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 HOSPITAL ASSOCIATION AND FEDERATION OF AMERICAN HOSPITALS AS AMICI CURIAE IN SUPPORT OF PETITIONER

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OTHER AUTHORITIES:

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Paul J. Barringer & Allen B. Kachalia, *Error Reporting and Injury Compensation: Advancing Patient Safety Through A State Patient Safety Organization*, 8 WYO. L. REV. 349 (2008) 12

Eric Scott Bell, *Make Way: Why Arkansas and the States Should Narrow Health Care Peer Review Privileges for the Patient Safety and Quality Improvement Act of 2005*, 62 ARK. L. REV. 745 (2009) 10, 18

California Hospital Patient Safety Organization, *CHPSO 2014 Annual Report* 11

Center for Patient Safety, *PSO "Safe Tables" Result in Fall Prevention Interventions* (June 26, 2012) 11

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Mary Coombs, *How Not to Do Medical Malpractice Reform: A Florida Case Study*, 18 HEALTH MATRIX 373 (2008) 16

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Institute of Medicine, *To Err Is Human: Building A Safer Health System* (Nov. 1999) 3, 7, 8

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NASA, *Aviation Safety Reporting System: Confidentiality and Incentives to Report* 13

Peter J. Pronovost, *et al.*, *Reducing Health Care Hazards: Lessons from the Commercial Aviation Safety Team*, HEALTH AFFAIRS, Apr. 2009 ..... 9, 10

William Riley, *Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improvement Act*, in *Advances in Patient Safety: New Directions and Alternative Approaches* (Kerm Henriksen, *et al.*, eds.) 15

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Laura V. Yaeger, *Amendment 7: Medical Tradition v. The Will of the People: Has Florida's Peer Review Privilege Vanished?*, 13 MICH. ST. U. J. MED. & L. 123 (2009)..... 17

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STATEMENT OF INTEREST

The American Hospital Association and Federation of American Hospitals respectfully submit this brief as *amici curiae*.[1]

[1] No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party, or person other than *amici curiae*, their members, or counsel made any monetary contribution intended to fund the preparation or submission of this brief. All parties were notified of *amici curiae*'s intent to submit this brief at least 10 days before it was due, and all parties have consented to the brief in letters that have been lodged with the Clerk.

The American Hospital Association represents nearly 5,000 hospitals, health care systems, and other health care organizations, plus 43,000 individual members. AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health policy.

The Federation of American Hospitals is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Members include teaching and non-teaching hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

AHA and the Federation have long understood that patient safety must be hospitals' first priority, and they and their members have long sought to foster the "culture of safety" that is essential to detecting and preventing medical errors. *See* 42 U.S.C. § 299b-21(5)(D). That is why AHA and the Federation supported the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (2005), and that is why they advocated for the Secretary of Health and Human Services to promptly promulgate rules implementing the Act.

The petition succinctly explains how the Florida Supreme Court's decision conflicts with the Patient Safety Act's text and conflicts with other courts on how to interpret the Act's broad privilege for provid-

ers' reports to patient safety organizations. Pet. 15-27. AHA and the Federation write to underscore two points. First, the Patient Safety Act—and its privilege for reports to patient safety organizations—is a critical tool for improving patient safety. Second, the Florida Supreme Court's decision, if allowed to stand, will thwart Congress's goals in passing the Act. Nationwide, over 2,200 hospitals participate in patient safety organizations. The Court should grant the writ and reassure these hospitals and other providers that they can report, study, and learn from errors and near-errors without fear of public disclosure—just as Congress intended.

SUMMARY OF ARGUMENT

I. Patient safety organizations, if allowed to function as Congress intended, can dramatically enhance patient safety. Starting with the Institute of Medicine's seminal 1999 report *To Err Is Human*, patient-safety advocates have recognized that the vast majority of medical errors are caused by broken systems, not reckless providers. But patient-safety advocates also understood that providers had little incentive to share and learn from each other's mistakes. Quite the contrary, in fact: the ever-present threat of medical-malpractice litigation encouraged practitioners to remain silent. Policymakers seeking to improve patient outcomes thus sought to create a "culture of safety" where errors and their causes could be openly discussed. Stakeholders agreed that a candid and protected airing of mistakes and their causes helps providers develop improved systems to prevent those errors from happening again.

Congress responded to this consensus by passing the Patient Safety and Quality Improvement Act. The Act encourages providers to create or join patient safety organizations, which will collect reports of errors and near-errors from providers, analyze those reports for the errors' root causes, and recommend ways the errors can be avoided in the future. Congress based this system on demonstrated successes from other fields—particularly the aviation industry. Congress anticipated that the patient safety organization model set out in the Patient Safety Act would have similar success.

Congress understood that providers would not report to patient safety organizations unless they were confident that their reports would remain privileged. It therefore built into the Patient Safety Act a promise of nearly absolute confidentiality for reports to patient safety organizations: the reports could not be used in any forum—state or federal, civil or criminal—assuring providers that they could honestly assess their mistakes without fear of repercussions. Congress, then, explicitly linked the Patient Safety Act's success to courts' enforcement of the Act's privilege for reports to patient safety organizations. If providers cannot rely on the privilege, patient safety organizations cannot achieve the Act's goals for them.

II. The Florida Supreme Court's decision below significantly compromises the effectiveness of the Patient Safety Act. Even before the Florida Supreme Court's opinion, providers hesitated to participate in patient safety organizations for fear that the Patient Safety Act's privilege would not be enforced by state courts. The decision below confirms those fears.

Under it, any adverse-event information about a patient recorded by a hospital or its providers are subject to disclosure, notwithstanding the Patient Safety Act's privilege. And given Florida's virtually limitless definition of adverse-event information, it is not clear what—if anything—can still be safely reported to patient safety organizations. Indeed, the Florida Supreme Court's decision appears to return the State to where it was before the Patient Safety Act was enacted. Providers have virtually no privileged way to conduct critical self-analysis. Confronted with that environment, many provider groups may simply choose to not join patient safety organizations.

Even if some provider groups soldier on, individual providers' reports may be chilled. Providers understandably focus on risk management and worry about the integrity of their professional reputation. They may rationally decide that the risk of disclosure in later litigation is too great. If enough providers feel this way, reports to patient safety organizations will dry up. And for the providers that *do* continue to report even in the face of the Florida Supreme Court's opinion, the uncertainty generated by the decision may lead to self-censored reports that are not as useful in analyzing or predicting patient-safety trends.

The Florida Supreme Court's decision is particularly unwarranted because it is unnecessary to assure negligent providers are held accountable for careless and avoidable mistakes. Plaintiffs still have access to their medical records, and they may use the traditional tools of discovery to find out the facts underlying an incident. All plaintiffs cannot do

under the federal Patient Safety Act is obtain the reports providers make to patient safety organizations. The Florida Supreme Court may not like that limitation, but that is the balance Congress struck, and it was a choice for Congress, not the courts, to make.

ARGUMENT

I. PATIENT SAFETY ORGANIZATIONS CAN DRAMATICALLY ENHANCE PATIENT SAFETY.

Patient safety organizations aggregate data from members; provide evidence-based analysis of the root causes of medical errors and near-misses; and propose systems-focused solutions to prevent future mistakes. Patient safety organizations can achieve these objectives, however, only if they receive a sufficient number of safety-event reports, which requires broad-based participation by providers. And providers will participate only if they can rely on the Patient Safety Act's guarantee of nearly absolute confidentiality for patient safety work product.

1. Patient safety "has emerged as a major health policy issue." S. Rep. No. 108-196, at 4 (2003).[2] The

[2] The Congressional reports cited in this brief relate to a previous 2003 version of the Patient Safety Act. But the 2005 version that was ultimately enacted "was to large extent simply a reintroduction of the Senate's 2003 version." *Tibbs* v. *Bunnell*¸ 448 S.W.3d 796, 811 n.12 (Ky. 2014) (Abramson, J., dissenting) (citing Robert A. Kerr, *The Patient Safety and Quality Improvement Act of 2005: Who Should Pay for Improved Outcomes?*, 17 HEALTH MATRIX 319, 328 (2007)). The 2003 legislative reports therefore provide "meaningful insight into the congressional intent animating the" Patient Safety Act. *Id.*

issue was brought to the fore by the Institute of Medicine's seminal report, *To Err Is Human*, which found that medical errors cost the country between $17 and $29 billion annually. Institute of Medicine, *To Err Is Human: Building A Safer Health System* 27 (Nov. 1999).

One of the study's critical findings was that eliminating medical errors takes more than "getting rid of bad apples." *Id.* at 49. Although most medical errors are the result of human factors, humans are not necessarily to "blame" for most medical errors. *Id.* at 53. Instead, the majority of errors are systemic, meaning that they are due to breakdowns in the systems providers rely on to deliver care. *Id.* at 51-53. In other words, errors are often "caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." Kelly G. Dunberg, Note, *Just What The Doctor Ordered? How The Patient Safety And Quality Improvement Act May Cure Florida's Patients' Right To Know About Adverse Medical Incidents*, 64 FLA. L. REV. 513, 533 (2012).

To Err Is Human's focus on the systems that cause error was revolutionary. Before it, existing medical-error-reduction programs emphasized skill and attention to detail; they believed that if medical staff tried harder, focused more, and were punished for their mistakes, errors could be avoided. *See* Abram J. Twerski, *Medical Errors: Focusing More on the What and Why, Less on Who*, J. OF ONCOLOGY PRACTICE, Mar. 2007, at 66, 66 ("Teaching hospitals have focused on the sequelae of errors rather than teaching ways to prevent them or the value of disclosing them."); *To Err Is Human*, *supra*, at 269

(noting that pre-existing error-review processes "stress[ed] the value of knowledge, skill, and alertness" and did "not tend to address systemic issues").

Medical-malpractice suits are emblematic of this older way of responding to medical errors. Malpractice cases "shame and blame" individual providers instead of improving the systems providers are a part of. David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation For Health Care*, 58 WASH. & LEE L. REV. 1427, 1446 n.80 (2001). To reform the systems responsible for most medical errors, the Institute of Medicine warned, the "culture of blame must be broken down." *To Err Is Human*, *supra*, at ix.

2. Congress responded to these concerns in the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (2005). The Act "focuses on creating a voluntary program through which health care providers can share information relating to patient safety events * * *, with the aim of improving patient safety and the quality of care nationwide." *Patient Safety & Quality Improvement*, 73 Fed. Reg. 70,732, 70,732 (Nov. 21, 2008).

The Act does so primarily through a system of patient safety organizations. To qualify as a patient safety organization, an organization must engage in "patient safety activities," which include collecting and analyzing safety reports from providers; developing and disseminating information to improve patient safety, "such as recommendations, protocols, or information regarding best practices"; and using providers' safety reports to "encourag[e] a culture of safety and of providing feedback and assistance to effectively minimize patient safety risk." 42 U.S.C.

§ 299b-21(5) (defining "patient safety activities"); *id.* § 299b-24(a) (patient safety organizations must engage in each of these patient safety activities). Patient safety organizations must also employ qualified staff to analyze the reports received and have contracts for "a reasonable period of time" with more than one provider for the purpose of collecting and analyzing safety-related reports. *Id.* § 299b-24(b)(1). Patient safety organizations, in short, must dedicate themselves to the collection, analysis, and dissemination of materials that promote patient safety.

By aggregating and analyzing safety reports from multiple providers, patient safety organizations can detect errors existing systems miss. They can identify "errors that occur on such an infrequent basis that they would be difficult to detect by any one single health organization." Bernadette Fernandez & Fran Larkins, Congressional Research Service, *Medical Malpractice: The Role of Patient Safety Initiatives* 11 (Jan. 2005).[3] And they also can spot "error trends or patterns which allude to system problems that may impact all health care organizations." *Id.* Identifying these errors and trends, the Congressional Research Service explained, "could facilitate the development of strategies to prevent more serious errors from occurring." *Id.*

Congress had good reason to think patient safety organizations would achieve these goals. A similar report-and-analyze model in the aviation industry—the Aviation Safety Reporting System—has been credited "with helping to greatly increase commercial aviation safety." *Id.* at 10; *see also* Peter J. Pro-

[3] *Available at* http://goo.gl/bt7orZ.

novost, *et al*., *Reducing Health Care Hazards: Lessons from the Commercial Aviation Safety Team*, HEALTH AFFAIRS, Apr. 2009, at 479, 482 (detailing the "dramatic improvement in aviation safety" due to a similar joint government-industry error-analysis program). And nuclear power and petrochemical processing, two other safety-focused industries, also use reporting and analysis to detect and prevent systemic errors. *Focusing More on the What and Why*, *supra*, at 66.

Although the health care sector's experience with error reporting and analysis is more limited, past successes suggest patient safety organizations' significant potential. In one prominent example, anesthesiology groups discovered that anesthesiologists sometimes connected oxygen tubing to nitrous-oxide tubing, harming patients. *Reducing Health Care Hazards*, *supra*, at 484. Using systems analysis, anesthesiology groups found a solution: redesign the equipment so that it is physically impossible for oxygen and nitrous-oxide tubing to be connected. *Id.* Similarly, the National Nosocomial Infection Survey, a voluntary system of reporting hospital-acquired infections, has been shown in controlled trials to be effective. Eric Scott Bell, *Make Way: Why Arkansas and the States Should Narrow Health Care Peer Review Privileges for the Patient Safety and Quality Improvement Act of 2005*, 62 ARK. L. REV. 745, 757 (2009). Hospitals that participated saw a 32% drop in infections compared to those that did not. *Id.* at 758.

Backers of patient safety organizations anticipated that they would achieve similar results. Senator Jeffords called the Patient Safety Act "among the

most significant healthcare legislation the Senate will consider." 151 Cong. Rec. S8741, S8742 (2005). President Bush, when he signed the Act into law, commended it as a "critical step toward our goal of ensuring top-quality, patient-driven health care for all Americans." 2005 U.S.C.C.A.N. S11 (July 29, 2005). And Congress expanded the Act's protections just last year, allowing health-information technology developers to participate in patient safety organizations as providers when reporting safety incidents related to electronic records and similar health-information technology. The 21st Century Cures Act, Pub. L. No. 114-255, § 4005, 130 Stat. 1033, 1181 (2016).

There are early examples that patient safety organizations are meeting those objectives. Patient safety organizations are offering recommendations on how to prevent falls in hospital settings and prevent errors due to patient misidentification; raising awareness about potential hazards when using electronic health records; and convening "safe tables," where health care providers candidly share patient safety experiences and lessons learned. *See* California Hospital Patient Safety Organization, *CHPSO 2014 Annual Report*[4]; ECRI Institute, *Case Study: Large Health System Improves Root Cause Analysis Process*[5]; Center for Patient Safety, *PSO "Safe Tables" Result in Fall Prevention Interventions* (June 26, 2012).[6]

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[4] *Available at* http://goo.gl/4jTc6s.

[5] *Available at* http://goo.gl/cYZOs9.

[6] *Available at* http://goo.gl/6q2jbZ.

3. For patient safety organizations to fulfill their promise, however, providers have to join them. Without widespread provider participation, important safety trends or systemic safety challenges may go undetected. And practically speaking, larger patient safety organizations have more leverage to put safety recommendations into practice. As one patient safety organization's director put it, large organizations, "representing hundreds of hospitals, can influence manufacturers in ways individual hospitals cannot." D. Scott Jones & Rory Jaffe, *Patient Safety Organizations: Champions for Quality—Ready for PPACA*, J. OF HEALTH CARE COMPLIANCE, Jan.-Feb. 2014, at 41, 42.

One of the biggest barriers to provider participation is the fear of professional liability. Commentators have observed that "healthcare providers have been uneager to participate in reporting medical error because of feared liability risks." Teresa M. Schreffler, Comment, *Systems Approaches to Improving the Quality of Healthcare: Strengths, Weaknesses, and the Ideal Model of Medical Error Reporting*, 53 U. KAN. L. REV. 1249, 1251 (2005). Or, as another commentator explained, "health policy experts have identified the legal system as an impediment to improving health care quality—precisely because of the chilling effect it has on providers' willingness to disclose." Paul J. Barringer & Allen B. Kachalia, *Error Reporting and Injury Compensation: Advancing Patient Safety Through A State Patient Safety Organization*, 8 WYO. L. REV. 349, 350-351 (2008).

Congress understood that. To convince providers to join patient safety organizations, the Patient Safety Act makes reports to patient safety organizations

from providers—called "patient safety work product," 42 U.S.C. § 299b-21(7)—confidential under almost all circumstances. The Act provides that patient safety work product is "privileged" and shall not be "subject to a Federal, State, or local civil, criminal, or administrative subpoena or order." *Id.* § 299b-22(a). Nor shall it be "subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding." *Id.* Nor shall it be "admitted as evidence in any Federal, State, or local government civil proceedings, criminal proceedings, administrative rulemaking proceeding, or administrative adjudicatory proceeding." *Id.*

Congress again drew on the Aviation Safety Reporting System's experience in crafting the Patient Safety Act's confidentiality provisions. Reports to the Safety Reporting System are absolutely confidential. NASA, *Aviation Safety Reporting System: Confidentiality and Incentives to Report*.[7] The Safety Reporting System's administrators take that guarantee seriously: They have processed over 1 million reports since 1975 without ever revealing a reporter's identity. *Id.* The protections for reporters are so well ingrained that industry organizations teach pilots "when in doubt, write it out"—a report can only help, and never hurts. Wally Miller, Aircraft Owners and Pilots Association, *Get Out of Jail Free*, FLIGHT TRAINING, June 2001 (capitalization altered).[8] Thanks to aviators' wide participation, the Aviation Safety Reporting System is "widely regarded as one of the world's largest sources of information on

[7] *Available at* https://goo.gl/ke8HGZ.

[8] *Available at* https://goo.gl/vGuhpu.

aviation safety and human factors." NASA, *ASRS Program Briefing* 15 (2015).[9]

Congress saw a similar link between confidentiality and effectiveness in the Patient Safety Act. The House Report explained that the Act's broad protections were "intended to encourage the reporting and analysis of medical errors and health care systems." H.R. Rep. No. 109-197, at 9 (2003). The Senate Report concurred. The Act's privilege for patient safety work product, it noted, was "required to encourage the reporting of errors and to create an environment in which errors became opportunities for learning and improvement." S. Rep. No. 108-196, at 3. If providers cannot trust that their reports will remain confidential, the Act will not be able to fulfill Congress's aims.

II. THE DECISION BELOW COULD UNDERMINE PATIENT SAFETY ORGANIZATIONS' EFFECTIVENESS.

The Patient Safety Act's success depends on voluntary participation by providers, and providers will participate only if they can rely on the Act's confidentiality guarantee. The Florida Supreme Court's holding (Pet. App. 19a) that plaintiffs may obtain any incident reports—their own or others'—relevant to their case creates significant uncertainty for providers. That, in turn, may depress reports to patient safety organizations, and may undermine those organizations' effectiveness.

1. Even before the decision below, some providers hesitated to join patient safety organizations because

[9] *Available at* https://goo.gl/Ty1hpx.

they feared that recalcitrant state courts would not interpret the Patient Safety Act's privilege protections as absolute. One expert warned that "[t]here is some hesitancy" to join patient safety organizations because the patient-safety work-product "privilege is not well tested." *Champions for Quality*, *supra*, at 42. Another predicted that the Safety Act's "untested" privilege would be "construed narrowly and be subject to exceptions by the courts." Charles M. Key, *Toward A Safer Health System: Medical Injury Compensation and Medical Quality*, 37 U. MEM. L. REV. 459, 470 (2007). And some "skeptics questioned" whether the Act's "firm requirements ensuring the protection of confidential information" would hold up. *Just What The Doctor Ordered*, *supra*, at 533. Because of these concerns, "progress in implementing the Act has been slow." William Riley, *et al.*, *Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improvement Act*, at 1, in *Advances in Patient Safety: New Directions and Alternative Approaches* (Kerm Henriksen, *et al.*, eds.).[10]

The Florida Supreme Court's decision confirms these fears. In holding Amendment 7 not preempted, the court allowed access to "any records made or received * * * relating to an adverse medical incident," and defined an "adverse medical incident" as "any * * * act, neglect, or default of a health care facility or health care provider that caused or could have caused injury to or death of a patient." Pet. App. 3a, 19a (quoting Fla. Const. art. X, § 25(a), (b)(3)). That is a definition with tremendous sweep;

[10] *Available at* http://goo.gl/19fqvy.

it is not clear what—if anything—a provider could report to its patient safety organization and *not* be subject to Amendment 7. *See* Pet. 28. A rational hospital general counsel confronted with these realities may hesitate before having her providers join a patient safety organization. And if enough of her peers similarly hesitate, patient safety organizations will not achieve their goals. *See supra* at pp. 11-14.

Indeed, commentators supported the Patient Safety Act precisely because they believed it would restore some safety reporting and self-critical analysis to Florida in the wake of Amendment 7. Commentators thought it obvious that "the disclosure mandated by Amendment 7 and forbidden by [the Patient Safety Act] are clearly in conflict," and that the Patient Safety Act would therefore preempt Section 7. Michael Arnold, *Peer Review is Threatened, but (P)So What: Patient Safety Organization Utilization in Florida After Amendment 7 is a Troubling Sign for PSQIA*, 46 COLUM. J.L. & SOC. PROBS. 297, 317 (2013). They therefore thought that "Florida healthcare providers can use [patient safety organizations] to secure [Patient Safety Act] privilege and confidentiality protections as a way of avoiding the disclosure mandated by Amendment 7." *Id.*; *see also* Brendan A. Sorg, Comment, *Is Meaningful Peer Review Headed Back to Florida?*, 46 AKRON L. REV. 799, 828 (2013) ("Florida hospitals that report peer review materials appropriately through a [patient safety organization] will attain protection for the type of documents that Amendment 7 desired to make discoverable."); Mary Coombs, *How Not to Do Medical Malpractice Reform: A Florida Case Study*,

18 HEALTH MATRIX 373, 417 (2008) (recognizing that the Patient Safety Act "may provide federal protection against discoverability" for records covered by Amendment 7). And commentators credited the protections provided by the Patient Safety Act vis-à-vis Amendment 7 for making Florida providers leaders in creating and joining patient safety organizations. *See* Philip M. Cox, *et al.*, *The Amendment 7 Decade: Ten Years Living With A "Patient's Right to Know" in Florida*, 25 U. FLA. J.L. & PUB. POL'Y 281, 310 (2014) (recognizing that "some Florida providers have either joined or established or established Patient Safety Organizations * * * seeking federally-created disclosure protections over their peer review and patient safety documents"); Laura V. Yaeger, *Amendment 7: Medical Tradition v. The Will of the People: Has Florida's Peer Review Privilege Vanished?*, 13 MICH. ST. U. J. MED. & L. 123, 149 (2009) (noting that "[s]ince the passage of Amendment 7, more hospitals may choose to voluntarily report patient safety work product to patient safety organizations to benefit from the federal privilege and confidentiality").

The decision below upsets these expectations and threatens to leave Florida providers where they were before the Patient Safety Act: Without many—if any—privileged ways to conduct critical self-analysis. And that inability to conduct privileged self-analysis will ultimately harm patients more than it harms hospitals. *See The Amendment 7 Decade*, *supra*, at 311 (under Amendment 7, "the greatest 'adverse incident' has been on patient safety"). Hospitals, after all, do not seek privileged self-analysis solely to manage litigation risk; they do so

to make their facilities safer for patients. Virtually eliminating the Patient Safety Act's protections in the State, as the Florida's Supreme Court decision does, makes it harder to improve the systems and processes that can lead to medical error.

Even for organizations that take the risk and participate in patient safety organizations, the Florida Supreme Court's decision may skew the reports that are made. Individual doctors may underreport or decline to report their errors and near-errors altogether, lest some later judge-ordered disclosure ruin the integrity of their professional reputations. *See Toward A Safer Health System*, *supra*, at 470 (noting these concerns); *Just What The Doctor Ordered?*, *supra*, at 534 (same). That fear is more than speculative; all authorities on error-reporting systems emphasize that they must be "nonpunitive" to achieve their goals. S. Rep. 108-196, at 4. In other words, patient safety organizations can "measurably improve patient safety," but only if "providers can report safely without concerns of litigation and embarrassment." *Make Way*, *supra*, at 760. The Florida Supreme Court's decision undermines these core principles.

2. The Florida Supreme Court's decision is all the more harmful because piercing the Patient Safety Act's privilege is not necessary to hold negligent providers accountable and compensate deserving plaintiffs. Accountability and compensation can be achieved through other avenues. Although the Patient Safety Act makes reports to patient safety organizations absolutely privileged, the Act is also explicit that it does not protect original patient or provider records, such as the patient's medical

records. *See* 42 U.S.C. § 299b-21(7)(B)(i). Congress also emphasized that the Act does not make the facts underlying an incident privileged. S. Rep. No. 108-196, at 8. Plaintiffs can still obtain their medical records and have their experts opine based on those records, and plaintiffs can still depose providers regarding an incident and discover their impressions about it. H.R. Rep. No. 109-97, at 15. All the Patient Safety Act does is deny plaintiffs a particular *kind* of discovery—the reports providers make to patient safety organizations.

The Senate Report noted that the Patient Safety Act's protection for patient safety work product but allowance for factual discovery "strikes the appropriate balance between plaintiff rights and creating a new culture in the health care industry that provides incentives to identify and learn from errors." S. Rep. No. 108-196, at 4. The Florida Supreme Court may have thought that the balance Amendment 7 struck was a better one. But "[o]nce Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for * * * the courts to enforce them when enforcement is sought." *Tennessee Valley Auth.* v. *Hill*, 437 U.S. 153, 194 (1978). This Court should grant the writ to restore the uniform, predictable privilege Congress promised providers in the Patient Safety Act.

CONCLUSION

For the foregoing reasons and those in the petition, the petition for writ of certiorari should be granted.

Respectfully submitted,

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