

**STATE OF NEW MEXICO, ex rel.
PATRICIA MADRID, Attorney General,**

07-cv-1749 (JBW)

Plaintiff

-against-

ELI LILLY & COMPANY,

Defendant

**ELI LILLY'S OPPOSITION TO PLAINTIFFS' OBJECTIONS TO
MAGISTRATE JUDGE MANN'S SEPTEMBER 24, 2008 ORDER
REGARDING DISCOVERY OF MEDICAL RECORDS**

I. INTRODUCTION

On September 24, 2008, Magistrate Judge Mann issued a thorough, well-reasoned opinion and order for these five cases finding that Lilly is entitled to discovery of medical records relevant to the parties' claims and defenses. Each of the States alleges that it reimbursed Zyprexa prescriptions that were not medically necessary, and four States also allege that Zyprexa caused Medicaid recipients to develop diabetes and related conditions. The States' claims are fundamentally about the health and healthcare of their Medicaid recipients. It is uncontestable that medical records would be relevant, essential evidence if each State's claim only involved one Medicaid recipient. As Magistrate Judge Mann correctly found, the fact that each State's claim involves thousands of Medicaid recipients does not magically transform relevant medical records into irrelevant ones – it simply means there are many more relevant records.

Magistrate Judge Mann's Order was comprised of three sub-parts: (1) a determination that the medical records Lilly seeks are relevant and reasonably calculated to lead to discovery of admissible evidence; (2) a determination that state physician-patient privilege laws do not preclude discovery of de-identified medical records; and (3) a determination that the medical records Lilly seeks are discoverable under Fed. R. Civ. P. 34(a)(1)(A) as documents

within the States' control. Each of these determinations by Magistrate Judge Mann was appropriate and supported by the reasoning in her Order, and none was clearly erroneous or contrary to law.

Because the specifics of the medical record discovery plan for each State are still being finalized by the parties and Magistrate Judge Mann, as noted below, Lilly respectfully suggests that the Court defer consideration of these issues until that process is complete. Part of finalizing the plan will involve case-specific evaluations of the alleged burden on the States and of how any burden should be distributed.¹ This would allow the parties to present concrete arguments about the alleged burden on the States and about the uses to which Lilly will be able to put the medical records it obtains in discovery.

II. FACTUAL BACKGROUND

A. The States' Claims

The damages sought by the States allegedly run into the billions.² In various combinations, the five States at issue have alleged in their complaints, and in their discovery responses, that:

- Zyprexa prescriptions paid for by the States were medically inappropriate or unnecessary and ineligible for Medicaid reimbursement, and constituted false claims to the States' Medicaid programs (and some other payor programs);³

¹ As Magistrate Judge Mann noted in her September 24, 2008 Memorandum and Order [hereafter, "Order"], which the States fail to acknowledge, Lilly, not the States, will bear the cost of copying and redacting the medical records it seeks. *See* Order at 19 n.12.

² *See, e.g.*, Tr. of Hr'g before Judge Weinstein on Sept. 9, 2008, at 23.

³ *See, e.g.*, *State of Connecticut v. Eli Lilly and Company*, No. 08-cv-955, Compl. ¶¶187-199; *State of Mississippi ex rel. Hood v. Eli Lilly and Company*, No. 07-cv-00645, First Am. Compl. ¶¶9.1-9.9; *State of New Mexico v. Eli Lilly and Company*, 07-cv-1749, Compl. ¶¶30-38; *State of Montana v. Eli Lilly and Company*, 07-cv-1933, Compl. ¶¶110-18.

- Zyprexa caused program recipients to develop diabetes.⁴
- Every Zyprexa prescription was induced by fraud or other improper promotional conduct by Lilly;⁵
- Every prescription of Zyprexa, promotional material from Lilly regarding Zyprexa, and interactions between Lilly personnel violated the States' consumer protection laws, exposing Lilly to liability for restitution, civil penalties of up to \$10,000 per prescription, and consequential damages;⁶

These five States have not elected to narrow their claims in a way that would meaningfully affect the need for medical record discovery.⁷ For purposes of devising a medical record discovery plan, Lilly's working understanding is that the States are claiming recovery for every prescription and doctor interaction since 1996, when Zyprexa was first marketed, and that every single claim their Medicaid programs paid for Zyprexa was a "false claim" that was ineligible for Medicaid reimbursement. Millions of claims and probably thousands of interactions with physicians are therefore being put in issue by the States.

⁴ See, e.g., *State of Mississippi ex rel. Hood v. Eli Lilly and Company*, No. 07-cv-00645, First Am. Compl. ¶¶ 8.1-8.3; *State of Connecticut v. Eli Lilly and Company*, No. 08-cv-955, Compl. ¶146.

⁵ See, e.g., State of Louisiana's Third Supplemental Objections and Responses to Eli Lilly and Company's Interrogs., Response to Interrog. Nos. 16, 29, 39, and 40; State of Connecticut's Supplemental Objections and Responses to Eli Lilly and Company's Interrogs., Response to Interrog. No. 37; State of Mississippi's Second Supplemental Objections and Responses to Eli Lilly and Company's Interrogs., Response to Interrog. No. 36.

⁶ See, e.g., *State of Connecticut v. Eli Lilly and Company*, No. 08-cv-955, Compl. ¶¶ 170, 231 (seeking \$5,000 civil penalty per violation of the Connecticut Unfair Trade Practices Act and requesting restitution, civil penalties, treble damages under RICO, costs, attorneys fees, and other relief); *Montana v. Eli Lilly and Company*, 07-cv-1933, Compl. p. 29. Louisiana does not seek civil penalties.

⁷ New Mexico has indicated that it is only seeking restitution and civil penalties. Depending on how it defines restitution, and upon completion of its data production, Lilly may require a different, and possibly smaller set of medical records than is being requested for the States with broader claims.

B. Current Status of Medical Record Discovery Plan.

As the States note, the details of the medical record discovery plan are still being worked out by the parties and Magistrate Judge Mann. Although this process has been significantly delayed by the States' failures to produce information about their Medicaid populations that is necessary to finalize the medical record discovery plan, the process is now moving ahead, as reflected in the status report attached hereto as Exhibit A, a copy of which was submitted to Magistrate Judge Mann on October 10, 2008. A conference with Magistrate Judge Mann on these topics is scheduled for October 15, 2008. Once the final shape of medical record discovery is determined, the parties will be able to present more concrete arguments about the alleged burdens of medical record discovery and the uses to which Lilly will be able to put the medical records it obtains.

Lilly therefore respectfully suggests that the Court defer ruling on these issues until the parties and Magistrate Judge Mann have completed a more specific plan for medical record discovery. The States' positions are protected by their having filed objections by September 29, 2008, as required by Magistrate Judge Mann.

III. ARGUMENT

If a party timely objects to a magistrate judge's ruling on a non-dispositive matter, the district judge "shall modify or set aside any portion of the magistrate judge's order found to be clearly erroneous or contrary to law." Fed. R. Civ. P. 72(a).

A. Relevance.

The threshold question for whether the medical records Lilly seeks are discoverable is whether they are "relevant to the claim or defense of any party," and whether

discovery of the records is “reasonably calculated to lead to the discovery of admissible evidence.”⁸

Here, the relevance of the medical records Lilly seeks is not a close question. As Magistrate Judge Mann noted, the relevance of these records “bears repeating,” and it “is plainly evident that ... disclosure of the medical records is ‘reasonably calculated to lead to the discovery of admissible evidence.’”⁹ The States do not dispute that information about the health conditions and diagnoses of Medicaid recipients is relevant when contained in electronic claims databases.¹⁰ That same category of information is just as relevant when contained in hard-copy medical records, which, as discussed below, are more complete than claims data and in fact are the underlying sources of the less complete databases. The fact that the States do not intend to rely on data taken directly from the underlying medical records does not make the records themselves irrelevant.

Moreover, it is not debatable that medical records would be relevant and discoverable if each State had reimbursed Zyprexa claims for only one Medicaid recipient. As is true of health insurers generally, the States’ own procedures contemplate that medical records are key sources of information to be reviewed in determining whether a claim is medically necessary, as discussed in Section III.A.2 below. The fact that the States are suing over Zyprexa

⁸ Fed. R. Civ. P. 26(b)(1); *see also, e.g., Kingsway Financial Services, Inc. v. Pricewaterhouse-Coopers LLP*, 2008 WL 4452134, *4 (S.D.N.Y. 2008) (quoting *Daval Steel Prods. v. M/V Fakredine*, 951 F.2d 1357, 1367 (2d Cir. 1991)); *Condit v. Dunne*, 225 F.R.D. 100, 105-6 (S.D.N.Y. 2004) (quoting *A.I.A. Holdings S.A. v. Lehman Bros.*, 2000 WL 763848 (S.D.N.Y. 2000)).

⁹ Order at 3 (quoting Fed. R. Civ. P. 23(b)(1)).

¹⁰ West Virginia disputed the relevance of its claims database, and although medical records are not at issue in West Virginia’s case, it is worth noting that this Court affirmed Magistrate Judge Mann’s Order compelling production of West Virginia’s Medicaid claims database. *See* Order, Case No. 1:06-cv-05826-JBW-RLM, Doc #90, at 2 (E.D.N.Y. Sept. 11, 2008) (“Magistrate Judge Mann’s findings on the relevance and burden regarding the ... Medicaid database data are not inappropriate.”).

claims for thousands of Medicaid recipients, rather than for a handful of Medicaid recipients, does not transform relevant medical records into irrelevant records – it simply means there are many more relevant records.

Thus, properly understood, the question is not whether medical records are relevant to the States' claims and Lilly's defenses – they clearly are – but whether Magistrate Judge Mann committed clear error in holding that the burden of medical record discovery is justified by Lilly's need for the evidence they contain. For the reasons stated in Magistrate Judge Mann's Order, in Lilly's submissions to Magistrate Judge Mann, and in the following discussion, discovery of medical records is essential to Lilly's ability to adequately defend these cases. Nothing in Magistrate Judge Mann's burden determinations to date is clearly erroneous, and, as noted previously, many of the specifics are continuing to be worked out at Magistrate Judge Mann's direction.

1. Lilly's discovery is not limited by the States' aggregate-proof theory.

Even if the States could establish a *prima facie* claim using only aggregate proofs instead of proving each allegedly fraudulent claim individually (that is a question for another day¹¹), that would not limit the evidence Lilly is entitled to discover and use in its defense.

¹¹ Nothing in this memorandum, or in Lilly's participation in plans for discovery of a sampling of medical records, rather than complete discovery of all records for every single patient and every single allegedly false claim at issue, should be construed as a waiver of Lilly's position that the States' aggregate theories cannot survive summary judgment, and that the States must pursue their claims, if at all, through subrogation and by presenting patient-by-patient, claim-by-claim evidence of the alleged falsity of each Zyprexa claim at issue. *See, e.g., United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007) (“Evidence of an actual false claim is ‘the *sine qua non* of a False Claims Act violation.’”); *McLaughlin v. American Tobacco Co.*, 522 F.3d 215, 223-24 & n.5 (2d Cir. 2008) (holding that, even in the context of a mass-marketed consumer product, “individualized proof is needed” to establish reliance and causation, and rejecting the view that the elements of causation and reliance could be loosened simply because the plaintiff alleges a “broad-based fraudulent scheme ... designed to distort the entire
(continued...)”)

Regardless of whether the States intend to use patient- or prescriber-specific evidence in their cases-in-chief, they may not dictate how Lilly presents its case to the jury, let alone select the evidence that Lilly is allowed to marshal in its defense. Lilly is not required to rely solely on the limited claims data the States prefer to use. Rather, Lilly is entitled to challenge the reliability of the States' statistical models, and/or to construct its own competing models, using the full database and more complete and accurate data taken directly from the underlying medical records. As another judge in this district recently held,

[Defendants are] entitled to relevant discovery of damages data in order to formulate defendants' own theory on the computation of ... damages. By the interrogatories here in dispute, [Defendant] seeks ... to enable its experts to put forth a distinct, competing theory of damages.... *While plaintiffs may disagree with the theory, there is no precedent which permits the plaintiffs to refuse to provide discovery based on their lack of agreement with defendants' theory of damages.* Similarly, defendants, in conducting damages discovery, are not limited by the documents considered by plaintiffs' experts. . . .¹²

Similarly, the Eighth Circuit held in an analogous case involving alleged misrepresentations by a medical device manufacturer to prescribing physicians that:

[A]ssuming this case fits within the *Group Health* category, and thus does not *require* the *plaintiffs* to present direct proof of individual reliance, *Group Health* surely does not *prohibit* [defendant] from presenting direct evidence that an individual plaintiff (or his or her physician) did not rely on representations from [defendant]. When such evidence is available, then it is highly relevant and probative on the question whether there is a causal nexus between alleged misrepresentations and any injury. Whatever *Group Health* means about the need for these plaintiffs to present direct evidence of individual reliance, it does not eliminate the

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body of public knowledge"); *In re St. Jude Medical, Inc.*, 522 F.3d 836, 838-40 (8th Cir. 2008) (noting large variety of ways in which physicians learn about and choose to prescribe a product).

¹² *Fox v. Cheminova, Inc.*, 2006 WL 508087, at *7 (E.D.N.Y. 2006) (emphasis added).

right of a defendant to present evidence negating a plaintiff's direct or circumstantial showing of causation and reliance.¹³

2. Medical records contain direct evidence of the medical necessity of Zyprexa prescriptions at issue and contain essential information not available from electronic claims data.

All five of the States covered by Magistrate Judge Mann's Order are pursuing Medicaid fraud claims against Lilly, on the theory that Lilly caused doctors and pharmacists to submit claims for reimbursement of Zyprexa prescriptions that were inappropriate or "medically unnecessary," and therefore ineligible for Medicaid reimbursement. Medical records contain direct evidence of the medical necessity, and hence eligibility for Medicaid reimbursement, of these Zyprexa prescriptions.¹⁴

As the Center for Medicare and Medicaid Services ("CMS") recently noted in conjunction with its ongoing review of Medicaid patient records, under federal Medicaid regulations "all medical records should contain documentation to support services rendered," including "the appropriateness and medical necessity of the payments."¹⁵ Doctors who prescribe Zyprexa to Medicaid patients are thus required, by federal law and by the States themselves, to document the medical necessity of each Zyprexa prescription in the patients' medical records.

For example, Montana Medicaid regulations specify that:

"All providers of service must maintain records which fully demonstrate the extent, nature and medical necessity of services and items provided to Montana Medicaid recipients. ... If a provider cannot provide medical records to prove that a service billed to Medicaid ... meets all requirements for reimbursement, the service will be deemed not to ... be

¹³ *In re St. Jude Medical, Inc.*, 522 F.3d 836, 840 (8th Cir. 2008) (italics in original).

¹⁴ Under 42 U.S.C. §1396r-8(k)(3), States must pay for Zyprexa when it is prescribed for a "medically accepted indication."

¹⁵ *Medicaid Program and State Children's Health Insurance Program (SCHIP); Payment Error Rate Measurement*, 72 F.R. 50490, 50498 (Aug. 31, 2007) (emphasis added); *see also* 42 C.F.R. §431.107(b) (requiring providers to maintain "any records necessary to disclose the extent of services to provider furnishes to recipients").

reimbursable due to lack the lack of documentation, and the department will recover all reimbursement paid to the provider.”¹⁶

Montana’s provider manual further specifies that the records doctors must keep and “furnish” to the Medicaid agency “upon request include (but are not limited to) the following:

- Original prescriptions
- Certification of medical necessity
- Treatment plans
- Medical records...[and]
- Pertinent medical history....”¹⁷

Similarly, the Mississippi Medicaid Provider Policy Manual states:

“A medical record is a legal document.... In order for [the Medicaid agency] to fulfill its obligation to verify services rendered to Medicaid beneficiaries and paid for by Medicaid, the provider must maintain auditable records that will substantiate the claim submitted to Medicaid.”¹⁸

Likewise, the Louisiana Medicaid provider agreement, which physicians who prescribe Zyprexa to Louisiana Medicaid recipients must sign, states:

“I understand that services ... provided by me must be medically necessary and medically appropriate for each individual patient based on needs presented on the date of service,” and “I agree to maintain all records necessary for full disclosure of services provided to individuals under the program....”¹⁹

The portion of the Louisiana provider agreement that governs electronic submission of claims to the State’s claims database also requires providers to maintain and provide to the State, “upon

¹⁶ Mont. Admin. R. §37.85.414(1) (emphasis added); *see also* Mont. Admin. R. §37.85.410 (regarding determination of medical necessity by the Medicaid agency).

¹⁷ Montana General Information for Providers (Exhibit H).

¹⁸ Mississippi Provider Policy Manual §7.03 (Exhibit G).

¹⁹ Enrollment Packet for the Louisiana Medical Assistance Program (Exhibit F). *See also* La. Rev. Stat. §§ 46:437.11(b) & 437.12(2) (requiring providers to provide only medically necessary treatments and to “[m]aintain medical assistance programs-related records in a systematic and orderly manner that the department requires and determines are relevant to the goods, services, or supplies being provided”).

request, sufficient documentation to substantiate the scope and nature of services provided for those claims submitted and for which reimbursement is claimed.”²⁰

New Mexico’s Medicaid regulations also require that medical records for Medicaid recipients must “fully disclose the nature, quality, amount and medical necessity of services provided to recipients,” and “must be sufficiently detailed to substantiate the ... diagnosis, and medical necessity of any service.”²¹ The regulations define medically necessary treatments as “clinically appropriate to the specific physical, mental and behavioral health care needs of the individual.”²²

Connecticut, too, requires its providers to maintain “any original documentation ... necessary to fully disclose and document the medical necessity of and extent of goods or services provided to clients receiving assistance,” including “medical records[; and] original prescriptions for and records of all treatments, drugs and services ... including the authority for and the date of administration of such treatment, drugs, or services,” as well as “pertinent diagnostic information...; current and all prior treatment plans prepared by the provider; [and] pertinent treatment notes signed by the provider.”²³

Contrary to the States’ assertion that medical records of individual patients “have no relevance” to the States’ claims,²⁴ in fact it is widely accepted and acknowledged that review of medical records is an important component of any effort to determine whether claims paid by Medicaid (or any insurer) were medically necessary. Medical records are also essential to

²⁰ Enrollment Packet for the Louisiana Medical Assistance Program (Exhibit F).

²¹ N.M. Admin. Code §8.302.1.17; *see also* N.M. Stat. Ann. §27-11-4 (same); New Mexico Provider Participation Agreement §1.12 (same) (Exhibit I).

²² N.M. Admin. Code §8.302.1.7(A).

²³ Connecticut Provider Enrollment Agreement ¶¶6, 21-22 (Exhibit E); *see also* Conn. Agencies Regs. §17b-262-526(7)

²⁴ States’ Memorandum at 6.

evaluate the States' claims for increased treatment costs for diabetes and other alleged side effects of Zyprexa. Electronic claims data alone are not an adequate substitute for review of the underlying records, as explained in the attached affidavits of Beth A. Virnig, Ph.D., an epidemiologist and expert on the use and analysis of Medicaid claims data.²⁵ Examples of information missing from the claims data include:

- Claims data will not show whether patients were unsuccessfully treated with, or experienced intolerable side effects from, other medicines before taking Zyprexa, information relevant to whether Zyprexa prescriptions were "medically necessary."
- Claims data will not show whether patients gained weight while taking Zyprexa, which is the mechanism by which Zyprexa is alleged to cause diabetes.
- Claims data will not show predisposing factors such as family history, weight, diet, physical activity or history of blood-sugar-related conditions, information necessary to evaluate either an individual's or a population's risk of diabetes conditions.

As Connecticut's Director of Medical Care Administration testified in his deposition, it is normal for the State of Connecticut to look at medical records and talk to physicians when it investigates whether a medical treatment is medically necessary.²⁶ As another example, New Mexico's Medicaid regulations require the State to make its determinations of medical necessity by "evaluating individual physical, mental and behavioral health information provided by qualified professionals who have personally evaluated the individual" and "have taken into consideration the individual's clinical history."²⁷ Private-sector

²⁵ See Affidavit of Beth A. Virnig, Ph.D. (May 9, 2008) (Exhibit B); Affidavit of Beth A. Virnig, Ph.D. (Oct. 10, 2008) (Exhibit C). See also Sean Hennessy et al., *Medicaid Databases*, in PHARMACOEPIDEMOLOGY 281 (Brian L. Strom ed., 4th ed. 2005) (Exhibit D).

²⁶ Tr. of Dep. of David Parella, Sept. 22, 2008, at 143-46 (Exhibit J).

²⁷ N.M. Admin. Code §8.302.1.7(B).

insurers also review medical records to determine whether claims are medically necessary.²⁸ Moreover, despite what the States suggest, medical record review for this purpose is not limited to small-scale investigations and audits – in fact, the CMS is currently in the midst of a large review of medical records in many states, including each of the five states at issue here.²⁹ As part of this effort, known as the Payment Error Rate Measurement (PERM) program, CMS is reviewing randomly selected patient records from thousands of Medicaid providers to determine the medical necessity of the services for which payment was claimed, from which CMS then creates statistical models of the universe of claims from which its samples are drawn.³⁰ Lilly should be permitted access to the same types of evidence to defend against allegations that Zyprexa prescriptions were medically unnecessary, as CMS, Connecticut and the other four States routinely use to determine medical necessity in the ordinary course of their operations.

Although, as noted above, the specifics of medical record discovery are still being worked out by the parties and Magistrate Judge Mann, the following is a general description of

²⁸ See, e.g., *Lenox Hill Radiology v. Global Liberty Ins.*, 858 N.Y.S.2d 587, 590 (N.Y.C. Civ. Ct. 2008) (“the [health insurance] carrier is entitled to inquire as to the medical necessity before it pays the bills”); *Bottemiller ex rel. Bottemiller v. Gentle Dental Service Corp.*, 114 Wash. App. 1078, *3 (Wash. App. 2002) (noting “common knowledge among [physicians ...] that insurance companies would occasionally request medical records to verify medical necessity”); *Green v. Blue Cross & Blue Shield of Massachusetts*, 713 N.E.2d 992, 994 (Mass. App. 1999) (noting that defendant health insurer “determines medical necessity based on a review of the medical records describing the subscriber’s condition and treatment”); *Neurocare, Inc. v. Principal Life Ins. Co.*, 1999 WL 33221123 (N.D. Cal. 1999) (permitting suit to proceed against health insurer where insurer denied claim as medically unnecessary without conducting adequate review of patient’s medical history).

²⁹ See PERM 101 Handout, at 5-6 (Exhibit K); *Medicaid Program and State Children’s Health Insurance Program (SCHIP); Payment Error Rate Measurement*, 72 F.R. 50490, 50497-98 (Aug. 31, 2007).

³⁰ See PERM 101 Handout, at 5-6 (Exhibit K); *Medicaid Program*, 72 F.R. 50490, 50497-98 (Aug. 31, 2007); see also Exhibit L (containing representative notices from state Medicaid agencies to providers describing the PERM program and providers’ obligations to produce medical records to the contractors implementing the medical-record-review portion of the program).

how Lilly will use medical records it obtains in discovery. To respond to the States' broad claims, Lilly will obtain a sample of medical records large enough to investigate two main propositions. First, to show that Zyprexa prescriptions were medically necessary, and were based on the exercise of sound medical judgment about patients' medical needs. Second, to develop evidence of the prevalence of confounding risk factors for diabetes and other conditions allegedly caused by Zyprexa that are not captured in claims data, including family history and obesity, compared to other antipsychotic medications. There will be other propositions beyond these two broader propositions that Lilly is investigating as well, which would include for example, testing the reliability of the data base;³¹ and also examining more particularly whether alleged misrepresentations were actually made to physicians in the plaintiff-States, and whether they relied upon them.

For a study of randomly selected data to be capable of producing statistically significant results, the sample must be large enough to study the propositions at issue.³² How large the sample must be depends on the size of the overall population that the sample is being selected from, and the proposition being investigated.³³ It is important to emphasize that this is discovery that Lilly is seeking in anticipation, but without knowledge, of the proof the States may eventually muster. Lilly is not intending, nor should it be required, to set forth what studies or analyses it may conduct in advance of the States ever setting forth what their experts will proffer on their wide ranging claims, and before Lilly has the discovery. As Magistrate Judge Mann has noted, "the manner in which the states are going to prove the misrepresentations is –

³¹ Hennessy, at 281 (Exhibit D).

³² Virnig 10/10/08 Aff., ¶C.2 (Exhibit C).

³³ *Id.*, ¶C.1.

and what the damages are – how the damages are going to be calculated, that’s still unclear to me, to Judge Weinstein, [and] to Lilly.”³⁴

Further, medical records that are not randomly selected or supportive of statistically significant results will also be probative and relevant, including for use in prescriber depositions, for illustrative purposes and for cross examination of the States’ witnesses. For example, medical records will be useful to cross-examine witnesses who testify that all Zyprexa claims were “false” or medically unnecessary.

B. Privilege

Magistrate Judge Mann correctly held that state physician-patient privilege laws “pose no obstacle” to discovery of de-identified medical records in these cases.³⁵ Nothing in Magistrate Judge Mann’s determination of this issue was clearly erroneous, and the Court should allow her ruling to stand.

As between State Medicaid agencies and individual providers, there appears no dispute that state privilege laws are no obstacle to collection and review of individual medical records. As illustrated by CMS’ ongoing PERM program discussed above and as discussed in Section III.C.1 below, CMS and State Medicaid agencies, like health insurers generally, have the right to review and collect copies of the medical records of individual Medicaid recipients. The only issue is whether, having collected medical records from providers, the State Medicaid agencies may then produce those records to Lilly. For the reasons stated in Magistrate Judge Mann’s opinion and discussed below, there is no reason the States’ may not produce de-identified patient records to Lilly.

³⁴ Tr. of Hr’g before Judge Mann on Sept. 16, 2008 at 94.

³⁵ Order at 4.

1. State privilege laws do not apply to these federal cases.

As this Court has repeatedly held, these are federal-question cases.³⁶ It is, as Magistrate Judge Mann noted, “axiomatic” that federal law – not state law – governs questions of privilege in federal-question cases.³⁷ “Rule 501 of the Federal Rules of Evidence provides that federal common law governs questions of privilege in cases involving federal question jurisdiction, while state law governs in other instances.”³⁸ In federal cases that also include state-law claims, “courts consistently have held that the asserted privileges are governed by the privileges of federal law.”³⁹ The Congressional policy behind the rule that ““in nondiversity jurisdiction civil cases, federal privilege law will generally apply”” is to promote consistency in cases where significant federal interests are at stake.⁴⁰ Application of state privilege law “to nondiversity and federal question civil cases where the interests of the United States are at stake” has been described as “erroneous.”⁴¹

As this Court has previously found, these cases present “an unavoidable central and disputed federal issue” that involves “not simply a federal standard, but also the added factor

³⁶ *E.g., Montana ex rel. McGrath v. Eli Lilly & Co.*, 2008 WL 398378, at *3 (E.D.N.Y. 2008) (quoting *West Virginia ex. rel McGraw v. Eli Lilly and Co.*, 476 F. Supp. 2d 230, 233 (E.D.N.Y. 2007)).

³⁷ *See* Order at 4.

³⁸ *Gragg v. Int'l Mgmt. Group (UK), Inc.*, No. 5:03-CV-0904, 2007 U.S. Dist. LEXIS 25780, at *16 (N.D.N.Y. April 5, 2007); *see also, e.g., United States v. The Louisiana Clinic*, 2002 WL 31819130, *2 (E.D.La. 2002) (“Rule 501 makes it clear that state privilege law will apply in diversity cases, and that federal privilege law will apply in federal question cases.”); *Nesselrotte v. Allegheny Energy, Inc.*, No. 06-01390, 2008 U.S. Dist. LEXIS 55730, at *20 (W.D. Pa. July 22, 2008) (“Because this Court has federal question jurisdiction over the instant matter, federal law controls as to the attorney client privilege.”); *Bondi v. Grant Thornton Int'l*, No. 04 Civ. 9771, 2006 U.S. Dist. LEXIS 44795, at *6-7 (S.D.N.Y. June 30, 2006).

³⁹ *Von Bulow v. Von Bulow*, 111 F.2d 136, 141 (2d Cir. 1987).

⁴⁰ *Gannet v. First Nat'l State Bank*, 546 F.2d 1072, 1076 (3d Cir. 1976) (quoting Conference Committee Notes to Fed. R. Evid. 501 (House Report No. 93-1597 on P.L. 53-595)) (applying federal law of privilege where jurisdiction was not based on diversity).

⁴¹ *Menses v. United States Postal Serv.*, 942 F. Supp. 1320, 1323 (D. Nev. 1996).

of an intricate federal regulatory scheme, including detailed federal funding provisions, requiring some degree of national uniformity in interpretation.”⁴² Application of a uniform federal rule as to privilege in these cases is exactly the kind of “national uniformity” that is desirable in these cases. The federal interests that favor a uniform privilege law are no weaker because federal-question jurisdiction over these cases is supported by *Grable* (Connecticut’s suit also includes a RICO claim). On the contrary, the federal interest in a uniform physician-patient privilege law in Medicaid fraud cases is so strong that even *state courts* presiding over Medicaid fraud cases have held that the federal interest overrides state physician-patient privileges. To the extent the state privilege laws the States rely on have any applicability to disclosure of medical records by the States pursuant to court order (as opposed to regulating voluntary disclosure by health care providers), they “must yield to the Medicaid disclosure requirements.”⁴³ “[T]he matter of physician-patient privilege simply does not arise under these circumstances.”⁴⁴

Because there is no physician-patient privilege under federal law, discovery of medical records in these cases is governed solely by HIPAA, which provides ample protection for confidential patient information, particularly when combined with the additional (and, strictly speaking, unnecessary) safeguard of de-identification required by Magistrate Judge Mann’s Order.⁴⁵

⁴² *Montana, ex rel. Mike McGrath v. Eli Lilly & Co.*, 2008 WL 398378, at *3 (E.D.N.Y. 2008) (quoting *West Virginia ex. rel McGraw, Jr. v. Eli Lilly & Co.*, 476 F.Supp. 2d 230, 233 (E.D.N.Y. 2007)).

⁴³ *Brillantes v. Superior Court of Los Angeles*, 51 Cal. App. 4th 323, 337 (Cal. App. 1996).

⁴⁴ *In re Search Warrant for 2045 Franklin, Denver, Colorado*, 709 P.2d 597, 601 (Colo. App. 1985).

⁴⁵ *See, e.g., United States v. The Louisiana Clinic*, 2002 WL 31819130, *5-*6 (E.D.La. 2002) (ordering production of unredacted patient records in Medicaid false claims case and holding that HIPAA preempted Louisiana doctor-patient privilege laws); *Sunrise Opportunities, Inc. v. Regier*, 2006 WL 581150, *8 (N.D. Ill. 2006) (ordering production of patient-identifiable

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2. Even if State privilege laws applied, redaction of identifying information resolves any obstacle posed by State privilege laws.

Even assuming that state privilege laws did apply to these federal-question cases, Magistrate Judge Mann’s Order analyzed the relevant state case law, and correctly concluded that de-identification of medical records would solve any obstacles posed by state privilege laws.⁴⁶ Nothing in the States’ submissions – much of which fail to acknowledge the difference between identifiable and de-identified patient information – undermines the careful, thorough legal analysis in her Order, let alone demonstrates clear error. Accordingly, rather than repeat here the points made in Magistrate Judge Mann’s Order, Lilly simply notes that the Order stands on its own merits and should be affirmed on this point.

C. Mechanism for Production

1. Medical records are discoverable under Rule 34 as documents within the control of the States.

Although the States complain that it will be difficult for them to collect medical records from providers within the deadlines set by Magistrate Judge Mann, they do not appear to seriously dispute the basic premise that medical records of Medicaid recipients are under their control for purposes of Fed. R. Civ. P. 34. Nor could they, as the law on this issue is clear. A

(continued...)

records of Medicaid recipients “in unredacted form” under the protection of a HIPAA-compliant protective order).

⁴⁶ Although as Magistrate Judge Mann’s Order noted, the outcome would be the same “even in the absence of HIPAA preemption,” *id.* at 10, Lilly notes that Magistrate Judge Mann’s finding of HIPAA preemption is also supported by case law not cited in her order. *See, e.g., United States v. The Louisiana Clinic*, 2002 WL 31819130, *4-*5 (E.D.La. 2002) (finding that HIPAA preempts all contrary state law concerning disclosure of patient records “*unless* the contrary state law [both (1)] ‘relates to the privacy of individually identifiable health information’ and [(2)] is ‘more stringent’ than HIPAA’s requirements.”) (italics in original).

document is within a party's "control" for purposes of Rule 34 if the party "has the legal right to obtain the documents on demand."⁴⁷

Federal law requires States to maintain full access to all records of services rendered to Medicaid participants, including all records necessary to determine "the extent of the services provided to individuals receiving assistance" and records needed for "claims against ... third parties...."⁴⁸ "On request," health care providers must "furnish [these records] to the Medicaid agency...."⁴⁹ State statutes, regulations, provider agreements and policy manuals also implement this federal requirement, mandating that individual providers must promptly forward medical records to the States upon request.⁵⁰

⁴⁷ *In re Bankers Trust Co.*, 61 F.3d 465, 469 (6th Cir. 1995) ("[D]ocuments are deemed to be within the "possession, custody or control" for purposes of Rule 34 if the party has *actual* possession, custody or control, or has the legal right to obtain the documents on demand."); *see also, e.g., In re NTL, Inc. Sec. Litig.*, 244 F.R.D. 179, 195 (S.D.N.Y. 2007) (same).

⁴⁸ 42 U.S.C. §§ 1936a(a)(25), 1396a(a)(27).

⁴⁹ 42 C.F.R. §431.107(b)(2); *see also* 42 U.S.C. §1396a(a)(27). *See also* Reply By Eli Lilly and Company to Plaintiffs' Memorandum Regarding Requested Discovery and Proposed Schedule, at pp. 9-10 (filed May 14, 2008).

⁵⁰ **Connecticut:** *See* Connecticut Provider Enrollment Agreement (Exhibit E) (requiring disclosure of records to State "upon request"); Conn. Agencies Reg. § 17b-262-526(7)-(8) (same). **Louisiana:** *See* La. Rev. Stat. §46:437.12(5) (requiring providers to "[p]ermit the department ... access to all medical assistance programs-related records..., including access to all patient records and other health care provider information if the health care provider cannot easily separate records for recipients from other records."); Enrollment Packet for the Louisiana Medical Assistance Program (Exhibit F) (same). **Mississippi:** *See* Mississippi Provider Policy Manual §7.03 (specifying that the Medicaid agency "shall have immediate access to the provider's ... records, documents, books, prescriptions, invoices, radiographs, and any other records relating to ... medical care, and services rendered to beneficiaries") (Exhibit G); Miss. Code §43-13-118(provider records are "subject to audit by the division"). **Montana:** *See* Mont. Admin. R. §37.85.410(4) ("The provider must upon request provide to the department or its designated review organization without charge any records related to services or items provided to a recipient."); Mont. Admin. R. §37.85.414(2) & (3)(a) (same); Montana General Information for Providers (Exhibit H) (same). **New Mexico:** *See* New Mexico Provider Participation Agreement ¶1.14 (requiring providers to "[f]urnish immediately to the Medicaid Agency ..., at no cost, access to records in any format requested.... If records are requested by mail, the provider shall furnish the records within five (5) working days....") (Exhibit I); N.M. Stat. Ann.

(continued...)

To the extent the States argue in their briefing and affidavits that they do not have a right to obtain patient medical records from their Medicaid providers on demand, they are mistaken and/or in violation of their obligations under federal law.⁵¹ As David Parella of the Connecticut Medicaid agency conceded in his deposition,⁵² and as is amply demonstrated by the ongoing, large-scale collection of medical records in conjunction with the CMS' PERM program, States have the legal right to demand medical records, and they in fact exercise that right.

2. Medical record discovery will not unduly burden the States.

The States argue that Magistrate Judge Mann failed to give adequate consideration to the burden on the States of producing medical records. This argument rings hollow, for several reasons.

First, the States fail to acknowledge that Lilly, not the States, will bear the cost of copying and redacting the medical records it seeks, as Magistrate Judge Mann noted in her

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§27-11-3(A) (same); N.M. Stat. Ann. §27-11-4 (requiring providers to provide records “within two business days”).

⁵¹ For example, Montana submitted a declaration from Dan Peterson of its Medicaid agency which claimed that Montana could not obtain Medicaid medical records from providers who challenged the State's right to the records. *See* Declaration of Dan Peterson (Exhibit D to States' Memorandum, MDL Doc #1905) (citing Mont. Code Ann. §50-16-535). By its own terms, the statute Mr. Peterson cites is inapplicable where a court has ordered production of medical records in discovery, Mont. Code Ann. §50-16-535(j), and in any event the more specific requirements of Mont. Admin. R. §37.85.410(4) and .414 make clear that providers must provide medical records to the Medicaid agency “without the written consent of the recipient or applicant.” §37.85.414(2). The statements in Mr. Peterson's declaration are also at odds with Montana's own notice to its providers advising them of the need to cooperate with contractors collecting medical records for the PERM program and assuring providers that disclosure of “the requested medical records is required by the Social Security Act and is permissible by HIPAA.” (Exhibit L, also available at <http://medicaidprovider.hhs.mt.gov/pdf/allproviders081208.pdf>).

⁵² Tr. of Dep. of David Parella, Sept. 22, 2008, at 143-46 (Exhibit J).

Order.⁵³ Second, to the extent the States fault Magistrate Mann for not considering the assertions in their recently-submitted affidavits, they have no one to blame but themselves, as there was no reason they could not have submitted such affidavits to Magistrate Judge Mann in the first instance, rather than waiting to submit them until after she issued her Order.

Moreover, the assertions in the States' affidavits are not persuasive, in any event. As an initial matter, the States' claims that providers will resist performing their legal and contractual obligation to turn over medical records to the States is simply speculation, and it is belied by the high degree of compliance providers have shown in other, similar medical-record-collection efforts. In the PERM medical record collection effort, for example, providers are given 90 days to produce the requested records, but, according to CMS, "experience has shown that our provider response rate is excellent, and that most providers submit records within 30 days of the original request. Therefore, we do not believe the timeframe should be extended...."⁵⁴

In contrast to the orderly collection procedure required by Magistrate Judge Mann's Order, the States' preferred method – requiring Lilly to issue large numbers of third-party subpoenas directly to providers – is almost guaranteed to result in satellite proceedings that will waste time and money, bog down the process, and ultimately prove more burdensome,

⁵³ Order at 19 n.12.

⁵⁴ *Medicaid Program*, 72 F.R. 50490, 50497 (Aug. 31, 2007) (emphasis added). Notably, the States have previously submitted similar affidavits protesting that other discovery sought by Lilly would take months or even years to complete – and then produced the discovery in days or weeks when faced with a hard court deadline. For example, West Virginia originally asserted that the production of its Medicaid data was overly burdensome and would take over 2,000 hours. *See* Affidavit of Marsha K. Morris, filed June 28, 2008, at ¶ 6. It also asserted that review of relevant documents would take 12-14 months. *Id.* at ¶ 7. Yet in light of the Court's Sept. 16th order, the State managed to produce both Medicaid data and approximately 4,000 pages of documents on September 25th. Similarly, at the Sept. 16th hearing, counsel for New Mexico asserted that it would take "weeks" to comply with its discovery obligations, a significant portion of which was completed much faster once the Court set a tighter deadline.

expensive and distracting for providers. If, as the States claim, they are concerned about the effect of medical record discovery on provider relations, it makes little sense for the States to advocate a contested third-party subpoena process rather than the streamlined procedure Magistrate Judge Mann ordered, which is similar to the PERM process that has already been shown to work smoothly.

Ultimately, however, some amount of discovery from, and intrusion upon, providers is an inevitable consequence of the very nature of the States' claims, which implicitly accuse prescribers of being either dupes or knowingly complicit in the submission of false claims to the Medicaid program. Unlike the States, Lilly believes that doctors who prescribed Zyrpexa to Medicaid recipients did so on the basis of expert, informed professional judgment, and Lilly is entitled to the discovery necessary to demonstrate that. The medical record discovery ordered by Magistrate Judge Mann is reasonably tailored to balance Lilly's legitimate discovery needs against the burdens imposed on prescribers and State Medicaid agencies.

D. Denial of medical record discovery would prejudice Lilly's defense.

As a matter of due process, the States may not prosecute Medicaid fraud claims against Lilly on the ground that Lilly caused Zyrpexa prescriptions to be written for medically unnecessary uses, without allowing Lilly access to medical records that, under the States' own regulations, document the medical necessity of each Zyrpexa prescription that was reimbursed by the States. Denial of medical record discovery would deprive Lilly of a "meaningful opportunity to establish the facts necessary to support" its defenses, and would result in discovery "so limited as to affect [Lilly]'s substantial rights."⁵⁵ "It is beyond question that

⁵⁵ *In re Agent Orange Prod. Liab. Litig.*, 517 F.3d 76, 103 (2d Cir. 2008).

defendant is entitled to discovery of the facts upon which plaintiff's claim of fraud is founded."⁵⁶ The pleading and discovery tools that require a fraud plaintiff to provide the defendant with the specific facts underlying a fraud claim are designed as "due process safeguards."⁵⁷ Where a defendant's due process right of access to crucial evidence collides with a privilege, either the privilege or the plaintiff's claims must yield. "[I]f the privilege deprives the defendant of information that would otherwise give the defendant a valid defense to the claim, then the court may grant summary judgment to the defendant."⁵⁸ These principles require that Lilly be allowed to develop the evidence from medical records necessary for its defense.

IV. CONCLUSION

Because nothing in Magistrate Judge Mann's Order is clearly erroneous, the Court should deny the States' objections to the Order.

⁵⁶ *Cornaglia v. Ricciardi*, 63 F.R.D. 416, 419 (E.D. Pa. 1974).

⁵⁷ *Ingalls Shipbuilding, Inc. v. United States*, 13 Cl. Ct. 757, 768 (Cl. Ct. 1987), *rev'd on other grounds*, 857 F.2d 1448, 1452 (Fed. Cir. 1988) (reversing discovery sanction but endorsing lower court's determination that fraud defendant "was entitled to have ... information" regarding specific facts underlying alleged fraud).

⁵⁸ *Kasza v. Browner*, 133 F.3d 1159, 1166 (9th Cir. 1998); *see also, e.g., El-Masri v. United States*, 479 F.3d 296, 309 (4th Cir. 2007) (affirming dismissal of plaintiff's suit where "the defendants could not properly defend themselves without using privileged evidence"); *Tenenbaum v. Simonini*, 372 F.3d 776, 777-78 (6th Cir. 2004) (same).

Respectfully submitted,

A handwritten signature in red ink that reads "Anthony Vale". The signature is written in a cursive style with a long, sweeping tail on the letter "e".

October 14, 2008

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Index of Exhibits

- Exhibit A Defendant Eli Lilly and Company's Second Status Report Regarding Medical Records and Physician Discovery (filed Oct. 10, 2008).
- Exhibit B Affidavit of Beth A. Virnig, Ph.D. (May 9, 2008).
- Exhibit C Affidavit of Beth A. Virnig, Ph.D. (October 10, 2008).
- Exhibit D Sean Hennessy et al., *Medicaid Databases*, in PHARMACOEPIDEMOLOGY 281 (Brian L. Strom ed., 4th ed. 2005).
- Exhibit E Connecticut Provider Enrollment Agreement (pertinent excerpts).
- Exhibit F Enrollment Packet for the Louisiana Medical Assistance Program (pertinent excerpts).
- Exhibit G Mississippi Provider Policy Manual §7.03.
- Exhibit H Montana General Information for Providers (pertinent excerpts).
- Exhibit I New Mexico Provider Participation Agreement.
- Exhibit J Excerpts from Transcript of Dep. of David Parella (Sep. 22, 2008).
- Exhibit K Centers for Medicare and Medicaid Services, *PERM 101 Handout* (also available at www.cms.hhs.gov/PERM/Downloads/PERM101Handout.pdf).
- Exhibit L Representative copies of notices from state Medicaid agencies to providers describing the PERM program and providers' obligations to produce medical records to the contractors implementing the medical-record-review portion of the program.

CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2008, I caused a true and correct copy of the foregoing **Eli Lilly's Opposition To Plaintiffs' Objections To Magistrate Judge Mann's September 24, 2008 Order Regarding Discovery Of Medical Records** to be served via ECF notification on the following counsel:

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