NO. 16-

In the

Supreme Court of the United States

GLAXOSMITHKLINE LLC

PETITIONER,

v.

M.M. EX REL. MEYERS, *et al.*,

RESPONDENTS.

On Petition for a Writ of Certiorari to the Illinois Appellate Court

PETITION FOR A WRIT OF CERTIORARI

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March 23, 2017

QUESTION PRESENTED

The Due Process Clause allows a state court to exercise specific personal jurisdiction over a non-resident defendant only when the plaintiff's claims "arise out of or relate to" the defendant's forum activities. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (citation omitted). The question presented is:

For a claim to "arise out of or relate to" a defendant's forum-state contacts, must there be a meaningful causal link between the defendant's forum-state contacts and the plaintiff's claim?

PARTIES TO THE PROCEEDING

1. Petitioner GlaxoSmithKline LLC was a defendant in the Circuit Court and the petitioner in the Illinois Appellate Court.

2. The following individuals were plaintiffs in the Circuit Court, appellees in the Illinois Appellate Court, and are respondents in this Court: A.H., a minor, by and through Dawn Hinton, her mother and next friend; H.C., a minor, by and through Amy Christy, her mother and next friend; H.H., a minor, by and through Kristen Hozempa, his mother and next friend; A.K., a minor, by and through Kathryn Keady, his mother and next friend; C.S., a minor, by and through Stacey Schutte, her mother and next friend; and C.E., a minor, by and through Shannon Emery, his mother and next friend.

3. The following individuals were plaintiffs in the Circuit Court but were not parties in the Illinois Appellate Court and are not parties in this Court: M.M., a minor, by Audrey Meyers, her mother and next friend; and P.M., a minor, by and through Linda Butler, his mother and next friend.

4. The following entities were defendants in the Circuit Court but were not parties in the Illinois Appellate Court and are not parties in this Court: Wolters Kluwer Health, Inc.; Wolters Kluwer United States, Inc.; and Walgreens Company.

RULE 29.6 DISCLOSURE STATEMENT

GlaxoSmithKline LLC is owned through several levels of wholly owned subsidiaries by GlaxoSmithKline plc, a publicly held public limited company organized under the laws of England.

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PETITION FOR A WRIT OF CERTIORARI

GlaxoSmithKline LLC ("GSK") respectfully petitions for a writ of certiorari to review the judgment of the Illinois Appellate Court in this case.

DECISIONS BELOW

The decision of the Appellate Court of Illinois, First District, Fifth Division, is reported at 61 N.E.3d 1026 (Pet. App. 2–31). The Supreme Court of Illinois' order denying GSK's petition for leave to appeal is reported at 65 N.E.3d 842 (Table) (Pet. App. 1).

JURISDICTION

The Illinois Appellate Court issued its decision on August 26, 2016. The Supreme Court of Illinois denied GSK's petition for leave to appeal on November 23, 2016. On February 10, 2017, Justice Kagan extended the time for filing a petition for certiorari to and including March 23, 2017. This Court has jurisdiction under 28 U.S.C. 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Due Process Clause of the Fourteenth Amendment, U.S. Const. amend XIV, § 1, provides:

> [N]or shall any State deprive any person of life, liberty, or property without due process of law. . . .

Section 2-209(c) of the Illinois Code of Civil Procedure permits Illinois courts to "exercise jurisdiction on any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States."

INTRODUCTION

This petition presents a question about personal jurisdiction that has deeply split the federal courts of appeals and state high courts. When a plaintiff seeks to establish specific jurisdiction over a non-resident defendant, must the plaintiff show that the defendant's forum-state contacts *proximately* caused the plaintiff's injuries, or is it enough that those contacts were a *but-for* cause of the plaintiff's injuries? Six courts adhere to a proximate-causation standard or a standard closely resembling proximate causation. Five courts, including the court below, have adopted a but-for causation standard or a standard closely resembling but-for causation. And four other courts apply an even looser standard that does not require any showing of causation. The disagreement is acknowledged in the courts below, and it is so acute that personal jurisdiction frequently turns on whether the plaintiff sues in federal or state court in a given state.

Recognizing that the conflict below is intolerable, the Court has already granted certiorari to resolve at least one side of the three-way split. In *Bristol-Myers Squibb Co. v. Superior Court*, No. 16-466, the question presented is "[w]hether a plaintiff's claims arise out of or relate to a defendant's forum activities when there is *no* causal link between the defendant's forum contacts and the plaintiff's claims—that is, where the plaintiff's claims would be exactly the same even if the defendant had no forum contacts." BMS Pet. i (emphasis added).

The Court should answer that question in the negative. Stopping there, however, would leave the

lower courts without needed guidance, as the but-for versus proximate causation split would persist. Moreover, because but-for causation lacks any limiting principle, it would accomplish little to reject California's amorphous non-causal standard only to leave in place a but-for standard that is no more predictable, and only marginally less malleable, in its application. The Court therefore should hold in *BMS* that a proximate causal link is required. *See* BMS Opening Br. 37–46, No. 16-466 (filed Mar. 1, 2017); GSK Amicus Br. 22–30, *BMS v. Superior Court*, No. 16-466 (filed Mar. 8, 2017) ("GSK *BMS* Amicus Br.").

If, however, the Court decides in *BMS* only that some form of causation is required, it should grant this petition. This case is an excellent vehicle to decide the but-for versus proximate cause side of the *BMS* split, and that aspect of the split is just as certworthy as the no-causation versus causation side. At a minimum, the Court should hold this petition pending its decision in *BMS* and then grant certiorari, vacate the decision below, and remand for further consideration in light of its decision in *BMS*.

Respondents here are six mother-child pairs who allege that petitioner GlaxoSmithKline LLC's drug Paxil caused birth defects. The respondent mothers were prescribed and ingested Paxil outside of Illinois, the respondent children suffered their alleged injuries outside of Illinois, and the respondents live outside of Illinois. GSK, for its part, is not incorporated in Illinois and does not have its principal place of business there. Yet respondents chose to sue in the Circuit Court for Cook County, Illinois.

Unwilling to openly embrace the causation-free personal jurisdiction theory under review in *BMS*, respondents went hunting for some way to tie GSK to Illinois. They seized on GSK's clinical trial program for Paxil, contending that their claims arose out of the alleged inadequacy of that program concerning birth-defect risk. The notion that respondents' birth-defect claims are meaningfully tied to the clinical trial program is difficult to credit, since that program—in accordance with FDA guidance cautioning against exposing developing fetuses to drugs under study—excluded pregnant women and thus was not designed to study birth-defect risk. More to the point, however, the clinical trial program had only the barest of connections to Illinois: it involved hundreds of trials conducted at thousands of study sites across the nation and around the world, with only a handful of sites in Illinois. And respondents made no allegations that anything that occurred at an Illinois site gave rise to their claims. In particular, they did not even allege that any pregnancies had occurred at the Illinois sites, let alone that GSK had failed to follow up to learn the outcome of such a pregnancy in a way that could be relevant to their claims.

The Illinois Appellate Court, despite all this, held that respondents' claims were sufficiently connected to GSK's Illinois activities. It reasoned that the data generated from the miniscule Illinois portions of the trials had been "aggregated" with the data generated in the 44 other states and nine other countries that had hosted trial sites. The decision below is little more than a dressed-up version of the California Supreme Court's causation-free approach

under review in *BMS*. While the court below relied on GSK's nationwide clinical trial program for Paxil, the *BMS* court invoked BMS' nationwide marketing program for Plavix. Under both decisions, a large company with nationwide operations is subject to jurisdiction on essentially any claim in essentially any state. When that approach was called by its true name—universal general jurisdiction—the Court rejected it, holding in *Goodyear* and *Daimler* that continuous and systematic activities in a state are not enough to justify jurisdiction not tied to the defendant's forum-state activities. Exercising jurisdiction without a meaningful link between the defendant's forum-state activities and the plaintiff's claim is just as "exorbitant" (*Daimler AG v. Bauman*, 134 S. Ct. 746, 751 (2014)) when, as in this case and in *BMS*, the lower courts call it "specific" jurisdiction.

If the Court does not resolve the proximate versus but-for causation side of the split in *BMS*, it should grant this petition to do so. The decision below powerfully illustrates the problems with not requiring a proximate causal link between the plaintiff's claim and the defendant's forum-state activities. The portion of GSK's clinical trial program that occurred in Illinois is far too miniscule to be viewed as a proximate cause of respondents' claims; proximate causation exists precisely to weed out such distant, attenuated, and insignificant events. If the handful of Illinois trial sites can be said to be a but-for cause of respondents' claims, then so can the trial sites hosted by each of the 44 other states and nine other countries. That just underscores the fundamental problem with but-for causation: many things can be but-for causes without thereby being

meaningful causes. Indeed, the court below rejected GSK's argument that there must be a "meaningful link" between its Illinois activities and respondents' claims. Pet. App. 25.

The relatedness requirement is what is supposed to distinguish specific, or case-linked, jurisdiction from general, or all-purpose, jurisdiction. A relatedness standard so low as to encompass links in a historical chain that are not material causes of the plaintiff's claim would fail to perform that basic function.

STATEMENT

A. Legal Background.

"The Due Process Clause of the Fourteenth Amendment limits the power of a state court to render a valid personal judgment against a nonresident defendant." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291 (1980). This Court has identified two categories of personal jurisdiction: "general or all-purpose jurisdiction, and specific or conduct-linked jurisdiction." *Daimler*, 134 S. Ct. at 751.

Under general jurisdiction, a company may be sued "on any and all claims against it, wherever in the world the claims may arise." *Id.* Under specific, or conduct-linked, jurisdiction, "the commission of some single or occasional acts of the corporate agent in a state" may suffice for jurisdiction, but only for a suit that "relat[es] to that in-state activity." *Id.* at 754 (citing *Int'l Shoe Co. v Washington*, 326 U.S. 310, 318 (1945)).

These constitutional limits serve two purposes. First, they "protect[] the defendant against the burdens of litigating in a distant or inconvenient forum." *World-Wide Volkswagen*, 444 U.S. at 292. Second, they prevent "the States through their courts" from "reach[ing] out beyond the limits imposed on them by their status as coequal sovereigns in a federal system." *Id.* at 291–93.

Three years ago, in *Daimler*, this Court held that a corporation is subject to general jurisdiction only where it is "at home," which typically means "where it is incorporated or has its principal place of business." 134 S. Ct. at 751, 760. Before *Daimler*, some courts had found general jurisdiction everywhere the defendant had "continuous and systematic" contacts, which amounted to universal general jurisdiction for large companies with nationwide operations. *See id.* at 761. *Daimler* explicitly rejected that standard and the "exorbitant exercises of all-purpose jurisdiction" it had spawned. *Id.*

B. Factual Background.

Petitioner is a pharmaceutical company that researches and develops medicines, vaccines, and consumer healthcare products. As a global company, GSK markets and sells its products in all 50 states. As relevant here, GSK manufactured Paxil, a drug that is FDA-approved to treat depression and certain anxiety disorders. GSK is a Delaware limited liability company with large corporate/administrative headquarters in Pennsylvania and North Carolina. Its sole member is GlaxoSmithKline Holdings (Americas) Inc., a Delaware corporation with its

principal place of business in Delaware. GSK is concededly not at home in Illinois.

Respondents are six mother-child plaintiff pairs from Florida, Colorado, Virginia, Michigan, and Wisconsin. They joined with two pairs from Illinois in order to sue GSK in the Circuit Court for Cook County, Illinois. Pet. App. 88–91. Each respondent alleges that her child suffered birth defects arising out of the mother's ingestion of Paxil. Pet. App. 87. Each claims that GSK failed to warn about Paxil's alleged dangers if used during pregnancy, that Paxil was defectively designed, that GSK was negligent, breached warranties, and negligently misrepresented and concealed the risks of Paxil use during pregnancy. Pet. App. 103–25.

C. GSK's Motion To Dismiss.

GSK moved to dismiss respondents' claims for lack of personal jurisdiction. GSK pointed out that respondents did not allege that they or their injuries had any connection to Illinois. Respondents live outside of Illinois. The physicians who treated them and wrote them prescriptions did so outside of Illinois. And they purchased and ingested Paxil outside of Illinois. GSK also noted that the only allegation about personal jurisdiction in the complaint—that GSK "does business in, and derives substantial revenue from, Cook County, Illinois"—was not enough to establish either general or specific jurisdiction. Pet. App. 92.

After jurisdictional discovery, respondents argued that the court had specific jurisdiction because GSK conducted portions of certain clinical

trials of Paxil in Illinois. Pet. App. 21–22. Seizing on GSK's clinical trial program as giving rise to their claims was a stretch to begin with, because none of GSK's clinical trials for Paxil was designed to study birth-defect risk (as it generally is inappropriate to include pregnant women in trials because of the risks posed to the fetus). Pet. App. 129. In fact, the trials excluded women who were pregnant or, in many cases, were not using clinically-accepted contraception. Pet. App. 130. Nonetheless, respondents contended that GSK had failed to follow up on pregnancies that occurred during trials. Pet. App. 10.

Seizing on GSK's clinical trial program as a basis to bring these claims *in Illinois* was even more of a stretch. The vast majority of GSK's clinical trials for Paxil—344 out of 361—had no connection at all to Illinois. Pet. App. 146. Only 17 trials, less than five percent of the total, involved even a single study site in Illinois. *Id.* Even those 17 trials had only a slight connection to Illinois; they were multi-center trials that occurred across hundreds of study sites in 45 states and many countries. Pet. App. 129. A mere three percent of the study sites in those 17 trials were in Illinois, involving a mere two percent of the study participants. *See* Pet. App. 130–46 (discussing locations of study participants). Because only five percent of the clinical trials had any connection to Illinois, and only three percent of the sites in *those* trials were in Illinois, Illinois hosted only 0.15 percent (five percent times three percent) of GSK's clinical trial program.

GSK thus responded that there was no personal jurisdiction in Illinois over a challenge to the clinical trial program as a whole because that program had only the tiniest connection to Illinois. And GSK explained that respondents did not even attempt to link their claims to the tiny Illinois sliver of the program. For example, respondents did not allege that GSK had failed to follow up on any pregnancies at the Illinois sites, or even that any pregnancies had occurred at the Illinois sites. Nor did respondents point to anything else about the Illinois portions of the trials that was supposedly relevant to their claims.

The trial court denied GSK's motion. The court reasoned that existing precedent did not supply a "bright line" for what percentage of GSK's clinical trials had to have occurred in Illinois to justify finding that respondents' claims arose from the Illinois portions of those trials. Pet. App. 11. The court thus decided to "muddle through it." Pet. App. 81. After suggesting that enforcing the arising-from requirement was less important because GSK is "a global company" with sales in all states—a view that echoes the California Supreme Court's "sliding scale" approach in *BMS*—the court concluded that "the plaintiffs['] claim[s] relate to or arise from" GSK's "substantial contacts" with Illinois. Pet. App. 82. The court encouraged GSK to petition for permission to appeal, expressing the hope that "if it goes up and case law is made, it will give us a better understanding and better standard." Pet. App. 12.

D. The Decision Below.

GSK sought interlocutory review of the Circuit Court's decision, which the Appellate Court granted. That court then affirmed. It began by observing that GSK "employed 16,323 people in the United States, 217 people who resided in Illinois, and it maintained an agent for service of process in Illinois." Pet. App. 8. The Appellate Court also emphasized that GSK "currently has 184 sales representatives who market GSK's products in Illinois" and that between 2000 and 2006 "GSK had anywhere between 79 and 121 employees marketing specifically Paxil in Illinois." *Id.* The court did not suggest that respondents' claims had anything to do with any of these Illinois contacts; instead, like the trial court and the *BMS* court, it seemingly mentioned these unrelated contacts to downplay the importance of enforcing the arising-from requirement.

When the court turned to the "arising from" standard, it emphasized that the Illinois Supreme Court had described that requirement as "lenient or flexible." Pet. App. 19 (quoting *Russell v. SNFA*, 2013 IL 113909, ¶ 83 (2013)). Applying that relaxed standard, the Appellate Court reasoned that the fact that less than one-fifth of one percent of the clinical trials had occurred in Illinois was immaterial because GSK "aggregated" the data collected in Illinois with the data collected everywhere else. Pet. App. 21. Because "[i]t was from that single set of data that defendant GSK drew its statistically significant conclusions with respect to Paxil's safety," the handful of Illinois study sites could not be discounted. *Id.* Likewise, the court stated that "[t]he

Illinois data was aggregated with the other data to inform the warning label content for Paxil, upon which the out-of-state plaintiff mothers relied in making their decision to take the drug." Pet. App. 21–22.

The court also invoked a declaration submitted by GSK that explained the clinical trial program. Pet. App. 18, 22. GSK explained that decisions about what hypotheses to study and how to design the clinical trials were made by GSK (and not in Illinois)—not by each individual investigator with whom GSK would then contract to conduct the study at sites around the world. The declaration noted that contract investigators were "responsible for recruiting study subjects and collecting data from the study participants at their respective site. However, the study site investigators have little or no input into or control over the study design protocol or analysis of the aggregate data collected from all study sites." Pet. App. 129. In the view of the court below, this declaration showed that the investigators at the Illinois study sites "had *some* degree of input into, and control over, the clinical trials." Pet. App. 22.

In any event, like respondents, the court did not identify anything that the Illinois investigators had allegedly done or failed to do that was relevant to respondents' claims. To the contrary, the court simply rejected GSK's argument that a "meaningful link" between its Illinois activities and respondents' claims was necessary. Pet. App. 25–26. The Illinois Supreme Court denied GSK's petition for leave to appeal. Pet. App. 1.

REASONS FOR GRANTING THE PETITION

This petition presents a deep and acknowledged split over whether the arising-from standard for specific jurisdiction requires a proximate causal link between the defendant's forum-state activities and the plaintiff's claim or whether a but-for link is enough. The Court has already granted certiorari on a closely related question. In *Bristol-Myers Squibb Company v. Superior Court*, No. 16-466 (cert. granted Jan. 19, 2017), the question presented is whether a plaintiff's claim can be said to arise from or relate to a defendant's forum activities when there is *no* causal link between the claim and the forum activities. The Court should hold in *BMS* that a proximate causal link is required. If, however, the Court does not reach that question in *BMS*, it should grant this petition to decide whether the plaintiff must show a proximate causal link or only a mere but-for link.

I. Federal and State Courts Are Split Over The Arising-From Requirement for Specific Jurisdiction.

As the *BMS* petition explained, the federal courts of appeals and state high courts are deeply divided over the arising-from standard for specific jurisdiction. Specific jurisdiction exists only "[w]hen a controversy is related to or 'arises out of' a defendant's contacts with the forum." *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984). But this Court has not yet explained "what sort of tie between a cause of action and a defendant's contacts with a forum is necessary to a

determination that either connection exists." *Id.* at 415 n.10.

Without this Court's guidance, "three [tests] predominate" in the lower courts. *Oldfield v. Pueblo De Bahia Lora, S.A.*, 558 F.3d 1210, 1222 n.32 (11th Cir. 2009). One group of courts holds that if a defendant's contact with a forum is merely a but-for cause of the plaintiff's claim, the relatedness inquiry is met. Another group requires that the defendant's contacts be the proximate, or foreseeable, cause of the plaintiff's injuries. Still another group has held that no causal connection is required at all. In some states, whether a defendant is subject to personal jurisdiction can depend on whether the suit is filed in state or federal court.

A. Courts Disagree Over Whether Specific Jurisdiction Requires But-For Causation, Proximate Causation, Or No Causation.

But-For Cause. One group of federal and state courts holds that a claim "arises out of or relates to" a defendant's contacts with the forum if the contacts are a but-for cause of the claim. According to these courts, a plaintiff must "show that he would not have suffered an injury 'but for' the [the defendant's] forum-related conduct." *Menken v. Emm*, 503 F.3d 1050, 1058 (9th Cir. 2007); *Tatro v. Manor Care, Inc.*, 625 N.E.2d 549, 553 (Mass. 1994) (adopting "a 'but for' test"). These courts take the position that the "but-for test is consistent with the basic function of the 'arising out of' requirement—it preserves the essential distinction between general and specific jurisdiction." *Shute v. Carnival Cruise Lines*, 897

F.2d 377, 385 (9th Cir. 1988), *rev'd on other grounds*, 499 U.S. 585 (1991); *see also Shute v. Carnival Cruise Lines*, 783 P.2d 78, 82 (Wash. 1989) ("We adopt the 'but for' test.").

Proximate Cause. A second group of courts disagrees with the but-for standard, criticizing it as "vastly overinclusive" because but-for causation "has no limiting principle" and instead "literally embraces every event that hindsight can logically identify in the causative chain." *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 322 (3d Cir. 2007) (alteration omitted).

The First and Sixth Circuits hold that proximate causation is required. *Nowak v. Tak How Invs., Ltd.*, 94 F.3d 708, 715 (1st Cir. 1996); *Beydoun v. Wataniya Rests. Holding, Q.S.C.*, 768 F.3d 499, 507–08 (6th Cir. 2014). Under this standard, "only consequences that *proximately* result" from "a party's contacts with a forum state will give rise to jurisdiction." *Id.* at 508 (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985). Under the proximate-causation test, "the defendant's in-state conduct must form an important, or [at least] material, element of proof in the plaintiff's case." *Harlow v. Children's Hosp.*, 432 F.3d 50, 61 (1st Cir. 2005) (internal quotation marks omitted).

The Third, Seventh, and Eleventh Circuits, along with the Oregon Supreme Court, apply tests resembling proximate cause but without using that term. According to the Third Circuit, specific jurisdiction "requires a closer and more direct causal connection than that provided by the but-for test." *O'Connor*, 496 F.3d at 323. The causal link must be

"intimate enough to keep . . . personal jurisdiction reasonably foreseeable." *Id.*

The Eleventh Circuit shares the Third Circuit's view, reasoning that "the contact must be a 'but-for' cause of the tort" as well as "a foreseeable consequence" of the defendant's conduct. *Oldfield*, 558 F.3d at 1222–23. The Oregon Supreme Court likewise holds that "the activity may not be only a but-for cause of the litigation; rather, the nature and quality of the activity must also be such that the litigation is reasonably foreseeable by the defendant." *Robinson v. Harley-Davidson Motor Co.*, 316 P.3d 287, 300 (Or. 2013) (en banc). *See also uBID, Inc. v. GoDaddy Grp., Inc.*, 623 F.3d 421, 430 (7th Cir. 2010) ("But-for causation would be 'vastly overinclusive,' haling defendants into court in the forum state even if they gained nothing from those contacts"); *Dudnikov v. Chalk & Vermilion Fine Arts, Inc.*, 514 F.3d 1063, 1079 (10th Cir. 2008) (Gorsuch, J.) (reserving the question whether but-for or proximate cause should be the standard).

No Causal Relationship. Another group of courts requires no causal relationship between the defendant's forum-state contacts and the plaintiff's claim. The California Supreme Court decision under review in *BMS* exemplifies that approach. There, 575 non-California residents joined with 86 California residents in suing BMS in California state court. The plaintiffs claimed that BMS' drug Plavix caused them personal injuries. The non-California plaintiffs were not prescribed Plavix in California, did not have their prescriptions filled by California

pharmacies, did not ingest Plavix in California, and did not suffer their alleged injuries in California.

The California Supreme Court nonetheless exercised what it called specific personal jurisdiction over the non-resident plaintiffs' claims. The court applied a "sliding-scale" approach, under which "the intensity of [the defendant's] forum contacts and the connection of the [plaintiff's] claim to those contacts [is] inversely related." *Bristol-Myers Squibb Co. v. Superior Court*, 377 P.3d 874, 885 (Cal. 2016). The court stated that "[a] claim need not arise directly from the defendant's forum contacts in order to be sufficiently related to the contact to warrant the exercise of specific jurisdiction" and that the defendant's forum contacts do not need to "be either the proximate cause or the 'but for' cause of the plaintiff's injuries." *Id.* Under those principles, the court thought it was enough that BMS' "nationwide marketing, promotion, and distribution of Plavix created a substantial nexus between [the plaintiffs'] claims and the company's contacts in California concerning Plavix." *Id.* at 888.

The Federal Circuit and the highest courts of the District of Columbia and Texas subscribe to a similarly relaxed view of the arising-from requirement. The Federal Circuit considers whether the defendant's conduct "relate[s] in some material way" to the plaintiff's suit, describing its approach as "far more permissive than either the 'proximate cause' or the 'but for' analyses." *Avocent Huntsville Corp. v. Aten Int'l Co.*, 552 F.3d 1324, 1336–37 (Fed. Cir. 2008). The D.C. Court of Appeals rejects "strict-causation-based tests" in favor of an approach

requiring only "a 'discernible relationship' between [the plaintiff's] claim and the" defendant's conduct. *Shoppers Food Warehouse v. Moreno*, 746 A.2d 320, 333, 336 (D.C. 2000) (en banc) (citation omitted). And the Texas Supreme Court says that its "standard does not require proof that the plaintiff would have no claim 'but for' the contacts, or that the contacts were a 'proximate cause' of the liability." *TV Azteca v. Ruiz*, 490 S.W.3d 29, 52–53 (Tex. 2016), *pet. for cert. filed*, No. 16-481 (Oct. 7, 2016).[1]

Clarity in the standards for specific jurisdiction is particularly important in light of this Court's decisions in *Daimler* and *Goodyear*, which reined in the permissive approach to general jurisdiction that some courts had adopted. Rather than grappling with whether a defendant's contacts gave rise to specific jurisdiction, some courts had inappropriately exercised general jurisdiction based on the defendant's "continuous and systematic" contacts with the forum state. In *Goodyear*, this Court faulted another state appellate court for "[c]onfusing or blending general and specific jurisdictional inquiries" in holding that an out-of-state defendant was subject to personal jurisdiction. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919–20 (2011). *Daimler* and *Goodyear* rejected this approach and reminded courts that they can exercise all-

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[1] The *TV Azteca* petition was scheduled to be considered at the Court's March 17, 2017 conference, but no action has been taken on it. If the Court intends to hold *TV Azteca* pending *BMS*, the same treatment is all the more warranted here, as this case is much more similar to *BMS*.

purpose jurisdiction over a defendant—that is, jurisdiction that is not "case-linked"—only if the defendant is "at home" in the forum.

Decisions like *BMS* and the decision below show that old habits die hard. The relatedness requirement is what is supposed to make "specific" jurisdiction specific. If the general jurisdiction standard the Court announced in *Goodyear* and reaffirmed in *Daimler* is to be respected—rather than circumvented in the guise of "specific" jurisdiction that is not meaningfully case-linked—the Court's clarification of the relatedness standard is badly needed.

B. This Case Is An Excellent Vehicle to Decide The But-For Versus Proximate Causation Side of the *BMS* Split.

The question presented in *BMS* is whether a plaintiff's claims can be said to arise from or relate to a defendant's forum activities when there is *no* causal link between the defendant's forum-state contacts and the plaintiff's claims. *See* BMS Pet. i. This Court will thus decide, at a minimum, whether the California Supreme Court's holding that no causation is needed is correct. BMS also asks the Court to adopt the proximate-causation standard. BMS Opening Br. 37–46. GSK agrees that the Court should hold that a causal connection is required and that proximate causation is the appropriate standard. *See* GSK *BMS* Amicus Br. 22–30. If, however, the Court does not decide that important issue in *BMS*, it should grant this petition for plenary consideration in order to do so. At a

minimum, the Court should hold this petition pending its decision in *BMS* and then grant, vacate, and remand.

This case is an excellent vehicle to resolve the but-for versus proximate cause side of the split. Although the court below did not explicitly acknowledge that it was applying a but-for standard, that is the only way to make any sense of its decision to uphold personal jurisdiction on a basis as distant and thin as the handful of study sites located in Illinois. Moreover, the court relied heavily on Illinois' "lenient" and "flexible" standard for determining whether respondents' claims "relate to" GSK's forum-state conduct. Pet. App. 22–23 (citing *Russell*, 2013 IL 113909 at ¶ 83).[2] That description fits a but-for standard but cannot plausibly be applied to a proximate causation standard. *Cf. Harlow*, 432 F.3d at 61 ("The relatedness requirement is not an open door; it is closely read, and it requires a showing of a material connection. This court 'steadfastly reject[s] the exercise of personal jurisdiction whenever the connection between the cause of action and the defendant's

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[2] Before the Illinois Supreme Court's decision in *Russell*, some Illinois courts had stated that the plaintiff's claims must "directly arise out of the contacts between the defendant and the forum." *Keller v. Henderson*, 834 N.E. 2d 930, 936 (Ill. App. 2005). As the decision below illustrates, *Russell*'s description of the standard as "lenient" and "flexible" has caused the Illinois courts to apply a standard more closely resembling but-for cause.

forum-state contacts seems attenuated and indirect.'") (citation omitted).

The key to the court's conclusion appears to be the notion that the clinical trial program is a unitary whole from which the portions that occurred in Illinois, however small, cannot be separated. The court thus declared that "[i]t was from that single set of data that defendant GSK drew its statistically significant conclusions with respect to Paxil's safety." Pet. App. 21. And from that premise, the court concluded that Paxil's warning labels "were informed, in part, by the results of the Illinois clinical trials." Pet. App. 20. The "in part" in that sentence is doing a lot of work, given how tiny a part the Illinois sites played in the whole. But for the court, it was sufficient that the Illinois sites were part of the historical chain—presumably along with the sites located in the other 44 states and nine countries. And respondents' failure to allege that anything relevant to their claims occurred at the Illinois sites did not dissuade the court; there was thus no basis to find that GSK's Illinois activities gave rise to respondents' claims in a more robust or direct sense.

This case would have been decided differently in the jurisdictions that apply the proximate-cause standard. Illinois' involvement in the clinical trial program was far too insignificant to say that it "form[s] an important, or [at least] material, element of proof in [respondents'] case." *Harlow*, 432 F.3d at 61 (internal quotation marks omitted). With no allegations about anything that occurred at the Illinois study sites, the court's finding of specific jurisdiction boils down to the happenstance that GSK

contracted with 17 investigators in Illinois, out of untold thousands worldwide.[3]

This case is also an excellent vehicle because it implicates the split described above *in Illinois*, where the Seventh Circuit and the Illinois state courts have required different causal links. The Seventh Circuit would have found no jurisdiction here, because that court holds that "[b]ut-for causation would be vastly overinclusive, haling defendants into court in the forum state even if they gained nothing from those contacts." *uBID*, 623 F.3d at 430 (citation omitted). While the Illinois state courts apply a "lenient" and "flexible" standard, the Illinois federal courts require the connection to be "close enough to make the relatedness quid pro quo balanced and reasonable." *Id.* at 430–31. Divergent results in courthouses across the proverbial street from each other on a question as fundamental as personal jurisdiction are a clear signal that this Court's intervention is needed. *Cf. Butner v. United States*, 440 U.S. 48, 55 (1979) ("Uniform treatment . . . by both state and federal courts within a State serves to reduce

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[3] To be clear, GSK does not believe that anything that happened at the Illinois sites was even a but-for cause of respondents' claims. As explained above (*supra* at 9), consistent with FDA guidance, GSK excluded pregnant women (and often also women not using clinically-accepted contraception) from the Paxil clinical trials. As a result, the clinical trial program was not and could not have been designed to study birth-defect risk. At this stage of the case, however, respondents' allegation that the program was inadequate in that regard has been taken as true. *See* Pet. App. 22.

uncertainty [and] to discourage forum shopping . . . .").

II. The Illinois Appellate Court's Decision Is Wrong.

Like the California Supreme Court's sliding-scale, the "lenient" and "flexible" standard adopted by the court below would expose non-resident defendants to suits not meaningfully related to the defendants' forum-state contacts—effectively reinstating the old standard for general jurisdiction that this Court rejected in *Daimler* and *Goodyear*. The decision below is contrary to the principles of federalism that animate the personal-jurisdiction doctrine.

A. The But-For Standard Is Infinitely Malleable and Subject to Abuse.

The core problem with relying on mere but-for causation is that connections that are not meaningful may nonetheless be termed but-for causes. The essential flaw of but-for causation is that it "has . . . no limiting principle; it literally embraces every event that hindsight can logically identify in the causative chain." *O'Connor*, 496 F.3d at 322 (quoting *Nowak*, 94 F.3d at 715). A railroad guard's well-intentioned effort to help a passenger onto the train might be called a but-for cause of the passenger dropping a package of fireworks onto the tracks. But the guard's actions did not *proximately* cause the fireworks to explode. *See Palsgraf v. Long Island R.R.*, 162 N.E. 99 (N.Y. 1928). "Life is too short to pursue every human act to its most remote consequences; 'for want of a nail, a kingdom was lost'

is a commentary on fate, not the statement of a major cause of action against a blacksmith." *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 287 (1992) (Scalia, J., concurring).

The proximate-cause standard requires a more substantial connection between the defendant's forum-state activities and the plaintiff's claim. Under that rule, "the defendant's in-state conduct must form an important, or [at least] material, element of proof in the plaintiff's case." *Harlow*, 432 F.3d at 61 (internal quotation marks omitted). The proximate-cause standard thus filters out situations where the defendant's conduct is a "but for" cause in a loose sense, but was not a meaningful cause of the plaintiff's injury. "A requirement of proximate cause thus serves . . . to preclude liability in situations where the causal link between conduct and result is so attenuated that the consequence is more aptly described as mere fortuity." *Paroline v. United States*, 134 S. Ct. 1710, 1719 (2014). *Cf. Caterpillar, Inc. v. Int'l Union, United Auto., Aerospace, and Agric. Implement Workers of Am.*, 107 F.3d 1052, 1068–69 (3d Cir. 1997) (en banc) (Alito, J., dissenting) (giving examples of weak but-for causes).

In fact, this Court has already strongly suggested that proximate cause rather than but-for cause is the appropriate standard. *See Burger King*, 471 U.S. at 473–74 ("[W]here individuals purposefully derive benefit from their interstate activities, it may well be unfair to allow them to escape having to account in other States for consequences that arise *proximately* from such activities.") (citation and internal quotation marks

omitted) (emphasis added). And it has repeatedly admonished that specific jurisdiction may not be based on "random, fortuitous, or attenuated" connections. *Id.* at 475; *see also, e.g., Walden v. Fiore*, 134 S. Ct. 1115, 1123 (2014).

Unlike the Illinois Appellate Court's approach, the proximate-cause standard furthers all the basic purposes of personal jurisdiction: fairness, predictability, and federalism. "The term 'proximate cause is 'shorthand for a concept: Injuries have countless causes, and not all should give rise to legal liability.'" *Pac. Operators Offshore, LLP v. Valladolid*, 565 U.S. 207, 223 (2012) (Scalia, J., concurring) (citation omitted). Put another way, "[e]very event has many causes . . . and only some of them are proximate, as the law uses that term. So to say that one event was a proximate cause of another means that it was not just any cause, but one with a sufficient connection to the result." *Paroline*, 134 S. Ct. at 1719. Under this standard, a plaintiff seeking to hale a nonresident defendant into court must show a "direct relation between the injury asserted and the injurious conduct alleged" in the forum state. *Holmes*, 503 U.S. at 268.

The proximate-cause standard fosters fairness. Specific jurisdiction "is premised on something of a *quid pro quo*: in exchange for 'benefitting' from some purposive conduct directed at the forum state, a party is deemed to consent to the exercise of jurisdiction for claims related to those contacts." *Dudnikov*, 514 F.3d at 1078. The proximate-cause standard respects the relationship between the benefits that a defendant receives from accessing a

forum state and the obligations the defendant incurs as a result. "But-for causation," on the other hand, "cannot be the sole measure of relatedness because it is vastly overinclusive in its calculation of a defendant's reciprocal obligations." *O'Connor*, 496 F.3d at 322. "If but-for causation sufficed, then defendants' jurisdictional obligations would bear no meaningful relationship to the scope of the benefits and protection received from the forum." *Id.* (internal quotation marks omitted).

The proximate-cause standard also enables defendants to predict what types of contacts with particular states could lead to what types of lawsuits there. That is because "[p]roximate cause is often explicated in terms of foreseeability or the scope of the risk created by the predicate conduct." *Paroline*, 134 S. Ct. at 1719. As the First Circuit explained, the "proximate cause standard better comports with the relatedness inquiry because it so easily correlates to foreseeability, a significant component of the jurisdictional inquiry." *Harlow*, 432 F.3d at 61 (quotation omitted).

Finally, "proximate cause" is a workable standard because it has a "familiar" meaning with a firm historical pedigree. *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 767 (2004). "It is a well-established principle of [the common] law, that in all cases of loss, we are to attribute it to the proximate cause, and not to any remote cause." *Waters v. Merchants' Louisville Ins. Co.*, 36 U.S. 213, 223 (1837). Proximate cause is based on "the familiar maxim, 'Causa proxima, non remota, spectatur,'" which means that in law the immediate, not the

remote, cause of an event is to be regarded. *The G.R. Booth*, 171 U.S. 450, 453 (1898).

This Court regularly draws on the established and familiar body of proximate-causation principles. Observing that "courts have a great deal of experience applying" proximate causation and that "there is a wealth of precedent for them to draw upon in doing so," the Court has "construed federal causes of action in a variety of contexts to incorporate a requirement of proximate causation." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 134 S. Ct. 1377, 1390 (2014). *See, e.g., Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005) (securities fraud); *Holmes*, 503 U.S. at 268 (RICO); *cf. Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 839 (1996) ("courts sitting in admiralty may draw guidance from . . . the extensive body of state law applying proximate causation requirements").

For all these reasons, it would be highly incongruous to hold that the relatedness requirement for specific jurisdiction is satisfied by mere but-for causation. In simple terms, what distinguishes but-for from proximate causation is that proximate causes must be meaningful, while but-for causes often are not. And it is difficult to see virtue in holding that links that are not meaningful can nonetheless serve to make jurisdiction "case-linked."

B. The Decision Below Reinstates The Old, Rejected Standard for General Jurisdiction.

In *BMS*, this Court should reject the California Supreme Court's nebulous "sliding-scale" approach

to specific jurisdiction. That test "inappropriately blurs the distinction between specific and general personal jurisdiction." *Dudnikov*, 514 F.3d at 1078 By "var[ying] the required connection between the contacts and the claims asserted based on the number of the contacts," the sliding-scale approach "improperly conflates these two analytically distinct approaches to jurisdiction." *Id.* Under the California Supreme Court's approach, the same "continuous and systematic" contacts that are not enough for *general* jurisdiction after *Daimler* and *Goodyear* are sufficient for *specific* jurisdiction—but without the meaningful link to the case that is the essence of specific jurisdiction.

The decision below suffers from the same flaws. In a concession to reality after *Goodyear* and *Daimler*, the court below did not hold that GSK was subject to general jurisdiction in Illinois. Rather, the court found what it called specific jurisdiction—but based it on clinical trials of Paxil that GSK conducted all over the country. As explained, that clinical trial program was in no way specific to Illinois, which hosted less than one-fifth of one percent of the total number of study sites. And respondents did not point to anything that occurred in Illinois that supposedly gave rise to their claims.

Under the court below's theory, respondents could just as well have chosen to sue in any of the other 44 states that hosted trial sites. But there is something obviously wrong with a theory of "specific" jurisdiction that permits jurisdiction on essentially any claim in essentially every state in the union. Under the Illinois court's analysis, a tire

manufacturer that sells tires worldwide could be sued in North Carolina for an accident that occurred abroad, on the view that its approach to product design or safety warnings may have been "informed, in part, by" information obtained from accidents in North Carolina. Pet. App. 20; *but see Goodyear*, 564 U.S. at 919 ("Because the episode-in-suit, the bus accident, occurred in France, and the tire alleged to have caused the accident was manufactured and sold abroad, North Carolina courts lacked specific jurisdiction to adjudicate the controversy.").

By holding that claims with no meaningful connection to Illinois nonetheless somehow arose from GSK's activities in Illinois, the court stretched specific jurisdiction beyond the breaking point and re-imposed the result this Court rejected. GSK's contacts with Illinois in connection with clinical trials have as much to do with respondents' claims as GSK's sales of Paxil in Illinois: nothing. Before *Goodyear* and *Daimler*, some courts would have thought it was enough that GSK did business in Illinois as well as in the other 49 states and would not have paused to consider whether there was a meaningful connection between respondents' claims and GSK's Illinois contacts. But that is the analysis this Court rejected, and recycling it in the guise of "specific" jurisdiction cannot obscure the conflict with those decisions. *See Daimler*, 134 S. Ct. at 751 ("Exercises of personal jurisdiction so exorbitant, we hold, are barred by due process constraints on the assertion of adjudicatory authority.").

Principles of federalism require rejecting this end-run around *Goodyear* and *Daimler* just as those

principles animated this Court's decisions in those cases. "The sovereignty of each State . . . implie[s] a limitation on the sovereignty of all of its sister States—a limitation express or implicit in both the original scheme of the Constitution and the Fourteenth Amendment." *World-Wide Volkswagen*, 444 U.S. at 293. Illinois lacks the constitutional authority to designate itself the hub of a nationwide multi-district litigation so it can adjudicate claims where the plaintiff, the defendant, the defendant's challenged conduct, and the claimed injury are all out of state. *See Daimler*, 134 S. Ct. at 762 n.20 ("Nothing in *International Shoe* and its progeny suggests that 'a particular quantum of local activity' should give a State authority over a 'far larger quantum of . . . activity' having no connection to any in-state activity.").

III. Like *BMS*, The Decision Below Implicates A Recurring Question of Significant National Importance.

The decision below deepens a split and departs from basic constitutional principles; that is reason enough to grant review. And the need for consideration by this Court is especially acute because, as this Court recognized in granting certiorari in *BMS*, the question presented is one of exceptional practical importance.

A. As GSK's amicus brief in *BMS* explains, plaintiffs' attorneys are exploiting the lack of clarity concerning the arising-from requirement to bring lawsuits in favored jurisdictions alleging out-of-state injuries to out-of-state plaintiffs with no connection to the forum. *See* GSK *BMS* Amicus Br. 6–14. GSK

is at ground zero of this forum-shopping epidemic. In mass-tort suits around the country, plaintiffs' lawyers are recruiting a few in-state plaintiffs to use as anchors to bring large numbers of claims by out-of-state plaintiffs in the lawyers' preferred jurisdictions. *Id.*

In Missouri, for example, 96 plaintiffs from 30 different states whose claims have no connection to Missouri joined with a mere three in-state plaintiffs to bring a mass action against GSK in St. Louis. *See Fitts, et al. v. GSK*, No. 1622-CC00539 (22nd Jud. Cir. Ct., City of St. Louis). And in California, plaintiffs' lawyers have filed multiple lawsuits that join plaintiffs who live all over the country with some California residents. *See* GSK *BMS* Amicus Br. 9.

GSK's experience exemplifies a larger forum-shopping problem involving many other non-resident defendants. Missouri, for example, is hosting dozens of lawsuits brought by out-of-state plaintiffs against Johnson & Johnson over alleged risks posed by talcum powder. *See, e.g., Timms v. Johnson & Johnson*, No. 4:16-cv-00733-JAR, 2016 WL 3667982 (E.D. Mo. Jul. 11, 2016) (80 unrelated plaintiffs from 31 states, with only three from Missouri). Pfizer, General Motors, and Janssen Pharmaceuticals are facing similar lawsuits. *See Robinson v. Pfizer Inc.*, No. 4:16-CV-439 (CEJ), 2016 WL 1721143 (E.D. Mo. Apr. 29, 2016) (remanding action brought by 64 plaintiffs from 29 different states to City of St. Louis Circuit Court); *Shell et al. v. General Motors*, No. 1522-cc00346 (22nd Jud. Cir. Ct., City of St. Louis); *Allen et al. v. Janssen Pharm. et al.*, No. 1522-CC00187-01 (22nd Jud. Cir. Ct., City of St. Louis

Nov. 9, 2016) (denying motion to dismiss for lack of personal jurisdiction in suit involving 64 plaintiffs from 30 different states). *See also* GSK *BMS* Amicus Br. 12–14.

Because trials in cases like this happen one plaintiff at a time, the few in-state plaintiffs' claims may never be litigated—further confirming that they serve only a forum-shopping purpose. The St. Louis trials in the talc cases, for example, have involved plaintiffs from Alabama, South Dakota, and California, and Tennessee. *See Hogans v. Johnson & Johnson*, No. 1422-CC09012-01 (22nd Jud. Cir. Ct., City of St. Louis Jan. 7, 2016). And in the Missouri Paxil cases, the first case set for trial involved a plaintiff from West Virginia. When a state court hosts what amounts to a nationwide multi-district litigation in which in-state plaintiffs barely participate, that is a sure sign that something is amiss.[4]

This Court's decision in *BMS* may or may not stem this forum-shopping tide. If the Court decides only that some causation standard is required but stops short of adopting proximate causation, forum-

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[4] The Missouri Supreme Court recently and correctly rejected "the proposition that, if a company is a national company that does the same 'type' of business in the forum state as in the rest of the country, it can be sued anywhere." *State ex rel. Norfolk S. Ry. Co. v. Dolan*, No. SC 95514, 2017 WL 770977, at *6 (Mo. Feb. 28, 2017). While the court's rejection of an openly non-causal standard like that applied by the *BMS* court is welcome, the court did not decide whether but-for or proximate cause is the appropriate standard.

shopping will continue to spread. As the decision below illustrates, it is a simple matter to shift from a non-causal sliding scale to an equally lenient and flexible approach that purports to link jurisdiction to in-state activities but does not require that link to be meaningful.

B. This forum-shopping complaint is not an abstract grievance. When plaintiffs' lawyers bring cases in jurisdictions far from where the relevant events occurred, they impose real costs on defendants, courts, and witnesses.

As GSK's amicus brief in *BMS* explains, the most obvious problem is how to obtain live trial testimony from out-of-state witnesses—particularly the prescribing physician, who is typically the most important witness—who are outside the forum state's subpoena power. *See* GSK *BMS* Amicus Br. 14–19. Potential witnesses generally do not jump at the opportunity to testify, particularly far from home. And defendants cannot force them to do so, because state courts lack the power to compel out-of-state witnesses to attend trial. *See, e.g.*, *Gridley v. State Farm Mut. Ins. Co.*, 840 N.E.2d 269, 279 (Ill. 2005) ("Illinois courts do not have subpoena power in Louisiana, so . . . State Farm would not be able to compel the attendance of the Louisiana witnesses in Illinois."). The inability to secure the live testimony of out-of-state witnesses impairs the out-of-state company's ability to defend itself. *See* GSK *BMS* Amicus Br. 17–18.

In practice, the defendant often is left to rely on videotaped deposition testimony. That is problematic. Assuming the defendant manages to

convince the local court and the foreign jurisdiction to allow a deposition of a doctor in a different state, the defendant will face a strategic dilemma. Because the defendant does not know what the doctor is going to say, the defendant has to combine a discovery and a cross-examination deposition into one, requiring defense counsel to artfully begin with open-ended questions and then close things off with cross-examination questions developed on the spot. Then, the defendant can splice together the deposition clips, producing a disjointed and awkward presentation. *See* GSK Amicus Br. 16–17.

In any event, the jury is deprived of the benefit of live testimony. And the defendant is denied the opportunity to prepare and deliver an effective cross-examination—"[t]he age-old tool for ferreting out truth in the trial process." *Perry v. Leeke*, 488 U.S. 272, 283 n.7 (1989). Instead, the judge turns down the lights, the screen comes on, and the jurors nod off. *See Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 511 (1947) ("[T]o fix the place of trial at a point where litigants cannot compel personal attendance and may be forced to try their cases on deposition, is to create a condition not satisfactory to court, jury or most litigants.").

* * *

Whether a mere but-for link is sufficient for case-linked jurisdiction is a frequently recurring and extremely significant question. The Court should hold in *BMS* that a proximate causal link between the defendant's forum-state activities and the plaintiff's claim is required. If, however, the Court

does not reach that question in *BMS*, it should grant this petition in order to do so.

CONCLUSION

The Court should hold this petition pending its decision in *BMS* and then should either grant, vacate, and remand for further consideration in light of *BMS* or grant this petition for plenary consideration.

Respectfully submitted,

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March 23, 2017

APPENDIX

APPENDIX

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APPENDIX A

SUPREME COURT OF ILLINOIS
SUPREME COURT BUILDING
200 East Capitol Avenue
SPRINGFIELD, ILLINOIS 62701-1721

[Filed November 23, 2016]

Mr. Alan Scott Gilbert
Dentons US LLP
233 S Wacker Dr Ste 5900
Chicago, IL 60606-6361

No. 121381 - M.M., a Minor, etc., et al., respondents, v. GlaxoSmithKline LLC, etc., petitioner. Leave to appeal, Appellate Court, First District.

The Supreme Court today DENIED the petition for leave to appeal in the above entitled cause.

The mandate of this Court will issue to the Appellate Court on December 28, 2016.

APPENDIX B

IN THE
APPELLATE COURT OF ILLINOIS
FIRST DISTRICT
Fifth Division

2016 IL App (1st) 151909
No. 1-15-1909

[Filed August 26, 2016]

M.M., a Minor, by and Through Audrey Meyers, Her Mother and Next Friend; A.H., a Minor, by and Through Dawn Hinton, Her Mother and Next Friend; P.M., a Minor, by and Through Linda Butler, His Mother and Next Friend; H.C., a Minor, by and Through Amy Christy, Her Mother and Next Friend; H.H., a Minor, by and Through Kristen Hozempa, His Mother and Next Friend; A.K., a Minor, by and Through Kathryn Keady, His Mother and Next Friend; C.S., a Minor, by and Through Stacey Schutte, Her Mother and Next Friend; and C.E., a Minor, by and Through Shannon Emery, His Mother and Next Friend,
Plaintiffs-Appellees,

v.

GLAXOSMITHKLINE LLC, f/k/a SmithKlineBeecham Corporation, d/b/a SmithKlineBeecham; WOLTERS KLUWER HEALTH, INC.; WOLTERS KLUWER

UNITED STATES, INC.; and)
WALGREENS COMPANY,)
Defendants)
)
(GlaxoSmithKline LLC, f/k/a)
SmithKlineBeecham Corporation, d/b/a)
SmithKlineBeecham, Defendant-Appellant).)
_____)

Appeal from the Circuit Court of Cook County.

No. 2014 L 006985

The Honorable Larry G. Axelrood, Judge Presiding.

JUSTICE GORDON delivered the judgment of the court, with opinion.

Justices Lampkin and Burke concurred in the judgment and opinion.

OPINION

¶ 1 In this lawsuit, eight minor plaintiffs from six states, including Illinois, filed a products liability suit in the circuit court of Cook County against defendant GlaxoSmithKline LLC (GSK), a pharmaceutical company, and others. The suit alleges that the minor plaintiffs suffered catastrophic birth defects as a result of their mothers' ingestion of defendant GSK's psychiatric drug, Paxil. Defendant GSK moved to dismiss the claims of the out-of-state plaintiffs due to lack of personal jurisdiction, arguing that the court lacked both general and specific jurisdiction.

¶ 2 However, the trial court found that Illinois had specific personal jurisdiction over defendant GSK based on (1) defendant GSK's substantial in-state contacts,

namely its contracts with 17 Illinois physicians to run 18 to 21 clinical trials on Paxil in Illinois as part of a multicenter study and (2) the fact that plaintiffs' claims arose from defendant GSK's acts or omissions related to those trials. On this permissive interlocutory appeal, pursuant to Illinois Supreme Court Rule 306(a)(3), defendant GSK argues that the trial court erred in denying its motion to dismiss the out-of-state plaintiffs' claims due to lack of personal jurisdiction. Ill. S. Ct. R. 306(a)(3) (eff. July 1, 2014) ("[a] party may petition for leave to appeal *** from an order of the circuit court denying a motion to dismiss on the grounds that defendant has done nothing which would subject defendant to the jurisdiction of the Illinois courts"). For the following reasons, we affirm.

¶ 3 BACKGROUND

¶ 4 I. Parties

¶ 5 The 16 plaintiffs in this case are eight minor plaintiffs and their mothers. In the discussion below, we refer to a minor plaintiff and his or her mother as a "mother-child pair." Two pairs are residents of Illinois, two pairs are residents of Florida, and the four remaining pairs reside in Colorado, Virginia, Michigan, and Wisconsin, respectively.

¶ 6 Defendant GSK is a limited liability company incorporated in Delaware, and its sole member, GSK Holdings Inc., is a Delaware corporation with its principal place of business in Delaware. Defendant GSK also has corporate and administrative headquarters in Pennsylvania and North Carolina.

¶ 7 II. Complaint

¶ 8 On July 2, 2014, plaintiffs filed a complaint that names the following as defendants: (1) GSK (f/k/a SmithKlineBeecham Corporation, d/b/a SmithKlineBeecham), the pharmaceutical company that designed, tested, manufactured, and sold the drug Paxil; (2) Wolters Kluwer Health, Inc. (WKH), and Wolters Kluwer United States, Inc. (WKUS), the companies that provided drug information about Paxil to pharmacies; and (3) Walgreen Co. (Walgreens), the company that sold Paxil to some of the plaintiffs. Only GSK brings this appeal. Against defendant GSK, plaintiffs' complaint sets forth six counts: (1) strict liability and failure to warn, (2) strict products liability and design defect, (3) negligence, (4) breach of implied warranty, (5) breach of express warranty, and (6) negligent misrepresentation and concealment.

¶ 9 Plaintiffs claim that the mothers' ingestion of Paxil—a branded paroxetine prescription drug that treats depression, obsessive compulsive disorder, and anxiety—caused catastrophic congenital birth defects, including heart abnormalities. Plaintiffs allege that the design of Paxil, its inadequate warnings, and the manner in which its risks were communicated to the mothers, rendered the drug defective. Moreover, plaintiffs allege that "[d]efendants failed in their acts and omissions related to [Paxil] to use reasonable care to avoid injuring Plaintiffs" and "breached implied and express warranties accompanying [its] sale *** to each mother Plaintiff." Plaintiffs allege that, collectively, the "defective nature of [Paxil] and Defendants' negligent conduct and breach of implied and express warranties proximately caused the minor Plaintiffs to develop

birth defects" in the form of severe and permanent structural and functional abnormalities.

¶ 10 Plaintiffs allege that, at the time that each mother was prescribed Paxil, defendant GSK knew that there was a "significantly increased risk of congenital defects in babies whose mothers ingested" the drug. Such knowledge was "scientifically knowable through appropriate research and testing." Plaintiffs allege that the Food and Drug Administration (FDA) requires defendant GSK "to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and [Paxil]." Despite defendant GSK's opportunity and duty to strengthen the drug's warnings, it "touted [Paxil] as being safe for pregnant women" and "aggressively *** promoted" the drug with labels that inadequately cautioned patients of the associated risk factors, thus, misrepresenting the drug to the public and to the medical profession. The complaint alleges that, had defendant GSK apprised plaintiffs' physicians of Paxil's risks, they would not have "prescribed or permitted" plaintiffs to use the drug. Likewise, had defendant GSK provided timely and "adequate warnings regarding the risks" of Paxil, plaintiffs would not have ingested the drug.

¶ 11 Plaintiffs also argue (1) that defendant GSK "failed to conduct appropriate tests to generate the necessary scientific data regarding the strength of the association between [Paxil] and birth defects"; (2) that defendant GSK "represented that Paxil was safe" when it knew or should have known of Paxil's dangerous impact on *in utero* development because such results were "scientifically knowable" through appropriate research; (3) that defendant GSK neglected to conduct

adequate preclinical, clinical, and postmarketing surveillance to determine whether Paxil was safe for its intended or foreseeable uses; and (4) that defendant GSK "intentionally conceal[ed]," "failed to disclose," and "negligently manipulated" clinical data that demonstrated Paxil's risks of birth defects. The complaint alleges that, as a direct result of defendant GSK's acts and omissions, plaintiffs sustained severe and permanent disfigurement, pain, suffering, and disability.

¶ 12 III. Motion to Dismiss

¶ 13 On August 7, 2014, defendant GSK moved to dismiss the out-of-state plaintiffs' claims due to a lack of personal jurisdiction, both general and specific, under sections 2-301 and 2-619 of the Code of Civil Procedure. 735 ILCS 5/2-301, 2-619 (West 2012). First, defendant GSK argued that it was not subject to general jurisdiction because Illinois is neither the state of its incorporation nor its principal place of business. Defendant GSK argued that it was not rendered "at home" in Illinois by its business activities here, under the United States Supreme Court's recent decision in *Daimler AG v. Bauman*, 571 U.S. ___, ___, 134 S. Ct. 746, 749 (2014).

¶ 14 Second, defendant GSK argued that Illinois lacks specific jurisdiction[1] because the out-of-state plaintiffs' claims did not arise from its Illinois activities. Moreover, defendant GSK claimed that its

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[1] Specific jurisdiction requires a "showing that [(1)] the defendant purposefully directed its activities at the forum state and [(2)] the cause of action arose out of or relates to the defendant's contacts with the forum state." *Russell v. SNFA*, 2013 IL 113909, ¶ 40.

actions or omissions in Illinois were not the "but for" cause of the alleged harm: plaintiffs did not serve as study subjects in Illinois, did not receive Paxil prescriptions in Illinois, did not ingest Paxil in Illinois, and did not suffer injury from Paxil in Illinois. Finally, defendant GSK argued that the out-of-state plaintiffs may not create personal jurisdiction by tacking their claims onto those of the two Illinois plaintiffs.

¶ 15 IV. Discovery

¶ 16 In the responses to plaintiffs' interrogatories, it was revealed that defendant GSK employed 16,323 people in the United States, 217 people who resided in Illinois, and it maintained an agent for service of process in Illinois. Defendant GSK's 2013 gross trade sales revenue for all products in the United States was $15,558,745,381.17, but it did "not collect *** data for gross revenue *** at the state level." Defendant GSK also disclosed that it currently has 184 sales representatives who market GSK's products in Illinois. Between the years 2000 and 2006, defendant GSK had anywhere between 79 and 121 employees marketing specifically Paxil in Illinois. Defendant GSK conducted 18 preclinical and clinical studies on Paxil in Illinois. An excerpt from one of these studies stated:

> "Subjects who became pregnant during the study were to be withdrawn from the study immediately. Subjects were instructed to notify the investigator if it was determined after completion of the study that they became pregnant either during the treatment phase of the study or within 30 days. Whenever possible, a pregnancy was to be followed to term, any premature terminations reported, and the status

of the mother and child was to be reported to the sponsor after delivery."

¶ 17 V. Plaintiffs' Response to Defendant GSK's Motion to Dismiss

¶ 18 On November 21, 2014, plaintiffs filed a response to defendant GSK's motion to dismiss. While the out-of-state plaintiffs were not domiciled, prescribed Paxil, or injured in Illinois, they argued that their claims arose directly out of or related to defendant GSK's purposeful contacts with Illinois—that is, defendant GSK's 18 to 21[2] "inadequate and manipulated" Paxil clinical trials in Illinois, conducted by 17 physicians in Illinois on a continuous basis spanning nearly two decades, from 1985 to 2003. Plaintiffs claimed that, in addition to these trials, defendant GSK collaborated on another Paxil clinical trial that occurred exclusively in Illinois between 2001 and 2003. Finally, plaintiffs argued that they have a separate and independent basis for exercising personal jurisdiction because defendant GSK's "conduct in Illinois is the same as its conduct in other states—and that conduct gave rise to the out-of-state Plaintiffs' claims." In other words, the nonresident plaintiffs' claims are based on "the same alleged wrongs as the claims of the Illinois resident Plaintiffs."

¶ 19 In their surresponse opposing defendant GSK's motion to dismiss, plaintiffs claimed: "[(1)] that GSK contracted with at least 17 principal investigators in

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[2] Plaintiffs' response states that "[i]t is not clear whether the three GSK-sponsored clinical trials conducted in Illinois *** are duplicative of, or in addition to, the eighteen such clinical trials GSK identified in its discovery answers."

Illinois to conduct clinical trials in Illinois regarding Paxil; [(2)] that the clinical trials resulted in at least eighteen pregnancies; [(3)] that GSK largely failed to track the outcomes of the pregnancies; [(4)] that of the few pregnancy outcomes that GSK did learn, there were fetal abnormalities, including a heart abnormality; and [(5)] that GSK failed to consider any of the pregnancy outcome data in assessing the safety of Paxil to unborn children."

¶ 20 VI. Argument

¶ 21 On June 10, 2015, the trial court heard argument on defendant GSK's motion to dismiss. Defense counsel argued that it was not subject to suit in Illinois, but only in Delaware, the state of defendant GSK's incorporation; in North Carolina and Pennsylvania, the states where defendant GSK "might be" "at home"; and in the states where the nonresident plaintiffs were injured. Defense counsel conceded purposeful contacts when he said, "no one disputes that GSK had purposeful contacts with Illinois."

¶ 22 However, defense counsel argued that plaintiffs' claims did not arise out of defendant GSK's contacts in Illinois, specifically, because Paxil clinical trials took place in 44 states and abroad. When the trial court asked defense counsel, "would [you] say that each of [the] 44 states would not be appropriate place[s] for [jurisdiction]?" he responded, "that would be our position." Defendant GSK argued that by emphasizing 17 of the 361 trials that it conducted in Illinois—or 100 of the 4272 clinical trial patients that took Paxil in Illinois—plaintiffs focused on "a tiny sliver" of the trials and drained all meaning from specific jurisdiction. The trial court responded: "What if [Illinois] had 1/10 of 1

percent [of the total trials], but it was that data that skewed the entire interpretation of the tests? How do I know? What's the magic number *** of [trials] that have to be conducted in Illinois in order to have specific jurisdiction?" "[Am I] trying to figure out where the best location for this litigation is, or whether or not there's a significant nexus to Illinois?"

¶ 23 Neither defense counsel nor plaintiffs' counsel were able to suggest a bright-line test for the number of Illinois trials that would give rise to personal jurisdiction in Illinois, but defense counsel argued that 17 trials was insufficient, whereas plaintiffs' counsel argued them sufficient. The trial court stated there was "no definitive number," so it "must look at it in terms of a pleading." Finally, defense counsel argued that plaintiffs' doctors and witnesses are out-of-state, but the trial court replied: "We have out of state witnesses every day."

¶ 24 In reply, plaintiffs argued that the "arising from" and "related to" standard is "lenient and flexible." Plaintiffs' claims arose from inadequate Paxil trials conducted in Illinois because the Illinois data "was aggregated with data from [the] other sites to reach statistical significance" and "the record compels the inference that the Illinois principal investigators had input into, and exercised control over, the overall design study protocol and analysis of the aggregate data."

¶ 25 However, plaintiffs stressed that they "don't have to prove on this motion *** whether the Illinois clinical trials were defective." They must only "make a *prima facie* case of personal jurisdiction." Plaintiffs argued that, by contracting with Illinois physicians to

run clinical trials on Paxil in Illinois, defendant GSK purposefully availed itself of the state's benefits and that their claims arose directly from defendant GSK's collective omissions in those trials.

¶ 26 VII. Trial Court's Order

¶ 27 On June 10, 2015, the trial court denied defendant GSK's motion, finding "[t]hat by contracting the principal investigators in Illinois to conduct clinical trials regarding Paxil, the defendant did purposefully avail itself [of] the privilege of conducting activities within Illinois." "[S]pecific jurisdiction exists when *** the cause of action arises out of defendant's contacts with the foreign state." Plaintiffs "assert that defendant failed to conduct appropriate tests to generate the necessary scientific data regarding the strength of the association between this drug and birth defects" and "may have failed to adequately interpret or *** collect *** and these clinical trials occurred in Illinois from 1985 to 2003." The trial court found that the "substantial contacts the defendant purposely engaged in and directed to Illinois *** which the plaintiffs[']claim[s] relate to or arise from *** satisfy both *** federal and Illinois due process." However, the trial court stated: "I don't think there is a bright line [test] for me." Earlier during argument, the trial court stated, "if it goes up and case law is made, it will give us a better understanding and better standard."

¶ 28 VIII. Petition for Leave to Appeal

¶ 29 Accordingly, on July 10, 2015, defendant GSK timely filed a petition for leave to appeal the trial court's denial of the motion to dismiss for lack of personal jurisdiction. GSK filed the petition pursuant

to Illinois Supreme Court Rule 306(a)(3) (eff. July 1, 2014) ("[a] party may petition for leave to appeal *** from an order of the circuit court denying a motion to dismiss on the grounds that defendant has done nothing which would subject defendant to the jurisdiction of the Illinois courts").

¶ 30 On September 10, 2015, this court granted that petition, and this appeal follows.

¶ 31 ANALYSIS

¶ 32 On this permissive interlocutory appeal, defendant GSK argues that the trial court erred in denying its motion to dismiss the out-of-state plaintiffs' claims due to lack of personal jurisdiction. For the following reasons, we affirm.

¶ 33 I. Standard of Review

¶ 34 It is well-settled that it is the plaintiff who "bears the burden of establishing a *prima facie* basis upon which jurisdiction over an out-of-state resident may be exercised" (*Roiser v. Cascade Mountain, Inc.*, 367 Ill. App. 3d 559, 561 (2006)), and that burden is "minimal." *TCA International, Inc. v. B&B Custom Auto, Inc.*, 299 Ill. App. 3d 522, 532 (1998). The "defendant may overcome [the] plaintiff's *prima facie* case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Russell*, 2013 IL 113909, ¶ 28.

¶ 35 On appeal, we "resolve in favor of the plaintiff any conflicts in the pleadings and affidavits." *MacNeil v. Trambert*, 401 Ill. App. 3d 1077, 1080 (2010). "When the circuit court decides a jurisdictional question solely on the basis of documentary evidence," and without an

evidentiary hearing, as it did in this case, our review is *de novo*. *Roiser*, 367 Ill. App. 3d at 561; *Russell*, 2013 IL 113909, ¶ 28. *De novo* consideration means we perform the same analysis that a trial judge would perform. *Khan v. BDO Seidman, LLP*, 408 Ill. App. 3d 564, 578 (2011).

¶ 36 In reviewing the trial court's decision on appeal, " 'this court reviews the judgment, not the reasoning, of the trial court, and we may affirm on any grounds in the record, regardless of whether the trial court relied on those grounds or whether the trial court's reasoning was correct.' " *US Bank, National Ass'n v. Avdic*, 2014 IL App (1st) 121759, ¶ 18 (quoting *Coghlan v. Beck*, 2013 IL App (1st) 120891, ¶ 24).

¶ 37 II. Applicable Statutory and Constitutional Provisions

¶ 38 Section 2-209 of the Code of Civil Procedure (Code), "commonly referred to as the Illinois long-arm statute, governs the exercise of personal jurisdiction by an Illinois court over a nonresident defendant." *Russell*, 2013 IL 113909, ¶ 29; 735 ILCS 5/2-209(c) (West 2012).

¶ 39 Subsection (a) of section 2-209, which governs specific jurisdiction, lists 14 different actions by a defendant that will subject him or her to Illinois jurisdiction. 735 ILCS 5/2-209(a)(1)-(14) (West 2012). For example, a defendant is subject to jurisdiction for "any cause of action arising from the doing of any *** acts" that include the transaction of business and "the making or performance of any contract *** substantially connected with" Illinois. 735 ILCS 5/2-209(a)(1), (a)(7) (West 2012).

¶ 40 Subsection (c) is a "catchall provision" that permits Illinois courts to " 'exercise jurisdiction on any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States.' " *Roiser*, 367 Ill. App. 3d at 561 (quoting 735 ILCS 5/2-209(c) (West 2002)). Subsection (c) permits an Illinois court to exercise personal jurisdiction to the extent permitted by the due process clause of the fourteenth amendment to the United States Constitution. *Klump v. Duffus*, 71 F.3d 1368, 1371 (7th Cir. 1995) (Illinois long-arm statute, subsection (c), is "coextensive with the due process requirements of the United States Constitution").

¶ 41 An exercise of jurisdiction under any of the statutory subsections must comport with the federal due process clause. U.S. Const., amend. XIV. The federal due process clause 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. *Roiser*, 367 Ill. App. 3d at 561. This court has described the minimum contacts standard as follows:

> "The minimum contacts standard ensures that 'requiring the out-of-state resident to defend in the forum does not " 'offend traditional notions of fair play and substantial justice.' " ' [Citation.] The minimum contacts analysis must be based on some act by which the defendant purposefully availed itself of the privilege of conducting activities within the forum state, in order to assure that a nonresident will not be haled into a forum solely as a result of random, fortuitous, or attenuated contacts with the forum or the

unilateral acts of a consumer or some other third person." *Roiser*, 367 Ill. App. 3d at 561-62.

¶ 42 The minimum contacts needed for jurisdiction depends on whether the jurisdiction asserted is general or specific jurisdiction. *MacNeil*, 401 Ill. App. 3d at 1081. General jurisdiction exists when a defendant's general business contacts with the forum state are continuous and systematic. *Knaus v. Guidry*, 389 Ill. App. 3d 804, 814 (2009); *MacNeil*, 401 Ill. App. 3d at 1081; see also *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.9 (1984).

¶ 43 "In the context of corporations, specific 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" (*Sabados v. Planned Parenthood of Greater Indiana*, 378 Ill. App. 3d 243, 248 (2007) (citing *Illinois Commerce Comm'n v. Entergy-Koch Trading, LP*, 362 Ill. App. 3d 790, 796 (2005))) such that it is reasonable to require the defendant to litigate in that state. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985) (citing *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 287 (1980)).

¶ 44 In the case at bar, plaintiffs do not argue that Illinois may exercise general jurisdiction over defendant GSK. Thus, we confine our analysis to specific jurisdiction, and that inquiry 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

(1984))); and (2) it must be reasonable for Illinois to exercise jurisdiction over the defendant. See *World-Wide Volkswagen Corp.*, 444 U.S. at 292 (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 317 (1945)).

¶ 45 III. Plaintiff's *Prima Facie* Showing

¶ 46 For the following reasons, we find that the out-of-state plaintiffs made a *prima facie* showing that Illinois has specific jurisdiction over defendant GSK.

¶ 47 First, plaintiffs made a *prima facie* showing that defendant GSK had sufficient minimum contacts with Illinois. "With specific jurisdiction, a nonresident defendant has minimum contacts with the forum state [(1)] when 'the defendant has "purposefully directed" [its] activities at *** the forum *** and [(2)] the litigation results from alleged injuries that "arise out of or relate to" those activities [citation].' " *Bell v. Don Prudhomme Racing, Inc.*, 405 Ill. App. 3d 223, 231 (2010) (quoting *Burger King Corp.*, 471 U.S. at 472).

¶ 48 A. Purposeful Activities

¶ 49 In the case at bar, defendant GSK conceded that it had purposefully directed its activities at Illinois. At the hearing before the trial court on June 10, 2015, GSK argued that "no one disputes that GSK had purposeful contacts with Illinois." Even if defendant GSK had not conceded this point, we would have to conclude that defendant purposefully availed itself of the state's benefits 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. See 735 ILCS

5/2-209(a)(7) (West 2012) (specific jurisdiction based on "the making or performance of any contract").[3] The quality of defendant GSK's relationship with Illinois can hardly be characterized as random, attenuated, or the like; the contracts with Illinois, over the course of two decades, were purposeful and directed. In addition, defendant GSK admitted (1) that between the years 2000 and 2006, it had anywhere between 79 and 121 employees marketing Paxil in Illinois; (2) that, as of October 16, 2014, it employed 217 people who resided in Illinois; and (3) that it maintained an agent for service of process in Illinois. Thus, defendant GSK purposefully availed itself of the privilege of conducting activities in Illinois.

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[3] "A nonresident defendant's contract with an Illinois resident alone does not automatically establish the required minimum contacts. [Citation.] Instead, in determining whether a defendant has purposefully availed himself of the benefits of Illinois law in forming the contract, the court considers the following factors: (1) who initiated the transaction; (2) where the contract was formed; and (3) where the contract was performed. [Citation.]" *Graver v. Pinecrest Volunteer Fire Department*, 2014 IL App (1st) 123006, ¶ 16.

With respect to the first and second factors, the amended declaration of Kalpesh Joshi, a GSK employee, states that "[w]hen a clinical trial is a multicenter study, GSK will contract with individual investigators *at* the various sites." (Emphasis added.) While the contracts do not appear in the record, this statement indicates that GSK both initiated the transaction and executed the contracts with Illinois physicians in Illinois. With respect to the third factor, the Illinois physicians performed the clinical trials in Illinois. Thus, these factors support the conclusion that defendant purposefully availed itself of the benefits of this state.

¶ 50 B. Directly Arose From or Related to

¶ 51 The out-of-state plaintiffs also made a *prima facie* showing that their claims directly arose from or related to defendant GSK's purposeful activities in Illinois. For specific jurisdiction to exist, the litigation must result from alleged injuries that arose out of or related to defendant's in-state activities. *Bell*, 405 Ill. App. 3d at 231 (quoting *Burger King Corp.*, 471 U.S. at 472). Our supreme court has observed: "Although the United States Supreme Court has not clarified what is meant by 'arising out of' or 'related to' in the context of a jurisdiction question [citation], several courts have determined that the applicable standard is lenient or flexible."[4] *Russell*, 2013 IL 113909, ¶ 83.

¶ 52 In the case at bar, plaintiffs claim that their injuries arose out of deficiencies in defendant GSK's Paxil clinical trials. Specifically, plaintiffs claim (1) that Paxil clinical trials resulted in at least 18 pregnancies, and defendant GSK largely failed to track their outcomes; (2) that, of the few pregnancies that defendant GSK did track, there were fetal

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[4] Our supreme court cited: "*Myers v. Casino Queen, Inc.*, 689 F.3d 904, 913 (8th Cir. 2012) (explaining the need for a flexible standard, including the consideration of a totality of the circumstances, when analyzing the 'relate to' factor of the Court's standard); *Schneider v. Hardesty*, 669 F.3d 693, 703 (6th Cir. 2012) (noting the 'arising from' requirement is subject to a 'lenient standard'); *CompuServe, Inc. v. Patterson*, 89 F.3d 1257, 1267 (6th Cir. 1996) (determining that '[i]f a defendant's contacts with the forum state are related to the operative facts of the controversy, then an action will be deemed to have arisen from those contacts'); *Northern Laminate Sales, Inc. v. Davis*, 403 F.3d 14, 25 (1st Cir. 2005) (recognizing that the 'arise out of' or 'relate to' requirement is a 'flexible, relaxed standard')." *Russell*, 2013 IL 113909, ¶ 83.

abnormalities, including a heart defect; (3) that defendant GSK failed to consider any of the pregnancy outcome data in assessing the safety of Paxil to unborn children; (4) that defendant GSK's Illinois data on Paxil "was aggregated with data from [the] other sites to reach statistical significance"; and (5) that "the record compels the inference that the Illinois principal investigators had input into, and exercised control over, the overall design study protocol and analysis of the aggregate data." 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.

¶ 53 In support of their first three propositions, plaintiffs identify a particular failure of defendant GSK, namely, that its Paxil clinical trials resulted in at least 18 pregnancies that it failed to adequately track. In response, defendant GSK argues that it did not consider the data to determine the correlation between Paxil and birth defects because it was required by the FDA to exclude pregnant women from its trials. However, as plaintiffs argue, the FDA also states:

> "Some groups in the general population may require special study because they have unique risk *** considerations that need to be taken into account during drug development ***. ***
>
> * * *

> In general, pregnant women should be excluded from clinical trials where the drug is not intended for use in pregnancy. If a patient becomes pregnant during administration of the drug, treatment should generally be discontinued if this can be done safely. Followup evaluation of the pregnancy, fetus, and child is *very important*." (Emphasis added.) International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials, 62 Fed. Reg. 66113-02, 66117 (Dec. 17, 1997).

Plaintiffs contend that defendant GSK "pointed to no ethical prohibition on retrospectively reviewing the outcomes of unintended in utero exposure to a drug during a clinical trial." Accordingly, if defendant GSK failed to adequately track the pregnancies of women who participated in its clinical trials, a portion of which occurred in Illinois, plaintiffs' claims would thus arise from or relate to defendant GSK's purposeful activities in Illinois.

¶ 54 In support of their fourth proposition regarding data analysis, plaintiffs argue that their claims arose from or related to defendant GSK's Illinois Paxil trials because the Illinois data was aggregated with the data from the other study locations in the multicenter Paxil study. It was from that single set of data that defendant GSK drew its statistically significant conclusions with respect to Paxil's safety. To echo the trial court: "What if [Illinois] had 1/10 of 1 percent [of the total trials], but it was that data that skewed the entire interpretation of the tests? How do I know?" The Illinois data was aggregated with the other data to

inform the warning label content for Paxil, upon which the out-of-state plaintiff mothers relied in making their decision to take the drug.[5]

¶ 55 Finally, in support of their fifth proposition regarding the Illinois physicians' degree of input, plaintiffs cite defendant GSK's own language in a sworn declaration: Illinois principal investigators had "little or no input into or control over the study design protocol or analysis of the aggregate data collected from all study sites." As plaintiffs argue, the word "little" invites the inference that the physicians had *some* degree of input into, and control over, the clinical trials, or else the word would have been omitted. Absent further guidance in the record, we "resolve in favor of the plaintiff any conflicts in the pleadings and affidavits." *MacNeil*, 401 Ill. App. 3d at 1080.

¶ 56 In light of the "lenient and flexible" "arising from" and "related to" standard, plaintiffs meet the low threshold of a *prima facie* showing that their claims arose from defendant GSK's Paxil trials in Illinois. As discussed above, "[o]n a motion to dismiss, plaintiff[s] need not prove [their] case, but rather must only establish a *prima facie* case, where all well-pleaded facts are taken as true." *Senese v. Climatemp, Inc.*, 222 Ill. App. 3d 302, 316 (1991) (citing *Mid-Town*

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[5] This fact was alleged in plaintiffs' complaint. Specifically, plaintiffs allege that, had defendant GSK provided timely and "adequate warnings regarding the risks" of Paxil, they would not have ingested the drug. Plaintiffs further allege that, despite defendant GSK's opportunity and duty to strengthen the drug's warnings, it "touted [Paxil] as being safe for pregnant women" and "aggressively *** promoted" the drug with labels that inadequately cautioned patients of the associated risk factors.

Petroleum, Inc. v. Dine, 72 Ill. App. 3d 296, 299 (1979)). Plaintiffs have satisfied this burden, and now the burden switches to defendant. *Russell*, 2013 IL 113909, ¶ 28. Defendant may "overcome [the] plaintiff's *prima facie* case for jurisdiction by offering uncontradicted evidence that defeats jurisdiction." *Russell*, 2013 IL 113909, ¶ 28.

¶ 57 IV. Defendant GSK Failed to Overcome Plaintiffs' *Prima Facie* Case

¶ 58 A. Minimum Contacts

¶ 59 Defendant GSK failed to overcome plaintiffs' *prima facie* showing that defendant GSK had minimum contacts in Illinois.

¶ 60 1. Purposeful Activities

¶ 61 First, defendant GSK conceded that it "had purposeful contacts with Illinois." However, it also argues that specific jurisdiction is lacking because it is a nonresident defendant being sued by nonresident plaintiffs who were injured outside of Illinois, and "Illinois courts have rejected specific jurisdiction where an out-of-state plaintiff tries to sue an out-of-state defendant." In support, defendant GSK cites *Sabados v. Planned Parenthood of Greater Indiana*, 378 Ill. App. 3d 243 (2007).

¶ 62 In *Sabados*, a female Illinois patient visited a clinic in Indiana that examined her and prescribed her birth control pills. *Sabados*, 378 Ill. App. 3d at 245. After she developed a blood clot back in Illinois, she brought a medical negligence suit in Illinois against the Indiana clinic. *Sabados*, 378 Ill. App. 3d at 245. The appellate court found that the Indiana clinic lacked

sufficient minimum contacts with Illinois to support specific jurisdiction. *Sabados*, 378 Ill. App. 3d at 250. Defendant GSK's reliance on this case is misplaced because the Indiana clinic did not conduct business in Illinois. In sharp contrast, in the case at bar, defendant GSK contracted with 17 principal investigators in Illinois to conduct clinical trials in Illinois.

¶ 63 Moreover, contrary to defendant GSK's assertion that Illinois courts may not entertain plaintiffs' claims, the United States Supreme Court has found that a state can exercise jurisdiction over a nonresident accused by a nonresident of causing injuries, most of which took place outside of the forum state. *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770, 780 (1984). In *Keeton*, a New York resident brought a libel suit in New Hampshire against a magazine publisher incorporated in Ohio with its principal place of business in California. *Keeton*, 465 U.S. at 772. The Court found the publisher's "regular circulation of magazines in [New Hampshire] *** sufficient to support an assertion of jurisdiction." *Keeton*, 465 U.S. at 773-74. The plaintiff could recover in New Hampshire for damages "throughout the United States" (*Keeton*, 465 U.S. at 774), even though it was "undoubtedly true that the bulk of [her] harm *** occurred outside New Hampshire." *Keeton*, 465 U.S. at 780. The Court found the fact that defendant conducted "a '*part* of its general business' in New Hampshire *** sufficient to support jurisdiction when the cause of action [arose] out of the very activity being conducted, *in part*, in New Hampshire." (Emphases added.) *Keeton*, 465 U.S. at 780. Finally, the Court concluded that it does not require that plaintiffs "have 'minimum contacts' with the forum State before permitting that

State to assert personal jurisdiction over a nonresident defendant." *Keeton*, 465 U.S. at 779. A "plaintiff's residence in the forum State is not a separate [jurisdictional] requirement, and lack of residence will not defeat jurisdiction established on the basis of the defendant's contacts." *Keeton*, 465 U.S. at 780.

¶ 64 Similarly, in the case at bar, defendant GSK conducted a *part* of its general business in Illinois, and plaintiffs' claims arose out of the very trials conducted, *in part*, in Illinois. The fact that the contested plaintiffs are not Illinois residents does not destroy the jurisdiction established on the basis of defendant GSK's activities here. As such, similar reasoning supporting specific jurisdiction applies, and defendant GSK's claim that nonresidents may not sue a nonresident in Illinois is unavailing.

¶ 65 2. Directly Arose From or Related to

¶ 66 Defendant GSK also failed in its burden to rebut plaintiffs' *prima facie* showing that their claims arose from or related to defendant GSK's Illinois contacts. While defendant GSK conceded purposeful contacts, it denied that plaintiffs' claims arose from them. Therefore, we dedicate a bulk of our analysis to this prong of the test.

¶ 67 First, defendant GSK argues that there is no "meaningful link" between plaintiffs' claims and the small fraction of Paxil trials that occurred in Illinois—17 of 361, or 5%, of all Paxil trials—and that such a "meaningful link" is what distinguishes general

jurisdiction from specific jurisdiction.[6] Put differently, defendant GSK argues that the scattered nature of the clinical trials across 44 states and foreign countries absolves it from personal jurisdiction in Illinois. In response, the trial court asked: "[Am I] trying to figure out where the best location for this litigation is, or whether or not there's a significant nexus to Illinois?" It is plaintiffs' burden to name a proper place for personal jurisdiction, not the best place—that issue is more apt for *forum non conveniens*. Plaintiffs satisfied that burden above. *Supra* ¶¶ 46-58.

¶ 68 Similarly, defendant GSK argues that its Illinois activities must meet both "legal cause" and "cause in fact" tests to give rise to personal jurisdiction. *Keller v. Henderson*, 359 Ill. App. 3d 605, 617 (2005). That is, defendant's forum activities "gave birth to" plaintiffs' injuries, and "but for" those activities, plaintiffs would not have been injured. *Keller*, 359 Ill. App. 3d at 617.

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[6] In support of its proposition that plaintiffs' claims did not arise from its forum activities, defendant GSK cites In re Plavix Related Cases, No. 2012-L-5688 (Cir. Ct. Cook Co.). First, this is a trial court case with no binding authority on this court. Second, this is an unreported case. We will not cite an unreported case. *State Farm Mutual Automobile Insurance Co. v. Progressive Northern Insurance Co.*, 2015 IL App (1st) 140447, ¶ 101 ("[W]e will not cite an unreported case."); *Skokie Castings, Inc. v. Illinois Insurance Guaranty Fund*, 2012 IL App (1st) 111533, ¶ 15 ("an unreported case" is "not binding on any court"); *People v. Moore*, 243 Ill. App. 3d 583, 584 (1993) ("the decision was unreported and of no precedential value"). "Unreported decisions have no precedential value ***." *American Family Mutual Insurance Co. v. Plunkett*, 2014 IL App (1st) 131631, ¶ 38; *Burnette v. Stroger*, 389 Ill. App. 3d 321, 329 (2009); *West American Insurance Co. v. J.R. Construction Co.*, 334 Ill. App. 3d 75, 82 (2002) (a "foreign, unreported decision *** is of no precedential value").

However, as the trial court correctly emphasized: "What if [Illinois] had 1/10 of 1 percent [of the total trials], but it was that data that skewed the entire interpretation of the tests? How do I know?" Beyond defense counsel's speculative response, "I don't think that could ever be true," defendant GSK did not offer "uncontradicted evidence" that defeats jurisdiction. See *Russell*, 2013 IL 113909, ¶ 28.

¶ 69 Next, defendant GSK argues that "[t]here was nothing unique about the Illinois *** trials" but cites no case that names "uniqueness" as a requirement for establishing jurisdiction.[7] Furthermore, defendant GSK argues that "95 percent of GSK's clinical program for Paxil had no connection at all to Illinois." This is no response to plaintiffs' argument that "in the context of specific personal jurisdiction, whether the Illinois contacts are meaningful depends entirely on their relation to the Plaintiffs' causes of action, and not at all on a percentage-based comparison between how much related conduct occurred outside of Illinois."

¶ 70 Defendant GSK further argues (1) that "[p]laintiffs do not even allege that any of these 18 pregnancies occurred in Illinois" and (2) that "[p]laintiffs do not allege that GSK made *** important decisions about clinical trials *** in Illinois." Yet, defendant GSK, which uniquely has access to this type of information—where the pregnancies and

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[7] The trial court also alluded to this point at argument. Defense counsel said, "I have a hard time believing that the plaintiffs are really going to say that their case is just about the Illinois clinical trials." The court responded, "does it have to be *just* about [the Illinois trials]?" (Emphasis added.)

decisionmaking, in fact, occurred—decided not to present it with its motion to dismiss. As the burden lies squarely with the defendant to provide "uncontradicted evidence that defeats jurisdiction" (*Russell*, 2013 IL 113909, ¶ 28), defendant GSK's responses are inadequate to negate plaintiffs' *prima facie* showing of specific jurisdiction.

¶ 71 Moreover, defendant GSK argues that the Illinois Paxil trials could not have given rise to plaintiffs' claims because the trials were not designed, nor could they have been designed, to test Paxil's impact on fetus development. Defendant GSK argues that Paxil was not tested for its efficacy in treating psychiatric disorders in pregnant women because it is unethical in the medical community to include pregnant women as study participants; thus, GSK excluded pregnant women or women who were not using adequate means of contraception. However, as plaintiffs note, defendant GSK "pointed to no ethical prohibition on retrospectively reviewing the outcomes of unintended in utero exposure to a drug during a clinical trial."

¶ 72 In sum, plaintiffs' injuries allegedly arose from acts of omission during the clinical trials and the resulting inadequate warning labels. These omissions, as alleged in plaintiffs' complaint, include defendant GSK's (1) failure to conduct appropriate research on the correlation between Paxil and birth defects when such information was "reasonably and scientifically knowable"; (2) failure to sufficiently investigate Paxil in preclinical, clinical, and postclinical stages with respect to safety for its intended and foreseeable uses; (3) negligence in manipulating data to conceal the birth

defect risk; and (4) false affirmance that Paxil was adequately tested. Defendant GSK has failed to overcome plaintiffs' *prima facie* showing that their claims arose from or related to defendant GSK's Illinois activities.

¶ 73 B. Reasonableness

¶ 74 Finally, to comply with federal due process, we must also consider the reasonableness of requiring the defendant to litigate in Illinois. See *Russell*, 2013 IL 113909, ¶ 87. 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; *World-Wide Volkswagen Corp.*, 444 U.S. at 292.

¶ 75 Here, Illinois has an indisputable interest in resolving litigation stemming, in part, from clinical trials held in Illinois, run by Illinois doctors on Illinois subjects. In addition, whether or not the out-of-state plaintiffs' claims are dismissed, this litigation will go forward in Illinois. Defendant GSK has not moved to dismiss the claims of the Illinois plaintiffs nor have the other defendants. Thus, litigation, concerning almost the same issues, will go forward in this state, with or without these particular plaintiffs. Defendants have not advanced any reason how piecemeal litigation in different forums advances the goals of "efficient judicial resolution of the dispute" and "substantive social policies." *Russell*, 2013 IL 113909, ¶ 87. Piecemeal litigation raises the cost, considerably, to the collective

plaintiffs, while also running the risk of inconsistent verdicts.

¶ 76 Defendants argued before the trial court that the out-of-state plaintiffs could sue in Delaware, North Carolina, or Pennsylvania—three states where none of the plaintiffs reside—or individually in each of the states where each one resides. This would result in at least two suits: (1) the suit that is going forward in Illinois with Illinois plaintiffs and (2) a suit with out-of-state plaintiffs. If plaintiffs sued in each of the states where they reside, that would result in suits in six different states. As noted above, this would be unnecessarily costly to the litigants, as well as a waste of judicial resources, and would run the risk of conflicting rulings.

¶ 77 Defendant GSK also argues that litigating the out-of-state plaintiffs' claims in Illinois is unreasonable because the evidence concerning their prescription and treatment is located out-of-state. However, the prescription and treatment evidence is scattered across six different states. Thus, this consideration does not weigh heavily for or against any of the six states in which plaintiffs reside. *Cf. Meyers v. Bridgeport Machines Division of Textron, Inc.*, 113 Ill. 2d 112, 121 (1986) (dismissal of a *forum non conveniens* motion is proper where potential witnesses and evidence are equally scattered). In addition, defendant's suggestion that the suit could go forward in Delaware, North Carolina, or Pennsylvania, which are the states of its incorporation and headquarters, does nothing to solve this problem.

¶ 78 Thus, considering the burden on the defendant, the forum state's interest, the plaintiffs' interest in

obtaining relief, and the interest of other states, we cannot find litigating in Illinois unreasonable.

¶ 79 CONCLUSION

¶ 80 As defendant GSK failed to overcome plaintiffs' *prima facie* showing of specific jurisdiction, the trial court did not err in denying defendant GSK's motion to dismiss the out-of-state plaintiffs' claims due to lack of personal jurisdiction.

¶ 81 Affirmed.

APPENDIX C

IN THE APPELLATE COURT
OF ILLINOIS
FIRST JUDICIAL DISTRICT

No. 1-15-1909

[Filed September 10, 2015]

MM, A MINOR, BY AUDREY MEYERS, ET AL.,
Plaintiffs-Respondents,

v.

GLAXOSMITHKLINE, LLC, f/k/a SMITHKLINEBEECHAM CORPORATION d/b/a SMITHKLINEBEECHAM,
Defendant-Appellant,

and

WOLTERS KLUWER HEALTH, INC.; WOLTERS KLUWER UNITED STATES, INC.; and WALGREEN CO.;
Defendants.

Appeal from the Circuit Court of Cook County

No. 2014 L 006985

Honorable Larry G. Axelrood, Judge Presiding.

ORDER

IT IS HEREBY ORDERED that the Petition for Leave to Appeal Pursuant to Illinois Supreme Court Rule 306(a)(3) is GRANTED.

DATED:_____

/s/_____
JUSTICE

/s/_____
JUSTICE

/s/_____
JUSTICE

_____
JUSTICE

APPENDIX D

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS COUNTY DEPARTMENT, LAW DIVISION

NO: 14-L-6985

[Filed June 10, 2015]

MM, a minor, by Audrey Meyers et al., Plaintiff(s)	)
-v-	)
Glaxosmithkline LLC et al., Defendant(s)	)

Motion Call "R"

ORDER

With all parties present, for the reasons set forth on the record, Defendant GSK's motion to dismiss for lack of personal jurisdiction is denied. Defendant GSK may petition for leave to appeal this decision to the appellate court pursuant to ILSC Rule 306. ~~Parties~~ This case is set for status on 7/15/15 at 130 pm.

ENTER:

JUDGE NO.

Atty Name: Tyler [illegible]
Atty for: [illegible]
Address: [illegible]
Phone: [illegible]
Atty: 45776

[original handwritten]

APPENDIX E

**IN THE CIRCUIT COURT OF
COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT - LAW DIVISION**

Case No. 14 L 06985

[Dated June 10, 2015]

M.M., as minor, by AUDREY MEYERS, et al.,
Plaintiffs,

vs.

GLAXOSMITHKLINE, LLC, et al.,
Defendants.

TRANSCRIPT OF PROCEEDINGS had in the above-entitled cause on the 10th day of June, A.D., 2015, at 11:00 o'clock a.m.

BEFORE: HONORABLE LARRY G. AXELROOD

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APPEARANCES:

TOR HOERMAN LAW, LLC
(234 S. Wabash Street, Suite 7th Floor,
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888-508-6752), by:
Mr. Tyler Schneider,
tschneider@torhoermanlaw.com,
- and -
Mr. Kenneth J. Brennan,
kbrennan@torhoermanlaw.com,
appeared on behalf of the Plaintiffs;

DENTONS US, LLP
(233 S. Wacker Drive, Suite 7800,
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312-876-2349), by:
Ms. Tiffany Amlot,
Tiffany.Amlot@dentons.com,
appeared on behalf of the Defendants;

KING & SPALDING
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jbucholtz@kslaw.com,
appeared on behalf of the Defendants;

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APPEARANCES (cont'd.)

JOHNSON & BELL
(33 West Monroe Street, Suite 2700,
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312-984-3422), by:
Mr. Isaac R. Melton,
meltoni@jbltd.com,
appeared on behalf of Walgreen's Corp.

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THE COURT: Good morning.

MR. BRENNAN: Good morning, your Honor, Kenneth Brennan for the plaintiffs.

MR. SCHNEIDER: Tyler Schneider for the plaintiffs.

MS. AMLOT: Good morning, your Honor, Tiffany Amlot for Defendant GlaxoSmithKline.

MR. BUCHOLTZ: Jeffrey Bucholtz also for GlaxoSmithKline.

MR. MELTON: Isaac Melton on behalf of Walgreen's.

THE COURT: Good morning. This is Defendant GlaxoSmithKline's Motion to Dismiss for Lack of Personal Jurisdiction.

Does Movant wish to make an opening statement?

MR. BUCHOLTZ: Yes. Thank you, your Honor.

As your Honor knows, there are eight pairs of plaintiffs, mother and child, in this case. Six of them are from outside of Illinois, from Colorado, Virginia, Oregon, Michigan and Wisconsin. Two of them are from Illinois. This motion only concerns the six non-Illinois plaintiffs. We're not

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challenging personal jurisdiction as to the claims of the Illinois parties.

The non-Illinois claimant's claims don't rise out of anything that GSK did in Illinois. They arise out of GSK's shipment of Paxil into Colorado, Virginia and Florida, et cetera, and GSK's alleged communications or failure to communicate with those plaintiffs' doctors in those states, plaintiffs' ingestion of Paxil in those states.

Plaintiffs' alleged injuries occurred in those states, not in Illinois.

THE COURT: Does the plaintiff assert that the defendant failed to conduct appropriate clinical trials to ascertain enough data to determine the risks for pregnant women taking Paxil and base that on in part of clinical trials that took place in Illinois from '85 to 2003?

MR. BUCHOLTZ: That's the plaintiffs' argument, yes.

THE COURT: Well, let me ask you a question. Did you do clinical trials in Illinois from '85 to 2003?

MR. BUCHOLTZ: Yes, your Honor, but the whole picture is important because we're talking

[p.6]

about specific jurisdiction, not general. No one thinks that GSK is at home and subject to all purpose or general jurisdiction in Illinois.

Specific jurisdiction is called specific jurisdiction because it's supposed to be specific to the plaintiffs' claims.

GSK conducted 361 clinical trials around the word for Paxil. The plaintiffs' are focusing on 17 out of 361. Those 17, they say, are Illinois trials.

That's not really the full picture, your Honor, because those 17 trials were multi-site and multi-center trials with different investigators all around the world conducting these studies.

Of those 17 trials, I want to make sure I give you honor the right number, those 17 trials had sites in Illinois, but they also had sites in 44 other states.

They had 14 total sites in Illinois for the trials that these records are available for, 14 out of the 17, 14 total sites in Illinois, 480 total sites. So a tiny percentage of these clinical trial sites were in Illinois, and the 17 trials the plaintiffs are focusing on is itself a tiny sliver

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of the real universe of clinical trials.

So the idea that the plaintiffs' claims arise out of GSK's clinical trial program, assuming that as a given that's the plaintiffs' theory, that doesn't mean that they arise in any meaningful way out of Illinois, out of GSK's contacts in Illinois.

They could just as easily say that their claims challenging the adequacy of GSK's clinical trials arise out of GSK's contact with Canada, where there were more sites than Illinois or 44 other states, where there were also sites, or 344 other trials that didn't even have a tip of a –

THE COURT: So in a global company, like GlaxoSmithKline, where people are harmed when they select a location, and the issue is demonstrated that they have -- that your multi -- well, your global company has a basis, in fact, to be sued in Illinois, am I try to figure out which is the best selection for the suit, for litigation?

MR. BUCHOLTZ: No, your Honor. This isn't an Forum non Convenience Motion.

Our point is simply the U.S. Supreme Court clarified personal jurisdiction greatly in the last few years, a few years ago in Goodyear, and then

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last year in Daimler.

And after Daimler, it's now clear that there are two types of personal jurisdiction, specific and general.

General is off the table here. Plaintiffs don't rely on it. General would require GSK to be incorporated in Illinois or have its principal place of business in Illinois, or something very close to that. No one alleges that.

THE COURT: Well, would specific jurisdiction exist when defendant purposely directs its activities at the forum state's residence and the cause of action arises

out of it; in other words, by some act the defendant purposely avails itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws?

MR. BUCHOLTZ: Yes, your Honor, but only if the claim really does in a meaningful sense arise directly out of GSK's contacts with Illinois.

That's the formulation that the Illinois Appellate Court has used over and over again, arise directly out of it.

And we submit, your Honor, that although

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it's true that GSK has contacts with Illinois that give rise to some people's claims, those contacts don't in any meaningful direct sense give rise to the out of state plaintiffs' claims here.

There's only the most attenuated relationship between the out of state plaintiffs' claims here and Illinois. There's nothing specific.

Again, that's the reason it's called specific jurisdiction, as it's supposed to be specific to the claims at issue.

The claims at issue, taken as a given, they challenge the adequacy of GSK's clinical trial program are not meaningfully connected with Illinois. They could just as easily be said to arise out of GSK's contacts with 44 other states or Canada.

THE COURT: But then you would say that each of 44 states would not be appropriate place for the same argument.

MR. BUCHOLTZ: Without further facts, that would be our position.

THE COURT: So, in essence, if you're a global company, and you're doing clinical trials everywhere, under your theory, there's no specific

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place other than the home state to be sued.

MR. BUCHOLTZ: Well, the two home states, the plaintiffs' states.

THE COURT: You don't have to answer that.

MR. BUCHOLTZ: No, but I want to make clear of what our position is because there's two places where the plaintiffs can only sue. One is where GSK is at home.

THE COURT: Where is that, North Carolina?

MR. BUCHOLTZ: GSK has two large administrative headquarters. One is in Research Triangle Park, North Carolina. One is in Philadelphia. And I think GSK might be at home in either of those places.

THE COURT: Well, "might be," meaning you're not certain.

MR. BUCHOLTZ: Well, because GSK is an LLC not a corporation, and that it's a little bit less clear at how the at home analysis applies.

THE COURT: Well, they also are incorporated in other nations throughout the world.

MR. BUCHOLTZ: Well, there are other entities that aren't defendants here that might be incorporated in other nations, but the entity that

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the defendant here is a limited liability company, GSK, LLC, that is a citizen of Delaware because its sole member is a corporation incorporated in Delaware.

It has large administrative headquarters, as I said, in Philadelphia and North Carolina. So I'm perfectly willing to assume that there's a general jurisdiction over GSK in North Carolina, in Pennsylvania, and in Delaware because that's where the members incorporated. It would depend on the facts, and I don't know if that's been litigated. But the point is the plaintiffs here aren't from any of those states.

And the second place where plaintiffs could always sue is a state where in a meaningful sense their claim arises out of, which is where they suffered their injury, where they took the drug, where their doctor prescribed it to them, where their doctor was, when the doctor had communications or not with GSK, and where they suffered the injury.

And here there's no reason why these out of state plaintiffs can't sue in Virginia or –

THE COURT: There's two from Illinois. You have Florida, Colorado, Virginia, Michigan and

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Wisconsin; is that correct?

MR. BUCHOLTZ: That's right.

THE COURT: And none of those are Pennsylvania or North Carolina?

MR. BUCHOLTZ: Right, exactly, which is why I was trying to say it really hasn't been briefed here.

I'm willing to assume for present purposes that GSK would be subject to general jurisdiction in all three of those places. That hasn't been litigated, but the point is none of the plaintiffs are from those states.

But there's no reason why they can't sue in their home state, and there's no reason why, if they don't like their home state for some reason, they can't sue where GSK is at home.

There's no injustice in saying that they can't sue here because the courts are perfectly open to them in their own states. The courts are perfectly open to them where GSK is subject to general jurisdiction. And there's no reason why their claims need to be joined in this case with the claims of two Illinois plaintiffs.

All we're asking is the Court to do the

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same thing that Judge Dooling did last year.

THE COURT: Well, Judge Dooling ruled in Plavix the claims -- she found there were no purposeful contacts.

If I find there's purposeful contacts in Illinois, then that Plavix case is distinguished, right?

MR. BUCHOLTZ: Right. The plaintiffs in the Plavix case didn't argue what the plaintiffs here are arguing about, clinical trials in Illinois, so to that extent, yes the case is distinguishable.

THE COURT: So if I find those clinical trials are purposeful contacts with Illinois, then Judge Dooling, her ruling would be distinguished from what I have to deal with here.

MR. BUCHOLTZ: But your Honor would also have to find not just that the clinical trials to the extent they occurred in Illinois represent purposeful contact with Illinois, your Honor would also have to find that out of state plaintiffs' claims here arise directly out of those clinical trials in Illinois. And that's the argument –

THE COURT: Well, no. Wouldn't that be an issue for trial, to determine whether there's a

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nexus between the clinical trials and the injury?

Are you telling me that I have to come down and rule that absolutely the failure to adequately evaluate the information or the lack of information from the clinical trials directly led to this injury, or isn't that what the ultimate trier of fact has to determine?

MR. BUCHOLTZ: We're not asking your Honor to decide at this point whether GSK's clinical trial program was adequate. We're not asking your Honor to decide whether the 17 trials the plaintiffs focus on were

adequate. That's not before your Honor. I agree with that.

What is before your Honor, what the Court is required to decide for personal jurisdiction purposes is whether the plaintiffs' claims arise directly out of those trials. And the Court can't just take the plaintiffs' word for it. It's not a pleading standard. It's a legal standard of whether the claims arise directly out of GSK's contacts with Illinois.

And the Illinois Appellate Court has emphasized the directly part of arise directly out of in the cases we cited in our papers, like,

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(phonetic) Wiggen and Sabados and several other cases.

And I think here if the plaintiffs' theory of specific jurisdiction is right that because there were a tiny fraction of clinical trials that had a fraction of their site in Illinois, with the total, I think it ends up being 42 patients took Paxil in clinical trials in Illinois out of a total of almost 4,000 patients around the country just in the 17 trials the defendants are talking about, which already is a tiny fraction of the 361 trials that form the clinical trial program.

The plaintiffs' theory of specific jurisdiction would mean that there's specific jurisdiction in any place where there was a single site in GSK's clinical trial program, which means in every state almost and as well as in other countries around the world, and my point is simply, your Honor, that I think there's something wrong with the theory of specific jurisdiction

that is so entirely unspecific, and that in order to give meaning –

THE COURT: Well, if, in fact, your client had purposeful contacts in Illinois, and if, in fact, their pleadings are that their clinical trials

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were flawed such that those flaws led to the injuries for their clients, you wouldn't say that that is sufficient?

You want that in order to find specific jurisdiction I have to go to the next level and say, what, that I have to accept that there were flaws in the clinical trial that led to the injuries in order for there to be specific jurisdiction?

Do I have to make that finding, or do I have to merely find that there were purposeful contacts in Illinois sufficient that based on their claim they have the right to litigate here?

MR. BUCHOLTZ: Your Honor, again, we're not asking the Court to decide the adequacy of any of the clinical trials, the parts that occurred in Illinois or the parts that occurred elsewhere.

Our point is simply that the merits of the case, the adequacy of the clinical trials, or any other merits or issues plaintiffs want to raise are not before the Court.

THE COURT: Well, wait. That's the point I'm trying to make to you, is that they have a claim, and their claim is that because of the clinical trials that took place in Illinois, our

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clients were hurt, and that those clinical trials are sufficient to demonstrate that there was a purposeful contact in Illinois from your client, and that you seem to be saying to me that the context in Illinois, even though they're purposeful contacts, that they're de minimus because of the numbers in comparison to other sites, and locations and other studies, right?

MR. BUCHOLTZ: That's right.

THE COURT: And so is that the standard that I have, is what's the best, or am I trying to determine if there's a better location for this litigation, or whether or not this litigation is able to go forward based on the standard that there was purposeful contacts in Illinois from Glaxco?

MR. BUCHOLTZ: The standard that your Honor, I think, is supposed to apply, we'll see what the plaintiffs say, but it's in the papers, I don't think there's disagreement about this, is whether the out of state plaintiffs' claims here arise directly out of the in-state contacts that they've identified, the clinical trials that occurred in very small part in Illinois.

THE COURT: Hang on a second.

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So they've asserted that they've been harmed, that your clients harmed them, and that the reason for the injury was the failure through clinical trials in Illinois and elsewhere for you to discover that there was this nexus between Paxil and these injuries.

MR. BUCHOLTZ: They've asserted that, yes.

THE COURT: So you're clear on what their theory is?

MR. BUCHOLTZ: Well, yes and no, your Honor.

THE COURT: I'm not asking you to give any credence to it, but you understand what their --

MR. BUCHOLTZ: Yes and no. The no part is because I have a hard time believing that the plaintiffs are really going to say that their case is just about the Illinois clinical trial.

THE COURT: Well, does it have to be just about?

MR. BUCHOLTZ: It has to be meaningful about the Illinois trials. It can't just be about the clinical trial program in an undifferentiated way because then it's not specific to Illinois.

It doesn't have to be only about Illinois.

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GSK doesn't have to conduct its clinical trials only in Illinois for specific jurisdiction to be proper, but there has to be something that distinguishes Illinois from every other state.

THE COURT: Did you say 361 sites?

MR. BUCHOLTZ: 361 trials with a total of thousands of clinical sites.

THE COURT: So 361 trials. What's the magic number? At what point -- what's the number of those that have to be conducted in Illinois in order to have specific jurisdiction?

MR. BUCHOLTZ: I'm not sure what the magic number is, but it has to be more than 2 percent, which is the number we're talking about here.

THE COURT: Why?

MR. BUCHOLTZ: Because if it's 2 percent and it's not specific. At 2 percent, then, there's 98 percent that occurred somewhere else, and there could equally be jurisdiction, under the same theory, in 44 other states.

THE COURT: But, again, is that what I'm looking for, is trying to figure out where the best location for this litigation is, or whether or not there's a significant nexus to Illinois?

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I'm not trying to give you a hard time. I'm trying to understand, because what you're telling me is throw them out of Illinois, the six, you're not telling me that the two Illinois residents –

MR. BUCHOLTZ: That's right.

THE COURT: Just the other six would join in this litigation.

MR. BUCHOLTZ: That's right.

THE COURT: You're telling me throw them out and have them go someplace else, and to do that, there's a number of things that bother me about that that I've already expressed to you. But there is no magic number on the percentages. Go ahead.

MR. BUCHOLTZ: I agree with you that there's no magic number, your Honor, and I think the specific theory that plaintiffs have come with about the clinical

trials out of site in Illinois that distinguish this from the Plavix case is a theory that I don't know that a lot of other plaintiffs have tried. So there's not a lot of case law about what the magic number is.

THE COURT: But there probably will be after I rule and somebody takes me up.

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MR. BUCHOLTZ: Maybe, but my only point is without being able to say exactly what the magic number is, it can't be as low as 2 percent.

THE COURT: Why?

MR. BUCHOLTZ: Because then it's non-specific.

THE COURT: Then what's the number, 9 percent?

MR. BUCHOLTZ: It would have to be more than 9 percent. It would have to be –

THE COURT: 15 percent?

MR. BUCHOLTZ: Maybe. I don't know. I think it would have to be higher.

THE COURT: 30 percent? Give me a number.

MR. BUCHOLTZ: 30 percent probably sounds about right.

THE COURT: Why? Seriously, why 30 percent?

You're telling me that you're okay at 30 percent. Why 30 percent? Why not 51 percent? Why not 50 plus some percentage?

MR. BUCHOLTZ: I think if it was 50 plus percent, then I think we would have to agree that there was a meaningful nexus between the clinical

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trials, 51 percent of which occurred in the foreign state, and the claim targeting those trials where there's a tiny fraction.

THE COURT: You can't give me a number, but you can tell me 2 percent isn't enough, 30 percent might be enough, and 50 percent or more would definitely be enough, right?

MR. BUCHOLTZ: There's no case law that I'm aware of about the specific question that would allow me to give you a precise number, your Honor.

My point is simply we have to remember this is specific jurisdiction. It's not general jurisdiction.

There's no third category where you have a really attenuated nexus between the in-state contacts and the claim. That's not good enough for specific jurisdiction. But based on other factors, it's just sort of fair overall to make the defendant defend in the state. There is no such third category.

THE COURT: Is your home office Chicago?

MR. BUCHOLTZ: Mine? No, it's Washington, D.C.

THE COURT: So regardless of whether it's

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Illinois, br Pennsylvania, or North Carolina, you're traveling, right?

MR. BUCHOLTZ: Right.

THE COURT: And so wherever this is, it's going to be inconvenient for somebody, right?

MR. BUCHOLTZ: Again, this isn't a forum non motion. We may get to that, your Honor.

THE COURT: I'm aware of that. I understand that.

But my point to you is that you're a global company with contacts. Is there any states in the United States that you don't have contact, that you're not selling your product, that you don't have doctors who are prescribing your medications?

MR. BUCHOLTZ: I doubt that there's any state in the United States where GSK has no contacts.

But, your Honor, that doesn't distinguish this from Goodyear and Daimler, where the Supreme Court held that Daimler had contacts with every state through its subsidiaries, and California was, as you would expect, one of the larger states for sales and for contacts. But the percentage there was, I think, 2.5 percent of nationwide sales were

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in California, and the Supreme Court said that doesn't mean that you can sue that company in California for things that aren't connected to California.

Our point simply here is the same, that there's no meaningful connection, and the legal standard your Honor is supposed to decide at this point is whether the claims arise directly out of, which is there's a meaningful connection, not an attenuated one.

THE COURT: How do I make a determination that it arises directly, if, in fact, they're correct that the failure to adequately interpret the data or adequately collect the data in the clinical programs in Illinois directly led to this? How would I make that determination? Do I have to accept or reject that now without any evidence?

MR. BUCHOLTZ: Your Honor doesn't have to reject that as a factual matter in that sense, but what your Honor should do -- even if it's true that to a tiny extent the clinical trial sites in Illinois contributed to the overall clinical trial program, and their claims arise out of the overall clinical trial program, that even if they turn out

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to be right, that the clinical trial program was not adequate, which, of course, we disagree with, but putting that aside, since that's a merits question, that the connection is just too limited between the 17 trials out of 361, that even had a single site in Illinois, and even those 17 trials were not in any meaningful sense Illinois trials. They had sites in three, four other states, as well.

So our point is simply that connection as a matter of law is insufficient for the arising directly out of standard that this Court is supposed to apply under appellate precedent.

Again, I don't think the parties disagree that that's the standard. That's the standard the plaintiffs cite in their papers, as well.

And the way that you can tell that that standard requires dismissal of the out of state plaintiffs' claims here as a matter of specific jurisdiction is as if it were otherwise, the plaintiffs would be able to obtain specific jurisdiction over GSK in essentially every state in the union, which means it can't be meaningfully specific.

There's no injustice in this because as in

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the Plavix case, the plaintiffs have the ability to sue GSK where plaintiffs live, where their claims much more meaningfully arose out of GSK's contacts with those states, or wherever GSK is at home if the plaintiffs want to sue there instead.

So there's no injustice. There's no reason for this Court to strain to keep out of state plaintiffs' claims in this court.

THE COURT: How was your client prejudiced or harmed by it staying here?

MR. BUCHOLTZ: In the Plavix case, your Honor, there were 500 plaintiffs. Here there are eight, but the principle is the same.

If plaintiffs' lawyers are allowed to take a large number of out of state cases that don't have a meaningful connection to the forum that they want to be in, find a couple forum cases, join them together, even though they don't need to be joined, it's not as if the out of state plaintiffs or the in-state plaintiffs here are related to each other, or something, then it means GSK is subject to suit wherever plaintiffs' lawyers choose, essentially, anywhere in the country, which is

contrary to what the Supreme Court has been trying to emphasize in

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the last five years about jurisdiction in Goodyear.

And so here it's a small number of plaintiffs 6 versus 2, but the same principle applied in Plavix, where it was 400-something out of the state plaintiffs, and I think 16 Illinois plaintiffs.

And if the Court here upholds the plaintiffs' theory, then the plaintiffs could join 400-something more out of state plaintiffs and make us defend all of those cases in this court.

Those plaintiffs' claims are not going to turn out to be meaningfully connected to Illinois. They're doctors aren't in Illinois. They're not in Illinois. Witnesses who could testify about their injuries or their medical history are not in Illinois. They're wherever they live. They're around the country.

And so there is significant issues about fairness to GSK in defending these cases where compulsory process to bring those witness here is not likely to be available, and where those cases don't belong in this court.

THE COURT: You don't think that you'll be able to compel witnesses to testify in Cook County?

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MR. BUCHOLTZ: If the witness is somewhere else in the country. I mean, the Court doesn't have

subpoena authority to require a witness to come here from Virginia.

THE COURT: We have out of state witnesses every day.

What else do you want to tell me?

MR. BUCHOLTZ: I think we've probably covered it, your Honor.

THE COURT: You've been on the hot seat long enough.

MR. BRENNAN: I will try to focus on what you were focusing on, your Honor, as we go forward.

Russell v. SFNA is the leading Supreme Court of Illinois case on the issue of specific jurisdiction. The Court has described the standard as a lenient and flexible one, and quoting a Sixth Circuit opinion explained that "If the defendant's contacts with the foreign states are related to the operative facts of the controversy, then an action will be deemed to have arisen from these contacts."

THE COURT: So their argument is that you're stretching reality to get jurisdiction here because you're relying on defective clinical studies

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that were conducted in Illinois, although they were a small portion of all worldwide, and that is significant only in trying to maintain jurisdiction. Do you want to address that?

MR. BRENNAN: When you say, "that's significant only in trying to maintain jurisdiction" --

THE COURT: Here.

MR. BRENNAN: Well –

THE COURT.: You don't understand my question?

MR. BRENNAN: I think what you're talking about now is whether or not our allegations that the clinical trials were inadequate are –

THE COURT: He's saying that you're using that theory only to retain jurisdiction. Is that correct? That's one of the theories you're using, right?

MR. BUCHOLTZ: Right.

THE COURT: So do you want to address that?

MR. BRENNAN: Sure. The answer is that's absolutely incorrect.

We've cited in our complaint these

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allegations, explaining that the inadequate clinical trials which lead to the warnings that go on the drug labels occur in large measure in Illinois.

These are not uncommon allegations that you'll see in pharmaceutical suits that there was inadequate product testing and inadequate clinical trials that gave rise to the plaintiffs' injuries.

So to the extent that the argument is we just threw these allegations in here solely for the purpose of obtaining personal jurisdiction over defendants, that's absolutely not the case.

THE COURT: Well, I think that the bigger point is why are the out of the state plaintiffs here instead of their home state or instead of the home state of Glaxco?

MR. BRENNAN: Sure. On this motion I think the question is whether or not they may be here, whether or not they can be here, whether or not jurisdiction is properly here, as opposed to I think the question that you just asked goes more to a forum non convenience question.

THE COURT: I'm sorry. Please don't interpret that way.

His argument is that there's not specific

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jurisdiction for those out of state plaintiffs for a number of reasons that he articulated during his argument, and the question to you is why are those six out of state witnesses, why are they here?

MR. BRENNAN: They are here because their claims arise out of and relate to these clinical trials that occurred in Illinois.

THE COURT: Why specific to the clinical trials in Illinois, as opposed to any of the other clinical trials somewhere else?

Do you know whether or not the flaw was in the trials in Illinois?

MR. BRENNAN: What I know is that from the affidavit that the defendant provided is that the data from Illinois was aggregated with data from these other sites to reach statistical significance.

THE COURT: So under your theory in anywhere that there was a clinical trial, there would be specific jurisdiction under Illinois standards.

MR. BRENNAN: No. That's sort of the opposite question of how low the threshold is, as opposed to how high the threshold. is.

I don't know the nature of the clinical

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trials that occurred in Colorado or Texas or Tennessee, whether there was one, or whether there was 100.

What I do know is that there were 14 to 17 in Illinois. There were 17 contracts entered into by GSK with Illinois physicians to conduct these clinical trials.

THE COURT: Well, Glaxco collects the data from all of the clinical trials worldwide, and they put them together, and they analyze them.

MR. BRENNAN: True.

THE COURT: So you don't know whether the defect is from Illinois or from someplace else or whatever.

Your theory is that there was a defect in the data, which led to the injuries, and the data was collected from clinical trials, some of which were in Illinois, right?

MR. BRENNAN: True.

THE COURT: So we don't know if 97 percent of the clinical trial data was perfect and would have prevented these injuries in the 2 percent that created

the issue was collected from Illinois, or under that same theory that Illinois' 2 percent was

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flawless, and the bads data that led to the injury was collected elsewhere, right?

MR. BRENNAN: Yes. And I think that gets back to the first question you asked me, which is are our allegations in the complaint plausible, is it reasonable for us to make these allegations?

THE COURT: I don't think I said -- I hope I didn't say anything that was asking that question, because that's not the issue in front of me.

MR. BRENNAN: Well, I think that the answer to the question would be to set this for trial, as you intimated earlier in the argument.

We don't have to prove on this motion that the clinical trials were defective, whether the Illinois clinical trials were defective.

What we have to do is make a prima facie case of personal jurisdiction. And the standard for personal jurisdiction has repeatedly been noted here.

Once we make that prima facie case, it is on the burden on the plaintiffs to come back with undisputed facts to show jurisdiction is not proper. So at this juncture, our allegations are sufficient as to undisputed facts.

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THE COURT: So I asked him, and from what he answered, I think somewhere between 30 and 50

percent is where he came from, 2 percent is okay for you in terms of the ties to Illinois?

MR. BRENNAN: Yes, absolutely. 2 percent is okay. And I think it's okay under the precedent of Russell v. SFNA.

THE COURT: What about 1/10 of 1 percent?

MR. BRENNAN: As you were questioning counsel, I was anticipating this question.

I don't think if there is a threshold below which one can say that the clinical trials did not give rise to or relate to the cause of action. And I don't know if that is properly characterized as the percentage or properly characterized as raw numbers.

What I do know is that the standard set by the Illinois Supreme Court is extremely lenient.

And, in fact, the dissent -- you read our briefs in great detail, your Honor, but the dissent in the Russell case was correctly explained that under the Russell holding a foreign defendant can now be held to a court in Illinois for even the most fleeting and inconsequential business contact with

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this state. Indeed, defendant is now subject to Illinois jurisdiction even though it never actually sold a single item to an Illinois consumer.

In that case the arising out of and relating to standard was met.

THE COURT: So it's just interesting to me that you take a case that you're citing for your side, and rather

than citing the holding, which is what you're relying on, you're quoting the dissent.

MR. BRENNAN: I'm quoting the dissent because the language is so stunning.

THE COURT: It is stunning language, isn't it? I just wanted to point out the irony that you're citing this case, but then the language you're choosing to use is dissent where they disagreed and found that the holding was potentially dangerous. "Dangerous" might be too strong of a word.

MR. BRENNAN: Perhaps. And I appreciate the irony, and I did read, and I can read some more from the majority opinion.

THE COURT: I didn't mean you need to continue quoting the opinion.

MR. BRENNAN: The language is striking.

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And I think it's an accurate description of what Illinois law is today and has been since 2013.

THE COURT: Anything else you would like to say?

MR. BRENNAN: No, your Honor.

THE COURT: You're the movant. You get rebuttal.

MR. BUCHOLTZ: Thank you, your Honor. I will be brief in rebuttal.

First, I think your question about 1/10 of 1 percent is actually on point because we have to remember what the universe here is, 361 clinical trials.

They haven't alleged anything special about the trials that had sites in Illinois. We won't call them Illinois trials because even that's misleading.

There's nothing special about the 17 trials they focused on, it's just that they happened to have had one site in Illinois along with lots of sites elsewhere. So only 5 percent of the 361 total trials had any connection to Illinois. 95 percent had not. So we are already talking about 5 percent.

THE COURT: Let me tell you quickly the

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problem with coming in with percentages is that when I asked each side to give me a percentage, you were not really able to do it.

And so when I look at it, I'm faced with having to determine whether or not Glaxco had purposeful contacts with Illinois.

Their pleading is that there were clinical trials held in Illinois that went towards the information that was used by your client, which either were inadequate or misinterpreted, or however you want to characterize it, but these clinical trials, when aggregated, was the data, the information, that Glaxco used to put this product in the marketplace, which then caused injuries because Glaxco didn't foresee or understand or catch, or however you want to characterize it, something from the clinical trials. Either they failed to adequately test, or they failed to adequately interpret the data, however you want to characterize it.

And so the problem that I have, quite honestly, is there's no percentages. There's no bright line for me to do it, right?

MR. BUCHOLTZ: There's no bright line set

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forth in existing case law, so, your Honor, I would submit, has to choose the approach that makes sense.

My friend said in answer to your question a moment ago that jurisdiction was proper here because the clinical trials that they challenge the adequacy of occurred "in large measure," that was his word, "in large measure" in Illinois.

THE COURT: It's not large measure.

MR. BUCHOLTZ: Like any standard.

THE COURT: A fractional standard. A fractional amount, right?

MR. BUCHOLTZ: Like any standard, it can't be described as in large measure. We're talking about 5 percent of the trials --

THE COURT: So let's put that aside.

You're the movant, so you're catching more heat than they are because you're asking me to do something.

In order for me to make this determination, I have to determine whether or not there's specific jurisdiction, and to do that I have to determine whether or not your company had purposeful contacts with

Illinois, right? And I can't do that by a percentage of the clinical trials

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because both of you have failed to be able to give me a mathematical answer to get out from under making a decision. So we go to the next level, right?

And you're right, this is not a forum motion, because a forum motion, if you do not prevail here, you have the opportunity to a forum motion. You have summary judgment.

You have a number of other dispositive motions between today and when we get to trial if you do not prevail here, right?

MR. BUCHOLTZ: Right.

THE COURT: So my question is at this juncture, the standard that -- and he cited the dissent, which to me crystalizes the core issue here at this particular pleading, and that is whether there were purposeful contacts with Illinois in order for at this juncture for them to proceed in Illinois.

MR. BUCHOLTZ: Your Honor, with respect, that's only half of the court issue. No one disputes that GSK had-purposeful contacts with Illinois.

The question here is do the plaintiffs'

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claims meaningfully, really, arise directly out of those Illinois contacts?

THE COURT: And how do I determine that based on these pleadings?

MR. BUCHOLTZ: Because it's undisputed that the right math is 3 percent of 5 percent. 5 percent of the clinical trials had some connection to Illinois, and of those only 3 percent of the sites were in Illinois.

So 3 percent of 5 percent, that's .015 percent, .0015 percent? Whatever the standard is, whatever the threshold is, it can't be lower than 1 percent, It can't be .0 something. Then that just takes all meaning out of specific jurisdiction.

It takes all meaning out of the arise directly out of standard because it would mean that they could just as easily say their claims arise directly out of contacts with some 44 other states, where the same facts would be true, or maybe even there were more, a relatively higher percentage of clinical trial sites in other states.

THE COURT: What if they had 1/10 of 1 percent, but it was that data that skewed the entire interpretation of the tests? How do I know?

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MR. BUCHOLTZ: Well, I don't think that could ever be true. Statistically, we're talking about .1 percent of the universe of data at large, but here they haven't alleged that there was anything special about the 17 trials that had a toe in Illinois. They just singled those out because they had at least one site.

THE COURT: I think that the point I'm trying to make to you, and none of us have a specific number other than he believes that whatever that number is,

it's way below what they have here and; you say that it has to be way above what they have here, which is nice, except there's no definitive number. And so I have to look at it in terms of a pleading, and I have to make a determination based on that.

MR. BUCHOLTZ: Let me try to answer your Honor's question this way.

Taking a step back from the numbers, the plaintiffs' theory here is that Paxil caused birth defects. And to the extent they're challenging the adequacy of GSK's clinical trial program, their allegation is that GSK should have studied the risks that Paxil would cause birth defects, failed to do

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so, or failed to do so adequately.

As we've explained in our papers, under the Food and Drug Administration guidelines, you're not supposed to give an experimental drug in clinical trials to pregnant women or women who might become pregnant, so their whole notion that we should have done the clinical trials differently to study birth defect risks is wrong to begin with.

Let's put that aside for a moment.

THE COURT: Are there instructions on Paxil, instructions to doctors that they can't prescribe it to women who are pregnant or may become pregnant?

MR. BUCHOLTZ: As of today, I don't have the answer to that, your Honor. We're talking about trials that occurred a long time ago, when Paxil wasn't

approved by the FDA yet or when it was being considered for additional indications.

THE COURT: How about today? If a woman goes to a doctor, and Paxil is for depression, among other things, and the doctor says, I'm going to put you on Paxil, does that doctor have to inquire of the patient are you pregnant or are you thinking of becoming pregnant, because this is contraindicated?

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MS. AMLOT: Your Honor, I do know that as of today, when you're pregnant, and you go into the doctor and ask for medication, they label them by letters, A, B, C, B, E, depending on -- A are the only class of medications that are specifically proven to be okay for pregnant women.

And I know that there are hardly any medications on that list. And I feel very comfortable stating before the Court that Paxil is not on that list, to the extent that helps at all.

THE COURT: I appreciate what you're telling me.

MS. AMLOT: I'm just saying factually.

THE COURT: I imagine beyond aspirin there's not much on that list.

MS. AMLOT: Baby aspirin, to my understanding, is not on that list.

THE COURT: The question that I asked was if a doctor is meeting with a patient, and the doctor is going to prescribe Paxil, does that doctor inquire of the patient whether or not she is pregnant or will be

pregnant, and then advise against or do a different medication?

MS. AMLOT: We have no idea what these

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plaintiffs discussed with their doctors, and I don't predispose to.

THE COURT: That wasn't the question I asked here.

The question I asked was let's assume I'm a 30-year old woman, and I suffer from depression. I go see my doctor, and I say, I'm stuffing from depression. Does that doctor, does she say to me, I can give you Paxil, unless you're pregnant or going to become pregnant?

MS. AMLOT: I'm not going to opine on any of that. I'm just suggesting to your Honor –

THE COURT: Because you know what the next question is going to be.

I appreciate your contribution. Thank you.

MR. BUCHOLTZ: First of all, GSK doesn't sell Paxil, so I don't know, and since I represent GSK, what the current label for generic Paxil other companies sell says about that. I can get back to your Honor with an answer. I don't know offhand.

The point I was trying to make, and I appreciate your Honor's indulgence with the time, is simply that let's pretend for a minute that GSK did

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do clinical trials about birth defect risks in pregnant women. That's not true, because the FDA tells GSK that GSK is not supposed to do that, and GSK didn't do that.

But let's say GSK did. Out of 361 clinical trials, there were lots of trials for depression, lots of trials for Obsessive Compulsive Disorder, lots of trials for various other indications, and small subset, let's say, 17 involved pregnant woman, specifically the study of the risk of birth defects. And then the plaintiffs' claims could be meaningfully said to arise out of those 17 trials.

The plaintiffs don't allege that, and it's not true. There were no trials specifically to study birth defect risk, and so the whole notion of plaintiffs' claims about birth defect causation arise out of the inadequacy of the clinical trial program is attenuated to begin with because GSK didn't and couldn't properly study birth defect risk in clinical trials because you're not supposed to give pregnant women experimental drugs in clinical trials.

THE COURT: I think that we're getting

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pretty far afield here, and it is my fault because I asked probably one too many questions.

But getting back to where we're at, the issue of purposeful contacts, and I asked each of you, and you all can't quantify it to a percentage for me, and I wasn't trying to be difficult, but I wanted to see what you

would say, because it's the same issue in my mind, as I don't see it maybe being to do it based on a mathematical equation. I don't think it's appropriate.

Do you wish to say anything else? This is your rebuttal argument. You're the movant.

MR. BUCHOLTZ: If your Honor has questions about Russell, I'd be happy to address that. I didn't address it yet. I don't want to take up a lot of your time.

THE COURT: You can have all the time in the world. My job is to make sure the litigants get enough time. I can't give everything, the result they want.

All I can give them is the opportunity to be heard. If I make a decision, right or wrong, that gives all you the opportunity to take it to the next level, which in a case like this will probably

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be dancing around the appellate and above for a time to come. And I can only give you the strongest record possible.

So I'm not going to cut you off at any point. I want to make sure both sides have an opportunity to vet their positions.

MR. BUCHOLTZ: Your Honor, I will take 30 seconds on Russell.

The main issue in Russell was not what arising directly out of means or requires. Russell didn't -- neither the majority nor the dissent didn't really analyze that issue very much.

They didn't cite the several Illinois court of appeals decisions that focus on and emphasize, including in italics, the original standard as arising directly out of.

Russell was about something else. It was about the threshold of contacts that is sufficient, that is necessary for a defendant to be subject to specific jurisdiction even where the claim arises directly out of those contacts.

It was a stream of commerce theory case where the defendant sold product that ended up causing injury. The defendant sold it through a

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distributer, not directly into Illinois.

And here the analogy would be if GSK never sold Paxil directly in Illinois, GSK only sold through a distributor, and only one bottle of Paxil ever made its way into Illinois, but it caused an injury in Illinois.

Would that attenuated, minor, tiny amount of contacts with Illinois be sufficient for a claim that arose directly out of those contacts? And that was really the issue in Russell.

That's not the issue here. Here I'm not disputing that GSK had sufficient contacts to meet that threshold for claims that arise directly out it, like the two Illinois plaintiffs' claims here.

The issue is different. Russell, I don't think, is very on point.

THE COURT: Do you have any case at all that you feel is directly on point with the issue before me now?

MR. BUCHOLTZ: Well --

THE COURT: You don't have that?

MR. BUCHOLTZ: The answer is important, your Honor.

This is the first case where the

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plaintiffs' have come up with this creative theory that it's about clinical trials and pointed to clinical trial sites in one state.

THE COURT: But it's bigger than that, though, isn't it?

I mean, the test is what is a purposeful contact, and in the context of the parties that want it litigated in Illinois, how do I quantify to determine whether or not specific jurisdiction is here?

That's the bigger issue, not that they came up with a creative idea, because what happens if it goes up and case law is made, it will give us a better understanding and better standard as to how we determine for, plain English, when enough is enough?

MR. BUCHOLTZ: Your Honor, there are lots of cases that are on point factually, but not on point in the sense that, as far as I know, the plaintiffs in this case that didn't make this particular argument.

Sabados is the Illinois Appellate decision. The defendant was Planned Parenthood. The plaintiff was from Illinois but went to a

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Planned Parenthood in, I believe, Wisconsin, and was injured and sued the Planned Parenthood of Wisconsin in Illinois.

Even though the plaintiff's injury occurred in Illinois, and even though that the Planned Parenthood in Wisconsin was advertised in Illinois and did a lot of business with Illinois residents, because it was close to the border, the Appellate Court said her claim, in italics, her claim didn't arise out of the defendant's contacts with Illinois because she went to Wisconsin. Planned Parenthood didn't go into Illinois and bring her from Illinois.

And so here the same thing is true, that the out of state plaintiffs' claims, they suffered their injuries in other states, their doctors prescribed them Paxil in other states, they ingested Paxil in other states, under any traditional analysis, including under Sabados, which is precedent here, their claims arise out of the contacts that GSK had with their states, with the doctors in their states, with the distributors who distributed the drug in those states. And that precedent applies here.

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And Judge Dooling's decision in the Plavix case, I understand your Honor said is distinguishable because the plaintiffs didn't make the argument about clinical trials, but it's directly on point in the sense of defects.

THE COURT: What if it's true, what if the clinical trial protocol in Illinois led to bad information or misinterpretation, which led to the injuries?

MR. BUCHOLTZ: As I was trying to say a couple minutes ago , your Honor, if the plaintiffs alleged that there was something special about the Illinois trials, the Illinois trials are a tiny universe of the overall universe of clinical trials.

THE COURT: Let me ask you the question two ways, then.

One, if it's part of the aggregate and there was a flaw in the testing, so you're saying that the flaw in the testing means that it doesn't matter that Illinois was flawed, as well?

MR. BUCHOLTZ: If it's part of the aggregate, like we're assuming to be true here, where the .0015 percent of the data that came from Illinois was combined with the data from the

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thousands of sites in the 361 total trials, then, no. Our position is that's not specific. That's not arising directly out of.

If there was something special about the Illinois trials in quality, even if in quantity they were a low percentage, then it would be a harder question, but the plaintiffs haven't alleged there's anything special about the Illinois trials.

THE COURT: I must not have been clear.

What if the clinical trials were, all of them, that there was a flaw in the protocol, or whatever, in the collection, in the interpretation, whatever it is, so that all the clinical trials were defective?

MR. BUCHOLTZ: All 361?

THE COURT: Every one, that there was a flaw in the protocol, there's a flaw in the interpretation, however you want to do it. The data collection was bad.

I mean, I have a problem with trying to come up with a way to quantify and give weight to exclude Illinois, even if it's a fractional. I have a problem with that, because when I ask each of you, you demonstrate to me that you have the same

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problem.

MR. BUCHOLTZ: I don't think I have the problem. I'm happy to adopt in large measure that opposing counsel suggested. I'm happy to assume that the answer could be something less than 50 percent plus 1. Here we're talking about .00 something.

And so with respect to hard questions about exactly where to draw the line, I don't think are really present here because here we're talking about such a tiny amount that the. only way to hold that there's specific jurisdiction because of a challenge to those 14 -- those 17 trials that had 3 percent of their site out of an overall trial program of 95 percent having no connection to Illinois would be to say there's specific jurisdiction for an out of state plaintiff suffering injury out of state, doctor out of the state, et cetera, challenging the adequacy of a clinical trial program in any state where there was a single clinical trial site.

And that, I submit, is just inconsistent with the very notion of specific jurisdiction.

It drains all meaning out of the arising

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directly out of standard. It resurrects the result that the Supreme Court rejected in Daimler and in Goodyear. The Supreme Court rejected that result under general jurisdiction. And the courts have said if you're a big company like GSK, and you do an absolute term, a substantial amount of business in every state, you can be sued for anything anywhere.

The Supreme Court said, No, you can only be sued for anything where you're at home. And if you're sued somewhere else other than when you're at home, the claim has to arise directly out of your contacts with that other state. That's the standard that exists in precedent and compels here.

Although the cases don't involve this kind of an argument about percentages of clinical trial sites, and so I can't point your Honor to a precedent specifically about the right level that set the percentage threshold, I don't think it would be consistent with existing precedent to set that threshold at any positive number above zero.

Here we're talking about .00 something. And wherever the threshold may be, it can't be .00 something because that drains all meaning out of specific jurisdiction.

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And the last thing I'll say is just, again, there's no good reason why these plaintiffs need to be here.

THE COURT: Well, let me ask you that.

Isn't that more of a forum non motion than a Motion to Dismiss?

MR. BUCHOLTZ: Yes. But all I'm saying is –

THE COURT: I mean, isn't there a significant distinction between personal jurisdiction and forum non?

MR. BUCHOLTZ: There is, your Honor. I'm simply making the point that the legal standard, as it applies for personal jurisdiction, in some cases if you apply it strictly, we would say correctly maybe it leads to an injustice.

Maybe the plaintiff doesn't really have a good place to sue, maybe that it's attempting to stretch the standard and let there be specific jurisdiction even when the connection really isn't that specific.

All I'm trying to say is there's no reason to do that here because there's every reason that these out of state plaintiffs can sue in Virginia,

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in Colorado, in Florida, and where their injuries directly arose.

THE COURT: That argument goes more toward a forum non than a Motion to Dismiss, doesn't it?

MR. BUCHOLTZ: I'm sorry. I'm not articulating clearly.

I'm not trying to make a balancing-type argument.

THE COURT: I'm not either. I'm saying that your argument is you're saying you should close the doors of

the courthouse in Illinois to these people because they can go elsewhere.

Well, that entire argument is on a forum non. The forum non is to determine whether or not this is the appropriate jurisdiction.

This is whether or not they can sue, whether or not they have personal jurisdiction to be here.

MR. BUCHOLTZ: And my position is they do not under the existing standard that this Court should apply.

My only additional point I was trying to make is there's no reason to shy away from applying that standard according to its terms in reaching

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that result because it doesn't cause any injustice. These plaintiffs can go sue in their home states.

THE COURT: And I think that the point I'm making to you is that's seem to touch more in terms of a forum non than on a Motion to Dismiss.

MR. BUCHOLTZ: Thank you, your Honor.

THE COURT: I'd like to thank the attorneys for being so well-prepared. I'd like to thank you for everything you filed. It was extraordinary and of the highest standard I've seen and that I see on a daily basis. I appreciate that.

I don't think there is a bright line for me, and I will muddle through it the best that I can.

So specific jurisdiction exists when the defendant purposely directs its activities the foreign state's resident and the cause of action arises out of defendant's contacts with the foreign state. That's Soria v. Chrysler Canada, 211 Ill. App. 2nd.

This requirement can be met only if some act the defendant purposely avails itself and proves conducting activities within the foreign state, just thus invoking the benefits and protections of its

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laws. Hanson v. Denckla, 357 U.S. 235.

In this instance the Court finds that by contracting the principal investigators in Illinois to conduct clinical trials regarding Paxil, the defendant did purposely avail itself to the privilege of conducting activities within Illinois.

The plaintiff asserts that defendant failed to conduct appropriate tests to generate the necessary scientific data regarding the strength of the association between this drug and birth defects. It also says it may have failed to adequately interpret or improperly collect, however you want to term it, and these clinical trials occurred in Illinois from 1985 to 2003.

That substantial contacts the defendant purposely engaged in and directed to Illinois to which the plaintiffs claim relate to or arise from and satisfy both the federal and Illinois due process.

The case that Judge Dooling had, the Plavix case, has been distinguished for reasons that I gave.

And I will note to the parties that while Defendant's Motion to Dismiss for lack of personal

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jurisdiction, respectfully, is denied, I know that there are going to be additional pleadings in this case, and there will be different standards that are appropriate to each of those dispositive motions.

How do you wish to proceed?

MR. BUCHOLTZ: Thank you, your Honor. I think your Honor is aware there is a prior order in this case that provides that we can file a forum non convenience motion, if this motion is denied.

THE COURT: Is that already written, or do you need time?

MR. BUCHOLTZ: No, it's not already written.

We do think this is the kind of issue the court of appeals should get a chance to hear. We will be petitioning the court of appeals.

THE COURT: Absolutely. You put the 403(a) language in the order, and you can take it up. So you need a status date. Are you going to file your forum motion or take this up first?

MR. BUCHOLTZ: It makes more since to take this up first, because if the court of appeals grants the leave to appeal, there wouldn't be a reason to proceed further.

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THE COURT: You will need a status date here. When do you want to come back?

Do you want to have a conversation among yourselves and suggest a date to me, or I do this at the bench?

MS. AMLOT: Well, your Honor, let me just ask a procedural question right now.

Judge Brewer had issued a stay in this matter pending resolution of this matter.

THE COURT: Why? Did the case get transferred from Judge Brewer to me?

MS. AMLOT: It did, yes.

THE COURT: The stay has ended. You're now in front of me.

MS. AMLOT: So that was just my question, your Honor, as we are contemplating an appeal in short order.

THE COURT: I will give you a status. Basically, you will have to file within 30 days, right?

MS. AMLOT: Yes.

THE COURT: So in order to do that, I will give you a status just to make sure that was done.

July 15th. That's a Wednesday, the 15th

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of July at 1:30. You can put in 304(a) language.

MS. AMLOT: Thank you.

MR. BRENNAN: Thank you, your Honor.

MR. BUCHOLTZ: Thank you.

(Off the record at 12:10 p.m.)

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STATE OF ILLINOIS)
) ss.
COUNTY OF COOK)

I, DANIEL M. PRISCU, a Certified Shorthand Reporter within and for the County of Cook, State of Illinois, do hereby certify that heretofore, to-wit, on the 10th day of June, 2015, the above-entitled Report of Proceedings was reported stenographically by me and afterwards reduced to typewriting and the foregoing is a true and correct transcript of the proceedings so given as aforesaid.

Dated: June 15, 2015

/s/ Daniel M. Priscu
Certified Shorthand Reporter
License No.: 084-003982

APPENDIX F

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CASE NO. 2014 L 006985

[Filed July 2, 2014]

MM, A MINOR, BY AUDREY MEYERS, HER MOTHER AND NEXT FRIEND; AH, A MINOR, BY DAWN HINTON, HER MOTHER AND NEXT FRIEND; PM, A MINOR, BY LINDA BUTLER, HIS MOTHER AND NEXT FRIEND; HC, A MINOR, BY AMY CHRISTY, HER MOTHER AND NEXT FRIEND; HH, A MINOR, BY KRISTEN HOZEMPA, HIS MOTHER AND NEXT FRIEND; AK, A MINOR, BY KATHRYN KEADY, HIS MOTHER AND NEXT FRIEND; CS, A MINOR, BY STACEY SCHUTTE, HER MOTHER AND NEXT FRIEND; AND, CE, A MINOR, BY SHANNON EMERY, HIS MOTHER AND NEXT FRIEND,	)
Plaintiffs,	)
v.	)
GLAXOSMITHKLINE LLC, f/k/a SMITHKLINEBEECHAM CORPORATION,	)

d/b/a SMITHKLINEBEECHAM; WOLTERS KLUWER HEALTH, INC.; WOLTERS KLUWER UNITED STATES, INC.; AND WALGREENS CO.,

Defendants.

JURY TRIAL DEMANDED

COMPLAINT

COME NOW Plaintiffs, by and through their attorneys, TorHoerman Law LLC, and complain and allege on personal knowledge as to Plaintiffs' acts and on information and belief as to all other allegations against GlaxoSmithKline LLC f/k/a SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), Wolters Kluwer Health, Inc. ("WKH"), Wolters Kluwer United States Inc., ("WKUS"), and Walgreen Co. ("Walgreens") (collectively, "Defendants"), as follows:

PRELIMINARY STATEMENT

1. This action arises from paroxetine-induced birth defects that each minor Plaintiff developed as a result of having been exposed *in utero* to paroxetine. Paroxetine is associated with a significantly increased risk of birth defects.

2. The design of paroxetine rendered it defective. The lack of adequate warnings accompanying paroxetine rendered it defective. The manner in which the warnings about the risks of paroxetine were communicated to the mother Plaintiffs and their physicians rendered it defective. Defendants failed in their acts and omissions related to paroxetine to use

reasonable care to avoid injuring Plaintiffs. GSK breached implied and express warranties accompanying the sale of paroxetine to each mother Plaintiff. The defective nature of paroxetine and Defendants' negligent conduct and breach of implied and express warranties proximately caused the minor Plaintiffs to develop birth defects.

PARTIES

3. At all times relevant hereto, Plaintiff Audrey Meyers and her child MM have been residents of the state of Illinois and are Illinois citizens. During her pregnancy, Plaintiff Audrey Meyers resided in Illinois and gave birth to her child, MM, in Illinois. Plaintiff Audrey Meyers was prescribed and used branded paroxetine, sold under the brand name Paxil, during her pregnancy with MM. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Audrey Meyers, Plaintiff Audrey Meyers was administered paroxetine for its intended purpose, namely, depression. On September 16, 2001, Plaintiff Audrey Meyer's child, MM, was born with pulmonary atresia, Patent Ductus Arteriosus, large collateral vessel, and Tetralogy of Fallot.

4. At all times relevant hereto, Plaintiff Dawn Hinton and her child AH have been residents of the state of Florida and are Florida citizens. During her pregnancy, Plaintiff Dawn Hinton resided in the state of Florida and gave birth to her child, AH, in the state of Florida. Plaintiff Dawn Hinton was prescribed and used branded paroxetine, sold under the brand name Paxil, during her pregnancy with AH. The paroxetine was defective and unreasonably dangerous when it

entered into the stream of commerce and when ingested by Plaintiff Dawn Hinton. Plaintiff Dawn Hinton was administered paroxetine for its intended purpose, namely, depression. On July 2, 2001, Plaintiff Dawn Hinton's child, AH was born with coarctation of the aorta and bicuspid aortic valve.

5. At all times relevant hereto, Plaintiff Linda Butler and her child PM have been residents Illinois. During her pregnancy, Plaintiff Linda Butler resided in Illinois and gave birth to her child, PM, in Illinois. Plaintiff Linda Butler was prescribed and used branded paroxetine, sold under the brand name Paxil, during her pregnancy with PM. The paroxetine was defective and unreasonable dangerous when it entered into the stream of commerce and when ingested by Plaintiff Linda Butler. Plaintiff Linda Butler was administered paroxetine for its intended purpose, namely, depression. On August 17, 1996, Plaintiff Linda Butler's child, PM, was born with hypospadias.

6. At all times relevant hereto, Plaintiff Amy Christy and her child HC have been residents of the state of Florida. During her pregnancy, Plaintiff Amy Christy resided in the state of Florida, and gave birth to her child, HC, in the state of Florida. Plaintiff Amy Christy was prescribed and used generic paroxetine during her pregnancy with HC. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Amy Christy. Plaintiff Amy Christy was administered paroxetine for its intended purpose, namely, depression. On July 21, 2006, Plaintiff Amy Christy's child, HC, was born with bicuspid aortic valve.

7. At all times relevant hereto, Plaintiff Kristin Hozempa and her child HH, have been residents of the state of Colorado. During her pregnancy, Plaintiff Kristin Hozempa resided in the state of Colordo, and gave birth to her child, HH, in the state of Colorado. Plaintiff Kristin Hozempa was prescribed and used branded paroxetine, sold under the brand name Paxil, and generic paroxetine during her pregnancy with HH. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Kristin Hozempa. Plaintiff Kristin Hozempa was administered paroxetine for its intended purpose, namely, depression. On November 24, 2008, Plaintiff Kristin Hozempa's child, HH, was born with cleft lip and cleft palate.

8. At all times relevant hereto, Plaintiff Kathryn Keady and her child AK have been residents of the state of Virginia. During her pregnancy, Plaintiff Kathryn Keady resided in the state of Virginia, and gave birth to her child, AK, in the state of Virginia. Plaintiff Kathryn Keady was prescribed and used branded paroxetine, sold under the brand name Paxil, during her pregnancy with AK. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Kathryn Keady. Plaintiff Kathryn Keady was administered paroxetine for its intended purposes, namely, depression and anxiety. On December 3, 2003, Plaintiff Kathryn Keady's child, AK, was born with Tetralogy of Fallot.

9. At all times relevant hereto, Plaintiff Stacey Schutte and her child CS have been residents of the state of Wisconsin. During her pregnancy, Plaintiff

Stacey Schutte resided in the state of Wisconsin, and gave birth to her child, CS, in the state of Wisconsin. Plaintiff Stacy Schutte was prescribed and used branded paroxetine, sold under the brand name Paxil, during her pregnancy with CS. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Stacy Schutte. Plaintiff Stacey Schutte was administered paroxetine for its intended purpose, namely, depression. On June 6, 1999, Plaintiff Stacy Schutte's child, CS, was born with Patent Ductus Arteriosus and Patent Foramen. Ovale with Respiratory Distress Syndrome.

10. At all times relevant hereto, Plaintiff Shannon Emery and her child CE have been residents of the state of Michigan. During her pregnancy, Plaintiff Shannon Emery resided in the state of Michigan, and gave birth to her child, CE, in the state of Michigan. Plaintiff Shannon Emery was prescribed and used generic paroxetine during her pregnancy with CE. The paroxetine was defective and unreasonably dangerous when it entered into the stream of commerce and when ingested by Plaintiff Shannon Emery. Plaintiff Shannon Emery was administered paroxetine for its intended purposes, namely, depression. On October 10, 2007, Plaintiff Shannon Emery's child, CE, was born with Transposition of the Great Arteries and Atrial Septal Defect.

11. Defendant GlaxoSmithKline LLC f/k/a SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") is a citizen of Delaware because its sold member, GSK Holdings, is a Delaware corporation that maintains its principal place of

business and its never center in Delaware. GSK does business in, and derives substantial revenue from, Cook County, Illinois. GSK designed, patented, manufactured, labeled, marketed, distributed, and sold paroxetine under the brand name Paxil for use by, among others, pregnant women, including Paxil ingested during pregnancy by the mother Plaintiffs.

12. GSK knew based on information, including "newly acquired information" within the meaning of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. and its implementing regulations, that the label for paroxetine did not adequately warn of the risk of paroxetine and knew there was a sufficient causal association between paroxetine and birth defects to justify strengthening the warning.

13. GSK had the power and obligation to unilaterally strengthen the paroxetine label to warn of the risk of birth defects. GSK could have strengthened and improved the label for paroxetine without the federal government's special permission and assistance.

14. GSK marketed paroxetine with labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, regulatory submissions, and other means.

15. GSK failed to conduct appropriate tests to generate the necessary scientific data regarding the strength of the association between paroxetine and birth defects, failed to warn of these dangers despite significant evidence of risk, and failed to implement available screening procedures which could identify

those patients who were not appropriate candidates for the drug.

16. Defendant Wolters Kluwer United States Inc. ("WKUS") is a Delaware corporation with its principal place of business in Illinois. According to the Pennsylvania Secretary of State, the business address of its President, its Vice President, its Secretary, and its Treasurer is 4025 W. Peterson Avenue, Chicago, Illinois 60646. According to the New York Secretary of State, the principal executive office of WKUS is "C/O Legal Department," 2700 Lake Cook Road, Riverwoods, Illinois 60015. Illinois is the nerve center of WKUS's business as it is the site of the corporation's headquarters and the place where the corporation's officers direct, control, and coordinate the corporation's activities. WKUS is a citizen of Illinois.

17. Defendant Wolters Kluwer Health, Inc. is a Delaware corporation. According to the Pennsylvania Secretary of State, the business address of its President, its Vice President, its Secretary, and its Treasurer is 4025 W. Peterson Avenue, Chicago, Illinois 60646. According to the New York Secretary of State, the principal executive office of WK health is "C/O WKUS Legal Department," 2700 Lake Cook Road, Riverwoods, Illinois 60015.

18. WKUS and WK Health and wholly owned subsidiaries of non-party Wolters Kluwer U.S. Corporation.

19. WKUS participates in the management of WK Health.

20. WKUS provides managerial services for WK Health.

21. WKUS enters into contracts on behalf of WK Health.

22. The principal executive office of WK Health is 'C/O WKUS Legal Department,' 2700 Lake Cook Road, Illinois. This is also the address of the principal office of WKUS. The business address of the Presidents, Vice Presidents, Secretaries, and Treasurers of both WK Health and WKUS is 4025 W. Peterson Avenue, Chicago, Illinois 60646.

23. In the business transactions with one another, the Wolters Kluwer Defendants do not maintain do not maintain an arms length relationship with one another or with their mutual parent corporation, Wolters Kluwer United States Corporation.

24. WK Health provides information products and services in the health sector as more particularly described herein.

25. WKUS also provides information products and services in the health sector as more particularly described herein. http://investing.businessweek.com/research/stocks/private/snapshot.asp?privcapId=1054877 (visited July 2, 2014).

26. Additionally, WKUS and WK Health are agents and alter egos of one another and it would promote injustice not to subject each to liability for the acts and omissions of the other.

27. WK Health and WKUS are hereafter collectively referred to as the Wolters Kluwer Defendants.

28. At all times relevant hereto, the Wolters Kluwer Defendants were in the business of providing drug information to pharmacies, including the pharmacies used by the mother Plaintiffs. Specifically, the WK Defendants were in the business of authoring, analyzing, creating, compiling, designing, drafting, disseminating, distributing, editing, evaluating, marketing, and supplying prescription drug information, labels, patient education monographs, patient inserts, warnings, and literature. The Wolters Kluwer Defendants intended that the prescription drug information, labels, PEMs, patient inserts, warnings, and literature be provided directly to consumers by their pharmacists for the purpose of warning consumers about the risks and side effects of the drugs, including paroxetine, which the consumer was taking.

29. The monographs prepared by the Wolters Kluwer Defendants are marketed as enhancing patient safety and reducing adverse drug events by providing comprehensive, authoritative, and unbiased presentations of drug information.

30. At all times relevant hereto, the Wolters Kluwer Defendants were in the business of providing drug information to physicians, physician groups, and hospitals, including the mother Plaintiffs' physicians, physician groups, and hospitals.

31. The Wolters Kluwer Defendants voluntarily and for profit, undertook to author, license, an provide drug information to the mother Plaintiffs' pharmacies, prescribing physicians, physicians, physician groups, and hospitals. The Wolters Kluwer Defendants therefore owed a duty of due care to the pursuant to common law, statute, regulations, and/or industry

standards, including the Keystone Guidelines, to provide truthful, accurate, adequate, useful, appropriate, up-to-date, and complete drug information, labels, patient education monographs, patient inserts, warnings, and literature regarding paroxetine to the mother Plaintiffs' physicians, physician groups, and hospitals.

32. The drug information, labels, patient education monographs, patient inserts, warnings, and literature prepared by the Wolters Kluwer Defendants were placed in the form that was intended to reach, and did reach, pharmacy customers, pharmacies, and physicians, including Plaintiffs, Plaintiffs' pharmacies, and Plaintiffs' physicians.

33. The Wolters Kluwer Defendants contracted with Plaintiffs' pharmacies to provide drug information, labels, patient education monographs, patient inserts, warnings and literature regarding paroxetine. The Wolters Kluwer Defendants voluntarily assumed a duty to exercise due care in issuing drug warnings by providing written drug information and warnings directed to patient end users. They provided this information in the form of literature delivered to patient end users by Plaintiffs pharmacies at the time the patient end users received their prescriptions.

34. The Wolters Kluwer Defendants contracted with Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals to provide drug information, labels, patient education monographs, patient inserts, warnings and literature regarding paroxetine.

35. Having voluntarily and for profit undertaken to instruct, advise, and warn Plaintiffs, Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals, regarding the dangers and risks of using paroxetine, the Wolters Kluwer Defendants had a duty to provide truthful, accurate, adequate, useful, appropriate, up-to-date, and complete information and warnings in the written paroxetine drug information, labels, patient education monographs, patient inserts, warnings, or literature that they authored, analyzed, created, compiled, designed, drafted, disseminated, distributed, edited, evaluated, marketed, modified, supplied, and made available for the ultimate purpose of informing consumers, pharmacies, and physicians, including Plaintiffs, Plaintiffs' pharmacies, Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals of the risks of paroxetine.

36. The Wolters Kluwer Defendants breached their duty of care, by directly or indirectly, negligently and/or defectively, authoring, analyzing, creating, compiling, designing, drafting, disseminating, distributing, editing, evaluating, marketing, modifying, and supplying prescription drug information, labels, patient education monographs, patient inserts, warnings, and literature that were unsuitable for their intended purpose of warning consumers, pharmacies, and physicians about the risks and side effects of paroxetine, particularly the risks and side effects relating to birth defects.

37. The Wolters Kluwer Defendants had actual or constructive knowledge that pharmacists, medical professionals, and consumers, such as Plaintiffs, would rely upon the information and warnings disseminated

in their drug information, labels, patient education monographs, patient inserts, warnings and literature for paroxetine, and that many patients, in accordance with their prescription and the information and warnings disseminated in the Wolters Kluwer Defendants' drug information, labels, patient education monographs, patient inserts, warnings, and literature for paroxetine, would be likely to be prescribed, receive, and ingest paroxetine.

38. The Wolters Kluwer Defendants knew, or should have known, that the incomplete, inaccurate, and misleading information and warnings disseminated in their drug information, labels, patient education monographs, patient inserts, warnings and literature for paroxetine they supplied to consumers and healthcare providers, including Plaintiffs, Plaintiffs' pharmacies, Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals, created an unreasonable risk of injury, including an unreasonable risk of birth defects. The Wolters Kluwer Defendants knew, or should have known, that Paxil increased the risk of birth defects in women ingesting Paxil while pregnant.

39. It was foreseeable that the Wolters Kluwer Defendants failure to provide truthful, accurate, adequate, useful, appropriate, up-to-date and complete information and warnings regarding paroxetine could cause harm to consumers, including Plaintiffs, could increase the risk of harm to consumers, including Plaintiffs, and that consumers, including Plaintiffs, could foreseeably suffer harm because of consumers' and medical professionals' reliance on the information the Wolters Kluwer Defendants undertook to provide

about paroxetine, that was intended to be provided directly to, or made available to, among others, consumers.

40. The Wolters Kluwer Defendants promote themselves as unbiased suppliers of up to date scientific drug information. They claim that their drug database and information reduce adverse drug events. The Wolters Kluwer Defendants also tout the monographs they provide as being comprehensive, authoritative, and unbiased presentations of key drug information to customers and patients. Further, on their website the Wolters Kluwer Defendants claim the following concerning their prescription drug information: "[u]p-to date and comprehensive, our drug databases provide clinicians, pharmacists, payers and pharmaceutical companies with the reliable drug information they need to work efficiently and protect patients. From databases with drug product and pricing information to clinical decision support databases that identify drug conflicts, to consumer-oriented information written to educate patients about their drug therapy, we have a database for most applications' needs across the health care continuum. Medi-Span®, a part of Wolters Kluwer Health, is the leading provider of prescription drug information and drug interactions database solutions for thousands of health care professionals worldwide." In truth, the Wolters Kluwer Defendants failed to ensure that the prescription drug information and warnings they provided regarding Paxil were truthful, accurate, adequate, useful, appropriate, up to date, and complete.

41. The Wolters Kluwer Defendants knew or should have known Paxil was unreasonably dangerous due to inadequate warnings and due to its defective design and knew or should have known that Paxil increases the risk of birth defects.

42. As a direct and proximate result of the Wolters Kluwer Defendants' negligent acts and omissions, Plaintiffs, Plaintiffs' pharmacies, Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals were unaware, and could not reasonably have known through reasonable diligence, that paroxetine exposed the Plaintiffs to the risks and injuries alleged herein.

43. Defendant Walgreen Co. ("Walgreens") is a citizen of Illinois because it maintains its principal place of business in Illinois and is organized under the laws of Illinois. Walgreens has conducted business in, and derived substantial revenue from, Cook County, Illinois. Walgreens has approximately 139 pharmacy locations in Cook County. Walgreens operates as a pharmacy and sells Paxil in Illinois to, among others, pregnant women. Walgreens sold Paxil or generic Paxil ingested by Audrey Meyers, Amy Christy, Kristin Hozempa, Kathryn Keady, Stacey Schutte and Shannon Emery.

44. Walgreens knew or should have known of a pre-existing condition or conditions of Plaintiffs Audrey Meyers, Amy Christy, Kristin Hozempa, Kathryn Keady, Stacy Schutte, and Shannon Emery that made them particularly susceptible to the side effects of paroxetine. Specifically, Walgreens knew or should have known of each mother Plaintiffs' preexisting condition or conditions, including but not limited to,

that each mother Plaintiff was not using prescription birth control and subsequently was pregnant, that rendered her unborn child particularly susceptible to birth defects.

FACTUAL ALLEGATIONS

45. GSK designed, manufactured, promoted, distributed, labeled, and marketed paroxetine hydrochloride under the trade name Paxil, Paxil Oral Suspension, and Paxil CR.

46. The United States Food and Drug Administration (FDA) approved paroxetine hydrochloride in 1992 for the treatment of depression in adults.

47. GSK has manufactured, marketed, distributed, and sold paroxetine hydrochloride under the brand name Paxil since 1992 and continues to do so.

48. At the time paroxetine hydrochloride was prescribed to each minor Plaintiff's mother, Defendants knew through animal studies, post-marketing reports, and other sources that paroxetine hydrochloride was associated with a significantly increased risk of congenital defects in babies whose mothers ingested paroxetine hydrochloride during pregnancy. They also knew other studies showed that increased levels of serotonin, the primary human substance affected by paroxetine hydrochloride, had profound effects on the pre-natal development of study animals.

49. Paroxetine hydrochloride is a teratogen. That is, it causes defects in embryo formation that result in structural and functional abnormalities. Medical

studies comparing the levels of paroxetine hydrochloride and its principal metabolite in mothers' blood to their concentration in umbilical cord blood at the time of delivery indicated that fetal exposure to paroxetine hydrochloride and its metabolite is approximately a third of the maternal exposure.

50. Each minor Plaintiff's mother and each mother's physicians were prevented from discovering information about significant fetal exposure to paroxetine hydrochloride and the risks paroxetine hydrochloride poses to fetal development sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that paroxetine hydrochloride is safe to take during pregnancy.

51. Notwithstanding this knowledge, Defendants aggressively and actively promoted paroxetine hydrochloride. They touted paroxetine hydrochloride as being a safe alternative for pregnant women. These Defendants have never informed doctors of these serious risks, even though research shows the association between Paxil and birth defects. They continue to represent to the patients and physicians that it is not known if paroxetine hydrochloride will harm the unborn children of pregnant women ingesting the drug.

52. During the entire time paroxetine hydrochloride has been on the market in the United States, FDA regulations have required GSK to issue stronger warnings whenever there existed reasonable evidence of an association between a serious risk and paroxetine hydrochloride. The regulations specifically state that a causal link need not have been proven to

issue the new warnings. Further, the regulations explicitly allowed GSK to issue such a warning without prior FDA approval.

53. Prior to minor Plaintiffs' mothers' pregnancies with minor Plaintiffs, GSK had the knowledge, the means, and the duty to provide the medical community and the consuming public with a stronger warning regarding the association between paroxetine hydrochloride and birth defects through all means necessary, including but not limited to labeling, continuing education, symposiums, posters, sales calls to doctors, advertisements, and promotional materials.

54. Defendants knew or should have known of the dangerous propensities of paroxetine hydrochloride, including the propensity of paroxetine hydrochloride to cause the injuries each minor Plaintiff sustained. Such knowledge was reasonably and scientifically knowable through appropriate research and testing by known methods, at the time they marketed, distributed, and sold paroxetine hydrochloride. Such knowledge was not known to ordinary physicians who would be expected to prescribe paroxetine hydrochloride for their patients or who would be expected to treat pregnant women.

CAUSES OF ACTION

COUNT 1

STRICT LIABILITY-FAILURE TO WARN – GSK

55. Plaintiffs incorporate the preceding paragraphs of this Complaint.

56. GSK failed to warn adequately of the risks of Paxil both in what risk information it conveyed and in the manner in which they conveyed risk information.

57. GSK failed to adequately warn Plaintiffs, their physicians, and others of the potential risks and hazards associated with Paxil.

58. GSK failed to provide appropriate and adequate warnings and instructions to render Paxil reasonably safe for its ordinary, intended, and reasonably foreseeable uses.

59. GSK failed to adequately communicate adequate warnings to Plaintiffs, their physicians, and others of the potential risks and hazards associated with Paxil use.

60. GSK failed to use labeling and methods of communication other than labeling to adequately communicate adequate warnings to Plaintiffs, their physicians, and others of the potential risks and hazards associated with Paxil use.

61. Plaintiffs' physicians would not have prescribed or permitted Plaintiffs to use Paxil had they received adequate warnings regarding the risks of ingesting Paxil.

62. Plaintiffs would not have ingested Paxil had they received adequate warnings regarding the risks of ingesting Paxil.

63. GSK failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiffs and to their physicians, in at least the following ways:

a. GSK failed to include adequate warnings and/or provide adequate clinically relevant information and date that would alert Plaintiffs and their physicians to the dangerous risks of Paxil, including, among other things, its tendency to increase the risk of and/or cause the development of birth defects;

b. GSK failed to provide adequate post-marketing warnings and instructions after the GSK knew or should have known of the significant risks of Paxil, including, among other things, its tendency to increase the risk of and/or cause the development of, among other things, birth defects;

c. GSK continued to aggressively promote and sell Paxil even after it knew or should have known of the unreasonable risks of developing birth defects from ingestion of Paxil; and

d. GSK failed to communicate both the risks of Paxil and that there existed safer and more or equally effective alternative drug products.

64. As a direct, foreseeable, and proximate result of GSK's marketing, sale, and distribution of Paxil in a defective condition due to inadequate warnings, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered,

and continues to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 2

STRICT PRODUCTS LIABILITY –
DESIGN DEFECT – GSK

65. Plaintiffs incorporate the preceding paragraphs of this Complaint.

66. Use of Paxil can cause birth defects.

67. The Paxil designed, manufactured, distributed, marketed, and sold by GSK failed to perform safely when used as intended and several safer and equally or more effective alternatives to Paxil were available.

68. Paxil failed to perform as Plaintiffs, their physicians, and ordinary consumers would expect when used in an intended or reasonably foreseeable manner, including when used by Plaintiffs and other pregnant women, because it caused birth defects.

69. The risk of danger inherent in the design of Paxil, that is, birth defects, outweighs the benefits of the design of Paxil.

70. As a direct, foreseeable, and proximate result of GSK's design, marketing, sale and distribution of Paxil in a defective condition due to inadequate warnings, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered, and continue to suffer, injury of a personal

and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 3

NEGLIGENCE – GSK

71. Plaintiffs incorporate the preceding paragraphs of this Complaint.

72. At all relevant times, it was the duty of GSK to use reasonable case in the design, manufacturing, marketing, distribution, and sale of Paxil.

73. In disregard of its aforesaid duty, GSK committed one or more of the following negligent acts or omissions:

a. Manufactured, produced, promoted, formulated, created, developed, designed, sold, and distributed Paxil without thorough and adequate pre and post-market testing of the product;

b. Manufactured, produced, promoted, advertised, formulated, created, developed, designed, and distributed Paxil while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Paxil;

c. Failed to undertake sufficient studies and conduct necessary tests to determine whether Paxil was safe for its intended or foreseeable uses;

d. Failed to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers, including Plaintiffs and their physicians that Paxil was unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users in the form of, but not limited to, the development of the injuries Plaintiffs sustained;

e. Failed to warn Plaintiffs, their physicians, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that safer and effective alternative medications were available to Plaintiffs and other consumers;

f. Failed to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would prescribe, use, and consume Paxil;

g. Advertised, marketed and recommended the use of Paxil, while concealing and failing to disclose or warn of the dangers GSK knew to be connected with, and inherent in, the use of Paxil;

h. Represented that Paxil was safe for its intended use when in fact GSK knew and should have known the product was not safe for its intended purpose;

i. Failed to disclose to and inform the medical community and consumers that other forms of safer and effective alternative medications were available for use for the purpose for which Plaintiffs were prescribed Paxil and for which Paxil was manufactured;

j Continued to manufacture and sell Paxil with the knowledge that Paxil was unreasonably unsafe and dangerous;

k. Failed to use reasonable and prudent case in the design, research, manufacture, and development of Paxil so as to avoid the risk of serious harm associated with the use of Paxil;

l. Failed to design and manufacture Paxil so as to ensure the drug was at least as safe and effective as medications designed to treat the conditions for which Plaintiffs were prescribed Paxil;

m. Failed to ensure Paxil was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Paxil and that use created a high risk of causing birth defects:

n. Failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Paxil.

74. As a direct, foreseeable, and proximate result of GSK's negligence, Plaintiffs were injured

catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered, and continue to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 4

BREACH OF IMPLIED WARRANTY – GSK

75. Plaintiffs incorporate the preceding paragraphs of this Complaint.

76. At the time GSK designed, manufactured, marketed, distributed, and sold for use by Plaintiffs, GSK knew the use for which Paxil was intended and impliedly warranted that the Paxil would be of merchantable quality and safe for such use. Specifically, GSK impliedly warranted to Plaintiffs and Plaintiffs' physicians, among other things, that the Paxil Plaintiffs were prescribed, purchased, and ingested was fit for the ordinary purposes for which Paxil is used, was adequately labeled, and conformed to the promises or affirmations of fact made on the label.

77. Plaintiffs and Plaintiffs' physicians and healthcare relied on the skill and judgment of the GSK in using and prescribing Paxil.

78. The Paxil Plaintiffs ingested was not merchantable because it was unreasonably dangerous.

79. The Paxil Plaintiffs ingested was not merchantable because it was not fit for the ordinary purpose for which such goods are used.

80. The Paxil Plaintiffs ingested was not merchantable because it was not adequately labeled.

81. The Paxil Plaintiffs ingested was not merchantable because it caused Plaintiff to develop birth defects.

82. As a direct, foreseeable, and proximate result of GSK's breach of implied warranty, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered, and continues to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 5

BREACH OF EXPRESS WARRANTY – GSK

83. Plaintiffs incorporate the preceding paragraphs of this Complaint.

84. GSK made affirmations of fact and promises and provided a description of its goods to Plaintiffs, specifically, GSK expressly warranted that the Paxil ingested by Plaintiffs was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other medications used to treat conditions treated by Paxil, that it was adequately tested and fit for its intended use, and that it was a safe or safer than other

alternative methods to treat Plaintiffs' condition. These warranties were made through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, an other means.

85. GSK's foregoing affirmations, promise, and descriptions formed part of the basis fo the bargain of Plaintiffs' being prescribed, purchasing, and ingesting Paxil.

86. GSK breached its express warranty because the foregoing affirmations, promises, and descriptions were false in material respects as described in this Complaint.

87. At the time of the making of the express warranties, GSK had knowledge of the purpose for which Paxil was to be used and warranted the same to be in all respects, fit, safe, and effective and proper for such purpose. Paxil was unaccompanied by adequate warnings of its dangerous propensities that were either known or knowable at the time of distribution.

88. Plaintiffs and Plaintiffs' physicians reasonably relied upon the skill and judgment of GSK, and upon said express warranty, in using and prescribing Paxil. The warranty and representations were untrue in that the product was unsafe and, therefore, unsuited for the use for which it was intended.

89. As a direct, foreseeable, and proximate result of GSK's breach of express warranty, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and

pecuniary damages. Plaintiffs suffered, and continue to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

90. After Plaintiffs were made aware or otherwise came to believe that the injuries discussed herein were a result of paroxetine, notice was duly given to GSK of the breach of said warranty.

COUNT 6

NEGLIGENT MISREPRESENTATION/CONCEALMENT – GSK

91. Plaintiffs incorporate the preceding paragraphs of this Complaint.

92. As a pharmaceutical company, and pursuant to § 311 of the Restatement (Second) of Torts entitles "Negligent Misrepresentation Involving Risk of Physical Harm," GSK has and had an affirmative duty to warn the public and medical community regarding known risks associated with its pharmaceutical products.

93. GSK concealed adverse information and provided inaccurate or biased information that was material to the prescribing decisions of physicians, which misled physicians and patients who were relying on those physicians' professional judgment, including Plaintiffs' prescribing physicians. This misleading information, along with omissions of material fact related to paroxetine's safety and effectiveness, caused health care providers, patients and the general public, including Plaintiffs and their doctors, to be misled about paroxetine's risks and benefits and deprived

doctors from making a proper risk/benefit assessment as to the use of paroxetine.

94. GSK has defrauded the medical profession (including Plaintiffs' prescribing physicians), the paroxetine patient population, and the general public in that it, among other acts: (a) Negligently and carelessly concealed paroxetine's association with birth defects; (b) Negligently and carelessly misrepresented the safety and efficacy of paroxetine; (c) Negligently and carelessly manipulated clinical trial data to obscure the birth defect risks; (d) Negligently and carelessly orchestrated the publication of medical journal articles touting the efficacy and safety of paroxetine by hiring medical communications companies to ghostwrite articles and recruiting (and paying) prominent physicians to append their names to these ghostwritten articles; (e) Negligently and carelessly misrepresented the safety and efficacy of paroxetine through its sales force and routine visits to physicians' offices, including the prescribing physician in this case; (f) Negligently and carelessly denied paroxetine's association with birth defects: (g) negligently and carelessly misrepresented the birth defect risk related to use of paroxetine during pregnancy.

95. When said representations and/or omissions were made by GSK, it knew those representations and/or omissions to be false, or negligently disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by GSK with the intent of inducing the public to take paroxetine and the medical community (including

Plaintiffs' prescribing physician) to recommend, prescribe, and dispense paroxetine.

96. At the time the aforesaid representations and/or omissions were made by GSK, and at the time Plaintiffs ingested paroxetine, they and their medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied on GSK's assertions, promulgated through its aggressive sales tactics, that the drug was safe and effective when, in fact, it was not.

97. In reliance upon said representations and/or omissions, Plaintiffs' medical providers prescribed paroxetine and Plaintiffs were induced to take paroxetine. Had the Plaintiffs' medical providers been made aware of paroxetine's risks, they would not have prescribed the drug or would have warned Plaintiffs to cease ingesting the drug upon becoming pregnant.

98. Had the Plaintiffs known of the actual dangers of paroxetine, through their medical providers or otherwise, they would not have ingested paroxetine, or they would have ceased taking it upon learning they were pregnant.

99. GSK's motive in failing to advise physicians and the public of paroxetine's risks of causing birth defects was for financial gain.

100. At all times herein mentioned, the actions of GSK, its agents, servants, and/or employees were negligently wanton, grossly negligent, or reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of Plaintiffs in particular and to the general public in that GSK did negligently or willfully and knowingly place the

dangerous and defective drug paroxetine on the market with the specific knowledge that it would be sold to, prescribed for, and used by members of the public and without adequate instructions for use.

101. As direct and proximate result of GSK's negligent actions, omissions and misrepresentations, Plaintiffs suffered physical injury, harm, damages, economic and non-economic loss, and will continue to suffer such harm, damages and losses in the future.

COUNT 7

STRICT LIABILITY – DESIGN DEFECT – WALGREENS

102. Plaintiffs Audrey Meyers, Amy Christy, Kristin Hozempa, Kathryn Keady, Stacey Schutte and Shannon Emery incorporate by reference the preceding paragraphs of this Complaint.

103. Use of paroxetine during pregnancy can cause birth defects.

104. The paroxetine marketed, distributed, and sold by Walgreens failed to perform safely when used as intended and several safer alternatives to paroxetine were available.

105. The paroxetine marketed, distributed, and sold by Walgreens failed to perform as the mother Plaintiffs, their physicians, and ordinary consumers would expect when used in an intended or reasonably foreseeable manner, including when used by pregnant women, because it caused birth defects.

106. The risk of danger inherent in the design of paroxetine, that is, catastrophic birth defects, outweighs the benefits of the design of paroxetine.

107. As a direct, foreseeable and proximate result of Walgreens' marketing, distribution, and sale of paroxetine in a defective condition, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered, and continue to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 8

NEGLIGENCE – WALGREENS

108. Plaintiffs Audrey Meyers, Amy Christy, Kristin Hozempa, Kathryn Keady, Stacey Schutte and Shannon Emery incorporate by reference the preceding paragraphs of this Complaint.

109. At all times relevant hereto, it was the duty of Walgreens to use reasonable care in the marketing, distribution, and sale of paroxetine because Walgreens was aware of each mother Plaintiffs' preexisting condition or conditions, including but not limited to, that each mother Plaintiff was not using prescription birth control and subsequently was pregnant, that rendered unborn child particularly susceptible to birth defects.

110. In disregard of its aforesaid duty, Walgreens committed one or more of the following negligent acts or omissions:

a. Sold, and distributed paroxetine without thorough and adequate pre and post-market testing of the product;

b. Promoted, advertised, distributed, and sold paroxetine while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of paroxetine by pregnant women;

c. Failed to undertake sufficient studies and conduct necessary tests to determine whether paroxetine was safe for its intended or foreseeable uses;

d. Failed to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers, including Plaintiffs and their physicians that paroxetine was unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users' unborn children in the form of, but not limited to, the development of the injuries Plaintiffs sustained;

e. Failed to warn Plaintiffs, Plaintiffs' physicians, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that safer and effective alternative medications were available to Plaintiff's mother and other consumers;

f. Failed to provide adequate instructions, guidelines, and safety precautions to

those persons to whom it was reasonably foreseeable would prescribe, use, and consume paroxetine;

g. Advertised, marketed, and recommended the use of paroxetine, while concealing and failing to disclose or warn of the dangers it knew to be connected with, and inherent in, the use of paroxetine;

h. Represented the paroxetine was safe for its intended use when in fact it knew and should have known the product was not safe for its intended purpose;

i. Failed to disclose to and inform the medical community and consumers that other forms of safer and effective alternative medications were available for use for the purpose for which Plaintiff's mother was prescribed paroxetine and for which paroxetine was manufactured;

j. Continued to sell paroxetine with the knowledge that paroxetine was unreasonably unsafe and dangerous;

k. Failed to ensure paroxetine was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of paroxetine by pregnant women and that use by pregnant women created a high risk of causing birth defects in unborn children of pregnant women;

l. Failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of paroxetine.

111. As a direct, foreseeable, and proximate result of the negligent acts and omissions of Walgreens, Plaintiffs have been injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs have suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

COUNT 9

NEGLIGENCE – WK HEALTH AND WKUS

112. Plaintiffs incorporate the preceding paragraphs of this Complaint.

113. The Wolters Kluwer Defendants voluntarily undertook a duty to warn of the risks of paroxetine in two independent ways, namely, i) by providing plain language warnings to the mother Plaintiffs though the mother Plaintiffs' pharmacies, and ii) by providing warnings to the mother Plaintiffs' physicians, physician groups, hospitals, and other healthcare providers, as more particularly described herein.

114. The Wolters Kluwer Defendants authored, licensed, and distributed materially misleading patient information monographs on the risks of paroxetine use. It is foreseeable that the users of paroxetine would rely upon the information provided directly or through pharmacies to patients with prescriptions for

paroxetine. It was foreseeable that physicians would rely upon the information provided to them regarding paroxetine.

115. At all times relevant to this Complaint, the Wolters Kluwer Defendants were in the business of authoring, analyzing, creating, compiling, designing, drafting, disseminating, distributing, editing, evaluating, marketing, and supplying prescription drug information, labels, patient education monographs ("PEMs"), patient inserts, warnings, and literature.

116. The WK Defendants make the following claim concerning their prescription drug information: "[u]p-to date and comprehensive, our drug databases provide clinicians, pharmacists, payers and pharmaceutical companies with the reliable drug information they need to work efficiently and protect patients. From databases with drug product and pricing information to clinical decision support databases that identify drug conflicts, to consumer-oriented information written to educate patients about their drug therapy, we have a database for most applications' needs across the health care continuum, 1 Medi-Span®, a part of Wolters Kluwer Health, is the leading provider of prescription drug information and drug interactions database solutions for thousands of health care professionals worldwide." In truth, the Wolters Kluwer Defendants failed to ensure that the prescription drug information and warnings it provided regarding paroxetine was truthful, accurate, adequate, useful, appropriate, up to date and complete.

117. The Wolters Kluwer Defendants promote themselves as an unbiased supplier of up to date scientific drug information. They claim that their drug

database and information reduce adverse drug events. The Wolters Kluwer Defendants also tout the monographs they provide as being comprehensive, authoritative, and unbiased presentations of key drug information to customers and patients.

118. The Wolters Kluwer Defendants intended that the prescription drug information, labels, PEMs, patient inserts, warnings, and literature be provided directly to consumers by their pharmacist for the purpose of warning consumers about the risks and side effects of the drugs, including paroxetine, which the consumer was taking.

119. The Wolters Kluwer Defendants voluntarily and for profit, undertook to author, analyze, create, compile, design, draft, disseminate, distribute, edit, evaluate, market, modify, and supply drug information, labels, patient education monographs, patient inserts, warnings and literature on drugs, including paroxetine. The Wolters Kluwer Defendants therefore owed a duty of due care to the medical community, pharmacists, Plaintiffs, Plaintiffs' prescribing physicians, physicians, physicians groups and hospitals pursuant to common law, statute, regulations and/or industry standards to provide truthful, accurate, adequate, useful, appropriate, up-to-date and complete drug information, labels, patient education monographs, patient inserts, warnings and literature regarding paroxetine.

120. The drug information, labels, patient education monographs, patient inserts, warnings and literature prepared by the Wolters Kluwer Defendants were placed in the form that was intended to reach, and did reach, pharmacy customers, including the mother Plaintiffs herein, as well as Plaintiffs'

physicians, physician groups, hospitals, and other healthcare providers. The monographs and drug information prepared by the Wolters Kluwer Defendants are marketed as enhancing patient safety and reducing adverse drug events providing comprehensive, authoritative, and unbiased presentations of drug information.

121. The Wolters Kluwer Defendants contracted with the mother Plaintiffs' pharmacies to provide drug information, labels, patient education monographs, patient inserts, warnings and literature regarding paroxetine.

122. Having voluntarily and for profit, undertaken to instruct, advise, and warn consumers regarding the dangers and risks of using paroxetine, the Wolters Kluwer Defendants has a duty to provide truthful, accurate, adequate, useful, appropriate, up-to-date and complete information and warnings in the written paroxetine drug information, labels, patient education monographs, patient inserts, warnings, or literature that it authored, analyzed, created, compiled, designed, drafted, disseminated, distributed, edited, evaluated, marketed, modified, supplied, and made available for the ultimate purpose of informing consumers, including the Plaintiffs. The scope of the Wolters Kluwer Defendants' voluntary undertaking extended to warning of risks of birth defects.

123. The Wolters Kluwer Defendants breached their duty of care, by directly or indirectly, negligently and/or defectively, authoring, analyzing, creating, compiling, designing, drafting, disseminating, distributing, editing, evaluating, marketing, modifying, publishing and supplying prescription drug

information, labels, patient education monographs, patient inserts, warnings and literature that were unsuitable for their intended purpose of warning consumers about the risks and side effects of paroxetine, particularly the risks and side effects relating to birth defects.

124. The Wolters Kluwer Defendants had actual or constructive knowledge that pharmacists, physicians, physician groups, hospitals, medical professionals, and consumers, such as Plaintiffs, would rely upon the information and warnings disseminated in its drug information, labels, patient education monographs, patient inserts, warnings and literature for paroxetine, and that many patients, in accordance with their prescription and the information and warnings disseminated in the Wolters Kluwer Defendants' drug information, labels, patient education monographs, patient inserts, warnings and literature for paroxetine, would be likely to be prescribed, receive, and ingest paroxetine.

125. The Wolters Kluwer Defendants knew, or should have known, that the incomplete, inaccurate, and misleading information and warnings disseminated in their drug information, labels, patient education monographs, patient inserts, warnings and literature for paroxetine it supplied to consumers, such as Plaintiffs, created an unreasonable risk of injury, including an unreasonable risk of birth defects.

126. It was foreseeable that the Wolters Kluwer Defendants' failure to provide truthful, accurate, adequate, useful, appropriate, up-to-date and complete information and warnings regarding paroxetine could cause harm to consumers, including Plaintiffs, could

increase the risk of harm to consumers, including Plaintiffs, and that consumers, including Plaintiff, could foreseeably suffer harm because of consumers' and medical professionals' reliance on the information the Wolters Kluwer Defendants undertook to provide about paroxetine, that was intended to be provided directly to, or made available to, consumers, including Plaintiff herein.

127. As a direct and proximate result of the Wolters Kluwer Defendants' acts and omissions, Plaintiffs and Plaintiffs' prescribing physicians, physicians, physician groups, and hospitals were unaware, and could not reasonably have known through reasonable diligence, that paroxetine exposed the Plaintiffs to the risk of birth defects.

128. As a direct, foreseeable, and proximate result of the negligent acts and omissions of the Wolters Kluwer Defendants, Plaintiffs were injured catastrophically, sustained severe and permanent disfigurement, pain, suffering, disability, impairment, loss of enjoyment of life, and economic and pecuniary damages. Plaintiffs suffered, and continue to suffer, injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income, and disability.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. On Counts 1 through 6 of the Complaint, judgment against GSK in an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged;

B. On Counts 7 and 8 of the Complaint, judgment against Walgreens in an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged;

C. On Count 9 of the Complaint, judgment against the Wolters Kluwer Defendants in an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged;

D. On all counts of the Complaint, costs of the action and such further relief as this Court deems proper.

JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated: July 2, 2014

Respectfully submitted,

/s/ Steven D. Davis
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Attorneys for Plaintiffs

APPENDIX G

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

CASE NO. 2014 L 006985
Judge Eileen M. Brewer

[Filed January 23, 2015]

MM, A MINOR, BY AUDREY MEYERS, HER MOTHER AND NEXT FRIEND; AH, A MINOR, BY DAWN HINTON, HER MOTHER AND NEXT FRIEND; PM, A MINOR, BY LINDA BUTLER, HIS MOTHER AND NEXT FRIEND; HC, A MINOR, BY AMY CHRISTY, HER MOTHER AND NEXT FRIEND; HH, A MINOR, BY KRISTEN HOZEMPA, HIS MOTHER AND NEXT FRIEND; AK, A MINOR, BY KATHRYN KEADY, HIS MOTHER AND NEXT FRIEND; CS, A MINOR, BY STACEY SCHUTTE, HER MOTHER AND NEXT FRIEND; AND, CE, A MINOR, BY SHANNON EMERY, HIS MOTHER AND NEXT FRIEND,	)
Plaintiffs,	)
v.	)
GLAXOSMITHKLINE LLC, f/k/a	)

SMITHKLINEBEECHAM CORPORATION, d/b/a SMITHKLINEBEECHAM; WOLTERS KLUWER HEALTH, INC.; WOLTERS KLUWER UNITED STATES, INC.; AND WALGREENS CO.,

Defendants.

JURY TRIAL DEMANDED

SPECIAL APPEARANCE

AMENDED REPLY IN SUPPORT OF MOTION TO DISMISS THE SIX OUT-OF-STATE PLAINTIFFS' CLAIMS FOR LACK OF PERSONAL JURISDICTION

* * *

EXHIBIT A

AMENDED DECLARATION OF KALPESH JOSHI

1. My name is Kalpesh Joshi. I am over the age of 18, have personal knowledge of the facts stated herein, and am competent in all respects to give the testimony contained herein.

2. I am currently employed by a wholly-owned subsidiary of GlaxoSmithKline plc. I am the Medical Advisor for Classic and Established Medicines.

3. I am familiar with the design and administration of clinical trials for pharmaceutical medications. I am familiar with

the clinical trials conducted by GlaxoSmithKline LLC, formerly SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), for paroxetine, the compound which was marketed by GSK in the United States under the brand names Paxil® and Paxil CR™ (collectively "Paxil").

4. Clinical trials are research studies designed to evaluate the efficacy and/or safety of pharmaceutical medications in humans. The particular objective of a clinical trial is set forth in the study protocol.

5. Large clinical trials, such as those conducted by GSK for Paxil, are often multicenter studies with numerous investigation sites located throughout the United States and, in some cases, in other countries. When a clinical trial is a multicenter study, GSK will contract with individual investigations at the various sites. Those investigators are responsible for recruiting study subjects and collecting data from the study participants at their respective site. However, the study site investigators have little or no input into or control over the study design protocol or analysis of the aggregate data collected from all study sites.

6. Because human fetuses are considered vulnerable, it is generally accepted in the medical and scientific community that inclusion of pregnant women in pharmaceutical clinical trials is improper and, perhaps, unethical.

7. For that reason, GSK excludes pregnant women from its clinical trials. Women who are planning

to become pregnant or who are not compliant with clinically-accepted contraception may also be excluded from clinical trials conducted by GSK.

8. Because pregnant women and women planning to become pregnant are excluded from the studies, clinical trials are not designed to and cannot evaluate whether a pharmaceutical medication is associated with a risk of birth defects. Instead, researchers can assess whether a medication is associated with a risk of birth defects by conducting animal studies or retrospective epidemiological studies.

9. I have specifically reviewed, to the extent available, the study reports for the clinical trials identified on pages 4 through 8 of Plaintiffs' Opposition to GSK's Motion to Dismiss.

10. I reviewed the study report, dated September 18, 1989, for "A Multicenter, Double-Blind, Placebo Controlled, Fixed Dose Evaluation of Four Doses of Paroxetine" (Study 9) (attached hereto as Exhibit 1).

a. The objective of this study was to establish the minimally effective dose of paroxetine and to compare the safety and efficacy of four doses of paroxetine and placebo in the treatment of outpatients with depression.

b. The study was conducted at ten separate study sites in the United States. Only one site was located in Illinois.

c. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing potential who were not practicing a medically accepted form of birth control were excluded from the study.

11. I reviewed the study report, dated June 25, 1993, for "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Comparison of Paroxetine and Fluoxetine In the Treatment of Major Depressive Disorder" (Study 115) (attached hereto as Exhibit 2).

a. The objective of this study was to compare the safety and efficacy of paroxetine to placebo and fluoxetine in the treatment of patients with major depressive disorder.

b. The study was conducted at 28 separate study sites in the United States. Only one site was located in Illinois.

c. This study enrolled and randomized 691 patients in total. Of those 691 patients, only 23 patients (or approximately 3%) were located in Illinois. Only 10 of those 23 patients were exposed to paroxetine (approximately 1% of the total study population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women were excluded from the study.

12. I reviewed the study report, dated September 7, 1994, for "Paroxetine Versus Clomipramine and Placebo in the Treatment of Obsessive-

Compulsive Disorder" (Study 118) (attached hereto as Exhibit 3).

a. The objective of this study was to demonstrate the effectiveness and safety of paroxetine in the treatment of obsessive-compulsive disorder.

b. The study was conducted at 13 Separate study sites in the United States. Only one site was located in Illinois.

c. The study enrolled and randomized 241 patients in total. Of those 241 patients only 23 patients (or approximately 9.5%) were located in Illinois. Only 8 of those 23 patients were exposed to paroxetine (approximately 3% of the total study population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing potential who were not using adequate means of contraception were excluded from the study.

13. I reviewed the study report, dated January 20, 1995, for "A Double-Blind, Multi-Centered, Flexible-Dose Study of Paroxetine, Alprazolam, and Placebo in the Treatment of Panic Disorder" (Study 223) (attached hereto as Exhibit 4). Although GSK previously identified this study as one with a study investigator located in Illinois, upon further review of the study report, I determined that there were no study investigators or study sites located in Illinois.

14. I reviewed the study report, dated September 11, 1995, for "Long-term Treatment with Paroxetine of Outpatients with Obsessive-Compulsive Disorders: An Extension of the Comparative Study" (Study 127) (attached hereto as Exhibit 5).

a. The objective of this study was to demonstrate the long-term clinical response to paroxetine and to assess its safety/tolerability in the treatment of outpatients with obsessive-compulsive disorder, and to assess the prevention of relapse of obsessive-compulsive disorder. This study was a continuation of Study 118 (discussed *supra* in Paragraph 12).

b. The study was conducted at 13 separate study sites in the United States. Only one site was located in Illinois.

c. This study was divided into two phases: (1) open-label phase to assess long-term clinical response of paroxetine; and (2) randomization phase to assess the prevention of relapse. The open-label phase enrolled 144 patients, and the randomization phase enrolled 44 patients, all of whom participated in the open-label phase. (All of these patients previously participated in Study 118.) Of the 144 patients in the open-label phase; only 16 patients (or approximately 11%) were located in Illinois. Only 9 of the Illinois-based patients completed the open-label phase of the study. Of the 44 patients enrolled in the randomization phase, only 3 patients (or approximately 7%) were located in Illinois. Only 1 of those 3 patients was exposed to paroxetine

(approximately 2% of the patients in the randomization phase).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, women of childbearing potential who were not using adequate means of contraception were excluded from the study.

15. I reviewed the study report, dated October 1, 1996, for "A Double-Blind, Placebo-Controlled, Comparison of Imipramine and Paroxetine in the Treatment of Bipolar Depression" (Study 352) (attached hereto as Exhibit 6).

a. The objective of this study was to compare the efficacy and safety of paroxetine and imipramine to placebo in the treatment of bipolar depression in patients stabilized on lithium therapy.

b. The study was conducted at 18 separate study sites in the United States. Only one site was located in Illinois.

c. The study enrolled and randomized 117 patients in total. Of those 117 patients, only 1 patient (or approximately 0.8%) was located in Illinois. That patient, however, was randomized to placebo and was not exposed to paroxetine.

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

16. I reviewed the study report, dated March 2, 1998, for "A Double-Blind, Placebo-Controlled, Flexible Dosing Trial to Evaluate the Efficacy of Controlled-Release Paroxetine in the Treatment of Panic Disorder" (Study 495) (attached hereto as Exhibit 7).

a. The objective of this study was to demonstrate the efficacy and to assess the safety of paroxetine controlled-release in the treatment of panic disorder.

b. The study was conducted at 29 separate study sites in the United States. Only one site was located in Illinois.

c. The study enrolled and randomized 328 patients in total. Of those 328 patients, only 3 patients (or approximately 0.9%) were located in Illinois. Only 1 of those 3 patients was exposed to paroxetine (approximately 0.3% of the total study population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

17. I reviewed the study report, dated December 4, 1998, for "A Double-Blind, Comparative Placebo-Controlled Trial of Paroxetine in the Prevention of Recurrent Depression" (Study 190) (attached hereto as Exhibit 8).

a. The objective of this study was to compare the efficacy of paroxetine and placebo in the

prevention of recurrence of depression in patients with a diagnosis of recurrent major depressive disorder.

b. The study was conducted at 11 separate study sites in the United States. Only one site was located in Illinois.

c. The study was divided into two phases: (1) Acute Treatment Phase (open-label); and (2) Maintenance Phase (patients who did not relapse and demonstrated a good therapeutic response were randomized to either paroxetine or placebo). The Acute Treatment Phase enrolled 225 patients, and the Maintenance Phase enrolled 125 patients, all of whom participated in the Acute Treatment Phase. Of the 225 patients in the Acute Treatment Phase, only 7 patients (or approximately 3%) were located in Illinois. Of the 125 patients enrolled in the Maintenance Phase, only 3 patients (or approximately 2%) were located in Illinois. Only 1 of those 3 patients was exposed to paroxetine (approximately 0.8% of the patients enrolled in the Maintenance Phase).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

18. I reviewed the study report, dated April 6, 2000, for "A Randomized, Double-Blind, Placebo Controlled, Fixed Dosage Trial to Evaluate the Efficacy and Tolerability of 20 and 40 mg/day

Paroxetine in Patients with General Anxiety Disorder" (Study 641) (attached hereto as Exhibit 9).

a. The objective of this study was to assess the efficacy and safety/tolerability of 20 mg and 40 mg of paroxetine versus placebo in the treatment of generalized anxiety disorder.

b. The study was conducted at 50 separate study sites (44 in the United States and 6 in Canada). Only one site was located in Illinois.

c. This study enrolled and randomized 566 patients in total. Of those 566 patients, there were no patients in Illinois.

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

19. I reviewed the study report, dated April 6, 2000, for "A Randomized, Double-Blind, Placebo Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of Paroxetine in Patients with General Anxiety Disorder" (Study 642) (attached hereto as Exhibit 10).

a. The objective of this study was to assess the efficacy and safety/tolerability of paroxetine versus placebo in the treatment of generalized anxiety disorder.

b. The study was conducted at 35 separate study sites (29 in the United States and 6 in Canada). Only one site was located in Illinois.

c. This study enrolled and randomized 331 patients in total. Of those 331 patients, only 11 patients (or approximately 3%) were located in Illinois. Only 5 of those 11 patients were exposed to paroxetine, and only 3 of the paroxetine-exposed Illinois-based patients completed the study (approximately 0.9% of the total patient population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

20. I reviewed the study report, dated June 13, 2000, for "A 12 Week, Double-Blind, Fixed Dose Comparison of 20-40 mg Daily of Paroxetine and Placebo in Patients Suffering from Posttraumatic Stress Disorder (PTSD)" (Study 651) (attached hereto as Exhibit 11).

a. The primary objective of this study was to compare the efficacy of paroxetine and placebo and to determine the optimal effective dose of paroxetine in the treatment of patients with Posstraumatic Stress Disorder ("PTSD"). The secondary objective was to assess the safety and tolerability of paroxetine and placebo in the treatment of patients with PTSD.

b. The study was conducted at 60 separate study sites in the United States. Only one site was located in Illinois.

c. This study enrolled and randomized 551 patients in total. Of those 551 patients, only 9 patients (or approximately 2%) were located in Illinois. Only 6 of those 9 patients were exposed to paroxetine, and only 2 of the paroxetine-exposed Illinois-based patients completed the study (approximately 0.4% of the total patient population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age who were not using a clinically accepted method of contraception were excluded from the study.

21. I reviewed the study report, dated November 14, 2001, for "A Randomized, Multicenter, 10-Week, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine. In Children and Adolescents with Obsessive-Compulsive Disorder (OCD)" (Study 704) (attached hereto as Exhibit 12).

a. The objective of this study was to assess the efficacy and safety/tolerability of paroxetine versus placebo in the treatment of children and adolescents with obsessive-compulsive disorder.

b. The study was conducted at 39 separate study sites (37 in the United States and 2 in Canada). Only one site was located in Illinois.

c. This study enrolled and randomized 203 patients in total, all of whom were between the ages of 7 and 17. Of those 203 patients, there were no patients in Illinois.

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant females and sexually-active females who were not using a reliable method of contraception were excluded from the study.

22. I reviewed the study report, dated May 28, 2002, for "A Double-Blind, Placebo-Controlled, 3-Arm Fixed Dose Study of Paroxetine CR Continuous Treatment (12.5 mg/day and 25 mg/day) for Premenstrual Dysphoric Disorder" (Study 677) (attached hereto as Exhibit 13).

a. The primary objective of this study was to compare the efficacy of continuous treatment of paroxetine controlled-release with that of placebo for the treatment of premenstrual dysphoric disorder ("PMDD"). The secondary objective was to evaluate the safety of continuous treatment of paroxetine controlled-release for the treatment of PMDD.

b. The study was conducted at 43 separate study sites in the United States. Only one site was located in Illinois.

c. This study enrolled and randomized 313 patients in total. Of those 313 patients, only 6 patients (or approximately 2%) were located in Illinois. Only 4 of those 6 patients were exposed to paroxetine, and only 3 of the paroxetine-exposed Illinois-based patients completed the

study (approximately 1% of the total patient population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women planning to become pregnant during the trial were excluded from the study. Additionally, in order to be considered for inclusion in the study, the woman must establish use of an adequate non-hormonal form of contraception.

23. I reviewed the study report, dated May 28, 2002, for "A Double-Blind, Placebo-Controlled, 3-Arm Fixed Dose Study of Paroxetine CR Continuous Treatment (12.5 mg/day and 25 mg/day) for Premenstrual Dysphoric Disorder" (Study 689) (attached hereto as Exhibit 14).

a. The primary objective of this study was to compare the efficacy of continuous treatment of paroxetine controlled-release with that of placebo for the treatment of premenstrual dysphoric disorder ("PMDD"). The secondary objective was to evaluate the safety of continuous treatment of paroxetine controlled-release for the treatment of PMDD.

b. The study was conducted at 47 separate study sites (29 in the United States and 18 in Canada). Only one site was located in Illinois.

c. This study enrolled and randomized 371 patients in total. Of those 371 patients, only 2 patients (or approximately 0.5%) were located in Illinois. Only 1 of those 2 patients was exposed

to paroxetine (approximately 0.3% of the total patient population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women planning to become pregnant during the trial were excluded from the study. Additionally, in order to be considered for inclusion in the study, the woman must establish use of an adequate non-hormonal form of contraception.

24. I reviewed the study report, dated September 5, 2002, for "A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of Paroxetine CR in Patients with Generalized Anxiety Disorder (GAD)" (Study 791) (attached hereto as Exhibit 15).

a. The objective of this study was to compare the efficacy and safety/tolerability of paroxetine controlled-release versus placebo in the treatment of generalized anxiety disorder.

b. The study was conducted at 32 separate study sites in the United States. Only one site was located in Illinois.

c. This study enrolled and randomized 335 patients in total. Of those 335 patients, only 15 patients (or approximately 4%) were located in Illinois.

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women of childbearing age

who were not using a clinically accepted method of contraception were excluded from the study.

25. I reviewed the study report, dated September 24, 2002, for "A 3-Month, Double-Blind, Placebo-Controlled, Fixed-Dose, Extension Study of Paroxetine CR (12.5 mg and 25 mg/day) Continuous Treatment for PMDD Patients Completing Studies 29060/677, 688, or 689" (Study 711) (attached hereto as Exhibit 16).

a. The objective of this study was to compare the efficacy and safety of continuous treatment with paroxetine controlled-release with that of placebo for the treatment of premenstrual dysphoric disorder ("PMDD"). This study was an extension of Study 677 (discussed *supra* at Paragraph 22), Study 688, and Study 689 (discussed *supra* at Paragraph 23). For that reason, all of the participants in this study had previously participated in Study 677, 688, or 689.

b. The study was conducted at 136 separate study sites (72 in the United States, 18 in Canada, 3 in Finland, 4 in Germany, 4 in Ireland, 8 in the Netherlands, 6 in Norway, 4 in South Africa, 8 in Sweden, and 9 in the United Kingdom). Only two sites were located in Illinois.

c. This study enrolled and randomized 1,059 patients in total. Of those 1,059 patients, only 8 patients (or approximately 0.8%) were located in Illinois. Only 5 of those 8 patients were exposed to paroxetine, and only 3 of the paroxetine-

exposed Illinois-based patients completed the study (approximately 0.3% of the total patient population).

d. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women planning to become pregnant during the trial were excluded from the study. Additionally, in order to be considered for inclusion in the study, the woman must establish use of an adequate non-hormonal form of contraception.

26. I reviewed the study report, dated July 9, 2004, for "An Open-label Study Assessing PAXIL CR (Paroxetine CR) in Patients with Major Depressive Disorder who Discontinued Treatment with Selective Serotonin Reuptake Inhibitors or a Selective Serotonin/ Norepinephrine Reuptake Inhibitor due to Intolerability" (Study 833) (attached hereto as Exhibit 17).

a. The objective of this study was to evaluate the safety and tolerability of paroxetine controlled-release in patients who stopped treatment with another SSRI or SNRI due to intolerance.

b. The study was conducted at 65 separate study sites in the United States. Only one site was located in Illinois.

c. Pursuant to the study protocol and consistent with accepted medical and scientific practice, pregnant women and women planning to become

pregnant during the course of the study were excluded from the study.

27. For the 14 clinical trials for which study reports or equivalent information were available (Studies 9, 115, 118, 352, 495, 190, 641, 642, 651, 704, 677, 689, 791, and 833), there were a total of 480 study sites across the trials. (Two studies (Study 127 and 711) were continuations or extensions of earlier studies discussed above and, thus, the study sites would already be counted as part of the sites of the initial studies.) Only 14 of those study sites (or approximately 3%) were located in Illinois.

28. Information regarding the total number of unique patients enrolled was available for 12 studies (studies 115, 118, 352, 495, 190, 641, 642, 651, 704, 677, 689, and 791). (Two studies (Study 127 and 711) were continuations or extensions of earlier studies discussed above and, thus, the patients would already be counted as part of the patient population of the initial studies.) Those 12 studies enrolled a total of 4,272 patients. Of those 4,272 patients, only 100 were located in Illinois, which accounts for approximately 2%.

29. Information regarding the number of patients located in Illinois who were randomized to or took paroxetine during the clinical trial was available for 11 studies (Studies 115, 118, 352, 495, 190, 641, 642, 651, 704, 677, and 689). Those 11 studies enrolled a total of 3,937 patients. Of those 3,937 patients, only 42 were

located in Illinois and exposed to paroxetine, which accounts for approximately 1%.

30. I have reviewed the GSK Clinical Study Register (www.gsk-clinicalstudyregister.com), which provides data from GSK-sponsored clinical studies. The Clinical Study Register includes 361 clinical trials conducted for paroxetine. Only 17 of those 361 studies (or approximately 5%) included a study site in Illinois.

31. The clinical trials relating to Paxil cannot and did not contribute any information as to the risks of birth defects and the use of Paxil.

32. Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statement set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that he verily believes to be true.

Signed this 16th day of December, 2014.

/s/Kalpesh Joshi
Kalpesh Joshi