No. 14-1140

IN THE

# Supreme Court of the United States

PHILLIP TIBBS, *et al.*,

*Petitioners,*

v.

KIMBERLY BUNNELL, JUDGE, CIRCUIT COURT OF KENTUCKY, FAYETTE COUNTY, *et al.*,

*Respondents.*

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

## REPLY BRIEF OF PETITIONERS


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## REPLY BRIEF

Respondents have confirmed what Petitioners set out to prove: the decision below sowed confusion about the operation of the privilege created by the Patient Safety Act, subjected federal law to state nullification, and chilled the medical community's participation in an important federal program. And Respondents' arguments cast no doubt on the appropriateness of this Court's review. Indeed, they acknowledge that the interpretation below preserves the ragged patchwork of state rules that Congress intended to cover with a uniform federal privilege.

Respondents nevertheless contend the decision below is correct, nonthreatening, and workable. These mistaken contentions are insufficient to overcome the need for certiorari review.

*First*, Respondents assert—contrary to the text of the Act—that Congress did not intend to displace existing state discoverability rules. But Congress did not enact a stillborn privilege; it superseded the porous state protections Respondents embrace. Despite the Act's express-preemption provision, Respondents and the court below turn preemption on its head by delimiting a federal privilege according to state laws it was designed to supplant.

*Second*, Respondents dismiss the decision's chilling effect as "illusory," Opp'n 17, because healthcare providers in states like Kentucky know their work product is discoverable under state law. This question-begging assessment ignores that Congress created the privilege precisely to incentivize participation in patient safety organizations ("PSOs") by providers who were previously unwilling to share patient-safety information because of the risk of disclosure. If the

Act merely deferred to preexisting state law, the voluntary PSO program's principal inducement would become a dead letter.

*Third*, Respondents note that judges regularly conduct *in camera* privilege review. True enough. But under the decision below, the *standard* that judges would apply *in camera* is hardly regular judicial fare: redlining privileged documents to disclose a nebulous category of "information normally contained in" records "mandated by the [State] as part of its regulatory oversight." Pet. App. 25a. This standard is not predictable, administrable, or remotely tethered to the statutory text.

As the brief in opposition starkly reveals, the decision below misconstrues federal law, reflects confusion among litigants and lower courts, and undermines a national program. This Court should grant the petition or, at a minimum, invite the United States to file a brief.

## I. REVIEW IS WARRANTED TO RESOLVE CONFUSION EVIDENT IN THE DECISION BELOW AND IN OTHER LOWER COURTS.

The petition showed that state and federal courts have applied a welter of approaches to the patient safety work product privilege—in this case, narrowing it to the vanishing point. Pet. 15–25. This confusion has only deepened since. Some courts have cited *Tibbs* in misconstruing the Act's exceptions. See *Brink* v. *Mallick*, No. 13-1314, 2015 WL 1387936, at *10 (Pa. Ct. Com. Pl. Mar. 27, 2015) (erroneously restricting the privilege when work product is shared under the statute). And others have followed the *Tibbs* dissent instead. See *Lewis* v. *Upadhyay*, No. CL-143682, 2015 WL 1417874, at *4 (Va. Cir. Ct. Mar. 3, 2015).

Respondents do not dispute the uncertainty engendered by these varying approaches. Nor do they dispute the outsized effect that the thorough opinions from the state high court below will have in future cases. And they do not contest that, in Kentucky and elsewhere, litigants will shop for the forum they perceive to be more or less hospitable to the privilege. Pet. 23. Instead, Respondents argue that the Kentucky Supreme Court correctly applied the privilege. Their unpersuasive arguments, however, only illustrate the confusion that decision caused.

1. Respondents' first argument—that the Act "was not intended to supplant … traditional state monitoring or regulation of health providers," Opp'n 7—is correct, but beside the point. It is common ground that the Act's patient safety system "resides alongside but does not replace" reporting activities mandated by state law. 73 Fed. Reg. 70,732, 70,742 (Nov. 21, 2008); see 42 U.S.C. § 299b-21(7)(B)(iii). But Respondents misunderstand the distinction between preserved state regulatory responsibilities and preempted state discoverability rules.

The Act distinguishes between records inside and outside the patient safety system. Documents that are "assembled or developed" through a patient safety evaluation system and "reported to" a PSO are patient safety work product, § 299b-21(7)(A)(i)(I), and therefore privileged, § 299b-22(a). On the other hand, documents that are "collected, maintained, or developed separately … from a patient safety evaluation system" are not patient safety work product, and therefore not privileged. § 299b-21(7)(B)(ii). This straightforward standard does not supplant existing state requirements, which "must be met with information that is *not* patient safety work product." 73 Fed. Reg. at 70,742 (emphasis added). "[O]versight

entities continue to have access to this original information in the same manner" as before the Act was passed. *Id.* The consequences of noncompliance likewise remain the same as before: penalties prescribed by state law, *e.g.*, Ky. Rev. Stat. §§ 216B.042, 216B.105, and possibly an adverse evidentiary inference in civil litigation, *cf. Univ. Med. Ctr., Inc.* v. *Beglin*, 375 S.W.3d 783, 791–92 (Ky. 2011) (permissible adverse inference from hospital's unexplained failure to produce "occurrence report"). And medical-malpractice plaintiffs may access the same materials—charts and other patient records—as before.

The approach adopted by Respondents and the court below, however, would collapse this distinction by treating information assembled for and reported to a PSO as discoverable if it is the sort "normally contained in" a record whose "collection, creation, maintenance, [or] utilization is mandated by the [State] as part of its regulatory oversight of its healthcare facilities." Pet. App. 25a–26a. If so, the "separate state law obligations … control," and the privilege disappears. Opp'n 14. This approach makes the scope of the federal privilege depend entirely on the extent of the provider's independent state-law obligations, notwithstanding the Act's express preemption language, § 299b-22(a), and notwithstanding this Court's consistent rejection of attempts to "nullify … unwanted federal legislation" through state law, *Gade* v. *Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 106 (1992).

To support this bizarre outcome, Respondents rely heavily on individual legislators' floor speeches. Opp'n 7–12. These statements broadly support the idea that the Act does not protect "information that is already currently collected or maintained separate[ly] from the new patient safety process." *Id.* at 9 (quot-

ing 151 Cong. Rec. S8741-02 (daily ed. July 22, 2005)). But—whatever the statements' probative value—the legislative intent Respondents divine is entirely consistent with a rule that turns on whether a record is part of the patient safety system. Importantly, the same legislative history makes clear that the Act "is intended to make medical professionals feel secure in reporting errors without fear of punishment," *id.* at 8 (quoting 151 Cong. Rec. S8713-02 (daily ed. July 21, 2005))—a purpose the decision below drastically undermines.

2. Respondents' applications of the privilege exceptions are no more successful.

First, Respondents invoke the exception for "a patient's medical record, billing and discharge information, or any other original patient or provider record." § 299b-21(7)(B)(i). Because the report "was completed by a healthcare provider on the day of the surgery regarding the surgery," Respondents infer that it must be an original provider record. Opp'n 13–14. This assumption—neither advanced nor endorsed below—is incorrect. An incident report, unlike a patient chart, is not used to guide treatment. Nor, unlike billing or discharge records, to manage the patient-provider business relationship. See 73 Fed. Reg. at 70,739 (contrasting unprivileged original medical and business records with privileged documents containing "candid consideration of quality and safety"). Indeed, an incident report is precisely the type of document the Patient Safety Act was created to protect: it is used by the provider to "improve patient safety and the quality of health care delivery." § 299b-21(5)(A). If this is not patient safety work product, almost nothing would be.

Second, Respondents point to the exception for records that are "collected, maintained, or developed

separately, or exist[] separately, from a patient safety evaluation system." § 299b-21(7)(B)(ii). But it is uncontested that the report was created within the hospital's patient safety system and then sent to the PSO. Pet. App. 17a–18a. And the report exists "exclusively" in that system. *Id.* at 18a. Accordingly, the report neither was "developed separately" nor "exists separately." § 299b-21(7)(B)(ii).

Respondents do not genuinely contest these facts. Instead, they aim to rewrite the law. In their view, the statutory phrase "exists separately" should be read to mean "separately required." Opp'n 14. A court's analysis of the federal privilege would turn on a potentially complicated interpretation of the provider's "separate state law obligations," *id.*, rather than the simple factual question whether the document at issue was part of the patient safety system, § 299b-21(7)(A)(i)(I). But "[i]t is not for [a court] to rewrite the statute so that it covers only what we think is necessary to achieve what we think Congress really intended." *Lewis* v. *City of Chicago*, 560 U.S. 205, 215 (2010). And Congress' language is clear: the privilege applies, "[n]otwithstanding any other provision of Federal, State, or local law." § 299b-22(a).

3. Respondents' contention that the "incident report in this case is likely protected health information under HIPAA," Opp'n 6, is a red herring. Where HIPAA applies, it requires disclosure to patients and nondisclosure to third parties. But in a provision Respondents ignore, Congress explicitly reconciled HIPAA and the Patient Safety Act: "For purposes of applying the HIPAA confidentiality regulations," PSOs "shall be treated as business associates," 42 U.S.C. § 299b-22(i)(1), to whom a provider "may disclose protected health information," 45 C.F.R. § 164.502(e)(1)(i), and whose "patient safety activi-

ties … are deemed to be health care operations … of the provider" under HIPAA, 42 U.S.C. § 299b-22(i)(2).

Further, Respondents are simply mistaken that applying the privilege would "restric[t] access to [patients], but mak[e] the report[s] available to thousands of healthcare providers around the Country." Opp'n 16. A patient's right of access under HIPAA extends only to her "designated record set," 45 C.F.R. § 164.524(a)(1), which encompasses medical and billing records or other documents used by the provider "to make decisions about" the patient, § 164.501(1)(i), (iii). Designated record sets do *not* embrace "a hospital's peer review files that include protected health information about many patients but are used only to improve patient care at the hospital, and not to make decisions about individuals." 65 Fed. Reg. 82,462, 82,606 (Dec. 28, 2000). And "[i]ncident report information is 'de-identified' of provider and patient information" before it is shared beyond the PSO itself. Br. of *Amicus Curiae* Alliance for Quality Improvement and Patient Safety 15; see § 299b-23(a) (shared work product is "nonidentifiable").

## II. THE DECISION DISRUPTS A FEDERAL PROGRAM AND IMPOSES INCONSISTENT AND UNPREDICTABLE LEGAL OBLIGATIONS.

1. The decision below will undoubtedly chill provider participation in the national PSO system. Fear of civil discovery is precisely why the healthcare community previously resisted widespread peer review, and precisely why Congress enacted the privilege as the centerpiece of the Patient Safety Act. Congress sought to "encourage the reporting and analysis of medical errors and health care systems by providing peer review protection of information reported to patient safety organizations." H.R. Rep.

109-197, at 9 (2005). The privilege is thus "*the foundation* to furthering the overall goal of the statute to develop a national system for analyzing and learning from patient safety events." 73 Fed. Reg. at 70,741 (emphasis added). The effect of *Tibbs*, however, is to give plaintiffs access to internal analysis that may be preliminary, disputed, or unfavorable. Pet. 25–31.

Rejecting the judgment of Congress, HHS, and the healthcare community, Respondents believe any resulting chilling effect is "illusory." Opp'n 17. They insist that (unidentified) "other incentives" will induce participation in the PSO system, *id.* at 18, but fail to explain how these could outweigh the manifest risks of disclosure. To the contrary, absent a clear privilege, providers "may rationally decide that the risk of disclosure in later litigation is too great," and decline to create patient safety materials that might later be used against them. Br. of *Amici Curiae* American Hospital Association and Federation of American Hospitals 5. Indeed, amicus briefs filed by numerous national healthcare organizations attest that the decision below, if permitted to stand, "will stifle the collection and use of 'patient safety work product.'" *E.g.*, Br. of *Amici Curiae* University Healthsystem Safety Intelligence PSO and American Medical Association, et al., 4.

In fact, were Respondents' statutory interpretation correct, little incentive would remain at all: under the decision below, the Act becomes a trap for the unwary, protecting almost nothing from discovery. As Respondents explain, "some States have quality assurance privileges, and some States do not. Hence, in some States, incident reports are discoverable" under state law, and in others, they are not. Opp'n 2. But Respondents overlook that a central purpose of the Act was to replace this "'decentralized and fragment-

ed'" regime with a nationwide patient-safety system bolstered by a uniform national privilege. Pet. 6. In their view, the decision below did not chill participation because the privilege induced no participation: the state-law patchwork remains, and providers in states (like Kentucky) that lack a strong peer-review privilege "are aware of the possibility that these documents might be obtained by the patients." Opp'n 18. To accept that position is to assume, in the face of statutory text and common sense, that Congress created a federal-law privilege on which no provider can sensibly rely. Yet that is the natural but illogical result of the decision below. See *supra* at 5; Pet. 20–21.

2. Respondents offer no response to Petitioners' showing that the approach adopted below subjects PSOs to conflicting legal obligations. A court could compel a PSO to violate its federal-law obligation not to release patient safety information, risking a penalty of up to $11,000 per act. Pet. 30. Indeed, this would be the expected result where, as here, a court orders disclosure of an incident report housed within a PSO. This outcome cannot be squared with the Act's purposes or this Court's duty to ensure consistent application of federal law.

3. Respondents insist that the decision below is amenable to "orderly" application because it is within trial judges' "traditional ambit … to assess claims of privilege" *in camera*. Opp'n 19. But Respondents fail to defend—or even mention—the standard judges would apply: excising information "normally contained in" state-mandated records from privileged work product. It is emphatically *not* "within the traditional ambit" of trial judges to understand state regulatory arcana, or to apply it to medical peer-review material never contemplated by those regulations. As the dissent below observed, this vague

standard "raises serious practical concerns since judges, not typically being medically trained, may have difficulty identifying what information is normally contained in an incident report." Pet. App. 28a n.19 (Abramson, J., dissenting). Providers will surely think twice before sharing sensitive medical analysis whose protection depends on such free-wheeling judicial analysis.

The only alternative to the approach below, Respondents contend, is to trust foxes with henhouses, or Nixon with the White House tapes, by deputizing providers to unilaterally police the boundaries of their own privilege. See Opp'n 20. Not so. The Act ensures judicial review of the privilege—according to the standard expressly set forth in the federal statute, not atextual limits inferred from various state healthcare regulations.

That test is whether a record was "assembled or developed … for reporting to," and "reported to," a PSO, § 299b-21(7)(A)(i)(I), and is not covered by the Act's carefully drawn exceptions, *e.g.*, for original patient records, § 299b-21(7)(B). Judges are quite capable of enforcing these limits. For example, in *Department of Financial & Professional Regulation* v. *Walgreen Co.*, the appellate court carefully considered pharmacy affidavits to determine whether the incident reports at issue were protected. 970 N.E.2d 552, 557–58 (Ill. App. Ct. 2012). Those affidavits explained that the reports were (as here) created through a patient safety system and submitted to a PSO. They also established that no other incident reports were created, and no reports were "collected or maintained separately from" the patient safety system. *Id.* at 558. Based on this showing, the court applied the statutory standard, see *id.* at 557, and held the reports privileged.

*Walgreen* illustrates the straightforward role that courts properly play in policing any abuse of the privilege (though Respondents identify no such abuse). A provider who inappropriately included original patient records in the patient safety system, or who never included a document in the system at all, would not be entitled to claim the privilege. And a court could surely require a privilege log or some other means of establishing these threshold facts. Contrary to Respondents' claims, resort to the *ad hoc* approach below is not necessary to avoid unreviewable provider control of the privilege.

## III. THIS CASE PRESENTS AN EXCELLENT VEHICLE FOR THIS COURT'S REVIEW.

Respondents' tepid arguments against review are unconvincing. They contend that the question is answered directly by statutory text and legislative history. But given the chasm between the rule announced below and that articulated by the dissent and other courts, resolution must come from this Court.

Respondents also assert that this case "hardly deals with a sweeping national privilege," because "it involves a single incident report." Opp'n 2; *id.* at 17. Petitioners emphatically agree that the case concerns one incident report, of the sort plainly contemplated by the Act, in the context of a distinct appellate proceeding. The Kentucky Supreme Court's decision, moreover, is ripe for this Court's review and tailored to the question presented—on which the opinion and dissent thoroughly present the opposing viewpoints. The record is uncluttered by extraneous factual issues. And the extensive amicus participation augurs well for robust presentation at the merits stage. Given the paucity of pertinent appellate proceedings appropriate for this Court's review, relative to the fre-

quent trial-court application of this "sweeping national privilege," this petition presents a valuable opportunity to resolve an important question of federal law on which courts and litigants are divided and confused.

## CONCLUSION

For the foregoing reasons, the Court should grant the petition or, at a minimum, invite the Solicitor General to provide the views of the United States.

Respectfully submitted,

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