**IN THE SUPREME COURT OF MISSOURI**

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| **STATE OF MISSOURI *ex rel.* BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER ESSURE INC., and BAYER HEALTHCARE PHARMACEUTICALS INC.,** | **No. SC96189** |
| **Relators,** | **Missouri Court of Appeals, Eastern District No. ED105183** |
| **vs.** | **Circuit Court of St. Louis City Cause No. 1622-CC01049-01** |
| **THE HON. JOAN L. MORIARTY,** | **Division No. 31** |
| **Respondent.** | |

# BRIEF OF RESPONDENT THE HON. JOAN L. MORIARTY

**HOLLORAN SCHWARTZ & GAERTNER LLP**

James P. Holloran, #20662
Thomas E. Schwartz, #44504
Mark J. Gaertner, #50291
Justin D. Guerra, #59003
9200 Litzsinger Road
St. Louis, MO 63144
314-772-8989 phone
314-279-1333 fax
jholloran@holloranlaw.com
tschwartz@holloranlaw.com
mgaertner@holloranlaw.com
jguerra@holloranlaw.com

**ATTORNEYS FOR PLAINTIFFS**

**FLEMING | NOLEN | JEZ, LLP**

G. Sean Jez
Jessica Kasischke
2800 Post Oak Blvd., Ste. 4000
Houston, Texas 77056
713-621-7944 phone
sean_jez@fleming-law.com
jessica_kasischke@fleming-law.com

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## JURISDICTIONAL STATEMENT

On January 27, 2017, Relators Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc. (collectively referred to as "Bayer") petitioned this Court for a writ of prohibition. Bayer requested that the Court prohibit Respondent the Hon. Joan L. Moriarty ("Respondent") from enforcing her December 20, 2016 Order denying Bayer's motion to dismiss on preemption and jurisdictional grounds, as well as its alternative motion to sever and transfer.

The Court issued a Preliminary Writ on July 7, 2017, requiring that Respondent show cause why the December 20, 2016 Order should not be vacated and the Writ made permanent. Respondent answered timely. The Court has jurisdiction to hear the Writ under Missouri Constitution Art. V § 4.1.

## INTRODUCTION

This writ of prohibition proceeding arises from Respondent's Order of December 20, 2016, issued before changes were effected in Missouri jurisdictional law. Bayer requests the Court's grant of a permanent writ prohibiting Respondent from enforcing the Order, which **denied dismissal of all Plaintiffs' claims** on two bases: **(1) lack of personal jurisdiction;** and **(2) preemption**. Bayer seeks also to overturn another portion of the same order that **(3) denied severance** and **transfer of venue** of the non-Missouri Plaintiffs' claims.

The extraordinary relief Bayer requests is improper in all respects. Therefore, the Court should deny the writ for the following three reasons:

1. Any change in the law of Missouri personal jurisdiction does not require the dismissal of Plaintiffs' claims against Bayer. What it does—if anything—is to emphasize the need for Plaintiffs' amended pleading alleging Bayer's multiple contacts with Missouri (unnecessary in the 2016 petition).

Nor does *Bristol-Myers Squibb*, which Bayer banks on primarily, change anything, as it is based on unique and inapposite facts and settled authority. The decision simply reaffirms the circuit court's proper assertion of jurisdiction over Bayer as to Plaintiffs' claims due to Bayer's substantial contacts with Missouri, from which Plaintiffs' claims arise.

Bayer attempts alternatively to have the Court order the vacatur of Respondent's ruling denying severance and transfer of venue of the non-Missouri Plaintiffs' claims. In addition to Plaintiffs' proper joinder and venue under Missouri law, this Court's

recent decision in *Barron v. Abbott Labs.* is controlling. Since any error in denying severance and transfer did not prejudice Bayer, that portion of the Order was not an abuse of discretion either.

2. Since Plaintiffs' pleadings repeatedly allege Bayer's violations of Missouri law that parallels federal law, Supreme Court precedent holds their claims are not expressly or impliedly preempted. Further, despite the questionable "total preemption" orders Bayer alleges, many courts have remanded claims against Bayer in cases it had removed and tried to have preempted. As preemption is improper, Respondent did not abuse her discretion in denying Bayer's motion.

## STATEMENT OF FACTS

### A. Overview of the Facts

The following factual statement is somewhat unusual, in that it is clearly divided between the years 2016 and 2017. But the chronological division is logical under the circumstances. The *Johnson* litigation began in 2016, and thus Plaintiffs' pleadings were drafted in accordance with extant Missouri jurisdictional authority—*i.e.*, "consent jurisdiction" through Bayer's designation of a registered agent for service in the state. Accordingly, as Respondent's December 2016 Order reflects, Bayer's contacts with Missouri were not required to be alleged in any detail for personal jurisdiction to be asserted.

But 2017 was a watershed year for personal jurisdiction in Missouri, because the traditional doctrine of consent jurisdiction has been judicially abolished since February 28. Consequently, Bayer's many contacts not alleged in the April 2016 petition are set out

below in the 2017 factual statement, derived from documents Bayer had previously produced.

**B. Facts: 2016**

The underlying litigation began on April 13, 2016, when Gloria Johnson, joined by 91 Plaintiffs, sued Bayer in the Circuit Court of St. Louis City, bringing product and personal injury claims related to Bayer's contraceptive device Essure. **Bayer A1–46.**

Gloria Johnson and six other Plaintiffs reside in Missouri, while the remaining 85 are from various other states. All Plaintiffs had Essure devices implanted, all suffered from Essure-related medical complications, and all had the devices removed. ***Id.* at 26–27 (¶¶ 141–42)**. Gloria Johnson had her Essure device implanted in the City of St. Louis. She suffered injuries from the device in the City, and had it explanted there as well. ***Id.* at A4 (¶ 2)**.

Plaintiffs' seven-count petition alleged the following Missouri state claims for injuries caused by Bayer's Essure® device: strict products liability; negligent failure to warn; negligence in training; negligence in manufacturing; negligence/negligence per se; negligent misrepresentation; and breach of express warranty. ***Id.* at A27, A30, A33, A35, A37, A40, A42.**

Throughout the petition Plaintiffs repeatedly cited the federal regulations Bayer had breached, and alleged as well the parallel Missouri state laws that Bayer had violated. ***Id.* at A14–16, A18–19, A26–28, A30–31, A33–40, A42 (¶¶ 122, 127–29, 139, 147–48, 161, 166–67, 178, 180–81, 187–89, 207)**. Additionally, Plaintiffs' opposition to Bayer's motion

to dismiss, filed in Respondent's court, included specifics as to Bayer's breaches of the Missouri laws paralleling the cited federal regulations. ***Id.* at A250, 290–91**.

Further, Bayer's contacts with Missouri are extensive. Not only did Bayer conduct clinical trials in Missouri, but it also developed its entire nationwide marketing strategy for Essure in Missouri. Bayer used Missouri-based marketing companies, Medical Consulting Group and Patientbuilder.com, to provide physicians all over the country with Essure marketing materials. **Respondent A175–257.**

Shortly after the *Johnson* petition was filed, Bayer removed it on federal question and diversity jurisdiction (No. 4:16-CV-729). Within days the U.S. District Court for the Eastern District of Missouri *sua sponte* ordered the action remanded for lack of subject matter jurisdiction. **Respondent A82–88**. Bayer then moved to dismiss and sever, followed by a motion to stay, in the closed federal proceedings. The motions were denied. **Respondent A89–90**.[1]

On June 20, 2016, Bayer moved for dismissal in Respondent's court based on preemption, lack of personal jurisdiction, forum non conveniens, and pleading inadequacy.

[1] Bayer also tried to appeal the remand to the U.S. Court of Appeals for the Eighth Circuit (No. 16-2923). The Eighth Circuit dismissed the appeal in late August 2016. **Respondent A91–92.**

**Bayer A47–84**.[2] Bayer then moved alternatively for the severance of the non-Missouri Plaintiffs' cases and a transfer of venue. **Bayer A332–93**.

On December 20, 2016, Respondent issued a 12-page order denying the dismissal of Plaintiffs' claims on all grounds Bayer asserted. The order denied severance and transfer as well. **Bayer A394–405**.

**C. Facts: 2017**

On January 13, 2017, shortly after Respondent had denied the motions, Bayer petitioned the appellate court for a writ of prohibition. It sought dismissal founded on preemption and lack of personal jurisdiction. **Bayer A406–35**. On January 18, 2017, the Missouri Court of Appeals, Eastern District, denied writ in a one-page order (No. ED105183). **Bayer A436**. Consequently, Bayer petitioned this Court for a writ of prohibition on January 27, 2017. The writ was accompanied by suggestions in support. **Bayer A437–66**.

Meanwhile, during the ongoing *Johnson* proceedings the Court changed the law upon which Respondent and Plaintiffs had relied, by ending consent personal jurisdiction in Missouri. That spurred Bayer's submission to the Court of supplemental suggestions on March 3, 2017. The suggestions cited *State ex rel. Norfolk S. Ry. Co. v. Dolan* as additional support for the grant of a writ dismissing all claims. **Respondent A93–94**.

Understandably, since Plaintiffs' original petition had adhered properly to Missouri authority on consent jurisdiction, they sought to amend their pleading post-*Norfolk*.

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[2] Bayer does not challenge its latter two positions in this proceeding. Br. at 5 n.1.

Accordingly, Plaintiffs served Bayer with a set of jurisdictional interrogatories and requests for production in May 2017. ***Id.* at A98–170.** But Bayer has refused to provide any meaningful responses, instead producing two pages of blanket objections. ***Id.* at A171–73.** Bayer had previously produced some documents establishing its contacts with Missouri in response to Plaintiffs' requests for Essure marketing materials. Copies of those documents are included in Respondent's Appendix at **A171–257.** *See also* ***id.* at A307.**

*Bristol-Myers Squibb*, the Supreme Court's decision on jurisdiction filed in late June 2017, spurred Bayer's filing with the Court of a second set of supplemental suggestions. Attaching a copy of the opinion, once again Bayer maintained that the Court should grant a writ of prohibition dismissing all claims. **Bayer A522–55.**

This Court issued a preliminary writ of prohibition on July 7, 2017, requesting Respondent to show cause why the writ should not be made permanent. ***Id.* at A467.** Respondent answered on July 25, 2017. ***Id.* at A469–75.**

Bayer filed its Relators' brief on August 24, 2017. Respondent's brief follows.

## ARGUMENT

## I. RESPONSE TO RELATORS' FIRST POINT RELIED ON: "BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS AS TO NON-MISSOURI PLAINTIFFS' CLAIMS BECAUSE BAYER IS NOT SUBJECT TO PERSONAL JURISDICTION WITH RESPECT TO THE CLAIMS OF THESE NON-MISSOURI PLAINTIFFS AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE."

### A. Introduction

Respondent did not abuse her discretion when she determined that Bayer was subject to personal jurisdiction over the non-Missouri Plaintiffs. Since the date when Respondent issued her order denying the relief Relators sought this Court issued *State ex rel. Norfolk S. Ry. v. Dolan*, 512 S.W.3d 41, 52 (Mo. banc 2017) and the Supreme Court issued *BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549 (2017) and *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco County*, 137 S. Ct. 1773, 1779 (2017). Nevertheless, Relators' contacts with Missouri meet the requirements of these recent precedents, as well as Due Process. If this Court finds otherwise, Respondent should be given the opportunity to consider these recent cases.

### B. Bayer does not Meet the "Extraordinary Relief" Standard Entitling It to a Writ of Prohibition

The writ of prohibition Bayer seeks is an extraordinary remedy that is discretionary with this Court. *See, e.g.*, *Derfelt v. Yocom*, 692 S.W.2d 300, 301 (Mo. banc 1985) (citation omitted). It must therefore be used with "great caution, forbearance, and only in cases of extreme necessity." *Id.* Nor does a writ issue as a matter of right. *State ex rel. Hannah v. Seier*, 654 S.W.2d 894, 895 (Mo. banc 1983). In other words, writ must be issued sparingly. *See State ex rel. Doe Run Resources Corp. v. Neill*, 128 S.W.3d 502, 504 (Mo. banc 2004).

Writ may be granted in only three situations: (1) where necessary to prevent a usurpation of judicial power; (2) to remedy an excess of jurisdiction or an abuse of discretion; or (3) to prevent an absolute irreparable harm to a party. *See State ex rel. Ford Motor Co. v. Manners,* 239 S.W.3d 583, 586 (Mo. banc 2007); *State ex rel. Director of Revenue, State of Mo. v. Gaertner*, 32 S.W.3d 564, 566 (Mo. banc 2000); *State ex rel. Chassaing v. Mummert*, 887 S.W.2d 573, 577 (Mo. banc 1994).

For reasons discussed below, Bayer is not entitled to the extraordinary relief it seeks. The Court should quash the writ of prohibition.

**C. No Consent Jurisdiction Over Bayer**

Respondent's jurisdictional analysis and conclusion in the December 20, 2016 Order was based in part on the traditional doctrine of "consent jurisdiction." When issued, the Order held properly that Bayer had consented to jurisdiction for all purposes by designating a registered agent for service in Missouri, in which it was doing business. *See, e.g.*, *Bryant v. Smith Interior Design Grp., Inc.*, 310 S.W.3d 227, 232 (Mo. banc 2010); *State ex rel. K-Mart Corp. v. Holliger*, 986 S.W.2d 165, 167 (Mo. banc 1999).

But this Court held recently that consent jurisdiction is no longer the law in Missouri:

> The plain language of Missouri's registration statutes does not mention consent to personal jurisdiction for unrelated claims, nor does it purport to provide an independent basis for jurisdiction over foreign corporations that register in Missouri.

*See Norfolk S. Ry.*, 512 S.W.3d at 52.

In seeking writ, Bayer argues to the Court that it did not consent to personal jurisdiction in Missouri. But that is no longer an issue. Because *Norfolk Southern Railway* has been the law of Missouri on consent jurisdiction since February 28, 2017, Respondent's brief does not argue personal jurisdiction on that basis.

**D. No General Jurisdiction Over Bayer**

Bayer points out that the December 20, 2016 Order did not address general personal jurisdiction. Br. at 15. Respondent included no such discussion in the Order because, given Bayer's consent to jurisdiction, there was no need to at the time.

Then, within months of this Court's conclusion that consent jurisdiction does not exist in Missouri, the U.S. Supreme Court handed down a decision on jurisdiction. *See BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549 (2017). Under the facts of the case, Tyrrell, a BNSF employee residing in North Dakota, sued in Montana state court for injury sustained outside the state. Although BNSF had railway tracks and employees in Montana, it was not incorporated in the state, nor did it maintain its principal place of business in Montana. Further, its in-state business was not substantial enough to make the corporation "at home"

in Montana. Therefore, the Supreme Court held that general jurisdiction was lacking over BNSF. *Id.* at 1559.

Since Plaintiffs had relied mainly on consent jurisdiction over Bayer (rather than all-purpose general jurisdiction) to oppose dismissal at the circuit court, they would not have argued that *BNSF* applied. And as Plaintiffs do not assert general jurisdiction here, *BNSF* does not apply to this proceeding either.

**E. Specific personal jurisdiction over Bayer is properly asserted because the law has not changed**

The Court's personal jurisdictional analysis regarding Bayer, a nonresident defendant, begins with its examination of "the relationship among [out-of-state Bayer], the forum, and the litigation." *See Bristol-Myers Squibb Co.*, 137 S. Ct. at 1779 (2017) (citing *Walden v. Fiore*, 134 S. Ct. 1115, 1121–23 (2014)); *Andra v. Left Gate Prop. Holding, Inc.*, 453 S.W.3d 216, 226–28 (Mo. banc 2015) (citing *Walden*; reversing jurisdictional dismissal due to nonresident defendant's sufficient contacts). Further, the Due Process Clause of the Fourteenth Amendment limits personal jurisdiction of the circuit court over Bayer when asserting jurisdiction would offend "traditional notions of fair play and substantial justice." *See Daimler AG v. Bauman*, 134 S. Ct. 746, 753–57 (2014); *Bryant v. Smith Interior Design Gp., Inc.*, 310 S.W.3d 227, 232 (Mo. banc 2010) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

Unlike general jurisdiction, where a Missouri court can hear any claim against an out-of-state defendant "at home" in Missouri, in "specific" or "case-linked" personal jurisdiction, Plaintiffs' claims against Bayer must "arise out of or relate to" its conduct with

Missouri.[3] *See Helicopteros Nacionales de Colombia SA v. Hall*, 466 U.S. 408, 414 (1984); *Daimler*, 134 S. Ct. at 751 (both cited in *Bristol-Myers*, 137 S. Ct. at 1780).

In late June 2017, the Supreme Court handed down *Bristol-Myers Squibb*, a decision on specific jurisdiction. Two things are significant about the decision:

**First**, *Bristol-Myers* did not in any way change the law. Rather, it adhered to longstanding precedent on specific jurisdiction: "Our settled principles regarding specific jurisdiction control this case." 137 S. Ct. at 1781. And **second**, the facts of *Bristol-Myers* are highly unusual and limited to that case alone.

Nonetheless, Bayer tries to fit the facts of this litigation into the unique facts of *Bristol-Myers*. Its attempt fails. *Bristol-Myers* involved non-California plaintiffs suing a non-California defendant—having no contacts of its own with that state related to the lawsuit—for injuries sustained through their ingestion of Plavix (a prescription anti-coagulant). 137 S. Ct. at 1778. Here, by contrast, Bayer has numerous personal contacts with Missouri.

*Bristol-Myers'* holdings, which rely on Supreme Court precedent cited repeatedly in the decision, may be summarized by the following quotations:

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

[3] A corporation is typically "at home" in a state where it is incorporated or has its principal place of business. *See Daimler*, 134 S. Ct at 760 (citation omitted).

- "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*, 134 S. Ct. at 754 ) (alterations in original; emphasis supplied).
- "[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).

*Bristol-Myers* involved in-state and out-of-state plaintiffs who sued in California regarding their use of Plavix. 133 S. Ct. at 1778. But as the Supreme Court stressed, "**[*Bristol-Myers*] 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 at all the case with Essure. Plaintiffs did not need to allege in 2016—nor could they have done so without Bayer discovery—the details of Bayer's substantial contacts with the State of Missouri. But they have alleged Bayer's jurisdictional contacts in a draft amended pleading. **Respondent A1–81.**

Bayer conducted clinical trials in Missouri and used the state to develop its nationwide marketing campaign. The Missouri clinical trials relate directly to **all Plaintiffs' claims**, regardless of state of residence, because without the Missouri clinical

trials and nationwide marketing arising from Missouri, no Plaintiff anywhere would have had her Essure device implanted.

A recent decision agrees. In *Cortina v. Bristol-Myers Squibb Co.*, a court analyzed this very issue:

> [T]he Court notes that the United States Supreme Court recently held in *Bristol-Myers Squibb Co.* . . 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.". . . . The present case is distinguishable. . . . 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). The same holds true here.[4] And ultimately out of those trials came the misinformation regarding the product's safety and effectiveness described in the Complaint. 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.").

Unlike Bristol-Myers and its drug Plavix, Bayer developed Essure using Missouri clinical trials, created a marketing strategy for Essure in Missouri, and worked on the regulatory approval of Essure using Missouri investigators and physicians. Thus, all Plaintiffs' claims arise through Bayer's contacts with Missouri.

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[4] Missouri also applies the "but for" test for causation: "[T]he 'but for' test continues to apply to the vast majority of cases in Missouri. We now reiterate that the 'but for' test for causation is applicable in all cases except those involving two independent torts, either of which is sufficient in and of itself to cause the injury. . . ." *Callahan v. Cardinal Glennon Hosp.*, 863 S.W.2d 852, 862–63 (Mo. 1993).

For example, Plaintiffs would have alleged—and do so now in their attached amended pleading—a host of false and misleading marketing tactics, all of which can be tied to the strategy Bayer developed in Missouri. **Respondent A4–9, A34–38 (¶¶ 9–12, 200–08)**. And Plaintiffs' amended pleading goes on to claim that Bayer's contacts with Missouri were integral to its ability to distribute Essure to all Plaintiffs and their implanting physicians. ***Id.* at A39–40, A62–63 (¶¶ 209, 214, 347–59)**. In other words, but for Bayer's conduct in Missouri; Plaintiffs would not have been harmed by Essure.

Bayer tries to minimize the importance of its clinical trial activity by claiming that because non-Missouri Plaintiffs did not participate in the clinical trials, this contact with Missouri is not sufficient for personal jurisdiction. Relators' Br. at 18. That is a ridiculous proposition, since the FDA **required** Essure clinical trials; and the Essure PMA **required** that Bayer continue to submit annual reports to the FDA based on its clinical trials. Bayer chose Missouri to carry out these required activities.

Bayer attempts to ignore the following facts dispositive of personal jurisdiction:

(1) Bayer chose Missouri to conduct these clinical activities, i***d.* at A5–9**;

(2) Bayer selected Missouri physician Dr. David Levine to market and promote Essure, i***d.* at A199–205**;

(3) Bayer developed a nationwide marketing strategy in Missouri, and ***id.* at A171–98, A207–57;**

(4) Bayer chose St. Louis, Missouri as the first city in the country to offer Essure in a commercial setting, through Dr. Levine. ***Id.* at A8 (¶ 10).**

In summary, **Bayer chose the State of Missouri.** Its contacts are much more far reaching than simply having a patient decide on Essure in her doctor's office in Missouri, as Bayer would have the Court believe. After having deliberately selected Missouri for the above-described activities, Bayer cannot now contend Missouri courts do not have jurisdiction over claims related to its conduct in the state.[5]

Further, Bayer's **marketing strategy developed in Missouri** amounts to significantly more than just a Missouri woman or physician seeing a commercial or print ad for Essure. The Essure marketing strategy, eventually rolled out nationwide, arose from Bayer's Missouri contacts. For example, Bayer used a **Missouri-based marketing company**, Medical Consulting Group (MCG), to publish a "Best Practices" section in episodic newsletters entitled "Essure Matters." ***Id.* at A177–92.** And as the newsletter itself admits, it is "for the Essure Physician Community"—this includes Plaintiffs' implanting physicians. In fact, Bayer refers to MCG as its "**partner**[] in creating the *Essure* Accreditation Program and the Consumer Awareness Campaign." ***Id.* at A179 (emphasis supplied); *see also id.* at A175.** Bayer also partnered with yet another Missouri-based

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[5] Bayer relies on *Jordan v. Bayer Corp.* in an attempt to bolster its personal jurisdiction arguments. No. 4:17-cv-865, 2017 WL 3006993 (E.D. Mo. July 14, 2017). However, *Jordan* was decided one day after the plaintiffs filed their motion for leave to file an amended complaint outlining all of Bayer's Missouri contacts. The opinion does not mention the first amended complaint, nor address any of the jurisdictional facts set forth in it.

company, Practice Development Consulting, LLC, to "further integrate *Essure* into practices." ***Id.* at A189.**

Indeed, in a letter to physicians, Bayer admits that "[i]n an effort to increase consumer awareness about the Essure procedure, [it] has shifted its marketing efforts away from regional campaigns towards a national scope. Last fall marked the beginning of [Defendants'] national advertising campaign." ***Id.* at A206**. Bayer went on state that the nationwide marketing had already produced "an increase in Essure website traffic and brand awareness numbers." ***Id.*** All of Bayer's consumer marketing efforts were directed towards its national programs, all created in Missouri. ***Id.***

Bayer used this same Missouri marketing company to put together a two-day seminar for physicians throughout the U.S., which included courses on the Essure Accreditation Program and the "patient awareness campaign." ***Id.* at A175**. Moreover, the same group created all radio advertisements for Essure **(*Id.* at A193)**, and presented numerous webinars to physicians on how to increase the number of Essure patients in their practice. ***Id.* at A203–57.**

In addition to the origination of all Bayer's Essure marketing in Missouri, Bayer also encouraged its Essure-partner physicians to market through patientbuilder.com, a Missouri-based advertising firm. ***Id.* at A221–24.** Bayer suggested physicians increase patient demand for Essure by utilizing marketing templates available through patientbuilder.com. ***Id.***

Thus, whether out-of-state Plaintiffs viewed the Essure marketing materials in Missouri is not the point. In *Bristol-Myers*, the Supreme Court noted that the defendant **did**

**not** "create a marketing strategy for Plavix in California." This is exactly opposite to the facts here. **Without Missouri**, Bayer's scheme of fraudulent and misleading marketing (as is alleged in Plaintiffs' amended pleading **Respondent A1–81**) would not have been possible. This distinction matters, since these Missouri activities satisfy the "but for" test for causation. Bayer cannot dodge jurisdiction by trying to minimize this point.

### F. Respondent Properly Denied Severance and Transfer of Venue

Almost as an afterthought, Bayer devotes two pages at the end of its lack of jurisdiction argument to claiming Respondent erred by not severing the non-Missouri Plaintiffs' claims and transferring their venue. Bayer is wrong again.

The Court should not vacate and reverse the order for the following three reasons:

- All Plaintiffs were properly joined under Missouri law. Their claims should not be severed, because, as statutorily required, they arise out of the same series of transactions or occurrences and share common questions of law or fact;
- Venue is proper for the entire action because Plaintiff Gloria Johnson was "first injured" in the City of St. Louis and all other Plaintiffs were properly joined with her; and
- Bayer suffered no prejudice from Respondent's failure to sever and transfer the non-Missouri Plaintiffs' claims.

**First**, the joinder of all *Johnson* Plaintiffs' claims is proper under the Missouri Annotated Statutes and the Rules of Civil Procedure. MO. ANN STAT. § 507.040, governing permissive joinder of parties, provides the following:

> All persons may join in one action as plaintiffs if they assert any right to relief jointly, severally, or in the alternative in respect of or arising out of the same transaction, occurrence or series of transactions or occurrences and if any question of law or fact common to all of them will arise in the action. . . . A plaintiff. . . need not be interested in obtaining. . . all the relief demanded. Judgment may be given for one or more of the plaintiffs according to their respective rights to relief. . . .

And MO. R. CIV. P. 52.05 allows for permissive joinder in a verbatim rule. Adopted from FED. R. CIV. P. 20, Rule 52.05 must be interpreted broadly, as is the federal rule. *See State ex rel. Allen v. Barker*, 581 S.W.2d 818, 826 (Mo. banc 1979) (relying on *United Mine Workers of Am. v. Gibbs*, 228 U.S. 715, 724 (1966)).

**Second**, venue in Missouri is determined statutorily. *State ex rel. Ford Motor Co. v. Manners*, 161 S.W.3d 373, 375 (Mo. 2005). The venue statute, MO. ANN. STAT. §508.010.4, provides the following:

> [I]n all actions in which there is any count alleging a tort and in which the plaintiff was first injured in the state of Missouri, venue shall be in the county where the plaintiff was first injured by the wrongful acts or negligent conduct alleged in the action.

Further, nothing in the text of § 508.010 or any other statutory provision, requires that every properly joined party satisfy the venue statute individually.

In short, Plaintiffs' petition, supported by the facts, precisely followed the joinder and venue statutes and rule. Plaintiffs alleged that their claims present common questions of fact and law, that their injuries resulted from Bayer's common course of conduct, and that their claims arise out of the same series of transactions or occurrences:

> The Plaintiffs are all properly joined in this action pursuant to Section 507.040 of the Missouri Revised Statutes as they assert a right to relief under the same series of occurrences, and questions of law and fact are common to all plaintiffs in this action.

**Bayer A10 (¶ 103).** And the petition alleges more venue facts about Gloria Johnson, a City of St. Louis resident who was first injured by Bayer's wrongful acts and negligent conduct in the City. Further, both the implant and removal of Bayer's Essure device occurred in the City of St. Louis. ***Id.* at A4 (¶ 2).** Bayer's lip-service argument does nothing to change those facts.

And **third**, this Court's recent decision on lack of prejudice is dispositive of the issue. *See Barron v. Abbott Labs., Inc.*, ___ S.W.3d___, 2017 WL 4001487 (Mo. banc Sept. 12, 2017).

*Abbott* concerns a plaintiff (Maddison Schmidt) with no connection to Missouri, who joined with four Missouri plaintiffs and 19 other non-Missouri plaintiffs to sue Abbott for personal injury in the Circuit Court of the City of St. Louis. Abbott appealed the

judgment on, among other grounds, the court's overruling of its motions to sever Schmidt's claims and to transfer venue. As does Bayer in this case, Abbot asserted that joinder was improper under Rule 52.05; and consequently, that venue in the City of St. Louis was improper as well.

Affirming the appellate court's judgment against Abbott, this Court disagreed. The Court relied on MO. R. CIV. P. 84.13(b), which provides that: "No appellate court shall reverse any judgment unless it finds that error was committed by the trial court against the appellant materially affecting the merits of the action." *Abbott*, 2017 WL 4001487, at *2. Therefore, the Court held that a showing of prejudice is required—and Abbott, arguing in conclusory fashion merely that the City of St. Louis was biased—showed none. Consequently, error, if any, was harmless and not grounds for reversal.

The same holds true here. Bayer made no showing of having been prejudiced by the ruling which denied severance and transfer. At best, it alleged a violation of its "due process rights" and a "needless waste of judicial resources in Missouri." Those are not grounds upon which to base a writ of prohibition.

**II. RESPONSE TO RELATORS' SECOND POINT RELIED ON: "BAYER IS ENTITLED TO A PERMANENT ORDER PROHIBITING RESPONDENT FROM ENFORCING HER ORDER DENYING BAYER'S MOTION TO DISMISS BECAUSE ALL PLAINTIFFS' CLAIMS ARE EXPRESSLY OR IMPLIEDLY PREEMPTED UNDER FEDERAL LAW AND RESPONDENT ABUSED HER DISCRETION AND USURPED JUDICIAL AUTHORITY IN HOLDING OTHERWISE."**

## A. Introduction

Respondent did not abuse her discretion when she determined that Plaintiffs' state-law claims were not preempted.

## B. Bayer does not Meet the "Extraordinary Relief" Standard Entitling It to a Writ of Prohibition

The writ of prohibition Bayer seeks is an extraordinary remedy that is discretionary with this Court. *See, e.g.*, *Derfelt v. Yocom*, 692 S.W.2d 300, 301 (Mo. banc 1985) (citation omitted). It must therefore be used with "great caution, forbearance, and only in cases of extreme necessity." *Id.* Nor does a writ issue as a matter of right. *State ex rel. Hannah v. Seier*, 654 S.W.2d 894, 895 (Mo. banc 1983). In other words, writ must be issued sparingly. *See State ex rel. Doe Run Resources Corp. v. Neill*, 128 S.W.3d 502, 504 (Mo. banc 2004).

Writ may be granted in only three situations: (1) where necessary to prevent a usurpation of judicial power; (2) to remedy an excess of jurisdiction or an abuse of discretion; or (3) to prevent an absolute irreparable harm to a party. *See State ex rel. Ford Motor Co. v. Manners,* 239 S.W.3d 583, 586 (Mo. banc 2007); *State ex rel. Director of Revenue, State of Mo. v. Gaertner*, 32 S.W.3d 564, 566 (Mo. banc 2000); *State ex rel. Chassaing v. Mummert*, 887 S.W.2d 573, 577 (Mo. banc 1994).

For reasons discussed below, Bayer is not entitled to the extraordinary relief it seeks. The Court should quash the writ of prohibition.

## C. A Writ of Prohibition Is Improper because Plaintiffs' Claims Are Not Preempted

Bayer asserts Respondent "clearly abused her discretion" in determining Plaintiffs' claims are not preempted by federal law. It maintains the claims are expressly preempted

by the Medical Device Amendments Act, 21 U.S.C. § 360k (MDA), or impliedly preempted under *Buckman*. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Its arguments lack merit.

In addition, Bayer's claim that there is no presumption against preemption is wrong. Bayer Br. at 25. In order to reach this erroneous conclusion, Bayer cites to a recent Supreme Court bankruptcy case,[6] not a medical device case with well-established exceptions to the express preemption clause. The law is clear: "Federal laws containing a preemption clause do not automatically escape the presumption against preemption." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 334 (2008). The Court further noted that the presumption against preemption was "operative even in construing a preemption clause." *Id.* at n.9.

The Court should pay no heed to Bayer's express preemption allegations because the plain language of the MDA's express preemption provision ends them. The wording applies only to state requirements that are "**different from, or in addition to, any requirement applicable under [federal law] to the device**." 21 U.S.C. § 360k(a) (emphasis supplied).

The Supreme Court has interpreted this language twice. First, it held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996), that states have "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements" for medical devices. And second, the Court concluded in *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008), that a state may provide "a damages remedy for

[6] *Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016).

claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements."

Respondent refers the Court to portions of the petition and opposition to dismissal cited above and included in the parties' appendices. Those allegations prove that Plaintiffs repeatedly cited federal law and parallel state claims.

Additionally, Bayer's argument concerning implied preemption must fail as well. *Buckman* did not extinguish cases based "on traditional state tort law principles," as opposed to novel fraud-on-the-FDA claims, 531 U.S. at 352.

In *Buckman*, the plaintiff's claim alleged the defendant had fraudulently obtained FDA approval to use certain orthopedic screws by deceiving the agency during the premarket approval process. 531 U.S. at 346. The Court noted that the statute itself "amply empowers the FDA to punish and deter fraud against the Administration"; and further, that "allowing fraud-on-the-FDA claims under state tort law" to proceed, even when the FDA had decided no action was appropriate, had the potential to skew "a somewhat delicate balance of statutory objectives." *Id.* at 348. But the Court took care to note that its decision was not intended to displace claims under "traditional state tort law which had predated the federal enactments in question." *Id.* at 353.

That is how the *Buckman* Court distinguished *Lohr*. It explained that the claims in that case "arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements." 531 U.S. at 352. As explained in detail below, Plaintiffs' claims are grounded in traditional tort theories, and they do not require the courts to second-guess any federal regulatory decision.

In this circumstance, "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Plaintiffs brought claims for several forms of negligence and products liability that caused their injuries:

- Strict liability for (a) failing to manufacture Essure according to reasonable standards of care and federal standards, including Good Manufacturing Practices, and (b) failing to report adverse events associated with the device, and thus ultimately providing defective warnings Plaintiffs and their physicians. **Bayer A27–30.**
- Breach of duty to report adverse events to the FDA, thereby breaching the duty to update Essure labeling to allow physicians and patients to have had direct access to accurate information about the true degree of risk presented by Essure. ***Id.* at A30–33.** Timely reporting and label update would have led to the dissemination of accurate information, alerted Plaintiffs and their physicians to the risks of using Essure, and would have discouraged Plaintiffs from using Essure, thus preventing the Plaintiffs' injuries.
- Breach of duty to properly certify and train the implanting physicians on the proper implantation of the device. ***Id.* at A33–35.**
- Breach of duty to manufacture Essure according to reasonable standards of care and federal standards, including Good Manufacturing Practices.

Plaintiffs' implants were therefore vulnerable to degradation, deterioration, leaching, and breakage. ***Id.* at A35–37.**

- Breach of duty to exercise reasonable care in the communications of the risks and benefits of Essure. Bayer disseminated material false misrepresentation to Plaintiffs and their physicians. ***Id.* at A40–43.**

As Plaintiffs' petition explains, both state and federal law impose an obligation on Bayer to maintain the accuracy of the warnings on its labels. ***Id.* at A30–31.** The pleading alleges Bayer has the power under federal law, as well as duties under federal and state law, to update its labels unilaterally if it learns of important risks. ***Id.* at A15.** The FDA's decision to require a black box warning after the events of this case points to Bayer's labeling during the relevant period as inadequate. ***Id.* at A24–26.** And the petition alleges that Bayer's failure to update the label caused Plaintiffs' injuries because an updated label would have alerted them to the risks of Essure. ***Id.* at A30–33**.

Bayer argues in a footnote that claims based on a failure to report adverse events to the FDA are impliedly preempted under *Buckman* as efforts to enforce FDA requirements. Relators' Br. at 26 n.3. But that argument is wrong as well.

In *Stengel v. Medtronic Inc.*, the Ninth Circuit held that a claim based on a state-law duty to notify the FDA of potential issues "is not preempted, either expressly or impliedly, by the MDA" because it is both independent of the premarket approval process (and therefore not covered by *Buckman*), and parallel to federal-law duties (and therefore not preempted under § 360k). 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc). The duty

arose under Arizona law in *Stengel*, but Missouri law imposes a substantially similar duty. *See Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 785 (Mo. Ct. App. 2008) ("Missouri has long recognized that a manufacturer has the duty to warn ultimate users of its products or articles which are inherently dangerous or are dangerous because of the use to which they are put."); s*ee also* WILLIAM L. PROSSER, LAW OF TORTS 665 (3d ed. 1964) ("The warning must be sufficient to protect third persons who may reasonably be expected to come in contact with the product and be harmed by it.").

Further, 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 [Premarket Approval] 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 A133**. And FDA's guidance establishes that it viewed Essure's current warnings as inadequate.

In addition, multiple courts have found no preemption of failure to warn claims premised on Bayer's failure to report Essure adverse events to the FDA—which is precisely Plaintiffs' claim. *See McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837–38 (E.D.Pa. 2016) (citing *Stengel*, 704 F.3d at 1233; *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 768

(5th Cir. 2011)); *De La Paz v. Bayer HealthCare LLC*, 159 F. Supp. 3d 1085, 1097 (N.D. Cal. 2016); *Medali v. Bayer HealthCare, LLC*, No. RG15771555 slip op. (Cal. Super. Ct. Feb. 16, 2016) (**Bayer A90–92**); *Noris v. Bayer Essure, Inc.*, No. BC589882(Cal. Super. Ct. Apr. 26, 2016) (**Bayer A116 at 20:16–20:18**); *Lance v. Bayer Corp.*, RG 16809860 (Cal. Super. Ct. Aug. 2, 2016) (multiple joined cases) (**Bayer A487**). The Court should follow this precedent. Put plainly, the great weight of authority is against Bayer's position on preemption.

Bayer fares no better regarding negligent training. Contrary to its contention, the cases Bayer cites do not support a ruling that negligent training is entirely preempted. For example, in *McLaughlin* negligent training was a parallel state law claim and not preempted as to "Bayer's alleged failure to (1) ensure that doctors successfully completed five preceptorings during training, (2) ensure that doctors read and understood the training manual, and (3) ensure that doctors successfully completed Essure simulator training." *McLaughlin v. Bayer Corp.*, CV 14-7315, 2017 WL 697047, at *6 (E.D. Pa. Feb. 21, 2017).

Further, Missouri law recognizes a duty to train insofar as it has adopted § 324A of the RESTATEMENT (SECOND) OF TORTS. *See Kaplan v. U.S. Bank, N.A.*, 166 S.W.3d 60, 70 (Mo. Ct. App. 2003), *opinion adopted and reinstated after retransfer* (Nov. 3, 2003). 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 it was sufficient to maintain a parallel state-law claim for negligent training. 172 F. Supp. 3d at 816–18. Bayer undertook a duty to train physicians on how to implant Essure, to ensure that physicians understood the training manual, and to train with an Essure simulator—but did so negligently.

Finally, 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*, 552 U.S. at 322. 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, 551–52 (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 F. App'x 436 (6th Cir. 2010) (same). And the *McLaughlin* court likewise denied Bayer's motion to dismiss negligent manufacturing claim involving Essure on preemption grounds. 172 F. Supp.3d at 835.

The same holds true for Plaintiffs' warranty claims. 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 Grp., Inc.*, 505 U.S. 504, 525 (1992) (holding breach of express warranty not preempted). "The FDA has not endeavored to regulate (and has not approved) medical device manufacturers' . . . warranties of their products." *Stefl v. Medtronic, Inc.*, 916 S.W.2d 879, 882 (Mo. Ct. App. 1996). Warranty claims are not common-law tort actions, but exist by positive legislative enactments of state law. *See* MO. ANN. STAT. §§ 400.2-313–315. 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., Inc.*, 914 F. Supp. 2d 1290, 1298 (N.D. Ga. 2012).

Bayer argued that the language in its warranties resembled language the FDA had approved for Essure's labeling, and so any requirement that it use different language would be preempted. But this argument is unpersuasive too.

Because warranties are not mandated by the FDA, they are not "requirements," and therefore not subject to preemption in the same way as, for example, the design aspects of Essure itself. As the petition explains, the FDA does not approve warranties, but instead informs manufacturers that if they choose to make warranties, those warranties must be accurate. **Bayer A24.** Thus, preemption is not at issue, and these claims should have been

permitted to proceed. Moreover, to the extent Bayer made statements in any way broader than the FDA-approved language, it cannot escape liability by pointing to the FDA's approval of different language. The materiality of the differences would instead be an issue for the fact-finder.

In summary, the holdings of Respondent's Order were the correct ones. As shown above, any error was harmless. Bayer is not entitled to a permanent writ of prohibition based on preemption of Plaintiffs' claims. The Court should deny relief on this basis as well.

## CONCLUSION

For all reasons above, Relators Bayer Corporation, Bayer Healthcare LLC, Bayer Essure Inc. and Bayer Healthcare Pharmaceuticals Inc. are not entitled a permanent writ prohibiting Respondent the Hon. Joan L. Moriarty from enforcing her Order dismissing Plaintiffs' claims based on either lack of personal jurisdiction or preemption. Additionally, Relators are not entitled to a writ ordering Respondent to sever and transfer venue of the non-Missouri Plaintiffs' claims.

Therefore, Respondent respectfully requests that this Court deny Relators any relief by quashing the preliminary writ of prohibition and remanding the case to the Circuit Court of the City of St. Louis, where the *Johnson* petition was originally filed. Further, Plaintiffs should be permitted to amend their original pleading in accordance with Missouri jurisdictional law, in a form substantially similar to the copy of the amended pleading included in Respondent's Appendix, **A1–81**.

Dated: October 4, 2017

Respectfully submitted,

**HOLLORAN SCHWARTZ & GAERTNER LLP**

James P. Holloran, #20662
Thomas E. Schwartz, #44504
Mark J. Gaertner, #50291
Justin D. Guerra, #59003
9200 Litzsinger Road
St. Louis, MO 63144
314-772-8989 phone
314-279-1333 fax
jholloran@holloranlaw.com
tschwartz@holloranlaw.com
mgaertner@holloranlaw.com
jguerra@holloranlaw.com

and

**FLEMING | NOLEN | JEZ, LLP**

G. Sean Jez
Jessica Kasischke
2800 Post Oak Blvd., Ste. 4000
Houston, Texas 77056
713-621-7944 phone
sean_jez@fleming-law.com
jessica_kasischke@fleming-law.com

**ATTORNEYS FOR PLAINTIFFS**

## CERTIFICATE OF SERVICE

The undersigned herby certifies that on this 4th day of October, 2017, a true and accurate copy of the Brief of Respondent Hon. Joan L. Moriarty, was served on the following attorneys for Relators/Defendants:

Rebecca K. Wood
Jonathan F. Cohn
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
Telephone: 202-736-8000
Facsimile: 202-736-8711
rwood@sidley.com
jfcohn@sidley.com

Gerard T. Noce
W. Jason Rankin
HEPLERBROOM LLC
One Metropolitan Square
211 North Broadway, Suite 2700
St. Louis, MO 63102
Telephone: 314-241-6160
Facsimile: 314-241-6116
gtn@heplerbroom.com
wjr@heplerbroom.com

The Hon. Joan L. Moriarty
Circuit Court of the
City of St. Louis, Division 31
10 N. Tucker Blvd.
St. Louis, MO 63101
Telephone 314-622-4927

## CERTIFICATE OF COMPLIANCE

The undersigned certifies that the Brief of Respondent Hon. Joan L. Moriarty complies with the Missouri Rules of Civil Procedure and the limitations contained in Rule 84.06(b). The Brief was prepared in Times New Roman with 13-point font and contains 8,795 words.

DATED: October 4, 2017

*/s/* Thomas E. Schwartz
***Attorney for Plaintiffs***