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THE PSQIA IN THE TRIAL COURTS

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Three Recent Successful Defenses of the PSQIA in the Trial Courts

- *Gooden v. CVS Caremark Corp., et al.*, C.A. No. 11-CV-08-10885 (Franklin County, Ohio, November 20, 2012)
- *Csaba Horvath v. IASIS Healthcare Holdings, Inc., et al.*, Case No. 12-CA-005132, (13th Judicial District, Hillsborough, Florida, October 17, 2012)
- *Carrie Marable v. CVS Pharmacy, et al.*, No. 2011-2723-4 (McLennan County, Texas, February 7, 2012)



Trial Court vs Appellate Court

- Both Federal and State Court Systems Include a Trial Court and Appellate Court
 - Federal Article III courts include (1) the U.S. District Courts, (2) the U.S. Circuit Courts of Appeal, and (3) the U.S. Supreme Court
 - 13 Courts of Appeal, 94 District Courts
 - Court of Appeals usually sits in panels of 3 justices but more significant cases get full 9 justice hearing
 - Each District Court has between 2 and 28 judges hearing cases individually
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Trial Court vs Appellate Court (cont.)

- State court systems vary but generally made up of:
 - (1) two sets of trial courts: (a) trial courts of limited jurisdiction (probate, family, traffic, etc.) and (b) main trial-level courts of general jurisdiction;
 - (2) intermediate appellate courts (in most states); and
 - (3) the highest state courts.
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Precedential Value of Federal Cases

- United States Supreme Court decisions are binding authority in all courts, federal and state, when addressing points of federal law
- United States court of appeals decisions are mandatory on district courts within its circuit and are persuasive authority for other courts of appeals and for lower courts. Federal courts of appeals decisions are not binding on state courts
- United States district court decisions are not binding on other district courts or state courts



Precedential Value of State Court Decisions

- State supreme court decisions are binding authority for all lower courts in that state on that state's laws. State supreme court decisions are also binding on federal courts that are interpreting the state's law under diversity jurisdiction.
- State appellate court decisions are mandatory on all lower courts in the state unless the appellate courts are divided into circuits or panels. In this instance, decisions of an individual circuit or panel are generally binding within the jurisdiction of that circuit or panel and persuasive authority in the other circuits or panel.
- State trial-level decisions are not binding and may only be persuasive authority.



Gooden v. CVS Caremark Corporation

FACTS

- In December 2010, plaintiff was dispensed metoprolol succinate rather than metoprolol tartrate. Plaintiff claimed to have called the pharmacy two weeks later and reported the error to pharmacy staff. The error was corrected. The patient profile was also corrected to prevent any future occurrence of the error.
- The pharmacist created an incident report on January 31, 2011, which was the day, or the day after, the pharmacy learned of the error. The defendant's PSO had immediate access to the report through functional reporting.
- Plaintiff filed suit and moved to compel the incident report to which Defendant objected because it constituted patient safety work product.



Plaintiff's Arguments

Plaintiff made two arguments to compel the incident report:

1. The PSQIA privilege protections no longer applied because the defendant admitted negligence in the case and the legislative history of the Act indicated that "the purpose of the act was to provide healthcare providers with confidence that they may collect patient safety information without concern that such information will give rise to malpractice liability."
 2. The defendant did not provide a privilege log identifying the incident report, describing it generally and asserting the privilege.
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Defendant's Response

1. Through the Affidavit of Director of Quality Assurance & Patient Safety, defendant established factual predicate to show that incident report was privileged patient safety work product.
 2. Defendant argued that the importance of patient safety work product transcended a single case and nothing in the PSQIA limited application of the privilege only to those matters where errors didn't occur. The plaintiff's interpretation would lead to an absurd result – offering protection only where no error occurred.
 3. Regarding the lack of a privilege log, defendant argued that it was form over substance. Defendant had identified the incident report in its original discovery responses and asserted the privilege. When plaintiff claimed lack of a privilege log, defendant provided one.
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Ohio Affidavit

Affidavit of

I, _____, of full age, being duly sworn according to law, upon oath deposes and says:

1. My current position with "Company" is Director for Quality Assurance and Patient Safety and I have held this position since _____.
2. Part of my job duties include collecting, maintaining, analyzing and transferring to [PSO], a federally-listed Patient Safety Organization ("PSO"), incident reports prepared and collected by "Company" to transfer to PSO.
3. On June 1, 2010, "Company" entered into a contract with PSO to provide patient safety services to "Company", including, but not limited to, the examination and analysis of incident reports. It has provided these patient safety services to "Company" continuously since that date.



Ohio Affidavit (cont.)

4. Whenever any employee is notified of an alleged error, the discovering staff is required by "Company" policy to prepare an electronic incident report. The report includes the store number, the name of the supervisor, the reporting staff, the verifying staff, the type of error which occurred, a description of the reason why the error occurred, patient information, label information, prescription information, action taken by the staff, and prescriber information, including when the prescriber was notified.
 5. Once the incident report is completed by staff, the PSO is provided immediate access to it. This is described as the "functional reporting" method permitted under federal regulations.
 6. At the time of completion, each incident report is electronically marked "Confidential-Patient Safety Work Product / PSES (date)."
The incident report database is part of "Company's" PSES. Under the applicable federal regulations, a "patient safety evaluation system" is simply the method by and through which providers, such as "Company" and PSOs, communicate.
 7. The incident report in this case was created on January 31, 2011. This report has been functionally reported to the PSO and is marked "Confidential-Patient Safety Work Product / PSES (date: 1-31-2011)."
[Company] maintains that this report is, therefore, privileged.
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Ruling

- Privilege log was not so untimely to warrant harsh sanction of waiver.
 - Irrational to construe the PSQIA as not protecting patient safety work product when liability is clear because requiring disclosure could affect damages award and would discourage reporting.
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Lessons Learned

1. Importance of a thorough affidavit explaining:
 - a. The Affiant's duties;
 - b. Provider / PSO relationship;
 - c. The general contents of an incident report;
 - d. General description of PSES, including method of transfer, marking of PSWP and contents of PSES;
 - e. That the report was, in fact, transferred.
 2. Court will uphold the "functional reporting" method of reporting.
 3. Need to be prepared for novel arguments.
 4. Importance of an initial objection through privilege log or otherwise.
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CSABA Horvath v. IASIS Healthcare Holdings, Inc.

FACTS

- The case was a medical malpractice action brought against a hospital, emergency room physicians and their practice. Plaintiff sought records of an incident report “related to adverse medical incidents occurring in the care and treatment of [decedent]” pursuant to Amendment 7 of the Florida Constitution which essentially opened to discovery peer review records of certain health care entities.
- Defendant identified a single incident report relating to the decedent but asserted that it was patient safety work product immune from discovery.



Legal Issues

1. Is the report "Patient Safety Work Product"?
 2. Is the report subject to Amendment 7?
 3. If the report is patient safety work product and subject to Amendment 7, does the PSQIA preempt or supersede Amendment 7?
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The Incident Report is PSWP

1. The Incident Report is Patient Safety Work Product
 - “Based on this definition [of PSWP], the Report is PSWP if it is collected as part of a patient safety evaluation system (PSES). Data, reports, records, memoranda, analyses, and statements are part of a PSES if they are collected, maintained, and analyzed “for reporting to or by a patient safety organization.”
 - The Court concludes that the incident report is PSWP, citing *Department of Financial & Professional Regulation v. Walgreen Co.*, 970 N.E.2d 552, 558 (Ill.App.Ct.2d Dist. 2012).
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Incident Report Falls Within the Parameters of Amendment 7

- Amendment 7 of the Florida Constitution provides that “patients have a right to have access to any records made or received in the course of business by a healthcare facility or provider relating to any adverse medical incident.” Art. X § 25(a), Fla. Const.
- Such records include records of “incidents that are reported to or reviewed by any healthcare facility peer review, risk management, quality assurance, credentials or similar committee, or any representative of any committees.”
- The Court found that the individual reports were subject to Amendment 7 and therefore discoverable, setting up the question of federal preemption through the PSQIA.



Preemption

Two Types

1. Express: The federal statute, by its terms, supersedes state law.
PSQIA: “Notwithstanding any other provision of federal, state or local law ...” patient safety work product is privileged and immune from discovery.

 2. Implied: Impossible to comply with both federal and state law.
 - a. The report is subject to Amendment 7 making it discoverable in litigation.
 - b. The report constitutes Patient Safety Work Product under the PSQIA making it immune from discovery.
 - c. Because the federal and state act are in direct opposition to one another, contravening the Congressional purpose, the state constitutional provision stands preempted.
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Lessons Learned

- Trial courts are increasingly recognizing the privilege.
 - The central importance of establishing a well-constructed Patient Safety Evaluation System.
 - The PSQIA preempts even state constitutional provisions.
 - But see, page 5, footnote 3 to opinion, where the court offers plaintiffs a glimmer of hope.
 - The defendant may have failed to meet its state statutory obligation to maintain an internal risk management program record that might be discoverable (i.e., PSQIA does not trump independent state reporting requirements – parallel systems).
 - “The Court also notes that the Defendant may be required under PSQIA to remove information from a PSES to comply with State reporting requirements.” (Incorrect)
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Marable v. CVS Pharmacy, et al.

FACTS

- Lawsuit brought for damages attributable to an alleged misfill. The incident report relating to the plaintiff was created in January 2010. The defendant had entered into a contract with a Patient Safety Organization on June 1, 2010.
- Defendant produced the incident report relating to this particular incident. Plaintiff sought incident reports of other alleged misfills made after June 1, 2010, to which the defendant objected.



Affidavit of

I, _____, of full age, being duly sworn according to law, upon oath deposes and says:

1. I am currently employed as [the Company's] Manager for Quality Assurance and Patient Safety and have been employed since April 2010.
 2. Part of my job duties including collecting, maintaining, analyzing and transferring to [PSO], a federally listed patient safety organization ("PSO"), incident reports prepared and collected by [Company] to transfer to [PSO].
 3. On June 1, 2010, [Company] entered into a contract with [PSO] to provide patient safety services to [Company], including but not limited to, the examination and analysis of incident reports. It has provided these patient safety services to [Company] continuously since that date.
 4. Whenever any pharmacist or other [Company] employee is notified of an alleged pharmacy error, the discovering pharmacist is required by CVS policy to prepare an electronic incident report. The report includes the store number, the name of the pharmacy supervisor, the reporting pharmacist, the verifying pharmacist, the type of error which occurred, a description of the reason why the error occurred, patient information, label information, prescription information, action taken by the pharmacist, and prescriber information, including when the prescriber was notified.
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Affidavit of (cont.)

5. Once the incident report is completed by the pharmacist, the PSO is provided immediate access to it. This is described as the “functional reporting” method permitted under federal regulations.
 6. At the time of completion, each incident report is electronically marked “Privileged and Confidential-Patient Safety Work Product under federal law PSES (date).” The incident report database is part of [Company’s] patient safety evaluation system. Under the applicable federal regulations, a “patient safety evaluation system” is simply the method by and through which providers, such as [Company] and PSOs, communicate.
 7. The incident report in this case was created in January 2010, six months prior to contracting with [PSO]. Accordingly, it was produced in this litigation.
 8. [Company] has a two-year document retention policy. Incident reports are purged on a daily basis going back every two years. The vast majority of incident reports, as requested by Plaintiffs, are no longer available.
 9. There are four incident reports, including the incident report previously produced in response to Plaintiffs’ requests for production, which are responsive to Plaintiffs’ requests. These reports were created on January 13, 2010 (produced), December 14, 2010, May 17, 2011 and May 27, 2011. These have been functionally reported to [PSO] and are each marked “Privileged and Confidential-Patient Safety Work Product under federal law PSES (date).” The [Company] maintains that these reports are, therefore, privileged.
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Plaintiff's Argument

1. Not privileged as similar documents were produced.
 2. No privilege log offered (although objections were set forth in letter from counsel).
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Ruling and Lessons Learned

- Judge overruled Plaintiff's objections from the bench.
 1. Another court recognizes the "functional reporting" method of reporting.
 2. Importance of thorough affidavit.
 3. Value in conservative approach.
 - Defendant recognized that it is possible to claim the PSQIA privilege back to the date of the passage of PSQIA, and certainly a strong argument could be made to protect documents back to the date when the defendant began creating its PSES, but the date of the contract with the PSO was definite.
 4. Importance of creating a privilege log.
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Protecting Privileged Documents

- The “universally accepted means” for claiming that requested documents are privileged is raising a valid objection thereto and producing a privilege log. *In re Grand Jury Subpoena*, 274 F.3d 563, 576 (1st Cir. 2001).
- A privilege log should identify each document, the date each document was created, the identity of the author and recipient, and provide a sufficiently detailed description of the documents, including the precise reasons given for the particular objection to discovery, to permit a judgment as to whether the document is at least potentially protected from disclosure. *United States v. Constr. Prods. Research, Inc.*, 73 F.3d 464, 473 (2d Cir. 1996).
- Failure by a party claiming a privilege to adequately describe the documents at issue, to sufficiently explain the basis for the privilege, or to assert the privilege in a timely manner may be grounds for rejecting the privilege claimed or a “waiver” of the claimed privilege. *Dorf & Stanton Communications, Inc. v. Molson Breweries*, 100 F.3d 919, 923 (Fed. Cir. 1996).



Protecting PSWP as a Nonparty

- A nonparty may receive a document subpoena pursuant to Federal Rule of Civil Procedure 45(c) or state equivalent.
- Must serve written objection, usually within 14 days of receipt, or risk waiver of privilege.
- Prepare and serve a privilege log with written objections. *But see Minnesota Sch. Bds. Ass'n. Ins. Trust v. Employers Ins. Co.*, 183 F.R.D. 627, 630 (N.D. Ill. 1999) ("Courts interpreting Rule 45(d)(2) have held that a party claiming privilege may provide a privilege log within a 'reasonable time' as long as objections are asserted within the fourteen-day time frame.").



Protecting PSWP as a Nonparty (cont.)

- Rules generally require parties to confer and exhaust efforts to resolve their discovery dispute before commencing motion practice.
 - If unable to resolve, objecting party must file motion to quash the subpoena or motion for a protective order.
 - The burden of proof on a motion to quash is borne by the recipient of the subpoena.
 - The issuing court must quash or modify a subpoena that requires disclosure of privileged material.
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Questions

