SUPREME COURT OF FLORIDA

JEAN CHARLES, JR., ETC., ET AL.,

Appellants,

Case No.: SC2015-2180

v.

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC., ETC., ET AL.,

Appellees.

(CORRECTED) BRIEF OF AMICUS CURIAE AARP IN SUPPORT OF APPELLANTS

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STATEMENT OF INTEREST

AARP is a nonprofit, nonpartisan membership organization dedicated to representing the needs and interests of people age fifty and older. Florida has the highest proportion of older adults in the United States, comprising 23.6 percent of the state.[1] This decision will significantly impact older adults living in Florida because older adults use a greater amount of health care services than other populations and suffer the most medical malpractice incidents.[2]

AARP supports the establishment and enforcement of laws and policies designed to protect the rights of older adults to obtain legal redress when they have been victims of medical harm, neglect or abuse. Through its charitable affiliate, AARP Foundation, AARP has filed amicus curiae briefs in courts throughout the country to promote greater transparency and accountability in the health care system.

SUMMARY OF ARGUMENT

The First District Court of Appeal eviscerated Florida residents' constitutional right to obtain access to vital information related to adverse medical incidents by determining that the federal Patient Safety Quality Improvement Act

[1] State of Fla. Dep't of Elder Affairs, *State Plan on Aging 2013-2016*, 2 (2012) http://elderaffairs.state.fl.us/doea/StatePlan/2013_2016StatePlan.pdf.
[2] Jeffrey M. Rothschild & Lucian L. Leape, AARP Pub. Policy Inst., *The Nature and Extent of Medical Injury in Older Patients* 13, 23, 26, 29 (2000).

of 2005 (the PSQIA) preempts the Patient's Right to Know About Adverse Medical Incidents Amendment to the Florida Constitution (Amendment 7). This Court should reverse the First District's decision and instead rely on long-held jurisprudence that respects state powers and only finds preemption where there is clear evidence of Congressional intent. Here, the plain language and legislative history of the PSQIA establish that Congress did not intend to preempt all state laws regarding the disclosure of adverse medical incidents or create a mechanism for providers to avoid litigation. Instead, Congress intended the PSQIA to work harmoniously with, and not supplant, state requirements to improve the quality of health care.

Congress would not have intended that the PSQIA preempt Amendment 7 because Amendment 7 is a complementary tool that promotes the PSQIA's overarching goal of improving health care. Amendment 7 is a citizen-initiated Florida constitutional amendment that provides individuals with the right to access information about health care providers' adverse medical incidents. Its purpose is to improve health care by creating transparency about adverse medical incidents while also ensuring that victims of medical harm can access the information needed to hold negligent health care providers accountable. If left standing, the First District's decision will have a draconian effect on victims of medical harm or

neglect. Older Florida residents will suffer the most impact, as they use the greatest amount of health care services and are at the greatest risk for harm.

ARGUMENT

I. Congress Did Not Intend for the PSQIA to Preempt State Laws and Amendments Such as Amendment 7 or Create a Tool for Providers to Avoid Liability but Rather Intended That the PSQIA Be Read Harmoniously with State Patient Protections.

The First District's ruling that the federal PSQIA preempts Amendment 7 should be reversed because it is contrary to Congressional intent. For nearly 70 years, the U.S. Supreme Court has applied an "assumption" that States' historic police powers "were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Because health and welfare have historically been regulated by the States, the PSQIA cannot preempt Florida's constitutional amendment and laws related to the disclosure of adverse medical incidents in the absence of Congress's clear intent to do so. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) ("In all pre-emption cases, and particularly in those in which Congress has legislated ... in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.").

Appellees cannot meet their heavy burden of proving preemption. A review of the plain language and legislative history of the PSQIA reveals that Congress did not intend to create a broad federal privilege protecting all adverse medical incidents from disclosure. Instead, Congress intended to balance the need to have a database that may improve communications about delivering quality care with the need to ensure that patients have access to critical records when they are victims of medical malpractice, neglect, or abuse.

A. The Records at Issue Are Not Privileged Patient Safety Work Product under the PSQIA.

The plain language of the PSQIA establishes that Congress distinguished between information that is privileged and confidential for the purposes of implementing the PSQIA and information that can be disclosed for purposes outside of the statute. The PSQIA does not preempt Amendment 7 because the amendment provides access to records that fall within the exceptions of the PSQIA privilege.

The PSQIA authorizes health care providers to voluntarily collect information through a patient safety evaluation system (PSES) and share it with a patient safety organization (PSO). 42 U.S.C. §§ 299b-21 – 22 (2005). Information collected and shared through the PSES will be categorized as patient safety work product (PSWP) and deemed privileged and confidential if it meets the definition

of PSWP set forth in the statute. 42 U.S.C. §299b-21(7). The PSQIA defines PSWP as including data, reports, records, memoranda, and analyses that the provider assembled or developed for the purpose of reporting to a patient safety organization (PSO) or reported to a PSO. *Id*. at § 299b-21(7)(A).

However, Congress carved out broad exceptions to the PSQIA's definition of PSWP. PSWP "does not include a patient's medical record, billing and discharge information, or any other original patient or provider record." 42 U.S.C. § 299b-21(7)(B)(i). PSWP also "does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product." *Id*. at § 299b-21(7)(B)(ii). Moreover, the PSQIA states:

> (iii) Nothing in this part shall be construed to limit –
>
> (I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;
> (II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, or other public health purposes or health oversight purposes; or
> (III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

Id. at § 299b-21(7)(B)(iii).

Consistent with these provisions of the PSQIA, Florida has various statutes and rules that require a health care provider to create and maintain adverse medical incident reports. *See* FLA. STAT. § 395.0197(4)-(7) (2015) (requiring risk program that includes adverse incident reports); *see also* FLA. ADMIN. CODE ANN. r. 59A-10.0055 (establishing system to report adverse incidents to the Florida Agency for Health Care Administration). Amendment 7 provides individuals the right to access "any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." FLA. CONST. ART X, §25(a).

As such, there can be no determination that the PSQIA completely preempts Amendment 7 because adverse medical incident records fall within the exceptions to the definition of PSWP. Adverse medical incident reports are not PSWP because Florida statutes and rules require providers to create and maintain them. *See* FLA. STAT. § 395.0197; FLA. ADMIN. CODE ANN. r. 59A-10.0055. Thus, they fall within the exception of information "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." *See the PSQIA* at § 299b-21(7)(B)(ii). In addition, their disclosure fits squarely within the providers' recordkeeping obligations under state law and, thus, are not PSWP. *Id*.

The reports also do not become PSWP simply because they were submitted to a PSO because providers have an independent obligation under Florida law to create and maintain them. *See id*. at § 299b-21(7)(B)(ii). Consequently, the adverse medical incident information disclosed under Amendment 7 cannot be classified as PSWP.

The Kentucky Supreme Court's decision in *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014) provides useful guidance here. In that case, the Kentucky Supreme Court held that the PSQIA privilege did not extend to a state-mandated incident report because it was "collected, maintained or developed separately… from a patient safety evaluation system," within the meaning of Section 299b-21(7)(B)(ii). *Tibbs*, 448 S.W.3d at 809 ("while the incident information may be relevant to [the PSQIA], it is not, nor can it be, patient safety work product, since its collection, creation, maintenance, and utilization is mandated by the [state] as part of its regulatory oversight"). Even the *Tibbs* dissent agreed with this general premise. *Id*. at 810 (Abramson, J., dissenting) ("I agree that the Patient Safety Act was never intended to displace state law and that Kentucky clearly requires hospitals to maintain incident investigation reports and other records which are discoverable by a patient or her estate.") Similarly, because Florida has statutes, rules, and a constitutional amendment that require providers to create, maintain,

and provide access to the adverse medical incident information, such information cannot be privileged under the PSQIA. *See* FLA. CONST. ART X, §25(a); FLA. STAT. § 395.0197; FLA. ADMIN. CODE ANN. r. 59A-10.0055.

B. Legislative History Reveals That Congress Intended the PSQIA To Work In Concert With Existing State Laws.

The legislative history of the PSQIA reveals that Congress did not mean to disrupt existing state law but instead intended to strike a balance between providing a limited federal privilege to certain categories of information while maintaining patients' protections. In addition, Congress did not intend for the PSQIA to be used by providers to thwart victims of medical malpractice from accessing the information needed to pursue legal relief.

The House Report on the PSQIA underscored this balance in describing how documents that were created and maintained separately from a PSES would not become PSWP and confidential simply because they were sent to a PSO:

> [T]here may be documents of communications that are part of traditional healthcare operations or record keeping (including but not limited to . . . primary information at the time of events). Such information may be in communications or copies of documents sent to a patient safety organization. Originals or copies of such documents are both original provider records and separate information that is developed, collected, maintained or exist separately from any patient safety evaluation system. Both these original documents and ordinary information about healthcare operations may be relevant to a patient safety evaluation system but are not themselves patient safety work product.

H.R. Rep. No. 109-197, 14 (2005).

Several Senators also echoed that Congress's intent was to strike a balance, yet protect patient's rights to hold negligent providers accountable. For example, Senator Ted Kennedy conveyed Congress's intent that the PSQIA should not be used as a shield to protect providers who have harmed patients:

> The legislation also creates a legal privilege for information reported to the safety organizations, but still guaranteeing that original records, such as patients' charts will remain accessible to patients. Drawing the boundaries of this privilege requires a careful balance, and I believe the legislation has found that balance. The bill is intended to make medical professionals feel secure in reporting errors without fear of punishment, and it is right to do so. <u>But the bill tries to do so carefully, so that it does not accidentally shield persons who have negligently or intentionally caused harm to patients</u>. The legislation also upholds existing state laws on reporting patient safety information.

151 CONG. REC. S8713 (July 21, 2005) (daily ed. statement of Sen. Kennedy) (emphasis added). In its opinion, the First District seemed to be dismissive of the idea that providers could use the PSQIA for mischief. *Southern Baptist Hospital of Fla., Inc. v. Charles*, 178 So.3d 102, 109 (Fla.1st DCA 2015). However, Congress was very well aware of this potential and did not intend to create a law that could be used as a vehicle for providers to avoid responsibility for negligent conduct. *Id*.; 151 CONG. REC. S8741 (daily ed. July 22, 2005) (statement of Sen. Enzi).

Senator Enzi, the Republican chair of the Committee that reported the bill, shared Senator Kennedy's position on the legislative intent. Senator Enzi emphasized that the PSQIA would not change existing state rights or harm plaintiffs' cases against negligent providers:

> It is not the intent of this legislation to establish a legal shield for information that is already currently collected or maintained separate from the new patient safety process, such as a patient's medical record. That is, information which is currently available to plaintiffs' attorneys or others will remain available just as it is today. Rather, what this legislation does is create a new zone of protection to assure that the assembly, deliberation, analysis, and reporting by providers to patient safety organizations of what we are calling ''Patient Safety Work Product'' will be treated as confidential and will be legally privileged.

Id. (emphasis added). Thus, information that was not privileged before the Act's enactment would not be privileged after its enactment.

Senator Jeffords, who introduced the bill, also stated Congress's intent that the PSQIA not affect state legal requirements or alter existing rights available to injured patients:

> Of course, we also live in a complex society - one in which medical errors that may have harmed a patient might also be the basis for litigation. It is a right under our laws to seek a remedy when harmed, and we need to preserve access to certain information for this redress of grievances. However, an unfortunate consequence of living in a litigious society is that hospitals and providers often feel that it's not

> in their best interests to share information openly and honestly. We know, in fact, that their attorneys and risk managers often advise them not to do so. So, in order for our system to work, it needs to balance these sometimes competing demands. I believe the Patient Safety and Quality Improvement Act strikes this balance. It calls for the creation of new entities we call Patient Safety organizations that would collect voluntarily reported data in the form of patient safety work products. This bill provides the protections of confidentiality and privilege to that patient safety data – but this bill also sets definite limitations on what can be considered confidential and privileged. This legislation does nothing to reduce or affect other Federal, State or local legal requirements pertaining to health related information. Nor does this bill alter any existing rights or remedies available to injured patients. The bottom line is that this legislation neither strengthens nor weakens the existing system of tort and liability law.

151 CONG. REC. S8743 (daily ed. July 22, 2005) (statement by Sen. Jeffords) (emphasis added). Instead, the purpose of the PSQIA was to "create a new, parallel system of information collection and analysis." *Id*. at S8744.

The legislative history establishes that Congress wanted the PSQIA to create a parallel system of review without affecting existing rights of injured parties to obtain redress. Recognizing Congress's intent to have the PSQIA exist harmoniously with existing state law, the Department of Health and Human Services explained that the Act created a parallel system but did not replace or destroy existing state laws and requirements:

> The Patient Safety Act establishes a protected space or system that is separate, distinct, and resides alongside but does not replace other information collection activities mandated by laws, regulations, and accrediting and licensing requirements as well as voluntary reporting activities that occur for the purpose of maintaining accountability in the health care system.

Patient Safety and Quality Improvement Act, 73 FED. REG. 70,732-01, 70,742 (Dep't of Health and Human Services Nov. 21, 2008) (emphasis added).

Thus, the PSQIA does not preempt Amendment 7. The constitutional amendment falls under the well-recognized state powers to protect the health and welfare of its residents. Congress did not intend to overtake this responsibility by passing the PSQIA. Thus, it certainly did not intend for the Department of Health and Human Services to inadvertently negate state law protections through its interpretation of the PSQIA. On the contrary, the legislative history demonstrates that Congress wanted to preserve states' authority to protect their citizens and the ability of injured patients to hold health care providers accountable while creating a nationwide system to review provider activities.

II. Congress Would Not Have Intended That the PSQIA Preempt Amendment 7 Because Amendment 7 Is a Complementary Tool That Promotes the PSQIA's Goal of Improving Health Care.

Amendment 7 gives Florida residents a constitutional right to broad access to adverse medical incident records. FLA. CONST. ART X, §25(a). This citizen-initiated constitutional amendment enhances the quality of health care because it

allows individuals to make informed decisions when choosing future health care providers and provides critical information for injured parties litigating as a result of negligent care. In addition, it fits directly within the state's traditional role of regulating the health, safety, and welfare of its citizens.

As this Court stated in *Florida Hospital Waterman, Inc. v. Buster*, 984 So. 2d 478, 488 (Fla. 2008), the purpose of the amendment is: (1) to provide individuals with information about adverse medical incidents so they can make better decisions about prospective health care; and (2) to allow injured patients to discover information about adverse medical incidents during litigation. Its appearance in the November 2004 election came after decades of frustration because citizens could not access information they needed to make informed decisions about their health care. *Id*. Out of 7.2 million Florida voters, more than 5.8 million people (or over 80%) voted in favor of this state constitutional right. *See* Fla. Dep't of State, Division of Elections, *Patient's Right to Know About Adverse Medical Incidents*, http://dos.elections.myflorida.com/initiatives/initdetail.asp?account=35169&seqnum=3 (visited on Feb. 17, 2016).[3]

[3] In addition, this Court unanimously approved the ballot initiative that resulted in Amendment 7. *In re Advisory Opinion to the Atty. Gen. re Patients' Right to Know About Adverse Medical Incidents*, 880 So.2d 617 (Fla. 2004). Justice

Florida residents' overwhelming support of the amendment is not surprising considering the critical role that increased transparency has in improving quality of health care. For individuals considering future medical treatment, the amendment provides transparency relating to the adverse medical incidents of a health care provider. Transparency in health care quality, including information about adverse medical incidents, allows consumers to make informed choices about doctors, hospitals, and health care services before they purchase these services – just as they would about any other major purchase. *See* Nicolaus Henke et al., *Transparency – the most powerful driver of health care improvement?*, 2011 HEALTH INT'L 65, 72-73 (2011). Providers and insurers then can use the consumers' feedback, shown through choice and other forms of communication, to determine what needs improvement. *Id*. Indeed, transparency may be the most important precondition to improving quality and reducing costs in the health care system. *Id*.

This amendment also gives citizens the constitutional right to access information critical to pursuing a successful tort action. Victims of negligent care and their families must have fair access to judicial remedial measures due to the prevalence of abuse and neglect in health care facilities and the inability of

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Pariente, Justice Lewis, and Justice Quince were members of the Court at the time it delivered that opinion.

regulatory authorities to effectively detect and remedy this problem. Resource constraints, such as budgetary restrictions, limit the U.S. Department of Justice, state regulatory agencies, and other law enforcement entities from investigating the delivery of poor care and health care fraud. *See* David Freeman Angstrom, *Private Enforcement's Pathways: Lessons from Qui Tam Litigation*, 114 COLUM. L. REV. 1913, 1986-87 (2014).

At the same time, health care providers, including nursing facilities, continue to have problems meeting quality-of-care standards. For example, in 2014, 95.6% of certified nursing facilities in Florida had at least one deficiency, defined as a problem that can result in a negative impact on the health and safety of facility residents. Charlene Harrington et al., *Percent of Certified Nursing Facilities with Deficiencies* (2015), http://kff.org/other/state-indicator/nursing-facilites-with-zero-deficiencies/ (last visited Feb. 10, 2016).

As patients are the ones who experience the harm, they are uniquely situated to bring a health care provider's violations to light and pursue legal redress. To do so, they need access to all relevant evidence. Their litigation is a form of oversight over healthcare providers. All areas of the economy, and healthcare especially, rely on plaintiffs wielding a private right of action to police negligence, fraud, and

other misconduct. *See generally*, James D. Cox, *Private Litigation and the Deterrence of Corporate Misconduct*, 60 LAW & CONTEMP. PROBS. 1 (1997).

Preemption here significantly hampers malpractice victims' ability to sue by blocking access to essential evidence. It opens the door for healthcare providers to claim PSQIA privilege to strike discovery requests by victims of medical malpractice. The result is that patients would be blocked from critical information about adverse medical incidents, as they were for years by state statutory privileges before a frustrated Florida electorate passed Amendment 7 by an overwhelming margin. *See* Talia Storch, *Medical Peer Review in Florida: Is the Privilege Under Attack?*, 32 NOVA. L. REV. 269, 282-83 (2009) (noting that Florida's pre-Amendment 7 statutory privileges to discovery of evidence had been used "as a perpetual weapon to combat discovery requests made by malpractice victims . . . regardless of the fact that such information may be pertinent, and many times indispensable, to a fair and just trial."). Such a result would directly conflict with the will of the overwhelming majority of Florida voters who voted in favor of Amendment 7.

III. The Court's Decision Will Disproportionately Impact Older Floridians Because They Have the Highest Utilization of Health Care Services and Suffer the Most Malpractice Incidents.

Older Floridians are particularly vulnerable to the impact of this decision because of their heavy reliance on the health care system. Florida has the highest proportion of older adults among its population. State of Fla. Dep't of Elder Affairs, *State Plan on Aging 2013-2016*, 2 (2012) http://elderaffairs.state.fl.us/doea/StatePlan/2013_2016StatePlan.pdf. Older adults utilize a greater amount of health care than other populations. In 2010, adults aged 65 and older constituted only thirteen percent of the population, yet accounted for thirty-four percent of health care spending. *Id.* Adults aged 65 and older are also twenty percent more likely than adults aged 18 to 44 to have visited a health professional in the past year. *See* Ctrs. for Disease Control & Prevention, *Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012*, at 95 tbl. 33 (2014), http://goo.gl/1abcJF. Similarly, adults aged 65 and older are four times more likely than persons aged 15 to 44 to receive in-patient hospital treatment. Ctrs. for Disease Control & Prevention, *National Hospital Discharge Survey: 2010 Table – Number and Rate of Hospital Discharges* (2010), http://goo.gl/16Oy9w.

Older Americans' high utilization rate for healthcare services puts them at greater risk of harm resulting from medical care. Thirteen percent of Medicare beneficiaries hospitalized in 2008 experienced a serious adverse event—e.g., an event prolonging their hospitalization, requiring life-sustaining intervention, or

resulting in permanent harm or death—during their stay. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-06-09-00090, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, at ii (2010), https://goo.gl/opFO6V. Relative to the rest of the population, adults aged 65 and older are more likely to be misdiagnosed or underdiagnosed (receive a delayed diagnosis) by doctors and twice as likely to be victims of serious medical error. Jeffrey M. Rothschild & Lucian L. Leape, AARP Pub. Policy Inst., *The Nature and Extent of Medical Injury in Older Patients* 13, 23, 26, 29 (2000). Altogether, older Americans' high level of interaction with the healthcare system imposes significant institutional and individual financial costs and exposes them to potential serious physical harm.

Their chronic conditions, high proportion among Florida's population, and disproportionate use of health services means that preemption of their Amendment 7 rights hurts older Americans the most, cutting the legs out from under the most vulnerable.

CONCLUSION

This case has far-reaching implications for Florida residents, including older adults because they use a greater amount of health care services and suffer the most malpractice incidents. As Congress intended the PSQIA to work

harmoniously with state laws to protect the health, safety, and welfare of citizens, this Court should find that the PSQIA did not preempt Amendment 7.

Dated: February 22, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 9.210(a)(2)

I HEREBY CERTIFY that this Brief complies with the font requirements of Florida Rule of Appellate Procedure 9.210(a)(2).

/s/ Maame Gyamfi