NO. 14-1140

In the
Supreme Court of the United States

PHILLIP TIBBS, *et al.*,

Petitioners,

v.

KIMBERLY BUNNELL, JUDGE, CIRCUIT COURT OF KENTUCKY, FAYETTE COUNTY, *et al.*,

Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Kentucky

BRIEF FOR *AMICUS CURIAE* THE JOINT COMMISSION IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF IN SUPPORT OF PETITIONERS

The Joint Commission provided the notice required by Supreme Court Rule 37 to all parties and received consent from petitioners and the Honorable Kimberly N. Bunnell to the filing of this brief. Because The Joint Commission was unable to secure consent from the remaining respondents, The Joint Commission hereby moves, pursuant to Supreme Court Rule 37.2(b), for leave to file an *amicus curiae* brief in support of petitioners.

Founded in 1951, The Joint Commission is the Nation's oldest and largest health care standards-setting and accrediting body. The Joint Commission's sole purpose is to assist health care organizations in improving patient care. In pursuit of that mission, The Joint Commission evaluates and certifies more than 20,000 health care organizations and programs in the United States, develops standardized performance measures used in connection with those evaluations, and conducts in-depth research on matters of vital importance to health care safety and quality.

The Joint Commission also periodically engages Congress on health care related issues in need of federal attention. As relevant here, The Joint Commission strongly encouraged and supported adoption of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, *et. seq.* ("Patient Safety Act"), and the patient safety work product privilege. The Joint Commission participated in the critical stakeholder meetings, drafted proposed

language, commented on the Act's provisions as they evolved, and was intimately involved in fashioning the final legislative product.

Supreme Court Rule 37.1 states that an "*amicus curiae* brief that brings to the attention of the Court relevant matter not already brought to its attention by the parties may be of considerable help to the Court." The Joint Commission's proposed *amicus* brief readily meets that requirement. As an organization at the forefront of efforts to improve health care quality and intimately involved in the formulation and passage of the Patient Safety Act, The Joint Commission is uniquely positioned to provide this Court with insight into the potentially dire consequences of the decision below and to highlight the decision's incompatibility with the Patient Safety Act.

For the foregoing reasons, The Joint Commission respectfully requests leave to file the attached brief in support of petitioners.

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

The Joint Commission on Accreditation of Healthcare Organizations ("The Joint Commission") is a not-for-profit corporation under Illinois law and a 501(c)(3) tax-exempt corporation.

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STATEMENT OF INTEREST[1]

The Joint Commission respectfully submits this *amicus curiae* brief in support of the petition for certiorari. Founded in 1951, The Joint Commission is the Nation's oldest and largest health care standards-setting and accrediting body. The Joint Commission is governed by a Board comprised of individuals with a wealth and diversity of experience in health care, including physicians, nurses, health care administrators, health care quality experts, and business leaders. Corporate members of The Joint Commission include The American College of Physicians, The American College of Surgeons, The American Dental Association, The American Hospital Association, and the American Medical Association. Accreditation from the Joint Commission is recognized as accomplishing compliance with various state and federal regulatory requirements, including Medicare and Medicaid hospital quality requirements. *See, e.g.*, 42 C.F.R. § 488.8.

The Joint Commission's sole purpose is to assist health care organizations in improving patient care. In pursuit of that mission, The Joint Commission evaluates and certifies more than 20,000 health care organizations and programs in the United States, develops standardized performance measures used in connection with those evaluations, and conducts in-depth research on matters of vital importance to

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief.

health care safety and quality. Those efforts have yielded substantial results in terms of patient safety. Indeed, many of the Nation's most important patient safety initiatives are a direct result of health care providers' efforts to comply with Joint Commission accreditation standards. *See* Kelly J. Devers et al., *What is Driving Hospitals' Patient-Safety Efforts?*, 23 No. 2 Health Aff. 103 (2004).

Part and parcel of its efforts to improve patient safety and care, The Joint Commission periodically engages Congress on health care related issues in need of federal attention. As relevant here, more than two decades ago The Joint Commission began asking Congress to adopt legislation encouraging health care organizations to uncover and analyze their own risks, report adverse events, and share the information gleaned from those self-evaluation efforts with entities like The Joint Commission. As The Joint Commission explained to Congress, federal legislation along these lines was necessary to reduce the risk that preventable errors would result in harm to patients.

The efforts of The Joint Commission on this score, as well as those of over 100 other professional and quality improvement organizations, resulted in the passage of the Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. § 299b-21, *et. seq.* ("Patient Safety Act"). Deeply involved in the crafting and adoption of the Act, The Joint Commission strongly encouraged and supported the Patient Safety Act from its inception, including the establishment of a robust federal privilege for "patient safety work product." The Joint Commission participated in the critical stakeholder meetings, drafted proposed

language, commented on the Act's provisions as they evolved, and was intimately involved in fashioning the final legislative product. While The Joint Commission is not a "patient safety organization" ("PSO"), *see* 42 C.F.R. § 3.102(a)(2)(ii)(A), health care organizations are expressly authorized to share patient safety work product with entities such as The Joint Commission, 42 U.S.C. § 299b.[2] And while The Joint Commission has no direct interest in the operation of PSOs, PSOs play an important role in the ongoing effort to improve patient safety and care.

As an organization at the vanguard of efforts to improve health care quality and intimately involved in the formulation and passage of the Patient Safety Act, The Joint Commission is uniquely positioned to provide this Court with insight into the potentially dire consequences of the decision below and to highlight the decision's incompatibility with the Patient Safety Act. More fundamentally, because the patient safety work product privilege is essential to improving patient safety, The Joint Commission has a strong interest in ensuring that the privilege is given its congressionally-intended scope.

SUMMARY OF ARGUMENT

Congress adopted the patient safety work product privilege and its companion preemption provision to encourage health care organizations to gather and share information about adverse patient safety events. As Congress recognized in taking this

[2] Affiliates of The Joint Commission may obtain certification as a PSO so long as certain firewalls are established, but The Joint Commission has not established an affiliated PSO.

extraordinary step, allowing health care organizations to share information about potential risks to patients, free from fear that the information will later be used against them in court or to damage their reputations, allows PSOs to evaluate that information and provide meaningful and effective advice.

The decision below is irreconcilable with the broad scope of the patient safety work product privilege and threatens to cut off vital information sharing efforts. In the absence of a clear and unambiguous rule protecting patient safety work product from disclosure, health care organizations will be understandably reluctant to cultivate and share information that is used by PSOs to save lives. That outcome is simply unacceptable. This Court's immediate review is warranted.

ARGUMENT

I. The Decision Below Is Irreconcilable With Congressional Intent And Jeopardizes Ongoing Efforts To Improve Patient Safety.

The Patient Safety Act creates an expansive privilege protecting "patient safety work product"—defined as "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" created for or supplied to a PSO—from release. 42 U.S.C. § 299b-21(7)(A). That expansive privilege is accompanied by an equally broad preemption provision, stating that "[n]otwithstanding any other provision of Federal, State, or local law," patient safety work product is protected from discovery in civil, criminal, and administrative proceedings. 42 U.S.C. § 299b-22(a)-(c). Reflecting Congress' intent that the privilege be

crystal clear and unassailable, the Patient Safety Act expressly states that "patient safety work product shall be privileged and shall not be … subject to a Federal, State, or local civil, criminal, or administrative subpoena or order …." *Id.*

As The Joint Commission knows based on its longstanding involvement with this issue, the broad patient safety work product privilege Congress adopted in the Patient Safety Act was necessitated by a gap in privilege protection that critically undermined the development and sharing of information in the name of improving patient safety. Before the Patient Safety Act, the only federal law addressing the issue was the Health Care Quality Improvement Act, 42 U.S.C. § 11101, which recognized the need for a federal law encouraging information sharing, but provided only civil immunity to health care providers engaged in the peer review process. And federal courts have long refused (and continue to refuse) to recognize a non-statutory federal privilege in this area. *See, e.g.*, *United States v. Aurora Health Care, Inc.*, No. 14-MC-77, 2015 WL 1261399 (E.D. Wis. Mar. 20, 2015); *Roberts v. Legacy Meridian Park Hosp., Inc.*, 299 F.R.D. 669 (D. Or. 2014); *In re Admin. Subpoena Blue Cross Blue Shield of Mass., Inc.*, 400 F. Supp. 2d 386 (D. Mass. 2005); *Mattice v. Mem'l Hosp. of S. Bend*, 203 F.R.D. 381 (N.D. Ind. 2001).

In recognition of the inadequacy of the then-governing law to provide the protections necessary to encourage self-evaluation and information sharing, as well as the fact that as many as 98,000 deaths may result from preventable medical errors every year,

Institute of Medicine, *To Err Is Human: Building a Safer System* 1 (1999), Congress adopted the patient safety work product privilege and its companion express preemption provision to create a nationwide "culture of safety" where patient risk is minimized through recordation, collaboration, and evaluation free from the fear that such efforts will later be Exhibit A in a civil jury trial. 42 U.S.C. § 299b-21(5)(D). The Joint Commission is pleased to report that Congress' effort is working. PSOs are improving patient care and safety and the patient safety work product privilege has played an important part in that success. While health care organizations are still sometimes hesitant to share information surrounding incidents that result—or come close to resulting—in patient harm, the patient safety work product privilege has made it much easier for PSOs to convince health care organizations to cultivate and share information about adverse patient safety events.

The evaluation of "sentinel events" through "root cause analysis" is a prime example. PSOs encourage hospitals to conduct a root cause analysis following any unexpected occurrence involving death or serious physical or psychological injury, or any procedural aberration that, if repeated, would create a significant risk of harm to patients. As the name "root cause analysis" suggests, that mode of analysis requires evaluation of systems and procedures above and beyond what may appear to be an individual mistake. This sort of analysis pays substantial dividends in terms of improving patient care and is made possible, at least in part, by the protection that the patient safety work product privilege provides.

The decision below puts the lifesaving progress enabled by methods such as root cause analysis at risk. At worst, a carveout for medical "information normally contained in" documents subject to a state reporting or record keeping obligation threatens to create an exception that swallows the rule. Pet. App. 24a-25a. As the petition explains, there will nearly always be a colorable argument that patient safety work product is information of the sort "normally contained in" documents subject to a state reporting or record keeping requirement. *See* Pet'n 25. As a result, the "normally contained in" exception could render Congress' patient safety work product privilege a nullity and eliminate the critical health care benefits that flow directly from that privilege. The vast majority of states have reporting and recordation requirements resembling the one at issue here. *See, e.g.*, 410 Ind. Admin. Code 15-1.2-1(e) (2015); 77 Ill. Admin. Code 250.990 (2015); Utah Admin. Code r. 432-100-38(4)(c) (2015); Wis. Admin. Code DHS § 124.11(3) (2015).

The alternative to the worst case scenario is no more tolerable. At an absolute minimum, the decision below creates substantial uncertainty in an area where Congress went to great lengths to create clear and predictable rules. The resulting ambiguity will make it much harder for PSOs to convince health care providers to share information regarding adverse patient safety events and severely handicap the ability of these entities to evaluate patient safety risks and prescribe effective remedies. *See* Zane R. Wolf & Ronda G. Hughes, *Error Reporting & Disclosure, in Patient Safety and Quality: An Evidence Based Handbook for Nurses*, 2-333 to 2-339 (2008).

II. Immediate Review Of The Question Presented Is Critical.

The Joint Commission respectfully submits that the Court should address the scope of the patient safety work product privilege now and not wait for some future case presenting a similar question. As the petition explains, while the question presented in this case is of paramount importance, it is unlikely to be presented to this Court in a final judgment with great frequency. Pet'n. 31. The scope of the patient safety work product privilege is most often litigated in state court medical malpractice suits and is only rarely the primary focus of a final judgment on the merits free from the distractions presented by the other issues in a malpractice case. Accordingly, this case presents the ideal vehicle for providing much-needed clarity on the scope of the patient safety work product privilege Congress created.

More importantly, in the absence of this Court's immediate intervention, a return to the pre-Patient Safety Act status quo is all but inevitable. Despite the manifest clarity of the statutory provisions at issue, lower courts are confused about the operation and scope of the privilege Congress created. *See* Pet'n 21-25. Decisions like the one at issue here diminishing the privilege make it highly unlikely that health care organizations will adopt a robust view of what constitutes patient safety work product. That means these organizations will be unwilling to cultivate and share the information necessary to develop practices and procedures that can save lives. As noted *supra*, PSOs already encounter difficulty when attempting to convince health care organizations to share

information about adverse patient safety events. The Joint Commission has encountered the same problem. In the wake of the decision below, PSOs are essentially back at square one in terms of convincing health care organizations that they can share information about adverse patient safety events free from fear of use in litigation.

While the decision below is limited in direct application to only one State, its effects will reverberate nationwide as health care organizations will almost certainly operate based on the least generous interpretation of the patient safety work product privilege for fear that patient safety work product will later be used against them in litigation. What is more, as health care delivery becomes increasingly complex, the need for information sharing free from the fear that no good deed will go unpunished will be even more imperative. This Court's immediate attention is warranted.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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