No. 16-1446

IN THE

Supreme Court of the United States

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC.,

Petitioner,

v.

JEAN CHARLES, JR., as next friend and duly appointed guardian of his sister, MARIE CHARLES, *et al.*,

Respondents.

On Petition for a Writ of Certiorari to the Florida Supreme Court

BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AND THE FLORIDA MEDICAL ASSOCIATION, *ET AL.*, AS *AMICI CURIAE* SUPPORTING PETITIONER*

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The Litigation Center of the American Medical Association and State Medical Societies; Florida Medical Association; Walgreen Company and The Patient Safety Research Foundation, Inc.; Wal-Mart Stores, Inc. and Safety Culture Patient Safety Organization; Children's Hospital Association; Child Health PSO; Ascension Healthcare Patient Safety Organization; Adventist Health System; IASIS Healthcare LLC, Florida Health Science Center, Inc., d/b/a Tampa General Hospital; Universal Health Services of Delaware, Inc.; Kentucky Hospital Association; Alliance for Quality Improvement and Patient Safety—a voluntarily membership organization of forty certified Patient Safety Organizations; MHA Keystone Center Patient Safety Organization, a subsidiary of the Michigan Health & Hospital Association; American Society for Radiation Oncology; California Hospital Association; Tennessee Hospital Association; Tennessee Center for Patient Safety; ECRI Institute PSO; AABB Center for Patient Safety; AHS PSO, LLC; American Medical Foundation Patient Safety Organization; Baptist Health Patient Safety Partnership; CHPSO; Carolinas HealthCare System Patient Safety Organization; Carolinas Rehabilitation – Patient Safety Organization; Clarity PSO; HealthSouth Patient Safety Organization, LLC; MCIC Vermont PSO; MEDNAX PSO, LLC; New Jersey Hospital Association Health, Research & Educational Trust Institute for Quality & Patient Safety; Ohio Patient Safety Institute, a subsidiary of the Ohio Hospital Association, Ohio State Medical Association, and Ohio Osteopathic Association; Pascal Metrics Inc.; PsychSafe; QA to QI LLC; Quality Alliance

Patient Safety Organization; Quality Circle for Healthcare, Inc.; Strategic Radiology Patient Safety Organization LLC; The PSO Advisory, LLC; The Texas A&M Health Science Center Rural and Community Health Institute; UHS Acute Care PSO; USAP PSO; Virginia PSO; Vizient PSO; Kentucky Institute for Patient Safety & Quality; Mid-Atlantic Patient Safety Organization; NC Quality Center PSO; Ardent Health; Carolinas Healthcare System; The George Washington University Hospital; University of Kentucky; Central Texas Medical Center; Manatee Memorial Hospital; Wellington Reginal Medical Center; Central Florida Behavioral Hospital; The Vines Hospital; Florida Hospital Orlando; Florida Hospital for Children; Florida Hospital Pepin Heart Institute; Adventist Medical Center Hinsdale; Saint Alexius Medical Center; Sacred Heart Hospital of Pensacola; Sacred Heart Hospital on the Emerald Coast; St. Vincent's Medical Center – Clay County; St. Vincent's Medical Center – Riverside.

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INTERESTS OF *AMICI CURIAE*

Congress enacted the federal statute at issue in this case, the Patient Safety and Quality Improvement Act of 2005 (the "Patient Safety Act"), Pub. L. No. 109-41, 119 Stat. 424 (codified at 42 U.S.C. §§ 299b-21, *et seq.*), to improve patient safety, health care quality, and health care outcomes by facilitating the sharing and analysis of patient-safety information. The Act achieves these laudable goals by, among other things, establishing federally-certified "patient safety organizations" (PSOs) that are charged with maintaining a network of patient-safety databases, where medical outcomes can be analyzed by healthcare professionals. 42 U.S.C. § 299b-23. To ensure that useful information is voluntarily contributed to these databases, the Act also establishes a nationwide privilege that attaches to "patient safety work product" reported by healthcare providers to these databases, shielding this work product from disclosure or use in a federal, state, or local civil, criminal, or administrative proceeding unless certain narrow exceptions are met. *Id.* § 299b-22(a).[1]

As explained in the Petition for a Writ of Certiorari, the decision below threatens to obliterate the

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[1] No counsel for a party in this case authored this brief in whole or in part. No person or entity—other than *amici*, their members, or their counsel—made a monetary contribution specifically for the preparation or submission of this brief. Consistent with Supreme Court Rule 37.1(a), the *amici* provided timely notice to the Petitioners and Respondents of the *amici*'s intent to file this brief. Petitioners and Respondent have consented to the filing of this brief, and those consents are on file with the Clerk.

privilege by subordinating it to state and local disclosure standards. Indeed, since the Florida Supreme Court issued its decision, *amici curiae* (a broad coalition of providers, hospitals and health systems, hospital and other professional associations, and PSOs) have experienced a decline in information that is collected and voluntarily shared as patient safety work product with PSOs and other affiliated providers. This Court's intervention is urgently needed to prevent a complete erosion of Congress's comprehensive plan to improve patient safety through the collection, reporting, analyzing and sharing of sensitive patient safety and quality-of-care information, a plan that can only be realized outside the culture of blame.

Broadly categorized, *amici curiae* and/or their health care provider members are organizations that collect and submit patient safety work product to PSOs, associations that advocate on their behalf, including the American Medical Association, and PSOs, which receive and analyze this information. The *amici* have a substantial interest in the outcome of this case: The decision below threatens to destroy the nationwide privilege established by Congress and thereby discourages healthcare providers from engaging in detailed patient safety discussions and internal reports out of fear that this information will be discoverable. Furthermore, the decision will deter providers from voluntarily contributing patient-safety work product to patient-safety databases for review and analysis so as to improve patient-safety outcomes, as contemplated by Congress through the enactment of the Patient Safety Act. This Court's review is urgently needed to ensure that healthcare providers will continue their efforts to improve pa-

tient safety in order to reduce patient deaths and injuries within the nation's health care system.

The lead *amici*, the American Medical Association ("AMA"), and the Florida Medical Association ("FMA"), are professional associations representing tens of thousands of physicians in Florida and around the country, including many who participate in and provide information to PSOs and some of whom have even established their own PSOs. The AMA and FMA join in their own right and as representatives of the Litigation Center of the AMA and the State Medical Societies, which is a coalition of the AMA and the medical societies of each state and the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts. The AMA and FMA are joined by other associations—the Alliance for Quality Improvement and Patient Safety; American Society for Radiation Oncology; California Hospital Association; Children's Hospital Association; Kentucky Hospital Association; Michigan Health & Hospital Association; New Jersey Hospital Association; Ohio Hospital Association; Ohio Osteopathic Association; Ohio State Medical Association; and the Tennessee Hospital Association—(collectively, the "Association *Amici*"), which have established or represent members who participate in one or more PSOs.

The Association *Amici* are joined by thirty-two certified PSOs, as defined by the Patient Safety Act, *id.* § 299b-21(4), from around the country that have contracted with thousands of participating hospitals, physicians, and other licensed providers (collectively, the "PSO *Amici*"). These PSOs collect patient-safety information from healthcare providers in order to

conduct various patient-safety analyses and studies to understand why certain errors occurred, improve the quality of health care services, and reduce patient risk. Each PSO is subject to a civil penalty of up to $10,000 if it "discloses identifiable patient safety work product" in violation of the Patient Safety Act. *Id.* § 299b-22(f)(1).

Finally, the *Amici* include eighteen hospitals and large, non-profit and for-profit health systems: Adventist Health System; IASIS Healthcare LLC; Florida Health Science Center, Inc., d/b/a Tampa General; Universal Health Services of Delaware, Inc.; Ardent Health; Carolinas Healthcare System; The George Washington University Hospital; Central Texas Medical Center; Manatee Memorial Hospital; Wellington Reginal Medical Center; Central Florida Behavioral Hospital; The Vines Hospital; Florida Hospital Orlando; Florida Hospital for Children; Florida Hospital Pepin Heart Institute; Adventist Medical Center Hinsdale; Saint Alexius Medical Center; Sacred Heart Hospital of Pensacola; Sacred Heart Hospital on the Emerald Coast; St. Vincent's Medical Center – Clay County; St. Vincent's Medical Center – Riverside; University of Kentucky (collectively, the "Hospital *Amici*"). Each of these hospitals or health systems participates in one of the PSO *Amici.*

Collectively, the *Amici* represent all sides of the collection, submission, and use of "patient safety work product" under the Patient Safety Act. They are filing this brief in support of the Petition for a Writ of Certiorari filed in this case.

SUMMARY OF ARGUMENT

PSOs and participating hospitals and providers are at the forefront of a paradigm shift occurring in the health care industry, which increasingly conditions reimbursement on the quality of medical services provided as measured against established standards and quality metrics. PSOs compile aggregated and de-identified studies through patient safety work product collected and reported to PSOs by participating hospitals and providers. The patient safety work product includes root cause analyses, peer review evaluations, and other patient safety information that hospitals and providers are not otherwise obligated to compile.

The reports, both public and confidential, compiled by PSOs and the information exchange facilitated by PSOs are then used by hospitals and providers to improve patient outcomes and reduce risk through safety alerts, best practices, and benchmarking studies.

As the Department of Health and Human Services recognized, the "foundation" for this national system of information exchange is the "substantial and broad" privilege provided for under the Patient Safety Act. 73 Fed. Reg. 70,732, 70,741 (Nov. 21, 2008). More specifically, the Patient Safety Act facilitates the exchange of sensitive information through a federally-mandated privilege that shields patient safety work product from disclosure or use in a federal, state, or local civil, criminal, or administrative proceeding unless certain narrow exceptions are met. 42 U.S.C. § 299b-22(a), (b). Absent this privilege, participating hospitals and providers would increase

their potential exposure to prospective plaintiffs through the generation of reports and information that they are not otherwise required to create or maintain under state or federal law.

The Florida Supreme Court's decision in *Charles* v. *S. Baptist Hosp. of Fla., Inc.*, 209 So. 3d 1199 (Fla. 2017) (cited in Pet. App. 1a-33a), threatens to significantly undermine and limit the scope of the privilege afforded under the Patient Safety Act, replacing the nationwide confidentiality protections for patient safety work product that Congress envisioned with a patchwork of conflicting state-law standards. Indeed, this erroneous decision has already had a chilling effect on the collection and reporting of "patient safety work product," and frustrates one of the fundamental purposes of the Act—to provide a nationwide repository where adverse healthcare outcomes can be studied and corrected beyond the reach of the "culture of blame," which, Congress found, actively discourages the creation and sharing of patient safety information. *See* S. Rep. No. 108-34, at 3, 5 (2003).

The effects of the Florida Supreme Court's decision are not, and will not be limited, to Florida. Indeed, hospitals and providers across the nation, particularly those physician and hospital provider groups that are located in multiple states, depend upon a uniform and predictable privilege when collecting and reporting patient safety work product to PSOs. The *Charles* decision reads an exception into the definition of patient safety work product so broad that the federal privilege is completely subordinated to state law, turning traditional preemption analysis on its head, despite clear language in the Patient

Safety Act that state laws that otherwise would allow discovery are preempted.

The *Charles* decision, if left to stand, thus calls into question the ability of Congress to guarantee uniformity and predictability of the privilege under the Patient Safety Act within the State of Florida and across state lines. As explained below, since the Florida Supreme Court issued its decision, *amici* have noted a decline in information that is voluntarily shared as patient safety work product as a result of the *Charles* decision.

Absent immediate clarification by this Court (or, at the very least, vacatur of the problematic decision below), hospitals, physicians and other licensed providers have no assurances that patient safety work product will remain privileged and confidential. As a result, providers will be deterred from engaging in important and necessary Patient Safety Act activities and reports and will not voluntarily contribute such work product to PSOs. This Court's intervention is urgently needed.

ARGUMENT

I. PSOs Compile Critical Studies and Reports that Lower Risk and Improve Patient Health Outcomes.

The Patient Safety Act encourages providers to collect and assemble identified "data, reports, records, memoranda, [and] analyses (such as root cause analyses)" relating to patient safety activities within their respective patient safety evaluation systems for reporting to a PSO. *See generally* 42 U.S.C. §§ 299b-

21(7)(A), 299b-23(a); 42 C.F.R. §§ 3.20, 3.204, 3.206. The Act realizes this objective by facilitating the creation of PSOs, which enter into contracts with providers to "collect patient safety work product . . . that permits valid comparisons of similar cases among similar providers," and to "utilize patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk." 42 C.F.R. § 3.102(b)(2)(i)(F), (G).

PSOs are heavily regulated entities. Under the Patient Safety Act, a PSO must obtain certification from the Secretary of the Department of Health and Human Services to serve as a repository for information within the patient-safety network established under the Act. 42 U.S.C. §§ 299b-21(4), 299b-24(a)(1). The Secretary, who has delegated these responsibilities to the Agency for Healthcare Research and Quality ("AHRQ"), is required to ensure that, among other things, the PSOs' "mission and primary activity . . . are to conduct activities that are to improve patient safety and the quality of health care delivery." *Id.* § 299b-24(b)(1). AHRQ describes a PSO's primary activity under the Act as follows:

> The primary activity of an entity or component organization seeking to be listed as a PSO must be to conduct activities to improve patient safety and health care quality. A PSO's workforce must have expertise in analyzing patient safety events, such as the identification, analysis, prevention, and reduction or elimination of the risks and hazards associated with the delivery of patient care.

AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, http://www.pso.ahrq.gov/faq#WhatisaPSO (last visited June 19, 2017).

Information submitted to PSOs qualifies as confidential patient safety work product, which is not subject to discovery in federal, state, or local proceedings, 42 C.F.R. §§ 3.20, 3.206, so long as the provider did not collect and assemble the patient safety information to satisfy other state or federal reporting obligations, *see* 81 Fed. Reg. 32,655, 32,656 (May 24, 2016).

The information submitted by providers to PSOs around the country includes sensitive patient incident reports, such as the reports at issue in this case, root cause analyses, peer review evaluations, and other patient safety information that providers are not otherwise obligated to report to state, federal or local governmental authorities.

The submission of patient safety information by providers has enabled PSOs around the country to provide safety alerts, identify best practices, and prepare comparative and benchmarking studies, as well as other confidential and public reports. This information, in turn, has benefited providers and the entire health care industry in their collective efforts to reduce risk and improve care. For example, PSOs have provided vital feedback that has improved health information technology ("HIT") associated with identifying and tracking adverse events, reduced incidents of pressure ulcers, improved medication safety, reduced surgical errors and patient falls, and facilitated a host of other patient-safety im-

provements. Recounted in the margin are publicly-available examples of the important work being performed by PSOs across the nation to improve patient safety and medical outcomes.[2]

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[2] *Amicus* Vizient® PSO has produced a number of "Applied Learnings" reports based on patient safety event data received from its participating providers. The purpose of these reports, which cover Health IT-related patient safety events, surgical pathology specimen errors, patient violence, retained sponges and guidewires and an analysis of suicide-related events, is to identify specific safety events, conduct analyses and make recommendations designed to improve the quality of patient care and reduce risk. *See* Vizient PSO, Aggregate Analyses and Leading Safety Practices (Dec. 2016), http://www.advansiv.net/clients/vizient/docs/2016-PSO-Summary-Analyses.pdf.

ECRI Institute PSO distributes information regarding the top patient safety concerns they have identified through the PSO and on HIT, pressure ulcers, medication safety, and other patient-care related issues. *See* Press Release, ECRI Institute PSO, Partnership for Health IT Patient Safety Issues Recommendations for the Safe Use of Health IT for Patient Identification (Feb. 20, 2017), https://www.ecri.org/press/Pages/HITPS-Issues-Recommendations-for-Patient-Identification.aspx; ECRI Institute PSO, Key Learnings from ECRI Institute PSO, https://www.ecri.org/resource-center/Pages/Key-Learnings-from-ECRI-Institute-Patient-Safety-Organization.aspx (last visited June 14, 2017).

Child Health Patient Safety Organization, which has 50 children's hospitals around the country as its members, has similarly published online "Patient Safety Action Alerts" in the areas of medication administration errors, fingertip amputation, cutaneous fungal outbreak, wrong-size tracheostomy selection, and blind pediatric NG tube placements, *see* Child Health Patient Safety Organization, Patient Safety Action Alerts, http://www.childrenshospitals.org/Quality-and-Performance/Patient-Safety/Patient-Safety-Action-Alerts (last visited June 14, 2017), and educates providers at conferences to help eliminate patient harm, *see* Child Health Patient Safety Organiza-

In addition to publicly-available studies, PSOs also participate in confidential, non-public reviews and analyses with individual providers and systems. This confidential information is then utilized internally by the providers to support their patient safety activities.

The goals of the Patient Safety Act—to improve the quality of patient services and to reduce medical errors—were meant to further a sea change in the health care industry, which increasingly ties reimbursement to quality metrics. Evidence of this "volume to value" movement has long been reflected in what is termed "pay for performance" standards implemented by private payers designed to increase quality and reduce costs. *See generally* Julia James, Health Policy Brief: Pay-for-Performance, *Health Affairs* (Oct. 11, 2012), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_78.pdf.

Pay for performance standards are not limited to the private sector. Indeed, the federal government has implemented numerous program requirements that condition reimbursement and the imposition of

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tion, 2017 Quality and Safety in Children's Health Conference, https://www.childrenshospitals.org/events/2017/03/19/2017-quality-and-safety-in-childrens-health-conference (last visited Jun 28, 2017).

Clarity PSO has published materials on surgical errors, medication dosing omissions, fall prevention, HIT, and other issues, which are available at Clarity PSO, Patient Safety Learning Series, http://www.claritygrp.com/clarity-patient-safety-organization/learning-library/pso-learning-series (last visited June 28, 2017).

payment penalties on meeting identified quality metrics as a means of reducing health care costs and improving care.[3] CMS has estimated that from January 2012 to December 2013, these performance-quality programs saved 50,000 lives and $12 billion in spending, and resulted in 150,000 fewer readmissions. Press Release, Dep't of Health & Human Servs., Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value (Jan. 26, 2015), http://www.hhs.gov/news/press/2015pres/01/20150126a.html.

In order to meet these quality outcome standards and metrics, hospitals, physicians, and other providers must adopt and implement processes that incorporate these metrics into their quality, risk, peer review and other patient safety activities. This ensures that the provider's compliance can be tracked and monitored, and remedial actions may be taken. Providers also engage in these patient safety activities because they help reduce malpractice liability and the associated costs in defending against such claims. Indeed, the resulting internal evaluations and reviews are used to correct substandard practices. These same materials also are reported to PSOs

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[3] For examples of quality-based requirements affecting hospitals, physicians and nursing facilities, *see* 42 U.S.C. §§ 1395w-4(p), 1395ww(o) (Value-Based Purchasing Program); 42 U.S.C. § 1395ww(p) (Hospital-Acquired Conditions Program); 42 U.S.C. § 1395ww(q) (Hospital Readmissions Reduction Program); 42 C.F.R. §§ 425.10 *et seq.* (Medicare Shared Savings Program); 81 Fed. Reg. 77,008 (Nov. 4, 2016) (Medicare Access and CHIP Reauthorization Act Program).

for further evaluation and analysis, all of which are considered patient safety work product.

II. Urgent Review Is Required by this Court to Counteract the Chilling Effect of the *Charles* Decision on Providers' and PSOs' Risk-Reduction and Quality-Improvement Efforts.

In the end, PSOs are only as useful as the information that their patient safety databases contain. Thus, the aggregated and de-identified studies that facilitate quality-improvement in health care would not be possible without the receipt of patient safety work product currently being collected and reported to PSOs by their participating hospitals and providers.

As Petitioner noted, and as the Department for Health and Human Services has recognized, Congress offered a "substantial and broad" privilege for patient safety work product as "the foundation to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events." 73 Fed. Reg. at 70,741; *see also* Pet. at 7-8. A critical element of the privilege is uniformity across state lines, which Congress sought to ensure by expressly preempting contrary state law, and requiring that patient safety work product be treated as privileged "[n]otwithstanding any other provision of Federal, State, or local law." 42 U.S.C. § 299b-22(a), (b). Indeed, AHRQ—the agency charged with regulatory oversight of PSOs—encourages participation by assuring prospective participants that information voluntarily submitted to PSOs will remain confidential and will not be used in legal pro-

ceedings. *See* AHRQ, Patient Safety Organization (PSO) Program, Frequently Asked Questions, https://www.pso.ahrq.gov/faq#BenefitstoMedicare Providers (last visited June 8, 2017).

The decision of the Florida Supreme Court undermines the privilege at the heart of the Patient Safety Act by adopting an indefensibly broad interpretation of an exception to the Patient Safety Act's definition of patient safety work product. *See* Pet. at 15-16 (analyzing 42 U.S.C. § 299b-21(7)(B)(ii)). The court compounds this problem through its inverted preemption analysis, which reasons that a state's disclosure obligations should negate the disclosure protections and the express preemption clause found in the Patient Safety Act. *See* Pet. at 20-22. The end result of the Florida Supreme Court's decision is that patient safety work product—including work product that was not prepared to satisfy, or otherwise evade, state or federal reporting obligations—is not entitled to protection under the Patient Safety Act if a state imposes any kind of disclosure or record maintenance obligation. Thus, under the *Charles* decision, the privilege remains subject to a patchwork of state laws and the uncertainties of litigation. This reality is plainly contrary to the goals of Congress, which sought to establish a national privilege and define the scope of that privilege with a level of clarity that is not even afforded to common-law privileges recognized under Rule 501 of the Federal Rules of Evidence.

The lack of uniformity and the increased uncertainty caused by the Florida Supreme Court's decision is already taking its toll on PSOs. Indeed, various *amici* have reported that certain hospitals in

Florida have actually shut down or greatly reduced the level of peer review and other patient safety analyses and reports they were preparing before the *Charles* decision, or they have limited the type of information that they create and submit to PSOs. For example, some hospitals have stopped sending in root-cause analyses from adverse incidents, which contain some of the richest data for PSOs to use to improve patient safety. Participating providers also are reluctant to engage in any kind of discussion concerning adverse incidents, out of concern that those conversations may expose them to liability.

Moreover, the chilling effect from the *Charles* decision is not confined to Florida. Hospitals and providers across the nation have taken note of the *Charles* decision and are debating whether participating in a PSO is worth the risk of producing potentially discoverable information following adverse incidents. Most of the patient safety work product disputes arise in medical malpractice actions, beyond the jurisdiction of the federal district courts. As a result, the scope of the privilege under the Patient Safety Act will evolve differently in the state courts without some direction by this Court. Moreover, the *Charles* decision signals that state courts may be free to severely undermined the protections clearly intended by Congress under the Patient Safety Act.

The *Charles* decision, if left to stand, will continue to discourage providers from compiling and submitting patient safety information, thereby undermining the ability of PSOs to review and analyze adverse patient incidents, and perversely impacting their efforts to improve quality and reduce risk to patient health. Providers also will not generate the ad-

ditional information contemplated by the Act if they believe that it might ultimately be used against them in a civil, criminal, or administrative proceeding.

PSOs, in turn, cannot fulfill their important responsibilities unless providers are able to submit patient safety, data reports, and related information on a confidential and privileged basis to their respective PSOs.

Because of the nationwide decrease of patient safety information creation and sharing that followed the *Charles* decision, it is critical that this Court intervene now to clarify the scope of the privilege afforded by the Patient Safety Act. Indeed, that decision has already defeated Congress's express goal of uniformity by subordinating the privilege to a patchwork of state disclosure standards. In the alternative, this Court should, at a minimum, vacate the judgment below so that it does not continue to wreak havoc for providers, hospitals, and PSOs inside and out of Florida. *See* Pet. at 33-34 (citing *U.S. Bancorp Mortg. Co.* v. *Bonner Mall P'ship*, 513 U.S. 18, 22 (1994)).

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted.

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