

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION	04-MD-1596 (JBW)
STATE OF LOUISIANA, ex rel. CHARLES C. FOTI, JR., Attorney General Plaintiff -against- ELI LILLY & COMPANY, Defendant	05-CV-1549 (JBW) 05-CV-1455 (JBW)
JIM HOOD, ATTORNEY GENERAL OF THE STATE OF MISSISSIPPI, ex rel. THE STATE OF MISSISSIPPI, Plaintiff -against- ELI LILLY & COMPANY, Defendant	07-CV-645 (JBW)
STATE OF MONTANA, ex rel. MIKE MCGRATH, Attorney General, Plaintiff -against- ELI LILLY & COMPANY, Defendant	07-CV-1933 (JBW)
STATE OF NEW MEXICO, ex rel. PATRICIA MADRID, Attorney General, Plaintiff -against- ELI LILLY & COMPANY, Defendant	07-cv-1749 (JBW)

**CERTAIN STATES' FURTHER OBJECTION TO MAGISTRATE'S ORDER
REGARDING PRODUCTION OF MEDICAL RECORDS IN VIOLATION OF
APPLICABLE STATE PRIVILEGES AND LAWS**

The States' Attorneys General in the above-captioned cases (the "States") join in the objections filed by the State of Connecticut, on behalf of the litigating States, on September 29, 2008 in response to the to the Honorable Magistrate Roanne L. Mann's Order of September 24, 2008 (the "Order"), and hereby further object to that Order on the basis of its incorrect interpretation of applicable States' laws governing the confidentiality of medical records. The crux of the States' position is this: (1) Federal Rule of Evidence 501 mandates application of state privilege laws; and (ii) the more stringent State protections governing even redacted records trump the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which by the Order's own analysis affords *no protections* to records redacted in compliance with HIPAA. Therefore, the Order is clearly erroneous and contrary to law because it ignores the State law privilege protections applicable to the medical records Lilly seeks. Finally, certain States' laws with respect to the handling of records in the custody of the Medicaid agency prevent, or severely limit, their disclosure outside the Medicaid agency. For those additional reasons, the Order of September 24, 2008 should be reversed.

I.

ARGUMENT AND AUTHORITIES

A. There Can Be No Doubt That The States' Privilege Laws Apply Under Fed. R. Evid. 501.

The Order erroneously questions whether the States' privilege laws apply to these matters pending in federal court. (Order at 6-7.) Such inquiry, however, ignores the plain language of Federal Rule of Evidence 501.

While this Court determined its jurisdiction over the States' claims founded in state law based upon the Supreme Court's decision in *Grable*, that jurisdictional assessment contemplates

an entirely different inquiry than whether state privilege laws apply under Rule 501. Indeed, Rule 501 could hardly be more explicit: where “*State law supplies the rule of decision*, the privilege of a witness, person, government, State, or political subdivision thereof *shall be determined in accordance with State law.*” Fed. R. Evid. 501 (emphasis added). Thus, notwithstanding the Court’s determination that issues relative to federal Medicaid funding provisions support *Grable* federal jurisdiction over the States’ claims brought under state law, there can be no mistake that state law will supply the “rule of decision” as to the State’s claims, and therefore State privileges obtain. While there may be a “paucity of case law on the issue” (Order at 6), there is no case supporting a reading of Rule 501 that is contrary to the plain meaning of the rule itself, regardless of the Court’s federal jurisdiction under *Grable*. Therefore, the States’ various privilege laws shielding medical records from unauthorized disclosure are entitled due consideration. See *N.W. Mem’l Hosp. v. Ashcroft*, 362 F.3d 923, 925 (7th Cir. 2004) (Posner, J.) (“[States] [are] free to enforce [their] more stringent medical-records privilege . . . in suits in state court to enforce state law and, by virtue of an express provision in Fed. R. Evid. 501, in suits in federal court (mainly diversity suits) as well in which state law supplies the rule of decision.”), *cited in* the Court’s Order of September 24, 2008.

B. Redaction Of The Medical Records Does Not Overcome State-Law Protections.

The Magistrate Judge ruled that redaction of medical records obviates adherence to State privileges and concomitant statutory requirements for disclosure. For the reasons that follow, that decision is clear error with respect to the below-mentioned States.

1. *Louisiana*

Far from “ha[ving] made clear that de-identified medical records are not privileged under Louisiana law,” as the Order proclaims (at 11 n.7), the Louisiana Supreme Court has consistently refused to issue any such broad pronouncement as that adopted by Magistrate Mann. Indeed,

neither the *Rezulin* opinion's *predictions* regarding *Texas* law, nor the Louisiana Supreme Court's per curiam opinions in *Speer v. Whitecloud* and *Jackson v. Baptist Retirement Center*, cited in the Order, provide a workable, legal framework for the Louisiana medical records Lilly seeks. That is because Louisiana law mandates an exclusive procedure for the discovery of medical records to overcome the patient-physician privilege that does not comport with mere redaction of personal information from the records.

As the State of Louisiana has repeatedly shown the Court, Louisiana law shields from disclosure non-party medical records unless one of two prerequisites are met: (1) the patient consents to disclosure, or (2) the court issues an order for the production of the records "***only: after a contradictory hearing with the patient . . . and after a finding by the court that the release of the requested information is proper . . .***" LSA-R.S. § 13:3715.1 (2008) (emphasis added).¹ In no uncertain terms, the Louisiana Supreme Court has interpreted the "plain language" of Revised Statute 13:3715.1(B)(5) as "clearly contemplat[ing] that in instances when

¹ Louisiana Revised Statute 13:3715.1 states:

B. The ***exclusive method*** by which medical, hospital, or other records relating to a person's medical treatment, history, or condition may be obtained or disclosed by a health care provider, shall be pursuant to and in accordance with the provisions of R.S. 40:1299.96 or Code of Evidence Article 510[patient-physician privilege], or a lawful subpoena or court order obtained in the following manner:

* * *

(2) Any attorney requesting medical records of a patient, who is not a party to the litigation in which the records are being sought[,], may obtain the records by written authorization of the patient whose records are being sought or if not such authorization is given, by court order, as provided in paragraph (5) hereof.

* * *

(5) A court shall issue an order for the production and disclosure of a patient's records, regardless of whether the patient is a party to the litigation, ***only: after a contradictory hearing with the patient***, or, if represented, with his counsel of record, or, if deceased, with those persons identified in Paragraph (3) hereof, and ***after a finding by the court that the release of the requested information is proper***; or with consent of the patient.

La. Rev. Code 13:3715.1 (2006) (emphasis added).

a non-party's medical records are being sought and the non-party . . . has not authorized the release of the medical records, there is to be a contradictory hearing and a finding by the . . . court that the release of the requested medical information is 'proper.'" *Moss v. State*, 925 So.2d 1185, 1197 (La. 2006). Any such hearing "must be resolved on [its] own facts." *Moss*, 925 So.2d at 1201. The party requesting the records bears the burden and can only prevail if there is a "substantial showing of relevance and need . . ." *Id.* Judge Mann's Order disregards the only permissible means to circumvent the Louisiana patient-physician privilege, and wrongly places the burden on the State to disprove relevance and need.

The Louisiana Supreme Court's per curiam *Speer v. Whitecloud* opinion—decided nearly seven years before *Moss*—lends only illusory support to the Court's Order. *See Speer*, 744 So.2d 1283 (La. 1999) (per curiam). *Speer* was a medical malpractice lawsuit by a lone plaintiff arising from the implanting of a pedicle screw device into the plaintiff's spine. *Id.* At issue were plaintiff's *interrogatories* to the defendant doctor "requesting names of the manufacturers and the model numbers" of pedicle screws used in a 1994 study published by the defendant doctor. *Id.* at 1283. The defendant refused to answer the interrogatories, citing plaintiff's failure to comply with LSA-R.S. § 13:3715.1. *Id.* at 1284. Significantly, the plaintiff specifically limited his discovery requests to "solely . . . the devices used in the study, *not the identity of the patients.*" *Id.* (emphasis added). The trial court ordered that the defendant respond to the interrogatories. *Id.* at 1284. Reversing the court of appeal, which had opined that the plaintiff must first comply with section 13:3715.1, the Louisiana Supreme Court held:

Under the unique circumstances of this case, we find the court of appeal erred in requiring plaintiff to follow the procedures set forth in La. R.S. 13:3715.1 in order to obtain the requested discovery. It is undisputed that the plaintiff does not seek any personal, identifying information regarding the patients in the study;

rather, he simply seeks to learn the model numbers and manufacturers of the pedicle screws in the study.

Id. at 1284 (emphasis added). The supreme court ordered the defendant doctor “to comply with the requested discovery” by supplying the requested model numbers and manufacturers in response to the plaintiff’s interrogatories. *See id.* at 1283-84. No medical records were required to be produced. *Id.*

While the per curiam opinion in *Speer* also broadly stated that “[o]nce any personal information which would identify the patients is redacted from these records, the requested discovery does not invade the physician-patient privilege, and the need for protections set forth in La. R.S. 13:3715.1 is eliminated,” that pronouncement was expressly made “[u]nder the unique circumstances of [the] case.” 744 So.2d at 1284.²

That express limitation by the Louisiana Supreme Court is also unsurprising in light of its refusal to hear appeals in the parallel case of *Foti, ex rel. Louisiana v. Janssen Pharmaceutica, Inc.* as well as in *Davis v. American Home Products Corp.* *See Janssen*, No. 2008-CC-1105, slip. op. at 1 (La. Sept. 19, 2008) (a true and correct copy of which is attached hereto as Exhibit

² Additionally, the statement is purely *obiter dictum* because it is unnecessary to the decision in the case and of no precedential value; as noted above, *Speer* necessitated no production of medical records at all. *Id.* at 1283-84. The Louisiana Supreme Court’s extensive analysis of R.S. 13:3715.1 in *Moss* over six years later makes no mention of *Speer* or states that redaction overcomes the necessity of complying with R.S. 13:3715.1 when non-party medical records are requested in discovery. *See n. 7, infra.*

Furthermore, absolutely no support may be garnered from the *Jackson* decision, on which the Order additionally relies in support of the position that redaction of personally identifying information overcomes LSA-R.S. § 13:3715.1. (Order at 11& n.7 (citing *Jackson*, 933 So.2d 131, 131 (La. 2006).) The *Jackson* opinion consists of three sentences, from which not even the nature or scope of the requested discovery, or whether patient medical records were sought at all, is determinable—indeed, the order might just as easily refer to nursing home *business* records containing patient-identifying information:

Granted in part. The trial court's order is modified to provide that defendants are required to produce the requested discovery subject to the provision that any personal information which would identify the non-party patients shall be redacted from the records prior to production. *See Speer v. Whitecloud*, 99-1879 (La.10/15/99), 744 So.2d 1283. In all other respects, the application is denied.

Jackson, 933 So. 2d at 131. If the Magistrate’s Order purports to follow the edicts of the highest court in Louisiana, *Moss*, not *Speer* or *Davis*, is the case that should be cited as controlling authority.

A, together with the opinion by the Louisiana Court of Appeal in *Janssen*, No. CW 08-00365, slip op. at 2; *Davis*, 727 So.2d 647, 648 (La. Ct. App. 1999). Contrary to *Speer* and *Jackson*, the discovery sought in *Janssen* and *Davis* most closely tracks Lilly's medical records discovery here.

In the *Janssen* case, involving substantially identical Medicaid fraud and related claims against the manufacturer of Risperdal, a competitor of Lilly's Zyprexa, defendant Janssen sought and received permission from the state trial court, over the state's objections, to discover medical records from an arguably "representative" sample of 6,000 Medicaid participants who had taken Risperdal.³ Soon thereafter, Janssen began subpoenaing the records from healthcare providers in Louisiana. Those efforts ground to an immediate halt, however, when healthcare providers who received subpoenas objected to the production of the records as violative of LSA-R.S. § 13:3715.1. The trial court, faced with those objections from healthcare providers, instead ordered the state Department of Health and Hospitals ("DHH") to obtain the records under its Medicaid fraud investigative powers on Janssen's behalf.⁴ Specifically, the trial court ordered the DHH to obtain and produce the 6,000 Medicaid participants' medical records from hospitals, physicians, and other healthcare providers. Upon collection, the DHH was then ordered to release those medical records to Janssen.

The state filed an emergency writ to the Louisiana Court of Appeal seeking relief from the order requiring it to collect the records.⁵ The appellate court rejected the trial court's order as violative of R.S. §§ 13:3715.1 and 46:56. (Ex. A.) Apparently recognizing Janssen's attempted

³ Counsel for Louisiana in this case also represents the State of Louisiana in its case against Janssen.

⁴ The Louisiana trial court considered, but rejected as impossibly burdensome, expensive, and time-consuming, redacting personally identifiable information from the entire medical histories of the 6,000 patients.

⁵ The State of Louisiana did not challenge the relevance of the records discovery in this interlocutory appeal, but amply preserved that issue in the trial court for later review.

end run around the applicable Louisiana privacy statutes, the court of appeal held that “[t]he State of Louisiana, through the Department of Health and Hospitals [Medicaid], cannot waive the patients’ privilege without the patients’ consent to do so.” (Ex. A.) The appellate court ordered the State to attempt to obtain consent from the Medicaid patients, and if consent was not forthcoming, for the trial court to proceed with contradictory hearings “in which these individuals would be compelled to attend and assert their privilege.” (Ex. A.)

Janssen, unhappy with the delay and burden that compliance with the statutory procedures would mean, sought a writ of certiorari regarding the court of appeal’s decision. However, as shown in Exhibit A, the Louisiana high court denied Janssen’s writ application. In glaring contrast to *Jackson* and *Speer*, on which Judge Mann’s Order so heavily depends, the Louisiana Supreme Court did not modify the trial court’s ruling to order that the medical records to be produced in *Janssen* merely be redacted.

Similarly, *Davis* involved a class action lawsuit on behalf of women claiming injury from the use of “Norplant” contraception devices manufactured by defendant American Home Products (“AHP”). 727 So.2d at 648. AHP sought discovery of unidentified, non-party patients’ medical records that underlay the plaintiffs’ expert witnesses’ opinions. *Id.* After the trial court granted that discovery, the court of appeal reversed in light of the fact that “the mandatory procedure set out in La. R.S. 13:3715.1(B)(5) was not followed.” *Id.* at 650. Importantly, the court of appeal rejected AHP’s argument that “the confidentiality of the physician-patient relationship would neither be subverted nor impinged upon by the court’s order because the trial court directed that all patient identifying information be *redacted* prior to production of the records.” *Id.* AHP argued in vain that “after redaction, the records would become anonymous case histories just as those described in medical journals or discussed in medical school

classrooms” that “could not reasonably be viewed as chilling to the doctor-patient relationship.” *Id.* The court of appeal declared there existed “no authority for the proposition that medical records become exempt from the mandatory requirements of . . . La. Rev. Stat. 13:3715.1 by the redaction or removal of ‘patient information.’” *Id.* In sum, the appellate court held that “[t]he information being sought is privileged and/or confidential. Absent the existence of a statutory exception, permission from the non-party patients,⁶ or a contradictory hearing, the medical records of non-party patients are not discoverable in Louisiana.” *Id.* Although AHP also sought a writ of certiorari from the Louisiana Supreme Court, the high court again denied that relief from the court of appeal’s decision.⁷

Given Louisiana’s mandatory legal prerequisites to medical records disclosure, it is simply too burdensome, expensive, and time-consuming for the Court and parties to engage in that discovery. Lilly’s inability to articulate a compelling need for the discovery underscores that conclusion, and nothing in *Rezulin* or *Speer* alters that result.

⁶ The State of Louisiana has earlier demonstrated for the Court that Louisiana Medicaid patients have not previously consented to the disclosure of their medical records to third parties such as Lilly by their enrollment in or acceptance of Medicaid benefits. (*See, e.g.*, No.05-CV-1549(JBW) Doc. 122, which is incorporated herein by reference as if repeated in full.)

⁷ Although denials of supervisory writs by the Louisiana Supreme Court lack precedential value in and of themselves, the high court’s refusals to hear the appeals in *Janssen Davis*, and the specific limitations the Supreme Court placed on the per curiam opinion in *Speer*, are certainly consistent. That is especially true in light of the supreme court’s most recent, and most thorough, analysis of LSA-R.S. § 13:3715.1 in *Moss*, in which the supreme court cited favorably to the court of appeal’s *Davis* opinion, declaring: “Our construction of the statute comports with that of the [*Davis* court of appeal]” *Moss*, 925 So.2d at 1199 n.9. Contrasting its recognition of *Davis*, *Moss* makes no mention of *Speer*, nor opines regarding the effect of redaction of personal information from medical records. *See Moss*, 925 So.2d at 1199-1200 (“In enacting LSA-R.S. 13:3715.1, and in particular Section B(5) thereof, the legislature has entrusted the courts with the duty of determining, ***in the context of a contradictory hearing, on a case by case basis, according to the unique facts presented***, whether disclosure of a non-party’s otherwise privileged medical information is ‘proper’ in a particular case in the absence of consent or a waiver.”) (emphasis added). In any event, with regard to potential remedies at the courts’ disposal, such as “in camera inspections, excising highly personal and/or irrelevant matters, or allowing depositions limited to specific relevant questions,” *Moss* makes clear that none of those remedies may be fashioned without individualized, case by case contradictory hearings. *Id.* at 1201.

2. *Mississippi*

Rezulin and Baptist Memorial Hospital v. Johnson, cited by the Court, likewise convey no support for the proposition that redaction of personally identifying information from medical records exempts them from confidentiality protections under Mississippi law. The State of Mississippi has previously demonstrated for the Court that Mississippi law guards patient medical records against unauthorized disclosure, generally allowing for their release only with the consent of the patient or his or her legally authorized representative. More specifically, Mississippi law recognizes the physician-patient privilege in two forms: (1) Mississippi Code Annotated § 13-1-21(1),⁸ and (2) Mississippi Rule of Evidence 503.⁹ The Mississippi Supreme Court has held that “the doctor-patient privilege should be inviolate in most circumstances.” *Cox v. State*, 849 So.2d 1257, 1272 (Miss. 2003). Further, “under no circumstances should a court order or require a person to release medical information *unconditionally*” *Scott v. Flynt*,

⁸ All communications made to a physician, osteopath, dentist, hospital, nurse, pharmacist, podiatrist, optometrist, or chiropractor by a patient under his charge or by one seeking professional advice are hereby declared to be privileged, and such party shall not be required to disclose the same in any legal proceeding except at the instance of the patient or, in the case of the death of the patient, at the instance of his personal representative or legal heirs in case there be no personal representative, or except, if the validity of the will of the decedent is in question, at the instance of the personal representative or any of the legal heirs or any contestant or proponent of the will.

Miss. Code Ann. § 13-1-21 (West 2008).

⁹ Rule 503 provides that a patient may refuse to disclose and prevent any other person from disclosing (a) knowledge derived by a physician or psychotherapist by virtue of his or her professional relationship with the patient, or (b) confidential communications made for the purpose of diagnosis or treatment of his physical, mental, or emotional condition. Miss. R. Evid. 503(b). A communication is “confidential” if it is not intended to be disclosed to third persons, except persons present to further the interest of the patient in the consultation, examination, or interview, persons reasonably necessary for the transmission of the communication, or persons participating in the diagnosis and treatment under the direction of the physician or psychotherapist, including the patient’s family members. *Id.* at 503(a)(4). The privilege may be claimed by the patient, his guardian or conservator, or the personal representative of a deceased patient. *Id.* at 503(c). The patient’s physician or psychotherapist at the time of the communication is also presumed to have authority to claim the privilege on behalf of the patient. *Id.* The rule provides for limited exceptions to the general privilege rule, none of which apply here. *Id.* at (d), (e), (f).

704 So.2d 998, 1003 (Miss. 1996) (emphasis in original) (adding, “[s]uch disregard for a patient's right to confidentiality will not be tolerated by this Court”).

On a handful of occasions, the Mississippi Supreme Court has recognized limited exceptions to the doctor-patient privilege, either statutory or policy-based. *See, e.g., Cox*, 849 So.2d at 1272-73; *Baptist Mem’l Hosp. v. Johnson*, 754 So.2d 1165, 1170-71 (Miss. 2000); *State v. Baptist Mem’l Hosp.*, 726 So.2d 554, 560-61 (Miss. 1999). However, in none of those instances did the supreme court deem the simple redaction of personally identifying information sufficient to overcome the privilege.

In the *Johnson* case cited in the Court’s Order, for example, the Mississippi Supreme Court addressed the narrow question (obviously inapposite to this litigation) of whether the patient-physician privilege protects a patient’s identity and medical records when that patient’s condition may affect the health of another *and* the patient is a potential fact witness in a negligence action. 754 So.2d at 1167. *Johnson* involved parents’ lawsuit against a hospital arising from the hospital’s mistakenly allowing their newborn daughter to be breastfed by a woman other than her mother. *Id.* The hospital refused to disclose the identity of the other woman who breastfed the baby, nor would it release the woman’s medical records to the plaintiffs. *Id.* The hospital took an interlocutory appeal from the trial court’s order to produce “all medical records, hospital records, and other similar documents, of any description, which relate in any way to the unidentified person” who mistakenly breastfed the plaintiffs’ daughter. *Id.* Under that particular set of circumstances, balancing the plaintiffs’ need for the information and the non-party witness’s “great” interest in the confidentiality of her medical records, the supreme court ordered the unidentified woman’s medical records to be turned over to the trial court judge *for in camera inspection* to determine, if possible from the records, whether the

plaintiffs' daughter's health was at risk. *Id.* at 1171. The non-party witness's medical records were never ordered produced, either in redacted or un-redacted form. *Id.*

Indeed, the Mississippi Supreme Court has most frequently commanded in camera inspections by the trial courts to determine the extent to which the doctor-patient privilege should be pierced, if at all. *See, e.g., Williamson v. Edmonds*, 880 So.2d 310, 321 (requiring the trial court to conduct an in camera inspection of all documents requested in discovery, including non-party medical records, although the court acknowledged at least partial waiver of the patient-physician privilege); *Cox*, 849 So.2d at 1272 (ordering, in a criminal case, an "in camera review by the court of the medical records to determine if the evidence is material, relevant, and exculpatory"). The Mississippi Supreme Court is, in fact, so disinclined to waive the patient-physician privilege without patient consent that research uncovered no cases in which the court ordered redacted disclosures *without* first ordering the trial court to undertake an in camera inspection for relevancy and materiality of the medical records in question.

Furthermore, where the supreme court *has* allowed for the production of redacted medical records following in camera inspection by the trial court, such redactions routinely extend well beyond mere deletion of personally identifying information. *See, e.g., Cox*, 849 So.2d at 1272 ("If the circuit court finds that the records are admissible, the records should be **redacted as much as possible to show only the evidence which is relevant . . .**"); *State v. Baptist Mem'l Hosp.*, 726 So.2d at 561 (mandating, with respect to certain hospital medical records subpoenaed by law enforcement as part of a criminal investigation, that the medical "records [requested] are to have the patients' personal information[] redacted, **and only contain patient medical information as it pertains to [the] particular injury**" at issue in the investigation; "[t]his does not mean law enforcement investigators will be able to go on a

fishing expedition"); see also *Williamson*, 880 So.2d at 321 (ordering non-party medical records in the defendant's possession to be reduced to "a chart which lists the persons, identified only as #1, #2, #3, etc. [and] . . . the medical diagnosis" for production to the plaintiffs, and if plaintiffs request verification of that information, for the trial court to inspect the medical records to verify the information on the chart); cf. *Morton v. City of Shelby*, 984 So.2d 323, 340 (Miss. Ct. App. 2008) (refusing plaintiff's attempted access to defendant's medical records where none of the circumstances of *Johnson* were present, and plaintiff was "engaged in nothing more than a fishing expedition").

The Mississippi Supreme Court's strict adherence to the patient-physician privilege means that simple redaction of personally identifying information as in *Rezulin* is insufficient under Mississippi law. At a minimum, the supreme court's interpretations of the State's privilege would require the Court to inspect in camera the medical records Lilly seeks, as well as to order the redaction of all medical information not material or relevant to the State's claims or Lilly's defenses. The manifest burden, expense, and delay caused by that effort enjoin such an undertaking.¹⁰

3. *Montana*

With all due respect, this Court has erred in its understanding of both the privacy rights of the Montana citizens whose medical records Lilly seeks and the nature of the procedures by which those records may be obtained. The Court has concluded, without any authority, that because the Montana patient medical records will ultimately be de-identified the records "do not fall within the ambit" of Montana's privilege law. The Court ignores the fact that the privilege

¹⁰ The State of Mississippi has also previously demonstrated for the Court that Mississippi medical assistance patients did not consent to the disclosure of their medical records to Lilly in this lawsuit by their enrollment in Medicaid or acceptance of medical assistance benefits. (See No.07-CV-645(JBW) Doc. 45, which is incorporated herein by reference as if repeated in full.)

lies between the physician and the patient and not between the patient and the State of Montana. The only way the State can obtain privileged medical records is from a patient's health care provider pursuant to Mont. Code. Ann. § 50-16-535. When the records are requested by compulsory process from the health care provider, the medical records clearly have patient identification information and are not de-identified or redacted. As such they are plainly "health care information" to which the statutory and constitutional privileges and protective procedures apply. For the State of Montana to obtain any Montana citizens medical records, it must comply with the statutory requirements in the first instance. Later redaction or de-identification does not cure that or waive those requirements for the State to obtain the records. By ignoring this, the Court pierces a fundamental privacy interest without any basis in Montana law, without meeting state law, and without showing of a compelling interest.

Montana citizens have an inalienable right to privacy under the Montana Constitution, Article II, Sec. 10. The State of Montana has previously demonstrated that this state constitutional right is broader than the right of privacy under the Federal Constitution. *State v. Siegal*, 934 P.2d 176, 191 (Mont. 1997); *State v. Bullock*, 901 P.2d 61, 72 (Mont. 1992). The Montana Supreme Court has held that the guarantee of privacy would "encompass, at a minimum, the sanctity of one's medical records." *State v. Nelson*, 941 P.2d 441 (Mont. 1997).

More specifically, there are substantial express protections provided to medical information which would prevent disclosure of patient information under any conceivable scenario in this litigation. For example, Mont. Code Ann. 26-1-807 restricts confidential relations and communications between a psychologist and his client, placing that privilege "on the same basis as provided by law for those between an attorney and his client." The statute goes on to

state: “Nothing in any act of the legislature shall be construed to require such privileged communications to be disclosed.”

In 2003, the Montana Supreme Court recognized the Montana Uniform Health Care Information Act allows discovery of health care information only upon a showing of a compelling state interest that outweighs the patient’s privacy interests. *St. James Community Hosp., Inc. v. District Court*, 77 P.3d 534, 535 (Mont. 2003). In the context of a class action in which one party sought the names of all patients who had requested medical records from certain health care providers, the Court wrote:

[T]he Health Care Information Act requires a showing of a compelling state interest before a Court can require production of health care information pursuant to a discovery request. More importantly, Article II, Section 10, Montana Constitution’s guarantee of privacy encompasses confidential “informational privacy.” The names of patients of the health care providers fall within the Act’s definition of “health care information.” Section 50-16-504(6), MCA (“any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and relates to the patient’s health care”).

Id. at 135.

In the case, while the Court has determined that individual medical records are “relevant” there has been no finding of a compelling interest that would outweigh a patient’s privacy interest.

While the Montana Supreme Court has uniformly upheld a patient’s right to privacy it has never limited the confidentiality of medical records to those that identify the patient. Rather, the State legislature has enacted strict procedural requirements to protect such privileged information, regardless of redaction. Even if we were to assume that individual identifiers could be properly redacted and the Court’s ruling were correct, Montana statutory law sets forth the proper procedure for producing medical records by compulsory process. *See supra* Mont. Code

Ann. § 50-16-536. This procedure will be costly and time consuming to get each patient's records and will impose directly on each Medicaid patient, who are not themselves parties, who have done nothing to waive any privacy rights they have to Lilly, and who derive no benefit from this imposition on them. Indeed, when signing up for Medicaid, the information they are provided assures them of their privacy.

When health care information is sought pursuant to a civil proceeding or investigation, by Montana statute “the person seeking discovery or compulsory process shall mail a notice by first class mail to the patient or the patient’s attorney of record of the compulsory process or discovery request at least 10 days before presenting the certificate...to the healthcare provider.”¹¹ Mont. Code Ann. § 50-16-536(1). Following notification to the patient, the requesting party or agency must serve the discovery request upon the health care provider with a signed, written certification identifying the subsection of 50-16-535 under which the discovery is being sought. Mont. Code Ann. § 50-16-536(2). “A person may sign the certification only if the person reasonably believes that the subsection of 50-16-535 identified in the certification provides an appropriate basis for the use of discovery or compulsory process.” *Id.* In response to the service request or compulsory process, the health care provider may deny access to the requested health care information. Mont. Code Ann. § 50-16-536(3). If the request is denied the health care provider “shall submit to the court by affidavit or other reasonable means an explanation of why the health care provider believes the information should be protected from disclosure.” *Id.*

¹¹ Montana law states that health care information may not be disclosed by a health care provider pursuant to compulsory process or discovery unless certain exceptions are met. Mont. Code. Ann. § 50-16-535. Those exceptions are set forth under § 50-16-535. Montana challenges this Court’s ruling on the basis that the while the Court deemed the records “relevant” there was no showing of a compelling state interest that outweighs the patient’s privacy interest. *See St. James Community Hosp., Inc. v. District Court*, 77 P.3d 534, 535 (Mont. 2003). This appears to be the only statutory exception by which this Court could order the production of medical records.

Lilly is attempting to seek all of the medical records for thousands of patients.¹² In order to gain access to such records the State of Montana would need to request the individual records from the patient's medical provider as set forth by the procedure detailed above. Moreover, the State would have to certify that there is a "compelling state interest," which in the light *St. James Community Hosp., Inc. v. District Court*, 77 P.3d 534, 535 (Mont. 2003) may not be sufficient. Lilly is attempting to seek all of the medical records for thousands of patients.¹³ Additionally, the procedure requires the individual requesting the information to certify to the medical provider that they reasonably believe that there is an appropriate basis for such requests under 50-16-535. The State has already thoroughly briefed its position that there is no appropriate basis for requests of individual medical records. Should the Court require the State to subpoena such records, rather than Lilly, the State would be faced with the position of providing a false certification to those doctors in which records are being sought.

Without question, this process would result in significant delay, would impose huge burdens on the State, its health care providers and the state district courts. The Montana courts would face the possibility of thousands of affidavits from health care providers challenging the production of patient records. In addition, as noted in the States' affidavits, such requests, made by the State of Montana, could jeopardize relationships with those doctors providing Medicaid services and would certainly impose burdens on the low income citizens of Montana who have nothing to gain by this litigation.

4. New Mexico

New Mexico has a strong statutory privilege for private medical information. N.M.R.A. 11-504 (PHYSICIAN-PATIENT AND PSYCHOTHERAPIST-PATIENT PRIVILEGE).

¹² Montana objects to the number of records sought by Lilly. See State AG Status Report, September 29, 2008.

¹³ Montana objects to number of records sought by Lilly. See State AG Status Report, September 29, 2008.

Further, New Mexico case authority limits the amount of medical information a defendant can receive even when the plaintiff is claiming a personal injury themselves. The defendant is only entitled to the medical records directly related to the condition claimed and is not entitled to discover the plaintiff's entire medical history. N.M.R.A. 11-504 §§ B, D(3); *Pina v. Espinoza*, 29 P.3d 1062 (N.M. 2001) (ordering personal injury plaintiff to execute a blanket release for her medical records was error; blanket release did not adequately protect privileged portions of records, as it did not address the applicability of privilege on a communication-by-communication basis, and plaintiff did not necessarily put her entire medical history in issue by filing a lawsuit which sought damages for pain and suffering or loss of enjoyment of life).

Moreover, there is no statute or regulation under New Mexico law that allows the State of New Mexico to disclose medical information even if it is redacted. *See* N.M.R.A. 14-6-1 (prohibiting expressly disclosure by governmental agencies of health insurance identifying specific individuals). In addition, the New Mexico Medicaid application represents to recipients that “information will only be used for eligibility purposes or to provide services. By law, confidential information may be released to other agencies that manage federal or federally-funded programs.” State Coverage (SCI) Application, available at www.nmsci.nm.us. Given these representations to Medicaid recipients, it would improper to compel the State of New Mexico to obtain and produce medical records to a defendant in litigation in which the recipient is not a party. At a minimum, these recipients should be given notice that their medical records will be disclosed with an opportunity to object. *See* New Mexico Medicaid Program Notice of Privacy Practices Summary (noting that recipients have right to “know to whom NM Medicaid has shared your information”), available at <http://www.hsd.state.us>.

C. **Redaction Of Medical Records Does Not Render HIPAA Preemptive Of State-Law Protections.**

Finally, the Order is simply mistaken in its suggestion that HIPAA alone governs redacted medical records, and that state privilege laws applicable to such records merely “fall away,” notwithstanding Federal Rule of Evidence 501’s mandate that state privilege laws shall control where state law supplies the rule of decision. (Order at 9-10 (citing *NW Mem’l Hosp.*) That is not the holding of *Northwestern Memorial Hospital*, on which the Order’s HIPAA analysis exclusively hinges.

Indeed, it is crucial to note that *Northwestern* involved a case pending before a federal district court ***founded upon federal question jurisdiction***. 362 F.3d at 925. Therefore, Judge Posner, writing for the majority of the United States Court of Appeals for the Seventh Circuit (“Seventh Circuit”) panel, correctly observed that state “privilege [such as Illinois’s strict laws proscribing disclosure of even redacted medical records] does not govern in federal-question suits” *Id.* In fact, the Seventh Circuit reached the same conclusion as Magistrate Mann with respect to privileges applicable to federal question lawsuits. *See NW Mem’l Hosp.*, 362 F.3d at 925-26 (“[a]lthough the issue is not free from doubt, we agree with the government that the HIPAA regulations do not impose state evidentiary privileges on suits to enforce federal law,” citing Fed. R. Evid. 501).

However, that holding cannot extend to those States that have asserted no federal claims, as shown above. The Seventh Circuit concluded that HIPAA simply provided a procedural mechanism for the discovery of redacted medical records in federal question lawsuits, ***but never held that mere redaction of records obviates compliance with state law governing medical records disclosure in lawsuits where state law supplies the rule of decision***, a limitation the entire panel recognized:

Such redacted records are afforded no privacy protection under HIPPA [sic], logically so because the redacted records have no identifiably private information to expose. And although Illinois law has adopted an expansive view of privilege that includes redacted medical records, *as the court recognizes, Illinois law does not govern this question [pursuant to Rule 501.]*

NW Mem'l Hosp., 362 F.3d at 935 (Manion, J., concurring and dissenting) (emphasis added).

The Order's confusion on this point stems from the *Northwestern* federal district court's attempt to bootstrap the application of Illinois privilege law to the federal question case via the "more stringent" standard for disclosure under HIPAA, ignoring Rule 501. *See* 362 F.3d at 925 ("The district court in our case ruled that the Illinois law, because it sets a 'more stringent' standard for disclosure than the HIPAA regulation, trumps that regulation by virtue of HIPAA's supersession provision."). The Seventh Circuit held such bootstrapping was impermissible, adding that *under HIPAA*, the "more stringent" requirement would not apply to de-identified medical records, and therefore, state privilege laws could not apply to the federal question case for that additional reason. But, the "more stringent" standard in HIPAA does *not* "fall away" if redacted records are no longer "afforded [any] privacy protections under HIPAA," *yet State privileges (applicable under Rule 501) nevertheless afford substantial protections to those same records*, as was the case under Illinois law in *Northwestern* and as is the case under the States' privilege laws here. *See* 362 F.3d at 926; *id.* at 935 (Manion, J., concurring and dissenting). Instead, the "more stringent" rubric of 45 C.F.R. § 160.203(b) dictates that state privilege laws would govern. Equal sensitivities to potential disclosure of abortion records of 45 women in *Northwestern* certainly apply to the tens of thousands of medical records, spanning over a 20-year period in some cases, which Lilly seeks.¹⁴ As Zyprexa is a medication indicated

¹⁴ In analyzing the burden of the production versus the benefit of the medical records discovery the government sought under Fed. R. Civ. P. 45(c), Judge Posner considered the following in ultimately affirming the

for the treatment of serious mental illnesses, many of those records may potentially “out” patients who would much prefer to keep their medical condition confidential, and who possess the legal right to expect the same.

D. Certain States’ Restrictions On The Handling Of Medical Records Within Medicaid’s Custody Prevent Their Disclosure To Lilly.

Even if the various Medicaid programs obtained the records pursuant to the means and methods established in the Order, utilizing their Medicaid fraud investigative powers, merely securing the records does not automatically mean the records may be disclosed to third parties such as Lilly, as shown below.

1. Louisiana

The State of Louisiana, on behalf of the Department of Health and Hospitals, is unable to disclose any medical records it obtains or maintains its possession or custody pursuant to Louisiana Revised Statute § 46:56, and particularly R.S. § 46:56(A) and (D). It is important to recall that the records Lilly seeks are not presently in the custody of the DHH. Instead, the DHH must first obtain the records, pursuant to the Court’s Order, from individual healthcare providers, then produce them to Lilly. Once the DHH obtains confidential medical services records, which

trial court’s quashing the subpoena for redacted medical records in that case (incidentally in accordance with Illinois privilege law):

Even if all the women whose records the government seeks know what “redacted” means, they are bound to be skeptical that redaction will conceal their identity from the world. . . . Some of these women will be afraid that when their redacted records are made a part of the trial record in New York, persons of their acquaintance, or skillful “Googlers,” sifting the information contained in the medical records concerning each patient’s medical and sex history, will put two and two together, “out” the 45 women, and thereby expose them to threats, humiliation and obloquy. As the court pointed out in *Parkson v. Central DuPage Hospital*, *supra*, 61 Ill.Dec. 651 435 N.E.2d at 144, “whether the patients’ identities would remain confidential by the exclusion of their names and identifying numbers is questionable at best. The patients’ admit and discharge summaries arguably contain histories of the patients’ prior and present medical conditions, information that in the cumulative can make the possibility of recognition very high.

326 F.3d at 928-29.

undoubtedly qualify as “case records” under R.S. § 46:56, then the confidentiality protections of R.S. § 46:56(A) apply, and the DHH cannot lawfully disclose the records to Lilly. This would certainly be the case with any medical records the DHH obtained in the course of conducting a fraud investigation of its own volition—absent the Court’s Order or Lilly’s prodding, as here.

Revised Statute section 46:56 provides, in pertinent part, as follows:

A. Applications for assistance and information contained in case records of clients of the Department of Health and Hospitals, the Department of Social Services, or the Office of Elderly Affairs, for the purposes of adult protective services, ***shall be confidential*** and, except as otherwise provided, ***it shall be unlawful for any person to solicit, disclose, receive, make use of, or to authorize, knowingly permit, participate in, or acquiesce in the use of applications or client case records or the information contained therein for any purpose not directly connected with the administration of the programs of the department.***

B.

* * *

(2) For the purposes of this Section, “case records” are assistance records, social service records, food stamp records, ***medical services records***, probation and parole records, records pertaining to the adoption of children, records of foster care services, records and investigative reports on abuse or neglect of children or adults, and records of other child welfare services administered by the department, including handicapped children’s services, nutrition, immunization, and other medical and public health services records pertaining to children or adults and where such records are in the custody of parish health units, and regional and central offices of the office of public health of the Department of Health and Hospitals.

* * *

D. Subject to the exceptions enumerated in R.S. 44:17 and Subsections E, F, and M of this Section, confidential information may be released to an outside source not directly connected with the administration of the programs of the department only upon written request of the outside source and only after written waiver of the applicant, client, or his legal representative. Governmental authorities, ***the courts***, and law enforcement agencies ***shall be***

considered the same as any other outside source, except as provided in R.S. 44:17 and Subsections E and F.

LSA-R.S. § 46:56(A), (B)(2), (D) (emphasis added).

As noted above, Revised Statute § 46.56(A) mandates that case records of DHH clients are confidential, and that it is unlawful for the DHH to “disclose . . . or to authorize, knowingly permit, participate in, or acquiesce in the use of . . . client case records or the information contained therein for any purpose not directly connected with the administration of the programs of the department.” LSA R.S. § 46:56(A). Subsection (D) of the statute carves out very narrow exceptions to this rule, under which confidential information may be disclosed to “outside sources.” LSA R.S. § 46:56(D). However, none of those statutory exceptions apply here. Therefore, under the plain language of the statute, the DHH is forbidden from disclosing “case records,” including “medical services records” of Medicaid patients, for any purpose or use not directly connected with the administration of the programs of the department. LSA-R.S. § 46.56(A). There can be no dispute that this litigation is not “directly connected” with the *administration* of the DHH’s programs.

The Louisiana Supreme Court declined to entertain Janssen’s appeal regarding an alternate interpretation of R.S. § 46.56 in its case against the State of Louisiana. (Ex. A.) Thus, even were the DHH to obtain the medical records Lilly seeks, those “medical services records,” which qualify as “case records” under LSA-R.S. § 46.56(A), could not legally be relinquished to Lilly.

2. Mississippi

Similar statutory protections shield records obtained or maintained by the Mississippi Division of Medicaid. Mississippi Code Annotated § 43-13-117 (West 2008) provides that “Notwithstanding any law or regulation, information obtained or maintained by the division

regarding the prescription drug program . . . is confidential and *not subject to disclosure except to other state agencies.*” Similarly, the administrative functions of the Mississippi Division of Medicaid require that the division “provid[e] safeguards for preserving the confidentiality of records” Miss. Code Ann. § 43-13-121 (1)(a)(v) (West 2008). The medical records required to be obtained under the Order by Mississippi Medicaid would, thus, fall under these additional protections, and could not be disclosed to Lilly without violating the same.

II. CONCLUSION

For the reasons stated herein as well as in the objection filed by the State of Connecticut on behalf of the litigating States, the Court should reverse the Honorable Magistrate’s September 24, 2008 Order.

Dated: September 29, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2008 the foregoing submission was filed with the CM/ECF system, which automatically served a copy upon all parties to the litigation.

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