No. 16-1171

IN THE

Supreme Court of the United States

GLAXOSMITHKLINE LLC,
Petitioner,

v.

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

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington DC 20004
(202) 835-3559

MARK HADDAD*
ALYCIA DEGEN
NAOMI IGRA
SIDLEY AUSTIN LLP
555 West Fifth Street
Los Angeles, CA 90013
(213) 896-6604
mhaddad@sidley.com

Counsel for Amicus Curiae
* Counsel of Record
[Additional Counsel Listed on Inside Cover]

April 27, 2017

CARTER G. PHILLIPS
REBECCA K. WOOD
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES Page

STATUTE

OTHER AUTHORITIES

TABLE OF AUTHORITIES – continued

TABLE OF AUTHORITIES – continued

INTEREST OF *AMICUS*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing medicines that help patients lead longer, healthier, and more productive lives. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates as *amicus* in cases, including by filing *amicus curiae* briefs with this Court in cases raising matters of significance to its members.

PhRMA filed an *amicus curiae* brief in support of the petitioner in *Bristol-Myers Squibb Co.* v. *Superior Court of California*, No. 16-466 ("*BMS*"). *BMS* asks whether a court may assert specific jurisdiction if "there is no causal link" between the defendant's forum contacts and the plaintiff's claims. The decision below illustrates that if this Court holds that a causal link is necessary, but provides no additional guidance about the nature of the causal link required, PhRMA's members will remain exposed to unconstitutionally expansive assertions of personal jurisdiction by state courts.

The question presented here is critically important to PhRMA's members because they, like petitioner

---

[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No one other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Letters from the parties consenting to the filing of *amicus curiae* briefs have been filed with the Clerk of the Court.

GlaxoSmithKline LLC, sponsor multicenter clinical trials, nationally and internationally, and are frequently subject to claims many years later that arise from the use of products that FDA approved, in part, on the basis of data collected across those trials. Individual sites that participate in multicenter clinical trials do not design their own research; instead, each is contractually bound to follow a single and detailed trial protocol. Under the standard applied below, PhRMA's members would effectively become subject to suit in every state for conducting multicenter clinical trials, even in the absence of facts that meaningfully connect the activities at one trial site in the chosen forum state with the plaintiff's out-of-state injury. The resulting litigation risks and burdens add to the already-substantial challenges of sponsoring multicenter clinical trial programs. These programs are vitally important to ensuring both data integrity and access to innovative treatments; legal uncertainties that threaten them also threaten medical progress and patient health.

PhRMA agrees with Petitioner that this Court should resolve *BMS* by holding that a state court may assert specific jurisdiction over a nonresident defendant only if the defendant's in-state activities are a proximate cause of the plaintiff's injuries. If, however, this Court's decision in *BMS* does not explain the nature of the connection that specific jurisdiction requires between a defendant's in-state activities and the plaintiff's injuries, then the Court should grant GlaxoSmithKline's petition. The decision below illustrates that, in the absence of a clear standard that requires a meaningful causal connection between the plaintiff's claims and the defendant's in-state conduct, some lower courts will assert near-limitless authority over nonresident defendants with nationwide

activities, particularly in product liability cases that involve PhRMA's members. PhRMA therefore urges the Court to grant the petition and clarify that specific jurisdiction requires a meaningful link between a nonresident defendant's in-state conduct and a plaintiff's injuries.

INTRODUCTION

The Due Process Clause guarantees businesses with multistate activities a right to the "fair and orderly administration of the laws," *Int'l Shoe Co.* v. *Washington*, 326 U.S. 310, 319 (1945), and "fair warning" that particular activities will subject them to a forum's adjudicatory power, *Burger King Corp.* v. *Rudzewicz*, 471 U.S. 462, 472 (1985). As this Court recently held, the Due Process Clause limits where companies with widespread activities may be haled into court on the assertion of general jurisdiction. *Daimler AG* v. *Bauman*, 134 S. Ct. 746, 760-62 (2014); *Goodyear Dunlop Tires Operations*, *S.A.* v. *Brown*, 534 U.S. 915 (2011). But since *Goodyear* and *Daimler*, plaintiffs have urged courts to expand the scope of specific jurisdiction to recapture the same jurisdictional territory those decisions placed out of reach.

The decision below illustrates that courts with expansive views of their own authority assert "lenient" and "flexible" standards of specific jurisdiction to claim near-boundless jurisdiction over companies with nationwide product-related activities. Pet. App. 19. The underlying case involves product liability claims brought by eight pairs of mothers and children who allege that Paxil, once manufactured by out-of-state Defendant/Petitioner GlaxoSmithKline ("GSK"), caused birth defects. *Id.* at 87-91. Six of the eight pairs are out-of-state plaintiffs who did not allege that

their injuries were proximately caused by anything that occurred in Illinois. They were not prescribed Paxil in Illinois, they did not purchase or take Paxil in Illinois, and they did not suffer their alleged injuries in Illinois. *Id.* The only allegation in the complaint that refers to GSK's conduct in Illinois asserts that "GSK does business in, and derives substantial revenue from, Cook County, Illinois." *Id.* at 92.

Under *Daimler* and *Goodyear*, this allegation would not suffice to show that GSK is subject to the general jurisdiction of Illinois courts for all product liability claims filed by any plaintiff anywhere. But the lower court allowed plaintiffs here to obtain jurisdictional discovery, which showed that 17 out of the 361 clinical trials for Paxil included a trial site in Illinois. These 17 trials were multicenter clinical trials that took place, in total, across 45 states and several countries. Overall, Illinois' role in the clinical trial program was negligible; GSK calculated that a mere 0.15 percent of the clinical trial program for Paxil took place in Illinois. Pet. at 9. Plaintiffs also did not allege that any event that occurred uniquely at an Illinois trial site caused their injuries; instead, they challenged the adequacy of the Paxil clinical trial program as a whole.

Applying a "lenient" and "flexible" standard, the Illinois court held that because a "portion" of the clinical trials occurred in Illinois, and the data from those trials was "aggregated" with other trial data to support the FDA's approval to market Paxil, the court could assert specific jurisdiction over GSK as to all of the claims of all of the out-of-state plaintiffs. Pet. App. 20-22. Nothing in any of this Court's specific jurisdiction decisions would lead a defendant to anticipate that result. A standard for specific jurisdiction as flexible as the one applied below does not provide fair warning that nationwide activity of

this nature will result in the equivalent of general jurisdiction in any state in which that activity occurred. Such a standard encourages plaintiffs to forum-shop based on an attenuated connection between defendant's in-state conduct and plaintiffs' claims that does not meaningfully distinguish the forum state from any other state.

The question presented is particularly important for PhRMA's members. Like the petitioner, many research-based pharmaceutical and biotechnology companies engage in some standardized activities across the 50 states, and indeed, around the globe, to bring their products to market. According to the decision below, any portion of those activities that takes place in a state will provide a hook for a court to assert specific jurisdiction in any product liability case brought by any plaintiff anywhere, even if none of the events that are legally relevant to the plaintiffs' claims took place in that state. The decision thus renders the protections of *Daimler* and *Goodyear* a nullity for consumer product manufacturers.

The problem is particularly acute for PhRMA's members who routinely engage in multicenter clinical trials across the country to provide FDA with the robust data necessary to support marketing approval of their life-saving and life-enhancing drugs. For PhRMA's members, under the decision below, these activities could subject them to the equivalent of general jurisdiction in any state where, at some point in the development of their product, they had an individual clinical trial site. The decision below thus perpetuates the very unfairness and uncertainty the petitioner and *amici* described in *BMS*.

The detrimental effects of the decision below extend beyond the parties to any particular product liability case. Multicenter clinical trials with a wide geographic

footprint help speed enrollment, ensure data integrity, create opportunities to reach diverse populations, facilitate valuable subgroup analyses, and provide access to promising drugs for patients across the country who may have no approved treatment options. If the standard below prevails, clinical trial sponsors will face undue litigation risks and burdens whenever they authorize a clinical trial site in a state with courts that have an unduly expansive view of specific jurisdiction. If, as the decision below encourages, sponsors choose clinical trial sites based on litigation considerations rather than scientific ones, clinical trials could take longer to complete, the quality of research data could suffer, and the citizens of some states could be denied access to experimental treatments as well as the economic benefits that a clinical trial site in their state could bring.

The Court may well resolve this issue in *BMS*. If the Court does not provide the lower courts with the necessary guidance in that case, however, then the decision below provides an excellent vehicle to clarify the nature of the causal link required for specific personal jurisdiction. As PhRMA described in its *amicus* brief in *BMS*, thousands of claims by out-of-state plaintiffs against out-of-state pharmaceutical companies are pending in the lower courts. See Brief of PhRMA as *Amicus Curiae* In Support of Petitioner, *BMS*, No. 16-466. Plaintiffs in these cases could easily characterize their claims as causally connected to data generated in multicenter clinical trials that supported drug approval. Thus, to the extent *BMS* leaves open whether specific jurisdiction requires a meaningful causal connection between the out-of-state plaintiff's injuries and the defendant's in-state conduct, the Court should grant GSK's petition to resolve that question.

ARGUMENT

I. WHETHER SPECIFIC JURISDICTION REQUIRES A MEANINGFUL CAUSAL LINK BETWEEN A DEFENDANT'S IN-STATE CONDUCT AND AN OUT-OF-STATE PLAINTIFF'S INJURIES IS AN IMPORTANT AND RECURRING QUESTION.

A. The Decision Below Defies Constitutional Limits On Personal Jurisdiction.

This Court's precedents have recognized that the Due Process Clause places important limits on the assertion of personal jurisdiction over businesses with nationwide activities.

This Court's "pathmarking" decision in *International Shoe*, see *Goodyear*, 564 U.S. at 919, confirmed that nonresident corporations have a due process right to the "fair and orderly administration of the laws," *Int'l Shoe*, 326 U.S. at 319. At a minimum, due process demands that defendants receive "fair warning that a particular activity may subject [them] to the jurisdiction" of a forum. *Burger King Corp.*, 471 U.S. at 472 (alteration in original). Personal jurisdiction standards must enable "potential defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *World-Wide Volkswagen Corp.* v. *Woodson*, 444 U.S. 286, 297 (1980). For that reason, a court may not use the nationwide conduct of a nonresident defendant corporation as a hook for asserting personal jurisdiction over any claim against the defendant arising anywhere. See *Daimler*, 134 S. Ct. at 754 & n.5; *Goodyear*, 564 U.S. at 920.

The decision below effectively abandons any due process protection for companies that engage in

product-related activities nationwide. Under the standard applied below, an out-of-state plaintiff need only point to some "portion" of a company's uniform nationwide activities that occurred within the forum state for that state's courts to assert specific jurisdiction over the claims of an out-of-state plaintiff whose claims otherwise have no causal connection to the forum. That approach conflicts with this Court's precedents. "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." *Daimler*, 134 S. Ct. at 762 n.20 (omission in original). And an assertion of jurisdiction like the one below, that is "presumably . . . available in every other State" in which a corporation's nationwide activities occurred is "unacceptably grasping" and "exorbitant." *Id.* at 761.

The undue exercise of jurisdiction below is a consequence of uncertainty about the kind of connection between a defendant's in-state conduct and an out-of-state plaintiff's claims that specific jurisdiction requires. That uncertainty has persisted in the lower courts for more than three decades. *See Helicopteros Nacionales de Columbia, S.A.* v. *Hall*, 466 U.S. 408, 415 n.10 (1984) (declining to address "what sort of tie between a cause of action and a defendant's contacts with a forum" is necessary to support personal jurisdiction). Like the California Supreme Court's decision in *BMS*, the decision below illustrates how some courts have seized upon the uncertain standard for specific jurisdiction to reclaim jurisdictional territory that *Goodyear* and *Daimler* placed out of the reach of general jurisdiction. If this Court does not have occasion in *BMS* to provide the lower courts with an administrable answer to the

decades-open question of "what sort of tie between a cause of action and a defendant's contacts with a forum" is necessary to support personal jurisdiction, *Helicopteros*, 466 U.S. at 415 n.10, then the Court should grant the petition and use this case as the vehicle to provide that much-needed guidance.

B. Resolution Of The Question Presented Is Vitally Important To Companies That Engage In Nationwide Activities To Bring Their Products To Market, And Particularly Research-Based Biopharmaceutical Companies.

The decision below creates constitutionally intolerable unfairness and uncertainty for all companies that engage in nationwide activities to carry out their business, and particularly for research-based biopharmaceutical companies. PhRMA's members, for example, routinely sponsor multicenter clinical trials nationwide that play a critical role in drug development and public health. PhRMA's members also face the inevitability of products liability litigation, because their products are approved for marketing because the anticipated benefits outweigh the anticipated risks of use – not because the use is risk-free. Clear and administrable jurisdictional standards are essential to avoid the risk of having litigation-based concerns distort decision-making in clinical trial programs.

1. By definition, a multicenter clinical trial is a study that is "conducted according to a single protocol but at more than one site."[2] A protocol is a set of

---

[2] Int'l Conf. on Harmonisation of Technical Requirements for Registration of Pharms. for Human Use, *Guideline for Good Clinical Practice E6* glossary 1.40 (1996), http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.

instructions that "describes the objective(s), design, methodology, statistical considerations, and organization of a trial."[3] As FDA has observed, modern multicenter clinical trials operate according to "clear, prospectively determined clinical and statistical analytic criteria."[4] These studies are highly valuable to FDA 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."[5]

Multicenter clinical trials are an essential part of modern drug development. A major efficacy study may require hundreds or thousands of subjects and a single site will often be unable to enroll enough subjects to provide robust data. Also, an individual 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

---

[3] *Id.* 1.44.

[4] Ctr. for Drug Evaluation & Research (CDER), Ctr. for Biologics Evaluation & Research (CBER), 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/downloads/Drugs/GuidanceCompliance%20RegulatoryInformation/Guidances/UCM078749.pdf+Providing+clinical+evidence+of+effectiveness+for+human+and+bio&client=FDAgov&site=FDAgov&lr=&proxystylesheet=FDAgov&output=xml_no_dtd&ie=UTF-8&access=p&oe=UTF-8.

[5] *Id.*

of the treatment in the general population.[6] The risk of data being distorted by 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.[7]

FDA's recent focus on diversity in clinical trials highlights the importance of multicenter clinical trials for clinical trial sponsors. In 2012, Congress directed FDA to study the inclusion and analysis of demographic subgroups in new drug applications, and make recommendations to improve the completeness and quality of subgroup analyses.[8] Since then, FDA has reiterated that "[m]edical products are safer and more effective for everyone when clinical research includes diverse populations."[9] For both scientific and ethical reasons, FDA has explained, "[i]t is important to test drugs and medical products in the people they

---

[6] Lawrence M. Friedman et al., *Multicenter Trials*, *in Fundamentals of Clinical Trials* 501 (Friedman et al. eds., 5th ed. 2015).

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

[8] Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012); U.S. Food & Drug Admin., *FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data* (Aug. 2014) ("*FDA Action Plan*"), https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf.

[9] U.S. Food & Drug Admin., *Diversity in Clinical Trial Participation*, https://www.fda.gov/forpatients/clinicaltrials/ucm407817.htm (last accessed on Apr. 24, 2017).

are meant to help."[10] Demographic subgroup analysis also advances the goals of personalized medicine, which involves tailoring treatment to patients based on individual characteristics that may be relevant to a treatment response.[11] Clinical trials that are geographically widespread increase the likelihood that a given trial will be able to enroll a sufficient number of subjects from demographic subgroups to make conclusions about their treatment response.

Multicenter clinical trials also play a special role in the effort to identify treatments for rare and particularly disabling diseases. 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.[12] And when patients suffer from a particularly disabling disease, travelling to a distant medical center for treatment may not be an option.[13] For these reasons, multicenter clinical trials are important not only for data integrity but also for giving patients access to clinical trials involving cutting-edge research.

The biopharmaceutical industry sponsors clinical trials in every state in the Union. A recent report identified 6,199 industry-sponsored clinical trials active in the United States in 2013 alone, with 1.1 million subjects at sites spread across all 50 states and

---

[10] *Id.*

[11] *FDA Action Plan,* Message from Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, *supra* note 8.

[12] *See* Erika F. Augustine, M.D. et al., *Clinical Trials in Rare Disease: Challenges and Opportunities*, 28 J. Child. Neurol. Sept. 1142 (Sept. 2013).

[13] *Id.*

the District of Columbia.[14] Forty-two states had more than 200 clinical trial sites active that year, and several states were hosting 2,000 or more active sites.[15]

A clinical trial is one part of a long and complex process of getting a medicine from basic science and preclinical research to regulatory approval. Then once a product is approved, there are many more steps before it gets to any particular patient, with suppliers, manufacturers, distributors, doctors, and pharmacies all involved in the process. If the mere fact that a clinical trial site happened to be located in a given state were enough for that state's courts to assert specific jurisdiction over any claim involving the studied drug, even if all the events that proximately caused the plaintiff's injuries occurred elsewhere, PhRMA's members could be subject to the equivalent of general jurisdiction in every state.

2. Pharmaceutical companies also are 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,[16] but those risks nonetheless are real and can never be wholly

---

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

[15] *Id.* at i, 11-12.

[16] *See* U.S. Food & Drug Admin., *Development and Approval Process (Drugs)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last accessed Apr. 24, 2017) (explaining that the FDA's drug approval process "ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks").

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. Resolution of the question presented is therefore vitally important to PhRMA's members and the biopharmaceutical industry as a whole.

The decision below illustrates the importance of a specific jurisdiction standard that requires a meaningful connection between a plaintiff's claims and a defendant's forum activities. Individual sites in a multicenter trial do not independently design the research they undertake. Typical product defect claims have no meaningful connection to any site-level activity. As below, plaintiffs generally do not allege that any event that took place at any particular clinical trial site proximately caused their injuries. Nevertheless, under the mistaken view propounded below, the use of any FDA-approved drug could, in some highly attenuated sense, be viewed as causally connected to the underlying data that supported its approval, and that supports its continued marketing.

If courts can point to the fraction of the data collected at a particular site as a jurisdictional hook for hearing product liability cases arising in other states, pharmaceutical companies would continue to be subject to the same unfairness, overreaching, and uncertainty that PhRMA and other *amici* described in their briefs submitted in *BMS*.[17] The nationwide

---

[17] *See* Brief of PhRMA as *Amicus Curiae* in Support of Petitioner at 10-23, *BMS*, No. 16-466; Brief of Chamber of Commerce of the United States of America, California Chamber of Commerce, and American Tort Reform Association as *Amicus Curiae* in Support of Petitioner at 16-23, *BMS*, No. 16-466; Brief of GSK as *Amicus Curiae* in Support of Petitioner at 6-17, *BMS*, No. 16-466.

spread of clinical research combined with a specific jurisdiction standard as far-reaching as the one below allows plaintiffs to engage in unlimited forum shopping and to compel burdensome jurisdictional discovery. It also allows state courts to exceed their authority as co-equals in a federal system, and denies PhRMA's members the fair and orderly administration of the law. As *amici* supporting BMS explained, defendants that are compelled to litigate their cases outside of the jurisdiction where legally relevant events took place are often denied the opportunity to put on a full defense because essential witnesses cannot be compelled to testify. Plaintiffs' lawyers can use boundless jurisdictional standards to draw cases into magnet jurisdictions perceived to be plaintiff-friendly. Once a jurisdiction emerges as a magnet for product liability disputes, that jurisdiction can distort the evolution of product liability law. And the costs of litigating jurisdictional issues, including the one-sided expense of jurisdictional discovery for corporations with nationwide operations, place undue burden on nonresident defendants even if they ultimately prevail.[18]

To avoid such distortion, and protect the due process rights of PhRMA's members and other businesses that engage in standardized nationwide activities to bring their products to market, the Court should clarify, if not in its decision in *BMS* then in this case, that activities conducted in one state that are comparable to the company's activities nationwide, and that do not create a meaningful causal connection with the specific claims of an out-of-state plaintiff, do not create a basis for asserting specific jurisdiction.

---

[18] *See id.*

C. The Uncertain Standard For Specific Jurisdiction Poses A Threat To Clinical Research.

Many factors affect the decisions of where to locate the sites for a multicenter clinical trial, but avoiding litigation risk should not be one of them. Yet that is exactly what the decision below encourages.

If allowed to stand, the decision below would have a distorting effect on clinical research by encouraging clinical trial site selection based on litigation considerations rather than scientific ones, with potentially serious consequences for data integrity, medical progress, and patient health. Limiting the location of clinical trial sites to those states that do not embrace an unduly expansive approach to their own jurisdiction could diminish some of the benefits of multicenter trials, rendering the data less likely to reflect the general population, and potentially reducing the quantity and quality of available demographic subgroup data. Such geographic limits also could cause delays in enrolling patients in clinical trials, for, and approval of, medications to treat serious unmet needs, and could reduce the access that patients in the restricted states have to cutting-edge experimental therapies.

The stakes are high also from a financial perspective. In 2013 the biopharmaceutical industry spent nearly $10 billion on site-level activities.[19] Legal standards that prompt the consolidation of clinical trial locations to states with predictable approaches to personal jurisdiction would artificially concentrate the economic benefits of clinical trial activities in those states, to the detriment of the

---

[19] Battelle Tech. P'ship Practice, at 9, 13, *supra* note 14.

citizens, institutions, and local governments elsewhere. [20]

The added risk and expense of litigating product liability cases in a legal environment that encourages plaintiffs to engage in forum shopping and costly jurisdictional discovery also could tip the balance against conducting experimental research in some instances. Large-scale clinical trials are enormously expensive and always carry the risk of failure, and the biopharmaceutical industry accounts for most of the investment in clinical trial sites in the United States.[21] The added burden on clinical trial sponsors that the approach to jurisdiction below imposes could result in a contraction of clinical research programs.

For these reasons too, the Court should grant this petition if *BMS* does not resolve the question GSK presents here.

II. THIS CASE IS AN EXCELLENT VEHICLE FOR ADDRESSING THE QUESTION PRESENTED

This case is an excellent vehicle for addressing the question presented because Petitioner's situation is typical in that many pharmaceutical companies are involved in extensive litigation in states that are neither their home states nor the home states of the plaintiffs. In these cases, out-of-state plaintiffs file their claims in what they perceive to be a more plaintiff-friendly jurisdiction than their own home state. If allowed to stand, the key facts cited below to support jurisdiction – the aggregation of data obtained from a clinical trial site in the forum with data from

---

[20] *See id.* at 9 (explaining the high-wage jobs and economic ripple effects that accompany the location of a clinical trial site).

[21] *Id.* at 1, 8-10.

other sites to support marketing approval – could be used to justify the assertion of specific jurisdiction in many cases involving PhRMA's members, even if nothing that occurred in the forum state is a proximate cause of the out-of-state plaintiff's injuries.

Nearly any product liability complaint involving a pharmaceutical product could easily include an allegation that the clinical trials, including one or more in the forum state, were inadequate in some way. The decision below therefore constitutes a set of pleading instructions for thousands of out-of-state plaintiffs in pharmaceutical product liability cases who seek to circumvent the due process limits on general jurisdiction through a limitless application of specific jurisdiction.

Finally, products liability cases are well-suited for announcing generally applicable jurisdictional rules. Jurisdictional disputes often arise in products liability cases, lower courts across the country have extensive experience with such cases, and this Court has often chosen to issue jurisdictional decisions in them.[22] A decision in this case would provide the lower courts with an administrable standard in a familiar context. Because the lower courts need a clear standard they can apply if *BMS* does not reach the question presented here, the petition should be granted.

---

[22] *E.g., Goodyear*, 564 U.S. 915 (allegedly defective tire); *J. McIntyre Mach., Ltd.* v. *Nicastro,* 564 U.S. 873 (2011) (plurality opinion) (allegedly defective metal-shearing machine); *Asahi Metal Indus. Co.* v. *Superior Court*, 480 U.S. 102 (1987) (allegedly defective motorcycle tire, tube and sealant); *World-Wide Volkswagen*, 444 U.S. 286 (allegedly defective gas tank and fuel system).

CONCLUSION

For the foregoing reasons, and those stated in the Petition, the Court should grant the Petition.

Respectfully submitted,

JAMES C. STANSEL
MELISSA B. KIMMEL
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, NW
Suite 300
Washington DC 20004
(202) 835-3559

MARK HADDAD*
ALYCIA DEGEN
NAOMI IGRA
SIDLEY AUSTIN LLP
555 West Fifth Street
Los Angeles, CA 90013
(213) 896-6604
mhaddad@sidley.com

CARTER G. PHILLIPS
REBECCA K. WOOD
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Counsel for Amicus Curiae

April 27, 2017

* Counsel of Record