Nos. 19-368 & 19-369

IN THE
Supreme Court of the United States

FORD MOTOR COMPANY,
Petitioner,
v.
MONTANA EIGHTH JUDICIAL DISTRICT COURT, ET AL.,
Respondents.

FORD MOTOR COMPANY,
Petitioner,
v.
ADAM BANDEMER,
Respondent.

On Writs of Certiorari to the Supreme Courts of Montana and Minnesota

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA
950 F Street, N.W.
Washington, D.C. 20004
(202) 835-3400

VIRGINIA A. SEITZ*
JONATHAN F. COHN
ERIKA L. MALEY
DANIEL J. HAY
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
vseitz@sidley.com

ALAN E. ROTHMAN
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Counsel for Amici Curiae
*Counsel of Record

March 6, 2020

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page

TABLE OF AUTHORITIES—continued

TABLE OF AUTHORITIES—continued

STATUTE

SCHOLARLY AUTHORITIES

TABLE OF AUTHORITIES—continued

OTHER AUTHORITIES Page

TABLE OF AUTHORITIES—continued

INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate public policies encouraging the discovery of life-saving and life-enhancing new medicines. PhRMA's members are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than $900 billion in the search for new treatments and cures, including an estimated $79.6 billion in 2018 alone. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as *amicus* in cases raising matters of significance to its members, including cases before this Court.

PhRMA and its members have a strong interest in the development of uniform, clear, and predictable standards for personal jurisdiction that comport with due process, interstate federalism, and fundamental fairness. The question presented in these cases is critically important to PhRMA's members because they, like the Petitioner, offer products nationwide and are frequently subject to claims of personal injury arising from the use of those products. In the absence of clear

---

[1] Petitioner (Ford) has submitted to the Clerk a letter granting blanket consent to the filing of amicus briefs, and counsel for Respondents has consented in writing to PhRMA's participation as amicus. Pursuant to Rule 37.6, PhRMA states that no counsel for a party authored this brief in whole or part, and that no person other than PhRMA, its members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

rules from this Court defining when a state court may exercise specific personal jurisdiction over out-of-state defendants, PhRMA members increasingly find themselves subject to litigation in jurisdictions that have no material connection to the dispute and where the PhRMA member is in no sense "at home." Unduly expansive interpretations of personal jurisdiction adopted by some courts have led to widespread forum shopping and have distorted the development of product liability doctrines.

PhRMA therefore urges the Court to reverse the judgments below, and to articulate a clear standard for when a plaintiff's claim arises out of or relates to a defendant's forum contacts for purposes of specific personal jurisdiction. This Court should resolve the split in the lower courts by holding, consistent with its precedents and fundamental principles of due process, that a claim arises out of or relates to a defendant's forum contacts only if those contacts have a material link to the specific claims asserted against the defendant.

SUMMARY OF ARGUMENT

It has "long been established that the Fourteenth Amendment limits the personal jurisdiction of state courts." *Bristol-Myers Squibb Co.* v. *Superior Court*, 137 S. Ct. 1773, 1779 (2017). The Due Process Clause permits courts to "expose[ ] defendants to the State's coercive power" only when doing so is fair and reasonable in light of "the defendant's relationship to the forum State" and the "specific claims at issue." *Id.* This Court has revisited this issue numerous times in recent years, including to correct lower court decisions that both "elided the essential difference between case-specific and all-purpose (general) jurisdiction," *Goodyear Dunlop Tires Operations, S.A.* v. *Brown*, 564 U.S. 915, 927 (2011), and created a "loose and spurious form

of general jurisdiction," *Bristol-Myers*, 137 S. Ct. at 1781.

In numerous contexts, however, these prior decisions have failed to solve the problem of overly capacious rulings on personal jurisdiction that far exceed constitutional limits. After this Court's clarification of the appropriately limited role of general jurisdiction, see *Goodyear*, 564 U.S. at 927; *Daimler AG* v. *Bauman*, 134 S. Ct. 746 (2014), most of the current problematic rulings have involved specific jurisdiction. Adopting a "lenient" and "flexible" standard, *M.M. ex rel. Meyers* v. *GlaxoSmithKline LLC*, 61 N.E.3d 1026, 1033 (Ill. App. Ct. 2016), some courts have improperly expanded the scope of specific jurisdiction to essentially re-create the "doing business" approach that this Court has disapproved numerous times in its general jurisdiction decisions, see *Daimler*, 134 S. Ct. at 760–61. Under these decisions, a company that operates nationwide can be haled into virtually any court on virtually any claim.

This phenomenon is of particular concern to PhRMA's members, who test and market drugs and medical devices nationwide. Despite this Court's decision in *Bristol-Myers*, plaintiffs' counsel have been permitted to take advantage of "lenient" personal jurisdiction tests to engage in extensive forum shopping, channeling plaintiffs from all over the country into a few preferred fora that they perceive as unusually hospitable to product liability suits. To keep their cases in these fora that are magnets for mass litigation, plaintiffs' counsel assert specific jurisdiction based on defendant contacts that have either no connection or only a highly attenuated "but-for" connection to the claims at issue.

For example, plaintiffs have asserted specific jurisdiction over PhRMA members based on the fact that a

product was bottled in a certain state, even though the bottling has no relevance to the claims asserted. See, *e.g.*, *Forrest* v. *Johnson & Johnson*, No. 1522-CC00419-01 (Mo. Cir. Ct. Oct. 15, 2018). More commonly, plaintiffs assert specific jurisdiction based on the fact that the state hosted a clinical trial site for a drug or medical device, on the theory that clinical trials are necessary for FDA approval and are therefore a "but-for" cause of any injuries associated with a product. But clinical trial sites are ordinarily spread throughout dozens of states (sometimes all 50) to provide FDA with the robust data necessary to support approval of pharmaceutical products. See pp. 10–16, *infra*. Thus, in practice, allowing personal jurisdiction over claims involving drugs or devices based on clinical trials in the state gives numerous states specific jurisdiction over *any* product liability claim by any out-of-state plaintiff, including those alleging injury out-of-state. Such lax standards place no meaningful limits on the exercise of personal jurisdiction.

Put differently, there is nothing "specific" about a theory of personal jurisdiction that countenances virtually any product liability claim by any plaintiff being brought in nearly any state. The Court should resolve the split in the lower courts and disapprove the unduly lax standards that effectively allow nationwide personal jurisdiction. The Court should clarify that specific jurisdiction requires the defendant's forum contacts to have a material link to each plaintiff's specific claims against that defendant, and reject the "but-for" causation standard recognized by some courts.

ARGUMENT

I. REQUIRING NO CAUSAL CONNECTION OR A MERE BUT-FOR CAUSAL CONNECTION IS INCONSISTENT WITH DUE PROCESS AND THIS COURT'S PRECEDENTS.

A. The Court Should Resolve What Type Of Connection Is Necessary To Support The Exercise Of Specific Personal Jurisdiction, And Reject The But-For Causation Standard.

1. For the sixth time in nine years, this Court is addressing whether a state court properly exercised personal jurisdiction over an out-of-state defendant when the defendant's contacts with the forum state have no or minimal relevance to the plaintiff's claim. See *Bristol-Myers*, 137 S. Ct. 1773; *BNSF Ry.* v. *Tyrrell*, 137 S. Ct. 1549, 1558–59 (2017); *Walden* v. *Fiore*, 134 S. Ct. 1115 (2014); *Goodyear*, 564 U.S. 915; *J. McIntyre Mach., Ltd.* v. *Nicastro*, 564 U.S. 873 (2011) (plurality opinion).

Here, as in those prior cases, this Court should hold that the lower courts lacked personal jurisdiction. For the reasons Ford explains in its opening brief, the lower courts' rulings that specific jurisdiction exists even though none of the defendant's forum contacts had any connection to the plaintiffs' claims are plainly incorrect. The Court should therefore reverse the decisions below.

The Court should also resolve "exactly how a defendant's activities must be tied to the forum for a court to properly exercise specific personal jurisdiction over a defendant." *SPV Osus Ltd.* v. *UBS AG*, 882 F.3d 333, 344 (2d Cir. 2018). The need for clear guidance on when "the plaintiff's claim … 'arise[s] out of or re-

late[s] to' the defendant's forum conduct," *Bristol-Myers*, 137 S. Ct. at 1786 (quoting *Helicopteros Nacionales de Colombia, S.A.* v. *Hall*, 466 U.S. 408, 414 (1984)), has become particularly acute since this Court's recent rulings on general jurisdiction. This Court made clear that general jurisdiction is not a license to sue companies in any state where they conduct "continuous and systematic" business. *Goodyear*, 564 U.S. at 923; see *id.* at 927. Rather, general jurisdiction exists only in states where the corporation is truly "at home"—except in unusual circumstances, only the states where it is incorporated and maintains its principal place of business. See, *e.g.*, *BNSF Ry.*, 137 S. Ct. at 1558–59. "A corporation that operates in many places can scarcely be deemed at home in all of them," *Daimler*, 134 S. Ct. at 762 n.20, and substantial business operations in a state are therefore insufficient "to support the demand that the corporation be amenable to suits unrelated to that activity," *Goodyear*, 564 U.S. at 927 (quoting *Int'l Shoe Co.* v. *Washington*, 326 U.S. 310, 318 (1945)).

Once the contours of general jurisdiction were clearly defined, plaintiffs shifted their focus to specific jurisdiction, seeking interpretations that would be sufficiently capacious to lead to the same result as the discredited general jurisdiction standard: the ability to sue corporations that operate nationwide in virtually any state on virtually any claim. In *Bristol-Myers*, this Court rejected one such tactic, a "sliding scale approach" under which "the strength of the requisite connection between the forum and the specific claims at issue is relaxed if the defendant has extensive forum contacts that are unrelated to those claims," deeming it a "loose and spurious form of general jurisdiction." 137 S. Ct. at 1781.

Since *Bristol-Myer*s's holding that the sliding scale approach is invalid, plaintiffs now use a different approach to achieve the same result. They argue that the "arise from or relate to" standard should be interpreted so broadly that virtually any forum contact—no matter how distant the "relationship"—will satisfy it. See § I.B, *infra*. In the cases below, the lower courts held that the "arise from or relate to" standard requires no causal connection at all between the plaintiffs' claim and the defendants' forum contacts. See *Bandemer* Pet. App. 15a ("[W]e decline to adopt Ford's causal standard."); *Gullett* Pet. App. 16a–20a (similar). PhRMA respectfully urges the Court not only to reject this approach, but also to define the nature of the required connection and provide the lower courts with additional guidance about its meaning. As Ford's Petitions for Certiorari explained, the lower courts are currently split as to both whether a causal connection is required at all, and the nature of any causal requirement. See *Bandemer* Pet. 11–18; *Gullett* Pet. 10–17. Holding only that *some* causal connection is needed will not resolve the split or provide acutely needed guidance to the lower courts.

2. PhRMA submits that this Court should again hold that specific personal jurisdiction exists only where the defendant's forum contacts are "the subject matter of the case" or are part of "the operative facts of" the plaintiff's claims. *Rush* v. *Savchuk*, 444 U.S. 320, 329 (1980). The Court should disapprove of far laxer standards requiring the plaintiff to show only "that he would not have suffered an injury 'but for' [the defendant's] forum-related conduct." *Menken* v. *Emm*, 503 F.3d 1050, 1058 (9th Cir. 2007). Due Process requires a closer relationship—that the defendant's forum contacts are materially linked to the plaintiff's specific

claims. Some courts have called this standard a "proximate cause," *Harlow* v. *Children's Hosp.*, 432 F.3d 50, 60–61 (1st Cir. 2005), or "legal cause" relationship, *Keller* v. *Henderson*, 834 N.E.2d 930, 939 (Ill. App. Ct. 2005). At the least, the Court should clarify that specific personal jurisdiction requires a "closer and more direct" relationship between the defendant's forum contacts and the plaintiff's claim than an untrammeled "but-for" causation test. *O'Connor* v. *Sandy Lane Hotel Co.*, 496 F.3d 312, 323 (3d Cir. 2007).

A mere "but-for" causation standard, without regard to whether there is a material link to the plaintiff's claims, imposes no meaningful limitations on courts' exercise of jurisdiction. But-for causation "embraces every event that hindsight can logically identify in the causative chain." *GCIU-Emp'r Ret. Fund* v. *Goldfarb Corp.*, 565 F.3d 1018, 1025 (7th Cir. 2009) (quoting *O'Connor*, 496 F.3d at 322). Without further limits, a but-for causation standard would subject defendants to perpetual *specific* jurisdiction in locations with no connection at all to the suit. For instance, "if the defendant is a lawyer who has received his or her legal education in the forum, that legal education may be said to be a 'but for' cause of any malpractice the lawyer commits anywhere in the nation." *Vons Cos.* v. *Seabest Foods, Inc.*, 926 P.2d 1085, 1106–07 (Cal. 1996). Indeed, on the same reasoning, the lawyer could also be subject to perpetual specific jurisdiction in the states where she attended high school and college, because those degrees were prerequisites to her legal education. See *Davis* v. *Baylor Univ.*, 976 S.W.2d 5, 8–9 (Mo. Ct. App. 1998) ("[A] defendant's birth is a historical but for cause of his subsequent tortious conduct, yet the location of one's birth normally should not determine personal jurisdiction."); Lea Brilmayer, *A General Look at Specific Jurisdiction*, 42 Yale J. Int'l

L. Online 1, 9–10 (2017) [hereinafter, Brilmayer, *A General Look*]. And for PhRMA's members, a but-for causation standard means that the manufacturer of a drug or device approved after clinical trials in 40 states can be sued in any of those 40 states for any claim regarding that drug or device by out-of-state plaintiffs who learned about, were prescribed, purchased, used, and were allegedly injured by the drug or device out-of-state under a theory that, but for the clinical testing, the drug or device would not have been approved. See pp. 10–16, *infra*.

Thus, a but-for causation standard fails to limit the degree of permissible attenuation between the claim and the forum, and is clearly insufficient to ensure that "the defendant's suit-related conduct … create[s] a substantial connection with the forum State." *Walden*, 134 S. Ct. at 1121. As the Seventh Circuit put it, "[m]aybe if Columbus hadn't discovered America the federal courts of appeals would not have been created in 1891; but it would be odd to say that the federal appellate judiciary 'arose from' Columbus's voyages." *James River Ins. Co.* v. *Kemper Cas. Ins. Co.*, 585 F.3d 382, 386 (7th Cir. 2009); accord William L. Prosser, *The Law of Torts* 236 (4th ed. 1971) ("[T]he consequences of an act go forward to eternity, and the causes of an event go back to the discovery of America and beyond. 'The fatal trespass done by Eve was cause of all our woe.'"). This Court should reject an unrestricted "but-for" causation standard for specific personal jurisdiction.

B. An Untrammeled But-For Causation Standard Is Especially Problematic In Cases Involving Pharmaceutical Products.

The dangers of an expansive specific jurisdiction standard are far from hypothetical. Numerous rulings

in recent years have found specific personal jurisdiction based on defendant contacts with a forum with either no causal connection to the plaintiff's claims, or at most, a highly attenuated "but-for" connection. The resulting problems have been particularly acute for the pharmaceutical industry. PhRMA members are forced to defend suits in states where neither the defendants nor the plaintiffs reside, and where none of the events at issue in the suit occurred. Instead, plaintiffs choose fora based on the fora's perceived hospitality to nationwide mass tort litigation. Plaintiffs then attempt to justify personal jurisdiction by asserting that a fact immaterial to the underlying claims is somehow "related to" or a factual "but-for cause" of the plaintiffs' alleged injuries.

As previously noted, in many cases, the asserted jurisdictional hook is that a clinical trial site for the product at issue was located in the forum state. Plaintiffs assert that their "injuries would not have occurred but for [the manufacturer's] contacts with [the state] because the … clinical trials conducted here were part of the unbroken chain of events leading to Plaintiff's alleged injury." *Cortina* v. *Bristol-Myers Squibb Co.*, No. 17-cv-00247-JST, 2017 WL 2793808, at *3 (N.D. Cal. June 27, 2017). Several courts have accepted this theory, on the ground that, "if the drug at issue had never been developed, tested, or approved, Plaintiff would not have been harmed by it." *Id.*; see *Dubose* v. *Bristol-Myers Squibb Co.*, No. 17-cv-00244-JST, 2017 WL 2775034, at *3 (N.D. Cal. June 27, 2017) (same).

For instance, the Illinois Court of Appeals has held that clinical trial sites in Illinois provide specific personal jurisdiction over a non-resident defendant for the claims of non-resident plaintiffs injured nationwide because the "Illinois data was aggregated with

the data from the other study locations" and "inform[ed] the warning label content for [the drug], upon which the out-of-state plaintiff mothers relied in making their decision to take the drug." *M.M.*, 61 N.E.3d at 1038; accord *Hamby* v. *Bayer Corp.*, 2019 IL App (5th) 180279-U, ¶ 23 (similar), *appeal allowed*, 132 N.E.3d 341 (Ill. 2019); see also, *e.g.*, *In re Pelvic Mesh Litig.*, No. 652 EDA 2018, 2019 WL 1486697, at *6 (Pa. Super. Ct. Apr. 3, 2019) (similar). To be clear, plaintiffs in these cases do not claim that they participated in the clinical trial themselves, or that their claims somehow directly arose from in-state clinical trial sites. Rather, courts found that specific personal jurisdiction existed because clinical trials generally were a "but-for" cause of the products being approved, and the approval in turn was a "but-for" cause of the plaintiffs taking the product that allegedly injured them.

Other courts have correctly rejected this same theory "that specific jurisdiction exists because [a product] could not have been approved without clinical trials, and some of those clinical trials occurred in" the forum state. *Dyson* v. *Bayer Corp.*, No. 4:17CV2584 SNLJ, 2018 WL 534375, at *5 (E.D. Mo. Jan. 24, 2018). These courts have rightly recognized that "clinical trials … are simply too attenuated [from plaintiffs' claims] to serve as a basis for specific personal jurisdiction," and are not "an 'adequate link' between [the state] and nonresidents' claims that their individual device injured them in another state." *Id.*; see *Roland* v. *Janssen Research & Dev., LLC*, No. 3:17-cv-00757-DRH, 2017 WL 4224037, at *4 (S.D. Ill. Sept. 22, 2017) (similar), *appeal dismissed*, No. 17-3205 (7th Cir. Nov. 21, 2017).

Indeed, recognizing specific personal jurisdiction wherever a clinical trial site was located fails to put any meaningful limits on the reach of state courts.

Multicenter clinical trials are an essential part of modern drug and device development. Clinical trials by nature must be spread across many states, and it is not unusual for dozens of states to host clinical trial sites for a single pharmaceutical product. By design, clinical trials often involve hundreds or even thousands of patients spread out across the country, and many FDA approvals involve multiple rounds of clinical testing. See, *e.g.*, Aaron V. Kaplan et al., *Medical Device Development: From Prototype to Regulatory Approval*, 109 Circulation 3068, 3070 (2004) ("[P]ivotal trials may require enrollment of 1000 or more patients at 30 to 50 sites ….").

FDA has encouraged the use of such multicenter clinical trials because they are "less vulnerable to certain biases, are often more generalizable, may achieve very convincing statistical results, and can often be evaluated for internal consistency across subgroups, centers, and multiple endpoints."[2] An individual clinical trial site may draw from a population with particular socioeconomic, lifestyle, or other demographic characteristics that could raise questions about whether the outcome would be the same in a more diverse population. If subjects are enrolled at many sites in many locations across the country and around the globe, the results are more likely to support conclusions about the effect of the treatment in the general population. See Lawrence M. Friedman et al., *Multicenter Trials*, *in* FUNDAMENTALS OF CLINICAL TRIALS 501 (5th ed. 2015). The risk of data being distorted by

---

[2] Ctr. for Drug Evaluation & Research, Ctr. for Biologics Evaluation & Research, U.S. Food & Drug Admin, *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* 12 (May 1998), https://www.fda.gov/media/71655/download.

unintended bias at any particular trial site is also reduced. And drawing on a broader population can facilitate the enrollment of subjects from previously underrepresented demographic subgroups, which is important to FDA for both scientific and social justice reasons.[3] Dispersing clinical trials nationwide is therefore best practice because, as FDA has recently stated, "[m]edical products are safer and more effective for everyone when clinical research includes diverse populations."[4]

Geographically diverse clinical trials are also essential in the treatment of rare diseases, where there may be only a handful of affected patients in any given state. When relatively few patients suffer from a condition, geographic dispersion of clinical trial centers may be important to ensure adequate enrollment and timely completion of studies. See, *e.g.*, Erika F. Augustine et al., *Clinical Trials in Rare Disease: Challenges and Opportunities*, 28 J. Child Neurology 1142 (2013). And those same patients, because of their rare disease, may be less able to travel to a hospital in another state for treatment.

Accordingly, it is unsurprising that the biopharmaceutical industry sponsors clinical trials in every state in the Union. In a recent study, PhRMA identified 6,199 industry-sponsored clinical trials active in the

---

[3] John J. Whyte, *An FDA Perspective on Patient Diversity in Clinical Trials*, Clinical Leader (Apr. 19, 2017), https://www.clinicalleader.com/doc/an-fda-perspective-on-patient-diversity-in-clinical-trials-0001.

[4] U.S. Food & Drug Admin., *Diversity in Clinical Trial Participation*, https://www.fda.gov/patients/clinical-trials-what-patients-need-know/diversity-clinical-trial-participation (last updated Aug. 14, 2018).

United States in 2013 alone, with 1.1 million subjects at sites spread across all 50 states and the District of Columbia.[5] Forty-two states had more than 200 clinical trial sites active that year, and several states were hosting 2,000 or more active sites.[6]

Pharmaceutical companies are also frequently and inevitably sued as defendants in product liability cases. FDA's approval reflects a judgment that the drug's anticipated benefits "outweigh their known risks" for the population as a whole,[7] but those risks nonetheless are real and can never be wholly eliminated. Pharmaceutical companies are thus routinely subject to litigation involving drugs that FDA has approved based upon data collected from multicenter clinical trials with sites all over the country. Thus, the upshot of a "but-for" causation test accepting clinical trial sites as a sufficient predicate for specific personal jurisdiction is that a drug or device manufacturer can be sued on virtually any product liability claim in virtually any state. See *Cortina*, 2017 WL 2793808, at *4 ("Defendants contend that application of the 'but for' test in multi-center clinical trials in multiple jurisdictions might have the effect of creating specific jurisdiction in courts in numerous states. *So it might* ….") (emphasis added).

---

[5] Battelle Tech. P'ship Practice, PhRMA, *Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies* 4, 12 (Mar. 2015), http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf.

[6] *Id.* at i, 11–12 & tbl.5.

[7] *See* U.S. Food & Drug Admin., *Development and Approval Process (Drugs)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited Mar. 3, 2020).

The cases where courts have exercised specific jurisdiction based on in-state clinical trial sites illustrate this point. In those cases, the clinical trial sites, consistent with the normal practice, were widespread and geographically dispersed. Thus, the lower courts exercised specific personal jurisdiction even though an identical argument could have been made that specific personal jurisdiction over the same plaintiff's claim existed in dozens of other states based on clinical trial sites in those states. See, *e.g.*, *M.M.*, 61 N.E. 3d at 1033, 1040–41 ("Paxil clinical trials took place in 44 states and abroad."); Reply in Support of Motion to Dismiss at 1–2, *Cortina*, 2017 WL 2793808 (No. 17-cv-00247-JST) (clinical trials took place "in 40 other states"); *Hamby*, 2019 IL App (5th) 180279-U ¶ 20 (plaintiffs alleged that Illinois was "one of eight states in which" one of numerous clinical trials for the product were performed). Thus, plaintiffs' lawyers can use these boundless jurisdictional standards to draw cases into magnet jurisdictions perceived to be plaintiff-friendly. The only way for defendants to avoid being subject to suit on all claims concerning a product in such jurisdictions would be to exclude them from its clinical trials. But excluding states from clinical trials for jurisdictional reasons is clearly undesirable for scientific integrity, medical progress, and patient health. Many factors affect the decisions of where to locate the sites for multicenter clinical trials, but avoiding litigation risk should not be one of them.

The presence of clinical trial sites is not the only attenuated hook for personal jurisdiction that certain courts have allowed in recent years. Plaintiffs' counsel have treated this Court's statement in the factual description of *Bristol-Myers* that "BMS did not develop, create a marketing strategy for, manufacture, label, package, or work on the regulatory approval for Plavix

in [California]" as a "blueprint for establishing personal jurisdiction." *Dyson*, 2018 WL 534375, at *4 (alteration in original). Following this erroneous blueprint, some courts have held that specific personal jurisdiction exists whenever a drug or device maker allegedly developed a "marketing strategy" or otherwise "work[ed] on the regulatory approval of the product" in the forum state. See, *e.g.*, *Hamby*, 2019 IL App. (5th) 180279-U ¶¶ 22–23; *Forrest*, No. 1522-CC00419-01, *supra*. This exceedingly expansive approach again leads to essentially nationwide specific jurisdiction for any claim concerning a pharmaceutical product, because information from every state where a product is sold impacts the manufacturer's marketing strategy, and is significant for obtaining and maintaining regulatory approval. Accordingly, plaintiffs often cut and paste virtually identical jurisdictional allegations to support claims by non-resident plaintiffs against non-resident defendants in numerous different states.[8]

Other cases have found personal jurisdiction based on contacts with suppliers in the forum, even though those contacts have no relation to the substantive claims. For example, in product liability litigation concerning talcum powder, state courts in Missouri have

---

[8] *See Hamby*, 2019 IL App (5th) 180279-U, ¶¶ 6, 22–23 ("Defendants created … the marketing strategy for Essure in Illinois."); *Jordan* v. *Bayer Corp.*, No. 4:17-cv-00865-AGF, 2018 WL 837700, at *4 (E.D. Mo. Feb. 13, 2018) (plaintiffs alleged that "Bayer used Missouri as 'ground zero' for its national campaign" of marketing for Essure); Complaint ¶¶ 117–18, *Leach* v. *Bayer Corp.*, No. 49D14-1803-CT-012218 (Ind. Super. Ct. Mar. 28, 2018) ("Bayer used Indiana to … create a marketing strategy for … Essure …."); Complaint ¶¶ 92–93, *Vasquez* v. *Bayer Corp.*, No. GD-18-002824 (Pa. Ct. Com. Pl. Feb. 28, 2018) ("[Bayer] used Pittsburgh, Pennsylvania to … create a marketing strategy for … Essure …."). In each of these cases, plaintiffs also alleged specific jurisdiction existed based on in-state clinical trial sites.

found specific jurisdiction based on an out-of-state defendant's contract with a Missouri company to bottle and label the product, even though the bottling and labeling was immaterial to the actual claims asserted. See, *e.g.*, *Forrest*, No. 1522-CC00419-01, *supra*. Likewise, in litigation concerning pelvic mesh, state courts in Pennsylvania have held that personal jurisdiction exists because the mesh was woven in Pennsylvania, even though the claims are not related to the weaving process. See *In re Pelvic Mesh Litig.*, 2019 WL 1486697, at *5–6; *Carlino* v. *Ethicon, Inc.*, 208 A.3d 92, 102 (Pa. Super. Ct. 2019); *Hammons* v. *Ethicon, Inc.*, 190 A.3d 1248, 1263 (Pa. Super. Ct. 2018), *appeal granted in part*, 206 A.3d 495 (Pa. 2019).

As these examples demonstrate, if plaintiffs can sue in any state where they can identify some link to a particular product, or some link in an alleged "but-for" causal chain, then many defendants, particularly in the pharmaceutical industry, will be subject to effectively all-purpose jurisdiction in any state court. This allows plaintiffs to engage in unlimited forum shopping and denies PhRMA's members the fair and orderly administration of the law.

II. DUE PROCESS REQUIRES THAT THE DEFENDANT'S FORUM CONTACTS HAVE A MATERIAL LINK TO THE PLAINTIFF'S SPECIFIC CLAIMS.

The Court should clarify that a suit "aris[es] out of or relat[es] to the defendant's contacts with the forum," *Bristol-Myers*, 137 S. Ct. at 1780, when those contacts have a material link to the plaintiff's specific claims against the defendant. A number of jurisdictions have adopted this standard, which is sometimes called the "proximate cause" or "legal cause" test. See *Harlow*, 432 F.3d at 60–61; *Beydoun* v. *Wataniya*

Rests. Holding, Q.S.C., 768 F.3d 499, 507–08 (6th Cir. 2014); *Keller*, 834 N.E.2d at 939.

This standard is rooted in the very nature of specific jurisdiction. The Court has often referred to specific jurisdiction as "case-linked" jurisdiction, because its exercise is dependent on an "affiliatio[n] between the forum and the underlying controversy, principally, an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation." *Goodyear*, 564 U.S. at 919 (alteration in original) (quoting Arthur T. von Mehren & Donald T. Trautman, *Jurisdiction to Adjudicate: A Suggested Analysis*, 79 Harv. L. Rev. 1121, 1136 (1966)); see generally Mary Twitchell, *The Myth of General Jurisdiction*, 101 Harv. L. Rev. 610 (1988) (describing general and specific jurisdiction as "dispute blind" and "dispute specific," respectively). And *Bristol-Myers* explained that "specific" or "case-linked" jurisdiction requires an "adequate link" between the defendant's forum contacts and the plaintiff's "specific claims." 137 S. Ct. at 1779–80, 1781–82. Thus, "[s]ubstantive relevance provides a natural test": the defendant's "contact is related to the controversy if it is the geographical qualification of a fact relevant to the merits." Lea Brilmayer, *How Contacts Count: Due Process Limitations on State Court Jurisdiction*, 1980 Sup. Ct. Rev. 77, 82. By contrast, any "purely jurisdictional allegation with no substantive purpose" should be disregarded. *Id.*; accord Brilmayer, *A General Look*, *supra*, at 3 (specific personal jurisdiction obtains where "the defendant's forum activities … somehow *contributed to* the plaintiff's claim").

Focusing the specific-jurisdiction inquiry on the facts that are material to the claim at issue aligns with another area of law with an "arising under" standard: federal-question jurisdiction. See 28 U.S.C. § 1331. To

determine whether a claim "aris[es] under the Constitution, laws, or treaties of the United States," *id.*, courts apply the well-pleaded complaint rule. See *Vaden* v. *Discover Bank*, 556 U.S. 49, 59–60 (2009). The well-pleaded complaint rule "stands for the proposition that the court … will look only to the claim itself and ignore any extraneous material." 13D Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 3566 (3d ed. Aug. 2019 update). Thus, "a plaintiff cannot gain admission" to federal court "by allegations to support his own case" that lack a material link to his claim. *Id.* For personal jurisdiction, just as for federal-question jurisdiction, such a standard would serve as an easily administrable "bright-line test," *id.*, that "makes sense as a quick rule of thumb," *Franchise Tax Bd.* v. *Constr. Laborers Vacation Tr. for S. Cal.*, 463 U.S. 1, 11 (1983). The facts relevant to specific jurisdiction are the facts that the plaintiff must allege in a complaint and prove at trial to prevail on the specific claim at issue, while any extraneous facts alleged as jurisdictional hooks should be disregarded.

Under this approach, specific jurisdiction will turn—as it should—on "the specific claims at issue," *Bristol-Myers*, 137 S. Ct. at 1781. It will not turn on extraneous features of the defendant or its products. For instance, if a plaintiff were allegedly injured in a clinical trial that the defendant conducted in Madison County, Illinois, then the conduct of the clinical trial would be material to the suit, and its location should be considered in assessing personal jurisdiction. But if a plaintiff were injured in Arizona by a drug that she contends the defendant defectively manufactured in New Jersey, then the fact that clinical trial sites for the drug were in Illinois (along with 40 other states) has no relevance to her claim, and therefore should have

no relevance to the specific personal jurisdiction analysis. That the clinical trials could be described as a "but-for" cause of the plaintiff's injuries in some attenuated way should be insufficient.

Grounding specific personal jurisdiction in what must be pleaded to make out the plaintiff's specific claim provides parties with certainty and predictability, and will reduce the number of cases requiring burdensome and invasive jurisdictional discovery. More importantly, this rule directly links the bases for a court's specific jurisdiction with the nature of the specific claim asserted, which is exactly the function that specific personal jurisdiction is supposed to perform. See *Bristol-Myers*, 137 S. Ct. at 1781 (For "case-linked" jurisdiction, "[w]hat is needed—and what is missing here—is a connection between the forum and the specific claims at issue."); Lea Brilmayer, *Related Contacts and Personal Jurisdiction*, 101 Harv. L. Rev. 1444, 1458 (1988) ("[T]he fact that some activity must be pleaded and proven matters, not because pleading itself is important, but because the fact that the activity must be pleaded and proven reflects concerns of substantive law.").

This Court used a similar concept to explain the contours of specific personal jurisdiction in *Rush*, which (like the cases on petition here) involved a car accident. The accident at issue occurred in Indiana, but the plaintiff brought his lawsuit in Minnesota to circumvent an Indiana law that would have barred his lawsuit. 444 U.S. at 322. The plaintiff asserted that jurisdiction was proper because the defendant's insurance company allegedly had connections with the state. *Id.* The Court rejected that theory, on the grounds that the insurance policy "is not *the subject matter of the case* … nor is it *related to the operative facts* of the negligence action." *Id.* at 329 (emphases

added). Specific jurisdiction should turn upon the specific claims at issue.

Finally, clearly limiting states' authority over out-of-state defendants to cases where the defendant's operative conduct is "subject to the State's regulation," *Goodyear*, 564 U.S. at 919, comports with the principles of interstate federalism. From its earliest days, the doctrine of specific personal jurisdiction has been molded by "the context of our federal system of government." See *Int'l Shoe*, 326 U.S. at 316–17; see also, *e.g.*, *Hanson* v. *Denckla*, 357 U.S. 235, 251 (1958) (specific personal jurisdiction is "a consequence of territorial limitations on the power of the respective States"). "[T]he States retain many essential attributes of sovereignty, including, in particular, the sovereign power to try causes in their courts." *Bristol-Myers*, 137 S. Ct. at 1780 (alteration in original) (quoting *World-Wide Volkswagen Corp.* v. *Woodson*, 444 U.S. 286, 293 (1980)). This "sovereignty of each State ... implie[s] a limitation on the sovereignty of all its sister States." *Id.* Indeterminate and unduly lax standards for specific personal jurisdiction, such as the "but-for" causation standard applied by some jurisdictions, lead to defendants "submitting to the coercive power of a State that may have little legitimate interest in the claims in question." *Id.* Clearly defining specific personal jurisdiction as existing only where the defendant's forum contacts are materially linked to the plaintiff's specific claim against that defendant properly aligns with states' legitimate authority to regulate activities within their borders. See Brilmayer, *A General Look*, *supra*, at 13–14.

CONCLUSION

For these reasons and those in Petitioner's briefs, the Court should reverse the judgments of the Supreme Court of Minnesota and Supreme Court of Montana.

Respectfully submitted,

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA
950 F Street, N.W.
Washington, D.C. 20004
(202) 835-3400

VIRGINIA A. SEITZ*
JONATHAN F. COHN
ERIKA L. MALEY
DANIEL J. HAY
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000
vseitz@sidley.com

ALAN E. ROTHMAN
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Counsel for Amici Curiae

*Counsel of Record

March 6, 2020