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 FOR *AMICUS CURIAE* THE JOINT COMMISSION IN SUPPORT OF PETITIONER

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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. § 488.4.

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 21,000 health care organizations and programs in the United States, develops standardized performance measures used in

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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. Counsel of record for the parties received timely notice of The Joint Commission's intent to file an amicus brief and counsel of record granted consent to The Joint Commission for the filing of this brief.

connection with those evaluations, and conducts in-depth research on matters of vital importance to 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 have been a direct result of health care providers' efforts to comply with The 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" or "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-22(c)(2)(E).[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 quality.

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 sensitive information from medical events to promote the identification, evaluation, and correction of systemic deficiencies. As Congress recognized,

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[2] A component of The Joint Commission may obtain certification as a PSO so long as certain firewalls are established, 42 C.F.R. § 3.102(a)(2)(iii), but The Joint Commission has not established a component PSO.

allowing health care organizations and providers to share information about potential risks to patients in a "non-punitive environment," free from fear that the information will later be used against them in court or to damage their reputations, is necessary to any meaningful evaluation of such information and implementation of effective improvements. S. Rep. No. 108-196, at 5 (2003). To that end, Congress understood that broadly applicable and absolute protections – ones which expressly preempt all conflicting federal, state, and local laws to the contrary – were essential to induce providers to participate in a voluntary information-sharing process.

The decision below is irreconcilable with the broad scope and purpose of the federal patient safety work product privilege and threatens to cut off such vital information-sharing efforts. Specifically, if state courts can unilaterally choose to negate at will the protections of the Patient Safety Act, then the Act is rendered without effect in states that decide to ignore it. As a result, in the absence of a clear and predictable rule in defining what is protected as patient safety work product, 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 decision below reflects a disregard for health care safety and quality improvement activities the

Patient Safety Act was designed to promote. The Patient Safety Act creates an expansive privilege protecting "patient safety work product," which the Act broadly defines as "any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements" created for or supplied to a patient safety organization, or PSO. 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 clear and unassailable, the Act 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 . . . ." 42 U.S.C. § 299b-22(a)(1). Without regard to the text of the Patient Safety Act, however, the Florida Supreme Court unilaterally created a new "sole purpose" exception to the definition of patient safety work product that directly contradicts the language and intent of the Act.

As The Joint Commission knows, based on its longstanding involvement with this issue, the broad privilege Congress adopted in the Patient Safety Act was necessitated by a gap in state law privilege protections that critically undermined the development and sharing of information to improve patient safety.[3] The inadequacy of then-governing state laws

[3] 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

to encourage effective self-evaluation and information sharing was proved empirically by the Institute of Medicine in its seminal publication, Institute of Medicine, *To Err is Human: Building a Safer Health System* (1999), which found that the then-existing legal framework failed to prevent numerous deaths from medical errors each year. In response to these state law failings, Congress adopted a national approach to encourage efforts within the health care industry for improving health care safety and quality. Through the privilege for patient safety work product and its express preemption provision Congress designed the Act as a means of enabling a nationwide-effort of private sector collaborations that minimize patient risk through documenting, analyzing, and discussing safety and quality issues 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). Acknowledging the understandable reluctance that comes with sharing information regarding incidents that result – or come close to resulting – in patient harm, the patient safety work product privilege encourages health care organizations to cultivate and share information about adverse patient safety events.

For example, PSOs encourage hospitals to conduct a "root cause analysis" following any unexpected occurrence involving death or serious injury, or any procedural aberration that, if repeated, would create a significant risk of harm to patients. As the name suggests, a "root cause analysis" evaluates the systems and procedures in health care delivery to look beyond the tendency of assuming mistakes are isolated or

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immunity to health care providers engaged in the peer review process.

random. 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. It is no coincidence that the Patient Safety Act's very definition of "patient safety work product" includes the term "root cause analyses" because this type of analysis is exactly the kind of activity the Act was intended to protect. 42 U.S.C. § 299b-21(7).

Occurrence reports, such as the ones the decision below found were not privileged, serve a similar purpose for advancing safety and quality. Occurrence reports provide health care employees an opportunity to share information on events that the reporter perceives as a deviation from the routine operation of the hospital or the routine care of a patient. Such documents alert health care providers to improvement opportunities for future care even for reported events that do not result in adverse consequences to a patient.

The decision below, however, puts the lifesaving progress enabled by methods such as root cause analysis and occurrence reporting at risk by muffling the Act's construct of shared learning. Under the reasoning of the Florida Supreme Court, any documents "not created *solely* for the purpose of submission to a patient safety evaluation system" would be excepted from the federal privilege. Pet. App. 31a (emphasis added). Neither the phrase "sole purpose" nor the concept as described in the decision below, can be found in the Patient Safety Act.[4] Moreover a "sole

[4] The Florida court's "sole purpose" exception also fails to recognize that the information protected by the patient safety work product privilege pertains to after-the-fact deliberations and analyses performed to improve patient safety and quality. Such analyses necessarily include impressions, ideas, and

purpose" test is entirely contrary to the purpose and intent of the Patient Safety Act.

First, while the Patient Safety Act itself lists certain exceptions to the privilege, the decision below impermissibly carves out an exception that renders the listed statutory exceptions meaningless. For example, the Patient Safety Act includes an exception for voluntary disclosures of patient safety work product to an accrediting body that would allow a hospital to prepare a document such as a root cause analysis for submission both to a PSO and also to The Joint Commission in the context of accreditation, without relinquishing the privilege provided by the Act. 42 U.S.C. § 299b-22(c)(2)(E); 42 U.S.C. § 299b-22(d)(1); 42 C.F.R. § 3.206(b)(8). In other words, the Patient Safety Act absolutely does protect patient safety work product that serves more than one purpose. The opportunity for dual disclosures built into the language of the Act itself – to the PSO and to The Joint Commission – is squarely at odds with a "sole purpose" test. The Florida court's order directing discovery of such information eviscerates the federal statute's intended force and defeats Congress' core purpose of improving the quality of health care nationally.

To improve systems and processes for enhancing safety, health care providers need to learn from patient safety experts both inside *and outside* their organizations. Thus, the purpose of the patient safety work product privilege is to encourage collaboration with outside experts in patient safety, so organizations

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suggestions for improvement; the specific facts about what occurred during the patient's care and treatment would remain otherwise available to a plaintiff through discovery of the original medical records.

can obtain analysis and feedback on processes and systems for additional critique and rapid advancement in patient safety and health care quality. The "sole purpose" exception, however, threatens to strip away the Act's protections whenever a health care provider puts patient safety work product to use.

Second, the effect of the decision below necessarily creates the very situation Congress sought to avoid – that of requiring duplicative quality systems: (1) one to collect patient safety work product and report it to PSOs; and (2) one to satisfy "other" purposes. 73 Fed. Reg. 70732, 70740-41 (November 21, 2008) (codified in 42 C.F.R. part 3). The decision below unnecessarily complicates the PSO Program by posturing the Patient Safety Act as if it were in conflict with state health licensure laws. The language of the Patient Safety Act does not limit state licensure obligations of reporting and record-keeping, but it distinguishes these obligations and places the burden upon the provider to comply with them. *See* 42 U.S.C. § 299b-21(7)(B)(iii). As explained by the Department of Health and Human Services, all the information collected in the patient safety evaluation system "is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state." 73 Fed. Reg. at 70742. If a provider needs to disclose information to comply with a state licensure obligation, then the provider may extract—or separate—the information from its patient safety evaluation system and disclose it before it is reported to the PSO. *See* 42 U.S.C. § 299b-21(7)(B)(ii); 42 C.F.R. § 3.20 (defining "patient safety work product"); 73 Fed. Reg. at 70742 (explaining this process by stating that providers are not required to "maintain duplicate systems to separate information to be reported to a PSO from information

that may be required to fulfill state reporting obligations."). Adding a "sole purpose" test to the Patient Safety Act frustrates the Act by effectively requiring duplicate systems that will discourage provider participation in the information sharing the Patient Safety Act was designed to promote.

Third, the decision's treatment of preemption in the Patient Safety Act poses a significant threat to its national effectiveness in promoting patient safety. As noted above, the plain language of the Act expresses Congressional intent to preempt state law. *See* § 299b-22(a). Moreover, as Justice Kennedy explains, the Supreme Court's "task in all pre-emption cases is to enforce the 'clear and manifest purpose of Congress' . . . [which] must be divined from the language, structure, and purposes of the statute as a whole." *Gade v. Nat'l Solid Wastes Management Ass'n*, 505 U.S. 88, 112 (1992) (Kennedy, J., concurring) (citations omitted). Not only is the language of the Patient Safety Act clear on its face, but its legislative history also confirms Congress' intent to preempt state law, stating that the Act would "preempt" any state laws governing civil procedure "that require the disclosure of information provided by a health care provider to a certified patient safety organization." H.R. Rep. 109-197 at 12 (2005). Further, the federal agency responsible for administering the Act confirms "the patient safety work product protections provided for under the statute generally preempt State or other laws that would permit or require disclosure of information contained within patient safety work product." 73 Fed. Reg. at 70774. Under the reasoning of the Florida Supreme Court, any state could avoid the preemptive effect of the Patient Safety Act and the application of the federal privilege by simply passing a law requiring the creation of or permitting discovery of documents

that the Patient Safety Act would otherwise protect. Such state-by-state variability in the availability of the privilege is antithetical to the purpose and construct of the Patient Safety Act and would bring to an abrupt halt the progress in improving patient safety that has been achieved since its passage.

Finally, and at a 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 to convince health care providers to share information regarding patient safety events and severely handicap the ability of outside entities to evaluate patient safety risks and prescribe effective remedies.

II. IMMEDIATE REVIEW OF THE QUESTION PRESENTED IS CRITICAL.

The Joint Commission respectfully submits that the Court should address the scope and applicability of the patient safety work product privilege and its preemption of conflicting state laws now. Although the resolution of the question presented will have ramifications across the nation, its exact nature is unlikely to be presented to this Court in a final judgment with great frequency. 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. In particular, the progress made in improving patient safety since the passage of the Act is threatened by the very real possibility that other state courts will likewise disregard the preemption language in the statute and carve out their own requirements and exceptions in a manner that ignores the statute and frustrates Congressional intent. Decisions like the one below diminishing the privilege and creating ambiguity, despite the manifest clarity of the statutory provisions at issue, 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. The Joint Commission already encounters some difficulty in convincing health care organizations of the benefits of sharing information about adverse patient safety events given the consequences that disclosure may bring in the absence of protections. The decision below will greatly increase that difficulty by permitting states to essentially "opt out" of the national reach of a federal statute.

As the petition aptly describes, in the wake of the decision below, the national scope and effectiveness of the Patient Safety Act will be effectively "neuter[ed]," Pet'n at 31, if other state courts similarly interpret the question of preemption in a manner that renders the federal privilege without effect in particular states. Such consequences 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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