UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

MEMORANDUM, ORDER & JUDGMENT

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In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MD-1596

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CECILIA GUILLLEN *in:*

TYNESHA BELCHER,

Plaintiff,

06-CV-2782

-against-

ELI LILLY & COMPANY,

Defendant.

---x

JACK B.WEINSTEIN, Senior United States District Judge:

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I. Introduction

Defendant Eli Lilly & Company ("Lilly") moves for summary judgment against Cecilia Guillen. Plaintiff commenced this action against Lilly in the Southern District of California on February 28, 2006. The case was transferred to the Eastern District of New York pursuant to an order of the Judicial Panel on Multidistrict Litigation.

The action is essentially a negligence claim, based on a failure to warn of deleterious secondary effects of Lilly's drug Zyprexa. Plaintiff Guillen seeks money damages for injuries, alleging that: (1) Zyprexa caused or exacerbated her diabetes and other conditions; (2) Lilly failed to warn of the dangers of Zyprexa; and (3) Zyprexa would not have been prescribed, and injuries would not have been suffered, if proper warnings had been given.

For the reasons detailed below, defendant's motion for summary judgment is granted. The California statute of limitations bars recovery; plaintiff's diabetes pre-dated her use of Zyprexa; there is no evidence that diabetes was aggravated by Zyprexa; there is no evidence that plaintiff's other conditions resulted from Zyprexa; and she cannot demonstrate that an alternative warning would have changed the prescribing decisions of her doctors.

II. History of Zyprexa Litigation

This massive and highly complex multidistrict litigation has included claims brought by individual Zyprexa users, states, third-party payors, and other entities alleging physical or

financial injury. Some 30,000 cases have been brought against Lilly by individual plaintiffs suffering from serious psychiatric problems who were treated with the Lilly antipsychotic drug Zyprexa. They principally allege that Zyprexa caused deleterious side effects of excessive weight gain, hyperglycemia, and diabetes; that Lilly misled them and their physicians about the likelihood of these side effects; and that, had they or their attending physicians been aware of the risks, they would not have taken Zyprexa.

Litigation against Lilly for injuries allegedly caused by Zyprexa was initiated in this court in March 2004. *See Benjamin v. Eli Lilly & Co.*, No. 04-CV-893 (E.D.N.Y. filed March 3, 2004). Thousands of cases were then transferred here from federal district courts throughout the United States pursuant to an order of the Judicial Panel on Multidistrict Litigation ("MDL"). *See* Letter from Multidistrict Litigation Panel to Clerk of the Eastern District of New York, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, Docket Entry No. 1 (E.D.N.Y. Apr. 14, 2004). Similar cases have been litigated in state courts, *see In re Zyprexa Prods. Liab. Litig.*, 239 F.R.D. 316 (E.D.N.Y. 2007) (Communication to State Judges on Cooperation Between Federal and State Judges); many of them were removed to federal courts and then transferred to this court.

The individual Zyprexa user litigation has been administered as a quasi-class action. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) ("The court, magistrate judge and special masters will continue to administer this litigation as a quasi-class action."); *In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458, 477 (E.D.N.Y. 2006) ("Recognizing its obligation to exercise careful oversight of this national 'quasi-class action,' the court has already utilized its equitable power to limit attorneys' fees and costs.") (citation omitted); *In re Zyprexa Prods. Liab. Litig.*, 433 F. Supp. 2d 268, 271 (E.D.N.Y. 2006) (finding

that individual Zyprexa user litigation "may be characterized properly as a quasi-class action subject to the general equitable power of the court"); *In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488, 491 (E.D.N.Y. 2006) (same); *In re Zyprexa Prods. Liab. Litig.*, 233 F.R.D. 122, 122 (E.D.N.Y. 2006) (same).

Cooperation between federal and state courts has been encouraged at all stages of the *Zyprexa* litigation. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 262 (E.D.N.Y. 2006) ("Cooperation with state courts will continue to be stressed."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 898105, at *1 (E.D.N.Y. Apr. 6, 2006) ("Coordination and cooperation between state and federal courts has been encouraged."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 197151 (E.D.N.Y. Jan. 26, 2006) (letter to state judges with Zyprexa cases suggesting coordination and cooperation); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2004 WL 3520248, at *4 (E.D.N.Y. Aug. 18, 2004) (directing defendant Lilly and Plaintiffs' Steering Committee I to "confer regarding procedures for coordination of state-court discovery with discovery in this [multidistrict litigation]").

A national system for resolving Medicare and Medicaid liens was approved. *See In re Zyprexa Prods. Liab. Litig.*, 451 F. Supp. 2d 458 (E.D.N.Y. 2006). All states and the federal government agreed to modify their lien demands to provide a national equitable system. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263, at *1 (E.D.N.Y. Dec. 4, 2006) ("In compliance with this court's instructions . . . all fifty states as well as the federal government have resolved their Medicare and Medicaid liens." (citation omitted)).

On April 16, 2004, a class action was filed on behalf of individuals claiming personal injury based on, among other claims, Lilly's failure to provide an adequate warning about the

risks of Zyprexa. *See Ortiz v. Eli Lilly & Co.*, No. 04-CV-1587 (E.D.N.Y.). A second and substantially similar class action was filed in this court on May 19, 2004. *See Tringali v. Eli Lilly & Co.*, No. 04-CV-2104 (E.D.N.Y.). On September 15, 2004, Lilly and plaintiffs' counsel in the two putative class actions entered into an agreement to execute stipulations of dismissal, with the effective date of dismissal to be November 1, 2004, or 167 days after the *Ortiz* action was filed. *See* Joint Memorandum of the Parties Regarding Stipulation of Voluntary Dismissal of Certain Claims, *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, Docket Entry No. 80-2 (E.D.N.Y. Sept. 15, 2004).

Discovery and negotiations were overseen in part by a court-appointed special discovery master and four special settlement masters. In November 2005, Lilly, without conceding liability, entered into a settlement covering some 8,000 individual plaintiffs. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2005 WL 3117302 (E.D.N.Y. Nov. 22, 2005). The settlement resolved virtually all cases then pending in the MDL, along with some state cases. *See id.*

An attorneys' fee structure for the individual cases was ordered, capping fees at 20% of recovery in smaller, lump-sum claims, and at 35% of recovery in other claims. *See In re Zyprexa Prods. Liab. Litig.*, 424 F. Supp. 2d 488 (E.D.N.Y. 2006). Costs related to the individual cases and charged to individual settling plaintiffs were limited. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443248 (E.D.N.Y. Aug. 24, 2006). Counsel for some 2,000 individual plaintiffs filed an appeal of an order capping fees, *see In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 2340789 (E.D.N.Y. Aug. 17, 2007), which is now pending before the Court of Appeals for the Second Circuit. The magistrate judge allocated funds from a

first common benefit fund after reviewing the first Plaintiffs' Steering Committee's ("PSC I") applications. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 805793 (E.D.N.Y. Mar. 15, 2007). Payments have been substantially completed for PSC I.

Following an influx of thousands of new cases, in January 2007 the parties announced another round of settlements, which are nearing completion. A second common benefit fund was established to compensate members of a second PSC for their work. *See In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d at 262.

Four motions for summary judgment by Lilly in individual Zyprexa cases were decided in June 2007. Three of those motions were denied and one was granted based on application of the statute of limitations, which barred that plaintiff's claim. *See Souther, et al. v. Eli Lilly & Co.*, 489 F. Supp. 2d 230 (E.D.N.Y. 2007).

A class action has been brought on behalf of third-party payor institutional plaintiffs, including pension funds, labor unions, and insurance companies that cover their members' health benefits; they have made outlays for Zyprexa prescriptions. Mail fraud under the Racketeer Influenced and Corrupt Organizations Act ("RICO") is alleged, *see* 18 U.S.C. § 1964, predicated on overpricing supported by excessive claims of utility as well as disavowal of adverse secondary effects of the drug, primarily weight gain and diabetes. That class has been certified. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. 69, 201 (E.D.N.Y. 2008). The certification decision is currently on appeal before the Court of Appeals for the Second Circuit. Individual plaintiffs who bought, or paid a portion of the purchase price for, Zyprexa for their own use also sought class action status on a similar theory. Certification of this individual payor class action was denied. *See id.* at 201-02.

Many state attorneys general have sued on behalf of their states' citizens seeking reimbursement for overpayments for Zyprexa made with state and federal funds via state Medicaid programs and other remedies based upon state law grounds. Currently pending in this court are actions on behalf of the citizens of several states. A putative *qui tam* action by a whistleblower representing California was dismissed. Order, *California ex rel. Jaydeen Vincente v. Eli Lilly & Co.*, No. 08-CV-600, Docket Entry No. 84 (E.D.N.Y. Apr. 23, 2008). Most state attorney general cases have been settled.

In March 2008, Lilly settled with the State of Alaska during a trial on Zyprexa-related claims. *See* Alex Berenson, *Alaska Suit Against Lilly Is Settled*, N.Y. Times, Mar. 27, 2008, at C1. That State's lawsuit sought reimbursement for the medical costs of Alaska Medicaid patients who developed diabetes while taking Zyprexa; the State's claim to recover costs associated with Lilly's off-label promotion of Zyprexa was dismissed before trial. *See* Alex Berenson, *Lilly Executive Discussed Off-Label Uses for Drug*, N.Y. Times, Mar. 15, 2008, at C1. Some of the materials introduced in that trial are available as part of the public record. Other *Zyprexa* settlements have followed. *See, e.g.,* Alex Berenson, *33 States to Get $62 Million in Zyprexa Case Settlement*, N.Y. Times, Oct. 7, 2008, at B7.

Some of Lilly's shareholders have filed suit because of the decline in share price. *See In re Eli Lilly & Co. Sec. Litig.*, No. 07-CV-1310 (E.D.N.Y.). This litigation has been dismissed on statute of limitations grounds. *See In re Zyprexa Prods. Liab. Litig.*, 549 F. Supp. 2d 496 (E.D.N.Y. 2008).

Current shareholders have sued in this court in the form of three separate shareholder derivative actions. *See Waldman v. Taurel*, No. 08-CV-560 (E.D.N.Y.); *City of Taylor*

Employees Retirement System v. Taurel, No. 08-CV-1554 (E.D.N.Y.); *Robins v. Taurel*, No. 08-CV-1471 (E.D.N.Y.). Similar cases are pending in other courts. Settlement negotiations are ongoing.

Additional cases transferred as part of the multidistrict litigation or commenced in this district are being managed by a special master, who is tracking settlements, setting timelines for discovery and the adjudication of dispositive motions, and scheduling trial dates. *See* Case Management Order No. 32, *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, Docket Entry No. 2072 (E.D.N.Y. Mar. 3, 2009). Individual actions originating in the Eastern District of New York have been placed on an expedited discovery and motion schedule so that trial on those actions may, if necessary, move forward without undue delay. Many cases originally set for trial in this court have been settled or withdrawn.

The court has ruled on *Daubert* motions challenging proposed expert testimony in a number of cases. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1357236 (E.D.N.Y. May 12, 2009) (ordering the exclusion of plaintiffs' proposed expert testimony in twenty cases); *see In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322286 (E.D.N.Y. May 12, 2009) (approving plaintiffs' proposed expert testimony in two cases); *In re Zyprexa Prods. Liab. Litig.*, 04-MD-1596, 2009 WL 1322292 (E.D.N.Y. May 12, 2009) (approving defendant's proposed expert testimony); *Souther*, 489 F. Supp. 2d at 281-91 (denying plaintiffs' and defendant's *Daubert* motions to exclude expert testimony).

A series of summary judgment motions by Lilly in individual Zyprexa user actions have been decided and others are pending. *See, e.g., Souther*. In the most recent series of motions, summary judgment has been granted against individual plaintiffs. *See, e.g., Eric Fuller v. Eli*

Lilly & Co., No. 06-CV-2782, 2009 WL 2485829 (E.D.N.Y. July 31, 2009). Several individual plaintiffs have appealed the grant of summary judgment. Review of those cases is pending before the Court of Appeals for the Second Circuit. Summary judgment has been denied with respect to other individual plaintiffs. *See Arlene Earl v. Eli Lilly & Co.*, --- F.Supp.2d ---, No. 07-CV-3912, 2009 WL 2762170 (E.D.N.Y. Aug. 28, 2009), *mot. for recons. denied*, Docket Entry No. 27 (E.D.N.Y. Oct. 14, 2009); *Venica Pruett v. Eli Lilly & Co.*, No. 07-CV-1931, 2009 WL 2245068 (E.D.N.Y. July 22, 2009).

III. Facts

A. Contents and Use of Zyprexa

Zyprexa's active ingredient is olanzapine, one of a class of medications known as "atypical" or "second generation" antipsychotics. It was approved for use in treating schizophrenia and acute manic episodes associated with bipolar disorder by the United States Food and Drug Administration ("FDA") in 1996. In 2004, the FDA also approved Zyprexa for the treatment of bipolar disorder generally.

B. Labeling and Warnings to Patients and Medical Professionals

1. FDA Labeling and "Dear Doctor Letter"

The original 1996 Zyprexa package insert accompanying the drug disclosed information about possible side effects of administration of olanzapine based on clinical trials. The insert provided, in part, the following information:

> Adverse Events Occurring at an Incidence of 1% or More Among Olanzapine-Treated Patients in Short-Term, Placebo-Controlled Trials - - Table 1 enumerates the incidence, rounded to the nearest percent, of treatment-emergent adverse events that occurred during acute therapy (up to 6 weeks) of schizophrenia in 1% or more of patients treated with olanzapine (doses ≥ 2.5 mg/day) where the

> incidence in patients treated with olanzapine was greater than the incidence in placebo-treated patients.
>
> The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses, and investigators. The cited figures, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the population studies.

Zyprexa Package Insert, Oct. 1, 1996, at 11 (emphasis in original).

Two tables in the insert provided the results of placebo-controlled clinical studies of olanzapine-treated patients. The data indicates that, over a six-week administration of Zyprexa, six percent of olanzapine-treated patients reported weight gain, while only one percent of the placebo-treated patients reported weight gain. *Id.* at 12-16.

For several years, this information on the insert remained substantially the same insofar as it provided physicians information on reported weight-gain-related adverse events. During this period, the results of longer-term studies and clinical experience with Zyprexa and competing drugs supporting weight gain, hyperglycemia, and diabetes became widely known. *See* Part III.B.4, *infra*.

In May 2000, the FDA undertook an analysis of the incidence of diabetes and hyperglycemia in patients using atypical antipsychotics. The director of the FDA's Division of Neuropharmalogical Drug Products requested additional safety information about Zyprexa from Lilly. In its letter, the FDA cited post-marketing reports of diabetes-related adverse events associated with Zyprexa use. In response, Lilly provided the FDA with clinical studies, data analysis, and case report reviews. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 119.

There is disagreement about whether the information given by Lilly to the FDA was complete and accurate.

On September 11, 2003, the FDA announced it would require a warning about risks of hyperglycemia and diabetes mellitus and treating precautions to appear in the package insert of all atypical antipsychotics, including Zyprexa. Designed for prescribing doctors, the label noted that epidemiological studies and other information indicated that the relationship between the drug and hyperglycemia and diabetes was not yet fully understood. It reads as follows:

> **WARNINGS**
> **Hyperglycemia and Diabetes Mellitus**
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersomolar coma or death has been reported in patients treated with atypical antipsychotics including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. . . .
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. . . .

Letter from Russell Katz, M.D., Dep't of Health & Human Servs., to Gregory T. Brophy, Ph.D., Eli Lilly & Co., Sept. 11, 2003, at 1-2. The label did not mention weight gain or diabetes in the "warning to patients" section.

Lilly added the FDA-required language to the Zyprexa label on September 16, 2003. *See* Zyprexa Package Insert, Sept. 16, 2003. At the FDA's request, on March 1, 2004, it sent a "Dear Doctor" letter to physicians in the United States informing them of the 2003 label change. *See In re Zyprexa Prods. Liab. Litig.*, 253 F.R.D. at 134-36.

2. Consensus Statement of American Diabetes Association and Other Learned Groups

In November 2003, the American Diabetes Association, American Psychiatric Association, American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity convened a consensus development conference (the "ADA consensus conference") on the subject of the association between antipsychotic drugs and diabetes. An eight-member panel heard presentations from fourteen experts drawn from the fields of psychiatry, obesity, and diabetes, FDA representatives, and atypical antipsychotic drug manufacturers. The panel reviewed the relevant peer-reviewed English language scientific articles.

The ADA consensus conference concluded that Zyprexa and Clozaril posed an increased risk of diabetes as compared to other atypical antipsychotic drugs. The consensus statement produced by the conference declared that these relative risks as well as advantages of the drugs for individual patients in a heterogeneous population "should . . . influence drug choice." In part, its report concluded:

There is considerable evidence, particularly in patients with schizophrenia, that treatment with [atypical antipsychotics] can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after 1 year of treatment. There is, however, considerable variability in weight gain among the various [atypical antipsychotics] . . . .

***

Clozapine [Clozaril] and olanzapine [Zyprexa] . . . produce the greatest weight gain.

***

Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine [Clozaril] or olanzapine [Zyprexa] compared with patients not receiving treatment with [first generation antipsychotics] or with other [atypical antipsychotics]. The risk in patients taking risperidone and quetiapine is less clear; some studies show an increased risk for diabetes, while others do not. The two most recently approved [atypical antipsychotics], aripiprazole and ziprasidone, have relatively limited epidemiological data, but available clinical trial experience with these drugs has not shown an increased risk for diabetes.

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[T]he risks of obesity, diabetes, and dyslipidemia have considerable clinical implications in this patient population and should . . . influence drug choice.

Even for those medications associated with an increased risk of metabolic side effects, the benefit to specific patients could outweigh the potential risks. For example, clozapine [Clozaril] has unique benefits for treatment-refractory patients and those at significant risk for suicidal behavior. Since treatment response in many psychiatric conditions is heterogeneous and unpredictable, physicians and patients can benefit from the availability of a broad array of different therapeutic agents.

***

These three adverse conditions [obesity, diabetes, and dyslipidemia] are closely linked, and their prevalence appears to differ depending on the [atypical antipsychotic] used. Clozapine

> [Clozaril] and olanzapine [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia. Risperidone and quetiapine appear to have intermediate effects. Aripiprazole and ziprasidone are associated with little or no significant weight gain, diabetes, or dyslipidemia, although they have not been used as extensively as other agents.
>
> The choice of [atypical antipsychotic] for a specific patient depends on many factors. The likelihood of developing severe metabolic disease should also be an important consideration.

American Diabetes Association, et al., Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, 27 Diabetes Care 596, 596-97 (Feb. 2004)

3. FDA March 2007 Letter

On March 27, 2007, the FDA raised new concerns about the adequacy of Zyprexa's warning label in a letter to Lilly:

> [W]e are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine [Zyprexa] use . . . .
>
> Our overall goal is to improve labeling with regard to these findings so that clinicians will be better informed on what the risks are for their patients. They cannot make reasonable treatment decisions until they have such information. We do not feel that current labeling for . . . Zyprexa provides sufficient information on these risks, and we fully intend to insure that . . . labels are enhanced with the best available information to characterize these risks.

In re Zyprexa Prods. Liab. Litig., 253 F.R.D. at 141 (quoting Letter from Thomas Laughren, FDA, to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007).

4. Findings on Medical Community's Knowledge of Zyprexa's Risks

A universally applicable date from which the statute of limitations is to be considered to run on an individual Zyprexa user's claim has not been determined. Numerous events represent moments at which a patient, health care provider, institution, or the medical community at large

arguably discovered that the cause of an alleged injury may have been the administration of Zyprexa. The evidence in this mass litigation, including medical records and the depositions of numerous doctors, suggests that it was widely known and understood in the late 1990s among treating and prescribing physicians that weight gain might follow the administration of Zyprexa. The association between weight gain and heightened risk of diabetes was also broadly recognized by that time.

Formal events bringing this information to the medical profession include the September 2003 Zyprexa label change and contemporaneous press release, the 2003 consensus statement of the American Diabetes Association, and the March 2004 "Dear Doctor" letter distributed nationwide to physicians by Lilly.

In its June 2007 memorandum, order, and judgment on four motions for summary judgment in individual Zyprexa injury cases, this court found that, for purposes of these motions, the March 2004 "Dear Doctor" letter would be considered the latest possible date on which members of the medical community knew or should have known about Zyprexa's obesity- and diabetes-related risks to patient health. *See, e.g., Souther*, 489 F. Supp. 2d at 278. In *Souther*, applying the relevant "learned intermediary" doctrine, it was determined that Souther's claim was barred by the statute of limitations:

> Diabetes developed and Zyprexa was prescribed [to plaintiff Cusella] years before the September 2003 label change. *At least from the date of March 2004 Dear Doctor letter, the causal connection between Zyprexa and diabetes was known to Dr. Ganime, Cusella's treating physician.* Since Lilly's duty to warn ran to Dr. Gamine rather than Cusella, it became Dr. Ganime's duty from that point onwards to disclose to Cusella that Zyprexa might exacerbate his diabetes, and that it may have been the impetus behind Cusella's insulin-dependancy in the first place.
>
> Dr. Ganime's medical records and deposition testimony . . . show that Cusella was warned numerous times about the link

> between Zyprexa and diabetes. While the pre-label change warnings Dr. Ganime received from Lilly *may* not have been adequate to absolve Lilly of liability to Cusella, those warnings Cusella received from Dr. Ganime following the label change placed him on notice that use of Zyprexa might have worsened his diabetes and caused him to become insulin-dependent.
>
> *Measured either against the date Cusella developed diabetes—August 1999—or the latest possible date Dr. Gamine was aware of the potential causal connection between Zyprexa and diabetes—March 2004*—Pennsylvania's two year statute of limitations had run on Cusella's claim before he filed this suit in April of 2006.

Id. (emphases added; citations to record omitted).

The March 1, 2004 date represents the "latest possible date" prescribing physicians and, in effect, their patients are deemed aware of the potential causal connection between Zyprexa and diabetes and from which the statute of limitations may run as to any individual plaintiff. Nevertheless, a fact-specific analysis is necessary for each case to determine when the plaintiff – whether independently or by operation of the learned intermediary doctrine – knew the potential causal connection between Zyprexa and adverse health effects. The facts in many individual cases indicate a much earlier date of discovery for purposes of the statute of limitations. *See, e.g.,* Appendices A-D of *Souther,* No. 06-CV-1729, Docket Entries Nos. 88-1 to 88-4 (June 11, 2007) (including relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain).

C. Medical History and Treating Physician's Decision to Prescribe Zyprexa

Plaintiff is a 53 year-old California resident. *See* Aff. of Susanne F. Brodock ("Brodock Decl."), Ex. A at 2. She has a history of coronary artery disease, a heart attack in 1997, obesity, hypertension, hyperlipidemia, hypothyroidism, depression with multiple suicide attempts, and schizoaffective disorder. *See* Brodock Decl., Ex. B at GUILLENC_YRMC_0890-91, -1254,

-1257-59, -1475, Ex. C at GUILLENC_MHMC_0069, -71, -75, -85, Ex. D at GUILLENC_HMC_0236, -557-58, -653-54, -6663.

On May 16, 1998, Ms. Guillen was admitted to Memorial Hospital Medical Center for chest pains. *See* Brodock Decl., Ex. C at GUILLENC_MHMC_0069, -71, -75. Records reflect that at that time she may have recently been diagnosed with diabetes. *Id.* at GUILLENC_MHMC_0085. As of June 1999 she was taking insulin for diabetes. *See* Brodock Decl., Ex. D at GUILLENC_HMC_0020. Dr. Stephen Hamburger, plaintiff's proffered expert witness, submitted a report indicating that plaintiff's diabetes diagnosis post-dated her Zyprexa use, but this conclusion is contradicted by plaintiff's medical records. In 2001, plaintiff suffered anoxic brain injury due to an apparent drug overdose. *See id.* at GUILLENC_HMC_1895. The medical records document that plaintiff's diabetes has remained largely uncontrolled since her diagnosis. *See id.* at GUILLENC_HMC_1498, -1712, -1736-37.

On December 18, 1999, plaintiff was taken to the Hemet Valley Medical Center emergency room after an apparent suicide attempt involving an overdose of Paxil and Klonopin. *See id.* at GUILLENC_HMC_0900, -0912. During the hospitalization, she was diagnosed with schizoaffective disorder and was evaluated as being severely depressed and having suicidal ideations, auditory hallucinations, and paranoid delusions. *See id.* at GUILLENC_HMC_0660-63. She weighed 199 pounds, 166% of her ideal body weight. *See id.* at GUILLENC_HMC_0666.

Ms. Guillen was discharged on Zyprexa, among other medications, and advised to follow-up with the attending physician, Dr. Prakashchandra Patel. *See id.* at GUILLENC_HMC_0653-54. Plaintiff received Zyprexa from December 1999 until July 2000.

See Brodock Decl., Ex. B at GUILLENC_YRMC_1046, -1074, Ex. D at GUILLENC_HMC_0089, -0573, -0654, -1614. Records are unclear as to the identity of the prescriber during this period. Plaintiff's fact sheet lists plaintiff's Zyprexa prescriber as "unknown." *See* Brodock Decl., Ex. A at 13.

In July 2000, Ms. Guillen was admitted to the Hemet Valley Medical Center emergency room after another suicide attempt. *See* Brodock Decl., Ex. D at GUILLENC_HMC_0557, -1614. At the time of this hospitalization, she weighed about 230 pounds. *See id.* at GUILLENC_HMC_1663. She described persistent auditory hallucinations that lasted a week, and reported that she had gained weight. *See* Brodock Decl., Ex. D at GUILLENC_HMC_0557. Dr. Patel discontinued Zyprexa during this hospital stay. *See id.* at GUILLENC_HMC_0573. He prescribed Risperdal for plaintiff. *See id.* A November 2000 note from Hemet Valley Medical Center indicates that plaintiff stopped taking Risperdal because it made her dizzy. *See id.* at GUILLENC_HMC_1602.

Plaintiff was hospitalized multiple times in 2001 and 2002 for attempted suicide through drug overdose as well as uncontrolled diabetes. *See id.* at GUILLENC_HMC_0236, -1736-37, -1751-56, -1895. Medical records do not indicate that Zyprexa was restarted after July 2000.

A June 2003 doctor's note indicates that plaintiff had been out of insulin for six months, and had not been under a doctor's regular care for over a year. *See* Brodock Decl., Ex. E at GUILLENC_KUCHERV_0056. Diabetes medications and 5 mg of Zyprexa were prescribed. *Id.* The treating physician, Dr. Valentina Kucher, testified that she was aware of the association between Zyprexa and weight gain and diabetes when she prescribed it to plaintiff, and attributed her knowledge to the medical literature. *See* Brodock Decl., Ex. F at 31-32. Dr. Kucher recalled

counselling Guillen on the need to monitor her blood sugar and to follow-up with a psychiatrist at Behavioral Health Services so that her medications could be re-evaluated. *See id.* at 31. She also recalled Guillen telling her that Zyprexa worked very well for her. *See id.*

IV. Law

A. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact and if the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). Dismissal is warranted when there is no genuine issue as to any material fact after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor. Fed. R. Civ. P. 56(c); *see Anderson*, 477 U.S. at 247-50, 255; *Sledge v. Kooi*, 564 F.3d 105, 108 (2d Cir. 2009).

The burden rests on the moving party to demonstrate the absence of a genuine issue of material fact. *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). If the moving party appears to meet this burden, the opposing party must produce evidence that raises a material question of fact to defeat the motion. *See* Fed. R. Civ. P. 56(e). This evidence may not consist of "mere conclusory allegations, speculation or conjecture." *Cifarelli v. Village of Babylon*, 93 F.3d 47, 51 (2d Cir. 1996); *see also Delaware & Hudson Ry. v. Consolidated Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) ("Conclusory allegations will not suffice to create a genuine issue.").

B. Choice of Law

A federal district court sitting in diversity applies the choice of law rules of the state in which it sits. *Souther v. Eli Lilly & Co.*, 489 F.Supp.2d 230, 264 (E.D.N.Y. 2007) (citing *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941)). An MDL transferee court applies the choice of law rules of the transferor court. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) (citing *Van Dusen v. Barrack*, 376 U.S. 612 (1964)). Because the instant action was originally commenced in California, that state's choice of law principles apply.

California's choice of law rules require that that state's substantive law apply to all of Ms. Guillen's claims. California uses a "governmental interests" approach to choice of law analysis. *See Kearney v. Salomon Smith Barney, Inc.*, 137 P.3d 914, 917 (Cal. 2006) (citing, *inter alia*, *Reich v. Purcell*, 432 P.2d 727 (Cal. 1967)). Using this approach, California law governs Ms. Guillen's claims because she resided in California when she was diagnosed with her alleged injury and when she took Zyprexa. *See Kearney*, 137 P.3d at 917-18.

Because Ms. Guillen filed suit in California, this court applies the California statute of limitations. *See Deutsch v. Turner Corp.*, 324 F.3d 692, 716 (9th Cir. 2003) ("Where the conflict concerns a statute of limitations, the governmental interest approach generally leads California courts to apply California law."). The state applies a two-year limitations period to actions for an injury allegedly caused by defendant's wrongful acts or neglect. Cal. Civ. Proc. § 335.1 (2002) (Previously § 340, amended in 2002 to extend the statute of limitations period from one to two years.)

C. California State Law

1. Statute of Limitations

The applicable California statute of limitations for personal injury actions is two years. *Id.* "[A] cause of action accrues at the time when the cause of action is complete with all of its elements." *Fox v. Ethicon Endo-Surgery, Inc.*, 110 P.3d 914, 920 (Cal. 2005) (citing *Norgart v. Upjohn Co.* 981 P.2d 79 (Cal. 1999)).

The "discovery rule" provides that a cause of action accrues when a plaintiff has knowledge of her injury and knowledge of facts which would create within her, or a reasonable person, a suspicion of wrongdoing. *Id.* California law bars plaintiffs from invoking the discovery rule to delay the accrual of a cause of action if the plaintiff failed to plead any facts in the complaint that would support such delay. *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1120 (9th Cir. 1994) (stating that plaintiff must allege: (1) the time and manner of discovery, and (2) the circumstances excusing a delayed discovery, in order to invoke the discovery rule (citing *G.D. Searle & Co. v. Super. Ct.*, 49 Cal. App. 3d 22, 26 (3d Dist. 1975)). Even if the discovery rule is applied, once a reasonable person's suspicions would be aroused as to a cause of action, the limitations period begins to run for all claims stemming from personal injury. *Fox*, 110 P.3d at 919 (citing *Norgart*); *see also Gutierrez v. Mofid*, 705 P.2d 886, 897 (Cal. 1985) (holding that a limitations period dependent on the discovery of the cause of action begins to run no later than the time plaintiff learns, or should have learned, the facts essential to his claim).

2. Learned Intermediary Doctrine

The learned intermediary defense is an

> aspect of proportionality that shifts at least some of the burden of protecting patients from pharmaceutical manufacturers to treating physicians . . . . [T]he learned intermediary rule cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored.

Souther, 489 F. Supp. 2d at 244. There is a strong trend in prescription drug failure-to-warn cases to reiterate and apply this well established doctrine. *See, e.g., Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician (citing *Plummer v. Lederle Labs., Div. of Am. Cyanamid Co.*, 819 F.2d 349, 358-59 (2d Cir. 1987)); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 780 (S.D. Tex. 2008) (granting summary judgment for defendant upon finding that prescribing physician was aware of Zyprexa's suicide-related risks that an adequate warning would have provided and that plaintiff had presented no evidence physician would not have prescribed Zyprexa had defendant provided him with an alternate warning label), *aff'd*, 321 F. App'x 350 (5th Cir. 2009); *Allgood v. GlaxoSmithKline PLC*, No. 06-3506, 2008 WL 483574, at *4 (E.D. La. Feb. 20, 2008) (granting summary judgment for defendant because prescribing doctor's "testimony clearly reveal[ed] that stronger warnings concerning the risk of suicide would not have changed his decision to prescribe"), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 341 F. App'x 701 (5th Cir. 2009).

In California, a pharmaceutical manufacturer owes a duty to the prescribing physician to provide adequate warning of dangerous side effects. *Carlin v. The Superior Court of Sutter County*, 920 P.2d 1347, 1354 (1996). California follows the learned intermediary doctrine, under which a manufacturer of prescription medications discharges its duty by providing an adequate warning to the prescribing physician, regardless of whether the doctor communicates this warning to the patient. *Id.* Under California law, a plaintiff asserting a claim based on a failure to warn must prove both that a warning was absent or inadequate and that the absence or

inadequacy of the warning caused the plaintiff's injury. *Plummer v. Lederle Labs.*, 819 F.2d 349, 358 (2d Cir. 1987) (applying California law); *Kirsch v. Pickler Int'l*, 753 F.2d 670, 671 (8th Cir. 1985); *Stanbuck v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981).

To prevail on the issue of causation, California courts have held that the plaintiff bears the burden of producing evidence that a different warning would have altered her physician's conduct. *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001); *Nix v. SmithKline Beecham Corp.*, No. 06-CV-43, 2007 WL 2526402, at *2 (D. Ariz. Sept. 5, 2007) (applying California law). Where the plaintiff does not produce such evidence, the court will enter summary judgment. *Motus*, 196 F. Supp. 2d at 999; *Nix*, 2007 WL 2526402, at *3-4.

V. Application of Law to Facts

A. Statute of Limitations

Ms. Guillen is included in the multi-plaintiff complaint captioned, *Tynesha Belcher, et al. v. Eli Lilly and Company*, where there is a common claim that Zyprexa caused unspecified injuries related to weight gain and diabetes. *See* Brodock Decl., Ex. G (First Am. Compl.). Defendant's Answer sets forth an Affirmative Defense that the action is time-barred under California's two-year statute of limitations. *See* Brodock Decl., Ex. H ¶ 94 (Answer). Ms. Guillen has failed to plead specific facts regarding the time and manner of discovery of the cause of her injury in her Complaint. *See* Brodock Decl., Ex. G (First Am. Compl.). The discovery rule does not apply to her claims.

Guillen may have been diagnosed with diabetes as early as May 1998. *See* Brodock Decl., Ex. C at GUILLENC_MHMC_0085. As of June 1999 she was taking insulin for diabetes. *See* Brodock Decl., Ex. D at GUILLENC_HMC_0020. She was first prescribed Zyprexa in

December 1999. *See id.* at GUILLEN_HMC_653-54. Guillen's physicians discontinued Zyprexa for the first time in August 2000 following a thirty-pound weight gain. *See id.* at GUILLENC_HMC_0573, -1663. She did not receive Zyprexa again until 2003. *See* Brodock Decl., Ex. E at GUILLENC_KUCHERV_0056. She testified that she first contacted a lawyer regarding her potential lawsuit in 2003. *See* Brodock Decl., Ex. I at 39-40. Her attorney says she is "incorrect in her deposition," and that she first contacted a law firm in 2006. Pl.'s Response in Opp'n, October 26, 2009, at 3. Her deposition appears to be reliable; no evidence to the contrary has been submitted.

Plaintiff had until July 2002, two years from when Zyprexa was first discontinued for her, to pursue her cause of action, but failed to file her Complaint until February 28, 2006, three-and-a-half years too late. Her claims are time-barred.

Under similar facts, this Court granted summary judgment to Lilly against plaintiff Robert Cusella in the *Souther* decision and against other plaintiffs in *Belcher v. Eli Lilly*. *See Souther*, 489 F. Supp. 2d at 278; *Belcher v. Eli Lilly & Co.*, No. 06-CV-2782, 2009 WL 3597447 (E.D.N.Y. Oct. 16, 2009); *Belcher v. Eli Lilly & Co.*, No. 06-CV-2782, 2009 WL 3596982 (E.D.N.Y. Oct. 20, 2009). In the instant case, plaintiff had discontinued use of Zyprexa in 2000 and was already discussing her potential case with a lawyer in 2003, more than two years prior to initiating a lawsuit. Plaintiff had discovered, or had the ability to discover, all of the facts essential to her claim and yet failed to proceed with her lawsuit until well after the statute of limitations had run.

B. Causation of Injuries

Plaintiff alleges that Zyprexa caused her to develop diabetes, a stroke, and a heart condition. The resolution of this motion does not require an expert witness, since plaintiff's medical records show that plaintiff had been diagnosed with diabetes and was being treated for it with insulin as of June 1999, prior to ever taking Zyprexa. *See* Brodock Decl., Ex. D at GUILLENC_HMC_0020. Similarly, the record contains numerous references to plaintiff's pre-existing cardiac problems. *See, e.g., id.* at GUILLENC_HMC_0812. Plaintiff's alleged "stroke" appears to have been an anoxic brain injury due to a drug overdose in 2001, during a period when Zyprexa had been discontinued. *See id.* at GUILLENC_HMC_1895. All of plaintiff's alleged injuries pre-dated her first Zyprexa use or occurred during a period in which she was not taking Zyprexa.

There is no evidence that Zyprexa exacerbated plaintiff's diabetic condition. It was well documented throughout plaintiff's medical records that she had been non-compliant with diabetic treatment and diet since the time of her diagnosis. When Dr. Kucher began treating her, Ms. Guillen had not seen a doctor in over a year and had not been taking insulin or medications for six months. *See* Brodock Decl., Ex. E at GUILLENC_KUCHERV_0056. No evidence is offered that Zyprexa caused her diabetes to worsen.

C. Learned Intermediary Doctrine

Ms. Guillen has offered no evidence that her physicians would have altered their prescription decisions. There is no testimony from Ms. Guillen's initial prescribing physicians indicating that they would have acted differently had Lilly provided a different warning. Nor has

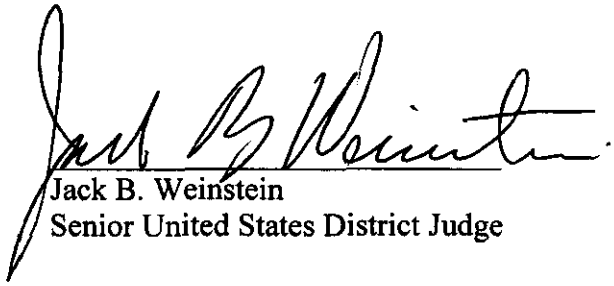
plaintiff produced any evidence that Dr. Kucher would have acted differently with a different warning.

As Dr. Kucher testified at her deposition, she was aware of the risks of weight gain, elevated blood sugar, and diabetes to some patients who take Zyprexa at the time she prescribed Zyprexa to plaintiff; she counselled plaintiff on the need for close monitoring of her blood glucose. *See* Brodock Decl., Ex. F at 31-32. Nevertheless, the treating physician chose to prescribe it in the exercise of her discretion as a learned intermediary.

VI. Conclusion

Summary judgment against the plaintiff is granted.

SO ORDERED.



Jack B. Weinstein
Senior United States District Judge

Date: December 10, 2009
Brooklyn, New York