IN THE SUPREME COURT OF THE STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

KATHERINE CARRON and RYAN CARRON, Individually and as Co-Administrators of the ESTATE OF KENNETH CARRON,

Plaintiff-Appellees

v.

RANDALL ROSENTHAL, M.D., NEWPORT OB-GYN ASSOCIATES, LTD., and NEWPORT HOSPITAL,

Defendant-Appellants.

No. SU15-0212
(CA No. NC2013-0479)
NEWPORT SUPERIOR COURT

AMICUS CURIAE BRIEF OF AMERICAN ASSOCIATION FOR JUSTICE IN SUPPORT OF PLAINTIFF-APPELLEES KATHERINE CARRON AND RYAN CARRON

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STATEMENT OF INTEREST OF *AMICI CURIAE*

The American Association for Justice ("AAJ"), formerly the Association of Trial Lawyers of America, respectfully submits this brief as *amicus curiae* in support of Plaintiff-Appellees Katherine Carron and Ryan Carron.

AAJ is a voluntary national bar association whose trial lawyer members primarily represent individual plaintiffs in civil suits and personal injury actions. Its members practice law in every state of the Union, including Rhode Island, as well as the District of Columbia and each of the U.S. territories. Throughout its history, AAJ has served as a leading advocate of the right to trial by jury, as well as for access to the courts and for the preservation of protections enjoyed by ordinary citizens that is afforded by the common law and state tort law.

In serving that purpose, AAJ represents its members and their clients in matters before the federal and state courts, Congress, and the Executive Branch. To that end, AAJ regularly files *amicus* briefs in cases that raise issues of vital concern to its members and their clients, including cases involving the preemptive effect of federal law. *See, e.g., Staub v. Proctor Hosp.,* 562 U.S. 411 (2011); *Altria Grp., Inc. v. Good*, 555 U.S. 70 (2008); *Taylor v. Extendicare Health Facilities, Inc.*, 147 A.3d 490 (Pa. 2016), *cert. denied,* 2017 WL 1114976 (U.S. Mar. 27, 2017); *Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (2015), *cert. denied,* 136 S. Ct. 896 (2016).

This case is of acute interest to *amicus curiae* because it concerns an attempt to assert a privilege granted by a federal statute that is inapplicable to the circumstances at hand and, if permitted, harms the search for truth and the deterrent effect of tort law. In this brief, the American Association for Justice restricts its argument to the first question presented, the import and applicability of Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 U.S.C. 299b-21 *et seq.*

INTRODUCTION AND SUMMARY OF ARGUMENT

The entirely preventable and tragic death of a newborn provides the backdrop for this case. In defending against liability for negligent actions that caused Kenneth Carron's death, Defendant-Appellant Newport Hospital seeks to shield facts subject to discovery by invoking the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 U.S.C. 299b-21, *et seq*. The United States Congress passed that law to improve patient safety and not to form a veil that could be used to hide records that must be made available to patients generally and to patient-litigants during discovery. The cynical ploy Newport Hospital attempts here should not receive the sanction of this Court.

Congress made clear that PSQIA provided privilege to new information that would not have been generated without its passage, not to original patient or provider records or to information that federal, state or local law requires a health provider to develop and maintain. Congress also designed PSQIA to assure that information previously available in administrative or court proceedings remained available.

The highest courts of Kentucky and Florida have properly rejected similar arguments in indistinguishable circumstances. Moreover, in interpreting its own law, the United States has made plain that it is not available to be used as Newport Hospital would use it. In fact, the Department of Health and Human Services labels the practice that Newport Hospital described in its brief of shifting all adverse incident reports into its patient safety evaluation system a "misuse" of the PSQIA privilege. This Court should follow these authoritative determinations from sister supreme courts and the federal government to affirm the lower court's decision that the records must be produced.

ARGUMENT

I. PSQIA BALANCES THE NEED FOR A PRIVILEGE WITH THE NEED FOR DISCOVERY IN LITIGATION IN A WAY THAT SUPPORTS DISCLOSURE HERE.

Newport Hospital and its *amici* erroneously assert that records designated by the hospital's risk manager for transmittal to a Patient Safety Organization (PSO) necessarily become privileged patient safety work product that is not subject to discovery. The claim that Congress lodged a broad, unfettered, and independently unreviewable authority in the hospital itself to shield hospital records from patients and from the search for truth in a litigated dispute cannot be sustained when the federal basis for the claim is scrutinized.

The Patient Safety and Quality Improvement Act of 2005 (PSQIA), 42 U.S.C. 299b-21, *et seq.,* consists of six statutes in Part C of Subchapter VII, Chapter 6A of Title 42 of the United States Code. Pub. L. No. 109-41, 119 Stat. 424, *codified at* 42 U.S.C. §§ 299b-21, *et seq*. It provides for the creation and maintenance of a patient safety database of information voluntarily reported to PSOs by healthcare providers, including hospitals. *See* 42 U.S.C. § 299b-23. PSOs are separate public or private entities certified by the United States Department of Health and Human Services (HHS) to collect patient safety information reported by health care providers. *Id.* at §§ 299b-21(4), 299b-24. PSOs compile and analyze the reports received and then "disseminate information back to providers in [an] effort to improve quality and patient safety." H.R. Rep. No. 197, 109th Cong., 1st Sess. 9 (2005) (House Rep.).

Newport Hospital asserts a breathtakingly broad privilege under PSQIA that would apply to any document that a provider places in its patient safety evaluation system, without regard to the document's content, as long as no state or federal law requires its creation – and then denies

that the reports at issue here are legally required. Both assertions are incorrect. PSQIA provides a privilege only for a subset of the information provided to PSOs.

For example, PSQIA denies patient safety work product status to "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." 42 U.S.C. § 299b-21(7)(B)(ii). However, collecting information in a patient safety evaluation system does not conclusively establish that the information is privileged. That placement is a condition precedent for assertion of the privilege, but it is not sufficient by itself. Even when collected in the prescribed manner, PSQIA denies any privilege for "a patient's medical record, billing and discharge information, or any other original patient or provider record." *Id.* at § 299b-21(7)(B)(i). Thus, original patient records cannot constitute patient safety work product, regardless the forms utilized or the place maintained. By asserting that the MERS reports'[1] status depends solely on its placement in a patient safety evaluation system, the Hospital ignores a "cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." *United States v. Menasche,* 348 U.S. 528, 538-39 (1955) (quoting *Inhabitants of Montclair Tp. v. Ramsdell,* 107 U.S. 147, 152 (1883) (internal quotation marks omitted)). Plainly, the MERS reports at issue are original patient records of the events underlying this action. These reports exist nowhere else and were written to put the facts of what occurred into the record regarding this patient.

PSQIA lays out several exclusions to categorizing certain records as privileged information, regardless of where it is maintained. First, Congress placed "a patient's medical

[1] In 2013, Newport Hospital implemented a patient safety evaluation system known as MERS (Medical Event Reporting System). Brief of Petitioner/Appellant Newport Hospital [hereinafter, "Newport Hosp. Br."] 3.

record, billing and discharge information, or any other original patient or provider record" outside the privilege. *Id.* at § 299b-21(7)(B)(i). Second, it excluded from privilege information "collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system." *Id.* at § 299b-21(7)(B)(ii). Third, it excluded any records or requirements mandated by federal, state, or local laws. *Id.* at § 299b-21(7)(B)(iii)(II) & (III); *see id.* § 299b-22(g)(5).

A. PSQIA Was Designed to Generate New Patient Safety Information, Not to Shield Information Previously Available in Discovery.

In creating these exclusions, Congress limited the PSQIA privilege to ensure that it does not prevent patients (including patient-litigants) and regulators from obtaining information they need. Congress was mindful of an observation in the landmark report that inspired PSQIA. The 1999 Institute of Medicine report concluded that preventable medical errors accounted for as many as 98,000 deaths each year and proposed a "national agenda for reducing errors in health care." Institute of Medicine, *To Err Is Human: Building a Safer Health System* 1, 5 (1999). The report further acknowledged that both litigation and mandatory reporting play an important role in deterring and redressing errors. *Id.* at 8-9, 86-88, 110.

Thus, Congress made clear that PSQIA "was intended to spur the development of *additional* information created through voluntary patient safety activities." 81 Fed. Reg. at 32657 (emphasis added); *see also* House Rep. 9. Congress made clear that, "[i]n general, information that [wa]s available to the public [before the Act] will continue to be available." *Id.* Plainly, PSQIA's privilege encourages the voluntary development and dissemination of new information about patient safety events. *Id.* Congress further specified that the Act would not interfere with federal and state reporting and recordkeeping requirements. 42 U.S.C. § 299b-21(7)(B)(iii)(II) & (III); *see id.* § 299b-22(g)(5).

PSQIA's legislative scheme makes plain that altering a hospital's reporting procedures to place routine information normally collected by the hospital within a patient safety system does not shield the information from discovery. To be sure, original records, legally required reports, and information maintained separately from a patient safety evaluation system "may be relevant" to patient safety and may be reported to a PSO. House Rep. 14. Still, no amount of alchemy can transform the nature of these materials; they "are not themselves patient safety work product" and not privileged even if they are reported. *Id.* Congress in fact emphasized that nothing in the Act "shall be construed to limit" the "discovery of or admissibility of" original records or separate information "in a criminal, civil, or administrative proceeding;" the reporting of such records or information "to a Federal, State, or local governmental agency"; or "a provider's recordkeeping obligation" with respect to such records or information "under Federal, state, or local law." 42 U.S.C. § 299b-21(7)(b)(iii); *see id.* at §§ 299b-22(g)(2) and (5).

B. Original Patient and Provider Records Are Not Privileged.

The Hospital appears to overlook one aspect of these exclusions from the privilege: the exemption for "any other original patient or provider record." *Id.* at § 299b-21(7)(B)(i). Congress was specific in stating that "original patient or provider record[s]" were not privileged and were not subject to limits on the "discovery of or admissibility of [such records] in a criminal, civil, or administrative proceeding," separately from "a provider's recordkeeping obligation with respect to [such records] under Federal, State, or local law." *Id.* at §§ 299b-21(7)(B)(i) and (iii); 73 Fed. Reg. at 8123. An "original patient or provider record" encompasses "hospital records" routinely prepared and maintained by hospital employees.[2] Here, the nurse who prepared one of the records

[2] This Court has long required that hospital records be produced and admitted when kept in the normal course of a hospital's business. *See Ribas v. Revere Rubber Co.*, 37 R.I. 189, 91 A. 58, 62 (1914).

at issue immediately after the event stated that the report was a "common report." Newport Hosp. Br. 33 (quoting Savage Dep. 120; App. 2, p.26). The House Committee report on PSQIA noted that the Act's definition of patient safety work product does not include "documents or communications that are part of traditional health care operations or record keeping," including "primary information at the time of events." House Rep. 14. The Committee explained that such documents are "original provider records" and thus do not qualify as privileged even if they are "relevant to a patient safety evaluation system" or "sent to a [PSO]." *Id.* The nurse's deposition testimony, cited approvingly by the Hospital, supports the conclusion that the report she prepared is outside the PSQIA privilege.

The Hospital reports that, under its system, the original record of an incident is a MERS report written into the patient safety system immediately by the health care provider – in this instance, a nurse. It then tells this Court that the report required by Rhode Island law is written subsequent to the MERS report by the Hospital's risk manager, utilizing a form provided by the Department of Health. That same risk manager is the recipient of the MERS report and determines whether to forward it to the PSO, Newport Hosp. Br. 5, without which there is no colorable claim of privilege. The risk manager thus has the benefit of the MERS report when composing the health department incident report required by law. Plainly, this makes the MERS report the original record of the event, rather than the risk manager's later filing with the Department of Health. The risk manager's report is thus plainly a derivative, second-hand report and not the type of independent and separate investigation that Newport Hospital claims insulates it from PSQIA's exclusionary criteria. *See id.* at 4.

C. Records Required by Law Are Not Privileged.

While the original nature of the MERS report as an incident report is sufficient by itself to hold that the records at issue are not privileged, a second reason supports disclosure – the information is required by state law and thus fits within the PSQIA exception for information that must be maintained pursuant to Federal, state, or local law. 42 U.S.C. § 299b-21(7)(b)(iii); *see id.* at §§ 299b-22(g)(2) and (5). The Hospital attempts to evade this exclusion from privilege by asserting that it maintains separate systems for its "Patient Safety Evaluation System," where it records "Patient Safety Events," apart from its notification system to the Department of Health, where it is obligated to record every "reportable incident," including birth injuries. Newport Hosp. Br. 3-4. Federal law is clear, regardless of whether separate systems are maintained: "Information is not patient safety work product if it is collected to comply with external obligations," such as "state incident reporting requirements." 73 Fed. Reg. at 70742.

One year ago, HHS issued guidance to "clarify" what information qualifies as patient safety work product. In that guidance, HHS specifically disapproved of the practice of using a patient safety evaluation system as the exclusive repository for original records. 81 Fed. Reg. at 32658.[3]

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[3] Under the *Chevron* doctrine, *see Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837 (1984), courts must accept a federal agency's reasonable construction of an ambiguous statute that falls under the agency's jurisdiction to administer. *See Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.,* 545 U.S. 967, 980 (2005). *Chevron* established a two-step procedure. First, a court must ask whether the statute's plain terms "directly address the precise question at issue." *Id.* at 986 (internal quotations omitted). Second, if the statute is ambiguous, the court must defer to the agency's interpretation "so long as the construction is a reasonable policy choice for the agency to make." *Id.* (internal quotations omitted). The interpretation of PSQIA is a question of federal law governed by the federal rules of statutory construction, including the *Chevron* doctrine. *See Smiley v. Citibank (S. Dakota), N.A.,* 517 U.S. 735, 737-39 (1996) (applying *Chevron* to resolve conflict amongst state courts construing a federal act). Alternatively, this Court must give a federal agency's interpretation substantial deference under the *Skidmore* doctrine. *See United States v. Mead Corp.*, 533 U.S. 218, 234 (2001) (discussing *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)).

Thus, when a "provider only maintains the original forms in that system," the "forms are original provider records and not privileged and confidential." *Id.* HHS added that "this scenario [of filing the documents under patient safety to shield them] would be a misuse of a P[atient]S[afety] E[valuation]S[ystem]." *Id.*

Newport Hospital's procedures similarly attempt to evade this mandate by first putting information into the patient safety system and then generating a more constrained incident report. Its subterfuge should be unavailing. The House Report emphasized that, "[i]n general, information that [wa]s available to the public [before the Act] will continue to be available." House Rep. 9. PSQIA's proponents further explained that "information which is currently available to plaintiffs' attorneys or others will remain available just as it is today." 151 Cong. Rec. 17120 (2005) (Sen. Enzi); *see also, e.g.*, *id.* at 17,780 (Rep. Dingell) ("[The Act] continues to allow public access to information that is available today.").

A principal sponsor of PSQIA was Senator Jeffords. He advised his fellow Senators that the legislation would not "reduce or affect" any other existing rights or remedies belonging to injured patients:

> 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. S8743-44 (Jul. 22, 2005).

The bipartisan proponents' assurances reflected a necessary and delicate balance Congress struck in crafting PSQIA. Thus, the Tennessee Supreme Court described PSQIA as a "tightly crafted federal privilege for 'patient safety work product' actually reported to a 'patient safety

organization.'" *Lee Med., Inc. v. Beecher,* 312 S.W.3d 515, 535 (Tenn. 2010). The Senate Committee Report echoes its House counterpart in stating that

> the adverse event or the medical error itself is not privileged; it is the analysis of and subsequent corrective actions related to the adverse event or medical errors that are privileged. ... These protections do not provide a basis for providers to refuse to comply with such reporting requirements simply because they have reported the same or similar information through the reporting system contemplated by this legislation.

S. Rep. No. 108-196, 108th Cong., 1st Sess. 4.

HHS has further directed that "[e]ven when laws or regulations require the reporting of the information regarding the type of events also reported to PSOs, the [PSQIA] does not shield providers from their obligation to comply with such requirements." 73 Fed. Reg. at 70742. After PSQIA, HHS stated, everyone "continues to have access to this original information in the same manner as such entities have had access prior to the passage of the [PSQIA]." *Id.*

Here, state law requires that hospitals prepare and maintain incident reports. R.I. Gen. Laws § 23-17-40 requires a hospital to issue an extensive report of an incident within 24 hours of the event. The report must include an "explanation of the circumstances surrounding the incident." *Id.* at § 23-17-40(e)(1). That information, plainly included in the incident report, dubbed by the Hospital a patient safety event report,[4] must be disclosed, regardless of how it was prepared and where it was maintained.

In giving effect to PSQUIA's statutory scheme, this Court ought to employ the interpretative canon that recognizes privileges "in general, are not favored in the law and therefore should be strictly construed." *Moretti v. Lowe*, 592 A.2d 855, 857 (R.I. 1991) (citation omitted).

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[4] It seems obvious that Newport Hospital renamed its "incident report" a "patient safety event" report to attempt to take advantage of the shield afforded by PSQIA. However, as this Court has recognized its function is to "'look beyond mere semantics and give effect to the purpose of the act.'" *Commercial Union Ins. Co. v. Pelchat,* 727 A.2d 676, 681 (R.I. 1999) (citations omitted).

See also Baldrige v. Shapiro, 455 U.S. 345, 360 (1982) (internal quotations omitted) (a statute granting a privilege must "be strictly construed so as to avoid a construction that would suppress otherwise competent evidence."); *Herbert v. Lando,* 441 U.S. 153, 175 (1979) ("Evidentiary privileges in litigation are not favored, and even those rooted in the Constitution must give way in proper circumstances.") (footnote omitted). Where the information contained in the MERS reports at issue would have been subject to disclosure before the passage of PSQIA, its assignment to the patient safety evaluation system does not change its susceptibility to discovery. The decision below should be affirmed.

II. CONSISTENT RULINGS FROM SISTER STATE SUPREME COURTS SUPPORT DISCLOSURE HERE.

Two sister supreme courts have examined the issue before this Court and have held that PSQIA poses no bar to discovery of the records that indistinguishable from the ones at issue here. In *Tibbs v. Bunnell,* 448 S.W.3d 796 (Ky. 2014), *cert. denied,* 136 S.Ct. 2504 (2016), health care providers resisted producing an incident report for a patient's death based on PSQIA. After examining the text and legislative history of PSQIA, the Kentucky Supreme Court held that incident reports, like the one at issue, "are required in the regular course of the hospital's business, are hospital records, and, thus, are generally discoverable," relying on a state statute that stated that "administrative reports shall be *established, maintained and utilized* as necessary to guide the operation, measure of productivity and reflect the programs of the facility," including "[i]ncident investigation reports" and "[o]ther pertinent reports made in the regular course of business." *Id.* at 804 (citing 902 KAR 20:016 § 3(3)(a)) (emphasis and brackets in original)).

Like Newport Hospital here, the University of Kentucky Hospital claimed that the information sought was properly placed in its patient evaluation system and thus covered by PSQIA. The Kentucky court found, however, that the placement was insufficient to establish the

privilege because the information was "incident information reported by a hospital surgical nurse that normally would be found in an incident report which is required by Kentucky regulations to be 'established, maintained and utilized as necessary to guide the operation ... of the facility.'" *Id.* at 809 (citation omitted). The court noted that, "while the incident information may be relevant to its endeavors under the Act, it is not, nor can it be, patient safety work product, since its collection, creation, maintenance, and utilization is mandated by the Commonwealth of Kentucky as part of its regulatory oversight of its healthcare facilities." *Id.*

The hospital unsuccessfully sought further review in the U.S. Supreme Court. Before deciding the petition, that court asked for the views of the United States, which filed a brief opposing certiorari and fully endorsing the Kentucky Supreme Court's analysis of PSQIA and the HHS regulations implementing it. Brief for the United States as Amicus Curiae, *Tibbs v. Estate of Goff,* No. 14-1140, available at 2016 WL 3014493 (May 24, 2016).

Subsequently, the Florida Supreme Court took up the issue in *Charles v. Southern Baptist Hospital of Florida, Inc.,* 209 So.3d 1199 (Fla. 2017). Florida has a constitutional amendment that gives patients a right of access to records relating to "adverse medical incidents." Fla. Const. art. X, § 25. In *Charles,* the court held that the hospital "cannot shield documents not privileged under state law or the state constitution by virtue of its unilateral decision of where to place the documents under the voluntary reporting system created by the Federal Act." 209 So.3d at 1203. The hospital had resisted producing certain documents, "primarily occurrence reports" that were "potentially responsive [to the discovery request] because they were adverse incident reports," on the grounds "they were privileged and confidential under [PSQIA] as patient safety work product." *Id.* at 1206. The Florida Supreme Court disagreed, holding that "place[ment] in a patient safety evaluation system or submi[ssion] to a patient safety organization" does not render the records

"confidential or privileged patient work product under the Federal Act" "because providers have an independent obligation under Florida law to create and maintain them." *Id.* at 1212.

Similarly, here, Rhode Island law traditionally made incident reports discoverable. PSQIA did not change that, regardless of the procedures Newport Hospital utilized.

To respond to these decisions, Newport Hospital proffers an intermediate appellate court's decision from Illinois. Newport Hosp. Br. 27-29. The case, *Dep't of Fin. & Prof'l Regulation v. Walgreen Co.*, 970 N.E.2d 552 (Ill. App. 2012), is inapposite. The case involved a state regulatory agency that issued subpoenas to a pharmacy, which successfully resisted compliance based on PSQIA. No argument was made by the state agency that the records sought were original patient records. And state law that required the maintenance of incident reports did not apply to pharmacies. *Id.* at 559. The decision provides no useful guidance on the issues presented in this case.

The decision of the court below should be sustained.

III. NEWPORT HOSPITAL CLAIMS AN INDEFENSIBLY BROAD PRIVILEGE.

Even without considering the statutory framework, Newport Hospital's own description of its procedures and claims demonstrates the poverty of the position it advances. At issue in this matter are two documents ("MERS reports"), each authored by a nurse involved in the care of the Carrons. Newport Hosp. Br. 10. According to the Hospital, its health care providers must generate a MERS report for every event that is "harmful to a patient." *Id.* at 33 (quoting Savage Dep. 118; App. 2, p. 24). However, despite that description by one of its employees, which the Hospital endorses as demonstrative of why these are not legally mandated business records subject to discovery, *id.*, the types of events the Hospital deems reportable under its MERS system has an astonishing breadth.

Incidents worthy of a MERS report include the fact that a hallway light bulb needs replacing or that a visitor to the hospital had fallen. *Id.* at 11, 33-34. Yet these are plainly not injuries to a patient and not necessarily matters of patient safety. The assertion that all MERS reports, including these, are subject to the PSQIA privilege demonstrates the overinclusive nature of the Hospital's claim. It is impossible to imagine the circumstances that would entitle the hospital to assert the PSQIA privilege against disclosing its MERS report relating to a visitor's slip and fall in the course of litigation with the injured visitor, yet Newport Hospital would either assert that position given its claims here or otherwise must abandon its claims that a MERS report necessarily qualifies for the PSQIA privilege. The fact that the Hospital's system assumes privilege and attempts to sweep all adverse reportage under the rug undermines its assertion that its patient safety system is designed to generate new information that, when compiled by a PSO, will result in studies suggesting procedures that hospitals throughout the nation should adopt to reduce medical errors, which is why PSQIA was established in the first place.

To be sure, the Hospital, in accordance with regulatory procedure, does state that its risk manager examines each MERS report to determine, *after it was generated,* whether it relates to patient safety and should be submitted to a PSO. *Id.* at 3. Yet, this can be a self-serving procedure. After all, by definition, a risk manager's job includes:

> assessing and identifying the different kinds of risks facing a person, an institution, or society because of its activities and environment, determining the likelihood of losses and other consequences from those risks, and taking appropriate actions, which include monitoring the risks and reducing the losses and other consequences from them.

James Fanto, *Anticipating the Unthinkable: The Adequacy of Risk Management in Finance and Environmental Studies,* 44 Wake Forest L. Rev. 731, 731 (2009).

That a risk manager's responsibilities include "reducing the losses and other consequences" of risks and that the risk manager is a hospital employee provides an incentive to push all events that may entail liability into the patient safety system in order to permit the assertion of privilege and insulate the report from discovery in litigation. Congress, however, recognized that possibility and wrote PSQIA to avoid it by insisting that information previously available in litigation would remain available. *See* 42 U.S.C. § 299b-21(7)(b)(iii); *see id.* at §§ 299b-22(g)(2) and (5); 151 Cong. Rec. 17120 (2005) (Sen. Enzi).

Moreover, in promulgating its 2008 regulations, HHS emphasized that "[i]nformation is not patient safety work product if it is collected to comply with external obligations, such as … state incident reporting requirements." 73 Fed. Reg. at 70742; *see also, e.g.*, *id.* at 8121 (similar). HHS thus cautioned that a provider should not maintain information required to satisfy its external obligations in its patient safety evaluation system. *Id.* at 70742-43. Here, Newport Hospital has attempted to place incident reports, required by Rhode Island law, behind a veil of patient safety. Its attempted subterfuge should not be permitted to succeed. It is, as HHS has advised, a "misuse" of the system. 81 Fed. Reg. at 32658. The information about the events that resulted in Kenneth Carron's death in the MERS reports is not new information, is not patient safety work product, and should not be deemed privileged.

CONCLUSION

For the foregoing reasons, this Court should affirm the decision below.

Respectfully submitted,

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