No. 14-1140

In The Supreme Court of the United States

PHILLIP TIBBS, ET AL.,

Petitioners,

v.

ESTATE OF LUVETTA GOFF, ET AL.,

Respondents.

On Petition For Writ Of Certiorari To The Supreme Court Of Kentucky

BRIEF IN OPPOSITION FOR RESPONDENT ESTATE OF LUVETTA GOFF

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QUESTION PRESENTED (RESTATED)

Whether, in spite of clear language to the contrary, the Patient Safety and Quality Improvement Act of 2005 extends a federal privilege to original provider records, whether the Act nullifies the protections afforded a patient under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and whether a healthcare provider can cloak original provider records with a privilege simply by creating the document on a Patient Safety Evaluation System or by submitting the records to a Patient Safety Organization ("PSO").

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The opinion of the Kentucky Supreme Court is reported as *Tibbs v. Bunnell*, 448 S.W.3d 796 (Ky. 2014).

JURISDICTION

This Court has jurisdiction pursuant to 28 U.S.C. §1257(a), except as argued herein.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Petitioners contend that the issues presented in this case involve the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2.

This case involves the Patient Safety and Quality Improvement Act of 2005 ("Patient Safety Act"), Pub. L. No. 109-41, 119 Stat. 424, codified at 42 U.S.C. §299b-21 *et seq.* Pet. App. 53a-66a.

INTRODUCTION

The Petitioners want this Court to read the Patient Safety Act as creating a sweeping, national quality assurance privilege. The state of the law is

such that some States have quality assurance privileges, and some States do not. Hence, in some States, incident reports are discoverable. The Petitioners would have this Court drastically change the state of the law, and construe the Patient Safety Act as displacing unfavorable state laws. It is common ground that the Patient Safety Act creates a statutory scheme to improve health care in this Country by sharing information in the hopes of reducing mortality rates. However, the clear language of the Act and its legislative history reveal that Congress did not intend to interfere with the States' regulation of healthcare providers.

This case, however, hardly deals with a sweeping national privilege and quality assurance documents nationwide, rather it involves a single incident report. Ms. Luvetta Goff suffered complications during an elective spine surgery, and her nurse wrote a report concerning the surgery on the day of the surgery. The Petitioners would have this Court interpret the Patient Safety Act to permit the report being shared with thousands of healthcare providers around the United States, while being kept from Ms. Goff – an interpretation the Kentucky Supreme Court correctly rejected.

STATEMENT OF THE CASE AND FACTS

Ms. Goff died as a result of complications from an elective spine surgery performed by three surgeons at the University of Kentucky Hospital. One of the surgical nurses completed a report concerning the surgery on the day of the surgery. The report contained details of the intraoperative complication that occurred – the date of the event, the person harmed by the incident, the location where the event occurred, and a description of the event.

Forty-five days after it was created, the report was submitted to University HealthSystem Consortium ("UHC") as the University of Kentucky Hospital's PSO. Upon submission to the PSO, the report was available to hundreds, if not thousands, of hospitals, doctors and other healthcare providers. However, the record concerning Ms. Goff's surgery completed by Ms. Goff's nurse was not shared with, nor made available to Ms. Goff's Estate.

Ms. Goff's Estate commenced an action for medical malpractice regarding the aforementioned elective spine surgery. As part of the action, the Estate sent Petitioners a discovery request seeking any and all incident reports. The Petitioners responded by filing a motion for protective order asserting that the only report that exists was created on the hospital's Patient Safety Evaluation System and is privileged under the Patient Safety Act.

The trial court denied the motion for protective order, and ordered the production of the report if it

was created by "someone involved in or with actual knowledge of the medical care."

The Petitioners sought a writ of prohibition preventing the trial court's order of production with the Kentucky Court of Appeals. The Court of Appeals granted the writ of prohibition finding that the Patient Safety Act creates a federal privilege, but finding that the privilege is limited to documents containing a "self-examining analysis." The Court of Appeals remanded to the trial court with instructions to conduct an *in camera* inspection of the document to determine if it contained a "self-examining analysis."

The Petitioners sought further review through a direct appeal on the writ of prohibition to the Kentucky Supreme Court. The Kentucky Supreme Court found that the single incident report in question was not privileged under the Patient Safety Act.

The Kentucky Supreme Court recited Kentucky Administrative Regulations which mandate the creation of incident reports. 902 KAR 20:016 §8(b)(1)-(2). Under Kentucky law, incident reports are discoverable. *Tibbs v. Bunnell*, 448 S.W.3d 796, 804 (Ky. 2014) (*citing Saleba v. Schrand*, 300 S.W.3d 177, 184 (Ky. 2009)). The Kentucky Supreme Court observed that the Patient Safety Act "did not intend to supplant, or invalidate, traditional state monitoring or regulation of healthcare providers." *Id*. at 807 (*citing* 42 U.S.C. §299b-21(7)(B)(i)-(iii)). Accordingly, the Kentucky Supreme Court concluded that the incident report "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*. at 809. The Kentucky Supreme Court noted that the facts of the instant case reveal the incident report information may be intermingled with other information on the Patient Safety Evaluation System. *Id*. Thus, the Kentucky Supreme Court held that information normally contained in incident reports is discoverable, and to the extent the information is not normally in incident reports, it can be excised during *in camera* inspection. *Id*.

The Petitioners have requested this Court's review claiming the Kentucky State Court has interfered with the Federal statutory scheme of the Patient Safety Act.

REASONS FOR DENYING THE WRIT

(ARGUMENT)

I. CERTIORARI IS NOT WARRANTED AS THE KENTUCKY COURT CORRECTLY CONSTRUED THE PATIENT SAFETY ACT

A. Petitioners' Approach Nullifies both State and Federal Law

The Petitioners' approach nullifies both state and federal law. Kentucky law mandates the creation of incident reports as part of its regulation of healthcare providers. 902 KAR 20:016 §8(b)(1)-(2). Kentucky law

also makes incident reports discoverable. *Saleba*, 300 S.W.3d at 184. Petitioners would nullify Kentucky law on this point by finding that a federal privilege under the Patient Safety Act prevents disclosure of incident reports.

The Petitioners' approach would also nullify federal law – in the form of the Patient Safety Act as well as HIPAA. The Patient Safety Act contains a limited federal privilege with stated exceptions. The incident report in this case fits within the Act's exceptions. Moreover, the Patient Safety Act was not intended to displace state law regulating healthcare providers. The Petitioners would have this Court ignore the Act's privilege exceptions, and turn a blind eye to Congressional intent.

Lastly, the Petitioners' approach would affect protections of health information under another Federal statutory scheme – HIPAA. The incident report in this case is likely protected health information under HIPAA. As such, HIPAA mandates access to the patient, and restricts access to third parties. The Petitioners' approach turns HIPAA on its head and restricts access to the patient while providing the report to hoards of third party healthcare providers.

1. The Patient Safety Act's Clear Language and Legislative History Reveal That the Act Did Not Intend to Supplant State Regulatory Law

The Petitioners assert that the Patient Safety Act creates a national privilege that displaces existing state law. The Patient Safety Act, however, was not intended to supplant, or invalidate, traditional state monitoring or regulation of health providers. 42 U.S.C. §299b-21(7)(B)(i)-(iii). The United States Department of Health and Human Services explained that:

> 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, 73 Fed. Reg. 70,732-01, 70,742 (Dep't of Health and Human Services Nov. 21, 2008) (to be codified at 42 U.S.C. §§299b-21, *et seq*.). The Petitioners' arguments notwithstanding, the Patient Safety Act was meant to co-exist with and not disrupt traditional state regulation of healthcare providers.

The House Report regarding the Patient Safety Act further reveals:

> [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).

The legislative history of the Patient Safety Act buttresses the idea that it was not meant to disrupt existing state law:

> 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. 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. The legislation also upholds existing state laws on reporting patient safety information.

151 Cong. Rec. S8713-02 (July 21, 2005) (statement by Sen. Kennedy).

> 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.
>
> Also, we believed very strongly that the definition of patient safety work product – that is, exactly what kind of information is to be protected – be drawn broadly enough to assure that providers will feel safe and secure in participating in a patient safety system – and that they not be chilled from participating by fear that their efforts to assemble, analyze, deliberate on, or report patient safety information to patient safety organizations

> would somehow fall outside of a too-narrow statutory definition of patient safety work product. With this in mind, we negotiated a definition in the agreement which takes great care to make clear to providers that the assembly of data, its analysis, deliberations about it, and its reporting to a patient safety organization will be firmly protected. We also clarified that information that is collected, maintained, or developed separately from the patient safety system will continue to be treated the same as it is under current law.

151 Cong. Rec. S8741, S8741-02 (July 22, 2005) (statement by Sen. Enzi).

> 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 workproducts. 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. S8741-02, S8743 (July 22, 2005) (statement by Sen. Jeffords).

> The bill would preclude this information, termed patient safety work product, from being used against providers in civil and administrative proceedings, disclosed pursuant to Freedom of Information Act requests, or used to carry out adverse personnel actions. The bill does not shield other information outside this patient safety work product from use in court cases. I believe it strikes an appropriate balance between encouraging the reporting of valuable information, which will be used to save lives, and safeguarding the ability of individuals to access necessary information to seek judicial redress when appropriate.

151 Cong. Rec. H6673-01 (July 27, 2005) (statement by Rep. Bilirakis).

> This bill achieves these goals by creating a helpful and non-punitive atmosphere for health care providers to share information with entities specialized in patient safety and quality improvement. Yet, it continues to allow public access to information that is available today.

151 Cong. Rec. H6673-01 (July 27, 2005) (statement by Rep. Dingell).

The Patient Safety Act's legislative history clearly shows that the Patient Safety Act does not supplant State regulation of its own healthcare providers, and, as the Act's language and legislative history reveal, was not intended to.

2. The Patient Safety Act Creates a Limited Federal Privilege

The Patient Safety Act does create a Federal privilege for patient safety work product. However, as the legislative history made evident, the privilege is not without limits. For instance, the Patient Safety Act clarifies that the privilege 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). The privilege also does not include "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).

The Patient Safety Act further clarifies that the privilege should not be construed:

> 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; except as provided in subsection (i) of this section, to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d-5 of this title (or regulations promulgated under such section).

42 U.S.C. §299b-22(g)(2)-(3).

Contrary to Petitioners' arguments otherwise, based upon the language of the Patient Safety Act itself, it is clear that Congress intended only to create a limited Federal privilege.

3. The Single Incident Report in This Case Fits Within the Exceptions to the Federal Privilege

This case involves a single incident report completed by Ms. Goff's nurse regarding the surgical procedure on Ms. Goff on the day of the surgery. The report was not completed by a risk manager at the hospital. It was completed by Ms. Goff's healthcare provider regarding the provision of healthcare to Ms. Goff.

The incident report in this case fits the two exceptions under the Patient Safety Act. First, the report was completed by a healthcare provider on the

day of the surgery regarding the surgery. In clear language, the Patient Safety Act excludes original provider records from the federal privilege. 42 U.S.C. §299b-22 ("does not include . . . any other . . . original . . . provider record").

Second, the report was completed to comply with mandatory Kentucky laws regarding the regulation of healthcare providers. Accordingly, the report fits the exception to the federal privilege of 42 U.S.C. §299b-21(7)(B)(ii).

To avoid this exception, the Petitioners would raise an existential point, namely that the report does not "exist separately" from the Patient Safety Evaluation System because all reports are created and maintained on a single web portal. However, this existential fact is not dispositive. One cannot forget the Latin phrase: *Esse quam videri* ("to be, rather than to seem"). While the report may not seem separate, its existence is separately required by Kentucky law, and is separately discoverable under Kentucky State law. The existence of separate state law obligations should control over appearance.

Because the single incident report at issue falls within the two exceptions to the Patient Safety Act privilege, the Kentucky Supreme Court correctly decided that the single incident report was not privileged.

4. The Single Incident Report in This Case is Protected Health Information Under HIPAA, and Its Dissemination Beyond the Patient Should Be Limited

HIPAA defines "health information" as information "whether oral or recorded in any form or medium, that – (1) is created by a health care provider . . . ; and (2) relates to the past, present, or future physical or mental health or condition of any individual; the provision of health care to an individual. . . ." 45 C.F.R. §160.103. The information is "individually identifiable health information" if it is a subset of health information that identifies the individual. 45 C.F.R. §160.103. "Protected health information" means "individually identifiable health information" that "is transmitted by electronic media or maintained in electronic media. . . ." 45 C.F.R. §160.103.

HIPAA limits the access others may have to a patient's protected health information, while giving access to the individual patient. *See* 45 C.F.R. §164.502(a) ("A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart. . . ."); 45 C.F.R. §164.502(a)(2) ("a covered entity is required to disclose protected health information to an individual when requested. . . .").

The incident report in this case fits the definition of protected health information. The incident report was created by Ms. Goff's healthcare provider and relates to the provision of care to her. As Petitioners'

affidavit filed in support of the motion for protective order below reveals, the report in this case contains individually identifiable information. Lastly, the information is maintained on electronic media in the form of the Petitioners' web portal. In spite of the report being Ms. Goff's health information, the Petitioners' approach paradoxically restricts access to Ms. Goff, but makes the report available to thousands of healthcare providers around the Country.

Under Petitioners' expansive reading of the Patient Safety Act, a patient's Federal right to access their personal health information under HIPAA would be circumvented simply by a healthcare provider placing that information in a Patient Safety Evaluation System or transmitting it to a PSO. Congress clearly could not have contemplated granting such unfettered authority to a healthcare provider in derogation of HIPAA.

It is clear that the Petitioners wish to have an expansive Federal privilege wherein any document kept in a Patient Safety Evaluation System or transmitted to a PSO is privileged. The Patient Safety Act, however, does not cloak a document or report with privilege simply by virtue of where it is maintained. The Act expressly excludes patient records, provider records, and documents which are required by State law from the expansive privilege sought by the Petitioners.

As if the expansive privilege wasn't enough, the Petitioners also seek to be their own referees, deciding

what is or is not privileged without recourse to the court system. This was not the system designed by Congress in the Patient Safety Act, and the Petitioners' dreams of an expansive Federal privilege do not warrant exercise of certiorari jurisdiction.

B. Review is Unnecessary Because Any Alleged Chilling Effect from Disclosure of the Incident Report is Illusory

The Petitioners maintain that this Court should exercise review because the Kentucky Supreme Court's opinion disrupts an important Federal program. The Petitioners fear a chilling effect from stymieing a "culture of safety through information sharing." The Petition should be denied because any alleged disruption to the system envisioned by the Patient Safety Act is illusory.

It is common ground that Kentucky law mandates both the creation of incident reports as well as their discovery. The Petitioners do not resist the idea that they have an obligation to turn over the incident report under State law. This case involves a single incident report regarding Ms. Goff's surgery, created by one of her healthcare providers on the day of the surgery.

When creating the document, the healthcare provider had an obligation to eventually turn over the report to the patient under State law. Thus, when the incident report was drafted, there was no expectation interest that it would never be turned over. In fact,

the opposite is true. Healthcare providers in jurisdictions such as Kentucky which permit discovery of incident reports are aware of the possibility that these documents might be obtained by the patients.

The Petitioners maintain that failure to extend a Federal privilege to incident reports would create a chilling effect where healthcare providers would not participate in the Patient Safety Act scheme. This argument is flawed. Under current State law, the incident reports are discoverable. Disclosure of the document according to established State law, then, does not alter the status quo, and does not affect healthcare providers' expectations. If a healthcare provider already anticipates having to turn over an incident report, then it is hard to fathom how not extending a privilege to the document creates a chilling effect.

Petitioners' argument also rests on the notion that the discoverability of incident reports is the desideratum for healthcare providers choosing whether or not to participate in the Patient Safety Act's scheme. The Patient Safety Act, however, extends a privilege to other documents and provides other incentives to healthcare providers. These incentives clearly outweigh any illusory disincentive created by not extending the federal privilege beyond the language of the Act.

Because any alleged chilling effect is illusory, this Court should find that certiorari review is unnecessary.

C. Review is Unnecessary Because it is Not an Extraordinary Challenge for a Court to Assess Privilege

It is within the traditional ambit of both State and Federal Courts to assess claims of privilege. One party makes a claim of privilege, the other side opposes it, and the court determines whether or not the privilege applies. The traditional approach found in countless instances in this Country's reported decisions is a privilege log is filed, an *in camera* inspection is conducted, and the court determines whether a privilege applies or does not. *See Hawkins v. Miller*, 301 S.W.3d 507, 509 (Ky. Ct. App. 2009) (a finding of privilege is an issue of law for the court); *Immuno AG v. Moor-Jankowski*, 77 N.Y.2d 235, 248 (N.Y. 1991) (recognizing "traditional role of State courts in applying privileges"). This process is repeated on a daily basis in the courts of this Country.

The Petitioners seek to disrupt this orderly system without providing a consistent rubric of their own. Instead, the Petitioners urge that this Court ratify a "healthcare provider decides" method. Under the Petitioners' method, whenever a healthcare provider decides that a document or report is privileged under the Patient Safety Act, they keep it within their PSO. If a healthcare provider decides that a document or report is not privileged, the provider can decide to remove it from the PSO and turn the document or report over. The court process is not involved in claims of privilege by healthcare providers. If a provider chooses not to turn over a document, and it

is in fact a document which the State requires disclosure of, the provider can simply accept the penalties of non-compliance. The Petitioners' method of no court involvement in claims of privilege is a complete and untenable departure from the traditional function of courts, and leaves litigants with little recourse.

The Petitioners' approach here is akin to that of President Nixon in *United States v. Nixon*, 418 U.S. 683 (1974). In that case, President Nixon maintained that the Executive Branch should be the final arbiter on a claim of executive privilege. This Court rejected that position and found that resolving privileges in a discovery dispute was the "kind of controversy courts traditionally resolve." *Id.* at 696. Chief Justice Burger, writing for the Court, found that, "[w]hatever the correct answer on the merits, these issues are 'of a type which are traditionally justiciable.'" *Id.* at 697.

Similarly, the Court here should reject Petitioners' arguments that resolving questions of privilege poses an extraordinary challenge for the courts, and therefore should be left to healthcare providers. Our system prevents the proverbial fox from guarding the henhouse – determining questions of privilege is well within the traditional role of our courts.

The Department of Health and Human Services under its own interpretation of the Patient Safety Act has also recognized that it will be the courts that resolve privilege issues under the Act. The Department stated that " . . . the privilege protections will be enforced through the court systems. . . ." Patient

Safety and Quality Improvement, 73 Fed.Reg. at 70,771.

This Court should find that certiorari review is unnecessary because resolving questions of privilege is within the traditional role of the courts, and poses no extraordinary challenge.

CONCLUSION

Based on the foregoing, Respondent respectfully requests that this Court deny the petition for writ of certiorari.

Respectfully submitted,

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