PSQIA Prompts Federal Courts to Reconsider a Federal Common Law Peer Review Privilege

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Health care entities and other organizations conducting medical peer review have, for years, faced uncertainty regarding whether documents created in the course of medical peer review will be discoverable in litigation. While all 50 states have enacted medical peer review statutes, which grant varying degrees of protection to documents used by peer review committees, courts often have narrowly interpreted the privileges created by such statutes. Furthermore, despite state peer review privileges, hospitals and other health care organizations often have been left without any protection at all for peer review documents when sued in federal courts due to the absence of a federal peer review statute or recognized federal common law privilege for peer review documents. Despite the unpromising federal terrain, in recent years hospitals and health care systems pressing for the recognition of a federal common law privilege have found more success. This article discusses the changing responses of some courts to such arguments, particularly in light of the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA).

Background

Generally, federal privileges, rather than state law privileges, apply in federal court to claims that arise under federal law, as well as to state law claims that are subject to supplemental federal jurisdiction.

Unlike state authorities, federal authorities have not historically provided support for a medical peer review privilege. The Supreme Court has never addressed whether a federal common law privilege exists for medical peer review, and in a somewhat analogous setting, rejected a peer review privilege that would have applied to tenure evaluations.[1] No blanket peer review privilege has ever been created by federal statute. The Health Care Quality and Improvement Act of 1986[2] (HCQIA) provides qualified immunity from suit for certain participants in medical peer review proceedings, and confidentiality for certain reports required by the law to the National Practitioner Data Bank, but no broader privilege for peer review materials. Additionally, the PSQIA, which created a framework for health care organizations to voluntarily share data regarding adverse events and to encourage the sharing of such data, grants broad confidentiality and privilege protections to "patient safety work product."[3] Importantly, however, "patient safety work product" is a defined statutory term that is predicated on the creation of a "patient safety evaluation system" (PSES) and engagement with and reporting to a "patient safety organization" (PSO).[4] Importantly, many documents created for purposes of hospital peer review are not created within a hospital PSES nor reported to a PSO, and therefore do not technically qualify for the statutory privilege under the PSQIA.

Rule 501 and Creating New Federal Common Law Privileges

Despite the absence of a federal statute or U.S. Supreme Court opinion recognizing the existence of a federal privilege, the Federal Rules of Evidence provide district courts with the "flexibility to develop rules of privilege on a case by case basis."[5] Rule 501 authorizes federal courts to define new privileges by interpreting "common law principles . . . in the light of reason and experience."[6]

In *Jaffe v. Redmond*, the most recent Supreme Court case to set forth a Rule 501 analysis, the Supreme Court acknowledged the traditional rule disfavoring testimonial privileges, but found that a proposed privilege can be justified when it "promotes sufficiently important interests to outweigh the need for probative evidence."[7] As the Court set out in its 1996 opinion, when considering whether to create a new federal common law privilege, district courts must evaluate: (1) whether the asserted privilege serves private and public interest; (2) the evidentiary benefit that would result from denial of the privilege; and (3) recognition of the privilege among the states.[8]

Federal Courts Traditionally Oppose Creation of Federal Peer Review Privilege

For many years, despite advocacy by the medical industry, district courts declined to recognize a federal common law privilege for medical peer review. Courts rejecting the privilege typically did so in cases involving employment discrimination or other civil rights claims, or antitrust claims, finding the medical industry's interest in medical peer review was not sufficient to override the federal policies implicated in such causes of action.[9] Following the lead of these cases, a number of district courts also declined to recognize a federal common law peer review privilege even in cases that did not present compelling federal public policy interests, such as Federal Tort Claims Act (FTCA) cases.[10] Critical to the reasoning of these cases was the analysis in *University of Pennsylvania v. E.E.O.C.*, where the Supreme Court noted that if Congress had the opportunity to create a privilege pursuant to statute, yet failed to do so, courts should be especially hesitant in recognizing a federal privilege.[11] Courts were persuaded that by enacting HCQIA, which provided qualified immunity for certain peer review participants but not a blanket privilege for peer review documents, Congress expressed a disinterest in a federal peer review privilege.

PSQIA Changes Federal Courts' Analysis of the Peer Review Privilege

The PSQIA's enactment has caused some federal courts to revisit the question of a federal common law peer review privilege. In one of the first opinions to turn the tide, the U.S. District Court for the District of Delaware recognized a federal common law peer review privilege in a FTCA case involving a child who was

enrolled in a National Institutes of Health (NIH) study evaluating whether implanting pacemakers in children with hypertrophic cardiomyopathy would improve their outcomes.[12] Plaintiff alleged the study worsened his condition. He sought documents related to the ongoing monitoring of the NIH research protocol in which he participated, while the United States asserted that the documents were privileged under the Maryland medical peer review statute, the federal self-critical analysis privilege, and federal common law.

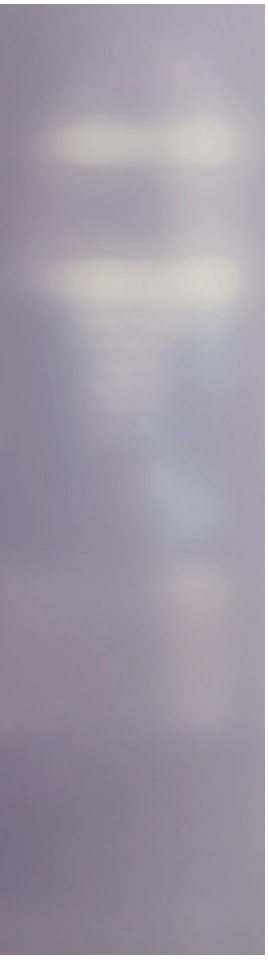
In concluding that a federal common law peer review applied, the court in *K.D. v. United States* held that the public and private interests at issue favored recognition of the privilege. In its analysis, the court emphasized that HCQIA was no longer the last word on the issue of medical peer review. Rather, the court reasoned that the PSQIA announced a more general approval of the medical peer review process, and more sweeping evidentiary protections for materials used therein. The court noted that the PSQIA "tackled the larger problem of systemic weaknesses in the delivery of health care"[13] and reflected Congress' intent to promote "a learning environment that is needed to move beyond the exiting culture of blame and punishment . . . to a 'culture of safety.'"[14] The PSQIA was designed to encourage this "culture of safety" by providing broad confidentiality and legal protections for information collected and reported voluntarily for the purposes of improving quality and patient safety. Importantly, the court emphasized that the PSQIA articulated an important federal policy that compelled recognition of the privilege—even though the factual predicates for application of the statutory PSQIA privilege did not apply under the facts of the case.[15]

The *K.D.* court also determined that, under the particular facts of the case, no other federal policy would be offended by protecting confidential and evaluative NIH review materials from disclosure. The underlying FTCA claims did not implicate the strong federal policy of rooting out invidious discrimination or enforcing antitrust laws. Moreover, the plaintiff's ability to build his case without the NIH review body materials would not be significantly impeded, since the plaintiff could obtain his own expert to evaluate the adequacy and safety of the NIH research protocol, rather than relying on NIH's own documents evaluating the issue.[16]

Following *K.D.*, a number of district courts have recognized a federal peer review privilege, on similar grounds.[17] These opinions have tended to emphasize that each of the 50 states have approved of a medical peer review privilege; that the PSQIA expressed a new federal policy in favor of broad protection for patient safety and quality review documents; and that a plaintiff's need to obtain peer review materials is diminished in cases in which the care provided is at issue (for example, in FTCA and Emergency

Medical Treatment and Labor Act (EMTALA) cases), rather than when the review process itself is contested (i.e., in antitrust and civil rights cases).

While these cases represent a trend, this new approach toward a federal peer review privilege is by no means universal. Courts continue to refuse to recognize a federal peer review privilege in cases involving civil rights and antitrust claims.[18] Moreover, while federal courts appear to be showing a greater receptivity to a federal peer review privilege when the underlying claims implicate FTCA or EMTALA, prospects for recognition of the privilege in medical malpractice cases against non-governmental entities that land in federal court seem less clear. Federal courts have applied federal privilege law to state malpractice claims that are pendent to federal claims being asserted in federal court.[19] In this context, if a federal common law peer review privilege were to firmly take hold, it could provide a platform for arguing to a federal district court in a jurisdiction where the state law peer review privilege is relatively weak—such as Kentucky or Florida—that peer review documents will nevertheless be protected under federal common law given the strong policy underpinnings that undergird the privilege, as recognized by Congress in the PSQIA and the federal courts. In contrast, federal courts follow state peer review privilege laws in diversity jurisdiction cases.[20] In the diversity jurisdiction context, while the state peer review privilege may provide the protection that is needed for peer review documents, if the state privilege is weak, defendants likely will be unable to seek protection from a federal common law peer review privilege.



Future of the Trend

The limited number of district court decisions recognizing a federal common law peer review privilege to date may not yet provide reliable comfort for hospitals and other health care organizations concerned about the confidentiality of their peer review materials. The recognition of the privilege is not widespread enough to create any certainty for organizations and may still take years to work its way up to the Supreme Court for definitive guidance.

Nevertheless, many of the same factors that compelled the Supreme Court to recognize a psychotherapist-patient privilege in *Jaffee*—uniform recognition of the privilege among the states, implication of significant private and public interests, and a minimal loss of evidentiary benefit—appear to be present as well in the context of medical peer review. Furthermore, to the extent that previous district courts have found that medical peer reviews "do not enjoy the historical or statutory support upon which other privileges have been recognized in federal law,"[21] the increased public attention on the quality of health care in the United States and the PSQIA may have finally tipped the scales in favor of recognizing the important public function served by peer review privilege.

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1 *See University of Pa. v. E.E.O.C.,* 493 U.S. 182, 189 (1990).

2 42 U.S.C. § 11101 *et seq.*

3 42 U.S.C. § 299b-22(a) (providing that, subject to certain exceptions, "patient safety work product shall be privileged and shall not be . . . subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding"). "Patient safety work product" means "any data, reports, records memoranda, analysis (such as root cause analysis), or written or oral statements (i) which (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." 422 U.S.C. § 299b-21(7)(A).

4 A "patient safety evaluation system" is "the collection, management, or analysis of information for reporting to or by a PSO." 42 C.F.R. § 3.20 (Definitions). PSOs include all organizations that collect and analyze patient safety work product and provide feedback to providers on strategies to improve patient safety and quality of care, and that have been listed by the Department of Health and Human Services as such. *K.D. v. United States,* 715 F. Supp. 2d 587, 596 (D. Del. 2010) (citing S. Rep. No. 108-196, at *5 (2003)).

5 *Trammel v. United States,* 445 U.S. 40, 47 (1980) (citing 120 Cong. Rec. 40891 (1974)).

6 *Id.* (citing Fed. R. Evid. 501).

7 *Jaffee v. Redmond,* 518 U.S. 1, 9-10 (1996).

8 *Jaffee,* 518 U.S. at 10-12.

9 *See, e.g., Adkins v. Christie,* 488 F.3d 1324, 1330 (11th Cir. 2007) (involving racial discrimination); *Virmani v. Novant Health, Inc.*, 259 F.3d 284, 289 (4th Cir. 2001) (concerning racial discrimination action); *Memorial Hops. v. Shadur*, 664 F.2d 1058, 1063 (7th Cir. 1981) (involving an antitrust action); *Johnson v. Nyack Hosp.* 169 F.R.D. 550, 561 (S.D.N.Y. 1996) (involving a racial discrimination action).

10 *See Tucker v. United States,* 143 F. Supp. 2d 619, 626 (S.D.W. Va. 2001) (involving negligence of a physician employed at a hospital that was covered by the FTCA); *Syposs v. United States*, 179 F.R.D. 406, 411 (W.D.N.Y. 1998) (reviewing negligence of a physician at a veterans' medical center).

11 *Tucker,* 143 F. Supp. 3d at 627; *Syposs,* 179 F.R.D. at 411.

12 *K.D. v. United States,* 715 F. Supp. 2d 587 (D. Del. 2010).

13 *Id.* at 595.

14 *Id.* (quoting S. Rep. No. 108-196, at *2 (2003)).

15 *Id.*. at 596.

16 *Id.* at 597.

17 *See, e.g., Grenier v. Stamford Hosp. Stamford Health Sys., Inc.,* No. 3:14-cv-0970, 2016 U.S. Dist. LEXIS 94424 (D. Conn. July 20, 2016); *Tep v. Southcoast Hosps. Grp., Inc.*, No. 13-1187-LTS, 2014 U.S. Dist. LEXIS 168052 (D. Mass. Dec. 4, 2014); *Sevilla v. United States*, 852 F. Supp. 2d 1057 (N.D. Ill. 2012); *Francis v. United States*, No. 09-4404, 2011 U.S. Dist. LEXIS 59762 (S.D.N.Y. May 31, 2011).

18 *See, e.g. Morshed v. St. Barnabas Hosp.,* 2017 U.S. Dist. LEXIS 19610 (Feb. 10, 2017).

19 *See, e.g., Grenier v. Stamford Hosp. Stamford Health Sys.,* Inc., 2016 U.S. Dist. LEXIS 94424 (D. Conn. July 20, 2016) (recognizing a federal common law peer review privilege, and applying it to plaintiff's federal EMTALA claim and pendent state medical malpractice claim).

20 *See* Fed. R. Evid. 501 ("[I]n a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision"); *Cleveland Clinic Health Sys.—E. Region v. Innovative Placements, Inc.,* 283 F.R.D. 362, 365-66 (N.D. Ohio 2012) (applying the Ohio peer review privilege to malpractice claims in a diversity jurisdiction case); *Hill v. Sandhu,* 129 F.R.D. 548 (D. Kan. 1990) (applying the Kansas peer review privilege in a malpractice case in federal court through diversity jurisdiction).

21 *Syposs,* 179 F.R.D. at 411.

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