IN THE SUPREME COURT OF FLORIDA

CASE NO. SC15-2180

JEAN CHARLES, JR., et al.,

Petitioner,

-vs-

SOUTHERN BAPTIST HOSPITAL OF FLORIDA, INC., et al.,

Respondents.
_____/

BRIEF OF AMICUS CURIAE, FLORIDA JUSTICE ASSOCIATION IN SUPPORT OF PETITIONERS

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INTRODUCTION

The Florida Justice Association ("the FJA") is a large, voluntary, and statewide association of more than 3,000 trial lawyers concentrating on litigation in all areas of the law. The members of the FJA are pledged to the preservation of the American legal system, the protection of individual rights and liberties, the evolution of the common law, and the right of access to courts.

This case is important to the FJA because it involves an attempt to eviscerate Article X §25 of the Florida Constitution ("Amendment 7"), a constitutional provision that grants individuals the right to access records of adverse medical incidents from certain healthcare providers. This issue is significant not only in the litigation of medical malpractice claims, but also with respect to the public's ability to obtain records relevant to their personal healthcare decisions.

There are also related issues of significance regarding the obligation of hospitals to maintain certain records and provide access to them pursuant to Florida statutes and regulations. Also, Southern Baptist Hospital of Florida, Inc. ("Baptist Hospital") argued in the trial court that it could not be compelled to provide a privilege log, and it did not unequivocally acknowledge the court's authority to conduct an in camera inspection of the documents and information in its patient safety evaluation system ("PSE system") (i.e. that which is provided to its patient safety organization ("PSO")). Certain language in the First District's

opinion could be construed to provide support to Baptist Hospital's position. This raises serious issues regarding the inherent authority of the court to determine claims of privilege and to make the necessary factual determinations to support such rulings.

SUMMARY OF THE ARGUMENT

The Patient's Safety and Quality Improvement Act ("PSQIA") contains multiple provisions clearly stating that it does not intend to preempt or supersede any State law regarding the recordkeeping or reporting of adverse medical incidents by healthcare facilities. The PSQIA, by its own terms, does not include within the definition of "patient safety work product" any information or records gathered for purposes other than for providing them to a PSO. This necessarily means that any data gathered, recorded, or reported pursuant to state law is not "patient safety work product." Additionally, the PSQIA specifically provides that it does not intend to affect State law regarding any information or records relating to adverse medical incidents that are governed by State law.

The Florida statutes contain extensive provisions regulating healthcare facilities by requiring certain committees, proceedings, records, and reporting requirements relating to the quality of healthcare. While virtually all of those statutory provisions originally contained limited confidentiality provisions, those restrictions on access were eliminated by the enactment of Amendment 7. Since

the PSQIA expressly disclaims any intent to preempt or supersede state law on these issues, it cannot act as a bar to Plaintiffs' Amendment 7 request in this case.

Finally, the suggestion that the PSQIA deprives the trial court of the authority to compel a privilege log or to conduct an in camera inspection of materials in a provider's PSE system must be rejected. The court's ability to make valid and independent determinations of privilege claims cannot be eliminated by legislation and there is no basis in the PSQIA or its legislative history to conclude that Congress intended that here.

ARGUMENT

THE FIRST DISTRICT'S DECISION DOES NOT PROPERLY RECOGNIZE THE PSQIA'S DEFERENCE TO THE STATE'S REGULATION OF HEALTCARE INFORMATION AND SHOULD BE REVERSED.

The FJA believes the best way it can be of assistance to the Court in this case is to present a simplified summary of the Patient's Safety and Quality Improvement Act ("PSQIA") as it relates to the confidentiality of healthcare information, summarize the Florida regulatory provisions governing record keeping and reporting requirements applicable to healthcare facilities, and briefly address the suggestion that the PSQIA prevents the courts from reviewing the contents of a provider's PSE system. A consideration of these subjects compels the conclusion that the First District's decision should be reversed.

The PSQIA Does Not Affect Existing State Law on the Maintenance of and Access to Healthcare Information

The PSQIA consists of six statutes in Part C of Subchapter VII, Chapter 6A of Title 42 of the United States Code. Simply stated, it provides for the creation and maintenance of a patient safety database from information voluntarily reported by patient safety organizations ("PSOs"), and healthcare providers. The Act also provides privilege and confidentiality protections to a subset of the information provided to or by PSOs.

Under the PSQIA the information provided to the PSOs is broken down into two broad categories. One category is "patient safety work product," a term of art defined in 42 U.S.C. §299b-21(2) and (3), which includes "any data, reports, records, memorandum, analyses (such as root cause analyses), or written or oral statements." 42 U.S.C. §299b-21(7). However, to qualify for certain confidentiality and privilege protections pursuant to 42 U.S.C. §299b-22(a) and (b), those types of materials are limited to those which (42 U.S.C. §299b-21(7)(i)):

> (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
>
> (II) are developed by a patient safety organization for the conduct of patient safety activities;
>
> and which could result in improved patient safety, health care quality, or health care outcomes; or

> (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

However, certain records and categories of information are explicitly excluded from the definition of "patient safety work product," and therefore are not entitled to the statutory confidentiality and privilege provisions of the Act. This includes customarily non-privileged patient medical records, 42 U.S.C. §299b-21(7)(B)(i),[1] and "information that is collected, maintained, or developed separately, or exists separately, from a patient's safety evaluation system." 42 U.S.C. §299b-21(7)(B)(ii) (hereafter "separate information").

The "patient safety organization system" is defined in the PSQIA as "the collection, management, or analysis of information for reporting to or by a patient safety evaluation." 42 U.S.C. §299b-21(6). Thus the "separate information" consists of data and records generated for reasons other than reporting them to a PSO. The PSQIA provides that the "separate information" includes data and materials reported to Federal, State, or local government agencies for public health purposes and information that is collected or maintained pursuant to a "provider's recordkeeping obligation under Federal, State, or local law." 42 U.S.C. §299b-21(7)(B)(iii)(II) and (III). The PSQIA provides that this "separate information" can

[1] The PSQIA describes these non-privileged medical records as "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).

be reported to a PSO, but it does not become "patient safety work product" as a result of being reported to a PSO. 42 U.S.C. §299b-21(7)(B)(ii).

As noted above, "separate information" which may be reported to a PSO is not considered patient safety work product and therefore is not entitled to the privilege and confidentiality protections of the PSQIA. See 29 U.S.C. §299b-22(a). Additionally, the statute providing for the confidentiality and privilege for patient safety work product states (42 U.S.C. §299b-22(g)(2)):

> Nothing in this section shall be construed --
>
> (2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section.

That statute also provides that nothing in it should be construed as preempting or otherwise affecting "any State law requiring a provider to report information that is not patient safety work product." 42 U.S.C. §299b-22(g)(5).

Thus, as explained in more detail in the Initial Brief, the PSQIA was explicitly designed not to affect State law provisions regarding recordkeeping and reporting by healthcare providers, nor to affect in any way provisions of State law pertaining to that information. This means that Amendment 7 is unaffected by the PSQIA with respect to information and records which are not "patient safety work product" as defined in the Act. In order to understand what is not "patient safety work product" in Florida, it is necessary to summarize the Florida statutory and

regulatory provisions addressing record keeping and reporting by healthcare facilities and providers. After doing that, this brief will address the concern regarding the trial court's authority to order a privilege log and conduct an in camera inspection.

Summary of Florida Statutory Provisions Addressing Recordkeeping and Reporting by Healthcare Providers

There are four important statutes addressing recordkeeping and reporting by healthcare facilities in Florida that are relevant to the PSQIA. These statutes represent a comprehensive and uniform scheme for regulation of healthcare facilities by the state. These statutes establish a framework for administering, inter alia, staff membership, clinical privileges, peer review, discipline, and risk management. The functioning of the various committees, boards, and personnel addressed in those statutes, and the state's ability to review and regulate them, would be drastically affected if the First District's interpretation of the PSQIA is accepted as the law in Florida.

Fla. Stat. §766.101 addresses medical review committees, which are broken down into twelve categories of committees. That statute provides, inter alia, that a medical review committee shall screen, evaluate, and review the professional and medical competence of applicants to, and members of, a hospital's medical staff. Fla. Stat. §766.101(2). Subsection (5) of that statute provided limited

confidentiality[2] for the "investigations, proceedings, and records" of a medical review committee. Additionally, a medical or peer review committee of a professional society may, by agreement with the Department of Health, conduct a review of any complaint regarding whether a physician's action constituted a breach of the prevailing professional standards of care. Fla. Stat. §766.101(7)(a). That agreement must require that the medical review committee submit an advisory report to the Department within a reasonable time of its decision. Id.

Fla. Stat. §395.0191 addresses staff membership and clinical privileges. That statute requires that the governing board of each licensed facility shall set standards and procedures for considering and acting upon applications for staff membership or clinical privileges; and those standards and procedures must be available for public inspection. Fla. Stat. §395.0191(5). Subsection (4) of that statute lists the mandatory considerations for staff membership and clinical privileges, and subsection (6) requires that a rejected applicant be provided a written statement of the reasons for denial. Subsection (8) provides limited confidentiality[3] for "the investigations, proceedings, and records" of the board making the staff membership and clinical privileges decisions.

Fla. Stat. §395.0193 addresses peer review and disciplinary powers of licensed facilities. Subsection (2) of that statute states that each licensed facility

[2] This limited confidentiality was drastically altered by Amendment 7.
[3] This limited confidentiality was drastically altered by Amendment 7.

shall provide for peer review of physicians, and that the procedures for doing so shall require, inter alia, the recording of agendas and minutes which do not contain confidential material, for review by the Division of Health Quality Assurance of the agency. Fla. Stat. §395.0193(2)(e).

That statute also provides that if a reasonable belief exists that the conduct of a staff member or physician may constitute grounds for discipline, a peer review panel shall investigate and provide recommendations to the governing board, which shall make the disciplinary decision. Fla. Stat. §395.0193(3). Many of the categories of conduct which can trigger such an investigation implicate adverse medical incidents which could be encompassed within the information reported to a PSO, i.e. "medical negligence," settlements of medical negligence claims, etc. Fla. Stat. §395.0193(3)(a)-(g) Subsection (4) of that statute requires that any disciplinary action shall be reported to the Division of Health Quality Assurance within 30 days of the occurrence of the misconduct. That statute also provides for limited confidentiality[4] for "the investigations, proceedings, and records" of the peer review panel. Fla. Stat. §395.0193(8).

Finally, Fla. Stat. §395.0197 addresses internal risk management and requires that every licensed hospital shall establish an internal risk management program that includes, inter alia, the investigation and analysis of the frequency

[4] This limited confidentiality was drastically altered by Amendment 7.

and causes of general categories and specific types of adverse incidents to patients. Each internal risk management program is required to utilize incident reports which (prior to Amendment 7) became "part of the workpapers of the attorney defending the licensed facility in litigation." Fla. Stat. §395.0197(4). The statute also requires that there be analyses of patient grievances relating to care and quality of medical services, and a system for informing the patient that he or she was a subject of an adverse incident, as defined in the statute. Fla. Stat. §395.0197(1)(c) and (d).

Subsection (e) of Fla. Stat. §395.197(1) also requires:

> (e) The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

Fla. Stat. §395.0197(6)(a) requires that each licensed facility must submit an annual report to AHCA summarizing the incident reports that had been filed in the facility for that year, and imposes specific requirements for the contents of that report. Additionally, specifically defined adverse incidents must be reported to AHCA within 15 days of occurrence. Fla. Stat. §395.0197(7). The statute provides limited confidentiality[5] for those reports. Id.

[5] This limited confidentiality was drastically altered by Amendment 7.

It appears clear that Congress did not intend the PSQIA to interfere with, or event affect, the record keeping and reporting requirements summarized above. However, the First District's decision grants hospitals the unilateral discretion to submit healthcare information to PSOs and thereby insulate access to it from patients and the state, which would necessarily impede the state regulatory scheme. While this proceeding does not directly involve all the statutory provisions summarized above, this Court's decision will necessarily affect them, and therefore the FJA believes it is important to consider the entire regulatory scheme in reaching a resolution of these issues.

Contents of a Patient's Medical Records Under Florida Law

The contents of a patient's medical records, which are not considered to be "patient safety work product" pursuant to 42 U.S.C. §299b-21(7)(B)(i), are regulated by provisions in the Florida Administrative Code.

Florida Administrative Code §59A-3.270 is titled "Health Information Management" and applies to all licensed hospitals (a copy of that regulation is attached hereto as an appendix). Subsection (3) of that regulation establishes the required contents for a patient's medical records. Subsection (4) addresses the records for patients "undergoing operative or other invasive procedures" and requires:

(a) The recording of preoperative diagnoses prior to surgery.

> (b) That operative reports be recorded in the health record immediately following surgery or that an operative progress note is entered in the patient record to provide pertinent information; and
>
> (c) Postoperative information shall include vital signs, level of consciousness, medications, blood components, complications and management of those events, identification of direct providers of care, discharge information from the post-anesthesia care area. [Emphasis supplied.]

Additionally, §59A-3.2085(3) addresses requirements for the records of a hospital surgical department and include the requirement that the department maintain a record with the patient's name, hospital number, other information regarding the surgery and "complications, if any." §59A-3.2085(3)(m)8.

There is an inherent tension between the requirement that "complications" and related information be included in certain patient records, and the ability of a hospital to insulate information from scrutiny by providing it to a PSO and claiming that it qualifies as patient safety work product. While the case sub judice does not involve a conflict regarding that issue, any resolution of this case will have implications regarding how a patient could ensure that his or her medical records are complete, as required by Florida law. While in theory, the PSQIA exempts a patient's medical records from being patient safety work product, see 42 U.S.C. §299b-21(7)(b)(i), it is certainly reasonable to anticipate that there will be conflicts in the future regarding that exemption. While this issue is not directly before the Court at this time, the FJA believes that this Court needs to consider that

scenario in order to adequately determine the scope and effect of its ultimate determinations regarding the interplay of the PSQIA and state authority over the contents of medical records and a patient's right to access them.

The Court's Authority to Require a Privilege Log and to Conduct an In Camera Inspection Cannot Be Eliminated by the PSQIA

The First District's decision contains a troubling section which seems to indicate that the trial court lacks authority to require a privilege log from a provider or to engage in an in camera inspection of documents within a provider's PSE system. It describes the provider's authority under the PSQIA as a "unilateral, unreviewable decision as to what is placed in its PSE system," 178 So.3d at 109; and dismisses concerns about potential "gamesmanship" by the providers because the PSQIA "clearly defines what can and what cannot constitute patient safety work product." Id.

With respect to documents and information that are arguably subject to the provider's state reporting or record keeping requirements, the First District stated that the remedy for an error by the provider "would not be for the trial court to 'rummage through' the provider's PSE system," but rather limited to addressing the non-compliance in the same manner as it could have been prior to the passage of the Act." Id. The First District does not actually identify the preexisting remedy, but the more troubling concern is the implication that a trial court does not

have authority to fully determine the privilege claim because it is not entitled to require a privilege log nor engage in an in camera inspection of the PSE system.

The First District's statements on this issue relied exclusively on the dissenting opinion in Tibbs v. Bunnell, 448 S.W. 3d 796, 815 (Ky. 2014) (Abramson, J., dissenting). In that dissenting opinion, Justice Abramson stated:

> **The federal privilege**, however, **precludes** an adverse party's--and **a trial court's--invasion of the patient safety evaluation system itself**, since under the Patient Safety Act providers must be assured that their participation in the patient safety system will not subject them to adverse consequences. [Emphasis supplied.]

The implication of that statement is that the concerns regarding potential liability of the providers for damaging information in the PSE system is so critical that a trial judge is not even authorized to conduct an in camera review of the contents of the PSE system. This is an unsettling assertion which finds no support in the PSQIA, nor in any existing jurisprudence.

There is no doubt that many special interests have found the courts to be pesky impediments to their goals and operations, but the jurisprudence of this country is blessedly bereft of any legislation which precludes the court from exercising its inherent authority to determine privilege claims through an in camera inspection. There is no language in the PSQIA, nor any basis in its legislative history, to justify the conclusion that Congress intended to strip the courts of that

authority and there is a serious question that Congress could do that even if it intended to do so.

The most sacrosanct of privileges, the attorney-client privilege, is not immune from in camera inspection when the conditions justify it. As noted in a treatise on the subject:

> **To reject in camera inspection is to reject the only approach to the review of allegedly privileged documents that ensures that a judicial officer will make an independent assessment of the communications in question** (thereby providing some verification of the accuracy of the adversarial descriptions of the documents' contents and circulation as well as a means by which other problem areas can be detected and subsequently explored). It is the accuracy of adversarial perceptions and descriptions that is at issue here, and personal observation by the factfinder–the judge –is the only objective way in which that can be accomplished.
>
> * * *
>
> **The argument that in camera inspection is an unwarranted prying or intrusion into a party's affairs is singularly unpersuasive since the judge has the sole responsibility for assessing the validity of the privilege claims, and in camera inspection is the only means by which that role can realistically be fulfilled.** Because this review is so critical to the proper performance of the judge's fact-finding role, privilege proponents must be held to have waived, to this limited degree, their privacy or confidentiality in the documents they seek to suppress through the privilege. [Emphasis supplied.]

2 Attorney-Client Privilege in the United States §11:16 (Dec. 2015). To suggest that those bedrock principles of our jurisprudence are to be abandoned out of concern for the potential liability of healthcare providers is frankly astonishing.

It is also clear that if Congress intended to take such an extraordinary action, the constitutionality of which would certainly be a hot topic, it would be very clear in doing so. It is significant that the Freedom of Information Act, 5 U.S.C. §552 et. seq., which allows access to a full range of information in governmental records, does not eliminate in camera review, even in those situations involving national security matters, domestic and foreign intelligence, and other extremely sensitive areas. Even in that situation, Congress recognized the court's authority to require a privilege log, sworn evidence regarding the contents and classification of documents, and, if necessary, an in camera inspection. See 5 U.S.C. §552(a)(4)(b).

In those actions in which a party seeks information under the Freedom of Information Act, the court's role is to determine de novo the validity of an agency's classification of documents as confidential, top secret, etc. Hayden v. Nat'l Security Agency, 608 F.2d 1381, 1384 (D.C. Cir. 1979). Even in cases involving highly sensitive security and intelligence information, the agency has the burden to justify its classification of the materials with sworn evidence, and to be subject to an in camera inspection of that showing is insufficient. See e.g. Weissman v. Central Intelligence Agency, 565 F.2d 692 (D.C. Cir. 1977) (Central Intelligence Agency); Doherty v.U.S. Dep't of Justice, 775 F.2d 49 (2d Cir. 1985) (Federal Bureau of Investigations); Larson v. Dep't of State, 565 F.3d 857 (D.C.

Cir. 2009) (National Security Agency, Central Intelligence Agency, and Department of State).

The hospital here apparently adopted the position that the court had limited, if any, authority to review its claim of privilege, as it argued that the trial judge could not compel the production of a privilege log or certain reports (Pet.'s App. 423, 433, 488-90). While the hospital conceded that possibly the court could engage in an in camera review, it clearly did not unequivocally recognize the court's authority to do so. Respectfully, any doubt on this issue, and certainly the First District's opinion creates doubt, needs to be eliminated by this Court. No special interest should be granted a status immune from the court's independent evaluation of its conduct and claims; and certainly the PSQIA does not provide any logical basis for reaching that conclusion in this context.

CONCLUSION

For the reasons stated above, the decision of the First District should be reversed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true copy of the foregoing was furnished to all counsel on the attached service list, by email, on February 22, 2016.

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Amicus Curiae, Florida Justice Association, hereby certifies that the type size and style of the Amicus Curiae Brief is Times New Roman 14pt.

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