

No. 14-1140

---

---

IN THE  
**Supreme Court of the United States**

PHILLIP TIBBS, *et al.*,  
*Petitioners,*

v.

HON. KIMBERLY BUNNELL, *et al.*,  
*Respondents.*

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

**MOTION FOR LEAVE TO FILE BRIEF AND BRIEF  
OF THE AMERICAN HOSPITAL ASSOCIATION AND  
FEDERATION OF AMERICAN HOSPITALS AS  
AMICI CURIAE IN SUPPORT OF PETITIONERS**

MELINDA REID HATTON  
MAUREEN MUDRON  
AMERICAN HOSPITAL  
ASSOCIATION  
800 Tenth Street, N.W.  
Two CityCenter  
Suite 400  
Washington, D.C. 20001

*Counsel for American  
Hospital Association*

CATHERINE E. STETSON  
*Counsel of Record*  
SEAN MAROTTA  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004  
(202) 637-5491  
cate.stetson@hoganlovells.com

*Counsel for Amici Curiae*

(additional counsel listed on inside cover)

---

---

Additional Counsel:

JEFFREY G. MICKLOS  
KATHLEEN TENOEVER  
FEDERATION OF AMERICAN  
HOSPITALS  
750 Ninth Street, N.W.  
Suite 600  
Washington, D.C. 20001

*Counsel for Federation of  
American Hospitals*

IN THE  
**Supreme Court of the United States**

---

No. 14-1140

---

PHILLIP TIBBS, *et al.*,  
*Petitioners,*

v.

HON. KIMBERLY BUNNELL, *et al.*,  
*Respondents.*

---

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

---

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

---

The American Hospital Association and Federation of American Hospitals respectfully move under Rule 37.2(b) for leave to file a brief as *amici curiae* in support of Petitioners in this matter.

All parties were timely notified of AHA and the Federation's intent to file an *amicus* brief. Petitioners and Respondent Circuit Judge Kimberly Bunnell have consented to the brief. Respondent the Estate of Luvetta Goff did not respond to repeated requests for consent, necessitating this motion.

AHA and the Federation are among the largest trade associations in the Nation representing hospitals' interests, and both regularly appear as *amici curiae* before this Court. *See, e.g., King v. Burwell,*

No. 14-114; *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012). As explained in the attached brief, AHA and the Federation are concerned that the Kentucky Supreme Court's decision below compromises the effectiveness of the Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (2005). Their brief explains the Act's importance, its design and intended function, and how the Kentucky Supreme Court's decision undermines its goals, underscoring the national importance of the question the petition presents. *See* Sup. Ct. R. 10(c).

For the foregoing reasons, the motion should be granted.

Respectfully submitted,

CATHERINE E. STETSON

*Counsel of Record*

SEAN MAROTTA

HOGAN LOVELLS US LLP

555 Thirteenth Street, N.W.

Washington, D.C. 20004

(202) 637-5491

cate.stetson@hoganlovells.com

*Counsel for Amici Curiae*

April 2015

## TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
STATEMENT OF INTEREST .....	1
SUMMARY OF ARGUMENT.....	3
ARGUMENT .....	6
I. PATIENT SAFETY ORGANIZATIONS CAN DRAMATICALLY ENHANCE PATIENT SAFETY .....	6
II. THE DECISION BELOW COULD UNDERMINE PATIENT SAFETY ORGANIZATIONS' EFFECTIVENESS .....	14
CONCLUSION .....	20

## TABLE OF AUTHORITIES

	Page
<b>CASES:</b>	
<i>Pollard v. FBI</i> , 705 F.2d 1151 (9th Cir. 1983).....	16
<i>Tennessee Valley Auth. v. Hill</i> , 437 U.S. 153 (1978).....	19
<b>STATUTES:</b>	
42 U.S.C. § 299b-21(5).....	8
42 U.S.C. § 299b-21(5)(D).....	2
42 U.S.C. § 299b-21(7).....	12
42 U.S.C. § 299b-21(7)(B)(i).....	19
42 U.S.C. § 299b-22(a).....	12
42 U.S.C. § 299b-24(a).....	8
42 U.S.C. § 299b-24(b)(1).....	9
Ky. Rev. Stat. Ann. § 216B.042(c).....	15
Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (2005).....	<i>passim</i>
<b>EXECUTIVE AND LEGISLATIVE MATERIALS:</b>	
151 Cong. Rec. S8741 (2005).....	10
2005 U.S.C.C.A.N. S11 (July 29, 2005).....	11
H.R. Rep. No. 109-197 (2003).....	13, 19
S. Rep. No. 108-196 (2003).....	6, 14, 17, 19
<b>REGULATIONS:</b>	
Ky. Admin. Regs. 20:016 § 3(3)(a).....	16

## TABLE OF AUTHORITIES—Continued

	Page
Ky. Admin. Regs. 20:016 § 3(4) .....	16
<i>Patient Safety &amp; Quality Improvement,</i> 73 Fed. Reg. 70,732 (Nov. 21, 2008) .....	8
<b>OTHER AUTHORITIES:</b>	
Am. Bar Ass’n Resolution 115 (adopted Aug. 11-12, 2008) .....	17
Paul J. Barringer & Allen B. Kachalia, <i>Error Reporting and Injury Compensation: Advancing Patient Safety Through A State Patient Safety Organization,</i> 8 WYO. L. REV. 349 (2008) .....	12
Eric Scott Bell, <i>Make Way: Why Arkansas and the States Should Narrow Health Care Peer Review Privileges for the Patient Safety and Quality Improvement Act of 2005,</i> 62 ARK. L. REV. 745 (2009) .....	10, 18
California Hospital Patient Safety Organization, <i>CHPSO 2014 Annual Report</i> .....	11
Center for Patient Safety, <i>PSO “Safe Ta- bles” Result in Fall Prevention Interven- tions</i> (June 26, 2012) .....	11
Kelly G. Dunberg, Note, <i>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,</i> 64 FLA. L. REV. 513 (2012) .....	7, 15, 17

## TABLE OF AUTHORITIES—Continued

	Page
ECRI Institute, <i>Case Study: Large Health System Improves Root Cause Analysis Process</i> .....	11
Bernadette Fernandez & Fran Larkins, Congressional Research Service, <i>Medical Malpractice: The Role of Patient Safety Initiatives</i> (Jan. 2005) .....	9
David A. Hyman & Charles Silver, <i>You Get What You Pay For: Result-Based Compensation For Health Care</i> , 58 WASH. & LEE L. REV. 1427 (2001) .....	8
Institute of Medicine, <i>To Err Is Human: Building A Safer Health System</i> (Nov. 1999) .....	3, 6, 7, 8
D. Scott Jones & Rory Jaffe, <i>Patient Safety Organizations: Champions for Quality—Ready for PPACA</i> , J. OF HEALTH CARE COMPLIANCE, Jan.-Feb. 2014 .....	11, 12
Katten, Muchin, Rosenman LLP, <i>Case Law Updates and Implications for Member PSES Activity</i> (Dec. 17, 2014) .....	18
Charles M. Key, <i>Toward A Safer Health System: Medical Injury Compensation and Medical Quality</i> , 37 U. MEM. L. REV. 459 (2007) .....	15, 17
Wally Miller, Aircraft Owners and Pilots Association, <i>Get Out of Jail Free</i> , FLIGHT TRAINING, June 2001 .....	13

## TABLE OF AUTHORITIES—Continued

	Page
NASA, <i>ASRS Program Briefing</i> (2014) .....	13
NASA, <i>Aviation Safety Reporting System: Confidentiality and Incentives to Report</i> .....	13
Peter J. Pronovost, <i>et al.</i> , <i>Reducing Health Care Hazards: Lessons from the Commercial Aviation Safety Team</i> , <i>HEALTH AFFAIRS</i> , Apr. 2009.....	9, 10
William Riley, <i>Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improve- ment Act</i> , in <i>Advances in Patient Safety: New Directions and Alternative Approach- es</i> (Kerm Henriksen, <i>et al.</i> , eds.) .....	15
Teresa M. Schreffler, Comment, <i>Systems Approaches to Improving the Quality of Healthcare: Strengths, Weaknesses, and the Ideal Model of Medical Error Reporting</i> , 53 <i>U. KAN. L. REV.</i> 1249 (2005) .....	12
Lois Shepherd, <i>Assuming Responsibility</i> , 41 <i>WAKE FOREST L. REV.</i> 445 (2006) .....	17
Abram J. Twerski, <i>Medical Errors: Focusing More on the What and Why, Less on Who</i> , <i>J. OF ONCOLOGY PRACTICE</i> , Mar. 2007 .....	7, 10, 18

IN THE  
**Supreme Court of the United States**

---

No. 14-1140

---

PHILLIP TIBBS, *et al.*,  
*Petitioners,*  
v.

HON. KIMBERLY BUNNELL, *et al.*,  
*Respondents.*

---

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

---

**BRIEF OF THE AMERICAN HOSPITAL  
ASSOCIATION AND FEDERATION OF AMERICAN  
HOSPITALS AS AMICI CURIAE IN SUPPORT OF  
PETITIONERS**

---

**STATEMENT OF INTEREST**

The American Hospital Association and Federation of American Hospitals respectfully submit this brief as *amici curiae*.<sup>1</sup>

---

<sup>1</sup> 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, but Respondent the Estate of Luvetta Goff did not respond to repeated requests for consent to file, necessitating the motion accompanying this submission.

The American Hospital Association represents more than 5,000 hospitals, health care systems, and other health care organizations, plus 42,000 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 investor-owned or managed community hospitals and health systems throughout the United States. 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 Kentucky Supreme Court's decision conflicts with the Act's text and adds to the confusion among the lower courts on how to interpret the Patient Safety Act's broad privilege for providers' reports to patient safety organizations. Pet. 15-25. 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 Kentucky 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, have the potential to 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 pa-

tient 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 Kentucky Supreme Court's decision below significantly compromises the effectiveness of the Patient Safety Act. Even before the Kentucky 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 time a generalist trial-court judge concludes that information in a patient safety report also had to be maintained under state law, the

report (or the portions of it subject to state law) must be divulged to a tort plaintiff. But trial-court judges are not doctors, and they are not health-law experts. Views on what information must be disclosed will vary from judge to judge, and providers will have no way to determine before the fact what will be kept safe from plaintiffs' discovery requests. Confronted with that uncertainty, 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 Kentucky Supreme Court's decision, 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 Kentucky 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 Kentucky 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.

The patient safety organizations contemplated by the Patient Safety Act have the potential to dramatically enhance patient safety. Patient safety organizations can 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 there is 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).<sup>2</sup> The 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,

---

<sup>2</sup> 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.” Pet. App. 30a-31a (Abramson, J., dissenting). The 2003 legislative reports therefore provide “meaningful insight into the congressional intent animating the” Patient Safety Act. *Id.* at 31a.

*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).<sup>3</sup> 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 “with helping to greatly increase commercial aviation safety.” *Id.* at 10; *see also* Peter J. Pronovost, *et al.*, *Reducing Health Care Hazards: Lessons from the Commercial Aviation Safety Team*, HEALTH AFFAIRS, Apr. 2009, at 479, 482 (detailing

---

<sup>3</sup> Available at <http://goo.gl/bt7orZ>.

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 there are early indications that patient safety organizations are meeting those objectives. For example, patient safety organizations are offering recommendations on how to prevent falls in hospital settings; 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*<sup>4</sup>; ECRI Institute, *Case Study: Large Health System Improves Root Cause Analysis Process*<sup>5</sup>; Center for Patient Safety, *PSO “Safe Tables” Result in Fall Prevention Interventions* (June 26, 2012).<sup>6</sup>

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 Quali-*

---

<sup>4</sup> Available at <http://goo.gl/4jTc6s>.

<sup>5</sup> Available at <http://goo.gl/cYZOs9>.

<sup>6</sup> Available at <http://goo.gl/6q2jbZ>.

ty—*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. Schrefler, 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 put it, “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, administra-

tive 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*.<sup>7</sup> 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).<sup>8</sup> Thanks to aviators’ wide participation, the Aviation Safety Reporting System is “widely regarded as one of the world’s largest sources of information on aviation safety and human factors.” NASA, *ASRS Program Briefing 15* (2014).<sup>9</sup>

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

---

<sup>7</sup> Available at <http://asrs.arc.nasa.gov/overview/confidentiality.html>.

<sup>8</sup> Available at <http://goo.gl/at2qj5>.

<sup>9</sup> Available at <http://goo.gl/MC0eID>.

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. 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 Kentucky Supreme Court's holding (Pet. App. 25a) that plaintiffs may obtain reports to patient safety organizations that contain information required to be kept by state law creates significant uncertainty for providers. That, in turn, may depress reports to patient safety organizations, and may undermine the organizations' effectiveness.

1. Even before the decision below, some providers hesitated to join patient safety organizations because 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 fears, “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.).<sup>10</sup>

The Kentucky Supreme Court’s decision confirms these fears. It held that because the information in a surgical nurse’s report to her hospital’s patient safety organization also had to be kept under Kentucky state law, the information in the report was not privileged. Pet. App. 24a-26a. And it directed the trial judge to review the nurse’s report and separate out the information subject to Kentucky’s state reporting requirements. Pet. App. 26a. That holding leaves Kentucky providers with no firm guidance as to what will qualify as privileged patient safety work product in the Commonwealth.

The breadth of Kentucky’s statutes suggests that not much will be privileged. State law commands hospitals to “[e]stablish \* \* \* procedures to ensure safe, adequate, and efficient \* \* \* health facilities and health services,” a sweeping mandate Ky. Rev. Stat. Ann. § 216B.042(c). And Kentucky’s administrative code provides few limits on the in-

---

<sup>10</sup> Available at <http://goo.gl/19fqvy>.

formation that might have to be maintained. It requires that “incident investigation reports” be kept, but does not explain what constitutes an incident investigation report other than a few illustrative examples not applicable here. 902 Ky. Admin. Regs. 20:016 § 3(3)(a); *id.* 20:016 § 3(4).

Providers, then, have little way to know in advance whether a particular report to a patient safety organization will be privileged in a later medical-malpractice suit. If a trial judge concludes that the report—or parts of the report—fall within Kentucky’s amorphous definition of “incident investigation report,” the report will be produced. But individual reporters—like the surgical nurse in this case—rarely have such technical legal definitions in mind when reporting to a patient safety organization.

The *in camera* review process mandated by the Kentucky Supreme Court’s decision (Pet. App. 26a) introduces even more uncertainty for providers. Trial judges are generalists, and medical reports are technical. Without adversarial briefing to guide them, judges may come to divergent conclusions as to what parts of an intermingled report are privileged. *Cf. Pollard v. FBI*, 705 F.2d 1151, 1153 (9th Cir. 1983) (noting that the “*ex parte*, non-adversarial nature of *in camera* review \* \* \* has prompted courts to proceed with caution in endorsing *in camera* review of documents”). That unpredictable variation will further erode the predictable, uniform privilege the Patient Safety Act was supposed to create.

2. Lawyers could perhaps help providers determine what will and will not be privileged. But on balance,

attorneys are an obstacle to robust and timely error-reporting systems. The omnipresent threat of tort liability is already blamed for providers' practice of "defensive medicine"—an overly cautious approach that places liability avoidance above efficiency. Lois Shepherd, *Assuming Responsibility*, 41 WAKE FOREST L. REV. 445, 449 (2006). In addition, providers' counsel are not qualified to make medical-reporting decisions. The American Bar Association has warned that "lawyers are not best suited to the task of defining an event that should be reported," and "[m]edical experts are needed to make these decisions." Am. Bar Ass'n Resolution 115, at 3 (adopted Aug. 11-12, 2008).<sup>11</sup> 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 11-14.

Even for providers that participate in patient safety organizations, the Kentucky 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

---

<sup>11</sup> Available at <http://goo.gl/D4ImQK>.

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 Kentucky Supreme Court’s decision undermines these core principles.

The harm extends to the institutional level, too. One law firm has already suggested that institutional providers separate factual incident information reported to the State from impressions and analyses reported to patient safety organizations. Katten, Muchin, Rosenman LLP, *Case Law Updates and Implications for Member PSES Activity* 16 (Dec. 17, 2014).<sup>12</sup> That is likely a rational response to the Kentucky Supreme Court’s decision. But it requires already busy providers to parse their reports to patient safety organizations. That additional burden may cause providers not to report incidents at all. Or it could result in self-censored reports that do not reflect the provider’s true impressions. Either outcome harms patient safety organizations’ effectiveness.

Again, the aviation industry’s experience is instructive. Much of the Aviation Safety Reporting System’s success is attributed to how it “makes reporting simple”; reporters fill out a one-page form on paper or online. *Focusing More on the What and Why, supra*, at 66; see also *Make Way, supra*, at 759 (identifying “simplicity” as a virtue of a successful voluntary-reporting system). The Kentucky Supreme Court’s decision complicates the reporting process and makes it harder for patient safety organizations to achieve their goals.

---

<sup>12</sup> Available at <http://goo.gl/Z6EtHT>.

3. The Kentucky 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 Kentucky Supreme Court may have thought that the balance its decision 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 and reject the Kentucky Supreme Court's variable, unpredictable rule to the contrary.

### **CONCLUSION**

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

Respectfully submitted,

CATHERINE E. STETSON

*Counsel of Record*

SEAN MAROTTA

HOGAN LOVELLS US LLP

555 Thirteenth Street, N.W.

Washington, D.C. 20004

(202) 637-5491

cate.stetson@hoganlovells.com

*Counsel for Amici Curiae*

April 2015