bayer cites do not support a ruling that negligent training is preempted. For example, *McLaughlin* held that a claim for negligent training was a parallel state law claim: A "negligent training claim does not seek to

impose training requirement different from those in the federal requirements and, thus, is not expressly preempted. . . . Moreover, we reject Bayer's argument that the negligent training claim is impliedly preempted because there is no state law on which to base a negligent training claim." *McLaughlin*, 2016 WL 1161578 at *6 (adoption of Section 324A of the Restatement 2d of Torts created parallel state law) (citations omitted).

Further, Illinois law recognizes a duty to train insofar as it has applied § 324A of the Restatement (Second) of Torts. *See Pippin v. Chicago Housing Authority*, 78 Ill. 2d 204, 210, 399 N.E.2d 596, 600 (1979). Specifically, § 324A states:

> [O]ne who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if . . . (b) he has undertaken to perform a duty owed by the other to the third person.

Indeed, *McLaughlin* considered this identical section, adopted under Pennsylvania law, and concluded that this was sufficient to maintain a parallel state-law claim for negligent training. Bayer undertook a duty to train physicians on how to implant Essure®, to ensure that physicians were trained in hysteroscopy, and to conduct training with a preceptor—and did so negligently.

Bayer further contends preemption is appropriate because Plaintiffs have not alleged any facts regarding how Bayer's training procedure deviated from the training procedure approved by the FDA. Bayer is mistaken.

First, Plaintiffs allege that Bayer failed to abide by the FDA-approved training guidelines in the training of their implanting physicians. FAC at ¶¶ 197–209, 365–373 (alleging how Bayer negligently trained Plaintiffs' implanting physicians). Second, Bayer breached its duty when it failed to ensure that Plaintiffs' implanting physicians were properly trained in hysteroscopy; when it failed to train Plaintiffs' implanting physicians with a designated preceptor (instead sending a sales representative to serve as the "preceptor"); and when it failed to disclose all known adverse

events to Plaintiffs' implanting physicians. *Id*. Plaintiffs are not alleging that the FDA-approved training standards were deficient in any way. Plaintiffs' claims rest on the premise that Bayer was negligent in applying those standards, which does not involve the jury deciding if the actual training material is inadequate under state law, as Bayer contends.

And to the extent Bayer asserts that Plaintiffs must identify specific provisions from the FDA-approved training materials,[9] "policing that limitation at the pleading stage would work especial hardship for plaintiffs in this context, who, prior to discovery, have access to generally applicable [requirements], but not to confidential PMA specifications." *Simoneau v. Stryker Corp.*, No. 3:13-CV-1200 (JCH), 2014 WL 1289426, at *5 (D. Conn. 2014) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010)). PMA specifications are "kept confidential as a matter of federal law," and therefore are unavailable without discovery. *Bausch*, 630 F.3d at 560 (citing 21 C.F.R. § 814.9).

(b) Negligent Training Claim Is Plausible

Bayer argues Plaintiffs failed to state facts regarding how the alleged inadequate training of their implanting physicians caused their injuries. But at the pleading stage all facts are assumed true and all inferences are made in Plaintiffs' favor. *See Doe v. Univ. of Chicago Med. Ctr.*, 2015 IL App (1st) 133735, ¶ 41, 31 N.E.3d 323, 331. Here, Plaintiffs allege that Bayer failed to properly train their physicians to implant the device, deal with post-implant complications, and remove the device in the event of complications. FAC at ¶¶ 197–209, 365–373. The *McLaughlin* court recently found that negligent training claims were not preempted, holding that plaintiffs had plausibly alleged that their implanting physicians "did not complete the required preceptoring until

[9] The Essure® publicly available label references a Physician's Training Manual, but fails to list the specific steps included in the training course. In addition, the PMA order fails to include the training steps.

competency, successfully complete the Essure Simulator Training, or understand the Physician Training Manual, and that Bayer negligently failed to ensure that these training requirements had been met." *McLaughlin v. Bayer Corp.*, No. CV 14-7315, 2017 WL 697047, at *5 (E.D. Pa. Feb. 21, 2017). The court went on to conclude that, while the complaint "does not contain specific allegations regarding the particular physicians who performed the Plaintiffs' procedures, including precisely how the implantations were negatively affected by the physicians' inadequate training, these are facts that can be developed in discovery." *Id.* at *6.

The same holds true here—it can be reasonably inferred that Plaintiffs' injuries could have been caused or worsened by Bayer's inadequate training of their physicians on how to implant the Essure® device or deal with post-implant complications. In the alternative, Plaintiffs request leave to amend to provide additional facts in support of their claim.

7. Manufacturing Defect Claims

(a) Manufacturing Defect Claim Is not Preempted

Federal requirements that "reflect important but entirely generic concerns about device regulation generally"—such as "federal manufacturing and labeling requirements applicable across the board to almost all medical devices"—lack preemptive effect. *Riegel v. Medtronic*, 552 U.S. 312, 322 (2008). Manufacturing defect claims are the quintessential parallel claims that escape preemption under §360k(a), since they are premised on the assertion that the medical device at issue did not conform to the design requirements of the PMA or FDA manufacturing regulations. Numerous decisions have definitively rejected arguments that such claims are preempted. *See, e.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (upholding state-law negligent-manufacturing claim based on violation of the FDA's Quality System Regulations and Current Good Manufacturing Practices requirements); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436 (6th Cir. 2010) (same). Contrary to Bayer's representation, the *McLaughlin* court likewise denied Bayer's motion to dismiss a negligent manufacturing claim involving Essure on preemption grounds. 2016 WL 1161578 at *22.

In *Hofts v. Howmedica Osteonics Corp.*, the court held a manufacturing defect claim not preempted where the plaintiff alleged that (1) the class III medical device "was defectively manufactured and not in compliance with Current Good Manufacturing Practice requirements approved by the FDA and had an impurity, imperfection, and/or another product defect allowed to be created, contained or placed within the product in defendants manufacturing process"; and (2) this "impurity, imperfection, and/or another product defect was a deviation from design and quality manufacturing standards for the [device] approved by the FDA." 597 F. Supp. 2d at 836. The court reasoned that "[u]nlike the claims the Supreme Court considered in *Riegel*, [plaintiff] bases his tort claims on his allegations that [defendant] failed in its obligation to meet the FDA's requirements,

not that [defendant] failed to exceed those requirements or to meet different requirements." *Id*. *See e.g.,* FAC at ¶¶ 174–192, 358–364.

(b) Negligent Manufacturing Claim Is Plausible

Plaintiffs alleged that Bayer violated federal law in the manufacture of Essure®. Specifically, Bayer violated federal regulations, Current Good Manufacturing Practices, the Essure® PMA, and the PMA Conditions of Approval resulting in the defective manufacture of her Essure®. As the Seventh Circuit reasoned, district courts "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases of her claim." *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). "[T]he victim of a genuinely defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem." *Id.* at 560. The Tenth Circuit has agreed, citing favorably to citing *Bausch* and discussing the possibility that a plaintiff may lack access to information at the pleading stage. *See also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015)

C. **Plaintiffs Properly Pled Their Fraud and Negligent Misrepresentation Claims**

Bayer next asserts that Plaintiffs have not pled their claim for negligent misrepresentation with sufficient particularity. Bayer Mem. at 24. This is simply not the case. In order to establish a claim for fraud, Plaintiffs must plead

> (1) a false statement of material fact; (2) the party making the statement knew or believed it to be untrue; (3) the party to whom the statement was made had a right to rely on the statement; (4) the party to whom the statement was made did rely on the statement; (5) the statement was made for the purpose of inducing the other party to act; and (6) the reliance by the person to whom the statement was made led to that person's injury.

Illinois State Bar Ass'n Mut. Ins. Co. v. Cavenagh, 2012 IL App (1st) 111810, ¶ 38, 983 N.E.2d 468, 481. As Bayer expressly acknowledged earlier in its Motion's preemption argument concerning these same claims (chart of alleged misrepresentations), Plaintiffs have expressly identified numerous, specific purported misrepresentations by Bayer in its advertising and promotional materials and have further alleged that those misrepresentations induced them to use the Essure device.

Further, Plaintiffs' Complaint contains multiple allegations that Plaintiffs relied on Bayer's negligent misrepresentations. *See* FAC at ¶¶ 193–218, 315–319. Moreover, at least one of the federal cases Bayer cites in its motion declined to dismiss plaintiff's negligent misrepresentation claims, finding them adequately pled even under federal pleading rules. *McLaughlin*, 172 F. Supp. 3rd. at 830. In summary, Plaintiffs have pled facts to support every element of their misrepresentation claims. Bayer's motion should be denied.

D. **Bayer's Forum Non Conveniens Arguments are Without Merit.**

1. Motion to Dismiss for Forum Non Conveniens should be Denied Outright Because Severance is not Appropriate.

Bayer's argument that the non-Illinois Plaintiff's claims should be dismissed under the doctrine of forum non conveniens (FNC) hinges upon a finding of improper joinder and severance.[10] As discussed in Plaintiffs' Opposition to Defendants' Motion to Sever, all Plaintiffs were properly joined in this action and severance is not appropriate. Because severance is not appropriate, this Court should deny Bayer's FNC motion outright.

2. Application of the FNC Doctrine is Not Warranted.

A plaintiff's right to choose a forum is a substantial one, and that choice should rarely be disturbed. *Dykstra v. A.P. Green Indus., Inc.*, 326 Ill. App. 3d 489, 496, 760 N.E.2d 1034, 1040 (2001). And that choice "should not be disturbed unless the factors weigh strongly in favor of transfer." *Pendergast v. Meade Elec. Co.*, 2013 IL App (1st) 121317, ¶ 20, 996 N.E.2d 34, 39. The court must evaluate the total circumstances of the case to determine whether the balance of factors strongly favors dismissal. *Id*. Ultimately, "the burden is on the defendant to show that relevant private and public interest factors strongly favor the defendant's choice of forum." *Laverty v. CSX Transp., Inc.*, 404 Ill. App. 3d 534, 537, 956 N.E.2d 1, 5 (2010), as corrected (Oct. 8, 2010).

The Illinois Supreme Court has listed three public interest factors and three private interest factors that courts should weigh in determining whether a suit should be dismissed on the grounds of inconvenient forum. The "private interest factors include (1) the convenience of the parties; (2) the relative ease of access to sources of testimonial, documentary, and real evidence; and (3) all other practical problems that make trial of a case easy, expeditious, and inexpensive[.]"

[10] Indeed, Bayer is only seeking dismissal of the **non-**Illinois Plaintiffs on the basis of FNC.

Langenhorst v. Norfolk S. Ry. Co., 219 Ill. 2d 430, 443–44, 848 N.E.2d 927, 935 (2006) (internal citations omitted). And the "public interest factors include (1) the interest in deciding controversies locally; (2) the unfairness of imposing trial expense and the burden of jury duty on residents of a forum that has little connection to the litigation; and (3) the administrative difficulties presented by adding litigation to already congested court dockets." *Id*. In weighing these factors—particularly in light of the fact that Defendants seek dismissal—courts should take care that the FNC doctrine does not "become a powerful weapon in the hands of the defendant who is seeking to avoid his obligations." Edward L. Barrett, Jr., *The Doctrine of Forum Non Conveniens*, 35 CALIF. L. REV. 380, 422 (1947).

The private and public interest factors in this case do not result in a balance that strongly favors dismissal. And, especially as is the case here, where Defendants have utterly failed to present any evidence to carry its burden in proving that Illinois is not a convenient forum, the Court should refrain from dismissing the case and disturbing Plaintiffs' choice of forum.

3. The FNC Factors do not Favor Dismissal.

(a) Private interest factors

Bayer has not offered any evidence to show that there are any practical problems that would prevent an easy, expeditious, and inexpensive trial of the claims in Illinois. In fact, the only private interest factor that Bayer alleges favors dismissal is the location of witnesses. Bayer Memo. at 11. However, Bayer has not produced any evidence with respect to the witnesses needed for trial—neither Plaintiffs' fact witnesses nor their own witnesses. Bayer failed to explain why it would be difficult to ensure the witnesses' attendance at trial, or why deposition testimony would be insufficient. Bayer also does not contend that witnesses will be unable to attend trial or that they might be prejudiced by having to present witnesses by deposition. Further, regardless of where Plaintiffs' claims are brought, the Bayer will have to travel to the location of Plaintiffs' witnesses—

the necessity of travel and its inherent inconvenience would manifest regardless of the location of the forum.

(b) Public interest factors

Nor do the public interest factors tip the balance in favor of dismissal. Defendants are members of the Bayer Group, "a global enterprise with companies in almost every country."[11] They maintain offices in Illinois and have employees in Illinois. Defendants sold Essure® in Illinois, to Illinois residents, who subsequently suffered complications due to the device. *See generally* FAC. Defendants also conducted clinical trials for Essure in Illinois, created their accreditation program in Illinois, and used Illinois as a test market for their nationwide marketing campaign. *Id.* This nationwide marketing scheme involved misrepresentations, breaches of warranty, and negligence which eventually expanded throughout Illinois. Illinois courts have an interest in hearing actions involving businesses in their community. *Id*. The simple fact that other forums may also have an interest in this litigation does not tip the balance in favor of dismissal.

In addition, the burden upon Illinois courts is not so substantial as to tip the balance of the factors in favor of dismissal. Bayer has presented no evidence that this Court has been unable to effectively manage large dockets. Defendants have likewise presented no evidence concerning this Court's inability to meet mandated deadlines or to keep pace with other district courts.

Bayer also claims that this Court will be burdened by the need to apply other states' laws. However, Illinois courts are capable of applying the laws of other states. This does not burden the court enough to support a dismissal.

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[11] *See Bayer—at Home throughout the World*, BAYER: SCIENCE FOR A BETTER LIFE, http://www.bayer.com/en/bayer-worldwide.aspx.

The evidence and arguments submitted by Bayer in support of the application of FNC simply do not constitute the type of weighty reasons that tip the balance strongly in favor of dismissal. Because FNC should be applied with caution, the Court should deny Bayer's motion.

III. CONCLUSION

As shown above, Bayer's motion to dismiss should be denied in its entirety. In the alternative, Plaintiffs should be granted to leave amend and/or conduct jurisdictional discovery.

DATED: February 9, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on February 9, 2018, a copy of the foregoing document was electronically filed with the Circuit Court of Madison County, Illinois, which sent notification to all parties of record as of that date. The undersigned further states that copies were also provided to the attorneys of record of all parties to the captioned cause by enclosing same in an envelope addressed to each attorney at their address(es) disclosed by the pleadings of record, with postage fully prepaid, and by depositing said envelope in a U.S. Post Office mailbox in Edwardsville, Illinois, on February 9, 2018:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY ET AL.,	)	
Plaintiffs,	)	Case No. 16-L-1617
v.	)	**JURY TRIAL DEMANDED**
BAYER CORPORATION, BAYER HEALTHCARE LLC., BAYER ESSURE INC. (F/K/A CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS INC., and DOES 1-10, inclusive,	)	
Defendants.	)	

BAYER'S REPLY IN SUPPORT OF ITS
MOTION TO DISMISS FIRST AMENDED COMPLAINT

Under *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017), this Court lacks personal jurisdiction over the claims of the 73 nonresident Plaintiffs who allege no connection between their claims and the State of Illinois—and almost all of whom appear to have refiled their complaints in other states post–*Bristol-Myers*, *see infra* 4. In addition, all of Plaintiffs' claims are squarely preempted by federal law, and federal and state courts nationwide have dismissed virtually identical claims concerning the Essure device on this basis. *See* Mot. to Dismiss ("Mot.") 2–3 (listing over a dozen cases dismissing similar or identical claims). Plaintiffs ask this Court to second-guess FDA's repeated determination that the device is safe and effective, and Congress's decision to preempt inconsistent state claims, but offer no basis to depart from the numerous, well-reasoned decisions finding preemption. This Court should dismiss Plaintiffs' claims for three reasons.

First, this Court lacks personal jurisdiction over the non-Illinois Plaintiffs' claims under *Bristol-Myers*. *See* § I, *infra*. Plaintiffs argue that their allegations about clinical trial and marketing activities in Illinois support personal jurisdiction, but numerous courts—including federal courts in Illinois and Missouri—have held in highly similar cases that such contacts are far too attenuated from Plaintiffs' claims to support personal jurisdiction under *Bristol-Myers*. *See infra* page 3–4, 8–9. The nonresident Plaintiffs have failed to allege that their devices were placed in Illinois, that their doctors were trained in Illinois, that they saw advertising in Illinois, that they participated in a clinical trial in Illinois, or any "adequate link" between Bayer's alleged Illinois contacts and their "specific claims." *Bristol-Myers*, 137 S. Ct. at 1781. There is no personal jurisdiction over their claims.

Second, the non-Illinois Plaintiffs' claims also should be dismissed under the doctrine of *forum non conveniens* or, at the very least, severed for the reasons explained in Bayer's briefs in support of its Motion to Sever. The non-Illinois Plaintiffs' claims accrued in the states where they were injured (not Illinois); their physicians, who will be key witnesses, are in the states where the injuries occurred (not Illinois); and their claims have no nexus to Illinois. Plaintiffs' only response is that the forum is appropriate because the claims should not be severed, but that is both incorrect and contrary to the balance of the *forum non conveniens* factors. Moreover, while Plaintiffs say their "right to choose a forum" should not be lightly disturbed, they omit that 69 of the 73 non-Illinois Plaintiffs appear to have also already chosen to refile their complaints in other states. *See infra* 4; *see also* 735 ILCS 5/2-619(a)(3) (dismissal proper where "there is another action pending between the same parties for the same cause"). Those choices, too, are substantial and relevant to the Court's analysis.

Third, the claims of all Plaintiffs are preempted. While Plaintiffs contend that decisions in other cases concerning the Essure device somehow support their complaint, in fact these decisions overwhelmingly reject the claims and confirm that they should be dismissed. Numerous decisions have found that in enacting a comprehensive federal statute governing medical devices and placing its exclusive enforcement in the FDA, Congress preempted the manufacturing, design, failure-to-warn, warranty/misrepresentation and failure-to-report claims that Plaintiffs bring here. Plaintiffs offer no reason to believe that they can rectify the infirmities in their First Amended Complaint; thus, the Court should dismiss with prejudice.

ARGUMENT

I. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR LACK OF PERSONAL JURISDICTION.

Plaintiffs ask this Court to disregard the U.S. Supreme Court's holding in *Bristol-Myers*, despite the long and growing list of decisions finding *Bristol-Myers* "dispositive" of the precise issue raised here. *See, e.g.*, *Dyson v. Bayer Corp.*, No. 4:17-cv-2584-SNLJ, 2018 WL 534375, at *2–5 (E.D. Mo. Jan. 24, 2018; *L. Jordan v. Bayer Corp.*, No. 4:17-cv-865-CEJ, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017), *reconsideration denied*, 2018 WL 339305 (E.D. Mo. Jan. 8, 2018), *amended claims dismissed*, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018); *State ex rel. Bayer Corp. v. Moriarty*, No. SC 96189, 2017 WL 6460354, at *5–6 (Mo. Dec. 19, 2017); *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017), *appeal voluntarily dismissed sub nom. Luddy v. Janssen Research & Dev.*, LLC, No. 17-cv-3205 (7th Cir. Nov. 20, 2017).

In the face of precedent and reason, Plaintiffs insist that this Court can exercise specific jurisdiction over *nonresident* Plaintiffs' claims on the grounds that Bayer allegedly conducted Essure marketing and clinical trial activities in Illinois. But, critically, it is fatal to this theory

that *none of the non-Illinois Plaintiffs' claims arise out of or relate to these Illinois contacts*. Thus, this Court lacks specific jurisdiction over the nonresident Plaintiffs' claims. *See Bristol-Myers*, 137 S. Ct. at 1781 (there must be an "adequate link between the State and the nonresidents' *claims*" (emphasis added)); *see also Dyson*, 2018 WL 534375, at *4 (finding similar allegations concerning "Essure marketing and clinical trials … too attenuated from those activities to prove specific, 'case-linked' personal jurisdiction"); *L. Jordan*, 2018 WL 837700, at *4 (same). Their arguments to the contrary fail.

To start, the non-Illinois Plaintiffs (and their counsel) seemingly recognize that *Bristol-Myers* is fatal to their theory of personal jurisdiction in this case. Upon information and belief, 69 of the 73 non-Illinois Plaintiffs (and even one Illinois Plaintiff) have refiled their complaints in other states. *See* Hay Declaration ¶¶ 3 (Exhibit A). In fact, one Plaintiff (Vanessa Ramos) appears to be a plaintiff in *four* other Essure Actions in *three* other states. *Id.* ¶ 14. Of the 69 refiling non-Illinois Plaintiffs, 68 did so after *Bristol-Myers* was decided on June 19, 2017, and are represented by attorneys who are counsel of record in this case. *Id.* ¶¶ 7–15. Each of these refiled complaints, moreover, was brought either in the Plaintiffs' home states or in California, where Conceptus (Bayer's predecessor) was based. Thus, not only will these Plaintiffs not be prejudiced by dismissal for lack of personal jurisdiction, but their claims are independently subject to dismissal under 735 ILCS 5/2-619(a)(3). *See A.E. Stanley Mgf. Co. v. Swift & Co.*, 419 N.E.2d 23, 27 (Ill. 1980) ("That one action is filed prior to the other therefore would not be determinative.").

On the merits, Plaintiffs fundamentally misrepresent the holding in *Bristol-Myers*. Contrary to Plaintiffs' assertions (at 5), the Supreme Court did not hold that specific jurisdiction would exist for claims by non-California residents against Bristol-Myers if the manufacturer

"develop[ed] Plavix in California, … create[d] a marketing strategy for Plavix in California, [or] manufacture[d], label[ed], package[d], or work[ed] on the regulatory approval of the product in California." *Bristol-Myers*, 137 S. Ct. at 1778. Rather, as the Eastern District of Missouri recently held, this language in the opinion's background section merely recites the absence of contacts in that case, and is not "a blueprint for establishing personal jurisdiction." *Dyson*, 2018 WL 534375, at *4; *see Jordan*, 2018 WL 837700, at *4 ("The language contained in the background section of *Bristol-Myers Squibb* does not authorize a federal court to exercise broad personal jurisdiction on the mere basis of nationwide contacts—such as the development of a marketing strategy—rather than the defendant's contacts within the forum state itself.").

The actual holding in *Bristol-Myers* makes plain that plaintiffs must demonstrate an "adequate link" between the defendant's forum contacts and each of the nonresident plaintiffs' specific claims for specific jurisdiction over those claims to exist. *See* 137 S. Ct. at 1781-82. As even Justice Sotomayor noted in dissent, "the upshot of [*Bristol-Myers*] is that plaintiffs cannot join their claims together and sue a defendant in a State in which only some of them have been injured" when this adequate link cannot be established. *Id.* at 1788-89 (Sotomayor, J., dissenting). The non-Illinois Plaintiffs have failed to meet that burden here.

A. The Alleged Marketing and Training Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs argue that personal jurisdiction exists because Bayer or its predecessor "specifically targeted Chicago, Illinois [among other cities in other states] as … part of a broader marketing plan to increase sales and revenue." FAC ¶ 11(k). But Plaintiffs do not argue (because they cannot do so) that any non-Illinois Plaintiff or her physician viewed or relied upon any Illinois marketing materials or the statements of any Illinois-based Key Opinion Leaders. This case is therefore no different than *Bristol-Myers*, where the Supreme Court rejected the

argument that extensive marketing in California created specific jurisdiction over the non-California plaintiffs' claims because it was part of a nationwide marketing strategy. 137 S. Ct. at 1781–82; *see* Mot. 10–11.

Plaintiffs argue that it is irrelevant whether the marketing materials they interacted with had any connection to Illinois because the marketing activity in Illinois was the "impetus" for Bayer's nationwide marketing strategy. Opp. 11. But other cases have rejected highly similar arguments that personal jurisdiction exists in Missouri because it served as "ground zero" for Essure's marketing and was a '"test marketing' campaign site[]." *Dyson*, 2018 WL 534375, at *4; *Jordan*, 2018 WL 83700, at *1 (same). These allegations are "too attenuated" from the non-resident plaintiffs' claims to support personal jurisdiction. *Dyson*, 2018 WL 534375, at *4; *Jordan*, 2018 WL 837700, at *1 (same). Allegations "[t]hat Missouri happened to be Essure's first marketed area has no bearing on the non-Missouri plaintiffs' claims where those plaintiffs did not see marketing in Missouri, were not prescribed Essure in Missouri, did not purchase Essure in Missouri, and were not injured by Essure in Missouri." *Dyson*, 2018 WL 534375, at *4; *see also Jordan*, 2018 WL 837700, at *4 (same). This same reasoning applies equally to Plaintiffs' highly similar allegations concerning Illinois.

Nor can Plaintiffs' allegations about the Essure Accreditation Program confer specific personal jurisdiction over the non-Illinois Plaintiffs' claims. The First Amended Complaint is devoid of any allegation that non-resident Plaintiffs' physicians participated in the Essure Accreditation Program, much less that their participation in the Essure Accreditation Program had any connection to Plaintiffs' alleged injuries. Just like the marketing allegations, these

allegations are far "too attenuated" from Plaintiffs' actual claims to support personal jurisdiction.[1] *Dyson*, 2018 WL 534375, at *4; *see also Jordan*, 2018 WL 837700, at *4 (same).

B. The Alleged Clinical Trial Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs next contend that specific jurisdiction exists because Bayer conducted clinical trials and studies using several Illinois physicians and patients—along with physicians and parties from numerous other states—that led to the approval of Essure. Opp. 8–11. But Plaintiffs do not allege any link, much less an "adequate link," between these trials and their claims. *See Jordan*, 2018 WL 837700, at *4 (dismissing for lack of jurisdiction where out-of-state plaintiffs "d[id] not allege that ... they participated in the clinical trials taking place in [the forum state"). No Plaintiff alleges that she participated in the Illinois trials, relied on them, or even knew about them. Nor does any non-Illinois Plaintiff allege that she was treated by an Illinois physician.

Plaintiffs contend that it is sufficient that their complaint includes allegations of misconduct in the clinical trials (at 10-11). But *none* of the non-Illinois Plaintiffs' actual claims purport to challenge the conduct of the clinical trials in Illinois—rather, Plaintiffs challenge the manufacture, marketing, and warnings of the device, not the clinical trials supporting its FDA approval. These allegations thus cannot support personal jurisdiction because there is no connection between them and the non-Illinois Plaintiffs' *claims*.

[1] It is also notable that while Plaintiffs argue here that the Essure Accreditation Program "was created solely in Illinois," Opp. 12, the same Plaintiffs' Counsel—when arguing for personal jurisdiction in Missouri—also relied on the Essure Accreditation Program, contending that it supported specific jurisdiction over non-residents' claims in Missouri because it was developed by a Missouri consulting group. *See* Ex. B (excerpt of Respondent's Brief, *Missouri ex rel. Bayer Corp. v. Moriarty*, No. SC96189 (Mo. filed Oct. 4, 2017), at 17.

Plaintiffs contend that there is a sufficient connection because (i) some clinical trials occurred in Illinois; (ii) clinical trials are required for device approval; (iii) Plaintiffs would not have used the device and been injured if the FDA had not approved it; and (iv) thus, their claims are "related to" the clinical trials. Plainly, this is not the specific connection between an individual's claim and injury and a defendant's forum contact that *Bristol-Myers* requires. This attenuated theory is an attempt to turn "a loose and spurious form of general jurisdiction" into personal jurisdiction. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, Plaintiffs concede that, under their theory, "[i]t does not matter how many clinical trials were conducted in Illinois versus other states" and that this same theory could result in *specific* jurisdiction over any Essure user's claim in many—perhaps *all*—states. Opp. 9 & n.3; *see* Mot. 13 (citing cases where Plaintiffs' Counsel has made identical arguments in support of specific jurisdiction in other jurisdictions). *Bristol-Myers* forecloses this theory.[2] *Cf. Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 2017 IL 121281, ¶ 19 (noting that, in its general jurisdiction cases, the U.S. Supreme Court "has expressly rejected … reasoning" that would "establish general jurisdiction … in all the other states where [defendant's] warehouses are located").

Numerous decisions—including a series of recent decisions by federal District Judge David Herndon—have accordingly rejected this same jurisdictional argument. *See, e.g., Roland*, 2017 WL 4224037, at *4 (holding that, pursuant to *Bristol-Myers*, there was no personal

[2] Contrary to Plaintiffs' contentions, the issue is neither "what percentage of clinical trial activity" occurred in a state, nor "the meaningfulness of the activity" (at 9 n.2), but rather whether there is an "adequate link" between clinical trials in the forum and the plaintiffs' specific claims. *Jordan*, 2018 WL 837700, at *3. If a clinical trial participant brought suit over injuries she sustained in the trial, there would be specific jurisdiction regardless of how many other clinical trial participants were in the state. And conversely, if a plaintiff's claims do not arise out of the clinical trials, the clinical trials do not provide for specific jurisdiction regardless of the percentage of clinical trial participants in the state.

jurisdiction based on allegations that defendant "purposefully targeted Illinois as the location for multiple clinical trials which formed the foundation for defendants' Xarelto Food and Drug Administration application," because the "non-Illinois plaintiffs do not claim injuries from ingesting Xarelto in Illinois, and all conduct giving rise to non-Illinois plaintiffs' claims occurred in other states"); *Bandy v. Janssen Research & Dev., LLC*, No. 17-cv-00753, 2017 WL 4224035, at *4-6 (S.D. Ill. Sept. 22, 2017) (same), *appeal voluntarily dismissed sub nom. Schultz v. Janssen Research & Dev*., LLC, No. 17-cv-3210 (7th Cir. Nov. 21, 2017); *Dyson*, 2018 WL 534375, at *5 (rejecting argument "that specific jurisdiction exists because Essure could not have been approved without clinical trials, and some of those clinical trials occurred in Missouri"); *Jordan*, 2018 WL 837700, at *3–4 (same).

Plaintiffs' continued reliance on *M.M. ex rel. Meyers v. GlaxoSmithKline* LLC, 2016 IL App (1st) 151909, is also misplaced and misleading. *M.M*. predates *Bristol-Myers* and involved a prescription drug, not a Class III premarket approved device, and thus the express preemption clause of 21 U.S.C. § 360k. The connection between clinical trial activities in the forum state and the plaintiffs' claims was also much closer in *GSK*, as explained in Bayer's Motion to Dismiss. *See* Mot. at 14 n.2. And even if *M.M.* applied to this case, it cannot apply in a way that conflicts with the later, controlling decision in *Bristol-Myers*. In fact, in *Roland* and *Bandy*, the plaintiffs also asserted that personal jurisdiction existed based upon *M.M.*[3] However, Judge Herndon clearly rejected those arguments in granting the defendants' motions to dismiss based upon *Bristol-Myers*.

[3] A copy of the *Roland* and *Bandy* plaintiffs' memoranda of law in support of remand are attached hereto as Exhibits C and D.

Similarly, Plaintiffs misstate the holding in *DellaCamera v. DePuy Orthopaedics, Inc.*, No. CJC-10-004649 (Cal. Sup. Ct. Nov. 1, 2017), an out-of-state decision in which the court exercised personal jurisdiction over a design-defect claim because the device was designed in the state. In *DellaCamera*, the "heart of th[e] lawsuit" was whether DuPuy's metal-on-metal hip implant was defectively designed, a design DuPuy reached in collaboration with two California-based physicians. That design was the basis for each non-California plaintiff's claims. *Id.* slip op. at 6. By contrast here, Plaintiffs' claims and injuries do not arise out of the Illinois-based clinical trials. Thus, *DellaCamera* involved the type of claim-specific contacts with the forum that Plaintiffs' claims lack.

Taking Plaintiffs' allegations as true, they have failed to connect their claims with Bayer's alleged Illinois contacts. They have thus failed to carry their burden. The non-Illinois Plaintiffs' claims should, therefore, be dismissed.

II. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR *FORUM NON CONVENIENS*.

Alternatively, this Court should dismiss the non-Illinois Plaintiffs' claims because they are brought in an inconvenient forum. Plaintiffs' Opposition is based primarily on the premise that their claims should not be severed. For the reasons set forth in the memoranda in support of Bayer's Motion to Sever and Transfer, their claims *should* be severed. Beyond that, Plaintiffs' tour through the *forum non conveniens* factors shows precisely why that doctrine applies here.

Plaintiffs' Opposition disregards the first consideration in considering a *forum non conveniens* motion, which is whether there is an alternative forum where "all parties are amenable to process" and "the parties will not be deprived of all remedies or treated unfairly." *In re Bridgestone/Firestone, Inc.*, 420 F.3d 702, 704 (7th Cir. 2005). The answer to that question is indisputably yes; each Plaintiff has an adequate forum in his or her home state. *See Fennell v.*

Ill. Cent. RR., 2012 IL 113812, ¶¶ 11-18. Nor can Plaintiffs dispute the availability of adequate alternative fora, because 69 of the 73 non-Illinois Plaintiffs have already refiled their claims in other states. While Plaintiffs assert that their "right to choose a forum is a substantial one" and suggest that they would be prejudiced if that choice was upset, Opp. 34, the Plaintiffs' choice of Illinois (a state with no meaningful contact to their claims) has to be viewed in light of their additional choice to bring identical claims in other states.

Furthermore, Plaintiffs' weighing of the private- and public-interest factors is skewed. First, Plaintiffs ignore the practical problems with trying the claims of 73 Plaintiffs from across the country concerning medical procedures that took place in nearly two dozen states. It is undeniable, though, that such a large and complex trial would be unwieldy and expensive. These practical concerns are amplified by the overriding public interest in avoiding court congestion and "having local controversies decided locally." *Id.* Plaintiffs fail even to address *Fennell*, which held it was an abuse of discretion to deny a *forum non conveniens* motion where "plaintiff [did] not reside in Illinois and the action did not arise here," and the State's contact with the litigation was minimal. 2012 IL 113812, ¶¶ 24-49. Trial of 86 claims arising out of 22 states, moreover, would weigh trial down with complex, often dispositive choice-of-law issues. Such an endeavor is not necessary and would waste time and resources. Such concerns would be eliminated or greatly reduced if Plaintiffs pursued their claims in their home states.

Accordingly, this Court should dismiss the non-Illinois Plaintiffs' claims under the doctrine of *forum non conveniens* if it does not dismiss them for lack of personal jurisdiction.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED OR OTHERWISE FAIL.

In any event, all Plaintiffs' claims are preempted and fail to meet Illinois pleading standards. Federal and state courts alike have dismissed virtually identical claims. *See Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485 (W.D.N.C. 2017), *appeal docketed*, No. 17-1715 (4th Cir.

2017); *Norman v. Bayer Corp*., No. 3:16-cv-00253, 2016 WL 4007547 (D. Conn. July 26, 2016), *appeal docketed*, No. 16-2966 (2d Cir. Aug. 26, 2016); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017); *Richardson v. Bayer HealthCare Pharm. Inc.*, No. 4:15-cv-00443, 2016 WL 4546369 (D. Idaho Aug. 30, 2016); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. 2016) ("*McLaughlin I*"); *McLaughlin v. Bayer Corp.*, Nos. 14-7315 et al., 2017 WL 697047 (E.D. Pa. Feb. 21, 2017) ("*McLaughlin II*"); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016); *Medali v. Bayer HealthCare LLC*, No. RG15771555, slip op. (Cal. Super. Ct. Feb. 16, 2016), (RJN, Ex. A); *Noris v. Bayer Essure, Inc.*, No. BC589882 (Cal. Super. Ct. Apr. 26, 2016) (RJN, Ex. B); *Lance v. Essure Inc.*, RG16809860, slip op. (Cal. Super. Ct. Aug. 2, 2016) (RJN, Ex. D); *In re Essure Products Cases*, JCCP No. 4887, slip op. (Cal. Super. Ct. Apr. 12, 2017) (RJN, Ex. E); *see also* Mot. 2–3.

Rather than address the more than a dozen decisions that have dismissed all or most claims in similar Essure-related litigation, Plaintiffs distort these cases and the general preemption framework. First, Plaintiffs argue that the groundswell of decisions dismissing identical causes of action are somehow "more favorable to Plaintiffs than they are to Bayer," because those cases were largely "dismissed due to perceived deficiency in pleadings. Opp. 12–13 & n.4. This justification is not credible, since the pleading deficiency in most of those cases was a failure to thread the "narrow gap" between express and implied preemption. *See* Mot. 18–19. *See, e.g.*, *Olmstead*, 2017 WL 3498696, at *4 ("Therefore, the Court concludes that, as a matter of law, the MDA expressly preempts Plaintiff's claims."); *Norman*, 2016 WL 4007547 (dismissing all claims with prejudice); *De La Paz*, 159 F. Supp. 3d 1085 (dismissing all claims as preempted); *Medali*, RJN Ex. B, at 2 ("The Complaint does not plead any facts amounting to conduct that violates the terms of [Essure's PMA] or otherwise violates [sic] federal law (and

simultaneously violates California law).”). Even where a dismissal was styled in terms of causation or other cause-of-action issues, that analysis was informed by the unique and exacting demands of pleading a non-preempted claim involving a PMA device under the MDA. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 835 (finding a manufacturing defect claim inadequately pleaded because the complaint did not meet the causation standard to state “a cognizable negligent manufacturing claim involving a medical device”).[4]

Plaintiffs’ invocation of the presumption against preemption (at 13–14) similarly fails. A recent U.S. Supreme Court case directly holds that where a “statute contains an express pre-emption clause”—such as 21 U.S.C. § 360k(a) of the MDA—courts “do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause.” *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016). Indeed, as another court recently held, “Plaintiff’s argument that there is a strong presumption against preemption and that this presumption applies to the MDA’s express preemption clause is frivolous.” *Olmstead*, 2017 WL 3498696, at *3 n.2. And *Buckman* likewise holds that “no presumption against pre-emption” applies to the question whether claims are impliedly preempted because they conflict with FDA’s regulatory authority. *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 348 (2001). No presumption against preemption applies here. The correct preemption framework is

[4] When Plaintiffs finally address the substance of these preemption decisions, their recounting is incomplete and misleading. For example, Plaintiffs describe *McLaughlin I*—which dismissed 10 of 12 causes of action—as supporting their position here. Yet Plaintiffs omit to mention two 2017 decisions in that case further narrowing the plaintiffs’ claims. *Compare, e.g.*, Opp. 14 (describing *McLaughlin I* as holding negligent manufacturing claims are not preempted), *with McLaughlin II*,, 2017 WL 697047, at *18 (“We therefore grant the Motion to Dismiss as to the negligent manufacturing claim … in its entirety.”); *Dunstan v. Bayer Corp.*, No. 16-1458, 2017 WL 4392046 (E.D. Pa. Oct. 3, 2017).

set forth in the Supreme Court's decisions in *Riegel* and *Buckman*. *See* Mot. 17–19. When it is applied, each of Plaintiffs' claims clearly fails as a matter of law.

A. Plaintiffs' Manufacturing Claims Are Preempted And Otherwise Fail.

Plaintiffs' manufacturing defect claims are preempted for at least two reasons. First, Plaintiffs fail to identify a "specific federal requirement in the PMA approval" with which Bayer did not comply. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig*. 623 F.3d 1200, 1206 (8th Cir. 2010). Plaintiffs cite only Current Good Manufacturing Practices ("CGMPs"), Opp. 16, but as Bayer previously explained, CGMPs do not create "specific federal requirement[s] in the PMA approval" and "do not save … claims from preemption." Mot. 20 (quoting *In re Medtronic*, 623 F.3d at 1206).

Second, and in any event, Plaintiffs fail to allege that *their* Essure devices were manufactured with an actionable defect. *See Norman*, 2016 WL 4007547, at *3 ("Plaintiff alleges that there may have been some devices produced with 'non-conforming materials,' but does not allege any plausible reason to think that *her* device came from the non-conforming batch, or that it suffered from any other manufacturing defect."); *De La Paz*, 159 F. Supp. 3d at 1094 (dismissing where plaintiff failed to "allege that the irregularities … resulted in a manufacturing defect that caused *her* injuries") (emphasis added). Instead, Plaintiffs rely on a series of alleged licensing and record-keeping violations that could not plausibly "cause a product abnormality," *McLaughlin I*, 172 F. Supp. 3d at 836, let alone an actionable injury. *See Norman*, 2016 WL 4007547, at *3 ("[Plaintiff] does not allege any facts that would make it plausible that the complications she suffered—which were known potential side effects—were due to any defect in the device."); *Burrell*, 260 F. Supp. 3d at 493 (dismissing where "plaintiff has not linked any manufacturing deficiency to the device that the plaintiff received and how it caused the alleged injuries"). Thus, they have failed to state a non-preempted claim.

Plaintiffs' Opposition points to three cases as supporting their manufacturing claims here; none is apposite. First, Plaintiffs cite *Patton v. Country Place Condo. Ass'n*, No. 4-00-0008, 2000 WL 33728374 (Ill. App. Ct. July 7, 2000), as holding that a negligent manufacturing claim parallels federal PMA requirements. Opp. 16. But *Patton* did not involve medical devices at all; that case presented a preemption issue under the Federal Insecticide, Fungicide, and Rodenticide Act, which preempts only challenges "to advertising or promotion." *Patton*, 2000 WL 33728374, at *3. *Patton* has no bearing on the much broader MDA preemption provision. Second, Plaintiffs point to *McLaughlin I* as holding that a negligent manufacturing claim is not preempted. Opp. 14. But in fact that case granted Bayer's motion to dismiss the negligent manufacturing claim for failing to "allege that any particular manufacturing defect actually caused Plaintiffs' injuries." *McLaughlin I*, 172 F. Supp. 3d at 836. And when plaintiffs attempted to replead, *McLaughlin II* "grant[ed] the Motion to Dismiss as to the negligent manufacturing claim … in its entirety." 2017 WL 697047, at *18.

Finally, Plaintiffs rely on *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), *see* Opp. 26–27, but a multitude of courts have rejected that decision as wrongly decided, *see, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, No. 11-1229, 2009 WL 1361313, at *3 (D. Minn. May 12, 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) ("*Hofts* is not binding on this Court, and the undersigned respectfully disagrees with that decision"); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (similar); *Ali v. Allergan USA, Inc.*, No. 1:12-cv-115, 2012 WL 3692396, at *13 (E.D. Va. Aug. 23, 2012) (similar). With the exception of *McLaughlin*, which they misrepresent, *supra* note 4, Plaintiffs do not address any of the well-reasoned Essure cases that hold similar manufacturing claims are preempted. *See, e.g.*,

Burrell, 260 F. Supp. 3d at 493; *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *3; *Richardson*, 2016 WL 4546369, at *5; *McLaughlin II*, 2017 WL 697047, at *18. The Court should follow those cases and dismiss Plaintiffs' manufacturing claims.

Plaintiffs' only response is to claim that they need "[f]ormal discovery" to substantiate their conclusory assertions. Opp. 32. But Plaintiffs cannot cite a supposed need for discovery to insulate their claims from review. Their inadequate manufacturing defect claims should be dismissed, as numerous other courts have done in similar circumstances. *See, e.g.*, *Burrell*, 260 F. Supp. 3d at 493; *Norman*, 2016 WL 4007547, at *3; *McLaughlin II*, 2017 WL 697047, at *18; *De La Paz*, 159 F. Supp. 3d at 1094-95.

B. Plaintiffs' Failure to Train Claim Is Preempted.

Plaintiffs assert that their claim for negligent failure to train is not preempted because it pleads a violation of state law that is "parallel" to a violation of federal requirements, but they offer no response to Bayer's demonstration that the duty to train alleged in their complaint is *not parallel* to the FDA training requirements for Essure. Mot. 21–23. Plaintiffs read *McLaughlin I* as holding broadly that *all* negligent training claims parallel Essure's PMA requirements, including claims that Bayer failed "to ensure that physicians were trained in hysteroscopy." Opp. 27–28. That is wrong. To the contrary, as *McLaughlin* and numerous other courts have held, "training in the basics of hysteroscopy" is not "part of the FDA-mandated training" for Essure. *McLaughlin I*, 172 F. Supp. 3d at 817 n.9; *see also McLaughlin II*, 2017 WL 697047, at *4 (Essure's PMA "cannot reasonably be construed as requiring that Bayer ensure that doctors are knowledgeable hysteroscopists prior to their engaging in Essure training"); *Williams*, 2017 WL 6001531, at *10 ("[W]e find nothing to suggest that Bayer was the one required to provide [hysteroscopy] training.") (citing *McLaughlin I*). Plaintiffs' allegations that preceptors must be medical professional and that physicians should have been trained in removal likewise are not

parallel to any FDA training requirements. And contrary to Plaintiffs' contention that FDA's training requirements are "confidential," and discovery is necessary to determine them, in fact under FDA regulations all training requirements are set forth in the device's public labeling, 21 U.S.C. § 360j(e); *see* Mot. 21–22.

Additionally, as with their manufacturing claim, Plaintiffs provide no allegations connecting their alleged injuries with the alleged deficiencies in Bayer's FDA-approved training. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 817; *De La Paz*, 159 F. Supp. 3d at 1096 (dismissing negligent-training claim); *see also Frere v. Medtronic, Inc.*, No. EDCV 15-02338-BRO, 2016 WL 1533524, at *10 (C.D. Cal. Apr. 6, 2016) (dismissing similar claim for failure to "allege any facts" showing a "causal connection between the potential deviations and her injuries"). Indeed, the First Amended Complaint contains no facts at all about Plaintiffs' individual physicians, their training and experience with Essure, or how the physicians' training could possibly have affected Plaintiffs' procedures. In their opposition, Plaintiffs rest on boilerplate allegations that their physicians were inadequately trained, but do not even attempt to allege that these vague alleged training deficiencies had anything to do with their alleged injuries. *See* Opp. 29.

If Plaintiffs prevailed on their negligent training claim, Bayer would be required to train implanting physicians in a manner different than that required by FDA. This would, by definition, impose additional, different obligations on Bayer; the claim is therefore preempted and should be dismissed, as numerous other courts have ruled. *Accord, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1096; *McLaughlin I*, 172 F. Supp. 3d at 817; *Noris*, Apr. 26, 2016 Hr'g Tr. at 25:16-17 (RJN Ex. C).

C. Plaintiffs' Misrepresentation And Warranty Claims Are Preempted And Otherwise Fail.

For a state-law claim based on "false or misleading statements in unapproved advertising or other promotional materials" to survive preemption, a plaintiff must show that those statements are "*inconsistent* with specific statements in approved FDA materials." *McLaughlin I*, 172 F. Supp. 3d at 827; *see De La Paz*, 159 F. Supp. 3d at 1097-98 (dismissing as preempted state-law claim based on Essure advertising statements because "[w]ith one exception, each of De La Paz's examples is a statement that has been approved … by the FDA as a descriptor for Essure"); *Burrell*, 260 F. Supp. 3d at 494–95 (similar); *Williams*, 2017 WL 6001531, at *4–6 ("To find that Bayer made fraudulent or negligent misrepresentations through the making of these statements would require a finding contrary to that reached by the FDA and would consequently impose requirements different from, or in addition to, those set during the premarket approval process.").

Plaintiffs' breach of express warranty and negligent misrepresentation claims are preempted because they are based on statements that are consistent with—indeed, substantively identical to—FDA's approved labeling language for Essure. *See Norman*, 2016 WL 4007547, at *5-6; *Williams*, 2017 WL 6001531, at *4–6. Plaintiffs first ask the Court to disregard Bayer's table showing that each alleged misrepresentation was entirely consistent with Essure's FDA-approved labeling. Mot. 24–25. Plaintiffs assert that considering such material is "not proper at the pleading stage," but a multitude of courts have done so in dismissing misrepresentation and warranty claims as preempted. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 827-28; *De La Paz*, 159 F. Supp. 3d at 1097-98 ; *Burrell*, 260 F. Supp. 3d at 494-95, at *7-8; *Williams*, 2017 WL 6001531, at *4–6. If the alleged misrepresentations are substantively identical to FDA-approved statements, then as a matter of law, any such claims are preempted.

Plaintiffs then respond with a chart of their own, purporting to show that five statements in the First Amended Complaint somehow deviated from FDA approved statements. Opp. 24–26. Plaintiffs' chart is unpersuasive. For starters, by their focus on these five discrete statements, Plaintiffs tacitly admit that the other statements discussed at pages 24 and 25 of Bayer's Motion *are* equivalent to FDA-approved statements. More fundamentally, Plaintiffs fail to show any inconsistency—indeed, Plaintiffs largely argue that the challenged statements were false, not that they were inconsistent with the labeling. And their attempts to demonstrate any inconsistencies fail. For example, Plaintiffs argue the claim that Essure is the "most effective form of permanent birth control" deviates from FDA-approved labeling. Opp. 24. However, Bayer has already shown that, in patient and physician labeling dating back at least to 2012, FDA *approved* statements showing that other forms of permanent birth control (tubal ligation and vasectomy) have higher failure rates. Mot. 25. Plaintiffs also point to statements about implanting physicians needing to be skilled hysteroscopists or have completed the Essure training procedure. Opp. 25. But Essure's physician labeling is clear: "This device should only be used by physicians who are knowledgeable hysteroscopists … and have successfully completed the Essure Training program." *E.g.*, RJN Ex. K, at 1; Ex. L, at 1; Ex. P, at 1. Finally, FDA has approved Bayer's description of Essure as being hormone free, *e.g.*, RJN Ex. N, at 5; of the occlusion process being "natural," *e.g.*, *id.* at 6; and of the research concerning PET fibers, *e.g.*, RJN Ex. K, at 4; Ex. O, at 12. Numerous cases have therefore dismissed claims challenging these same statements as preempted.[5]

[5] Plaintiffs' chart also includes a "misrepresentation" concerning nickel sensitivity that appears *verbatim* in Essure's FDA-approved labeling. *See, e.g.*, RJN Ex. K, at 5; Ex. P, at 1. And the alleged source of this misrepresentation is a safety and effectiveness document that is part of Essure's PMA and available on FDA's website as part of Essure's regulatory history. Opp. 26.

Relying on *Hofts*, 597 F. Supp. 2d 830, Plaintiffs make an alternative argument that their misrepresentation claims escape preemption because they are challenging Essure's alleged failure to "live up to the FDA-approved promises." Opp. 26. Plaintiffs' reasoning plainly fails because FDA approved *both* Essure's labeling *and* the device itself; before granting pre-market approval, the agency must "evaluate[] safety and effectiveness under the conditions of use set forth on the label," as well as "determine that the proposed labeling is neither false nor misleading." *Riegel*, 552 U.S. at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). Moreover, Plaintiffs' proffered saving construction bears no resemblance to the First Amended Complaint, which alleges "that the statements made by Bayer were false *ab initio*, and would have been so regardless of whether Bayer adhered to FDA requirements." *Williams*, 2017 WL 6001531, at *5 n.7. Thus, whether Plaintiffs claims are construed as alleging that the device is defective or that its labeling is inadequate, they are equally inconsistent with FDA's considered judgment, and equally preempted.

Finally, Plaintiffs argue their express warranty claims are not preempted because warranties are imposed by voluntary contract, not the FDA or state law, and thus are exempt from MDA preemption. But as Plaintiffs concede, a cause of action for breach of express warranty is imposed by state law. Opp. 23.[6] Moreover, whether the cause of action is captioned as misrepresentation or breach of express warranty, imposing liability for statements that FDA has approved interferes with FDA's authority to regulate medical devices. Accordingly, multiple courts have recognized that the MDA preempts express warranty claims. *See, e.g., In re*

[6] Plaintiffs incorrectly suggest it is relevant for preemption purposes whether a cause of action arises under the common law or "positive legislative enactments." The MDA preempts any state requirement—regardless of its source—different from or in addition to federal requirements. *See* 21 U.S.C. § 360k.

Medtronic, Inc., 623 F.3d at 1208 (the "express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted"); *Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012) ("express warranty claims cannot be used to impose requirements greater than that provided by the FDA regulations"); *Horowitz*, 613 F. Supp. 2d at 285 (similar); *Norman*, 2016 WL 4007547, at *5 (finding breach of express warranty claim preempted); *De La Paz*, 159 F. Supp. 3d at 1098 ("The misrepresentation claims are based on the same statements that form the basis of De La Paz's claim for breach of express warranties, and they are preempted for the same reasons as that claim (namely, the statements conformed to statements approved by the FDA)."); *Williams*, 2017 WL 6001531, at *5.

And even if the MDA's preemption provision did not apply to "a voluntary *contractual* promise," *Cline v. Advanced Neuromodulation Systems, Inc.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012) (emphasis added), Plaintiffs did not allege that they entered into "contracts" with Bayer here. Rather, the alleged warranties are identical to the alleged misrepresentations, and are simply advertising statements.[7]

D. Plaintiffs' Failure To Warn Claims Are Preempted.

In its Motion to Dismiss, Bayer demonstrated that Plaintiffs' failure to warn claims are preempted. *See* Mot. 26–30. This is true both for Plaintiffs' claims challenging Essure's labeling, and for those based on an alleged failure to report adverse events.

[7] Plaintiffs also argue that their warranty and misrepresentation claims are not preempted because they fall within the "exemptions from federal preemption" set forth in 21 C.F.R. § 808.1(d)(1), Opp. 26–27. "But the *Riegel* plaintiffs made this same argument, and the Supreme Court rejected it, holding that the regulation 'fail[ed] to alter [the Court's] interpretation' of Section 360k(a)." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (quoting *Riegel*, 552 U.S. at 330), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

1. Claims Challenging The Adequacy of Essure Labeling Are Preempted.

Plaintiffs argue that their claims challenging the adequacy of Essure labeling are not preempted because Bayer could have, but did not, update the Essure label. Opp. 17–18 (citing 21 C.F.R. § 814.39(d)). As Bayer explained in its Motion to Dismiss, *see* Mot. 27, the regulation Plaintiffs cite says only that certain changes "may be placed into effect" prior to FDA approval. 21 C.F.R. § 814.39(d). A state-law *obligation* to change the label is necessarily different from or in addition to federal *permission* to change the label, and thus expressly preempted. *In re Medtronic*, 623 F.3d at 1205; *Riegel*, 552 U.S. at 329 (stating that the MDA § 360k(a) "[s]urely … would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings"); *see also Norman*, 2016 WL 4007547, at *3 ("[It] is clear that plaintiff cannot bring a claim because defendants failed to warn plaintiff personally … because such a claim would be expressly preempted as imposing obligations beyond those of the FDCA."). Nor does anything in 21 U.S.C. §§ 331 or 352 authorize or require Bayer to update Essure's labeling without FDA approval.

Plaintiffs further argue that MDA preemption does not apply to this question at all, because "express preemption under the MDA only exists where FDA has established device-specific federal requirements." Opp. 18. This argument disregards the core holding of *Riegel*, which is that a Class III device's PMA *does* "impose[] requirements under the MDA." 552 U.S. at 322. Through the PMA process, FDA approved Essure's label; FDA did not require (and indeed generally prohibited) Bayer to make unilateral changes to the label. *See* 21 U.S.C. § 360e(d)(6)(A)(i); *Riegel*, 522 U.S. at 319 (changes to label evaluated under "largely the same

criteria" as the initial application). Plaintiffs' attempt to force Bayer to make such changes through a state tort action are thus expressly preempted.[8]

2. Claims Challenging Adverse Event Reporting Are Preempted.

Likewise, Plaintiffs' claims based on an alleged failure to report adverse events to FDA are preempted. These claims are nothing more than "an attempt by [a] private part[y] to enforce the MDA," and are barred by both 21 U.S.C. § 337(a) and the Supreme Court's ruling in *Buckman*, as the Eighth Circuit recognized in *In re Medtronic*, 623 F.3d at 1205. To thread the narrow gap Congress left for state law in this area, Plaintiffs' claim must be "premised [on] the type of conduct that would traditionally give rise to liability under state law—*and* that would give rise to liability under state law even if the FDCA had never been enacted." *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013) (emphasis added). Simply put, "the failure to properly or timely to warn the FDA via the MDR process, as opposed to warning … doctors or patients of a device's dangers, is not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted." *Id.* at 1017. To hold differently would permit Plaintiffs to "make an end run around the rule precluding suit by re-casting violations of the FDCA reporting requirements … as violations of state common law." *Id.* at 1016.

Plaintiff also relies upon *Stengel v. Medtronic Inc.*, in which the Ninth Circuit held a failure-to-warn claim was not preempted where the plaintiff alleged that he was injured by a

[8] Plaintiffs rely on an amicus brief in *Medtronic, Inc. v. Stengel*, 2014 WL 2111719 (U.S. May 20, 2014), which they claim provides FDA's views. Opp. 18–19. It does not; it provides the views of the U.S. Solicitor General, not those of FDA, which is an independent federal agency. On the merits, as the amicus brief acknowledges, *no court* has adopted its proposed approach to analyzing preemption under the MDA. 2014 WL 2111719, at *15. Simply put, Plaintiffs rely on a document that conflicts with the law.

failure to provide information to FDA because "Arizona law contemplates a warning to a third party such as the FDA." 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *see also Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (same, "[a]ssuming that a failure to warn [the FDA] claim may be pursued under Mississippi law"). *Stengel* is contrary to the Supreme Court's holding in *Buckman*, as numerous other courts have recognized. *See, e.g.*, *Medtronic*, 623 F.3d at 1205-06; *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017).

In addition, a *Stengel*-type cause of action requires each Plaintiff to show that state law "contain[s] reporting requirements" or "contemplates a warning to a third party such as the FDA." *Kubicki ex rel. Kubicki v. Medtronic, Inc.*, No. 12–cv–734, 2018 WL 707428, at *34 n.25 (D.D.C. Feb. 5, 2018). Plaintiffs have not asserted any Illinois duty to warn a third-party such as the FDA, much less a corresponding duty under the laws of each of the 21 non-Illinois jurisdictions represented by Plaintiffs. In fact, an Illinois appellate court recently rejected a *Stengel*-type claim as a matter of state law because "there is no Illinois requirement that parallels" a manufacturer's duty to report adverse events to FDA. *See Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, ¶28. Numerous courts have rejected other Essure plaintiffs' misrepresentation claims for this same reason. *See, e.g., id.* (distinguishing *Stengel* under D.C. law); *Burrell*, 260 F. Supp. 3d at 492–93 (distinguishing *Stengel* under North Carolina law); *Norman*, 2016 WL 4007547 at *4 (distinguishing *Stengel* under Connecticut law); *Pearsall v. Medtronic, Inc.*, 147 F. Supp. 3d 188, 201-02 (E.D.N.Y. 2015) (distinguishing *Stengel* under New York law). This Court should do likewise.[9]

[9] If the Court does not dismiss this claim as preempted, the need to identify a state-by-state parallel obligation further underscores why the Court should sever-and-transfer the claims of non-Illinois Plaintiffs or dismiss those Plaintiffs claims under the *forum non conveniens* doctrine.

Plaintiffs have also failed to allege a plausible causal link between their injuries and Bayer's alleged reporting violations. In this regard, *Norman* and *Burrell* are directly on point. *See Norman*, 2016 WL 4007547, at *4; *Burrell*, 260 F. Supp. 3d at 492. As *Norman* explained: "Plaintiff's theory of causation seems to be that, had defendants kept up with their reporting requirements, this black box warning would have been issued earlier, and she would not have chosen to get the device implanted. But the FDA was aware of these reporting issues years before plaintiff's device was implanted, and the new type of warning did not change any of the warnings' substance—defendants, for example, were already required to advise physicians about the possibility of perforations." *Norman*, 2016 WL 4007547, at *4; *see Burrell*, 260 F. Supp. 3d at 492 ("[T]he newly-implemented black box warning … does not provide *new* information not otherwise noted; the same information was available on the prior labeling.").

Plaintiffs concede that FDA "receiv[ed]" the adverse-event reports. Opp. 21. And FDA did not take action with respect to Essure in response. Nearly three years later, FDA put a box around the warning, but "the warnings' substance" did not change, *Norman*, 2016 WL 4007547, at *4; *Burrell*, 260 F. Supp. 3d at 492, and FDA gave no indication that it was acting on information that was previously withheld. Plaintiffs' attempt here fails for the same reason it failed in *Norman* and *Burrell* – they have failed to allege that any failure to warn caused their injuries.

CONCLUSION

The Court should grant Bayer's motion to dismiss the complaint as to the non-Illinois Plaintiffs for lack of personal jurisdiction or under the doctrine of *forum non conveniens* and as to all Plaintiffs' claims because they are preempted.

DATED: February 19, 2018

Respectfully submitted,

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I hereby certify that, on February 19, 2018, a true and correct copy of the foregoing was served upon the following by electronic mail:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY, et. al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 16-L-1617
	)	
BAYER, CORP., et al.,	)	
	)	
Defendants.	)	
	)	
	)	

PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Plaintiffs, by and through their undersigned counsel, hereby request that this Court grant leave to file their Supplemental Response in Opposition to Defendants' Motion to Dismiss. In support thereof, Plaintiffs state as follows:

1. Bayer filed its Motion to Dismiss on December 15, 2017.
2. Plaintiffs filed their Response to Bayer's Motion to Dismiss on February 9, 2018. Bayer filed its Reply on February 16. This Court heard argument on Bayer's Motion on February 22.
3. On February 27, 2018, additional evidence came to light, further strengthening Plaintiffs' contention that Defendants are subject to personal jurisdiction in Illinois.
4. Plaintiffs seek leave to file a supplemental response to Defendants' Motion to Dismiss to include this additional evidence. The additional memorandum, attached as Exhibit A, will be helpful to the parties and to this Court in ruling on the issues presented.

I. ADDITIONAL ILLINOIS CONTACTS

In 2008, Defendants contracted with a company named Sterigenics to conduct Essure device sterilization. Pursuant to their agreement, Defendants were to send Sterigenics a forecast of the sterilization requirements for each calendar year. Should Defendants' sterilization requirements exceed the provided forecast, Sterigenics had a "right of first refusal" as to the opportunity to perform sterilization services on the devices that exceed the original forecast. Sterigenics is headquartered in Oak Brook, Illinois.

Not only did Defendants conduct clinical trials in Illinois, create the physician training program in Illinois, and launch the patient awareness marketing campaign in Illinois, but they also contracted with Illinois-based Sterigenics to sterilize **all** Essure devices. These Illinois contacts "aris[e] out of or relat[e] to" Plaintiffs' manufacturing defect claims in this matter. *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014); *see also Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1780 (2017). Indeed, Plaintiffs' specifically allege that Defendants became aware of the production of non-sterile devices, and failed to use pre-sterile and post-sterile cages in the manufacture of Essure. These additional Illinois contacts give added credence to Plaintiffs' claims that Defendants are subject to personal jurisdiction in this Court.

II. FORUM NON CONVENIENS SHOULD BE DENIED

Even though Defendants did not meet their burden in demonstrating that Plaintiffs' claims should be denied based on forum non conveniens, these additional Illinois contacts further cement this point. In addition to choosing Illinois-based Sterigenics to sterilize all Essure devices, Defendants also agreed that Illinois would have **exclusive personal jurisdiction** over the

agreement—the "validity, construction, interpretation and enforcement" of their agreement with Sterigenics "shall be governed solely by the laws of the State of Illinois." Defendants went on to agree that "[a]ny and all suits or proceedings relating to this Agreement . . . **shall be brought only in the state or federal courts located in Illinois**. Each party consents to the **exclusive personal jurisdiction** and venue of the state of Illinois." Defendants' claims that Illinois is an inconvenient forum are belied by the fact that they have agreed to Illinois jurisdiction in other circumstances.

WHEREFORE, Plaintiffs request this Court grant their Motion for Leave to File Their Supplemental Response in Opposition to Defendants' Motion to Dismiss, and for such other relief as the Court deems proper.

Respectfully submitted,

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The undersigned herby certifies that a true and accurate copy of the foregoing was served on all counsel of record through and served the following counsel via electronic mail on this 5th day of March 2018.

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY et al., Plaintiffs, v. BAYER CORP., BAYER HEALTHCARE LLC, BAYER ESSURE, INC., (f/k/a CONCEPTUS, INC.), BAYER HEALTHCARE PHARMACEUTICALS INC., and BAYER A.G., Defendants.	Case No. 16-L-1617 **JURY TRIAL DEMANDED**

BAYER'S RESPONSE TO PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL RESPONSE IN OPPOSITION TO BAYER'S MOTION TO DISMISS

Plaintiffs seek leave to file what is effectively a sur-reply introducing a new fact to support its meritless arguments regarding personal jurisdiction. This new fact does not provide any support for Plaintiffs' position that there is personal jurisdiction in Illinois for the claims of Plaintiffs who do not live in Illinois, did not obtain Essure in Illinois, did not view marketing in Illinois, and were not injured in Illinois. As a matter of law, Plaintiffs' jurisdictional theory fails, as numerous courts have recently held.[1] There simply is no constitutionally adequate

[1] *See, e.g.*, *Dyson v. Bayer Corp.*, No. 4:17-cv-2584-SNLJ, 2018 WL 534375, at *2–5 (E.D. Mo. Jan. 24, 2018); *L. Jordan v. Bayer Corp.*, No. 4:17-cv-865-CEJ, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017), *reconsideration denied*, 2018 WL 339305 (E.D. Mo. Jan. 8, 2018), *amended claims dismissed*, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018); *State ex rel. Bayer Corp. v. Moriarty*, No. SC 96189, 2017 WL 6460354, at *5–6 (Mo. Dec. 19, 2017); *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017), *appeal voluntarily dismissed sub nom. Luddy v. Janssen Research & Dev.*, LLC, No. 17-cv-3205 (7th Cir. Nov. 20, 2017).

"connection between the forum and *the specific claims* at issue." *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1781 (2017).

The new fact on which Plaintiffs now rely—a partial and misleading description of a 2008 contract between Conceptus and a sterilization company (Sterigenics)—is irrelevant. The contract does not even relate to this forum. Nor does it relate to Plaintiffs' devices or, most importantly, to Plaintiffs' claims against Bayer. Plaintiffs' claims are not – and could not be – based on this contract and thus cannot support personal jurisdiction in Illinois. Indeed, Plaintiffs' new argument is even more attenuated than the marketing and clinical-trial arguments advanced previously, and fails to establish personal jurisdiction for the same reasons. *See* Mot. to Dismiss 10-16; Reply 5-10.

Plaintiffs contend that the contract between Sterigenics and Conceptus establishes that there is personal jurisdiction in Illinois because Sterigenics is an Illinois-based company. Despite relying on this contract, Plaintiffs do not attach it to their motion, and the reason is apparent: the contract states explicitly that Sterigenics would sterilize Essure devices at facilities *in California and New Mexico*. *See* Ex. A, at 1, 8(A-1).[2] Under the contract, Sterigenics did not agree to provide any services to Conceptus in Illinois, nor did the contract provide for any sterilization services to occur in Illinois. That certain Essure devices may have been sterilized in other states by an Illinois-based company that is not even a party to this action does not create any link—much less a constitutionally adequate one—between Plaintiffs' claims against Bayer and the State of Illinois. Indeed, *Bristol-Myers* squarely rejected an argument that a defendant's contract with a third party resident of the forum creates personal jurisdiction. 137 S. Ct. at 1783

[2] Bayer will file a motion for leave to file Ex. A, the contract referenced in Plaintiffs' proposed supplemental brief, under seal because the contract includes confidential information regarding terms and pricing.

("In a last ditch contention, respondents contend that BMS's 'decision to contract with a California company McKesson to distribute Plavix nationally' provides a sufficient basis for personal jurisdiction" for claims concerning Plavix, but "[t]he bare fact that BMS contracted with a California distributor is not enough to establish personal jurisdiction in the State.").

Moreover, Plaintiffs fail to identify any link between the Sterigenics contract and the non-Illinois Plaintiffs' devices or their claims for relief. The non-Illinois Plaintiffs do not allege in the Complaint that their own devices were sterilized by Sterigenics, that the sterilization of their own devices was inadequate, or that inadequate sterilization caused their injuries, much less that any of these activities occurred in Illinois. Indeed, the contract did *not* provide for any sterilization services to occur in Illinois. Ex. A. And while Plaintiffs incorrectly represent that Conceptus contracted with Sterigenics "to sterilize all Essure devices," the contract concerned only a certain design of the Essure device, which the non-Illinois Plaintiffs do not allege they obtained. Mot. 2; Ex. A, at 10–11 (A-1 to A-2). Thus, Plaintiffs' new arguments fail to address the critical deficiency in the non-Illinois Plaintiffs' claims: there remains no connection whatsoever between their devices, their claims against Bayer, and this forum. *Bristol-Myers*, 137 S. Ct. at 1781-82 (Due Process "require[s]" a "connection between the forum and the specific claims at issue.").

Finally, Plaintiffs' attempt to bootstrap personal jurisdiction from the contract's forum-selection clause only underscores the inadequacy of the connection between their own claims and this forum. In the contract, Conceptus entered into a commercial relationship with a party located in Illinois, and "consent[ed] to the exclusive personal jurisdiction and venue of the state

of Illinois" *with respect to claims regarding the contract.* Mot. 3.[3] Thus, if Conceptus sued Sterigenics for breach of contract, there would be personal jurisdiction over that suit in Illinois. But the non-Illinois Plaintiffs were not parties to the contract, and are not suing for breach of the contract. The non-Illinois Plaintiffs' claims have no connection at all to Illinois, and Bayer never consented to have these claims tried in Illinois.

Plaintiffs' belated attempt to supplement its argument with this contract thus adds no support to their arguments. Plaintiffs themselves seem not even to buy what they are selling, as it appears that 69 of the 73 non-Illinois Plaintiffs have already filed post-*Bristol-Myers* cases in their home states or in California. For the reasons explained previously, the Court should dismiss the non-Illinois Plaintiffs' claims for lack of personal jurisdiction or *forum non conveniens*, and should also dismiss the remaining Plaintiffs' claims as preempted by federal law.

Dated: March 26, 2017

Respectfully submitted,

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[3] Plaintiffs' quotation of the venue-selection clause is incomplete. Plaintiffs omit the contract language consenting to suit in the U.S. District Court for the *Northern* District of Illinois. Ex. A, at 4 § 8.2.

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CERTIFICATE OF SERVICE

I hereby certify that, on March 26, 2018, a true and correct copy of the foregoing was served upon the following by electronic mail:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

NICHOLE HAMBY, et al.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	Case No. 16-L-1617
	)	
BAYER CORP., et al.,	)	
	)	
Defendants	)	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR LEAVE TO FILE A SUPPLEMENTAL RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

COME NOW Plaintiffs, by and through their counsel of record, and for their Reply in Support of Their Motion for Leave to File a Supplemental Response in Opposition to Defendants' Motion to Dismiss, state as follows:

Bayer's Response to Plaintiffs' Motion is nothing more than another desperate attempt to distance itself from this forum. Bayer claims there is no specific jurisdiction, and yet Plaintiffs continue to discover more and more evidence of its Essure-related, Illinois-based contacts. And every time, Bayer is forced to try to come up with some reason why those contacts don't matter. But the fact is they do matter. And when taken together, it reveals that Bayer's Essure-related Illinois contacts run deep.

I. ADDITIONAL ILLINOIS CONTACTS

Bayer's contention that the Sterigenics contract does not relate to this forum is preposterous. Bayer's response reads like the Sterigenics contract is the only contact it has with Illinois. As this Court is well aware, Bayer has substantial Essure-related contacts with Illinois through its clinical

trial activity, marketing activity, and patient awareness campaigns. It's Essure-related contact with Illinois goes far beyond the contact described by the Supreme Court in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1780 (2017). This contract simply provides yet another reason why this Court should deny Bayer's Motion to Dismiss.

In addition, the Sterigenics contract gives rise or relates to Plaintiffs' manufacturing defect claims in this matter. This *exclusive* contract deals solely with Essure, and contains a provision agreeing that Illinois law, venue, and jurisdiction would govern all aspects. Plaintiffs' manufacturing defect claims are tied to this contract as well—Plaintiffs specifically plead that Bayer produced non-sterile devices and were cited by FDA for failing to use pre-sterile and post-sterile cages. This contract further proves that Bayer is subject to personal jurisdiction in Illinois.

The contract Plaintiffs reference in their Motion was produced by a third party in the California litigation. Plaintiffs did not attach the contract because, even though the contract has not been marked confidential, the Protective Order in the California litigation allows for third-party production to be designated "Confidential" within thirty days after production. At the time of the filing of their Motion, thirty days had not elapsed. Furthermore, Bayer could have marked this contract "Confidential" in this case, had it bothered to respond to Plaintiffs' Request for Production 167 (served in *Rios*), which specifically asks for "all contracts or other agreements entered into by [Bayer] which select he law of Illinois in a choice of law provision."[1] Nevertheless, Plaintiffs are more than happy to provide the contract to the Court for review.

[1] Bayer's failure to produce this responsive document to Plaintiffs' discovery requests certainly raises questions as to additional responsive documents Bayer has failed to produce.

II. CONCLUSION

As shown above, and for the reasons outlined in Plaintiffs' Response to Defendants Motion to Dismiss, Bayer's motion to dismiss should be denied in its entirety. In the alternative, Plaintiffs should be granted leave to amend.

Respectfully submitted,

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The undersigned herby certifies that a true and accurate copy of the foregoing document was served upon all counsel of record via electronic mail on this **29th** day of **March**, **2018**, as follows:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS ET AL.,	)	Case No. 16-L-1046
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., BAYER HEALTHCARE PHARMACEUTICALS INC., and DOES 1-10, inclusive,	)	
Defendants.	)	

DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER 735 ILL. COMP. STAT. §§ 5/2-301, 5/2-619.1, 5/2-619(a)(9) AND 5/2-615

For the reasons set forth in their Memorandum of Law, defendants Bayer Corporation, Bayer HealthCare LLC., Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") move to dismiss the Plaintiffs' Complaint with prejudice under Sections 5/2-301, 5/2-619.1, 5/2-619(a)(9), and 5/2-615 of Title 735 of the Illinois Compiled Statutes.

DATED: DECEMBER 15, 2017

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I hereby certify that, on December 15, 2017, a true and correct copy of the foregoing was served upon the following by enclosing same in an envelope addressed as below, with proper first class postage fully prepaid, and depositing same in the U. S. Mail at Edwardsville, Illinois, at 5 p.m.:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS ET AL.,	)	Case No. 16-L-1046
Plaintiffs,	)	
v.	)	**JURY TRIAL DEMANDED**
BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., BAYER HEALTHCARE PHARMACEUTICALS INC., and DOES 1-10, inclusive,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT UNDER 735 ILL. COMP. STAT. §§ 5/2-301, 5/2-619.1, 5/2-619(a)(9), AND 5/2-615

INTRODUCTION

In *Bristol-Myers Squibb Co. v. Superior Court of California*, 137 S. Ct. 1773, 1782 (2017), the U.S. Supreme Court rejected the precise jurisdictional artifice Plaintiffs attempt to use in this case. The Supreme Court made clear that a court cannot exercise specific jurisdiction over the claims of out-of-state plaintiffs against an out-of-state defendant when "the conduct giving rise to the nonresidents' claims occurred elsewhere." *Id.* at 1781. That holding is "dispositive of the specific personal jurisdiction issue" in this case, where 87 of the 95 Plaintiffs ("non-Illinois Plaintiffs") have *no* connection at all to Illinois and bring claims against non-Illinois defendants for events that occurred elsewhere. *Jordan v. Bayer Corp.*, No. 4:17-CV-865, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017); *see also, e.g.*, *BeRousse v. Janssen Research & Dev.*, LLC, No. 3:17-cv-00716, 2017 WL 4255075, at *4 (S.D. Ill. Sept. 26, 2017 ("Similar to BMS . . ., this Court lacks specific personal jurisdiction over defendants regarding the non-Illinois plaintiffs' claims."), *appeal docketed*, No. 17-3200 (7th Cir. Oct. 24, 2017).

Recognizing that *Bristol-Myers* rejects personal jurisdiction over the non-Illinois Plaintiffs' claims, Plaintiffs have filed an amended complaint that adds a series of jurisdictionally irrelevant claims about Essure's sales, marketing, training, and clinical trial activities. But the newly added allegations of purported "extensive contacts," First Am. Compl. ("FAC") ¶ 11(a), do not identify any connection—let alone a constitutionally "adequate" one—to the "specific claims" of the individual non-Illinois plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1776. The First Amended Complaint does not, for instance, allege that any of the non-Illinois plaintiffs participated in clinical trial activities in Illinois, saw any marketing in Illinois, or purchased their devices in Illinois. These allegations do not distinguish Illinois from any other state across the country where Bayer sold, marketed, or studied Essure; indeed, plaintiffs in other states

(including plaintiffs represented by *the same plaintiffs' counsel*) have relied on identical allegations to argue that specific jurisdiction over non-residents' claims exists in those states as well. *See infra* pages 8-9, 11-12. The First Amended Complaint fails to allege an adequate "connection between the forum and the specific claims at issue," *Bristol-Myers*, 137 S. Ct. at 1776, and there is no personal jurisdiction.

Turning to the merits, Plaintiffs' claims are preempted by federal law and fail to meet Illinois pleading standards, and numerous courts have rejected virtually identical claims. Four federal courts have dismissed all of the claims, and others have dismissed almost all of them. *See, e.g.*, *Burrell v. Bayer Corp.*, No. 1:17-CV-00031, 2017 WL 1955333 (W.D.N.C. May 10, 2017) (dismissing all claims with prejudice); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017) (same); *Norman v. Bayer Corp.*, No. 3:16-cv-00253, 2016 WL 4007547 (D. Conn. July 26, 2016) (same); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (dismissing all claims); *Richardson v. Bayer HealthCare Pharms. Inc.*, No. 4:15-cv-00443, 2016 WL 4546369 (D. Idaho Aug. 30, 2016) (dismissing almost all claims, after which plaintiff voluntarily dismissed case); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838-39 (E.D. Pa. 2016) (dismissing 10 of 12 claims) ("*McLaughlin I*"); *McLaughlin v. Bayer Corp.*, No. 14-7315, *et al.*, 2017 WL 697047, at *18 (E.D. Pa. Feb. 21, 2017) ("*McLaughlin II*") (further narrowing claims).

Plaintiffs have fared no better in state courts. *See Medali v. Bayer HealthCare LLC*, No. RG15771555 (Cal. Super Ct. Feb. 16, 2016) (demurrer sustained with leave to amend certain claims) (order attached as Exhibit A to concurrently filed Request for Judicial Notice ("RJN")); *Noris v. Bayer Essure, Inc.*, No. BC589882, (Cal. Super. Ct. April 26, 2016) (demurrer sustained with leave to amend two claims) (RJN, Ex. B); *Williams v. Bayer Corp.*, No. 15BA-CVNo.

WD8023802526 (Mo. Ct. App. Dec. 5, 2017) (affirming dismissal with prejudice of most claims) (RJN, Ex. C); *Lance v. Bayer Essure Inc.*, No. RG16809860 (Cal. Super. Ct. Aug. 2, 2016) (demurrer sustained in part with leave to amend certain claims) (RJN, Ex. D); *In re Essure Prods. Cases*, JCCP No. 4887 (Cal. Super. Ct. Apr. 12, 2017) (further narrowing claims) (RJN, Ex. E).

These courts have had no trouble dismissing the claims at issue because, at bottom, Plaintiffs are attempting to second-guess the Food & Drug Administration ("FDA"). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204-08 (8th Cir. 2010); *see also* 21 U.S.C. §§ 360k(a), 337(a). FDA has the exclusive authority to regulate Class III medical devices like Essure, and has decided—numerous times—that Essure is safe and effective. FDA has balanced the benefits and risks of the device and recently confirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," and that "FDA continues to believe that the benefits of the device outweigh its risks." FDA News Release (RJN, Ex. F); FDA Activities (RJN, Ex. M). Plaintiffs' boilerplate allegations also do not suffice under Illinois pleading standards. *See* Ill. Comp. Stat. § 5/2-615. This Court should dismiss the Complaint.

BACKGROUND

A. Statutory And Regulatory Background

Congress has spoken. Federal law grants FDA the exclusive power to regulate medical devices. In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). The legislation "swept back" much of the state regulation that had emerged in patchwork form, and instead "imposed a regime of detailed

federal oversight." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). As part of this regime, Congress adopted a "general prohibition on non-Federal regulation" to avert the "undu[e] burden[]" of differing state regulations that can stifle innovation and ultimately harm public health. H.R. Rep. No. 94–853, at 45 (1976). Congress preempted all state laws that impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

Instead of state regulation, FDA provides the necessary oversight. Under this regime, "each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). A device intended "for a use in supporting or sustaining human life," or that otherwise "presents a potential unreasonable risk of illness or injury" is deemed a Class III device. 21 U.S.C. §§ 360c(a)(1)(C)(i)-(ii). FDA subjects a small percentage of innovative Class III devices, such as Essure, to the most "rigorous" level of FDA scrutiny. These devices must receive Premarket Approval ("PMA") before they can be marketed or sold. *Riegel*, 552 U.S. at 318; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1152 (Ill. 1999).

To receive such approval, the device manufacturer "must submit what is typically a multivolume application," and the "FDA spends an average of 1,200 hours reviewing each application," ultimately "grant[ing] premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317-18 (quoting 21 U.S.C. § 360e(d)); *see also Weiland*, 721 N.E.2d at 1152 (describing premarket approval process); *Ala. Tissue Ctr. of Univ. of Ala. Health Serv. Found., P.C. v. Sullivan*, 975 F.2d 373,

374-75 (7th Cir. 1992) (describing premarket approval process). A "manufacturer must furnish" numerous materials to FDA, including "detailed information about the device's testing, design, components, performance standards, manufacturing, packaging, and labeling." *Leavitt*, 470 F.3d at 74. FDA then heavily scrutinizes these applications, "'weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)).

As part of this process, FDA reviews a device's proposed labeling, which includes the Instructions for Use ("IFU") (for physicians) and Patient Information Booklet ("PIB") (for patients). The agency "evaluates safety and effectiveness under the conditions of use set forth on the label," and "must determine that the proposed labeling is neither false nor misleading" before granting approval. *Id.* (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). Once a device has been approved, a manufacturer cannot make changes to the labeling without FDA permission, 21 U.S.C. § 360e(d)(6)(A)(i), under "largely the same criteria" as the initial application. *Riegel*, 522 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). The statute likewise "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)). FDA may demand additional information from the manufacturer at any time, *see* 21 U.S.C. § 360e(c)(1)(H), and may require revisions to any component of the application, *see* 21 C.F.R. § 814.44(c). Only upon successfully "running the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996), may a Class III device lawfully be marketed in the United States.

A device manufacturer's obligations under federal law do not end with pre-market approval. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1336 (10th Cir. 2015). By design,

FDA enjoys wide and exclusive enforcement authority. Congress has made clear that actions to enforce the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a), and this judgment forecloses any private right of action under that statute, *see Buckman*, 531 U.S. at 349 n.4. FDA may investigate manufacturers of drugs and devices, and the agency "has at its disposal a variety of enforcement options that allow it to make a measured response" to any violations it uncovers. *Buckman*, 531 U.S. at 349; *see also* 21 U.S.C. §§ 332, 333, 334.

B. Factual Background

FDA has long recognized that Essure is a safe and effective method of permanent female contraception. In 2002, FDA granted Essure PMA, and FDA has never withdrawn or suspended that PMA. *See* FDA, Premarket Approval Order, Essure System (RJN, Ex. G); Summary of Safety and Effectiveness Data for Essure System (RJN, Ex. H); FDA, Regulatory History (RJN, Ex. I). Rather, FDA has granted numerous supplemental approvals, including as recently as December 2016. PMA Supplements (RJN, Ex. J). FDA repeatedly has reviewed and approved Essure's design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling. Premarket Approval Order (RJN, Ex. G at 4); Summary of Safety and Effectiveness (RJN, Ex. H); Professional Labeling (2002) ("2002 IFU") (RJN, Ex. K); Professional Labeling (2013) ("2013 IFU") (RJN, Ex. L). In fact, FDA recently rejected challenges to the device, reconfirming that "FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," and that "FDA continues to believe that the benefits of the device outweigh its risks." FDA News Release (RJN, Ex. F); FDA Activities (RJN, Ex. M).

Plaintiffs, who are 95 unrelated women from 27 different states, allege that they have sustained a wide variety of injuries including device migration, pain, weight gain, heavy

menstrual bleeding, and perforated organs. *See, e.g.*, FAC ¶¶ 238-332. After Bayer moved to dismiss the complaint, Plaintiffs sought leave to file a First Amended Complaint adding additional allegations concerning Essure's sales, marketing, training, and clinical trial activities. *See id.* ¶¶ 9-12. The Court granted leave to file the amended complaint "without prejudice to Defendants raising any arguments in a motion to dismiss or motion to sever and transfer venue as to the claims in the First Amended Complaint."

STANDARD OF REVIEW

Under Illinois law, a complaint must be dismissed "where it is apparent that no set of facts could be proven that would entitle the plaintiff to relief." *Turcios v. DeBruler Co.*, 32 N.E.3d 1117, 1122 (Ill. 2015); *see also Richter v. Prairie Farms Dairy, Inc.*, 53 N.E.3d 1, 7 (Ill. 2016). The Court "must disregard the conclusions that are pleaded and look only to well-pleaded facts to determine whether they are sufficient to state a case of action against the defendant. If not, the motion must be granted, 'regardless of how many conclusions the count may contain and regardless of whether or not they inform the defendant in a general way of the nature of the claim against him.'" *City of Chi. v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1112-13 (Ill. 2004) (quoting *Knox Coll. v. Celotex Corp.*, 430 N.E.2d 976, 985 (Ill. 1981)).

ARGUMENT

I. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR LACK OF PERSONAL JURISDICTION.

Pursuant to 735 Ill. Comp. Stat. § 5/2-301, Bayer is not subject to personal jurisdiction with respect to the claims of the 87 Plaintiffs who are neither citizens of Illinois nor allege that they underwent the Essure procedure in Illinois. Plaintiffs bear the burden to show that personal jurisdiction exists. *See Russell v. SNFA*, 987 N.E.2d 778, 784 (Ill. 2013). To meet this burden, Plaintiffs must plead allegations, which, if taken as true, would establish sufficient contacts to

satisfy the requirements of due process. *Id*. Here, the non-Illinois Plaintiffs do not plead sufficient—or any—facts to show specific jurisdiction over Bayer. *See, e.g.*, *Bristol-Myers*, 137 S. Ct. at 1782; *Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 761 n.19 (2014); *Jordan*, 2017 WL 3006993, at *3-4.

Plaintiffs have abandoned their argument that any of the Bayer Defendants are subject to general jurisdiction in Illinois, *see* FAC ¶¶ 9-10, and their allegations are plainly insufficient to justify such all-purposes jurisdiction over Bayer, *see Daimler AG v. Bauman*, 134 S. Ct. 746, 760, 761 n.19 (2014); *BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549, 1559 (2017). As the Supreme Court has held and repeatedly reaffirmed, a court has general jurisdiction only where a defendant's affiliations with the State are so 'continuous and systematic' as to render them essentially at home in the forum State." *BNSF*, 137 S. Ct. at 1558 (quoting *Daimler*, 134 S. Ct. at 754). Thus, a corporate defendant is subject to general jurisdiction in the states where it is incorporated and has its principal place of business, *id.* at 1558–59, and in in an "exceptional" case, where its "operations" are "so substantial and of such a nature as to render the corporation at home" *id.* at 1558 (giving as an example of an "exceptional case" *Perkins v. Benguet Consol. Mining Co*., 342 U. S. 437 (1952), where "war had forced the defendant corporation's owner to temporarily relocate the enterprise from the Philippines to Ohio"). "[S]imply doing continuous and systematic business in a state is not enough to establish general jurisdiction." *Jinright v. Johnson & Johnson, Inc.*, No. 4:17CV01849, 2017 WL 3731317, at *3 (E.D. Mo. Aug. 30, 2017).[1]

[1] It is not surprising that Plaintiffs have abandoned their argument that any of the Bayer Defendants are subject to general jurisdiction in Illinois. Here, no Defendant is incorporated in Illinois or has its principal place of business in Illinois. *See* Declaration of Keith Abrams, Ex. A, hereto.

Nor is Bayer subject to specific personal jurisdiction with regards to the non-Illinois Plaintiffs' claims. "In order for a state court to exercise specific jurisdiction, 'the *suit*' must 'aris[e] out of or relat[e] to the defendant's contacts with the *forum*.'" *Bristol-Myers*, 173 S. Ct. at 1780 (quoting *Daimler*, 134 S. Ct. at 754) (alterations in original). Here, Plaintiffs allege that specific personal jurisdiction exists because Bayer "engaged in substantial business activities in the State of Illinois." FAC ¶ 9. In particular, Plaintiffs allege that specific jurisdiction exists over the non-Illinois Plaintiffs' claims because of sales and marketing of Essure in Illinois, physician training and accreditation events held in Illinois, and Essure clinical trial activities in Illinois. But these allegations fail as a matter of law because they do not demonstrate a constitutionally "adequate link between the State" and the specific claims of the individual non-Illinois plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, the allegations of marketing and sales activities are no different than the allegations that the U.S. Supreme Court rejected as constitutionally inadequate in *Bristol-Myers*.

In the First Amended Complaint, the non-Illinois Plaintiffs do not allege that "they acquired the Essure device from [an Illinois] source or that they were injured or treated in [Illinois]." *Jordan*, 2017 WL 3006993, at *4. Nor does the First Amended Complaint include any factual allegations that Plaintiffs' Essure devices were developed, manufactured, packaged, or labeled in Illinois. *See id.* In fact, Conceptus—the original developer and manufacturer of Essure—was indisputably located in California and undertook these activities largely in California. *See Jordan*, 2017 WL 3006993, at *4 (noting the same in a nearly identical Essure case). Nor does the First Amended Complaint allege that any of the non-Illinois Plaintiffs' own doctors were trained or accredited in Illinois. In short, "all the conduct giving rise to the [non-Illinois Plaintiffs'] claims occurred elsewhere," *Bristol-Myers*, 137 S. Ct. at 1782, and those

plaintiffs therefore are not entitled to bring their claims in Illinois, *see Jordan*, 2017 WL 3006993, at *4.

The Supreme Court has clearly rejected any argument that this court has personal jurisdiction over the claims of the 87 non-Illinois plaintiffs simply because they are joined with "and allegedly sustained the same injuries as" the Illinois Plaintiffs. *Bristol-Myers*, 137 S. Ct. at 1781. And the defendants' alleged sales, marketing, training, and clinical trial activities in Illinois cannot give rise to personal jurisdiction because there is no "adequate link between the State" and the *specific claims* of any non-Illinois plaintiff. *Bristol-Myers*, 137 S. Ct. at 1781. The Supreme Court's holding is clear: there is no basis—consistent with federal Due Process—to exercise personal jurisdiction over Bayer with respect to the non-Illinois Plaintiffs' claims. *See, e.g.*, *id.* at 1782; *BNSF*, 137 S. Ct. at 1559; *see also Jordan*, 2017 WL 3006993, at *3-4.

A. The Alleged Sales, Marketing, and Training Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs' argument that Essure sales and marketing activities in Illinois give rise to personal jurisdiction for the non-Illinois plaintiffs' claims cannot be distinguished from arguments that *Bristol-Myers* rejected. Plaintiffs allege that Conceptus and Bayer developed sales, marketing, and training in Illinois (along with other states), and that Essure marketing "specifically targeted" doctors in Illinois. *See* FAC ¶ 11. But they do not allege that any of the non-Illinois Plaintiffs in this case underwent the Essure procedure in Illinois, were exposed to marketing about Essure in Illinois, or that their doctors participated in training in Illinois.

Thus, these allegations are no different than those in *Bristol-Myers.* In that case, the California Supreme Court had held that specific jurisdiction existed because "all the plaintiffs' claims arise out of BMS's nationwide marketing and distribution of Plavix," *Bristol-Myers Squibb Co. v. Superior Court*, 377 P.3d 874, 889 (Cal. 2016), and "BMS market[ed] and

advertise[d] Plavix in this state, it employs sales representatives in California, contracted with a California-based pharmaceutical distributor, operates research and laboratory facilities in this state," and "BMS actively and purposefully sought to promote sales of Plavix to California residents, resulting in California sales of nearly $1 billion over six years," *id*. at 886. But the U.S. Supreme Court *reversed* that decision, holding that none of those activities could provide specific jurisdiction because "[t]he relevant plaintiffs are not California residents and do not claim to have suffered harm in that State." *Bristol-Myers*, 137 S. Ct. at 1782.

The Supreme Court held that "[t]he mere fact that other plaintiffs were prescribed, obtained, and ingested [the drug] in California—and allegedly sustained the same injuries as did the nonresidents—does not allow the State to assert specific jurisdiction over the nonresidents' claims." 137 S. Ct. at 1781. Rather, "settled principles regarding specific jurisdiction" require each plaintiff to identify "an 'affiliation between the forum and the underlying controversy, principally [an] activity or an occurrence that takes place in the forum state.'" *Id*. at 1781 (alteration in original). Because "[t]he relevant plaintiffs [were] not California residents" and "all the conduct giving rise to the nonresidents' claims occurred elsewhere," specific personal jurisdiction did not exist. *Id*. at 1782.

Here, as in *Bristol-Myers*, the non-Illinois Plaintiffs "were not prescribed [Essure] in [Illinois], did not purchase [Essure] in [Illinois], . . . and were not injured by [Essure] in [Illinois]." *Id*. at 1781. Plaintiffs' argument that Essure sales, marketing, and training in Illinois creates specific jurisdiction over non-Illinois Plaintiffs' claims, *e.g.*, FAC ¶ 11(c), (k), is thus directly contrary to *Bristol-Myers*. Allegations that Bayer or Conceptus "specifically targeted Chicago, Illinois as . . . part of a broader marketing plan to increase sales and revenue," FAC ¶ 11(k), cannot provide specific jurisdiction over the non-Illinois Plaintiffs' claims, because these

Plaintiffs do not allege that they viewed Essure advertising in Illinois. *See Jordan*, 2017 WL 3006993, at *4. Indeed, such allegations could be used to argue specific jurisdiction exists in any state where Bayer or Conceptus marketed Essure—as plaintiffs' counsel is in fact arguing in other states. *Cf.* Resp't App. at A8 ¶ 10(i), *State of Missouri ex rel. Bayer Corp. v. Moriarty*, No. SC96189 (Mo. filed Oct. 4, 2017) (RJN Ex. U) ("The Defendants specifically targeted St. Louis, Missouri, as . . . part of a broader marketing plan to increase sales and revenue.").

The same conclusion applies to Plaintiffs' allegations regarding "Key Opinion Leaders" who allegedly "promote[d] Illinois" in Illinois—none of the non-Illinois plaintiffs alleges that she (or her physician) viewed or relied upon statements made by a "Key Opinion Leader" located in Illinois. *See* FAC ¶ 11(*l*); *cf* RJN Ex. U, at A8–9 ¶ 10(j) (making identical allegations about Key Opinion Leaders in Missouri). And finally, allegations concerning a physician training and accreditation program in Illinois are plainly inadequate to confer personal jurisdiction over the non-Illinois Plaintiffs' individual claims, since there is no allegation that the non-Illinois Plaintiffs' own physicians participated in that program—much less that non-Illinois Plaintiffs' alleged injuries were connected to that program.

The First Amended Complaint thus does not provide the court with specific jurisdiction over the claims of non-Illinois Plaintiffs, because the new allegations provide no "connection between the forum and the specific claims at issue," *Bristol-Myers*, 137 S. Ct. at 1781, and specific jurisdiction over the claims of the non-Illinois plaintiffs therefore does not exist.

B. The Alleged Clinical Trial Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs' allegations regarding Conceptus's clinical trial activities in Illinois are also inadequate as a matter of law. In particular, Plaintiffs cite clinical studies which allegedly involved Illinois patients and doctors (as well as patients and doctors from many other States)

and were part of the process that led to FDA approval, which in turn led to the approved labeling and marketing campaigns for Essure. *See, e.g.*, FAC ¶ 11(e) (acknowledging that the clinical trials involved Illinois only "in part"). But Plaintiffs do not allege that they participated in an Illinois clinical study or that they reviewed and relied on an Illinois clinical study in deciding to use Essure. Their attenuated argument based on clinical trials fails for multiple reasons.

First, to the extent Plaintiffs are arguing that specific jurisdiction exists because clinical trials wrongfully led to Essure's approval, such assertions are both inconsistent with the other allegations in their Complaint and obviously deficient. *See id.* ¶ 11(b), (f), (h) (alleging clinical studies that were conducted, in part, in Illinois led to Essure's approval and "formed the basis" of its FDA-approved labeling); *cf* RJN Ex. U, at A5, A7 ¶ 10(b), (g) (making identical allegations about clinical trial activity in Missouri); Plaintiffs' Notice of Supplemental Authority (ECF No. 65), *Vigil v. Bayer Corp*., No. 1:16-CV-848 (D.N.M. July 12, 2017) (RJN Ex. V) (making identical allegations about clinical trial activity in New Mexico). The Complaint does not allege that the product was wrongfully approved, much less that it was wrongfully approved due to clinical trial misconduct occurring in Illinois.

Moreover, any such theory clearly would be preempted by federal law: FDA approved Essure, it has never withdrawn that approval, and it has never found that the clinical trials were in any way flawed. *See* 21 U.S.C. § 360k; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). To the contrary, FDA has specifically *rejected* allegations that there was any misconduct in the clinical trials, RJN Ex. N, at 8 (Re-Evaluation of Case Reports Summary and Key Findings (Feb. 29, 2016)) (concluding that there was no "evidence of systematic or intentional modification of study subject responses in an effort to falsify (provide a more favorable device profile) the data relied upon by FDA to make the original PMA approval

decision in 2002."). The Plaintiffs' allegations are an effort to second-guess FDA's decision that the clinical trials demonstrated the safety and efficacy of the device and supported its approval, and thus would plainly be preempted. The clinical trials are not and cannot be relevant to the plaintiffs' claims, and they therefore cannot provide a basis for personal jurisdiction.[2]

In addition, *Bristol-Myers* forecloses Plaintiffs' theory that clinical trial activity in Illinois gives rise to personal jurisdiction in all Essure cases even when the Plaintiffs' claims have no connection to Illinois. The U.S. Supreme Court repeatedly emphasized that "[w]hat is needed . . . is a connection between the forum *and the specific claims at issue*." *Bristol-Myers*, 137 S. Ct. at 1781 (emphasis added). Plaintiffs do not come close to establishing such a connection here. Clinical studies in Illinois involve an Illinois physician providing Essure to an Illinois patient; they no more demonstrate that the Court has personal jurisdiction over the claims of non-Illinois plaintiffs against Bayer than does any other Illinois physician's provision of Essure to an Illinois patient. Instead, each non-Illinois plaintiff must show a specific connection between *her claim* and Bayer's activities in Illinois. But here, the non-Illinois plaintiffs do not allege that any non-Illinois Plaintiffs participated in these trials, or that anything that occurred in

[2] In their opposition to Bayer's motion to dismiss the original complaint (at 7), Plaintiffs relied on *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, 61 N.E.3d 1026 (Ill. App. Ct. 2016). But in *M.M.*, which predates *Bristol-Myers*, the connection between clinical trial activities in the forum state and the plaintiffs' claims was much closer. The plaintiffs were minors and their mothers who alleged that the mothers' ingestion of a prescription drug caused birth defects. *See M.M.*, 61 N.E.3d at 1029. Plaintiffs sought to establish personal jurisdiction in Illinois based on allegations that GSK concealed data on fetal abnormalities *of clinical trial participants*, and thereafter failed to warn that the drug was unsafe for pregnant women. *See id.* at 1032. Here, none of Plaintiffs' claims arise from alleged acts or omissions in clinical trials in Illinois. Moreover, the express preemption provision governing medical device cases was not at issue in *M.M.*, which involved drugs, and thus the plaintiffs could and did raise claims challenging the FDA-approved labeling. To the extent *M.M.* suggested that personal jurisdiction would exist whenever clinical trials for a product are held in a state, even when these factors are absent, it is no longer good law after *Bristol-Myers* and should not be followed.

the Illinois clinical trials gave rise to their claims. Rather, their theory appears to be simply that specific jurisdiction exists because the product could not have been approved without clinical trials, and the clinical trials "in part" occurred in Illinois and numerous other states. Under this theory, any plaintiff could sue a medical device manufacturer in nearly any state in the country, because clinical trials require many participants and are typically very widespread geographically.

To hold that the clinical trial activities that occurred in Illinois provide personal jurisdiction over the claims of all Plaintiffs involving the Essure device—even if the plaintiffs did not participate in clinical trials in Illinois and their claims do not concern the clinical trials in Illinois—would eviscerate *Bristol-Myers*'s ruling that each plaintiff must "identify[] an[] adequate link between the State" and her own specific claims. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, Essure plaintiffs in other jurisdictions—including plaintiffs in other states represented by the same plaintiffs' counsel—are likewise arguing that clinical trial activities conducted in *those* states provide specific jurisdiction for identical Essure claims brought by all non-resident plaintiffs in those forums. *See* RJN Ex. U, at A5–8 (concerning clinical trials in Missouri); *see also* RJN Ex. V ("[O]ne of the two post-approval studies mandated by the FDA was performed in part in New Mexico," and "[h]ad the post-approval study performed in New Mexico been adequate and follow-up been competently performed, the true safety profile of Essure would have been made known to Plaintiffs ... years earlier").

This attempt to create an end-run around the Supreme Court's decision should be rejected. As in *Bristol-Myers*, Plaintiffs' reasoning "resembles a loose and spurious form of general jurisdiction," 137 S. Ct. at 1781, that is entirety inconsistent with the Due Process Clause. *See also, e.g.*, *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL

4224037, at *4 (S.D. Ill. Sept. 22, 2017) (holding that there was no personal jurisdiction based on allegations that defendant "purposefully targeted Illinois as the location for multiple clinical trials which formed the foundation for defendants' Xarelto Food and Drug Administration application," because the "non-Illinois plaintiffs do not claim injuries from ingesting Xarelto in Illinois, and all conduct giving rise to non-Illinois plaintiffs' claims occurred in other states"); *Bandy v. Janssen Research & Dev., LLC*, No. 17-cv-00753, 2017 WL 4224035, at *4-6 (S.D. Ill. Sept. 22, 2017) (same). The Court therefore should dismiss the claims of the 87 non-Illinois Plaintiffs for lack of personal jurisdiction.

II. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED UNDER THE DOCTRINE OF *FORUM NON CONVENIENS*.

Alternatively, this Court should dismiss the non-Illinois Plaintiffs' claims under the *forum non conveniens* doctrine. *See* Supreme Court Rule 187. *Forum non conveniens* applies where (1) there is an alternative forum where "all parties are amenable to process" and "the parties will not be deprived of all remedies or treated unfairly," and (2) public and private interest factors favor dismissal. *In re Bridgestone/Firestone, Inc.*, 420 F.3d 702, 704 (7th Cir. 2005); *accord Fennell v. Ill. Cent. RR.*, 987 N.E.2d 355, 359-60 (Ill. 2012); *Vinson v. Allstate*, 579 N.E.2d 857, 859 (Ill. 1991). The private interest factors include ease of access to and cost of obtaining witnesses, as well as other practical problems. *See id.* The public interest factors include avoiding court congestion, the interest in having localized controversies decided locally, the interest in having trial in a forum that is at home with the applicable law, the interest in avoiding conflict of laws questions, and the unfairness of burdening Illinois citizens with jury duty to decide claims unrelated to Illinois. *See Fennell*, 987 N.E.2d at 360.

All of these factors are met here. Adequate alternative fora indisputably exist in the non-Illinois Plaintiffs' home states, key evidence and witnesses (including Plaintiffs' doctors) will be

more easily accessible there, and there is no reason to burden this Court or Illinois juries with the claims of 87 non-Illinois Plaintiffs regarding events that took place entirely outside of Illinois and regarding which there will be substantial conflicts of law issues. *See Fennell*, 987 N.E.2d at 361-66 (holding that circuit court abused its discretion in denying *forum non conveniens* motion where "plaintiff [did] not reside in Illinois and the action did not arise [t]here" and "Illinois' only connection with th[e] lawsuit [was] the offices of the parties' counsel," "documents in the possession of defendants' counsel," and an expert witness); *Vinson*, 579 N.E.2d at 859 (holding that circuit court abused discretion where plaintiff was an out-of-state resident at the time of the incident and filing of suit, the incident took place out-of-state, and most witnesses lived out of state); *Kamel v. Hill-Rom Co.*, 108 F.3d 799, 802-05 (7th Cir. 1997) (affirming dismissal under *forum non conveniens* where adequate alternative forum exists, and where private and public interests favor dismissal); *see also McIver v. Am. Med. Sys. Inc.*, No. 5-17-0011, 2017 WL 6327143, at *7-8 (Ill. App. Ct. Dec. 8, 2017) (noting a public "interest in having local controversies decided locally" and holding the district court abused its discretion by not granting *forum non conveniens* motion where "nearly all of the … witnesses" resided in other states and trial would "impos[e] jury duty upon residents of a county with no connection to the litigation").

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW.

As other courts have held in dismissing similar complaints against Essure, federal law preempts claims like Plaintiffs' here, and they should be dismissed with prejudice pursuant to 735 Ill. Comp. Stat. § 5/2-619(a)(9). *See Norman*, 2016 WL 4007547; *De La Paz*, 159 F. Supp. 3d at 1100; *see also Richardson*, 2016 WL 4546369, at *9 (dismissing nine out of ten claims); *McLaughlin*, 2016 WL 1161578, at *25-26 (dismissing ten of 12 claims); *see also supra* pages 2-3 (collecting additional cases). Federal law expressly preempts any state tort claim against medical device manufacturers that would impose safety or effectiveness requirements on a Class

III medical device "different from, or in addition to, any requirement" imposed by FDA. 21 U.S.C. § 360k(a)(1); *Riegel*, 552 U.S. at 321; *Norman*, 2016 WL 4007547, at *2; *De La Paz*, 159 F. Supp. 3d at 1091; *see also Herron v. Smith & Nephew, Inc.*, 7 F. Supp. 3d 1043, 1048 (E.D. Cal. 2014). Claims against Essure are expressly preempted unless Plaintiffs adequately allege (and ultimately prove) a violation of FDA "requirements related to" their devices as well as "a causal nexus between the[ir] alleged injur[ies] and the violation" of federal requirements. *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013); *see also Medali*, No. RG15771555, at 2 (RJN Ex. A); *Noris*, No. BC589882, Tr. at 25:20-25 (RJN Ex. B).

In addition, because FDA has extensive and exclusive authority to enforce its own requirements, federal law impliedly preempts claims based solely on the violation of FDA requirements. *Buckman*, 531 U.S. at 349 n.4; *see* 21 U.S.C. § 337(a) (all actions to enforce the FDCA "shall be by and in the name of the United States"). Plaintiffs cannot second-guess FDA or its decision on how to enforce those requirements. *Riegel*, 552 U.S. at 343; *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014) (explaining that a "claim may be impliedly preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist") (emphasis and internal quotation omitted).

Thus, to survive preemption, state-law claims against Bayer concerning Essure must fit within a "narrow gap": "The 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 (such a claim would be impliedly preempted under *Buckman*)." *Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010)). To fit within this

narrow gap, each Plaintiff must plead and prove (1) that Bayer violated some federal requirement; (2) that this federal violation also ran afoul of an independent and "parallel" state law requirement; and (3) that the federal violation actually caused her individual injuries. *Id*; *see also Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009) ("to survive preemption under the MDA a plaintiff must demonstrate a cognizable link between the defendant's federal violations and plaintiff's injury"); *Norman*, 2016 WL 4007547, at *2.

Plaintiffs' claims do not fall within this "narrow gap" and are therefore preempted. They raise four meritless theories of liability: (1) their Essure devices were defectively manufactured; (2) Bayer negligently trained physicians in the Essure procedure; (3) Bayer made misrepresentations concerning Essure; and (4) Bayer inadequately warned of the risks of Essure. All of them are preempted.[3]

A. Plaintiffs' Manufacturing Defect Claims Are Preempted.

Plaintiffs bring manufacturing defect claims under negligence and strict liability theories (Counts I and II). *See, e.g.*, FAC ¶¶ 377, 395. As numerous courts have held, federal law preempts these claims because Plaintiffs fail to allege facts plausibly showing that a deviation from Essure's FDA-approved manufacturing process resulted in a defect in their devices that caused their individual alleged injuries. *See, e.g.*, *Burrell*, 2017 WL 1955333, at *6; *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *3; *Richardson*, 2016 4546369, at *5; *McLaughlin II*, 2017 WL 697047, at *18.

[3] To the extent Plaintiffs raise a design-defect claim, *see, e.g.*, FAC ¶ 397, it is preempted as well. FDA specifically approved the design of Essure and found it safe and effective, *see* pp. 6–7, *supra*; thus, a design-defect claim "cannot survive preemption, inasmuch as [plaintiff] cannot allege that Bayer departed from" the FDA-approved design. *De La Paz*, 152 F. Supp. 3d at 1095.

As an initial matter, Plaintiffs' manufacturing claims are expressly preempted because they are not based on a failure to follow a "specific federal requirement in the PMA approval." *In re Medtronic*, 623 F.3d at 1206; *Norman*, 2016 WL 4007547, at *3. "In order to avoid preemption on a manufacturing defect claim, [a] plaintiff must allege that her device was not manufactured in conformance with the specification approved by the FDA." *Norman*, 2016 WL 4007457, at *3. Every manufacturing "requirement" Plaintiffs identify is actually a generally applicable FDA Current Good Manufacturing Practice ("CGMP"). *See, e.g.*, FAC ¶¶ 374, 376(h), 377, 380. As the Eighth Circuit explained in *In re Medtronic*, CGMP requirements are merely an "umbrella quality system," that do not create "specific federal requirement[s] in the PMA approval"—and thus "do not save . . . claims from preemption." *In re Medtronic*, 623 F.3d at 1206; *see also Olmstead*, 2017 WL 3498696, at *4 ("[A]llowing a suit to continue on the basis of the CGMPs would necessarily impose 'standards that are 'different from, or in addition to' those imposed by the MDA—precisely the result that the MDA preemption provision seeks to prevent.'"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) (CGMPs are too "intentionally vague and open-ended" to save claims from preemption); *Horowitz*, 613 F. Supp. 2d at 284 (CGMPs are "too generic" to save claims from preemption).

In addition, as other courts have held in dismissing Essure claims based on similar allegations, the claims also are preempted and inadequately pled because Plaintiffs fail to allege facts plausibly showing that any deviation from FDA requirements "resulted in a manufacturing defect that caused [their] injuries." *De La Paz*, 159 F. Supp. 3d at 1094. In order to avoid preemption on a manufacturing defect claim, "[a] plaintiff must allege that her device was not manufactured in conformance with the specification approved by the FDA," *Norman*, 2016 WL 4007547, at *3, and that such deviation "resulted in a manufacturing defect that *caused her*

injuries," *De La Paz*, 159 F. Supp. 3d at 1094 (emphasis added). Plaintiffs' conclusory allegation that Bayer (or its predecessor) manufactured Essure at an unlicensed facility, used non-conforming material in the manufacturing of Essure, and failed to adequately document its use, FAC ¶ 376, offer:

- "no description of the 'non-conforming material' used in manufacturing the device, or how the use of that material caused a defect in the product itself," *De La Paz*, 159 F. Supp. 3d at 1095,
- no "explanation of the function of 'pre-sterile and post-sterile cages' in the manufacturing process," *id.*,
- no "explanation for how Bayer's alleged operation without a license led to any manufacturing defect," *id.*,
- no "plausible reason to think that [their] device[s] came from [a] non-conforming batch, or that [they] suffered from any other manufacturing defect," *Norman*, 2016 WL 4007457, at *3,
- no "facts that would make it plausible that the complications [they] suffered . . . were due to any defect in the device," *id.*

Accordingly, as in *Burrell*, *Norman*, and *De La Paz*, Plaintiffs' claims fail. As those courts explained, Plaintiffs "cannot state a claim based *solely*" on an alleged failure to follow various manufacturing regulations, "since any such claim would 'exist solely by virtue of the [MDA],'" and is therefore impliedly preempted under *Buckman*. *De La Paz*, 159 F. Supp. 3d at 1094-95 (quoting *Buckman*, 531 U.S. at 353) (emphasis added).

B. Plaintiffs' Negligent Training Claim Is Preempted.

In Count I, Plaintiffs also claim that Bayer was negligent because it "fail[ed] to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device." FAC ¶ 374(f). FDA specifically approved Essure requirements for physician training. When FDA specifies training requirements for Class III medical devices, the training

requirements must appear in the FDA-approved labeling. 21 U.S.C. § 360j(e). Essure's labeling provides that:

> Device to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions tor Use and Physician Training Manual; and have successfully completed the Essure training program, including preceptoring in placement until competency is established, typically 5 cases.

RJN Ex. L, at 1 (2013 IFU).

Here, Plaintiff's negligent training claim alleges state-law duties that are wholly absent from these FDA training requirements. FDA did not place a duty on Bayer to monitor and supervise implanting physicians. *See Glennen v. Allergan, Inc.*, 247 Cal. App. 4th 1, 14 (2016) ("[T]he specific procedures used in the practice of medicine by a professional are not part of the manufacturer regulation process . . . . The PMA process does not obligate . . . manufacturers to follow their products into the surgery room."). Nor was Bayer required to train and certify physicians on the use of hysteroscopic equipment; the FDA-approved labeling makes clear that the onus was on the *physician* to acquire those skills prior to beginning Bayer's Essure training. *See* RJN Ex. L, at 1 (2013 IFU) (Essure should be "used only by physicians who are knowledgeable hysteroscopists"). As the *McLaughlin* court held, "training in the basics of hysteroscopy" is simply not "part of the FDA-mandated training" for Essure. 172 F. Supp. 3d at 817 n.9. Because the FDA-approved training requirements do not include Bayer training in hysteroscopy, the claim seeks to impose a state requirement, which is in addition to FDA's own safety requirements and, therefore is expressly preempted. *Norman*, 2016 WL 4007547, at *5; *De La Paz*, 159 F. Supp. 3d at 1096.

The negligent training claim is also preempted because Plaintiffs fail to "allege . . . any facts that give rise to a recognizable theory as to how any departure from the training guidelines may have caused [Plaintiff's injuries]." *McLaughlin I*, 172 F. Supp. 3d at 817; *see also De La*

Paz, 159 F. Supp. 3d at 1096 (dismissing negligent-training claim); *Frere v. Medtronic, Inc.*, No. EDCV 15-02338-BRO, 2016 WL 1533524, at *10 (C.D. Cal. Apr. 6, 2016) (dismissing similar claim for failure to "allege any facts" showing a "causal connection between the potential deviations and her injuries"). Indeed, Plaintiffs allege *no* facts regarding how their respective doctors were trained, how that training violated FDA requirements, or how the vague and overbroad alleged inadequacies in the training caused Plaintiffs' respective injuries. *See* FAC ¶¶ 214, 217(a)-(d), 374(f).

This Court should dismiss the Plaintiffs' training claim for these reasons. Indeed, numerous courts have done the same with respect to highly similar claims against Essure. *See De La Paz*, 159 F. Supp. 3d at 1096 (dismissing claim because "De La Paz has not alleged that Bayer ever deviated from the approved training as to Essure"); *McLaughlin*, 2016 WL 1161578, at *7; *Noris*, Apr. 26, 2016 Hr'g Tr. at 25:16-17 ("[T]raining is out. I will sustain [Bayer's motion to dismiss] the training without leave [to amend].") (RJN Ex. B); *Norman*, 2016 WL 4007547, at *5 (dismissing claim for negligent training because "Plaintiff fails to allege any facts that could plausibly suggest that her injuries were the result of the alleged negligent training").

C. Plaintiffs' Misrepresentation and Warranty Claims Are Preempted.

Plaintiffs assert claims for negligent misrepresentation, breach of express warranty, and fraudulent misrepresentation (Counts I, III, V) based on allegations that Bayer "disseminated false information" and "[e]ngaged in [f]alse and [m]isleading [s]ales and [m]arketing [t]actics." FAC ¶ 355; *see also id.* ¶¶ 202-227, 356-66, 415-423, 440-46. These claims are preempted, because the alleged misrepresentations track FDA-approved language in the Essure labeling, *see, e.g.*, *Burrell*, 2017 WL 1955333, at *7-8; *De La Paz*, 159 F. Supp. 3d at 1097-99; *Norman*, 2016 WL 4007547, at *3-6; *Williams*, Ex. C, at 8-11:

Alleged Misrepresentation by Bayer	Labeling Statement Approved by the FDA
• Essure was the "[o]nly FDA approved female sterilization procedure to have **zero pregnancies** in the **clinical trials**." FAC ¶ 212(a).	• "In the Essure **clinical studies**, **zero (0) pregnancies** were reported in women who had the Essure inserts for up to 5 years." *See* 2015 PIB at 12 (RJN, Ex. O); 2012 PIB at 12 (RJN, Ex. P) (similar); 2008 IFU at 3 (RJN Ex. Q) (similar).
• Essure is **"[s]urgery-free."** FAC ¶ 212(b). • "Essure eliminates the risks, discomfort, and recovery time associated with surgical procedures." FAC ¶ 212(f).	• Essure is "**Non-Surgical**." *See* 2015 PIB at 5 (RJN, Ex. O); 2012 PIB at 5 (RJN, Ex. P). • The "benefits of Essure" include that it is that "No General Anesthesia [is] Required" and that "most women return to normal activity within one to two days." *See* 2015 PIB at 5 (RJN, Ex. O).
• Essure is "**[w]orry free**." FAC ¶ 212(c). • Essure is a "**simple** procedure **performed in your doctor's office" that takes less than 10 minutes.**" FAC ¶ 212(c). • "[C]orrect placement . . . is performed easily because of the design of the microinsert." FAC ¶ 212(h).	• "Essure may be right for you if . . . You would like to **stop worrying** about getting pregnant" and "prefer a method or procedure that . . . [i]s **simple** and **does not take a lot of time**." 2012 PIB at 4 (RJN, Ex. P); 2015 PIB at 4 (RJN, Ex. O). • "[T]he Essure procedure is usually **performed in your doctor's office**." *See* 2012 PIB at 6 (RJN, Ex. P); *see also* RJN Ex. 2008 PIB at 6 (RJN, Ex. R) (similar). • "The entire process usually takes **less than ten minutes**." *See* 2012 PIB at 9 (RJN, Ex. P).
• "Essure inserts stay secure, forming a long **protective barrier** against pregnancy. They also remain visible outside your tubes, so your doctor can **confirm** that they're properly in place." FAC ¶ 212(d).	• "[Y]our body will form tissue around the Essure inserts. This will develop a **natural barrier** within the fallopian tubes." 2012 PIB at 6 (RJN, Ex. P); *see also* 2008 PIB at 4 (RJN, Ex. R) (similar). • During "Essure Micro-Insert Placement Procedure," "[e]xpanded outer coils of the Essure micro-insert trailing into the uterus indicates **ideal placement**." *See* 2011 IFU at 5 (RJN, Ex. S); 2013 IFU at 8 (RJN, Ex. L) (similar). • "Th[e] **viewable portion** of the micro-insert serves to **verify placement** . . . ." *See* 2008 PIB at 10 (RJN, Ex. R).
• "Essure inserts are made from the same trusted, silicone free material used in **heart stents**." FAC ¶ 212(e).	• "These same materials have been **used for many years** in **cardiac stents** and other medical devices placed in other parts of the

	body." *See* 2012 PIB at 11 (RJN, Ex. P); 2015 PIB at 11 (RJN, Ex. O); 2008 PIB at 4 (RJN, Ex. R) (similar).
• "Essure is the **most effective** permanent birth control available." FAC ¶ 212(g).	• "The Essure procedure is **99.83% effective** based on five-year clinical study data." 2012 PIB at 5 (RJN, Ex. P). • Comparing Essure with both tubal ligation and vasectomy procedures, and **reporting a rate of failure for each that is higher than that of Essure**. 2012 PIB at 15-16 (RJN, Ex. P); *see also* 2008 IFU at 3 (RJN, Ex. Q) (same); 2013 IFU at 5-6 (RJN, Ex. L); 2015 PIB at 15-19 (RJN, Ex. O).
• "[T]he PET fibers are what caus[es] the tissue growth." FAC ¶ 212(i).	• "PET fiber causes tissue in-growth into and around the insert, facilitating insert retention." *See* 2013 IFU at 2 (RJN, Ex. L).

Because these purported "misrepresentations" and "warranties" track FDA-approved statements, Plaintiffs' claims for negligent and fraudulent misrepresentation and for breach of express warranty are expressly preempted.[4] *See* 21 U.S.C. § 360k(a); *see also Williams*, Ex. C, at 8-11 (affirming dismissal of misrepresentation claims based on statements "functionally equivalent to those in the Essure labeling," because prevailing on such claims "would require a finding contrary to that reached by the FDA"); *Norman*, 2016 WL 4007547, at *5-6 (dismissing as preempted Essure plaintiff's claims for breach of warranty and negligent misrepresentation because claims were "so similar to the approved language as to be substantively the same"); *De La Paz*, 159 F. Supp. 3d at 1098 (dismissing as preempted Essure plaintiff's claims for "negligent

[4] Plaintiffs' negligent misrepresentation claim is also inadequately pled. Under Illinois law, negligent misrepresentation requires proof of, among other elements, "a false statement of a material fact" and "action by the other party in reliance on the truth of the statement." *Capiccioni v. Brennan Naperville, Inc.*, 791 N.E.2d 553, 562 (Ill. App. Ct. 2003). Here, Plaintiffs plead *no* plaintiff-specific facts regarding which statements the Plaintiffs reviewed, when they reviewed the statements, and how each of them relied upon the statements. *See* FAC ¶¶ 202-227. The misrepresentation claim should be dismissed for this additional reason. *Norman*, 2016 WL 4007547, at *6 (dismissing a similar claim because plaintiff did "not allege that she read or saw any of the[] statements").

misrepresentation" concerning Essure because "the statements conformed to statements approved by the FDA"); *Burrell*, 2017 WL 1955333, at *8 (dismissing misrepresentation claims based on statements "indistinguishable from FDA-approved labeling statements"); *Richardson*, 2016 WL 4546369, at *9 (holding similar).

Plaintiffs' claims based on such statements are preempted because their success depends on "second-guess[ing] the FDA's judgment, a result that the express preemption provision of the MDA prevents." *Williams*, Ex. C, at 11. Claims that target "marketing that complied with the FDA-approved requirements" must be dismissed, "because success on [such a] claim[] requires a showing that the FDA requirements themselves were deficient." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 933 (5th Cir. 2006).

D. Plaintiffs' Failure To Warn Claims Are Preempted.

Plaintiffs base their failure to warn claims on two theories. Like the plaintiffs in *In re Medtronic*, Plaintiffs here "d[o] not allege that [Bayer] modified or failed to include FDA-approved warnings." 623 F.3d at 1205. Instead, they (1) challenge the FDA-approved labeling as false, misleading, and inadequate, and (2) allege that Bayer failed to report adverse events and other information to FDA. Neither type of claim falls within the "gap" between express and implied preemption.

First, Plaintiffs allege that Essure's labeling failed to adequately warn consumers and the medical community of its risks. *See* FAC ¶¶ 144-45, 151, 340-43, 387-90, 439-42, 447-48. Plaintiffs, however, do not allege that the warnings Bayer provided in any way deviated from the FDA-approved language. Courts have routinely held that state-law claims that would require additional warnings or information beyond what FDA required are "precisely the type[s] of state requirements that [are] 'different from or in addition to' the federal requirement[s] and therefore

are preempted." *In re Medtronic*, 623 F.3d at 1205; *Gomez*, 442 F.3d at 929; *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993) (claims challenging the adequacy of "FDA-regulated packaging and labeling" were preempted); *Caplinger*, 784 F.3d at 1345; *Perez*, 711 F.3d at 1118; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011). For this reason, highly similar claims concerning Essure have been consistently dismissed as preempted. *See Norman*, 2016 WL 4007547, at *3.

Plaintiffs allege that Bayer could have unilaterally provided additional warnings, *see, e.g.*, FAC ¶ 144, but these allegations do not save their claims. "Because § 814.39 *permits*, but does not *require*, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation" and is expressly preempted. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489-90 (7th Cir. 2005) (emphasis added); 21 C.F.R. § 814.39(d); *see also In re Medtronic*, 623 F.3d at 1205.

Second, Plaintiffs allege that Bayer failed to report adverse events in a timely and adequate manner to FDA. *See, e.g.*, FAC ¶¶ 342-47, 387, 439. Plaintiffs claim that had Bayer "timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physician, of those adverse events," and that "if Plaintiffs and Plaintiffs' physicians had been adequately warned of these serious and adverse events, they would not have agreed to or used the Essure implant." *Id.* ¶¶ 347, 351.

Burrell, *Norman*, and *De La Paz* dismissed this claim as well. *See Norman*, 2016 WL 4007547; *De La Paz*, 159 F. Supp. 3d 1085; *Burrell*, 2017 WL 1955333, at *5. The claim is impliedly preempted under *Buckman*, because it is "simply an attempt by [a] private part[y] to enforce the MDA." *In re Medtronic*, 623 F.3d at 1205; *see also Norman*, 2016 WL 4007547, at *3-4. In *Buckman*, the Supreme Court made clear that "it is the Federal Government rather than

private litigants who are authorized to file suit for noncompliance" with FDA reporting requirements. 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337). Because Plaintiffs' state law action for such noncompliance would "inevitably conflict with the FDA's responsibility to police fraud consistently," it is impliedly preempted by federal law. *Id.* at 350. Plaintiffs cast their claim as one of Illinois common law, but "a common law claim"—to the extent it exists under state law—"may be *impliedly* preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014) (internal quotes omitted).[5]

This claim also fails because Plaintiffs do not allege a plausible causal nexus between Bayer's supposed failure to report adverse events and their injuries. According to Plaintiffs' allegations, FDA is now in possession of all of the supposedly withheld information. FAC ¶¶ 159-60 (alleging that FDA analyzed various complaints in connection with its 2011 inspection); *id.* ¶¶ 170-71 (alleging that FDA analyzed various complaints in connection with

[5] In *Stengel v. Medtronic Inc.*, the Ninth Circuit held a failure-to-warn claim was not preempted where the plaintiff alleged a failure to provide information to FDA because "Arizona law contemplates a warning to a third party such as the FDA." 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *see also Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (same, "[a]ssuming that a failure to warn [the FDA] claim may be pursued under Mississippi law"). *Stengel* is inapposite because there, unlike in this case, "given the nature of the warning and the relationship of the third party, there [was a] reasonable assurance that the information w[ould] reach" plaintiff's physician and affect his treatment decision had it been disclosed. 704 F.3d at 1233. Here, by contrast, FDA's recent Guidance confirms that the allegedly new information would not have made a difference. *See* FDA Guidance (RJN, Ex. T); *see also* pp. 29–30, *infra*. Moreover, because *Stengel* runs counter to the Supreme Court's holding in *Buckman*, it is wrongly decided, and this court should follow the persuasive decision of the Eighth Circuit, *In re Medtronic*, 623 F.3d at 1205-06. Nor is there an equivalent cause of action for failure to warn third parties in this context under Illinois law. *See Norman*, 2016 WL 4007547, at *4 (distinguishing *Stengel* under Connecticut law); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 200-01 (E.D.N.Y. 2015) (same under New York law).

2013 inspection).[6] Despite having reviewed and considered these allegedly withheld reports and additional medical literature, FDA has never withdrawn its approval of Essure. To the contrary, FDA found "no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure," FDA Activities (RJN, Ex. M), and reaffirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," FDA News Release (RJN, Ex. F).

As *Norman* held, Plaintiffs' attempt to invoke FDA's recent boxed warning and Patient Decision Checklist only further undermines their claims. 2016 WL 4007547, at *4. After holding a public hearing "concerning the safety and efficacy of [] Essure," during which FDA considered the allegedly withheld complaints, *see* FAC ¶ 226, FDA did not require Bayer to change its disclosures on the percentage of patients who may be injured, the number of adverse events, or the rate of unintended pregnancies. Instead, FDA released a "boxed warning" for all "devices of this type," because the agency believes "that some women are not receiving or understanding information regarding the risks and benefits." FDA Guidance at 5-6 (RJN, Ex. T). As *Norman* held, this "new *type* of warning did not change any of the warnings' substance," 2016 WL 4007547, at *4. Rather, the same information was already in Essure's labeling:

[6] Plaintiffs' repeated attempts to highlight the number of complaints received by Bayer relative to the number of MDRs submitted, *see, e.g.*, FAC ¶ 160, also ignore the fact that there is no obligation blindly to report all "complaints" to the agency. *See* 21 C.F.R. § 820.198(d) (providing additional procedures for "[a]ny complaint that represents an event which must be reported to FDA"). Plaintiffs point to no FDA finding that the complaints on these spreadsheets were adverse events that should have been reported to FDA but were not.

Essure Labeling *RJN, Ex. P (2012 PIB)* *RJN, Ex. S (2011 IFU)*	**Boxed Warning** *RJN, Ex. T (2016 FDA Guidance)*
• "To reduce **the risk of uterine perforation**, the procedure should be terminated if excessive force is required to achieve cervical dilation . . . ." (IFU, 2).	• "Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including **perforation of the uterus and/or fallopian tubes**, identification of **inserts in the abdominal or pelvic cavity**, **persistent pain**, and **suspected allergic or hypersensitivity reactions**. If the device needs to be removed to address such an adverse event, **a surgical procedure will be required**." (Guidance, 9).
• "In rare cases, part of an Essure insert may **puncture the fallopian tube.**" (PIB, 7).	
• "Potential adverse events" include "[p]erforation of **internal bodily structures other than the uterus and fallopian tube**." (IFU, 2).	
• "A very small percentage of women in the Essure procedure clinical trials reported recurrent or **persistent pelvic pain.**" (IFU, 2).	
• "Patients who are allergic to nickel may have an **allergic reaction** to the inserts. **Symptoms** include rash, itching and hives." (PIB, 8).	
• "[I]f device removal is required for any reason, it will likely **require surgery**, including an **abdominal incisions** and general anesthesia, and possible hysterectomy." (IFU, 2).	

Thus, Plaintiffs' conclusory assertion that had Bayer "timely and adequately reported the adverse events to the FDA," it would have resulted in additional warnings to physicians is insufficient to allege causation, and the claim is preempted. FAC ¶ 347. As *Burrell*, *Norman*, and *De La Paz* held, it should be dismissed.

IV. PLAINTIFFS FAIL TO PLAUSIBLY PLEAD A CLAIM FOR RELIEF.

Plaintiffs' complaint also fails for the separate reason that, pursuant to 735 Ill. Comp. Stat. § 5/2-615, it does not state any valid cause of action under Illinois law. First, as described above, Plaintiffs assert a claim based on Bayer's alleged failure to report adverse events to FDA, but no such claim has been recognized under Illinois law. *See* n.4, *supra*. In addition, all of the claims fail to make more than conclusory allegations that Bayer's actions caused Plaintiffs' alleged injuries, a necessary element of each cause of action. Plaintiffs' fraud claims also fail

because they do not allege adequate facts to establish that Bayer made false statements or that Plaintiffs and their physicians relied on them—necessary elements of each claim.

A. Plaintiffs Fail To Plead Causation Adequately.

Under Illinois law, "[i]t is a fundamental principle applicable alike to breaches of contract and to torts, [that] in order to found a right of action there must be a wrongful act done and a loss resulting from that wrongful act; the wrongful act must be the act of the defendant, and the injury suffered by the plaintiff must be the natural and not merely a remote consequence of the defendant's act." *Town of Thornton v. Winterhoff*, 92 N.E.2d 163, 166 (Ill. 1950). "Cause in fact can only be established when there is a reasonable certainty that a defendant's acts caused the injury." *Yager v. Ill. Bell Tel. Co.*, 667 N.E.2d 1088, 1093 (Ill. App. Ct. 1996). Plaintiffs fail to make such a showing for any of their claims, and thus, they should be dismissed.

Plaintiffs do not plead facts connecting any alleged wrongful act by Bayer with their injuries. For most of the claims, they state only that, "[a]s a proximate result" of Bayer's actions, "Plaintiffs suffered and will continue to suffer [injuries]." FAC ¶ 390; *see also id.* ¶¶ 417 (similar), 430 (similar), 455 (similar), 457 (similar). Such "[p]leadings which state mere conclusions and characterize acts rather than set forth facts are insufficient to state a cause of action." *Dangeles v. Muhlenfeld*, 548 N.E.2d 45, 48 (Ill. App. Ct. 1989); *see also City of Chi.*, 821 N.E.2d at 1112-13 (quoting *Knox Coll.*, 430 N.E.2d at 985). The Complaint should be dismissed for this additional reason, as multiple courts have held in other Essure cases. *See, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *6.

B. Plaintiffs Fail To Plead Their Misrepresentation Claims Adequately.

Plaintiffs' fraud claims are deficient because they are not pleaded with sufficient particularly. Plaintiffs allege that Bayer "made affirmative representations to Plaintiffs . . . [that] Essure was safe and effective" and "intentionally, willfully, and maliciously concealed and/or

suppressed" material facts regarding Essure from Plaintiffs and their physician. FAC ¶¶ 447-48. Such claims must satisfy heightened pleading standards, which require that Plaintiffs "allege, with specificity and particularity, facts from which fraud is the necessary or probable inference, including what misrepresentations were made, when they were made, who made the misrepresentations and to whom they were made." *Connick v. Suzuki Motor Co., Ltd.*, 675 N.E.2d 584, 591 (Ill. 1996). Plaintiffs must allege with "sufficient particularity the facts that make the defendant's omission or concealment material." *White v. DaimlerChrysler Corp.*, 856 N.E.2d 542, 550 (Ill. App. Ct. 2006).

As in *McLaughlin I*, the Complaint here "makes no effort to inject[] precision by either pleading the date, place or time of the alleged fraud or by using any alternative means to substantiate the allegations." 172 F. Supp. 3d at 829. The Complaint does not specifically allege who was responsible for the supposedly fraudulent utterances or omissions, or when they were made (or not made), or indicate *when*, *where*, and *how* Plaintiff encountered or relied upon the myriad misstatements or omissions alleged. Bayer is thus without notice of the precise misconduct that is allegedly fraudulent. As *McLaughlin I* recognized, this is precisely the sort of prejudice that heightened pleadings standards are designed to avert. *See id*. Because Plaintiffs have not satisfied this burden, these fraud claims should be dismissed.

Finally, Plaintiffs' complaint includes several requests for punitive damages. *E.g.*, FAC ¶¶ 459–67. Under 735 Ill. Comp. Stat. § 5/2.604.1, "no complaint shall be filed containing a prayer for relief seeking punitive damages." Any of Plaintiffs' claims for punitive damages should therefore be struck.

CONCLUSION

For these reasons, the Court should dismiss the complaint as to the non-Illinois Plaintiffs for lack of personal jurisdiction, 735 Ill. Comp. Stat. § 5/2-301, and the complaint as to all

Plaintiffs as being preempted pursuant to 735 Ill. Comp. Stat. § 5/2-619, and for being insufficient in law pursuant to 735 Ill. Comp. Stat. § 5/2-615.

DATED: DECEMBER 15, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on December 15, 2017, a true and correct copy of the foregoing was served upon the following by enclosing same in an envelope addressed as below, with proper first class postage fully prepaid, and depositing same in the U. S. Mail at Edwardsville, Illinois, at 5 p.m.:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et. al.,	)	
	)	
Plaintiffs,	)	Case No. 16-L-1046
	)	
v.	)	Hon. Dennis R. Ruth
	)	
BAYER, CORP., et al.,	)	
	)	
Defendants.		

PLAINTIFFS' RESPONSE IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

Defendants' (collectively "Bayer" or "Defendants") attempt at making this case go away should be rejected for several reasons:

1. Bayer's reliance on *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County* (*BMS*) is misplaced. 137 S. Ct. 1773 (2017). *BMS* does not apply to this case. Bayer tirelessly quotes *BMS* throughout its motion to dismiss, all the while ignoring every fact that makes this case materially distinguishable from *BMS*.

2. Bayer's mischaracterization of Plaintiffs' claims as an effort to second guess the FDA is unavailing. Bayer's recitation of federal preemption law is far too narrow. As **all** of the cases Bayer relied upon—as well as many others—have found, preemption does not afford indiscriminate immunity from liability for violations of state law that parallel federal regulations.

3. Plaintiffs' claims are adequately pled to satisfy the Illinois pleading requirements. Plaintiffs have alleged violations of Illinois law which mirror federal laws and regulations. And Plaintiffs have adequately tied those violations to their injuries.

4. Bayer's improperly seeks this Court's dismissal of the nonresident Plaintiffs based on forum non conveniens because FNC is premised on severance of their claims. Further, it is

Bayer's burden to prove FNC is warranted, which it does not come close to doing in the roughly one page it devoted to FNC in its Motion.

As Plaintiffs will demonstrate below, Bayer's Motion to Dismiss should be denied in its entirety.

I. BACKGROUND

A. Essure Medical Device

Essure® is a Class III medical device designed as a form of permanent female birth control through bilateral occlusion of the fallopian tubes. Essure® consists of (1) micro-inserts; (2) a disposable delivery system; and (3) a disposable split introducer. The micro-inserts contain an inner coil made of stainless steel, polyethelene terephthalate (PET) fibers, and an outer coil made of nickel titanium (Nitinol). Physicians implanting Essure® visualize the procedure through hysteroscopic guidance using equipment supplied by Bayer. The hysteroscopic equipment needed to place Essure® was manufactured by a third party and is not a part of Essure®. The micro-inserts or coils are supposed to remain securely in place in the fallopian tubes for the life of the consumer and not migrate, break, or corrode.

B. Medical Device Statutory Background

In 1976, Congress enacted the Medical Device Amendment (MDA) to extend the coverage of the Food, Drug & Cosmetic Act (FDCA) to medical devices. The MDA "classifies medical devices in three categories based on the risk that they pose to the public." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). "Class III devices 'presen[t] a potential unreasonable risk of illness or injury' and therefore incur the FDA's strictest regulation." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)(II)). "Before a new Class III device [like Essure®] may be introduced to the market, the manufacturer must provide the FDA

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

The MDA includes an express preemption clause, 21 U.S.C. § 360k(a). This clause preempts any state-law "requirement" with respect to a particular medical device "(1) which is different from, or in addition to, any requirement applicable under this chapter to the device and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." *Id.*

C. **Essure® PMA**

Premarket Approval (PMA) is the process the FDA uses to evaluate the safety and efficacy of Class III medical devices, such as Essure®. Class III medical devices are "generally the highest risk devices." Class III devices are those that "present a potential, unreasonable risk of illness or injury," among other things. In November 2002, the FDA approved Bayer's PMA application for Essure®.

In order to comply with the Essure® PMA, Bayer was required to comply with a number of post-approval conditions as well:

- Submit post-approval reports including "unpublished reports of data from any clinical investigations or nonclinical laboratory studies . . . and reports in the scientific literature concerning the device."
- Report any adverse reaction not addressed in Essure® labeling; or if the reaction was addressed in the label report, if the reaction was occurring with unexpected severity or frequency.
- Report adverse events under the Medical Device Reporting (MDR) Regulation if Essure® may "have caused or contributed to a death or serious injury; or [h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur"; and

- Include in its Annual Report any failures of the device meeting the specifications outlined in the PMA, which would have been correctable by procedures described in the Essure® labeling.

II. ARGUMENT

A. Illinois Courts Have Personal Jurisdiction Over Bayer

1. Standard for Personal Jurisdiction

When a court considers whether it should exercise personal jurisdiction over a nonresident defendant, it is the plaintiff who bears the initial burden to establish a prima facie case for exercising jurisdiction. *Russell v. SNFA,* 2013 IL 113909, ¶ 28, 987 N.E.2d 778, 784 (Ill. 2013). We resolve any conflicts in the pleadings and affidavits in favor of the plaintiff seeking jurisdiction, "but the defendant may overcome [the] plaintiff's prima facie case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Id.*

Personal jurisdiction analysis begins by looking at "the relationship among the defendant, the forum, and the litigation." *Walden*, 134 S. Ct. at 1121. There are two types of personal jurisdiction, specific and general. *Id*. at n.6. A court has specific jurisdiction over an out-of-state defendant when a suit arises out of or relates to the defendant's contact with the forum. *Id*.

Personal jurisdiction is established by the forum-state's laws and constitutional due process. *See Intercon, Inc. v. Bell Atl. Internet Solutions*, 205 F.3d 1244, 1247 (10th Cir. 2000). Illinois's long-arm statute provides that "a court may exercise jurisdiction in any action arising within or without this State against any person who: [i]s a natural person or corporation doing business within." 735 ILCS 5/2-209(b)(4). Additionally, a catch-all provisions allows the Court to "exercise jurisdiction on any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States." 735 ILCS 5/2-209(c). Because of the catch-all provision, Illinois' long-arm statute is now coextensive with constitutional limitations imposed by the Due Process Clause. *Russell*, 2013 IL 113909, ¶ 28.

2. Bayer's Reliance on *BMS* is Misplaced

Throughout its motion, Bayer touts *BMS* as dispositive of personal jurisdiction here. But *BMS* does not govern this case. To have *Hamby* fall within *BMS*, Bayer must ignore the dispositive differences between the facts of *BMS* and these.

BMS involved in-state and out-of-state plaintiffs who sued in California regarding their use of Plavix. 133 S. Ct. at 1778. The holdings of *BMS* can be summarized as follows:

- "The primary focus of our personal jurisdiction inquiry is the *defendant's* relationship to the forum State." *Id.* at 1779 (citing *Walden v. Fiore*, 134 S. Ct. 1115, 1121–23 (2014)) (emphasis supplied).

- "In order for a state court to exercise specific jurisdiction, 'the *suit*' must 'aris[e] out of or relat[e] to the defendant's contacts with the '*forum*.'" *Id.* at 1780 (quoting *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014)) (alterations in original).

- "[T]here must be 'an affiliation between the forum and the underlying controversy, principally, [an] activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation.'" *Id.* (quoting *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011)) (alteration in original).

- "When there is no such connection, specific jurisdiction is lacking regardless of the extent of a defendant's unconnected activities in the State." *Id.* at 1781 (citing *Goodyear*, 564 U.S. at 931 n.6).

But the Supreme Court observed that **"BMS did not develop Plavix in California, did not create a marketing strategy for Plavix in California, and did not manufacture, label, package, or work on the regulatory approval of the product in California."** *Id.* That is not the case with Essure. Bayer tries to stretch the *BMS* opinion too far. Bayer goes to great lengths to try to diminish its Illinois clinical trial activity and development of a nationwide marketing and

accreditation campaign, to convince this Court that those activities are the type that *BMS* found insufficient. As Plaintiffs have alleged in their First Amended Complaint, Bayer conducted clinical trials in Illinois and used Illinois as a testing ground for its nationwide marketing campaign and physician training program. The clinical trials conducted in Illinois directly relate to all Plaintiffs' claims, regardless of state, because without these clinical trials Plaintiffs would never have had Essure implanted. *Id*. At least one court agrees with this approach. In *Cortina v. Bristol-Myers Squibb Co.*, a court analyzed this very issue:

> Lastly, the Court notes that the United States Supreme Court recently held in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, that the fact that a defendant had research and laboratory facilities, sales representatives, and sales and marketing operations in a forum state was insufficient to justify the exercise of specific jurisdiction in the absence of an "adequate link between the State and the nonresidents' claims." —— S.Ct. ——, 2017 WL 2621322, at *8 (2017). The present case is distinguishable from *Bristol-Myers*. . . . In this case, Plaintiff alleges that "nearly every pivotal clinical trial necessary for NDA approval involved studying of the Saxagliptin drugs throughout the State of California," and that "but for the pre-NDA development of the Saxagliptin drugs within the State of California, the drugs would not have been sold and marketed throughout the U.S. nor ingested by Plaintiff." ECF No. 27 at 5. This linkage between Defendants' in-state clinical trial activity and Plaintiff's injury is sufficient to satisfy the Ninth Circuit's "but for" test.

No. 17-CV-00247-JST, 2017 WL 2793808, at *4 (N.D. Cal. June 27, 2017). And, as already discussed, the First District has previously followed similar reasoning. *See M.M. ex rel. Meyers*, 61 N.E.3d at 1041. This case is no different.

Bayer developed Essure using Illinois clinical trials, created a marketing strategy for Essure in Illinois, and worked on the regulatory approval of Essure using Illinois investigators and physicians. The conduct about which Plaintiffs complain occurred through Bayer's contacts with Illinois. For example, Plaintiffs cite a whole host of false and misleading marketing tactics, all of which can be tied to the strategy developed in Illinois. *See* FAC ¶¶ 10, 11, 202–227. Plaintiffs go

on to claim that Bayer's contacts with Illinois were integral to its ability to distribute Essure to all Plaintiffs and Plaintiffs' implanting physicians. *See, e.g.*, *id.* at ¶ 321. But for Bayer's conduct in Illinois, Plaintiffs would not have been harmed.

Furthermore, the patient awareness marketing strategy developed in Illinois is much more than just an Illinois woman or physician seeing a commercial or print ad for Essure. The Essure marketing strategy that was eventually rolled out to the entire country was created from of Bayer's Illinois contacts. In *BMS*, the Court noted that the defendant **did not** "create a marketing strategy for Plavix in California." This is not the case here. **Without Illinois**, Bayer's scheme of fraudulent and misleading marketing, as alleged in Plaintiffs' First Amended Complaint, would not have been possible. This distinction matters jurisdictionally. These activities in Illinois establish specific jurisdiction.

Bayer ignores facts significant to personal jurisdiction:

(1) Bayer chose Illinois to conduct these clinical activities,

(2) it developed a nationwide marketing strategy in Illinois, and

(3) it chose Chicago, Illinois as a test-bed city for its physician marketing and accreditation program.

In short, Bayer chose Illinois for Essure. These jurisdictional contacts are much more far reaching than simply having a patient choose Essure in her doctor's office in Illinois, as Bayer would like this Court to believe. After having chosen Illinois testing and developing a marketing plan, Bayer cannot now contend that Illinois courts do not have jurisdiction over claims related to its conduct there.

3. Court has Specific Jurisdiction

In support of Plaintiffs' prima facie showing of this Court's personal jurisdiction over Defendants, Plaintiffs have attached the Affidavit of Cheryl Blume, PhD as Exhibit A. Dr. Blume

has been repeatedly recognized as an expert on drug and medical device safety and regulatory approval by multiple courts. Dr. Blume's opinions demonstrate that Plaintiffs' claims arose out of, or relate to Defendant's clinical trial, marketing, and physician training activities in Illinois. Specific jurisdiction exists because Plaintiffs' claims arise out of Bayer's conduct in Illinois, and Plaintiffs' claims are related to this conduct. Specific jurisdiction is established by the following facts:

- The Defendants conducted the pivotal clinical trials for Essure in Illinois. FAC at ¶¶ 11, 122; *see also* Aff. of Cheryl Blume, attached as Exhibit A;
- Data from the Illinois trials was included in the Essure PMA material and was directly related to its regulatory approval. FAC at ¶ 11, 134; *see also* Ex. A;
- Bayer contracted with Illinois doctors and facilities to help conduct the clinical trials, even selecting Illinois-based physician, Rafael Valle, to respond directly to specific comments from FDA. FAC at ¶¶ 11, 205; *see also* Ex. A;
- Illinois was a critical test bed for the Defendants marketing and advertising for Essure, and that success of that program was utilized to conduct marketing nationwide. FAC at ¶¶ 10, 11, 206, 213; *see also* Ex. A; and
- Bayer launched its Essure Accreditation Program, a physician training program, in Illinois. FAC at ¶¶ 11, 207, 213; *see also* Ex. A.

4. Bayer's Clinical Trial Activity

Bayer ran its clinical trials relating to Essure in Illinois from at least 2000 to 2002. FAC at ¶¶ 11, 12, 134. And in addition to pre-approval clinical trials, Defendants also conducted one of their post-approval FDA mandated studies—conducted to assess the long-term safety and effectiveness of Essure—in Illinois. FAC at ¶ 11. And ultimately out of those trials came the misinformation

regarding the product's safety and effectiveness described in the Complaint. *Id* at ¶¶ 11, 12. Almost the exact same circumstances were considered in *M.M. ex rel. Meyers v. GlaxoSmithKline LLC*, and were found to be sufficient for specific personal jurisdiction as to both resident and non-resident plaintiffs. *See* 2016 IL App (1st) 151909, ¶ 71–72, 61 N.E.3d 1026, 1041 (1st Dist. 2016) *appeal denied sub nom. M.M. v. GlaxoSmithKline LLC*, 65 N.E.3d 842 (Ill. 2016), *and cert. denied*, No. 16-1171, 2017 WL 1153625 (U.S. Oct. 2, 2017) ("[P]laintiffs' injuries allegedly arose from acts of omission during the clinical trials and the resulting inadequate warning labels. . . . Defendant GSK has failed to overcome plaintiffs' *prima facie* showing that their claims arose from or related to defendant GSK's Illinois activities.").[1] In fact, Bayer is conducting **three** Essure clinical trials in Illinois **right now**. FAC at ¶ 11(j).

Further, Bayer complains that exercising jurisdiction based on clinical trial activities would subject it to jurisdiction "in nearly any state in the country." Mot. at 15. However, if the Court were to entertain this contention, it would require a bright-line rule setting out some threshold level of activity that would confer jurisdiction.[2] That is not the law. It does not matter how many clinical trials were conducted in Illinois versus other states,[3] but rather the question turns on the

[1] Bayer tries to distance itself from *Meyers* by claiming that it was pre-*BMS* and therefore any holding regarding clinical trials and personal jurisdiction is "no longer good law" post-*BMS*. Resp. at 11. However, this position is directly contrary to Bayer's position in other cases. Indeed, Bayer just finished arguing that *BMS* did **not** change the law, but rather was based on "settled principles regarding specific jurisdiction." *See State ex rel. Bayer Corp. v. Hon. Joan Moriarty*, No. SC96189, Reply Brief of Relators, at 6. According to this version of Bayer's argument, since *BMS* did not change the law, it is irrelevant that *Meyers* was decided pre-*BMS*.

[2] If the meaningfulness of the activity is not considered, the Court would have to decide what percentage of clinical trial activity was enough for personal jurisdiction. For example, surely one-hundred percent of clinical trial activity in a forum state would give rise to personal jurisdiction; but what about seventy-five percent, or forty-five percent?

[3] Bayer's claim that since Essure plaintiffs in other states are also arguing that Bayer's clinical trials confer specific jurisdiction in those states misses the point. Mot. at 13. Personal jurisdiction turns on whether the trials in those states equate to meaningful contacts in relation to Plaintiffs'

meaningfulness of those contacts. *In re Syngenta Mass Tort Actions*, No. 3:16-CV-00255-DRH, 2017 WL 2117728, at *5 (S.D. Ill. May 15, 2017) ("It did not matter that a small percentage of the clinical trial took place in Illinois, a plaintiff only has to prove a *proper* place for personal jurisdiction. And a proper place for personal jurisdiction is when there is a nexus between a defendant's actions and plaintiff's cause of action that does not disrupt the quid pro quo.") (citing *Meyers*, 61 N.E.3d at 1040).

A California court recently issued a decision which supports Plaintiffs' claims. *DellaCamera v. DePuy Orthopaedics, Inc.*, involved plaintiffs from Connecticut and a defendant based in Indiana. No. CJC-10-004649, at 6 (Cal. Sup. Ct. Nov. 1, 2017) (attached as Exhibit B). The court held that defendant's use of two California surgeons in developing the design of the ASR hip implant was sufficient for personal jurisdiction over nonresident defendants. *Id.* at 5. The court reasoned that "the Nonresident Defendants' decision to consult and/or collaborate with two California residents on the design of the product at issue, even making one of them 'lead surgeon designer' for the product, demonstrates that Plaintiffs' claims 'arise out of' the Nonresident Defendants conduct in California." *Id.* at 6.

The same holds true here. Bayer chose to "consult and/or collaborate with" Illinois physicians to evaluate the safety and effectiveness of Essure in the Pivotal Trial. Moreover, **all** Plaintiffs' claims can be tied to the clinical trial activity in Illinois. Plaintiffs do not need to allege that they were clinical trial participants, or had Essure implanted in Illinois to satisfy their *prima facie* burden on personal jurisdiction, as Bayer would have this Court believe. Plaintiffs have alleged

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causes of action, and "not at all on a percentage-based comparison between how much related conduct occurred outside of Illinois." *Meyers*, 61 N.E.3d at 1041. It very well may be that Bayer is subject to personal jurisdiction in multiple states due to its clinical trial activity, if Bayer's contacts with those states are meaningful.

that Bayer negligently conducted clinical trials (FAC ¶ 9), falsified records of clinical trial participants (FAC ¶ 137), misrepresented the number of pregnancies in the clinical trials (FAC ¶ 212), and but for Bayer's actions in its Illinois clinical trial, Plaintiffs never would have had Essure implanted. FAC ¶ 12. These contacts are enough to meet Plaintiffs' burden regarding personal jurisdiction.

5. Bayer's Marketing and Accreditation Activities

Even though its clinical trial activity is enough to bestow personal jurisdiction in Illinois, Bayer also orchestrated a patient awareness marketing campaign and Essure Accreditation Program in Illinois. FAC at ¶¶ 10, 11, 206, 213; *see also* Ex. A. The marketing campaign included radio, print, and direct mail advertisements, scheduled to arrive weekly to the offices of local Chicago physicians. *Id.* In addition, the pilot program for the Essure Accreditation Program—a physician training program—that Conceptus created was carried out in the Chicago area. If the Chicago-area campaign was successful, Conceptus's goal was to roll out additional consumer campaigns in other cities across the U.S. FAC at ¶¶ 11, 207.

Bayer tries to trivialize these programs by suggesting that they do not create personal jurisdiction because the non-Illinois Plaintiffs did not view the materials in Illinois. Mot. at 11–12. But that is not what Plaintiffs allege. In fact, Plaintiffs allege that the success of the patient awareness campaign, forged in Illinois, was the impetus for rolling out the identical campaign across the country, including Plaintiffs' home states. The false and misleading marketing that proved so successful in Illinois was ultimately disseminated nationwide. Without the success of the Illinois patient awareness program, Plaintiffs would not have seen, nor relied upon, the misrepresentations outlined in their First Amended Complaint.

In addition, the FDA *required* Bayer to adhere to training guidelines and requirements. The physician training program Bayer developed to meet this requirement—the Essure Accreditation

Program—was created solely in Illinois. Every single implanting physician was required to undergo training. And Plaintiffs have adequately tied their injuries to this Illinois training program. Plaintiffs specifically pled that Bayer failed to train their implanting physicians, including the failure to ensure their physicians successfully completed five preceptorings, to ensure they understood the Essure training manual, and to ensure they successfully completed simulator training. FAC ¶ 389. Thus, Bayer's inadequate training program, developed exclusively in Illinois, is meaningfully connected to **all** Plaintiffs' claims. Accordingly, these activities in Illinois establish specific jurisdiction.

B. **Plaintiffs' Claims are not Preempted.**

Preemption is not wholesale immunity from liability. It is axiomatic that Congress did not intend to give complete protection from civil liability to medical device manufacturers for violations of federal law that injure patients. As the Supreme Court has repeatedly held, violations of state law claims that parallel federal requirements are not preempted. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 312 (2008); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). In pleading parallel state law claims, a plaintiff's only burden is to put forth facts that make the claim plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

Nevertheless, despite this powerful precedent allowing claims such as Plaintiffs' to proceed, Bayer attempts to persuade this Court that it should enjoy complete insulation from liability. As this Court will see, Bayer's attempt fails.

First, Bayer greatly exaggerates those orders. Bayer Motion at 13. In reality, the orders Bayer relies upon are more favorable to Plaintiffs than they are to Bayer. In fact, the orders cited

did not expressly or impliedly preempt many of the plaintiffs' claims.[4] A close examination of these orders establishes that Plaintiffs' claims are not preempted for several reasons:

- Their claims are due to Bayer's conduct that violated provisions of the Food, Drug, & Cosmetic Act (FDCA), the Medical Device Amendments (MDA), or Essure® Premarket Approval (PMA);
- Their claims are based on parallel state law claims that are not "different from, or in addition to" Essure® federal requirements. *See Riegel*, 552 U.S. at 312; and
- Bayer's conduct in violation of both state and federal law caused their injuries.

Additionally, Bayer also contends that Plaintiffs' claims fail to meet plausibility standards. But as the FAC shows, Plaintiffs have sufficiently alleged that Bayer's conduct was the cause of their injuries. Should the Court find the complaint at all deficient, however, Plaintiffs respectfully ask leave to amend.

1. Anti-Preemption Presumption

There is a "basic presumption against pre-emption." *See Bates v. Dow Agrosciences, LLC*, 544 U.S. 431, 449 (2005). Parties seeking preemption protection must overcome a considerable burden. "The presumption against preemption is heightened 'where federal law is said to bar state action in fields of traditional state regulation.'" *Riegel*, 552 U.S. at 334 (quoting *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)). "Federal laws containing a preemption clause do not automatically escape the presumption against preemption." *Id.* When a statutory preemption clause is subject to more than one plausible interpretation, courts usually "accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at

[4] Rather than preemption, some of the plaintiffs' claims were dismissed due to perceived deficiency in pleadings. But to the extent that plaintiffs' claims were dismissed, they were almost always allowed leave to amend. Specifically related to *Norman*, the complaint had already been amended a number of times, and therefore the court determined that further amendment would be futile. While Plaintiffs do not agree with this finding, it is inapplicable here as Plaintiffs have only amended their complaint once.

449. This presumption is particularly strong in tort cases like this one because the states have historically enjoyed broad powers to protect the "lives, limbs, health, comfort, and quiet of all persons." *Slaughter House Cases*, 16 Wall 36, 62 (1873).

Accordingly, preemption under the MDA is not unlimited. *Riegel*, 552 U.S. at 330. Rather, state law claims that are not different from or in addition to federal law are not expressly preempted, as such duties "parallel," rather than add to, federal requirements. *Id*. This exception to preemption includes state law claims based on a Class III device's violation of its own premarket approval standards—precisely the case here. *Id.*

2. Overview: Few Preemption Holdings

Bayer maintains that "other courts" have preempted claims like Plaintiffs'. But Bayer exaggerates the reach of preemption. A closer look at the orders Bayer cites establishes that Plaintiffs' claims are ***not*** subject to preemption. For instance, the *McLaughlin* court found:

- Negligent Risk Management: **Not preempted** to the extent Plaintiff seeks to hold Bayer to federal risk management standards; and
- Breach of Express Warranty: **Not preempted** because the claim arose from alleged contracts between the parties; and
- Negligent Misrepresentation: **Not preempted** to the extent that the misrepresentations were inconsistent with FDA materials; and
- Negligent Manufacturing: **Not preempted** to the extent that the manufacturing differed from federal requirements; and
- Negligent Failure to Warn the FDA: **Not preempted** because independent state law exists under Section 388 of the Restatement 2d of Torts.

See generally McLaughlin v. Bayer Corp., 172 F. Supp.3d 804 (E.D. Pa. 2016).[5]

[5] *McLaughlin* held that Pennsylvania did not recognize strict liability claims. *Id.* at 833–34. However, another case out of the Eastern District of Pennsylvania has already disagreed with this

The same pattern holds true for the other orders Bayer relies upon—no court has held blanket preemption applies to claims regarding Essure. *See generally De La Paz*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (claims for negligent training and failure to warn not preempted and leave to amend granted to plead non-preempted claims on express warranty, misrepresentation, and manufacturing defect); *Williams v. Bayer Corp.*, No. 15BA-CV02526 (Mo. Cir. Ct. July 18, 2016) (Bayer RJN, Ex C) (dismissed with no analysis and therefore not helpful to the Court); *Medali v. Bayer HealthCare LLC*, No. RG15771555, slip op. (Cal. Super Ct. Feb. 16, 2016) (Bayer RJN, Ex. A) (denying demurrer on manufacturing defect and failure to warn, granting leave to amend breach of express warranty); *Noris v. Bayer Essure, Inc.*, No. BC589882, Cal. Super. Ct. Apr. 26, 2016) (Bayer RJN, Ex. B) (denying demurrer on manufacturing defect and failure to warn); *Lance v. Bayer Corp.*, RG 16809860 (Cal. Super. Ct. Aug. 2, 2016) (multiple joined cases) (Bayer RJN, Ex. D) (denying preemption demurrer on failure to warn FDA, breach of warranty and misrepresentation; granting leave to amend for manufacturing defect and negligent training); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017) (dismissing the complaint because plaintiff failed to cite parallel state law and based her claims were based *entirely* on federal law).[6]

"The United States Supreme Court has cautioned that in the interest of preventing federal encroachment on the state's authority, a court interpreting a federal statute pertaining to areas traditionally controlled by state law should be reluctant to find preemption." *State ex rel. Proctor*

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holding. *Smith v. Howmedica Osteonic Corp.*, No. 17-1174, 2017 WL 1508992, at *4 (E.D. Pa. Apr. 27, 2017). *Smith* held that the court "predicts that the Pennsylvania Supreme Court would **not** bar strict liability claims." *Id.* at *5 (emphasis supplied).

[6] Bayer also relies upon *Burrell v. Bayer Corp.*, No. 1:17-CV-00031, 2017 WL 1599333 (W.D.N.C. May 10, 2017). However, this case is currently pending on appeal.

v. Messina, 320 S.W.3d 145, 148 (Mo. 2010) (citing *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 667 (1993)). In finding preemption, a court must conclude that it "was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

3. Specific Claims are not Preempted and Are Plausible

Plaintiffs' claims are not preempted. Each claim is all brought under Illinois law, which parallels federal requirements:

Count	Federal Requirement	Illinois Law
Strict Liability	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39(d)	*Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 525, 901 N.E.2d 329, 335 (2008), *opinion modified on denial of reh'g* (Dec. 18, 2008) (strict liability for product defects would further the adoption of strict liability generally).
Negligent Manufacturing	21 C.F.R. § 820.20 *et seq.* Essure® PMA conditions Current Good Manufacturing Practices; 21 U.S.C. § 351(f)	*See Patton v. Country Place Condo. Ass'n*, 4-00-0008, 2000 WL 33728374, at *4 (Ill. App. Ct. 4th Dist. July 7, 2000)
Negligent Failure to Warn	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) Essure® PMA conditions	*Broussard v. Houdaille Indus., Inc.*, 183 Ill. App. 3d 739, 744, 539 N.E.2d 360, 363 (1st Dist. 1989); *Brobbey v. Enter. Leasing Co. of Chicago*, 404 Ill. App. 3d 420, 430, 935 N.E.2d 1084, 1093 (1st Dist. 2010) (discussing RESTATEMENT (SECOND) OF TORTS § 388)).
Negligence/Negligence Per Se	21 C.F.R. § 803.50, *et seq.* 21 C.F.R. § 814.82(a)(9) 21 C.F.R. § 814.39(d) 21 C.F.R. § 820.20 *et seq.* Essure® PMA conditions	*Bier v. Leanna Lakeside Prop. Ass'n*, 305 Ill. App. 3d 45, 58–59, 711 N.E.2d 773, 783 (2d Dist. 1999), *as modified on denial of reh'g* (May 19, 1999)

Negligent Misrepresentation/Fraud	Essure® PMA conditions Essure advertising and promotional materials	*Bd. of Educ. of City of Chicago v. A, C & S, Inc.*, 131 Ill. 2d 428, 452, 546 N.E.2d 580, 591 (1989); *Illinois State Bar Ass'n Mut. Ins. Co. v. Cavenagh*, 2012 IL App (1st) 111810, ¶ 38, 983 N.E.2d 468, 481.
Breach of Express Warranty	Preemption Not Applicable - *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525 (1992)	*See Moorman Mfg. Co. v. Nat'l Tank Co.*, 91 Ill. 2d 69, 72, 435 N.E.2d 443, 444 (1982).
Negligent Training	Essure®-specific training guidelines Physicians' Training Manuel	*See Pippin v. Chicago Housing Authority*, 78 Ill. 2d 204, 210, 399 N.E.2d 596, 600 (1979) (citing to RESTATEMENT (SECOND) OF TORTS § 324A).

4. Negligent Failure to Warn Claims

(a) Negligent Failure to Warn Claim Is not Preempted

Bayer asserts that Plaintiffs' failure to warn claim is preempted. Bayer Motion at 19. Insofar as Plaintiffs' failure to warn claims are based on Bayer's negligence in failing update the Essure® label to "add or strengthen a contraindication, warning, precaution, or information about an adverse reaction; . . . that add or strengthen an instruction that is intended to enhance the safe use of the device; . . . [or] that delete missing, false, or unsupported indications," they are not preempted because the claims do not require FDA approval prior to the change. *See* 21 C.F.R. § 814.39(d). "At this early stage in the litigation, there was no reason for the Court of Appeals to preclude altogether the [plaintiffs'] . . . labeling claims to the extent that they rest on claims that

Medtronic negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under federal law." *Medtronic v. Lohr*, 518 U.S. 470, 496 (1996).

A state duty to update warnings in response to new safety information would not be "different from, or in addition to" federal requirements, because federal law itself requires medical devices to carry adequate warnings. 21 U.S.C. §352(f)(2) provides that a device is misbranded "unless its labeling bears . . . adequate warnings against use . . . where its use may be dangerous to health . . . as are necessary for the protection of users" and 21 U.S.C. §331 prohibits the sale of misbranded devices. Indeed, the premarket approval letter for Essure® makes it a condition of approval that "[a] PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Bayer Motion, Ex. G. And FDA's draft guidance establishes that the agency views Essure®'s current warnings as inadequate.

In addition, as FDA explained to the Supreme Court in response to a request for its views in *Stengel*, express preemption under the MDA only exists where FDA has established device-specific federal requirements. *See* Brief for the U.S. as Amicus Curiae, *Medtronic, Inc. v. Stengel*, No. 12-1351, 2014 WL 2111719, at 8–9 (May 2014) (citing *Lohr*, 518 U.S. at 500; 21 C.F.R. 808.1(d)), (copy of brief attached as Ex. G to Aff. of G. Sean Jez). Federal requirements that "reflect . . . entirely generic concerns about device regulation generally," such as general federal labeling and manufacturing requirements, "ordinarily do not have a preemptive effect under Section 360k(a)." *Id.* at 9 (quoting *Lohr*, 518 U.S. at 501); *id.* at 10 (noting that "*Riegel* reaffirmed that distinction between 'manufacturing and labeling requirements applicable across the board to almost all medical devices' and 'requirements specific to the device in question.' 552 U.S. at 322"). "Section 360k(a) does not preempt [Stengel's] straightforward claim that [Medtronic] should have

brought new safety information to physicians' attention through a CBE revision to the device's labeling, because such a claim implicates no preemptive device-specific federal requirement." *Id.* at 7.

The FDA elaborated:

> Under *Riegel*, FDA's premarket approval of petitioner's device established preemptive requirements with respect to the design, manufacturing, and labeling of the device. Those would preempt any claim alleging in substance that FDA should have conditioned its approval on adopting some other design, manufacturing specification, or labeling. Such were the nature of the claims at issue in *Riegel*, and those claims were therefore preempted.
>
> But here, respondents attack petitioner's conduct after its device received premarket approval. . . . That conduct . . . would have been governed not by the terms of the device's premarket approval, but rather by FDA's general regulations governing adverse-event reporting and labeling revision in light of new safety information. Accordingly, respondents' failure-to-warn claim—whether styled as arising from petitioner's failure to make adverse event reports to FDA or from its failure to make a CBE revision to the device's labeling—is not expressly preempted.

Id. at 12. This FDA position is entitled to judicial deference. *See Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 210 (2011) (deferring to agency position set forth in amicus brief). As the Supreme Court has noted, §360k "authoriz[es] the FDA to determine the scope of the Medical Devices Amendments' preemption clause." *Wyeth v. Levine*, 555 U.S. 555, 576 (2009).

The basis of Bayer's preemption argument is that any claim for negligent failure to warn FDA regarding adverse events is impliedly preempted as an attempt by a private party to enforce the MDA. Motion at 21. But many courts have repeatedly rejected that argument, including the Ninth and Fifth Circuit Courts of Appeal; and the four courts analyzing the issue as to Essure® in particular. Specifically, the Northern District of Illinois rejected this exact argument. *Laverty v. Smith & Nephew, Inc.*, No. 15 C 9485, 2016 WL 3444191, at *7 (N.D. Ill. June 23, 2016).

> The Lavertys' claims more closely resemble non-preempted claims approved by the Ninth and Fifth Circuits. In *Stengel*, the Ninth Circuit declined to find preemption where the plaintiffs asserted a failure-to-warn claim under Arizona law based on the failure to comply with post-approval requirements established by the

> FDA. The court explained that the plaintiffs' failure-to-warn claim was not preempted, because "Arizona law contemplates a warning to a third party such as the FDA." *Stengel*, 704 F.3d at 1233. Accordingly, the claim rested "on a state-law duty that parallels a federal-law duty under the MDA, as in *Lohr*." *Id.* Similarly, in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 764, 776 (5th Cir.2011), the Fifth Circuit found that the MDA neither expressly nor impliedly preempted plaintiffs' failure-to-warn claim under Mississippi law based on post-approval failure to abide by disclosure requirements set by the FDA. As explained above, Illinois has long recognized negligence and strict liability torts arising out of a failure to warn, placing a duty on a product manufacturer not to communicate directly with an end user, but to engage in "reasonable conduct for the benefit" of the end user. Here, that reasonable conduct includes fully and correctly complying with FDA disclosure requirements. The Lavertys' claims are not impliedly preempted.

Id.

In addition, as previously discussed, multiple courts have found no preemption of a failure to warn claim premised on Bayer's failure to report Essure adverse events to the FDA—which is precisely Plaintiffs' claim. *McLaughlin*, 172 F. Supp. 3d at 838 (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) and *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 768 (5th Cir. 2011)); *De La Paz*, 159 F. Supp. 3d at 1097; *Medali*, No. RG15771555 (Bayer RJN, Ex. A); *Noris*, No. BC589882 (Bayer RJN, Ex. B at 20:16–20:18); *Lance v. Bayer Corp*., RG 16809860 (Cal. Super. Ct. Aug. 2, 2016) (multiple joined cases) (Bayer RJN, Ex. D). The Court should follow this precedent. Put plainly, the great weight of authority is against preemption and Bayer.

(b) Negligent Failure to Warn Claim Is Plausible

In arguing for preemption, Bayer also asserts that Plaintiffs have failed to plausibly allege a causal nexus between Bayer's failure to report and their injuries. Bayer is incorrect. Plaintiffs have alleged a multitude of failures by Bayer to warn the FDA of adverse events and alleged that those failures caused their injuries. FAC at ¶¶ 142–182. Further, as mentioned above, at the pleading stage those allegations are assumed true and all inferences are made in Plaintiffs' favor. Accordingly, Plaintiffs have pled a plausible failure to warn claim.

For instance, Plaintiffs allege that from January 2008 to June 2013, Bayer failed to disclose over 32,000 complaints to the FDA as required under the MDA and Essure's® PMA. *E.g.,* FAC at ¶¶ 159, 170–177, 180. The FDA had no warning of these adverse events until well after Plaintiffs were implanted with the Essure® coils. *Id*. And, after receiving Bayer's previously unreported adverse events, the FDA ultimately strengthened the warning for Essure®, including the addition of its strongest warning—a black-box warning. *Id*. at ¶ 4, 228–237.

A black-box warning "appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks."[7] "If a problem may lead to death or serious injury, FDA may expect [the manufacturer] to highlight the warning by placing it in a box."[8] Even though some of the contents of the boxed warning are reflected in previous labeling of Essure®, the very fact that the FDA wanted to place a black box warning at all shows that the FDA agreed that the prior warnings were not strong enough.

In addition to the boxed warning, the FDA proposed a patient checklist to accompany all Essure® implantations. The patient checklist demonstrates that Bayer negligently failed to warn the FDA about all of the known risks associated with Essure®, including the injuries suffered by Plaintiffs. Further, the FDA determined that these risks were significant enough to include in the materials presented directly to a patient. During the September 2015 advisory committee meeting, patients, physicians, and researchers testified regarding problems with Essure®—and they were just the tip of the iceberg. Finally, the patient checklist reinforces the allegation that Bayer

[7] FDA Consumer Health Information, *A Guide to Drug Safety Terms at FDA*, available at http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM107976.pdf

[8] FDA, *Guidance on Medical Device Patient Labeling*, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm070782.htm

continued to negligently fail to warn the FDA about these risks the women who are suffering have come forward, a duty that it should have fulfilled.

Bayer implies that the causal connection is broken because the FDA released a statement that Essure® "remained an appropriate option." Bayer Memo. at 22. However, that means only that the FDA decided not to recall it from the market. The finding has *nothing* to do with whether Essure®'s warnings were sufficient. In fact, the FDA's addition of a black-boxed warning and a patient checklist furnishes compelling evidence that the warnings *were not* sufficient. Had the FDA found that Bayer was adequately warning patients, there would be no need for a patient checklist.

Due to Bayer's negligence in warning the FDA of these adverse events, Plaintiffs' physicians were not able to adequately convey the risks and warnings associated with Essure® to Plaintiffs. FAC at ¶¶ 159, 170–177, 180. Had Plaintiffs, or their implanting physicians, known of these warnings through adequate reporting of adverse events, the physicians would not have recommended the implant of Essure®, and Plaintiffs would not have had the device implanted. *Id* at ¶¶ 347–352. Instead Plaintiffs suffered: chronic pelvic pain, weight gain, heaving bleeding with clotting, painful intercourse, hair loss, and depression. Had they known that these were possible risks of Essure® they would not have agreed to the procedure. *Id*.

Accordingly, Plaintiffs have adequately pled negligent failure to warn in their complaint: Bayer had a duty to warn the FDA of adverse events associated with Essure® and Bayer breached that duty, thereby failing to warn Plaintiffs' implanting physicians and causing their injuries. If the Court should find otherwise, Plaintiffs respectfully request leave to amend in order to provide additional facts in support of their claims.

5. Negligent Misrepresentation and Warranty Claims

(a) Negligent Misrepresentation and Warranty Claims Are not Preempted

A warranty is a promise voluntarily made—the "requirement[s] imposed by an express warranty claim are not imposed under State law, but rather imposed by the warrantor." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 525 (1992) (holding breach of express warranty not preempted). Many courts have found that express warranties exist outside the FDCA, founded in traditional state law. *See, e.g.*, *Houston v. Medtronic, Inc.*, 957 F.Supp.2d 1166 (C.D. Cal 2013); *Beavers–Gabriel v. Medtronic, Inc.*, 15 F.Supp.3d 1021 (D. Haw. 2014); *Schouest v. Medtronic, Inc.*, 13 F.Supp.3d 692 (S.D. Tex. 2014); *Arvizu v. Medtronic, Inc.*, 41 F.Supp.3d 783 (D. Ariz. 2014). Warranty claims are not common-law tort actions, but exist by virtue of positive legislative enactments of state law. *See* 810 ILCS §§ 5/2-314–15. Because warranty claims do not concern the breach of a promise pertaining to safety or effectiveness required by the FDA, but rather a voluntary contractual promise made by the defendant, separate and apart from any FDA requirements, a determination of warranty claims does not "require a finder of fact to challenge or usurp the FDA's conclusions of safety and effectiveness." *Cline v. Advanced Neuromodulation Sys.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012).

Bayer claims that Plaintiffs' claims of false and misleading advertising and promotional materials are the "same as" language FDA approved. However, as is clear from Bayer's Motion, the language is not the same. Further, any exercise in comparing and contrasting the false advertising materials with FDA-approved language is not proper at the pleadings stage.

Nevertheless, if the Court were inclined to compare the language in the marketing materials with FDA language, Bayer's motion still fails. By cherry-picking certain representations and warranties, Bayer tries to persuade this Court that all representations and warranties were contained in the label. This is not so. For example, Bayer touted Essure® as the most effective form of permanent birth control, and yet nowhere in the Essure® labeling does it state that Bayer

actually conducted a clinical trial comparing different forms of permanent birth control. In fact, Dr. Patricia Carney, Bayer Healthcare's Director of Medical Affairs for Women's Healthcare, admitted this at the September 2015 FDA Advisory Committee Meeting: "[T]here are no head-to-head prospective clinical trials of Essure versus tubal ligation." Aff. of G. Sean Jez, Ex. E (Advisory Committee Meeting Transcript) at 50. And yet, when Plaintiffs were implanted with Essure®, Bayer was claiming that it was the most effective form of permanent birth control.

Further, Bayer made representations and warranties about Essure® that it never reported to the FDA. They warranted that implanting physicians must complete hands-on training. FAC at ¶ 389. In reality, the "training" was conducted by a Bayer sales representative with no medical education. *Id*. Saying that Essure was a "gentle procedure," for example, is not "the same" as the FDA-approved language that the "majority of women . . . experienced mild to moderate pain during and immediately following the procedure." In fact, there were many negligent misrepresentations and warranties that Bayer made to physicians and patients that do not mirror the FDA-approved Essure® language:

BAYER MISREPRESENTATION/WARRANTY	**FDA-APPROVED LANGUAGE**
Bayer warranted that "[s]ince Essure does not contain hormones, it should not cause weight gain." FAC at ¶ 212.	**FDA-approved language does not mention weight gain:** No language in Instructions for Use (Bayer Motion, Exs. K, L, P, R); No language in Summary of Safety and Effectiveness Data (Bayer Motion, Ex. H); Language from 2015 Patient Guide does not mention weight gain (Bayer Motion, Ex. O).
Bayer declared that the "Essure procedure is the most effective form of permanent birth control available." FAC at ¶ 212; Aff. of G.	**FDA-approved language does not say most effective:**

Sean Jez, Exhibit F (Patient Brochure); Aff. of G. Sean Jez, Exhibit D (Essure® Physicians' Website "Essure Technology")	"While the one and two-year effectiveness rates for Essure compare quite favorably to the effectiveness rate for other methods [. . .] longer term data on Essure are not available and may not compare favorably." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 20. "Long-term nature of the tissue response to Essure device is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 months, the nature of the cellular/fibrotic response and the ability of the response and the device to maintain occlusion are not known." Bayer Motion, Ex. K (Instructions for Use 2002) at 4; Ex. S (Instructions for Use 2011), at 1; FAC at ¶ 136.
Bayer warranted that to be trained in Essure®, the physician "must skilled operative hysteroscopist." FAC at ¶ 124. Further it warranted that its training program was "comprehensive." *Id*. at 207; 217. Physicians performing Essure® procedures must have achieved "Signed Off" training status for the procedure. FAC at ¶ 217; Aff. of G. Sean Jez, Exhibit C (Essure® FAQ Training Website); Aff. of G. Sean Jez B (Essure® Website "Learning Library Overview")	**Bayer's program was not comprehensive and was inadequate. Further, Bayer "signed-off" on implanting physicians who were not trained in operative hysteroscopy, like Plaintiffs' implanting physicians.** FAC at ¶ 217. Further, **Sales consultant or sales representative—who possessed no actual medical training—would train physicians.** FAC at ¶ 217.
Bayer represented that the "mechanism of action is the body's natural healing response" and the PET fibers "on the inner core of the micro-insert elicit a benign tissue healing response and acts as a scaffolding into which tissue growth occurs, completely occluding the fallopian tubes in three months' time. The tissue response has been found to be reliable and localized to the micro-insert." FAC at ¶ 212; Aff. of G. Sean Jez, Exhibit D (Essure® Physicians' Website "Essure Technology")	**FDA-approved language does not mention "natural healing" or that "tissue response has been found to be reliable and localized":** "Long-term nature of the tissue response is not known." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 5; Bayer Motion, Ex. K (Instructions for Use 2002) at 4; Ex. S (Instructions for Use 2011), at 1; FAC ¶ 136.

CONTRAINDICATIONS . . . known hypersensitivity to nickel confirmed by skin test." Bayer Motion, Ex. H (Summary of Safety Effectiveness Data) at 1.	**Regarding nickel hypersensitivity and/or allergic reaction: "**And studies have also demonstrated that there's no correlation between skin-testing results and allergic reactions to Essure." Aff. of G. Sean Jez, Ex. E (Advisory Committee Meeting Transcript) at 33 (Testimony from Dr. Edio Zampaglione on behalf of Bayer HealthCare).

For these reasons, the *McLaughlin* court properly rejected Bayer's preemption arguments concerning Plaintiffs' warranty and misrepresentation claims. The court noted that 21 U.S.C. §352(q) expressly prohibits the use of false or misleading advertising and concluded that Plaintiffs' could state viable, non-preempted warranty and misrepresentation claims based on false and misleading statements in Bayer's unapproved advertising and other promotional materials. *McLaughlin,* 2016 WL 1161578 at *11, *15. This Court should come to the same conclusion.

Even statements the FDA approved can survive preemption if plaintiffs do not claim the statements were defective. Rather, they should allege that defendants did not live up to the FDA-approved promises. *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009). That court opined that defendants were confusing the warranty claim with a claim for defective labeling, and noted that plaintiffs were not alleging the FDA-approved label was defective. *Id.* That is the case here. Even the FDA-approved warranties still survive, as Plaintiffs are not alleging that the label was defective—but that Essure® simply did not live up to its claims.

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

to approve Bayer's warranties, stating in the Essure® PMA: "CDRH [The Center for Devices and Radiological Health] does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

But Plaintiffs' misrepresentation claims do not impose requirements on Bayer related to the safety and efficacy of Essure. As the Supreme Court has held in *Cipollone*, misrepresentation claims, including those based on allegedly false statements made in advertisements, are not preempted because they are predicated on the duty not to deceive. 505 U.S. at 525.

(b) Negligent Misrepresentation and Warranty Claims Are Plausible

Plaintiffs have also adequately alleged that Bayer's misrepresentations and breach of warranty caused their injuries. For instance, Bayer misrepresented that Essure® was more effective than other permanent birth control. *See, e.g.*, FAC at ¶¶ 7, 212. Had Plaintiffs or their implanting physicians known of the misrepresentation, Plaintiffs would not have had the Essure® coils implanted. *Id*. at ¶¶ 204, 315–319. Similarly, Bayer's failure to follow through on its promise to adequately train Plaintiffs' implanting physicians also caused or worsened their injuries. *See infra* (section on negligent training).

6. Negligent Training Claim

(a) Negligent Training Claim Is not Preempted

As noted above, and contrary to Bayer's contention, the cases Bayer cites do not support a ruling that negligent training is preempted. For example, *McLaughlin* held that a claim for negligent training was a parallel state law claim: A "negligent training claim does not seek to impose training requirement different from those in the federal requirements and, thus, is not expressly preempted. . . . Moreover, we reject Bayer's argument that the negligent training claim

is impliedly preempted because there is no state law on which to base a negligent training claim." *McLaughlin*, 2016 WL 1161578 at *6 (adoption of Section 324A of the Restatement 2d of Torts created parallel state law) (citations omitted).

Further, Illinois law recognizes a duty to train insofar as it has applied § 324A of the Restatement (Second) of Torts. *See Pippin v. Chicago Housing Authority*, 78 Ill. 2d 204, 210, 399 N.E.2d 596, 600 (1979). Specifically, § 324A states:

> [O]ne who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if . . . (b) he has undertaken to perform a duty owed by the other to the third person.

Indeed, *McLaughlin* considered this identical section, adopted under Pennsylvania law, and concluded that this was sufficient to maintain a parallel state-law claim for negligent training. Bayer undertook a duty to train physicians on how to implant Essure®, to ensure that physicians were trained in hysteroscopy, and to conduct training with a preceptor—and did so negligently.

Bayer further contends preemption is appropriate because Plaintiffs have not alleged any facts regarding how Bayer's training procedure deviated from the training procedure approved by the FDA. Bayer is mistaken.

First, Plaintiffs allege that Bayer failed to abide by the FDA-approved training guidelines in the training of their implanting physicians. FAC at ¶¶ 207, 214–18, 374, 383–89 (alleging how Bayer negligently trained Plaintiffs' implanting physicians). Second, Bayer breached its duty when it failed to ensure that Plaintiffs' implanting physicians were properly trained in hysteroscopy; when it failed to train Plaintiffs' implanting physicians with a designated preceptor (instead sending a sales representative to serve as the "preceptor"); and when it failed to disclose all known adverse events to Plaintiffs' implanting physicians. *Id*. Plaintiffs are not alleging that the FDA-approved training standards were deficient in any way. Plaintiffs' claims rest on the premise that

Bayer was negligent in applying those standards, which does not involve the jury deciding if the actual training material is inadequate under state law, as Bayer contends.

And to the extent Bayer asserts that Plaintiffs must identify specific provisions from the FDA-approved training materials,[9] "policing that limitation at the pleading stage would work especial hardship for plaintiffs in this context, who, prior to discovery, have access to generally applicable [requirements], but not to confidential PMA specifications." *Simoneau v. Stryker Corp.*, No. 3:13-CV-1200 (JCH), 2014 WL 1289426, at *5 (D. Conn. 2014) (citing *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010)). PMA specifications are "kept confidential as a matter of federal law," and therefore are unavailable without discovery. *Bausch*, 630 F.3d at 560 (citing 21 C.F.R. § 814.9).

(b) Negligent Training Claim Is Plausible

Bayer argues Plaintiffs failed to state facts regarding how the alleged inadequate training of their implanting physicians caused their injuries. But at the pleading stage all facts are assumed true and all inferences are made in Plaintiffs' favor. *See Doe v. Univ. of Chicago Med. Ctr.*, 2015 IL App (1st) 133735, ¶ 41, 31 N.E.3d 323, 331. Here, Plaintiffs allege that Bayer failed to properly train their physicians to implant the device, deal with post-implant complications, and remove the device in the event of complications. FAC at ¶¶ 207, 214–18, 374, 383–89. The *McLaughlin* court recently found that negligent training claims were not preempted, holding that plaintiffs had plausibly alleged that their implanting physicians "did not complete the required preceptoring until competency, successfully complete the Essure Simulator Training, or understand the Physician Training Manual, and that Bayer negligently failed to ensure that these training requirements had

[9] The Essure® publicly available label references a Physician's Training Manual, but fails to list the specific steps included in the training course. In addition, the PMA order fails to include the training steps.

been met." *McLaughlin v. Bayer Corp.*, No. CV 14-7315, 2017 WL 697047, at *5 (E.D. Pa. Feb. 21, 2017). The court went on to conclude that, while the complaint "does not contain specific allegations regarding the particular physicians who performed the Plaintiffs' procedures, including precisely how the implantations were negatively affected by the physicians' inadequate training, these are facts that can be developed in discovery." *Id.* at *6.

The same holds true here—it can be reasonably inferred that Plaintiffs' injuries could have been caused or worsened by Bayer's inadequate training of their physicians on how to implant the Essure® device or deal with post-implant complications. In the alternative, Plaintiffs request leave to amend to provide additional facts in support of their claim.

7. Manufacturing Defect Claims

(a) Manufacturing Defect Claim Is not Preempted

Federal requirements that "reflect important but entirely generic concerns about device regulation generally"—such as "federal manufacturing and labeling requirements applicable across the board to almost all medical devices"—lack preemptive effect. *Riegel v. Medtronic*, 552 U.S. 312, 322 (2008). Manufacturing defect claims are the quintessential parallel claims that escape preemption under §360k(a), since they are premised on the assertion that the medical device at issue did not conform to the design requirements of the PMA or FDA manufacturing regulations. Numerous decisions have definitively rejected arguments that such claims are preempted. *See, e.g.*, *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (upholding state-law negligent-manufacturing claim based on violation of the FDA's Quality System Regulations and Current Good Manufacturing Practices requirements); *Howard v. Sulzer Orthopedics, Inc.*, 382 Fed. Appx. 436 (6th Cir. 2010) (same). Contrary to Bayer's representation, the *McLaughlin* court likewise denied Bayer's motion to dismiss a negligent manufacturing claim involving Essure on preemption grounds. 2016 WL 1161578 at *22.

In *Hofts v. Howmedica Osteonics Corp.*, the court held a manufacturing defect claim not preempted where the plaintiff alleged that (1) the class III medical device "was defectively manufactured and not in compliance with Current Good Manufacturing Practice requirements approved by the FDA and had an impurity, imperfection, and/or another product defect allowed to be created, contained or placed within the product in defendants manufacturing process"; and (2) this "impurity, imperfection, and/or another product defect was a deviation from design and quality manufacturing standards for the [device] approved by the FDA." 597 F. Supp. 2d at 836. The court reasoned that "[u]nlike the claims the Supreme Court considered in *Riegel*, [plaintiff] bases his tort claims on his allegations that [defendant] failed in its obligation to meet the FDA's requirements, not that [defendant] failed to exceed those requirements or to meet different requirements." *Id*. *See e.g.,* FAC at ¶¶ 183–201, 377–82.

(b) Negligent Manufacturing Claim Is Plausible

Plaintiffs alleged that Bayer violated federal law in the manufacture of Essure®. Specifically, Bayer violated federal regulations, Current Good Manufacturing Practices, the Essure® PMA, and the PMA Conditions of Approval resulting in the defective manufacture of her Essure®. As the Seventh Circuit reasoned, district courts "must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases of her claim." *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). "[T]he victim of a genuinely defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem." *Id.* at 560. The Tenth Circuit has agreed, citing favorably to citing *Bausch* and discussing the possibility that a plaintiff may lack access to information at the pleading stage. *See also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335 (10th Cir. 2015)

C. Plaintiffs Properly Pled Their Fraud and Negligent Misrepresentation Claims

Bayer next asserts that Plaintiffs have not pled their claim for negligent misrepresentation with sufficient particularity. Bayer Mem. at 24. This is simply not the case. In order to establish a claim for fraud, Plaintiffs must plead

> (1) a false statement of material fact; (2) the party making the statement knew or believed it to be untrue; (3) the party to whom the statement was made had a right to rely on the statement; (4) the party to whom the statement was made did rely on the statement; (5) the statement was made for the purpose of inducing the other party to act; and (6) the reliance by the person to whom the statement was made led to that person's injury.

Illinois State Bar Ass'n Mut. Ins. Co. v. Cavenagh, 2012 IL App (1st) 111810, ¶ 38, 983 N.E.2d 468, 481. As Bayer expressly acknowledged earlier in its Motion's preemption argument concerning these same claims (chart of alleged misrepresentations), Plaintiffs have expressly identified numerous, specific purported misrepresentations by Bayer in its advertising and promotional materials and have further alleged that those misrepresentations induced them to use the Essure device.

Further, Plaintiffs' Complaint contains multiple allegations that Plaintiffs relied on Bayer's negligent misrepresentations. *See* FAC at ¶¶ 202–227, 336, 350, 428. Moreover, at least one of the federal cases Bayer cites in its motion declined to dismiss plaintiff's negligent misrepresentation claims, finding them adequately pled even under federal pleading rules. *McLaughlin*, 172 F. Supp. 3rd. at 830. In summary, Plaintiffs have pled facts to support every element of their misrepresentation claims. Bayer's motion should be denied.

D. **Bayer's Forum Non Conveniens Arguments are Without Merit.**

1. Motion to Dismiss for Forum Non Conveniens should be Denied Outright Because Severance is not Appropriate.

Bayer's argument that the non-Illinois Plaintiff's claims should be dismissed under the doctrine of forum non conveniens (FNC) hinges upon a finding of improper joinder and severance.[10] As discussed in Plaintiffs' Opposition to Defendants' Motion to Sever, all Plaintiffs were properly joined in this action and severance is not appropriate. Because severance is not appropriate, this Court should deny Bayer's FNC motion outright.

2. Application of the FNC Doctrine is Not Warranted.

A plaintiff's right to choose a forum is a substantial one, and that choice should rarely be disturbed. *Dykstra v. A.P. Green Indus., Inc.*, 326 Ill. App. 3d 489, 496, 760 N.E.2d 1034, 1040 (2001). And that choice "should not be disturbed unless the factors weigh strongly in favor of transfer." *Pendergast v. Meade Elec. Co.*, 2013 IL App (1st) 121317, ¶ 20, 996 N.E.2d 34, 39. The court must evaluate the total circumstances of the case to determine whether the balance of factors strongly favors dismissal. *Id*. Ultimately, "the burden is on the defendant to show that relevant private and public interest factors strongly favor the defendant's choice of forum." *Laverty v. CSX Transp., Inc.*, 404 Ill. App. 3d 534, 537, 956 N.E.2d 1, 5 (2010), as corrected (Oct. 8, 2010).

The Illinois Supreme Court has listed three public interest factors and three private interest factors that courts should weigh in determining whether a suit should be dismissed on the grounds of inconvenient forum. The "private interest factors include (1) the convenience of the parties; (2) the relative ease of access to sources of testimonial, documentary, and real evidence; and (3) all other practical problems that make trial of a case easy, expeditious, and inexpensive[.]"

[10] Indeed, Bayer is only seeking dismissal of the **non-**Illinois Plaintiffs on the basis of FNC.

Langenhorst v. Norfolk S. Ry. Co., 219 Ill. 2d 430, 443–44, 848 N.E.2d 927, 935 (2006) (internal citations omitted). And the "public interest factors include (1) the interest in deciding controversies locally; (2) the unfairness of imposing trial expense and the burden of jury duty on residents of a forum that has little connection to the litigation; and (3) the administrative difficulties presented by adding litigation to already congested court dockets." *Id*. In weighing these factors—particularly in light of the fact that Defendants seek dismissal—courts should take care that the FNC doctrine does not "become a powerful weapon in the hands of the defendant who is seeking to avoid his obligations." Edward L. Barrett, Jr., *The Doctrine of Forum Non Conveniens*, 35 CALIF. L. REV. 380, 422 (1947).

The private and public interest factors in this case do not result in a balance that strongly favors dismissal. And, especially as is the case here, where Defendants have utterly failed to present any evidence to carry its burden in proving that Illinois is not a convenient forum, the Court should refrain from dismissing the case and disturbing Plaintiffs' choice of forum.

3. The FNC Factors do not Favor Dismissal.

(a) Private interest factors

Bayer has not offered any evidence to show that there are any practical problems that would prevent an easy, expeditious, and inexpensive trial of the claims in Illinois. In fact, the only private interest factor that Bayer alleges favors dismissal is the location of witnesses. Bayer Memo. at 11. However, Bayer has not produced any evidence with respect to the witnesses needed for trial—neither Plaintiffs' fact witnesses nor their own witnesses. Bayer failed to explain why it would be difficult to ensure the witnesses' attendance at trial, or why deposition testimony would be insufficient. Bayer also does not contend that witnesses will be unable to attend trial or that they might be prejudiced by having to present witnesses by deposition. Further, regardless of where Plaintiffs' claims are brought, the Bayer will have to travel to the location of Plaintiffs' witnesses—

the necessity of travel and its inherent inconvenience would manifest regardless of the location of the forum.

(b) Public interest factors

Nor do the public interest factors tip the balance in favor of dismissal. Defendants are members of the Bayer Group, "a global enterprise with companies in almost every country."[11] They maintain offices in Illinois and have employees in Illinois. Defendants sold Essure® in Illinois, to Illinois residents, who subsequently suffered complications due to the device. *See generally* FAC. Defendants also conducted clinical trials for Essure in Illinois, created their accreditation program in Illinois, and used Illinois as a test market for their nationwide marketing campaign. *Id.* This nationwide marketing scheme involved misrepresentations, breaches of warranty, and negligence which eventually expanded throughout Illinois. Illinois courts have an interest in hearing actions involving businesses in their community. *Id*. The simple fact that other forums may also have an interest in this litigation does not tip the balance in favor of dismissal.

In addition, the burden upon Illinois courts is not so substantial as to tip the balance of the factors in favor of dismissal. Bayer has presented no evidence that this Court has been unable to effectively manage large dockets. Defendants have likewise presented no evidence concerning this Court's inability to meet mandated deadlines or to keep pace with other district courts.

Bayer also claims that this Court will be burdened by the need to apply other states' laws. However, Illinois courts are capable of applying the laws of other states. This does not burden the court enough to support a dismissal.

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[11] *See Bayer—at Home throughout the World*, BAYER: SCIENCE FOR A BETTER LIFE, http://www.bayer.com/en/bayer-worldwide.aspx.

The evidence and arguments submitted by Bayer in support of the application of FNC simply do not constitute the type of weighty reasons that tip the balance strongly in favor of dismissal. Because FNC should be applied with caution, the Court should deny Bayer's motion.

III. CONCLUSION

As shown above, Bayer's motion to dismiss should be denied in its entirety. In the alternative, Plaintiffs should be granted to leave amend and/or conduct jurisdictional discovery.

DATED: February 9, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on February 9, 2018, a copy of the foregoing document was electronically filed with the Circuit Court of Madison County, Illinois, which sent notification to all parties of record as of that date. The undersigned further states that copies were also provided to the attorneys of record of all parties to the captioned cause by enclosing same in an envelope addressed to each attorney at their address(es) disclosed by the pleadings of record, with postage fully prepaid, and by depositing said envelope in a U.S. Post Office mailbox in Edwardsville, Illinois, on February 9, 2018:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et al., Plaintiffs, v. BAYER CORP., an Indian corporation; BAYER HEALTHCARE LLC, a Delaware corporation; BAYER ESSURE®, INC., (f/k/a CONCEPTUS, INC.) a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation, Defendants.	)	Case No: 16-L-1046 **JURY TRIAL DEMANDED**

BAYER'S REPLY IN SUPPORT OF ITS
MOTION TO DISMISS FIRST AMENDED COMPLAINT

Under *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773 (2017), this Court lacks personal jurisdiction over the claims of the 87 nonresident Plaintiffs who allege no connection between their claims and the State of Illinois—and almost all of whom appear to have refiled their complaints in other states post–*Bristol-Myers*, *see infra* 4. In addition, all of Plaintiffs' claims are squarely preempted by federal law, and federal and state courts nationwide have dismissed virtually identical claims concerning the Essure device on this basis. *See* Mot. to Dismiss ("Mot.") 2–3 (listing over a dozen cases dismissing similar or identical claims). Plaintiffs ask this Court to second-guess FDA's repeated determination that the device is safe and effective, and Congress's decision to preempt inconsistent state claims, but offer no basis to

depart from the numerous, well-reasoned decisions finding preemption. This Court should dismiss Plaintiffs' claims for three reasons.

First, this Court lacks personal jurisdiction over the non-Illinois Plaintiffs' claims under *Bristol-Myers*. *See* § I, *infra*. Plaintiffs argue that their allegations about clinical trial and marketing activities in Illinois support personal jurisdiction, but numerous courts—including federal courts in Illinois and Missouri—have held in highly similar cases that such contacts are far too attenuated from Plaintiffs' claims to support personal jurisdiction under *Bristol-Myers*. *See infra* page 3–4, 8–9. The nonresident Plaintiffs have failed to allege that their devices were placed in Illinois, that their doctors were trained in Illinois, that they saw advertising in Illinois, that they participated in a clinical trial in Illinois, or any "adequate link" between Bayer's alleged Illinois contacts and their "specific claims." *Bristol-Myers*, 137 S. Ct. at 1781. There is no personal jurisdiction over their claims.

Second, the non-Illinois Plaintiffs' claims also should be dismissed under the doctrine of *forum non conveniens* or, at the very least, severed for the reasons explained in Bayer's briefs in support of its Motion to Sever. The non-Illinois Plaintiffs' claims accrued in the states where they were injured (not Illinois); their physicians, who will be key witnesses, are in the states where the injuries occurred (not Illinois); and their claims have no nexus to Illinois. Plaintiffs' only response is that the forum is appropriate because the claims should not be severed, but that is both incorrect and contrary to the balance of the *forum non conveniens* factors. Moreover, while Plaintiffs say their "right to choose a forum" should not be lightly disturbed, they omit that 82 of the 87 non-Illinois Plaintiffs appear to have also already chosen to refile their complaints in other states. *See infra* 4; *see also* 735 ILCS 5/2-619(a)(3) (dismissal proper where "there is

another action pending between the same parties for the same cause"). Those choices, too, are substantial and relevant to the Court's analysis.

Third, the claims of all Plaintiffs are preempted. While Plaintiffs contend that decisions in other cases concerning the Essure device somehow support their complaint, in fact these decisions overwhelmingly reject the claims and confirm that they should be dismissed. Numerous decisions have found that in enacting a comprehensive federal statute governing medical devices and placing its exclusive enforcement in the FDA, Congress preempted the manufacturing, design, failure-to-warn, warranty/misrepresentation and failure-to-report claims that Plaintiffs bring here. Plaintiffs offer no reason to believe that they can rectify the infirmities in their First Amended Complaint; thus, the Court should dismiss with prejudice.

ARGUMENT

I. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR LACK OF PERSONAL JURISDICTION.

Plaintiffs ask this Court to disregard the U.S. Supreme Court's holding in *Bristol-Myers*, despite the long and growing list of decisions finding *Bristol-Myers* "dispositive" of the precise issue raised here. *See, e.g.*, *Dyson v. Bayer Corp.*, No. 4:17-cv-2584-SNLJ, 2018 WL 534375, at *2–5 (E.D. Mo. Jan. 24, 2018; *L. Jordan v. Bayer Corp.*, No. 4:17-cv-865-CEJ, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017), *reconsideration denied*, 2018 WL 339305 (E.D. Mo. Jan. 8, 2018), *amended claims dismissed*, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018); *State ex rel. Bayer Corp. v. Moriarty*, No. SC 96189, 2017 WL 6460354, at *5–6 (Mo. Dec. 19, 2017); *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017), *appeal voluntarily dismissed sub nom. Luddy v. Janssen Research & Dev.*, LLC, No. 17-cv-3205 (7th Cir. Nov. 20, 2017).

In the face of precedent and reason, Plaintiffs insist that this Court can exercise specific jurisdiction over *nonresident* Plaintiffs' claims on the grounds that Bayer allegedly conducted Essure marketing and clinical trial activities in Illinois. But, critically, it is fatal to this theory that *none of the non-Illinois Plaintiffs' claims arise out of or relate to these Illinois contacts*. Thus, this Court lacks specific jurisdiction over the nonresident Plaintiffs' claims. *See Bristol-Myers*, 137 S. Ct. at 1781 (there must be an "adequate link between the State and the nonresidents' *claims*" (emphasis added)); *see also Dyson*, 2018 WL 534375, at *4 (finding similar allegations concerning "Essure marketing and clinical trials … too attenuated from those activities to prove specific, 'case-linked' personal jurisdiction"); *L. Jordan*, 2018 WL 837700, at *4 (same). Their arguments to the contrary fail.

To start, the non-Illinois Plaintiffs (and their counsel) seemingly recognize that *Bristol-Myers* is fatal to their theory of personal jurisdiction in this case. Upon information and belief, 82 of the 87 non-Illinois Plaintiffs (and even one Illinois Plaintiff) have refiled their complaints in other states. *See* Hay Declaration ¶¶ 3 (Exhibit A). In fact, three Plaintiffs (Amanda Lilly, Amy Smith, and Chelica Thompson) appear to be plaintiffs in at least two other Essure cases. *Id.* ¶ 14. Of the 82 refiling non-Illinois Plaintiffs, all did so after *Bristol-Myers* was decided on June 19, 2017, and all but one are represented by attorneys who are counsel of record in this case. *Id.* ¶¶ 7–16. Each of these refiled complaints, moreover, was brought in California, where Conceptus (Bayer's predecessor) was based. Thus, not only will these Plaintiffs not be prejudiced by dismissal for lack of personal jurisdiction, but their claims are independently subject to dismissal under 735 ILCS 5/2-619(a)(3). *See A.E. Stanley Mgf. Co. v. Swift & Co.*, 419 N.E.2d 23, 27 (Ill. 1980) ("That one action is filed prior to the other therefore would not be determinative.").

On the merits, Plaintiffs fundamentally misrepresent the holding in *Bristol-Myers*. Contrary to Plaintiffs' assertions (at 5), the Supreme Court did not hold that specific jurisdiction would exist for claims by non-California residents against Bristol-Myers if the manufacturer "develop[ed] Plavix in California, … create[d] a marketing strategy for Plavix in California, [or] manufacture[d], label[ed], package[d], or work[ed] on the regulatory approval of the product in California." *Bristol-Myers*, 137 S. Ct. at 1778. Rather, as the Eastern District of Missouri recently held, this language in the opinion's background section merely recites the absence of contacts in that case, and is not "a blueprint for establishing personal jurisdiction." *Dyson*, 2018 WL 534375, at *4; *see Jordan*, 2018 WL 837700, at *4 ("The language contained in the background section of *Bristol-Myers Squibb* does not authorize a federal court to exercise broad personal jurisdiction on the mere basis of nationwide contacts—such as the development of a marketing strategy—rather than the defendant's contacts within the forum state itself.").

The actual holding in *Bristol-Myers* makes plain that plaintiffs must demonstrate an "adequate link" between the defendant's forum contacts and each of the nonresident plaintiffs' specific claims for specific jurisdiction over those claims to exist. *See* 137 S. Ct. at 1781-82. As even Justice Sotomayor noted in dissent, "the upshot of [*Bristol-Myers*] is that plaintiffs cannot join their claims together and sue a defendant in a State in which only some of them have been injured" when this adequate link cannot be established. *Id.* at 1788-89 (Sotomayor, J., dissenting). The non-Illinois Plaintiffs have failed to meet that burden here.

A. The Alleged Marketing and Training Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs argue that personal jurisdiction exists because Bayer or its predecessor "specifically targeted Chicago, Illinois [among other cities in other states] as … part of a broader marketing plan to increase sales and revenue." FAC ¶ 11(k). But Plaintiffs do not argue

(because they cannot do so) that any non-Illinois Plaintiff or her physician viewed or relied upon any Illinois marketing materials or the statements of any Illinois-based Key Opinion Leaders. This case is therefore no different than *Bristol-Myers*, where the Supreme Court rejected the argument that extensive marketing in California created specific jurisdiction over the non-California plaintiffs' claims because it was part of a nationwide marketing strategy. 137 S. Ct. at 1781–82; *see* Mot. 10–11.

Plaintiffs argue that it is irrelevant whether the marketing materials they interacted with had any connection to Illinois because the marketing activity in Illinois was the "impetus" for Bayer's nationwide marketing strategy. Opp. 11. But other cases have rejected highly similar arguments that personal jurisdiction exists in Missouri because it served as "ground zero" for Essure's marketing and was a '"test marketing' campaign site[]." *Dyson*, 2018 WL 534375, at *4; *Jordan*, 2018 WL 83700, at *1 (same). These allegations are "too attenuated" from the non-resident plaintiffs' claims to support personal jurisdiction. *Dyson*, 2018 WL 534375, at *4; *Jordan*, 2018 WL 837700, at *1 (same). Allegations "[t]hat Missouri happened to be Essure's first marketed area has no bearing on the non-Missouri plaintiffs' claims where those plaintiffs did not see marketing in Missouri, were not prescribed Essure in Missouri, did not purchase Essure in Missouri, and were not injured by Essure in Missouri." *Dyson*, 2018 WL 534375, at *4; *see also Jordan*, 2018 WL 837700, at *4 (same). This same reasoning applies equally to Plaintiffs' highly similar allegations concerning Illinois.

Nor can Plaintiffs' allegations about the Essure Accreditation Program confer specific personal jurisdiction over the non-Illinois Plaintiffs' claims. The First Amended Complaint is devoid of any allegation that non-resident Plaintiffs' physicians participated in the Essure Accreditation Program, much less that their participation in the Essure Accreditation Program

had any connection to Plaintiffs' alleged injuries. Just like the marketing allegations, these allegations are far "too attenuated" from Plaintiffs' actual claims to support personal jurisdiction.[1] *Dyson*, 2018 WL 534375, at *4; *see also Jordan*, 2018 WL 837700, at *4 (same).

B. The Alleged Clinical Trial Activities In Illinois Do Not Provide Personal Jurisdiction Over The Non-Illinois Plaintiffs' Claims.

Plaintiffs next contend that specific jurisdiction exists because Bayer conducted clinical trials and studies using several Illinois physicians and patients—along with physicians and parties from numerous other states—that led to the approval of Essure. Opp. 8–11. But Plaintiffs do not allege any link, much less an "adequate link," between these trials and their claims. *See Jordan*, 2018 WL 837700, at *4 (dismissing for lack of jurisdiction where out-of-state plaintiffs "d[id] not allege that ... they participated in the clinical trials taking place in [the forum state"). No Plaintiff alleges that she participated in the Illinois trials, relied on them, or even knew about them. Nor does any non-Illinois Plaintiff allege that she was treated by an Illinois physician.

Plaintiffs contend that it is sufficient that their complaint includes allegations of misconduct in the clinical trials (at 10-11). But *none* of the non-Illinois Plaintiffs' actual claims purport to challenge the conduct of the clinical trials in Illinois—rather, Plaintiffs challenge the manufacture, marketing, and warnings of the device, not the clinical trials supporting its FDA approval. These allegations thus cannot support personal jurisdiction because there is no connection between them and the non-Illinois Plaintiffs' *claims*.

[1] It is also notable that while Plaintiffs argue here that the Essure Accreditation Program "was created solely in Illinois," Opp. 12, the same Plaintiffs' Counsel—when arguing for personal jurisdiction in Missouri—also relied on the Essure Accreditation Program, contending that it supported specific jurisdiction over non-residents' claims in Missouri because it was developed by a Missouri consulting group. *See* Ex. B (excerpt of Respondent's Brief, *Missouri ex rel. Bayer Corp. v. Moriarty*, No. SC96189 (Mo. filed Oct. 4, 2017), at 17.

Plaintiffs contend that there is a sufficient connection because (i) some clinical trials occurred in Illinois; (ii) clinical trials are required for device approval; (iii) Plaintiffs would not have used the device and been injured if the FDA had not approved it; and (iv) thus, their claims are "related to" the clinical trials. Plainly, this is not the specific connection between an individual's claim and injury and a defendant's forum contact that *Bristol-Myers* requires. This attenuated theory is an attempt to turn "a loose and spurious form of general jurisdiction" into personal jurisdiction. *Bristol-Myers*, 137 S. Ct. at 1781. Indeed, Plaintiffs concede that, under their theory, "[i]t does not matter how many clinical trials were conducted in Illinois versus other states" and that this same theory could result in *specific* jurisdiction over any Essure user's claim in many—perhaps *all*—states. Opp. 9 & n.3; *see* Mot. 13 (citing cases where Plaintiffs' Counsel has made identical arguments in support of specific jurisdiction in other jurisdictions). *Bristol-Myers* forecloses this theory.[2] *Cf. Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 2017 IL 121281, ¶ 19 (noting that, in its general jurisdiction cases, the U.S. Supreme Court "has expressly rejected … reasoning" that would "establish general jurisdiction … in all the other states where [defendant's] warehouses are located").

Numerous decisions—including a series of recent decisions by federal District Judge David Herndon—have accordingly rejected this same jurisdictional argument. *See, e.g., Roland*, 2017 WL 4224037, at *4 (holding that, pursuant to *Bristol-Myers*, there was no personal

[2] Contrary to Plaintiffs' contentions, the issue is neither "what percentage of clinical trial activity" occurred in a state, nor "the meaningfulness of the activity" (at 9 n.2), but rather whether there is an "adequate link" between clinical trials in the forum and the plaintiffs' specific claims. *Jordan*, 2018 WL 837700, at *3. If a clinical trial participant brought suit over injuries she sustained in the trial, there would be specific jurisdiction regardless of how many other clinical trial participants were in the state. And conversely, if a plaintiff's claims do not arise out of the clinical trials, the clinical trials do not provide for specific jurisdiction regardless of the percentage of clinical trial participants in the state.

jurisdiction based on allegations that defendant "purposefully targeted Illinois as the location for multiple clinical trials which formed the foundation for defendants' Xarelto Food and Drug Administration application," because the "non-Illinois plaintiffs do not claim injuries from ingesting Xarelto in Illinois, and all conduct giving rise to non-Illinois plaintiffs' claims occurred in other states"); *Bandy v. Janssen Research & Dev., LLC*, No. 17-cv-00753, 2017 WL 4224035, at *4-6 (S.D. Ill. Sept. 22, 2017) (same), *appeal voluntarily dismissed sub nom. Schultz v. Janssen Research & Dev*., LLC, No. 17-cv-3210 (7th Cir. Nov. 21, 2017); *Dyson*, 2018 WL 534375, at *5 (rejecting argument "that specific jurisdiction exists because Essure could not have been approved without clinical trials, and some of those clinical trials occurred in Missouri"); *Jordan*, 2018 WL 837700, at *3–4 (same).

Plaintiffs' continued reliance on *M.M. ex rel. Meyers v. GlaxoSmithKline* LLC, 2016 IL App (1st) 151909, is also misplaced and misleading. *M.M*. predates *Bristol-Myers* and involved a prescription drug, not a Class III premarket approved device, and thus the express preemption clause of 21 U.S.C. § 360k. The connection between clinical trial activities in the forum state and the plaintiffs' claims was also much closer in *GSK*, as explained in Bayer's Motion to Dismiss. *See* Mot. at 14 n.2. And even if *M.M.* applied to this case, it cannot apply in a way that conflicts with the later, controlling decision in *Bristol-Myers*. In fact, in *Roland* and *Bandy*, the plaintiffs also asserted that personal jurisdiction existed based upon *M.M.*[3] However, Judge Herndon clearly rejected those arguments in granting the defendants' motions to dismiss based upon *Bristol-Myers*.

[3] A copy of the *Roland* and *Bandy* plaintiffs' memoranda of law in support of remand are attached hereto as Exhibits C and D.

Similarly, Plaintiffs misstate the holding in *DellaCamera v. DePuy Orthopaedics, Inc.*, No. CJC-10-004649 (Cal. Sup. Ct. Nov. 1, 2017), an out-of-state decision in which the court exercised personal jurisdiction over a design-defect claim because the device was designed in the state. In *DellaCamera*, the "heart of th[e] lawsuit" was whether DuPuy's metal-on-metal hip implant was defectively designed, a design DuPuy reached in collaboration with two California-based physicians. That design was the basis for each non-California plaintiff's claims. *Id.* slip op. at 6. By contrast here, Plaintiffs' claims and injuries do not arise out of the Illinois-based clinical trials. Thus, *DellaCamera* involved the type of claim-specific contacts with the forum that Plaintiffs' claims lack.

Taking Plaintiffs' allegations as true, they have failed to connect their claims with Bayer's alleged Illinois contacts. They have thus failed to carry their burden. The non-Illinois Plaintiffs' claims should, therefore, be dismissed.

II. THE NON-ILLINOIS PLAINTIFFS' CLAIMS SHOULD BE DISMISSED FOR *FORUM NON CONVENIENS*.

Alternatively, this Court should dismiss the non-Illinois Plaintiffs' claims because they are brought in an inconvenient forum. Plaintiffs' Opposition is based primarily on the premise that their claims should not be severed. For the reasons set forth in the memoranda in support of Bayer's Motion to Sever and Transfer, their claims *should* be severed. Beyond that, Plaintiffs' tour through the *forum non conveniens* factors shows precisely why that doctrine applies here.

Plaintiffs' Opposition disregards the first consideration in considering a *forum non conveniens* motion, which is whether there is an alternative forum where "all parties are amenable to process" and "the parties will not be deprived of all remedies or treated unfairly." *In re Bridgestone/Firestone, Inc.*, 420 F.3d 702, 704 (7th Cir. 2005). The answer to that question is indisputably yes; each Plaintiff has an adequate forum in his or her home state. *See Fennell v.*

Ill. Cent. RR., 2012 IL 113812, ¶¶ 11-18. Nor can Plaintiffs dispute the availability of adequate alternative fora, because 82 of the 87 non-Illinois Plaintiffs have already refiled their claims in other states. While Plaintiffs assert that their "right to choose a forum is a substantial one" and suggest that they would be prejudiced if that choice was upset, Opp. 34, the Plaintiffs' choice of Illinois (a state with no meaningful contact to their claims) has to be viewed in light of their additional choice to bring identical claims in other states.

Furthermore, Plaintiffs' weighing of the private- and public-interest factors is skewed. First, Plaintiffs ignore the practical problems with trying the claims of 87 Plaintiffs from across the country concerning medical procedures that took place in over two dozen states. It is undeniable, though, that such a large and complex trial would be unwieldy and expensive. These practical concerns are amplified by the overriding public interest in avoiding court congestion and "having local controversies decided locally." *Id.* Plaintiffs fail even to address *Fennell*, which held it was an abuse of discretion to deny a *forum non conveniens* motion where "plaintiff [did] not reside in Illinois and the action did not arise here," and the State's contact with the litigation was minimal. 2012 IL 113812, ¶¶ 24-49. Trial of 95 claims arising out of 27 states, moreover, would weigh trial down with complex, often dispositive choice-of-law issues. Such an endeavor is not necessary and would waste time and resources. Such concerns would be eliminated or greatly reduced if Plaintiffs pursued their claims in their home states.

Accordingly, this Court should dismiss the non-Illinois Plaintiffs' claims under the doctrine of *forum non conveniens* if it does not dismiss them for lack of personal jurisdiction.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED OR OTHERWISE FAIL.

In any event, all Plaintiffs' claims are preempted and fail to meet Illinois pleading standards. Federal and state courts alike have dismissed virtually identical claims. *See Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485 (W.D.N.C. 2017), *appeal docketed*, No. 17-1715 (4th Cir.

2017); *Norman v. Bayer Corp*., No. 3:16-cv-00253, 2016 WL 4007547 (D. Conn. July 26, 2016), *appeal docketed*, No. 16-2966 (2d Cir. Aug. 26, 2016); *Olmstead v. Bayer Corp.*, No. 3:17-cv-387, 2017 WL 3498696 (N.D.N.Y. Aug. 15, 2017); *Richardson v. Bayer HealthCare Pharm. Inc.*, No. 4:15-cv-00443, 2016 WL 4546369 (D. Idaho Aug. 30, 2016); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804 (E.D. Pa. 2016) ("*McLaughlin I*"); *McLaughlin v. Bayer Corp.*, Nos. 14-7315 et al., 2017 WL 697047 (E.D. Pa. Feb. 21, 2017) ("*McLaughlin II*"); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016); *Medali v. Bayer HealthCare LLC*, No. RG15771555, slip op. (Cal. Super. Ct. Feb. 16, 2016), (RJN, Ex. A); *Noris v. Bayer Essure, Inc.*, No. BC589882 (Cal. Super. Ct. Apr. 26, 2016) (RJN, Ex. B); *Lance v. Essure Inc.*, RG16809860, slip op. (Cal. Super. Ct. Aug. 2, 2016) (RJN, Ex. D); *In re Essure Products Cases*, JCCP No. 4887, slip op. (Cal. Super. Ct. Apr. 12, 2017) (RJN, Ex. E); *see also* Mot. 2–3.

Rather than address the more than a dozen decisions that have dismissed all or most claims in similar Essure-related litigation, Plaintiffs distort these cases and the general preemption framework. First, Plaintiffs argue that the groundswell of decisions dismissing identical causes of action are somehow "more favorable to Plaintiffs than they are to Bayer," because those cases were largely "dismissed due to perceived deficiency in pleadings. Opp. 12–13 & n.4. This justification is not credible, since the pleading deficiency in most of those cases was a failure to thread the "narrow gap" between express and implied preemption. *See* Mot. 18–19. *See, e.g.*, *Olmstead*, 2017 WL 3498696, at *4 ("Therefore, the Court concludes that, as a matter of law, the MDA expressly preempts Plaintiff's claims."); *Norman*, 2016 WL 4007547 (dismissing all claims with prejudice); *De La Paz*, 159 F. Supp. 3d 1085 (dismissing all claims as preempted); *Medali*, RJN Ex. B, at 2 ("The Complaint does not plead any facts amounting to conduct that violates the terms of [Essure's PMA] or otherwise violates [sic] federal law (and

simultaneously violates California law)."). Even where a dismissal was styled in terms of causation or other cause-of-action issues, that analysis was informed by the unique and exacting demands of pleading a non-preempted claim involving a PMA device under the MDA. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 835 (finding a manufacturing defect claim inadequately pleaded because the complaint did not meet the causation standard to state "a cognizable negligent manufacturing claim involving a medical device").[4]

Plaintiffs' invocation of the presumption against preemption (at 13–14) similarly fails. A recent U.S. Supreme Court case directly holds that where a "statute contains an express pre-emption clause"—such as 21 U.S.C. § 360k(a) of the MDA—courts "do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause." *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 136 S. Ct. 1938, 1946 (2016). Indeed, as another court recently held, "Plaintiff's argument that there is a strong presumption against preemption and that this presumption applies to the MDA's express preemption clause is frivolous." *Olmstead*, 2017 WL 3498696, at *3 n.2. And *Buckman* likewise holds that "no presumption against pre-emption" applies to the question whether claims are impliedly preempted because they conflict with FDA's regulatory authority. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). No presumption against preemption applies here. The correct preemption framework is

[4] When Plaintiffs finally address the substance of these preemption decisions, their recounting is incomplete and misleading. For example, Plaintiffs describe *McLaughlin I*—which dismissed 10 of 12 causes of action—as supporting their position here. Yet Plaintiffs omit to mention two 2017 decisions in that case further narrowing the plaintiffs' claims. *Compare, e.g.*, Opp. 14 (describing *McLaughlin I* as holding negligent manufacturing claims are not preempted), *with McLaughlin II*,, 2017 WL 697047, at *18 ("We therefore grant the Motion to Dismiss as to the negligent manufacturing claim … in its entirety."); *Dunstan v. Bayer Corp.*, No. 16-1458, 2017 WL 4392046 (E.D. Pa. Oct. 3, 2017).

set forth in the Supreme Court's decisions in *Riegel* and *Buckman*. *See* Mot. 17–19. When it is applied, each of Plaintiffs' claims clearly fails as a matter of law.

A. Plaintiffs' Manufacturing Claims Are Preempted And Otherwise Fail.

Plaintiffs' manufacturing defect claims are preempted for at least two reasons. First, Plaintiffs fail to identify a "specific federal requirement in the PMA approval" with which Bayer did not comply. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig*. 623 F.3d 1200, 1206 (8th Cir. 2010). Plaintiffs cite only Current Good Manufacturing Practices ("CGMPs"), Opp. 16, but as Bayer previously explained, CGMPs do not create "specific federal requirement[s] in the PMA approval" and "do not save … claims from preemption." Mot. 20 (quoting *In re Medtronic*, 623 F.3d at 1206).

Second, and in any event, Plaintiffs fail to allege that *their* Essure devices were manufactured with an actionable defect. *See Norman*, 2016 WL 4007547, at *3 ("Plaintiff alleges that there may have been some devices produced with 'non-conforming materials,' but does not allege any plausible reason to think that *her* device came from the non-conforming batch, or that it suffered from any other manufacturing defect."); *De La Paz*, 159 F. Supp. 3d at 1094 (dismissing where plaintiff failed to "allege that the irregularities … resulted in a manufacturing defect that caused *her* injuries") (emphasis added). Instead, Plaintiffs rely on a series of alleged licensing and record-keeping violations that could not plausibly "cause a product abnormality," *McLaughlin I*, 172 F. Supp. 3d at 836, let alone an actionable injury. *See Norman*, 2016 WL 4007547, at *3 ("[Plaintiff] does not allege any facts that would make it plausible that the complications she suffered—which were known potential side effects—were due to any defect in the device."); *Burrell*, 260 F. Supp. 3d at 493 (dismissing where "plaintiff has not linked any manufacturing deficiency to the device that the plaintiff received and how it caused the alleged injuries"). Thus, they have failed to state a non-preempted claim.

Plaintiffs' Opposition points to three cases as supporting their manufacturing claims here; none is apposite. First, Plaintiffs cite *Patton v. Country Place Condo. Ass'n*, No. 4-00-0008, 2000 WL 33728374 (Ill. App. Ct. July 7, 2000), as holding that a negligent manufacturing claim parallels federal PMA requirements. Opp. 16. But *Patton* did not involve medical devices at all; that case presented a preemption issue under the Federal Insecticide, Fungicide, and Rodenticide Act, which preempts only challenges "to advertising or promotion." *Patton*, 2000 WL 33728374, at *3. *Patton* has no bearing on the much broader MDA preemption provision. Second, Plaintiffs point to *McLaughlin I* as holding that a negligent manufacturing claim is not preempted. Opp. 14. But in fact that case granted Bayer's motion to dismiss the negligent manufacturing claim for failing to "allege that any particular manufacturing defect actually caused Plaintiffs' injuries." *McLaughlin I*, 172 F. Supp. 3d at 836. And when plaintiffs attempted to replead, *McLaughlin II* "grant[ed] the Motion to Dismiss as to the negligent manufacturing claim … in its entirety." 2017 WL 697047, at *18.

Finally, Plaintiffs rely on *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), *see* Opp. 26–27, but a multitude of courts have rejected that decision as wrongly decided, *see, e.g.*, *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig*., No. 11-1229, 2009 WL 1361313, at *3 (D. Minn. May 12, 2009), *aff'd*, 623 F.3d 1200 (8th Cir. 2010) ("*Hofts* is not binding on this Court, and the undersigned respectfully disagrees with that decision"); *Gross v. Stryker Corp*., 858 F. Supp. 2d 466, 495 (W.D. Pa. 2012); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284 (E.D.N.Y. 2009) (similar); *Ali v. Allergan USA, Inc*., No. 1:12-cv-115, 2012 WL 3692396, at *13 (E.D. Va. Aug. 23, 2012) (similar). With the exception of *McLaughlin*, which they misrepresent, *supra* note 4, Plaintiffs do not address any of the well-reasoned Essure cases that hold similar manufacturing claims are preempted. *See, e.g.*,

Burrell, 260 F. Supp. 3d at 493; *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *3; *Richardson*, 2016 WL 4546369, at *5; *McLaughlin II*, 2017 WL 697047, at *18. The Court should follow those cases and dismiss Plaintiffs' manufacturing claims.

Plaintiffs' only response is to claim that they need "[f]ormal discovery" to substantiate their conclusory assertions. Opp. 32. But Plaintiffs cannot cite a supposed need for discovery to insulate their claims from review. Their inadequate manufacturing defect claims should be dismissed, as numerous other courts have done in similar circumstances. *See, e.g.*, *Burrell*, 260 F. Supp. 3d at 493; *Norman*, 2016 WL 4007547, at *3; *McLaughlin II*, 2017 WL 697047, at *18; *De La Paz*, 159 F. Supp. 3d at 1094-95.

B. Plaintiffs' Failure to Train Claim Is Preempted.

Plaintiffs assert that their claim for negligent failure to train is not preempted because it pleads a violation of state law that is "parallel" to a violation of federal requirements, but they offer no response to Bayer's demonstration that the duty to train alleged in their complaint is *not parallel* to the FDA training requirements for Essure. Mot. 21–23. Plaintiffs read *McLaughlin I* as holding broadly that *all* negligent training claims parallel Essure's PMA requirements, including claims that Bayer failed "to ensure that physicians were trained in hysteroscopy." Opp. 27–28. That is wrong. To the contrary, as *McLaughlin* and numerous other courts have held, "training in the basics of hysteroscopy" is not "part of the FDA-mandated training" for Essure. *McLaughlin I*, 172 F. Supp. 3d at 817 n.9; *see also McLaughlin II*, 2017 WL 697047, at *4 (Essure's PMA "cannot reasonably be construed as requiring that Bayer ensure that doctors are knowledgeable hysteroscopists prior to their engaging in Essure training"); *Williams*, 2017 WL 6001531, at *10 ("[W]e find nothing to suggest that Bayer was the one required to provide [hysteroscopy] training.") (citing *McLaughlin I*). Plaintiffs' allegations that preceptors must be medical professional and that physicians should have been trained in removal likewise are not

parallel to any FDA training requirements. And contrary to Plaintiffs' contention that FDA's training requirements are "confidential," and discovery is necessary to determine them, in fact under FDA regulations all training requirements are set forth in the device's public labeling, 21 U.S.C. § 360j(e); *see* Mot. 21–22.

Additionally, as with their manufacturing claim, Plaintiffs provide no allegations connecting their alleged injuries with the alleged deficiencies in Bayer's FDA-approved training. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 817; *De La Paz*, 159 F. Supp. 3d at 1096 (dismissing negligent-training claim); *see also Frere v. Medtronic, Inc.*, No. EDCV 15-02338-BRO, 2016 WL 1533524, at *10 (C.D. Cal. Apr. 6, 2016) (dismissing similar claim for failure to "allege any facts" showing a "causal connection between the potential deviations and her injuries"). Indeed, the First Amended Complaint contains no facts at all about Plaintiffs' individual physicians, their training and experience with Essure, or how the physicians' training could possibly have affected Plaintiffs' procedures. In their opposition, Plaintiffs rest on boilerplate allegations that their physicians were inadequately trained, but do not even attempt to allege that these vague alleged training deficiencies had anything to do with their alleged injuries. *See* Opp. 29.

If Plaintiffs prevailed on their negligent training claim, Bayer would be required to train implanting physicians in a manner different than that required by FDA. This would, by definition, impose additional, different obligations on Bayer; the claim is therefore preempted and should be dismissed, as numerous other courts have ruled. *Accord, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1096; *McLaughlin I*, 172 F. Supp. 3d at 817; *Noris*, Apr. 26, 2016 Hr'g Tr. at 25:16-17 (RJN Ex. C).

C. Plaintiffs' Misrepresentation And Warranty Claims Are Preempted And Otherwise Fail.

For a state-law claim based on "false or misleading statements in unapproved advertising or other promotional materials" to survive preemption, a plaintiff must show that those statements are "*inconsistent* with specific statements in approved FDA materials." *McLaughlin I*, 172 F. Supp. 3d at 827; *see De La Paz*, 159 F. Supp. 3d at 1097-98 (dismissing as preempted state-law claim based on Essure advertising statements because "[w]ith one exception, each of De La Paz's examples is a statement that has been approved … by the FDA as a descriptor for Essure"); *Burrell*, 260 F. Supp. 3d at 494–95 (similar); *Williams*, 2017 WL 6001531, at *4–6 ("To find that Bayer made fraudulent or negligent misrepresentations through the making of these statements would require a finding contrary to that reached by the FDA and would consequently impose requirements different from, or in addition to, those set during the premarket approval process.").

Plaintiffs' breach of express warranty and negligent misrepresentation claims are preempted because they are based on statements that are consistent with—indeed, substantively identical to—FDA's approved labeling language for Essure. *See Norman*, 2016 WL 4007547, at *5-6; *Williams*, 2017 WL 6001531, at *4–6. Plaintiffs first ask the Court to disregard Bayer's table showing that each alleged misrepresentation was entirely consistent with Essure's FDA-approved labeling. Mot. 24–25. Plaintiffs assert that considering such material is "not proper at the pleading stage," but a multitude of courts have done so in dismissing misrepresentation and warranty claims as preempted. *See, e.g.*, *McLaughlin I*, 172 F. Supp. 3d at 827-28; *De La Paz*, 159 F. Supp. 3d at 1097-98 ; *Burrell*, 260 F. Supp. 3d at 494-95, at *7-8; *Williams*, 2017 WL 6001531, at *4–6. If the alleged misrepresentations are substantively identical to FDA-approved statements, then as a matter of law, any such claims are preempted.

Plaintiffs then respond with a chart of their own, purporting to show that five statements in the First Amended Complaint somehow deviated from FDA approved statements. Opp. 24–26. Plaintiffs' chart is unpersuasive. For starters, by their focus on these five discrete statements, Plaintiffs tacitly admit that the other statements discussed at pages 24 and 25 of Bayer's Motion *are* equivalent to FDA-approved statements. More fundamentally, Plaintiffs fail to show any inconsistency—indeed, Plaintiffs largely argue that the challenged statements were false, not that they were inconsistent with the labeling. And their attempts to demonstrate any inconsistencies fail. For example, Plaintiffs argue the claim that Essure is the "most effective form of permanent birth control" deviates from FDA-approved labeling. Opp. 24. However, Bayer has already shown that, in patient and physician labeling dating back at least to 2012, FDA *approved* statements showing that other forms of permanent birth control (tubal ligation and vasectomy) have higher failure rates. Mot. 25. Plaintiffs also point to statements about implanting physicians needing to be skilled hysteroscopists or have completed the Essure training procedure. Opp. 25. But Essure's physician labeling is clear: "This device should only be used by physicians who are knowledgeable hysteroscopists … and have successfully completed the Essure Training program." *E.g.*, RJN Ex. K, at 1; Ex. L, at 1; Ex. P, at 1. Finally, FDA has approved Bayer's description of Essure as being hormone free, *e.g.*, RJN Ex. N, at 5; of the occlusion process being "natural," *e.g.*, *id.* at 6; and of the research concerning PET fibers, *e.g.*, RJN Ex. K, at 4; Ex. O, at 12. Numerous cases have therefore dismissed claims challenging these same statements as preempted.[5]

[5] Plaintiffs' chart also includes a "misrepresentation" concerning nickel sensitivity that appears *verbatim* in Essure's FDA-approved labeling. *See, e.g.*, RJN Ex. K, at 5; Ex. P, at 1. And the alleged source of this misrepresentation is a safety and effectiveness document that is part of Essure's PMA and available on FDA's website as part of Essure's regulatory history. Opp. 26.

Relying on *Hofts*, 597 F. Supp. 2d 830, Plaintiffs make an alternative argument that their misrepresentation claims escape preemption because they are challenging Essure's alleged failure to "live up to the FDA-approved promises." Opp. 26. Plaintiffs' reasoning plainly fails because FDA approved *both* Essure's labeling *and* the device itself; before granting pre-market approval, the agency must "evaluate[] safety and effectiveness under the conditions of use set forth on the label," as well as "determine that the proposed labeling is neither false nor misleading." *Riegel*, 552 U.S. at 318 (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). Moreover, Plaintiffs' proffered saving construction bears no resemblance to the First Amended Complaint, which alleges "that the statements made by Bayer were false *ab initio*, and would have been so regardless of whether Bayer adhered to FDA requirements." *Williams*, 2017 WL 6001531, at *5 n.7. Thus, whether Plaintiffs claims are construed as alleging that the device is defective or that its labeling is inadequate, they are equally inconsistent with FDA's considered judgment, and equally preempted.

Finally, Plaintiffs argue their express warranty claims are not preempted because warranties are imposed by voluntary contract, not the FDA or state law, and thus are exempt from MDA preemption. But as Plaintiffs concede, a cause of action for breach of express warranty is imposed by state law. Opp. 23.[6] Moreover, whether the cause of action is captioned as misrepresentation or breach of express warranty, imposing liability for statements that FDA has approved interferes with FDA's authority to regulate medical devices. Accordingly, multiple courts have recognized that the MDA preempts express warranty claims. *See, e.g., In re*

[6] Plaintiffs incorrectly suggest it is relevant for preemption purposes whether a cause of action arises under the common law or "positive legislative enactments." The MDA preempts any state requirement—regardless of its source—different from or in addition to federal requirements. *See* 21 U.S.C. § 360k.

Medtronic, Inc., 623 F.3d at 1208 (the "express warranty claim interferes with the FDA's regulation of Class III medical devices and is therefore conflict preempted"); *Bass v. Stryker Corp.*, 669 F.3d 501, 515 (5th Cir. 2012) ("express warranty claims cannot be used to impose requirements greater than that provided by the FDA regulations"); *Horowitz*, 613 F. Supp. 2d at 285 (similar); *Norman*, 2016 WL 4007547, at *5 (finding breach of express warranty claim preempted); *De La Paz*, 159 F. Supp. 3d at 1098 ("The misrepresentation claims are based on the same statements that form the basis of De La Paz's claim for breach of express warranties, and they are preempted for the same reasons as that claim (namely, the statements conformed to statements approved by the FDA)."); *Williams*, 2017 WL 6001531, at *5.

And even if the MDA's preemption provision did not apply to "a voluntary *contractual* promise," *Cline v. Advanced Neuromodulation Systems, Inc.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012) (emphasis added), Plaintiffs did not allege that they entered into "contracts" with Bayer here. Rather, the alleged warranties are identical to the alleged misrepresentations, and are simply advertising statements.[7]

D. Plaintiffs' Failure To Warn Claims Are Preempted.

In its Motion to Dismiss, Bayer demonstrated that Plaintiffs' failure to warn claims are preempted. *See* Mot. 26–30. This is true both for Plaintiffs' claims challenging Essure's labeling, and for those based on an alleged failure to report adverse events.

[7] Plaintiffs also argue that their warranty and misrepresentation claims are not preempted because they fall within the "exemptions from federal preemption" set forth in 21 C.F.R. § 808.1(d)(1), Opp. 26–27. "But the *Riegel* plaintiffs made this same argument, and the Supreme Court rejected it, holding that the regulation 'fail[ed] to alter [the Court's] interpretation' of Section 360k(a)." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009) (quoting *Riegel*, 552 U.S. at 330), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

1. Claims Challenging The Adequacy of Essure Labeling Are Preempted.

Plaintiffs argue that their claims challenging the adequacy of Essure labeling are not preempted because Bayer could have, but did not, update the Essure label. Opp. 17–18 (citing 21 C.F.R. § 814.39(d)). As Bayer explained in its Motion to Dismiss, *see* Mot. 27, the regulation Plaintiffs cite says only that certain changes "may be placed into effect" prior to FDA approval. 21 C.F.R. § 814.39(d). A state-law *obligation* to change the label is necessarily different from or in addition to federal *permission* to change the label, and thus expressly preempted. *In re Medtronic*, 623 F.3d at 1205; *Riegel*, 552 U.S. at 329 (stating that the MDA § 360k(a) "[s]urely … would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings"); *see also Norman*, 2016 WL 4007547, at *3 ("[It] is clear that plaintiff cannot bring a claim because defendants failed to warn plaintiff personally … because such a claim would be expressly preempted as imposing obligations beyond those of the FDCA."). Nor does anything in 21 U.S.C. §§ 331 or 352 authorize or require Bayer to update Essure's labeling without FDA approval.

Plaintiffs further argue that MDA preemption does not apply to this question at all, because "express preemption under the MDA only exists where FDA has established device-specific federal requirements." Opp. 18. This argument disregards the core holding of *Riegel*, which is that a Class III device's PMA *does* "impose[] requirements under the MDA." 552 U.S. at 322. Through the PMA process, FDA approved Essure's label; FDA did not require (and indeed generally prohibited) Bayer to make unilateral changes to the label. *See* 21 U.S.C. § 360e(d)(6)(A)(i); *Riegel*, 522 U.S. at 319 (changes to label evaluated under "largely the same

criteria" as the initial application). Plaintiffs' attempt to force Bayer to make such changes through a state tort action are thus expressly preempted.[8]

2. Claims Challenging Adverse Event Reporting Are Preempted.

Likewise, Plaintiffs' claims based on an alleged failure to report adverse events to FDA are preempted. These claims are nothing more than "an attempt by [a] private part[y] to enforce the MDA," and are barred by both 21 U.S.C. § 337(a) and the Supreme Court's ruling in *Buckman,* as the Eighth Circuit recognized in *In re Medtronic*, 623 F.3d at 1205. To thread the narrow gap Congress left for state law in this area, Plaintiffs' claim must be "premised [on] the type of conduct that would traditionally give rise to liability under state law—*and* that would give rise to liability under state law even if the FDCA had never been enacted." *Pinsonneault v. St. Jude Med., Inc.*, 953 F. Supp. 2d 1006, 1016 (D. Minn. 2013) (emphasis added). Simply put, "the failure to properly or timely to warn the FDA via the MDR process, as opposed to warning … doctors or patients of a device's dangers, is not the type of conduct that would traditionally give rise to liability under state law even if the FDCA had never been enacted." *Id.* at 1017. To hold differently would permit Plaintiffs to "make an end run around the rule precluding suit by re-casting violations of the FDCA reporting requirements … as violations of state common law." *Id.* at 1016.

Plaintiff also relies upon *Stengel v. Medtronic Inc.*, in which the Ninth Circuit held a failure-to-warn claim was not preempted where the plaintiff alleged that he was injured by a

[8] Plaintiffs rely on an amicus brief in *Medtronic, Inc. v. Stengel*, 2014 WL 2111719 (U.S. May 20, 2014), which they claim provides FDA's views. Opp. 18–19. It does not; it provides the views of the U.S. Solicitor General, not those of FDA, which is an independent federal agency. On the merits, as the amicus brief acknowledges, *no court* has adopted its proposed approach to analyzing preemption under the MDA. 2014 WL 2111719, at *15. Simply put, Plaintiffs rely on a document that conflicts with the law.

failure to provide information to FDA because "Arizona law contemplates a warning to a third party such as the FDA." 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *see also Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011) (same, "[a]ssuming that a failure to warn [the FDA] claim may be pursued under Mississippi law"). *Stengel* is contrary to the Supreme Court's holding in *Buckman*, as numerous other courts have recognized. *See, e.g.*, *Medtronic*, 623 F.3d at 1205-06; *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319 (11th Cir. 2017).

In addition, a *Stengel*-type cause of action requires each Plaintiff to show that state law "contain[s] reporting requirements" or "contemplates a warning to a third party such as the FDA." *Kubicki ex rel. Kubicki v. Medtronic, Inc.*, No. 12–cv–734, 2018 WL 707428, at *34 n.25 (D.D.C. Feb. 5, 2018). Plaintiffs have not asserted any Illinois duty to warn a third-party such as the FDA, much less a corresponding duty under the laws of each of the 26 non-Illinois jurisdictions represented by Plaintiffs. In fact, an Illinois appellate court recently rejected a *Stengel*-type claim as a matter of state law because "there is no Illinois requirement that parallels" a manufacturer's duty to report adverse events to FDA. *See Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, ¶28. Numerous courts have rejected other Essure plaintiffs' misrepresentation claims for this same reason. *See, e.g., id.* (distinguishing *Stengel* under D.C. law); *Burrell*, 260 F. Supp. 3d at 492–93 (distinguishing *Stengel* under North Carolina law); *Norman*, 2016 WL 4007547 at *4 (distinguishing *Stengel* under Connecticut law); *Pearsall v. Medtronic, Inc.*, 147 F. Supp. 3d 188, 201-02 (E.D.N.Y. 2015) (distinguishing *Stengel* under New York law). This Court should do likewise.[9]

[9] If the Court does not dismiss this claim as preempted, the need to identify a state-by-state parallel obligation further underscores why the Court should sever-and-transfer the claims of non-Illinois Plaintiffs or dismiss those Plaintiffs claims under the *forum non conveniens* doctrine.

Plaintiffs have also failed to allege a plausible causal link between their injuries and Bayer's alleged reporting violations. In this regard, *Norman* and *Burrell* are directly on point. *See Norman*, 2016 WL 4007547, at *4; *Burrell*, 260 F. Supp. 3d at 492. As *Norman* explained: "Plaintiff's theory of causation seems to be that, had defendants kept up with their reporting requirements, this black box warning would have been issued earlier, and she would not have chosen to get the device implanted. But the FDA was aware of these reporting issues years before plaintiff's device was implanted, and the new type of warning did not change any of the warnings' substance—defendants, for example, were already required to advise physicians about the possibility of perforations." *Norman*, 2016 WL 4007547, at *4; *see Burrell*, 260 F. Supp. 3d at 492 ("[T]he newly-implemented black box warning … does not provide *new* information not otherwise noted; the same information was available on the prior labeling.").

Plaintiffs concede that FDA "receiv[ed]" the adverse-event reports. Opp. 21. And FDA did not take action with respect to Essure in response. Nearly three years later, FDA put a box around the warning, but "the warnings' substance" did not change, *Norman*, 2016 WL 4007547, at *4; *Burrell*, 260 F. Supp. 3d at 492, and FDA gave no indication that it was acting on information that was previously withheld. Plaintiffs' attempt here fails for the same reason it failed in *Norman* and *Burrell* – they have failed to allege that any failure to warn caused their injuries.

CONCLUSION

The Court should grant Bayer's motion to dismiss the complaint as to the non-Illinois Plaintiffs for lack of personal jurisdiction or under the doctrine of *forum non conveniens* and as to all Plaintiffs' claims because they are preempted.

Dated: February 19, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on February 19, 2018, a true and correct copy of the foregoing was served upon the following by electronic mail:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et. al.,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	Case No. 16-L-1046
BAYER, CORP., et al.,	)	
	)	Hon. Dennis R. Ruth
Defendants.	)	
	)	
	)	
	)	

PLAINTIFFS'MOTION FOR LEAVE TO FILE SUPPLEMENTAL RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Plaintiffs, by and through their undersigned counsel, hereby request that this Court grant leave to file their Supplemental Response in Opposition to Defendants' Motion to Dismiss. In support thereof, Plaintiffs state as follows:

1. Bayer filed its Motion to Dismiss on December 15, 2017.
2. Plaintiffs filed their Response to Bayer's Motion to Dismiss on February 9, 2018. Bayer filed its Reply on February 16. This Court heard argument on Bayer's Motion on February 22.
3. On February 27, 2018, additional evidence came to light, further strengthening Plaintiffs' contention that Defendants are subject to personal jurisdiction in Illinois.
4. Plaintiffs seek leave to file a supplemental response to Defendants' Motion to Dismiss to include this additional evidence. The additional memorandum, attached as Exhibit A, will be helpful to the parties and to this Court in ruling on the issues presented.

I. ADDITIONAL ILLINOIS CONTACTS

In 2008, Defendants contracted with a company named Sterigenics to conduct Essure device sterilization. Pursuant to their agreement, Defendants were to send Sterigenics a forecast of the sterilization requirements for each calendar year. Should Defendants' sterilization requirements exceed the provided forecast, Sterigenics had a "right of first refusal" as to the opportunity to perform sterilization services on the devices that exceed the original forecast. Sterigenics is headquartered in Oak Brook, Illinois.

Not only did Defendants conduct clinical trials in Illinois, create the physician training program in Illinois, and launch the patient awareness marketing campaign in Illinois, but they also contracted with Illinois-based Sterigenics to sterilize **all** Essure devices. These Illinois contacts "aris[e] out of or relat[e] to" Plaintiffs' manufacturing defect claims in this matter. *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014); *see also Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1780 (2017). Indeed, Plaintiffs' specifically allege that Defendants became aware of the production of non-sterile devices, and failed to use pre-sterile and post-sterile cages in the manufacture of Essure. These additional Illinois contacts give added credence to Plaintiffs' claims that Defendants are subject to personal jurisdiction in this Court.

II. FORUM NON CONVENIENS SHOULD BE DENIED

Even though Defendants did not meet their burden in demonstrating that Plaintiffs' claims should be denied based on forum non conveniens, these additional Illinois contacts further cement this point. In addition to choosing Illinois-based Sterigenics to sterilize all Essure devices, Defendants also agreed that Illinois would have **exclusive personal jurisdiction** over the agreement—the "validity, construction, interpretation and enforcement" of their agreement with

Sterigenics "shall be governed solely by the laws of the State of Illinois." Defendants went on to agree that "[a]ny and all suits or proceedings relating to this Agreement . . . **shall be brought only in the state or federal courts located in Illinois**. Each party consents to the **exclusive personal jurisdiction** and venue of the state of Illinois." Defendants' claims that Illinois is an inconvenient forum are belied by the fact that they have agreed to Illinois jurisdiction in other circumstances.

WHEREFORE, Plaintiffs request this Court grant their Motion for Leave to File Their Supplemental Response in Opposition to Defendants' Motion to Dismiss, and for such other relief as the Court deems proper.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned herby certifies that a true and accurate copy of the foregoing was served on all counsel of record through and served the following counsel via electronic mail on this 5th day of March 2018.

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et al., Plaintiffs, v. BAYER CORP., an Indian corporation; BAYER HEALTHCARE LLC, a Delaware corporation; BAYER ESSURE®, INC., (f/k/a CONCEPTUS, INC.) a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation, Defendants.	Case No: 16-L-1046 **JURY TRIAL DEMANDED**

BAYER'S RESPONSE TO PLAINTIFFS' MOTION FOR LEAVE TO FILE SUPPLEMENTAL RESPONSE IN OPPOSITION TO BAYER'S MOTION TO DISMISS

Plaintiffs seek leave to file what is effectively a sur-reply introducing a new fact to support its meritless arguments regarding personal jurisdiction. This new fact does not provide any support for Plaintiffs' position that there is personal jurisdiction in Illinois for the claims of Plaintiffs who do not live in Illinois, did not obtain Essure in Illinois, did not view marketing in Illinois, and were not injured in Illinois. As a matter of law, Plaintiffs' jurisdictional theory fails, as numerous courts have recently held.[1] There simply is no constitutionally adequate

[1] *See, e.g.*, *Dyson v. Bayer Corp.*, No. 4:17-cv-2584-SNLJ, 2018 WL 534375, at *2–5 (E.D. Mo. Jan. 24, 2018); *L. Jordan v. Bayer Corp.*, No. 4:17-cv-865-CEJ, 2017 WL 3006993, at *4 (E.D. Mo. July 14, 2017), *reconsideration denied*, 2018 WL 339305 (E.D. Mo. Jan. 8, 2018), *amended claims dismissed*, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018); *State ex rel. Bayer Corp. v. Moriarty*, No. SC 96189, 2017 WL 6460354, at *5–6 (Mo. Dec. 19, 2017); *Roland v. Janssen Research & Dev., LLC*, No. 3:17-cv-00757, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017), *appeal voluntarily dismissed sub nom. Luddy v. Janssen Research & Dev.*, LLC, No. 17-cv-3205 (7th Cir. Nov. 20, 2017).

"connection between the forum and *the specific claims* at issue." *Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1781 (2017).

The new fact on which Plaintiffs now rely—a partial and misleading description of a 2008 contract between Conceptus and a sterilization company (Sterigenics)—is irrelevant. The contract does not even relate to this forum. Nor does it relate to Plaintiffs' devices or, most importantly, to Plaintiffs' claims against Bayer. Plaintiffs' claims are not – and could not be – based on this contract and thus cannot support personal jurisdiction in Illinois. Indeed, Plaintiffs' new argument is even more attenuated than the marketing and clinical-trial arguments advanced previously, and fails to establish personal jurisdiction for the same reasons. *See* Mot. to Dismiss 10-16; Reply 5-10.

Plaintiffs contend that the contract between Sterigenics and Conceptus establishes that there is personal jurisdiction in Illinois because Sterigenics is an Illinois-based company. Despite relying on this contract, Plaintiffs do not attach it to their motion, and the reason is apparent: the contract states explicitly that Sterigenics would sterilize Essure devices at facilities *in California and New Mexico*. *See* Ex. A, at 1, 8(A-1).[2] Under the contract, Sterigenics did not agree to provide any services to Conceptus in Illinois, nor did the contract provide for any sterilization services to occur in Illinois. That certain Essure devices may have been sterilized in other states by an Illinois-based company that is not even a party to this action does not create any link—much less a constitutionally adequate one—between Plaintiffs' claims against Bayer and the State of Illinois. Indeed, *Bristol-Myers* squarely rejected an argument that a defendant's contract with a third party resident of the forum creates personal jurisdiction. 137 S. Ct. at 1783

[2] Bayer will file a motion for leave to file Ex. A, the contract referenced in Plaintiffs' proposed supplemental brief, under seal because the contract includes confidential information regarding terms and pricing.

("In a last ditch contention, respondents contend that BMS's 'decision to contract with a California company McKesson to distribute Plavix nationally' provides a sufficient basis for personal jurisdiction" for claims concerning Plavix, but "[t]he bare fact that BMS contracted with a California distributor is not enough to establish personal jurisdiction in the State.").

Moreover, Plaintiffs fail to identify any link between the Sterigenics contract and the non-Illinois Plaintiffs' devices or their claims for relief. The non-Illinois Plaintiffs do not allege in the Complaint that their own devices were sterilized by Sterigenics, that the sterilization of their own devices was inadequate, or that inadequate sterilization caused their injuries, much less that any of these activities occurred in Illinois. Indeed, the contract did *not* provide for any sterilization services to occur in Illinois. Ex. A. And while Plaintiffs incorrectly represent that Conceptus contracted with Sterigenics "to sterilize all Essure devices," the contract concerned only a certain design of the Essure device, which the non-Illinois Plaintiffs do not allege they obtained. Mot. 2; Ex. A, at 10–11 (A-1 to A-2). Thus, Plaintiffs' new arguments fail to address the critical deficiency in the non-Illinois Plaintiffs' claims: there remains no connection whatsoever between their devices, their claims against Bayer, and this forum. *Bristol-Myers*, 137 S. Ct. at 1781-82 (Due Process "require[s]" a "connection between the forum and the specific claims at issue.").

Finally, Plaintiffs' attempt to bootstrap personal jurisdiction from the contract's forum-selection clause only underscores the inadequacy of the connection between their own claims and this forum. In the contract, Conceptus entered into a commercial relationship with a party located in Illinois, and "consent[ed] to the exclusive personal jurisdiction and venue of the state

of Illinois" *with respect to claims regarding the contract.* Mot. 3.[3] Thus, if Conceptus sued Sterigenics for breach of contract, there would be personal jurisdiction over that suit in Illinois. But the non-Illinois Plaintiffs were not parties to the contract, and are not suing for breach of the contract. The non-Illinois Plaintiffs' claims have no connection at all to Illinois, and Bayer never consented to have these claims tried in Illinois.

Plaintiffs' belated attempt to supplement its argument with this contract thus adds no support to their arguments. Plaintiffs themselves seem not even to buy what they are selling, as it appears that 82 of the 87 non-Illinois Plaintiffs have already filed post-*Bristol-Myers* cases in their home states or in California. For the reasons explained previously, the Court should dismiss the non-Illinois Plaintiffs' claims for lack of personal jurisdiction or *forum non conveniens*, and should also dismiss the remaining Plaintiffs' claims as preempted by federal law.

Dated: March 26, 2018

Respectfully submitted,

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[3] Plaintiffs' quotation of the venue-selection clause is incomplete. Plaintiffs omit the contract language consenting to suit in the U.S. District Court for the *Northern* District of Illinois. Ex. A, at 4 § 8.2.

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CERTIFICATE OF SERVICE

I hereby certify that, on March 26, 2018, a true and correct copy of the foregoing was served upon the following by electronic mail:

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IN THE CIRCUIT COURT
THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

CHRISTY RIOS, et al., Plaintiffs v. BAYER, CORP., et al., Defendants	)))))))))	Case No. 16-L-1046

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR LEAVE TO FILE A SUPPLEMENTAL RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

COME NOW the Plaintiffs, by and through their counsel of record, and for their Reply in Support of Their Motion for Leave to File a Supplemental Response in Opposition to Defendants' Motion to Dismiss, state as follows:

Bayer's Response to Plaintiffs' Motion is nothing more than another desperate attempt to distance itself from this forum. Bayer claims there is no specific jurisdiction, and yet Plaintiffs continue to discover more and more evidence of its Essure-related, Illinois-based contacts. And every time, Bayer is forced to try to come up with some reason why those contacts don't matter. But the fact is they do matter. And when taken together, it reveals that Bayer's Essure-related Illinois contacts run deep.

I. ADDITIONAL ILLINOIS CONTACTS

Bayer's contention that the Sterigenics contract does not relate to this forum is preposterous. Bayer's response reads like the Sterigenics contract is the only contact it has with Illinois. As this Court is well aware, Bayer has substantial Essure-related contacts with Illinois through its clinical

trial activity, marketing activity, and patient awareness campaigns. It's Essure-related contact with Illinois goes far beyond the contact described by the Supreme Court in *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1780 (2017). This contract simply provides yet another reason why this Court should deny Bayer's Motion to Dismiss.

In addition, the Sterigenics contract gives rise or relates to Plaintiffs' manufacturing defect claims in this matter. This *exclusive* contract deals solely with Essure, and contains a provision agreeing that Illinois law, venue, and jurisdiction would govern all aspects. Plaintiffs' manufacturing defect claims are tied to this contract as well—Plaintiffs specifically plead that Bayer produced non-sterile devices and were cited by FDA for failing to use pre-sterile and post-sterile cages. This contract further proves that Bayer is subject to personal jurisdiction in Illinois.

The contract Plaintiffs reference in their Motion was produced by a third party in the California litigation. Plaintiffs did not attach the contract because, even though the contract has not been marked confidential, the Protective Order in the California litigation allows for third-party production to be designated "Confidential" within thirty days after production. At the time of the filing of their Motion, thirty days had not elapsed. Furthermore, Bayer could have marked this contract "Confidential" in this case, had it bothered to respond to Plaintiffs' Request for Production 167, which specifically asks for "all contracts or other agreements entered into by [Bayer] which select he law of Illinois in a choice of law provision."[1] Nevertheless, Plaintiffs are more than happy to provide the contract to the Court for review.

[1] Bayer's failure to produce this responsive document to Plaintiffs' discovery requests certainly raises questions as to additional responsive documents Bayer has failed to produce.

II. CONCLUSION

As shown above, and for the reasons outlined in Plaintiffs' Response to Defendants Motion to Dismiss, Bayer's motion to dismiss should be denied in its entirety. In the alternative, Plaintiffs should be granted leave to amend.

Respectfully submitted,

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The undersigned herby certifies that a true and accurate copy of the foregoing document was served upon all counsel of record via electronic mail on this **29th** day of **March, 2018**, as follows:

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HAMBY INDEX TO RECORD ON APPEAL

RIOS INDEX TO SUPPORTING RECORD