UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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MEMORANDUM, ORDER & JUDGMENT

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION

04-MDL-1596

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In re: ELI LILLY AND COMPANY SECURITIES LITIGATION

07-CV-1310

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APPEARANCES:

For Lead Plaintiffs Danske Invest Administration A/S and Maine State Retirement System:

Schiffrin Barroway Topaz & Kessler, LLP
By: Katharine M. Ryan
Michael K. Yarnoff
Benjamin J. Sweet
Jennifer L. Keeney

Grant & Eisenhofer P.A.
By: Jay W. Eisenhofer
Geoffrey C. Jarvis
John C. Kairis
James R. Banko
Jeff Almeida
Naumon A. Amjed

Bernstein, Shur, Sawyer & Nelson, P.A.
By: Paul McDonald

For Defendants Eli Lilly and Company, Sidney Taurel, Alan Brreier, M.D., John C. Lechleiter, Charles M. Beasley, Jr., M.D., Gerhard Mayr, and Gary D. Tollefson, M.D.:

Pepper Hamilton LLP
By: Robert L. Hickok
Gay Parks Rainville
Christopher J. Huber
Kenneth J. King

JACK B. WEINSTEIN, Senior United States District Judge:

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I. Introduction

Zyprexa (olanzapine) is an antipsychotic drug manufactured and produced by Eli Lilly and Company ("Lilly"). It was approved in 1996 by the United States Food and Drug Administration ("FDA") for use in the treatment of schizophrenia. In 2000, the FDA extended approval for use in the short-term treatment of acute mixed or manic episodes associated with bipolar disorder, and, in 2004, granted approval for maintenance treatment of bipolar disorder. One of Lilly's top-selling drugs, Zyprexa has been prescribed to over twelve million people worldwide. Its sales are in the billions of dollars annually, based on prescribing physicians' observations that it helps their patients substantially improve their lives.

Litigation in federal and state courts involving Zyprexa has as plaintiffs individuals, organizations and governmental entities from all over the United States. It falls under eight categories: (1) individual plaintiff personal injury litigation, transferred to this court by the Judicial Panel on Multidistrict Litigation ("JPML"), involving approximately 30,000 individuals who were prescribed Zyprexa and claim that as a result they suffer from weight gain, diabetes and other aliments; (2) class action securities litigation involving parties who purchased Lilly stock of which the instant case is an example; (3) class action individual and third-party payer litigation involving tens of thousands of health care insurers and unions who claim that they overpaid for Zyprexa; (4) individual state and federal claims by Attorneys General of states alleging that governments overpaid for Zyprexa; (5) claims involving federal Medicaid and Medicare liens on individual personal injury recoveries, which have essentially been settled; (6) a suit by a third-party payer against the plaintiffs' attorneys, now reportedly settled; (7) shareholder derivative suits on behalf of the corporation against corporate officials; and (8) a *qui tam* action on behalf of one state for overpayment that has been dismissed.

Pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and Rule 10b-5 promulgated by the Securities and Exchange Commission, plaintiffs in this class action seek to recover damages for their purchasers of Lilly stocks. They allegedly sustained damages because of Lilly's fraudulent material misrepresentations regarding Zyprexa. Those named purport to represent a class of all purchasers of Lilly's publicly traded securities from August 1, 2002 to December 22, 2006. The Maine State Retirement System separately asserts various federal and state law claims on behalf of itself and of other states' systems it purports to represent.

Federal and Maine securities laws require plaintiffs to file suit within two years from when they knew or reasonably should have known of their claims, but no later five years after the alleged violation. Plaintiffs filed this action on March 28, 2007. Thus their claims are barred by the statute of limitations if there was public information sufficient to place plaintiffs on inquiry notice of their claims before March 28, 2005.

Allegedly, defendant Lilly and named employees misrepresented or did not disclose the link between Zyprexa and heightened blood glucose levels and diabetes as compared to other atypical antipsychotics, and they misstated or omitted notice of Lilly's marketing of Zyprexa for off-label uses—a practice prohibited by the FDA. Plaintiffs contend that defendants' misrepresentations and conduct was publicly disclosed for the first time by three articles published in *The New York Times* between December 17 and 21, 2006.

Defendants moved to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure on the ground that the claims are time-barred under the two-year statute of limitations and that plaintiffs failed to meet the pleading requirements of the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4.

At the court's direction, the motion was converted into one for summary judgment on the statute of limitations defense. Opportunity for discovery was granted. A full hearing was conducted.

Concerns about Zyprexa's adverse side effects and Lilly's off-label promotion of the drug had been known to the many scientists, members of the legal profession and stock market advisers long before the two-year statute of limitations began to run on plaintiffs' claims. *See* Parts II.B., C., D., E., *infra*. The plethora of publicly available information to such specialists over many years demonstrates as a matter of law that plaintiffs' claims are time-barred. A multitude of public sources repeatedly reported to market specialists and those that followed their warnings information that plaintiffs claim defendants misstated or did not disclose. Both before and during the putative class period, the large traders were well aware of the alleged relationship between Zyprexa and adverse events such as weight gain, hyperglycemia, and diabetes through public disclosures made by Lilly, its competitors, investment analysts, published medical literature, various news media, regulatory agencies, product liability plaintiff-lawyers' advertising, press releases, and court filed documents. The available literature also established that physicians and psychiatrists prescribed Zyprexa for off-label uses at Lilly's suggestion; individual plaintiffs had alleged in other litigation that Lilly engaged in illegal off-label marketing, and that various government agencies were investigating Lilly for alleged off-label promotion.

Under ruling law, what is referred to as "storm warnings" from information available to the stock market, place every hypothesized reasonably astute and well informed investor on notice of the need for further inquiry, beginning the running of the applicable two-year statute of limitations. *See* Part IV, *infra*. The individual unsophisticated investor's lack of awareness is

ignored; the law tilts the substantive-procedural balance against such a consumer. It applies the much-debated *caveat emptor* principle favoring greater and freer commerce by limiting litigation, and requiring dismissal of this case.

Because plaintiffs cannot prove a primary violation of section 10(b), their derivative claims under Section 20(a) against individual defendants also fail. Absent an underlying violation of the securities laws, there can be no controlling-person liability of Lilly's employees.

II. Facts and Procedural History

A. Plaintiffs' Theory

Plaintiffs allege two grounds for Rule 10b-5 liability: (1) defendants misrepresented or did not disclose the alleged "link between Zyprexa and heightened blood glucose levels and diabetes" as compared to other atypical antipsychotics, *see* Complaint ¶ 44; and (2) defendants misstated or omitted Lilly's alleged "active[ ] market[ing of] Zyprexa for illegal off-label uses," *see id.* ¶ 9. They contend that three articles published in *The New York Times* between December 17 and 21, 2006 "publicly disclosed for the first time" Lilly's alleged "decade-long effort to mislead the public about the link between Zyprexa and heightened glucose levels and diabetes as compared to other [atypical antipsychotics]," and Lilly's alleged "active[ ] market[ing of] Zyprexa for illegal off-label uses." *Id.* ¶ 9; *see In re Zyprexa Prod. Liab. Litig.*, 474 F. Supp. 2d 385 (E.D.N.Y. 2007); *Eli Lilly Said to Play Down Risk of Top Pill*, N.Y. Times, Dec. 17, 2006, attached as Ex. 201 to Lilly's Motion to Dismiss dated Oct. 9, 2007 ("Lilly's Motion"); *Drug Files Show Maker Promoted Unapproved Use*, N.Y. Times, Dec. 18, 2006, attached as Ex. 202 to Lilly's Motion; *Disparity Emerges in Lilly Data on Schizophrenia Drug*, N.Y. Times, Dec. 21, 2006, attached as Ex. 203 to Lilly's Motion. The publication of these articles allegedly caused a $3.49 per share decline in Lilly's stock price between December 17 and 22, 2006. *See* Complaint ¶ 9.

B. Consideration of Publicly Available Information

In deciding a motion to dismiss or summary judgment, a court may consider documents upon which plaintiffs relied in framing the complaint. *See Rothman v. Gregor*, 220 F.3d 81, 88-89 (2d Cir. 2000); *Cortec Indus., Inc. v. Sum Holdings, L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991). Considered here are all documents upon which plaintiffs claim that they relied in bringing this action, including:

> (1) public documents pertaining to Lilly and the Defendants; (2) Lilly's filings with the Securities and Exchange Commission ("SEC"); (3) press releases published by Lilly; (4) analyst reports concerning the Company; (5) pleadings in litigation naming Lilly as a defendant including briefing associated with the parties' motions for summary judgment (and certain confidential exhibits filed therewith) in *In re Zyprexa Products Liability Litigation*, No. 04-MD-1596 [ ] (E.D.N.Y.); (6) internal Lilly documents that have been made publicly available over the internet; and (7) newspaper and magazine articles (and other media coverage) regarding Lilly, its business or any Defendant.

Complaint at 1 (footnote omitted; parenthesis in original).

Considered also are documents required to be publicly disclosed that have been filed with the SEC, *see Rothman*, 220 F.3d at 88 and matters of which a court may take judicial notice. *See Leonard F. v. Israel Discount Bank of N.Y.*, 199 F.3d 99, 107 (2d Cir. 1999). Judicial notice can be taken of prior complaints and legal proceedings, press releases and news articles and published analyst reports in determining what the market knew. *See Shah v. Meeker*, 435 F.3d 244, 249 (2d Cir. 2006) ("Information contained in articles in the financial press may trigger the duty to investigate."); *LC Capital Partners, LP v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 153-55 (2d Cir. 2003) (taking judicial notice of prior litigation filings, press releases, articles and financial publications); *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 273 F. Supp. 2d 351, 358 (S.D.N.Y. 2003) (publicly available analysts' reports). Public documents issued by government agencies such as the Food and Drug Administration ("FDA") may also be

considered. *See, e.g., Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-CV-1030 (RPM), 2005 WL 4161977, at *2 (D. Colo. Oct. 20, 2005) (denying motion to strike FDA guidance documents, reasoning that such public documents are related to FDA's "process for reviewing new drug applications and that process is central to an evaluation of the claims made in this case."); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1218 (S.D. Cal. 2001) (recognizing that, on motion to dismiss, a court may properly consider transcript of FDA advisory committee meeting), *aff'd*, 32 Fed. Appx. 260 (9th Cir. 2002). The parties have created an enormous record for the instant motion. *See infra* section II.G.

C. Public Debate Regarding Zyprexa

"As in political controversy, science is, above all, an adversary process. . . . an arena in which ideas do battle. . . . " *McMillan v. Togus Regional Office*, 294 F. Supp. 2d 305, 317 (E.D.N.Y. 2003) (quoting David Goodstein, How Science Works, Federal Judicial Center, Reference Manual on Scientific Evidence 74 (2d ed. 2000) (internal quotation marks omitted). In the context of Zyprexa, news media, investment analysts, advocacy organizations, and product liability plaintiff-lawyers have actively reviewed the evolving medical and legal literature and offered views of various research results. This robust and public debate regarding Zyprexa's risks and benefits began long before plaintiffs filed this action. It continues to this day.

1. 1996-1999

From the time that Zyprexa was first marketed in October 1996, its product labeling has listed diabetes mellitus, hyperglycemia, ketosis, and diabetic acidosis among the infrequent (i.e., 1/100-1/1000 patients) or rare (i.e., fewer than 1/1000 patients) adverse events observed during clinical trials. *See* Zyprexa Package Insert, *Physicians' Desk Reference* 1512, 1515 (52d ed. 1998), attached as Ex. 259 to Lilly's Motion. Zyprexa's original labeling stated that weight gain

was a commonly observed adverse event in clinical trials and it provided information describing the frequency and magnitude of gain observed in Zyprexa-treated test patients. *Id.* ("In placebo-controlled, 6-week studies, weight gain was reported in 5.6% of [Zyprexa] patients compared to 0.8% of placebo patients. [Zyprexa] patients gained an average of 2.8 kg, compared to an average 0.4 kg weight loss in placebo patients . . . .").

Within one year of Zyprexa's approval, medical literature began reporting weight gain as an adverse event. A Lilly-sponsored study reported that weight gain was one of the most commonly observed treatment-emergent adverse events (reported by at least 10% of patients in either the Zyprexa, or Risperdal, a competing drug, treatment groups). *See* Pierre V. Tran, et al., *Double-Blind Comparison of Olanzapine Versus Risperidone in the Treatment of Schizophrenia and Other Psychotic Disorders*, 17 J. Clin. Psychopharmacology 407, 411-12 (1997), attached as Ex. 83 to Lilly's Motion. This publication noted that, over the course of twenty-eight weeks of double-blind therapy, weight gain was statistically significantly more often reported for Zyprexa-treated patients. *Id.* at 412. Zyprexa-treated patients experienced significantly greater weight gain (4.1 +/- 5.9 kg) than Risperdal-treated patients (2.3 +/- 4.8 kg, $p = 0.015$). *Id.* at 414; *see also* Charles B. Nemeroff, *Dosing the Antipsychotic Medication Olanzapine*, 58 J. Clin. Psychiatry 45, 48 fig. 6 (1997) (reporting mean weight gain of 12 kg at one year of treatment in patients treated with Zyprexa 12.5 mg to 17.5 mg/day), attached as Ex. 82 to Lilly's Motion.

In 1998 and 1999, several additional studies reported weight gain in patients being treated with Zyprexa. *See, e.g.*, Sanjay Gupta, et al., *Olanzapine-Induced Weight Gain*, 10 Ann. Clin. Psychiatry 39 (1998) (finding that mean weight gain in patients treated with Zyprexa was approximately 11 kg following seven months of treatment), attached as Ex. 85 to Lilly's Motion; Donna A. Wirshing, et al., *Novel Antipsychotics: Comparison of Weight Gain Liabilities*, 60 J.

Clin. Psychiatry 358, 361 fig. 1 (1999) (reporting that over 30% of patients treated with Zyprexa gained ≥ 10% of their baseline weight), attached as Ex. 91 to Lilly's Motion. In November 1999, a leading psychiatry journal published the results of a comprehensive literature review revealing that mean weight increases seen among the atypical antipsychotics ranged from 4.45 kg and 4.15 kg at the high end (for clozapine and Zyprexa, respectively) to 0.04 kg for ziprasidone (now Geodon). David B. Allison, et al., *Antipsychotic-Induced Weight Gain: A Comprehensive Research Synthesis*, 156 Am. J. Psychiatry 1686, 1691 (1999), attached as Ex. 87 to Lilly's Motion.

2. 2000

By 2000, investment analysts were aware of the Zyprexa weight-gain literature, and pointed to this danger as Zyprexa's "major therapeutic liability." Salomon Smith Barney, *PFE: Details of Zeldox® Big Win at FDA* (July 20, 2000), at 2 (comparing Zyprexa to Zeldox (now Geodon)), attached as Ex. 26 to Lilly's Motion; *id.* at 1 (describing Zyprexa's weight gain adverse effect as "Achilles heel"); *see also* Leerink Swann & Company, *Trends in Psychiatric Medication Usage* (June 26, 2000), at 3 ("Increasingly, psychiatrists are becoming sensitive to Zyprexa's weight gain issue, which is perceived to be more substantial than indicated by the product's label and some published studies."), attached as Ex. 25 to Lilly's Motion; SG Cowen, *Pharmaceutical Therapeutic Categories Outlook* (Oct. 2000), at 89 ("Our physician consultants believe that the weight gain occurs in 20-25% of patients treated with Zyprexa."), attached as Ex. 27 to Lilly's Motion; Banc of America Securities, *October Prescription Report* (Nov. 28, 2000), at 20 (noting "need for new antipsychotics that are not associated with increased cardiovascular risk factors such as weight gain"), attached as Ex. 28 to Lilly's Motion.

Also reported in 2000 was the fact that patients whose weight increased while being treated with Zyprexa gained a statistically significant greater amount of weight than those patients who gained weight when taking Risperdal. *See* Constance Guille, et al., *A Naturalistic Comparison of Clozapine, Risperidone, and Olanzapine in the Treatment of Bipolar Disorder*, 61 J. Clin. Psychiatry 638, 639 (2000) (finding that, over a 12-week period, patients treated with Zyprexa gained 10.6 +/- 7.7 kg compared to 1.7 +/- 6.1 kg in Risperdal-treated patients), attached as Ex. 94 to Lilly's Motion; *see also* Tawny L. Bettinger, et al., *Olanzapine-Induced Glucose Dysregulation*, 34 Ann. Pharmacotherapy 865, 866 (2000) (reporting a 13 kg weight gain in a patient treated with olanzapine for a period of 14 weeks), attached as Ex. 93 to Lilly's Motion. In December 2000, *The Wall Street Journal* reported that a study comparing Zyprexa's efficacy and safety in the treatment of bipolar disease to that of the market leader, Depakote, showed that weight gain occurred in 25% of the patients who were treated with Zyprexa, but in only 10% of the patients who received Depakote. *See* Thomas M. Burton, *Older Treatment for Manic Illness May Be Superior*, Wall St. J., Dec. 12, 2000, at B1, attached as Ex. 141 to Lilly's Motion.

In May 2000, the FDA, with cooperation from Lilly and manufacturers of other atypical antipsychotics, undertook targeted monitoring and analysis of data regarding diabetes or hyperglycemia-related adverse events in patients using these medicines. *See, e.g.*, Leerink Swann & Company, *Research Note: Zyprexa Side Effects To Garner Increasing Attention* (Aug. 1, 2002), at 2 ("We understand that the FDA has asked the manufacturers for information on adverse event reporting within the last six to nine months as it investigates side effects."), attached as Ex. 42 to Lilly's Motion. The FDA's evaluation included "a thorough review from a number of sources, including clinical trial data, spontaneous post-marketing reports,

epidemiological studies, published case series, published clinical pharmacology studies, published preclinical studies, and unpublished studies" for each atypical antipsychotic medication. *See* Warning Letter from U.S. Food and Drug Administration, Division of Drug Marketing, Advertising and Communications to Janssen Pharmaceutica, Inc. 2 (Apr. 19, 2004), attached as Ex. 206 to Lilly's Motion; *see also* SG Cowen, *Pharmaceutical Therapeutic*, *supra*, at 89.

In October 2000, Dr. Kristina Melkersson and colleagues evaluated fasting blood glucose and fasting serum insulin levels in fourteen Zyprexa-treated outpatients who had been diagnosed with schizophrenia, schizophreniform, or schizo-affective disorder according to DSM-IV criteria. *See* Kristina I. Melkersson, et al., *Elevated Levels of Insulin, Leptin, and Blood Lipids in Olanzapine-Treated Patients With Schizophrenia or Related Psychoses*, 61 J. Clin. Psychiatry 742, 743 (2000), attached as Ex. 95 to Lilly's Motion. Three patients were found to have elevated fasting blood-glucose levels (>108.1 mg/dL); ten were found to have elevated insulin levels. *Id.* at 745. Dr. Melkersson concluded that Zyprexa treatment was associated with hyperinsulinemia and insulin resistance; she also noted that three of the patients in the study were diagnosed with diabetes. *Id.* at 747.

During the same period, SG Cowen reported that, according to its physician consultants, "Zyprexa may impair insulin sensitivity and hinder glucose transport in some patients, although clinical studies must be performed to determine the clinical consequences of these changes." SG Cowen, *Pharmaceutical Therapeutic, supra*, at 89; *see also* Salomon Smith Barney, *PFE: Details, supra*, at 2 (noting that some patients taking Zyprexa gained as much as 25-50 pounds and opining that weight gain "can precipitate disturbances in glucose metabolism (prodiabetic effect")); Leerink Swann & Company, *Trends in Psychiatric, supra*, at 3 (noting that Zyprexa

has also been associated with "rare, but serious, adverse effects on blood glucose metabolism"); SG Cowen, *Eli Lilly: Near-Term Challenges Balance Long-Term Opportunities* (Feb. 28, 2000), at 6 (noting "emerging data on Zyprexa's adverse impact on glucose metabolism"), attached as Ex. 24 to Lilly's Motion.

3. 2001

In February 2001, Bruce Kinon and his colleagues—including individual defendant Gary D. Tollefson—reported the results of a retrospective analysis of 573 patients receiving Zyprexa treatment and 103 patients receiving the first generation antipsychotic, haloperidol, for 39 weeks or more from a Lilly clinical trial of 1996 patients randomly assigned 2:1 to either Zyprexa or haloperidol. Bruce J. Kinon, et al., *Long-Term Olanzapine Treatment: Weight Change and Weight-Related Health Factors in Schizophrenia*, 62 J. Clin. Psychiatry 92 (2001), attached as Ex. 98 to Lilly's Motion. The Kinon study found that the mean weight change for Zyprexa-treated patients at endpoint after a median treatment duration of 2.54 years was 6.26 kg (13.8 pounds) with a median weight gain of 5.90 kg (13.0 pounds). *Id.* This quantity of Zyprexa-associated weight gain was statistically significantly higher than the amount found in haloperidol-treated patients, who gained a mean of 0.69 kg (1.5 pounds) after a median treatment duration of 1.15 years ($p < 0.001$). *Id.* The study also reported that 22% of Zyprexa-treated patients gained between 10 and 20 kg, and 9% gained more than 20 kg; 52% of Zyprexa-treated patients gained greater than 7% of their body weight. *Id.* at 94; *see also* Barry Jones, et al., *Weight Change and Atypical Antipsychotic Treatment in Patients with Schizophrenia*, 62 J. Clin. Psychiatry 41, 41-42 (2001) (reporting that 7% of Zyprexa-treated patients gained >20 kg after two years), attached as Ex. 97 to Lilly's Motion.

In March 2001, at the College of Psychiatric and Neurologic Pharmacists annual meeting held in San Antonio, Texas, David Allison and colleagues reported the results of a meta-analysis of mean baseline to endpoint changes in random blood-glucose concentrations during antipsychotic treatment of schizophrenic patients in double-blind, randomized, controlled clinical trials. Poster Presentation, David B. Allison, et al., *Analysis of Random Blood Glucose Concentration Data From Patients with Schizophrenia Treated with Typical and Atypical Antipsychotic Agents During Double-Blind, Randomized, Controlled Clinical Trials* (Mar. 25-28, 2001) (presented at College of Psychiatric and Neurologic Pharmacists), attached as Ex. 261 to Lilly's Motion. In this analysis, estimated relative hazards of developing glucose values that reached or exceeded specific thresholds (126, 140, 160, and 200 mg/dl) were compared during treatment, using Zyprexa, haloperidol, risperidone, clozapine, or a placebo. Dr. Allison found that mean random blood-glucose concentrations during treatment with Zyprexa were increased significantly more than with haloperidol (4.56 mg/dl vs. 0.22, $p<0.001$) or a placebo (0.77 vs. -1.26 mg/dl, $p<0.004$), not significantly more than Risperdal (4.51 vs. 2.58 mg/dl, $p=0.06$), and significantly less than Clozaril (3.17 vs. 13.22, $p<0.001$). *Id.* Categorical analyses of mean blood glucose levels that exceeded 126, 140, 160, or 200 mg/dl, however, did not identify any statistically significant differences between Zyprexa and any of the comparator agents. *Id.*

In March 2001, Salomon Smith Barney issued a report that included a summary of some of the recent literature regarding atypical antipsychotics and their purported effects on glucose control. Salomon Smith Barney, *PFE: Geodon and Market Profile* (Mar. 1, 2001), at 5, attached as Ex. 30 to Lilly's Motion. This report discussed Lilly's "rejoinders" to the literature, including a "6-month study of Zyprexa v. Risperdal show[ing] an equal incidence (0.6%) of diabetes onset." *Id.* The analyst predicted an "ongoing debate" of the question: "*Is diabetes onset*

associated with antipsychotics only due to weight gain, or is there some other drug induced mechanism?" *Id.* (emphasis in original).

At the American Psychiatric Association ("APA") conference held in May 2001, Pfizer presented data from a head-to-head trial comparing Geodon with Zyprexa. *See* SG Cowen, *Pharmaceutical Industry Pulse. While Outlook Mixed, Better Performance Expected in H2* (July 2001), at 94, attached as Ex. 33 to Lilly's Motion; *see also* Banc of America Securities, *December Prescription Report* (Feb. 12, 2002), at 25 (reporting results of trial), attached as Ex. 35 to Lilly's Motion; Press Release, Pfizer, *Pfizer's New Antipsychotic Geodon Shows Significant Superiority over Zyprexa in Important Safety Measures. . . .* (May 8, 2001), attached as Ex. 218 to Lilly's Motion. As reported by SG Cowen, "Geodon showed efficacy comparable to Zyprexa, with less weight gain, lipid elevations, and glucose changes." *See* SG Cowen, *While Outlook Mixed*, *supra*, at 94. SG Cowen noted that because of the doses used in the trial, the "study was not a representative comparison of either drug, although this is not unusual in company-sponsored studies." *Id.*

Analysts from Leerink Swann & Company attended the APA Conference and reported that "[a]bstracts highlight that Zyprexa was more likely to cause lipid and glucose metabolic abnormalities than either Pfizer's Geodon or Janssen's Risperdal. Another abstract highlighted the greater weight gain seen with Zyprexa versus Geodon." Leerink Swann & Company, Shrink-Wrap: *Highlights from the American Psychiatric Association Conference* (May 16, 2001), at 3, attached as Ex. 31 to Lilly's Motion. The analysts went on to explain that, in the experience of their consultant, who participated in Janssen's clinical trials,

> average weight gain approximates 25-30 pounds, with a more significant increase in 15-20% of patients on [Zyprexa]. Perhaps more than 50% of patients on Zyprexa maintenance therapy meet National Institute of Health guidelines for

> being overweight as opposed to less than 10% for Geodon and aripiprazole [later known as Abilify].

Leerink Swann & Company, *Shrink-Wrap*, *supra*, at 3; *see also* Prudential Financial, *Eli Lilly: Coverage Initiated with a Hold Rating* (July 17, 2001), at 16 (noting that weight gain is Zyprexa's "single biggest side effect" and that "[i]n up to 20% of patients, a weight gain of 20-45 pounds can occur"), attached as Ex. 34 to Lilly's Motion; Merrill Lynch, *Geodon: Physicians Indicate a Potential Calm Before the Storm* (June 18, 2001), at 1 (noting that "Zyprexa's primary weakness in the eyes of the physicians is weight gain . . . leaving quite an opening for a new agent such as Geodon."), attached as Ex. 32 to Lilly's Motion; Deutsche Bank, *Reflections on Risperdal – Thoughts Following Conference Call with Psychiatrists* (Feb. 9, 2001), at 3 (comparing Geodon (originally called Zeldox) with Zyprexa), attached as Ex. 29 to Lilly's Motion. Despite these concerns, Leerink Swann's consultants considered Zyprexa a "useful agent and expect[ed] to continue to use it in selected patients." Leerink Swann & Company, *Shrink-Wrap*, *supra*, at 3.

It is apparent that by 2001, investment analysts were aware of extensive medical literature reporting that Zyprexa presented a higher risk of weight gain than did the two newest atypicals, Geodon and Abilify, and that this side effect could adversely affect sales. *See, e.g.*, SG Cowen, *While Outlook Mixed*, *supra*, at 94.

4. 2002

In April 2002, the Japanese Ministry of Health, Labour and Welfare ("MHLW") required Lilly to include information regarding diabetes and hyperglycemia in the warnings, contraindications and precautions section of Zyprexa's product labeling in Japan. News of the Japan label change was widely reported in news articles and trade journal articles. *See, e.g.*, Richard Woodman, *Britain Alerts Doctors over Lilly's Zyprexa*, Reuters, May 3, 2002, attached

as Ex. 151 to Lilly's Motion; Jeff Swiatek, *Lilly's Stock Rallies Despite Dour Reports; Many Investors Expected Worse; '03 Promising*, Indianapolis Star, Apr. 16, 2002, at 423, attached as Ex. 146 to Lilly's Motion; AFX News Limited, *Lilly (Eli) & Cost Quarter Results* (Apr. 15, 2002), at 452, attached as Ex. 148 to Lilly's Motion; Lilly, 4/15/02 Conf. Call Tr., at 14, attached as Ex. 14 to Lilly's Motion; *Lilly (Eli) & Co. 1st Quarter Results*, Regulatory News Service, Apr. 15, 2002, at 2, attached as Ex. 149 to Lilly's Motion; *Lilly Announces First-Quarter Earnings per Share of $.58*, Bus. Wire, Apr. 15, 2002, attached as Ex. 207 to Lilly's Motion; Lilly, 10/23/02 Conf. Call Tr., attached as Ex. 16 to Lilly's Motion; *Corrected - Lilly Sees Japanese Warning on Zyprexa After Deaths*, Reuters, Apr. 15, 2002, attached as Ex. 145 to Lilly's Motion; FDC Reports, *Lilly Foresees No Zyprexa Diabetes Warning in U.S.; Pfizer Sees Opening,* The Pink Sheet, Apr. 22, 2002, at 23 (reporting that Lilly expects updated Japanese labeling for Zyprexa to include a contraindication for patients with diabetes or a history of diabetes), attached as Ex. 150 to Lilly's Motion.

References to the Japanese label change for Zyprexa continued to appear in the trade literature for months. *See, e.g.,* FDC Reports, *Lilly Expects Zyprexa Sales To Flatten During Bristol Abilify Launch in Q4*, The Pink Sheet, Oct. 28, 2002, at 24 ("One element of uncertainty around Zyprexa's safety profile is its effect on glucose levels, particularly in diabetic patients. In Japan, Zyprexa was recently relabeled to add a contraindication against use in patients with diabetes or a history of diabetes after report of severe hyperglycemia and death from diabetic coma."), attached as Ex. 158 to Lilly's Motion; FDC Reports, *Zyprexa Will Not Be "Singled Out" for Diabetes Label Change, Lilly Says,* Health News Daily, Oct. 24, 2002 ("Zyprexa's Japanese labeling was recently revised to add a contraindication against use in patients with

diabetes or a history of diabetes after reports of severe hyperglycemia and death from diabetic coma."), attached as Ex. 157 to Lilly's Motion.

Lilly communicated the news from Japan in its quarterly reports that year. *See* Lilly 1Q 2002 Form 10-Q (filed 5/13/02), at 9 (reporting that "in April the Ministry of Health Labor and Welfare in Japan specified a label change for Zyprexa in the Japanese market to include a contraindication in patients with diabetes or a history of diabetes."), attached as Ex. 1 to Lilly's Motion. Lilly also discussed the Japanese label change during the April 15, 2002 earnings conference call with security analysts. *See* Lilly, 4/15/02 Conf. Call Tr., at 5, attached as Ex. 14 to Lilly's Motion.

Some investment advisers found the Japanese labeling change "troubling." *See* Lehman Brothers, *Earnings Review* (Apr. 15, 2002), at 2, attached as Ex. 37 to Lilly's Motion. Many did not. *See, e.g.,* Goldman Sachs, *Prescription Trend Monitor* (Apr. 18, 2002), at 11, attached as Ex. 38 to Lilly's Motion. As an analyst from Goldman Sachs explained:

> In our opinion, this is not a new issue for atypical antipsychotics, and all companies in this market have provided data with regard to diabetic complications to FDA some time ago. Based on the risk/reward profile of schizophrenia and the product's large safety database in the US, we remain comfortable with our estimates for the class and Zyprexa specifically.

Id.; *see also* Leerink Swann & Company, *Xigris and Manufacturing Remain Thorns* (Apr. 15, 2002), at 2 ("Zypexa's side effects of weight gain and diabetes are well known in clinical practice, but are not prominent in product labeling."), attached as Ex. 36 to Lilly's Motion; JP Morgan, *Highlights from the JP Morgan Psychiatric Symposium* (May 17, 2002), at 5 (noting that JPMorgan Psychiatric Symposium panelist, Dr. Jeffrey Lieberman, expressed the belief that "the label change in Japan was an exception because the Japanese have a higher diabetes risk to begin with and the regulatory environment there has a very low threshold for adverse events," that the panel believed that the causal risk of developing diabetes "can only be confirmed by

conducting prospectively designed clinical studies," and that "the FDA has been collecting actual use data on this issue from all manufacturers for the past couple of years"), attached as Ex. 39 to Lilly's Motion.

In April 2002, the United Kingdom's Medicines Control Agency Committee on Safety of Medicines ("MCA") reported in its newsletter, *Current Problems in Pharmacovigilance*, that Zyprexa "can adversely affect blood glucose" and that the product label for Zyprexa sold in the U.K. had been amended "to include appropriate statements regarding diabetes . . . ." *See Medicines Control Agency Committee on Safety of Medicines*, 28 Current Problems in Pharmacovigilance 3 (Apr. 2002), attached as Ex. 112 to Lilly's Motion. The publication states:

> Olanzapine (Zyprexa), an atypical antipsychotic indicated for the treatment of schizophrenia, can adversely affect blood glucose. Forty reports of hyperglycemia, diabetes mellitus or exacerbation of diabetes have been received in the UK. Four were associated with ketoacidosis and/or coma including 1 with a fatal outcome. . . .
>
> . . . .
>
> [T]he product information for olanzapine has been amended to include appropriate statements regarding diabetes as well as the very rare reports of ketoacidosis.
>
> *The product information for olanzapine recommends that in diabetics and patients with risk factors for diabetes mellitus, appropriate clinical and blood glucose monitoring is conducted.*

Id. (emphasis in original). This document was available on the MCA's website at www.mca.gov.uk at publication.

Developments were reported by investment news services, such as Reuters. *See, e.g.*, Richard Woodman, *Britain Alerts Doctors over Schizophrenia Drug*, Reuters, May 3, 2002, attached as Ex. 152 to Lilly's Motion; Leerink Swann & Company, *Update on the SOBP and APA Annual Meetings* (May 29, 2002), at 1, attached as Ex. 40 to Lilly's Motion; Prudential

Financial, *Highlights from the Prudential Securities Healthcare Group* (Oct. 30, 2002), at 19-20, attached as Ex. 45 to Lilly's Motion. Both the Japan and U.K./EU label changes were a matter of public record by mid-2002. The World Health Organization also published information regarding the U.K. and Japan label changes for Zyprexa in 2002. *See Olanzapine; Risk of Hyperglycaemia,* WHO Pharm. Newsletter 3, 5-6 (2002), attached as Ex. 101 to Lilly's Motion. As analysts from Leerink Swann pointed out in May 2002:

> The metabolic sides effects of Zyprexa . . . (weight gain, elevated blood sugar, and high lipid levels) are real and relatively widespread, according to our consultants. *Awareness of these issues is gradually gaining more attention in the U.S. physician community following recent re-labeling of the product in Japan and England.* Given the body of data supporting Zyprexa's efficacy, the product's usage will likely to [sic] continue to grow in the near term, unless the FDA meaningfully alters Zyprexa's labeling, although usage could decelerate in the longer term.

Leerink Swann & Company, *Update on the SOBP and APA Annual Meetings* (May 29, 2002), at 1 (emphasis added), attached as Ex. 40 to Lilly's Motion.

In 2002, additional contributions were made to the medical literature regarding atypical antipsychotics and diabetes-related adverse events. Several epidemiological studies conducted on large samples throughout the United States, the United Kingdom and Canada appeared in the published literature. Many of these studies reported increased diabetes risk in association with Zyprexa. Due to significant methodological limitations, however, they did not resolve the issue of whether Zyprexa caused or contributed to the development of diabetes. The literature continued to report Zyprexa's weight gain effect. *See* Geeta Anand & Thomas M. Burton, *Drug Debate: New Antipsychotics Pose a Quandary for FDA, Doctors—Eli Lilly's Big Seller, Zyprexa, Can Help Schizophrenics; Is it Linked to Diabetes?—Warnings Abroad, Not in U.S.*, Wall St. J., Apr. 11, 2003, at 1-2, attached as Ex. 160 to Lilly's Motion; Jonathan M. Meyer, *A Retrospective Comparison of Weight, Lipid, and Glucose Changes Between Risperidone- and*

Olanzapine-Treated Inpatients: Metabolic Outcomes After 1 Year, 63 J. Clin. Psychiatry 425, 427 (2002), attached as Ex. 108 to Lilly's Motion.

In April, the *American Journal of Psychiatry* published a report by Dr. Michael Sernyak of the Veterans Administration ("VA") in Connecticut regarding the first large retrospective epidemiological analysis of Zyprexa and diabetes-related adverse events. Michael J. Sernyak, et al., *Association of Diabetes Mellitus with Use of Atypical Neuroleptics in the Treatment of Schizophrenia*, 159 Am. J. Psychiatry 561 (2002), attached as Ex. 110 to Lilly's Motion. This cross-sectional, retrospective analysis evaluated the prevalence of diabetes among patients taking antipsychotics and determined odds ratios for patients on atypical versus typical antipsychotics in a large VA database. Sernyak reported that patients treated with Zyprexa had a greater risk of developing diabetes compared to patients treated with typical agents (odds ratio 1.11 (95% CI 1.04 to 1.18; $p<0.002$)). *Id.* at 564 (Table 2). When patients were analyzed by age, those younger than 40-years, those aged 40-49 years, and those aged 50-59 years, all showed a significantly higher risk of diabetes with Zyprexa than with typicals. *Id.* Reuters Health ran an article regarding the Sernyak analysis and highlighted the fact that Sernyak and colleagues "suggest[] that the atypical drugs, rather than precipitating the onset of diabetes, hasten its onset among those at risk." *See* Reuters Health, *Atypical Neuroleptics Seen To Increase the Risk of Diabetes Mellitus Somewhat* (Apr. 2002) at 7, attached as Ex. 144 to Lilly's Motion.

In June 2002, the *Journal of Clinical Endocrinology & Metabolism* published results from the first of two bio-mechanistic studies by Lilly, which utilized the hyperglycemic "clamp" technique. *See* Margaret O. Sowell et al., *Hyperglycemic Clamp Assessment of Insulin Secretory Responses in Normal Subjects Treated with Olanzapine, Risperidone, or Placebo*, 87 J. Clin. Endocrinology & Metabolism 2918 (2002), attached as Ex. 111 to Lilly's Motion. The

hyperglycemic clamp technique evaluates pancreatic insulin production in response to circulating levels of hyperglycemia that are maintained via a glucose infusion. *Id.* at 2919. Recognizing and responding to the debate regarding Zyprexa's purported diabetogenic effects, Lilly conducted this study to determine whether Zyprexa had acute effects on insulin production. Sowell and colleagues found no evidence that Zyprexa decreased insulin secretory response to a prolonged hyperglycemic challenge. *Id.* at 2921-22. The results of the hyperglycemic clamp study did not support the hypothesis that Zyprexa directly impaired pancreatic beta-cell function. The study found an association between treatment-emergent weight gain and decreased insulin sensitivity in Zyprexa-treated patients. *Id.* at 2922. This finding, however, was not confirmed in Lilly's subsequent hyperinsulinemic, euglycemic clamp study, which was designed to evaluate treatment-emergent changes in insulin sensitivity. *See* Margaret Sowell, *Evaluation of Insulin Sensitivity in Healthy Volunteers Treated with Olanzapine, Risperidone, or Placebo: A Prospective, Randomized Study Using the Two-Step Hyperinsulinemic, Euglycemic Clamp*, 88 J. Clin. Endocrinology & Metabolism 5875, 5879 (2003), attached as Ex. 119 to Lilly's Motion.

In July, a review of the FDA MedWatch data regarding Zyprexa and diabetes-related adverse events that was published in *Pharmacotherapy* sparked extensive media coverage about whether Zyprexa causes glucose dysregulation. *See, e.g.,* Bill Alpert, *Tech Trader: Diabetes Link Could Cool Lilly's Hottest Drug*, Barron's, Aug. 19, 2002, at T1, attached as Ex. 156 to Lilly's Motion; Sarah Avery, *Potential Side Effect of Eli Lilly Drug Is Unlisted on United States' Labels*, News & Observer, Aug. 17, 2002, attached as Ex. 155 to Lilly's Motion; Ted Griffith, *Eli Lilly, Pharma Stocks Under Pressure; Biotech off,* CBSMarketWatch.com, Aug. 1, 2002, attached as Ex. 154 to Lilly's Motion; Shannon Dininny, *Lilly Shares Decline Amid Concerns about Zyprexa Side Effects,* Associated Press, Aug. 1, 2002 (noting that analysts had raised

concerns following recent publication of the Koller/Doraiswamy data), attached as Ex. 153 to Lilly's Motion; *Researchers Warn Antipsychotic Drug Might Be Linked to Diabetes,* Associated Press, June 28, 2002, attached as Ex. 147 to Lilly's Motion. In their article, Dr. Elizabeth Koller, an FDA medical officer, and Dr. P. Murali Doraiswamy, a psychiatrist at Duke University, reported that a total of 237 cases of Zyprexa-associated hyperglycemia or diabetes had been identified during their review. Elizabeth Koller & P. Murali Doraiswamy, *Olanzapine-Associated Diabetes Mellitus*, 22 Pharmacotherapy 841 (2002), attached as Ex. 104 to Lilly's Motion. They concluded that the data suggested, but did not prove, a causal relationship between Zyprexa and the development or worsening of diabetes. *Id.* at 849. As Dr. Doraiswamy explained to the media: "While our report does not prove a causal relationship between the drug and diabetes, doctors should be aware of such potentially adverse effects . . . ." *Researchers Warn Antipsychotic, supra*, at 1. At least one analyst suggested that "there does seem to be a causal relationship between *Zyprexa* and newly diagnosed hyperglycemia and diabetes." Prudential Financial, *Data Watch: Clinical Journal Review for Pharmaceutical Investors*, July 24, 2002, at 17 (emphasis in original), attached as Ex. 41 to Lilly's Motion.

In an August 1, 2002 report, analysts from Leerink Swann offered the following assessment of the Koller/Doraiswamy study:

> While the authors stop short of concluding causality due to the retrospective nature of this analysis, there are clear concerns that are raised. Since time to onset of diabetes was variable in the study, with six cases within one week of treatment, it seems to indicate that weight gain alone is not likely to be the culprit. Also pointing to a drug effect is the younger than expected age of onset of approximately 40 years, as well as the improvement observed in cases where Zyprexa therapy was stopped.

Leerink Swann & Company, *Research Note: Zyprexa Side Effects To Garner Increasing Attention* (Aug. 1, 2002), at 1-2, attached as Ex. 42 to Lilly's Motion. They concluded that "*Zypexa side-effect issues" would be "a major risk factor in [Lilly's] long-term outlook*," and

that "*increased scrutiny could cause near-term share price volatility.*" *Id.* at 2 (emphasis in original).

Barron's writer, Bill Alpert offered the following analysis of the impact of the "latest Zyprexa worries" on Lilly's bottom line, and warned of a possible off-label issue:

> Wall Street's latest Zyprexa worries were fanned by the Boston-based broker Leerink Swann, which publicized recent medical reports of diabetes incidence among Zyprexa patients. Lilly itself has studied the issue, and company researchers say that blood-sugar problems also accompany other schizophrenia drugs—and indeed, accompany schizophrenia itself. Any diabetes issue should therefore not affect Zyprexa's market share, Lilly tells doctors and investors.
>
> *But the evidence to date convinces leading psychiatry researchers that Zyprexa does pose a greater risk of diabetes than other widely prescribed—and equally effective—schizophrenia drugs.* For the large number of psychiatric patients who have pre-existing risk factors for diabetes or heart disease, informed psychiatrists have started to prescribe the rival drugs of manufacturers like AstraZeneca, Johnson & Johnson and Pfizer, says Dr. John W. Newcomer of Washington University in St. Louis. From his experience as advisor to Missouri's Medicaid program, *Newcomer believes that some of Zyprexa's continuing sales growth may reflect off-label prescription by primary care doctors who are trying the drug on less severe mental illnesses. He has no direct evidence that Lilly encourages off-label use. From his Medicaid work, Dr. Newcomer is also aware that Zyprexa is priced about two-thirds higher than J&J's Risperdal.*

Alpert, *Tech Trader, supra*, at T1 (emphasis added).

On August 8, 2002, Lilly held a special conference call with stock analysts for the purpose of discussing the "recent spate of negative publicity," including the Japanese labeling change and the Koller study. Lilly, 8/8/02 Conf. Call Tr., at 1, attached as Ex. 15 to Lilly's Motion. During the call, individual defendant Breier made the following points regarding differences among the atypicals with respect to weight gain and diabetes related conditions:

> Some of the large epidemiological studies will indicate there's no difference [in diabetes risk] among the atypicals. Some of the studies will indicate that there might be some differences. We know there are weight gain differences among these drugs. That could be one hypothesis.

Id. at 4.

> [T]here is the most weight gain with clozapine, there is the second most weight gain with Olanzapine, third most with Quetiapine, third [sic] with risperidone. . . . And then it gets back to are [*sic*] there differences among the drugs? And some studies suggest there may be, other studies suggest there are not.

Id. at 11.

> Now, back to the issue of differences among the drugs. There are studies that demonstrate differences among the drugs. There are other studies that indicate there are not differences.

Id. at 4-14. In a subsequent analyst conference call, individual defendant Lechleiter also acknowledged that Lilly "clearly own[ed] weight gain" with Zyprexa. Lilly, 10/21/04 Conf. Call Tr., at 8, attached as Ex. 23 to Lilly's Motion.

5. 2003

Additional published studies fueled the scientific debate surrounding Zyprexa and diabetes-related adverse events in 2003. In addition to scientific data, increasing competitive pressure heightened scrutiny and debate surrounding Zyprexa's association with diabetes-related adverse events. In June 2003, Pfizer announced the implementation of an educational program for psychiatrists and nurses that was "designed to raise the level of awareness of metabolic complications associated with some atypical antipsychotic therapies." *See* FDC Reports, *Pfizer Pays Back Lilly: Geodon Promotions Focus on Zyprexa Diabetes Risk*, The Pink Sheet, June 2, 2003, at 18 (internal quotation marks omitted), attached as Ex. 164 to Lilly's Motion.

Trade papers in 2003 reported that Zyprexa had received the "most attention regarding the potential for treatment-emergent diabetes." FDC Reports, *Antipsychotics & Diabetes: Pfizer Highlighting Differences Between Drugs,* Pharm. Approvals Monthly, June 1, 2003, attached as Ex. 163 to Lilly's Motion. In February, the *Journal of Clinical Epidemiology* published results from an analysis of antipsychotic medications and diabetes conducted by Dr. John B. Buse using data from the AdvancePCS prescription claims database. *See* John B. Buse, et al., *A*

Retrospective Cohort Study of Diabetes Mellitus and Antipsychotic Treatment in the United States, 56 J. Clin. Epidemiology 164 (2003), attached as Ex. 113 to Lilly's Motion. Buse found that, compared with the incidence in the AdvancePCS general patient population, the incidence of diabetes during exposure to antipsychotics was several times higher. *See id.* at 167.

On April 11, 2003, *The Wall Street Journal* published an article, recounting the ongoing scientific inquiry about whether Zyprexa "is linked to diabetes." Anand & Burton, *Drug Debate, supra*, at A1; *see also* Erica Goode, *Leading Drugs for Psychosis Come Under New Scrutiny*, N.Y. Times, May 20, 2003, at A1, attached as Ex. 162 to Lilly's Motion. The article recognized that "[i]t is up the FDA to decide whether Zyprexa or any competing drugs are responsible for the illnesses and deaths—and what to do about it." Anand & Burton, *Drug Debate*, *supra* at A1. It noted that the FDA "hasn't arrived at a definitive answer on whether Zyprexa or any other atypical antipsychotics harm some patients. The resulting quandary illustrates a difficult challenge the agency, manufacturers and physicians regularly face: what to do with otherwise effective drugs that may cause serious side effects." *Id.*

Investment experts' reaction to *The Wall Street Journal* article was that it did not present any new concerns. As analysts from Banc of America Securities explained:

> *Front-page article in today's Wall Street Journal discusses concerns regarding Eli Lilly's antipsychotic drug Zyprexa causing diabetes.* Although we strongly believe in the unmatched efficacy of Zyprexa in treating schizophrenia and bipolar mania, its side-effect profile, which includes weight gain and possibly increased insulin resistence, has been something we are aware of and believe the medical community is comfortable with the risks.

Banc of America Securities, *Wall Street Journal Article Regarding Zyprexa Causing Spontaneous Diabetes – These Concerns are Not New* (Apr. 11, 2003), at 1 (emphasis in original), attached as Ex. 47 to Lilly's Motion.

Other information adverse to Zyprexa appeared in published literature in 2003. *See e.g.*, Matthew A. Fuller, et al., *Comparative Study of the Development of Diabetes Mellitus in Patients Taking Risperidone and Olanzapine*, 23 Pharmacotherapy 1037 (2003) (presenting data from a retrospective analysis of the Veteran's Integrated Service Network 10 VA database and reporting that Zyprexa was statistically significantly associated with a 37% increased risk of developing diabetes compared to risperidone), attached as Ex. 116 to Lilly's Motion; Christoph F. Ebenbichler, et al., *Olanzapine Induces Insulin Resistance: Results From a Prospective Study*, 64 J. Clin. Psychiatry 1436 (2003) (presenting data from a prospective, controlled, open study that compared body weight, fat mass, and index of insulin resistance/sensitivity in ten schizophrenic inpatients treated with Zyprexa with ten mentally and physically healthy volunteers and reporting that fasting glucose and fasting insulin levels increased significantly from baseline to endpoint in patients taking Zyprexa), attached as Ex. 115 to Lilly's Motion.

A landmark analysis conducted by Francesca Cunningham ("Cunningham study" or "VA study"), presented at the annual meeting of the International Society for Pharmacoepidemiology in August of 2003, highlighted the scientific debate and prompted the FDA to request a class warning on hyperglycemia and diabetes for all atypicals. *See* Francesca Cunningham, et al., *Antipsychotic Induced Diabetes in Veteran Schizophrenic Patients*, 12 Pharmacoepidemiology & Drug Safety S154 (2003), attached as Ex. 114 to Lilly's Motion. Dr. Cunningham evaluated diabetes risk for schizophrenic patients treated with Zyprexa, Risperdal, Seroquel, and Clozaril, using data obtained from Veterans Administration pharmacy and patient-care databases for fiscal years 1999 through 2001. *Id.* She found that, in comparison with typical antipsychotic medications, all four atypical agents were associated with increased diabetes risk. *Id.* (Hazard ratios (95% CI) were: 1.27 (1.04 to 1.56) for Zyprexa; 1.49 (1.22 to 1.81) for Risperdal, 3.34

(2.51 to 4.45) for Seroquel, and 1.48 (0.65 to 3.37) for Clozaril.). Cunningham concluded that "[r]isk of diabetes among veteran patients with schizophrenia appears to be increased with the use of [Zyprexa], [Risperdal], and [Seroquel] and should be taken into consideration in managing patients with this condition." *Id.* at S154-55.

News of this conclusion spread quickly. *See* FDC Reports, *VA Antipsychotic Diabetes Risk Studies Continue; First Report Helps Zyprexa*, The Pink Sheet, Sept. 1, 2003, at 3, attached as Ex. 169 to Lilly's Motion. The impact on the market was immediate, with AstraZeneca's stock falling nearly one percent after the Seroquel results were presented. *See* Reuters, *AstraZeneca Slips on Worries over Seroquel Drug*, Aug. 22, 2003 (reporting that AstraZeneca's stock slipped nearly one percent following a report its $1.2 billion-a-year seller Seroquel could be linked to a higher incidence of diabetes), attached as Ex. 165 to Lilly's Motion. The *Wall Street Journal* quoted remarks from Dr. William M. Glazer, associate clinical professor of psychiatry at Harvard Medical School. Glazer commented that based on the Cunningham study, "I don't see how the FDA could give individual labeling to any drug." Thomas M. Burton, *New Antipsychotic – Drug Class Is Tied to Increase in Diabetes*, Wall St. J., Aug. 22, 2003, at B4, attached as Ex. 166 to Lilly's Motion. Investment analysts echoed this sentiment. *See, e.g.*, Lehman Brothers, *Eli Lilly Company Update* (Aug. 25, 2003), at 2 ("The drive-home message of this study reconfirmed our view that *Zyprexa should not be singled out* in potential patient lawsuits and possible label change with diabetes contraindication among all atypical antipsychotics.") (emphasis in original), attached as Ex. 48 to Lilly's Motion.

On September 11, 2003, after review of the medical data, the FDA notified manufacturers of its conclusion that "the product labeling for *all* atypical antipsychotics [should be updated] to include a warning about additional information on hyperglycemia and diabetes." *See* Press

Release, Lilly, Lilly Announces FDA Notification of Class Labeling for Atypical Antipsychotics Regarding Hyperglycemia and Diabetes (Sept. 17, 2003), at 10 (emphasis added), attached as Ex. 208 to Lilly's Motion; Burton, *New Antipsychotic, supra*, at B4; Erica Goode, *3 Schizophrenia Drugs May Raise Diabetes Risk Study Says*, N.Y. Times, Aug. 25, 2003, at A8, attached as Ex. 168 to Lilly's Motion; Lehman Brothers (Equity Research), *Eli Lilly Company Updated* (Aug. 25, 2003), at 1-4, attached as Ex. 49 to Lilly's Motion. The FDA explained that it "recognize[d] that the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood, but epidemiological studies have suggested some increased risk." Press Release, Lilly, Lilly Announces FDA Notification, *supra*. The agency also concluded that there was a "lack of evidence to support a ranking of risk [for diabetes] among the atypical antipsychotics." Warning Letter from U.S. Food and Drug Administration, Division of Drug Marketing, Advertising and Communications to Janssen Pharmaceutica, Inc. 4 (Apr. 19, 2004), attached as Ex. 206 to Lilly's Motion. As the FDA explained, it was "unable to conclude, based on unpublished and published studies, whether the differences in results represent true differences in risk for diabetes mellitus among drugs or are due to limitations in the study designs or in some cases, the limited samples sizes examined." *Id.*

The class warning read as follows:

WARNINGS

Hyperglycemia and Diabetes Mellitus

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hypersmolar 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 baseline 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. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Letter from FDA to Eli Lilly and Co., (Sept. 11, 2003) (bold in original), attached as Ex. 205 to Lilly's Motion.

Lilly issued a press release with this information on September 17, 2003. Press Release, Lilly, Lilly, Announces FDA Notification, *supra*. Journalists promptly seized upon the class warning; news of the labeling change spread throughout the press and trade journals. *See, e.g.*, Matthew Herper, *Using the FDA in a Marketing Battle*, Reuters, Sept. 18, 2003 (noting that Eli Lilly had taken the "unusual step of publishing on its Web site a letter from the FDA adding new warning language to Lilly's top-selling drug, the schizophrenia treatment Zyprexa"), attached as Ex. 172 to Lilly's Motion; *FDA Seeks Diabetes Warning on Antipsychotic Drugs*, Forbes, Sept. 17, 2003, attached as Ex. 170 to Lilly's Motion; Christopher Bowe, *Regulator Sides with Eli Lilly in Drug Caution*, FT, Sept. 17, 2003, attached as Ex. 171 to Lilly's Motion; FDC Reports, *FDA Sides With Lilly; Seeks Class Warning on Antipsychotic Diabetes Risk,* The Pink Sheet, Sept. 22, 2003, at 20, attached as Ex. 173 to Lilly's Motion.

The FDA approved Lilly's addition of the class warning in the Zyprexa package insert on January 14, 2004. *See* U.S. Food and Drug Administration, Center for Drug Evaluation, *[Zyprexa] Label and Approval History*, attached as Ex. 204 to Lilly's Motion. Following discussions with the FDA, at the FDA's direction Lilly disseminated a "Dear Doctor Letter" regarding the new hyperglycemia and diabetes class warning on March 1, 2004. On or about March 1, 2004, the FDA posted a copy of Lilly's Dear Doctor Letter to the agency's Medwatch webpage. *See* U.S. Food and Drug Administration, *2004 Safety Alert: Zyprexa (olanzapine)*, Mar. 1, 2004, attached as Ex. 205 to Lilly's Motion. News of the Dear Doctor Letter appeared in trade papers later that month. *See* Sue Sutter, *Lilly Zyprexa 'Dear Doctor' Letter Warns of Diabetes Risk,* The Pink Sheet Daily, Mar. 23, 2004, attached as Ex. 184 to Lilly's Motion; FDC Reports, *Lilly Zyprexa 'Dear Doctor' Letter Warns of Classwide Diabetes Risk,* The Pink Sheet, Mar. 29, 2004, at 25, attached as Ex. 186 to Lilly's Motion.

6. 2004

In April 2004, a supplement to the *British Journal of Psychiatry* published the results of a retrospective analysis of Lilly's pooled clinical trial data for Zyprexa. *See* Patrizia Cavazzoni, et al., *Retrospective Analysis of Risk Factors in Patients with Treatment-Emergent Diabetes During Clinical Trials of Antipsychotic Medications*, 185 Br. J. Psychiatry S94 (2004), attached as Ex. 122 to Lilly's Motion. The study found that Zyprexa was not significantly associated with an increased risk of diabetes. *Id.* at S98. Instead, the presence of multiple baseline risk factors and/or elevated blood glucose at baseline were the best predictors of treatment-emergent diabetes. *Id.* at S98-S100.

Even after the FDA requested a class warning for hyperglycemia and diabetes, the scientific debate regarding potential differential risk among the atypical medications, including

Zyprexa, continued. In early 2004, *Diabetes Care* published a "Consensus Statement" on antipsychotic drugs, obesity and diabetes that had been prepared by a consensus panel convened by the American Diabetes Association ("ADA"), the American Psychiatric Association ("APA"), the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity. American Diabetes Association, *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes*, 27 Diabetes Care 596 (2004), attached as Ex. 120 to Lilly's Motion. According to the ADA, the need for a consensus statement arises when "clinicians or scientists desire guidance on a subject for which there is a relative deficiency of 'evidence' that might otherwise allow for a more definitive statement to be made." *See* American Diabetes Association, *Committee Reports & Consensus Statements*, 30 Diabetes Care S91 (2007), attached as Ex. 136 to Lilly's Motion. Although Consensus Statements lack the force of an ADA position statement, which represents an official point of view or belief of the ADA, the publication spurred continuing interest in the on-going controversy surrounding Zyprexa. *See* FDC Reports, *Geodon, Abilify Have Low Diabetes Risk, ADA Says; Lilly Disagrees,* The Pink Sheet, Feb. 2, 2004, at 31 (reporting that, in comparison to ziprasidone and aripiprazole, "the consensus statement says that patients taking Lilly's Zyprexa (olanzapine) . . . are at increased risk for diabetes, dyslipidemia and weight gain"), attached as Ex. 178 to Lilly's Motion; *see also* FDC Reports, *Lilly Zyprexa "Dear Doctor" Letter Warns of Classwide Diabetes Risk,* The Pink Sheet, Mar. 29, 2004, at 25 (noting that the recent ADA consensus statement concluded that increased risk of diabetes had not been observed in ziprasidone and aripiprazole clinical trials), attached as Ex. 186 to Lilly's Motion.

The Consensus Statement noted: "Despite limitations in study design, the data consistently show an increased risk for diabetes in patients treated with clozapine or [Zyprexa]

compared with patients not receiving treatment with [typicals or other atypicals]." American Diabetes Association, *Consensus Development*, *supra*, at 598. In its summary, the Consensus Statement stated that "[c]lozapine and [Zyprexa] are associated with the greatest weight gain and highest occurrence of diabetes and dyslipidemia." *Id.* at 600.

Business journalists and analysts discussed the Consensus Statement at length. *See, e.g.*, Toni Clarke, *Antipsychotic Drugs Raise Diabetes Risk*, Reuters, Jan. 27, 2004, attached as Ex. 175 to Lilly's Motion; Reuters, *Novartis Plays Down Impact of Antipsychotics Warning*, Reuters, Jan. 27, 2004, attached as Ex. 176 to Lilly's Motion; *Drugmakers Not Swayed by ADA Risk Study on Antipsychotics*, Drug Indus. Daily, Jan. 29, 2004, attached as Ex. 177 to Lilly's Motion; *Risks Linked with Atypical Antipsychotics Highlighted by Medical Organizations*, Pharma Marketletter, Feb. 4, 2004, attached as Ex. 179 to Lilly's Motion; Miriam E. Tucker, *Watch for Dyslipidemia in Patients on Antipsychotics: Weigh Individual Risks vs. Benefits; Clinical Rounds*, Family Practice News, Feb. 15, 2004, attached as Ex. 181 to Lilly's Motion; Press Release, American Diabetes Association, *Antipsychotic Drugs Raise Obesity, Diabetes and Heart Disease Risks: Joint Panel Urges Increased Screening, Monitoring of Side Effects*, PR Newswire, Jan. 27, 2004, attached as Ex. 221 to Lilly's Motion; SG Cowen, *ADA Opinion Paper Consistent with Views of Our Physician Experts* (Jan. 27, 2004), attached as Ex. 56 to Lilly's Motion; Leerink Swann & Company, *Eli Lilly: Best-in-Class Earnings Outlook* (Sept. 8, 2004), attached as Ex. 62 to Lilly's Motion; Friedman Billings Ramsey, *Eli Lilly: Strong New Product and Pipeline Story, but Key Product Weakness Continues o Weigh on the Company* (Dec. 10, 2004), attached as Ex. 66 to Lilly's Motion; CIBC World Markets, Weekly Scrip Monitor, Feb. 9, 2004, attached as Ex. 180 to Lilly's Motion.

Lilly issued a press release, expressing its disagreement with the Consensus Statement and pointing out the stark discrepancies between the Consensus Statement and the FDA's position on these issues. Press Release, Lilly, *Lilly Expresses Concerns with Opinion of ADA Panel on Antipsychotic Drugs and Obesity and Diabetes; Company Reaffirms 2004 Earning Guidance* (Jan. 27, 2004), attached as Ex. 209 to Lilly's Motion.

Later that year, representatives of the FDA's Division of Neuropharmacological Drug Products ("DNDP"), wrote a letter to *Diabetes Care*, expressing the DNDP's disagreement with the Consensus Statement's ranking of diabetes risks among the atypical antipsychotics. Gerard Boehm, et al., *Response to Consensus Statement*, 27 Diabetes Care 2088 (2004), attached as Ex. 121 to Lilly's Motion. As the letter explained:

> Although the ADA ranked the diabetes risk for second-generation antipsychotics (SGAs), the . . . [DNDP] *does not believe that the evidence currently available allows such a ranking*. . . .
>
> *[W]e must point out that the clinical trial data have not provided strong evidence of a diabetes risk for any of the SGAs.* It is not clear whether this is due to the timing of glucose measurements (random in most cases), the low absolute frequency for diabetes events, the short duration of many of the trials, or other factors. Therefore, the DNDP does not consider the absence of a signal in clinical trial data to rule out the risk of diabetes with SGAs.
>
> Based on a review of epidemiological studies, the ADA concluded that there is an increased risk of diabetes with olanzapine and clozapine and discrepant results with quetiapine and risperidone. The ADA correctly identifies many of the limitations of these epidemiological studies, including "their retrospective nature, heterogeneity of methodology, selection or ascertainment bias, and absence of appropriate or well-characterized control subjects, . . . relatively short periods of study, failure to control for a possible treatment sequence bias in 'switchover' studies, and . . . not always using clinically equivalent dosages of the medications." The DNDP believes that although these studies support an increased risk of treatment-emergent hyperglycemia or diabetes, compared with patients treated with older antipsychotic drugs, *the limitations of these studies preclude firm conclusions about the relative risk for diabetes among the studied SGAs.*
>
> The ADA asserts that "weight gain and changes in body composition may account for many of the purported metabolic complications associated with SGA

> therapy, e.g. diabetes . . ." *The ADA correctly points out that SGAs have different weight gain liabilities.* Although weight gain may be a factor in explaining the increased diabetes risk for SGAs, DNDP is not aware of evidence proving that the treatment-emergent diabetes risk for these drugs is wholly or in part due to treatment-emergent weight gain. *Although weight gain is widely recognized as a risk factor for diabetes in the general population, the clinical trial and epidemiological evidence has not shown a direct link between these treatment-emergent side effects.* A substantial proportion (-25%) of adverse event reports submitted to the U.S. Food and Drug Administration do not mention weight gain as part of the presentation of SGA-associated hyperglycemia or diabetes.

Id. at 2088-89 (emphasis added).

The DNDP explained that, while it agreed with the ADA's recommendation "to monitor patients treated with SGAs for evidence of diabetes," it did not believe "that the available evidence allows the ranking of diabetes risk for these drugs at this time." *Id.* at 2089. The DNDP explained that it "agree[d] with the ADA that additional studies are needed to clarify many of the issues surrounding the diabetes-SGA risk relationship," and recommended in the meantime that "clinicians remain vigilant in monitoring all patients treated with SGAs to assure their safe use." *Id.*

Despite the FDA's public rejection of the Consensus Statement's ranking of the atypicals according to diabetes risk, *Forbes* observed that the "message" of Zyprexa's alleged higher diabetes risk was "starting to stick." Matthew Herper, *Lilly's Big Fat Risk; Why Zyprexa Could Be the Next Drug Lawsuit*, Forbes, Nov. 15, 2004, attached as Ex. 189 to Lilly's Motion. Accordingly, "Zyprexa growth has stalled, and the trial lawyers are calling. A hundred cases have been filed, some alleging death resulting form Zyprexa, with hundreds more on the way." *Id.*

7. 2005

In September 2005—approximately six months after the March 28, 2005 statute of limitations two-year cutoff date (the suit it will be recalled was commenced on March 28,

2007)—the *New England Journal of Medicine* published phase I results from much-anticipated Clinical Antipsychotic Trials of Intervention Effectiveness study ("CATIE"). *See* Jeffrey A. Lieberman, et al., *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia*, 353 New Eng. J. Med. 1209 (2005), attached as Ex. 130 to Lilly's Motion. The release of these results captured a great deal of media attention. *See, e.g.*, Scott Allen, *Schizophrenia Drugs Work Poorly, Study Suggests*, The Boston Globe, Sept. 20, 2005, at A2, attached as Ex. 194 to Lilly's Motion; Shankar Vedantam, *New Antipsychotic Drugs Criticized; Federal Study Finds No Benefit over Older, Cheaper Drugs*, Wash. Post, Sept. 20, 2005, at A1, attached as Ex. 197 to Lilly's Motion; Benedict Carey, *Study Finds Little Advantage in New Schizophrenia Drugs*, N.Y. Times, Sept. 20, 2005, at F1, attached as Ex. 195 to Lilly's Motion; Goldman Sachs, *Eli Lilly and Company (LLY): CATIE Data Are out but We Expect Little Impact* (Sept. 9, 2005), at 1-2, attached as Ex. 68 to Lilly's Motion.

CATIE was the largest independent prospective randomized trial regarding the effectiveness and safety of atypical antipsychotics in treating schizophrenia. A total of 1493 patients with schizophrenia were recruited at 57 sites in the United States and randomly assigned to receive Zyprexa, perphenazine, Seroquel, or Risperdal for up to 18 months. *See* Lieberman, *Effectiveness of Antipsychotic*, *supra*, at 1209. Geodon was later included following its approval by FDA. *Id.* Time to treatment discontinuation was chosen as the primary outcome measure. As the CATIE researchers explained, "stopping or changing medication is a frequent occurrence and major problem in the treatment of schizophrenia." *Id.* at 1211.

Although the CATIE Phase I's primary outcome measure was time to discontinuation of treatment for any cause, changes in laboratory analyses were included as secondary outcomes. *Id.* As Lilly reported in a press release on September 19, 2005, the CATIE Phase I results

showed "that patients taking Zyprexa had greater weight gain and increases in measures of glucose and lipid metabolism versus patients using other antipsychotics that were studied." Press Release, Lilly, *According to CATIE, Zyprexa® More Effective on Discontinuation Rate than Other Antipsychotics; Patients Taking Zyprexa Had a Longer Duration of Successful Treatment* (Sept. 19, 2005), attached as Ex. 211 to Lilly's Motion; *see also* Press Release, Lilly, *Reports $.73 EPS and 10 Percent Sales Growth in the Third Quarter; Newer Products Contribute More Than $650 Million, or 18 Percent of Total Q3 Sales* (Oct. 20, 2005), at 2, attached as Ex. 212 to Lilly's Motion.

Reuters observed that the CATIE Phase I's "head-to-head comparison" among Zyprexa and four other atypicals "found that most newer treatments are no better than an older generic drug, despite their higher cost. . . . The lone exception, Eli Lilly and Company's Zyprexa, may be better than the other medicines but users experienced dramatic weight gain and developed a higher risk of diabetes. . . ." Gene Emery, *Most Newer Schizophrenia Drugs No Better – Study*, Reuters News, Sept. 19, 2005, at 1, attached as Ex. 192 to Lilly's Motion. These observations were echoed by investment analysts. *See, e.g.*, Credit Suisse First Boston, *CATIE Results Positive for Zyprexa* (Sept. 20, 2005), attached as Ex. 71 to Lilly's Motion. As analysts from Credit Suisse First Boston explained, the "increased side effects" were "not worse than expected":

> Zyprexa's potential to induce meaningful weight gain and negative metabolic changes has been well known among prescribing psychiatrists, and in our opinion, already largely accounted for in Zyprexa's current share of the market for schizophrenia treatments. Lilly also acknowledges the side effects of Zyprexa, and the company is implementing efforts to help patients and their physicians manage them more effectively. Yet, discontinuation due to intolerability was not different among drugs studied in CATIE even though patients on Zyprexa gained more weight . . . , had higher increase in markers of diabetes, such as increases in HbA1c . . . , and discontinued use more often due to these side effects . . . .

Id. at 5; *see also* Natexis Bleichroeder Inc., *Eli Lilly: First Call Note* (Sept. 16, 2005), at 1 ("We do not think this trial will meaningfully improve Zyprexa market share because the trial confirmed existing physician perception that Zyprexa is the most potent antipsychotic but also causes the most weight gain and diabetes."), attached as Ex. 63 to Lilly's Motion.

While results from phase I of the CATIE study were published approximately six months after March 28, 2005—the critical date when Lilly claims there was already public information sufficient to place plaintiffs on inquiry notice—it is important to note that press coverage for the ongoing CATIE study can be traced back to October 1999. It was then that the University of North Carolina at Chapel Hill first announced that it had won a $42.1 million federal contract to determine the effectiveness and safety of atypical antipsychotics in treating people with schizophrenia and those with psychotic and disruptive behaviors associated with Alzheimer's disease. *See, e.g.,* Press Release, Leslie H. Lang, *UNC-CH Wins $42.1 Million Federal Contract to Study Drugs for Schizophrenia and Alzheimer's* (Oct. 14, 1999), attached as Ex. 217 to Lilly's Motion; Jane Stancill, *Study Represents Hope for Mentally Ill,* The News & Observer (Raleigh, N.C.), Oct. 15, 1999, at B1, attached as Ex. 139 to Lilly's Motion; Sarah Avery, *Landmark Drug Study Set to Begin,* The News & Observer (Raleigh, N.C.), Nov. 18, 2000, at B1, attached as Ex. 140 to Lilly's Motion; Catherine Clabby, *Hope for 'Doomed from the Womb,'* The News & Observer (Raleigh, N.C.), Jan. 14, 2001, at B1, attached as Ex. 143 to Lilly's Motion; *see also* FDC Reports, *VA Antipsychotic Diabetes Risk Studies Continue; First Report Helps Zyprexa,* The Pink Sheet, Sept. 1, 2003, at 3, 4 (noting that the NIMH-sponsored CATIE study had completed enrollment) , attached as Ex. 169 to Lilly's Motion. The possible adverse results of CATIE hung like a cloud over Lilly's stock for many years prior to March 28, 2005.

D. Off-Label Use Of Zyprexa

Plaintiffs claim that Lilly promoted Zyprexa for off-label uses, and that sales based on such alleged off-label promotion artificially inflated the company's stock price. It is common knowledge that physicians can and do prescribe products for indicated and non-indicated uses in their discretion. Dissemination of Information on Unapproved/New Uses for Marketed Drugs, 63 Fed. Reg. 31143, 31153 (proposed Jun. 8, 1998) (to be codified at 21 C.F.R. pts. 16, 99) ("[The] FDA has long recognized that in certain circumstances, new (off-label) uses of approved products are appropriate, rational, and accepted medical practice. There are important off-label uses of approved products.").

Well before the beginning of plaintiffs' putative class period, investment analysts were aware—and reported—that Zyprexa was "often used off label for a broad range of applications." JP Morgan, *Highlights from the JPMorgan Psychiatric Symposium* (May 17, 2002), at 4, attached as Ex. 39 to Lilly's Motion. Two months into the putative class period, analysts were reporting that Lilly's Zyprexa sales representatives were calling on primary care physicians. As Prudential Financial explained in October 2002:

> Strong sales of Zyprexa may be partially due to increased marketing efforts by Lilly's primary care salesforce . . . . It appears that about 10% of Lilly's details to primary care physicians (PCPs) shifted from Prozac weekly to Zyprexa around June of this year, putting Zyprexa detailing at a level of approximately 25%-30% of Lilly's total PCP detailing efforts, according to physician-reported data from ImpactRx.

Prudential Financial, *Highlights from the Prudential Securities Healthcare Group* (Oct. 30, 2002), at 20, attached as Ex. 45 to Lilly's Motion; *see also* Alpert, *Tech Trader, supra*, at T1 (noting that Dr. John Newcomer of Washington University believed that "some of Zyprexa's continuing sales growth may reflect off-label prescription by primary care doctors who are trying the drug on less severe mental illnesses").

E. Zyprexa Litigation and Government Investigation History

1. 2001 and 2002

The first Zyprexa complaint alleging diabetes-related injuries was filed in the Second Judicial District Court of the State of Nevada on April 20, 2001. The personal injury complaint, filed on behalf of Victor L. Brown, alleged that Mr. Brown was prescribed Zyprexa for an unapproved use, and "[a]s a direct and proximate result of the effects of the drug, Zyprexa, and the failure of the Defendants . . . to protect and warn users of said drug, Plaintiff was injured ... and caused to suffer severe, permanent and disabling injuries . . . ." Complaint ¶ 14, *Brown v. Eli Lilly and Company*, No. CV01-0215 (Nev. 2d Jud. Dist. Ct. Apr. 20, 2001), attached as Ex. 226 to Lilly's Motion. The *Brown* complaint specifically alleged that, after taking Zyprexa, the plaintiff was diagnosed with acute pancreatitis, diabetes, and acute renal failure. *Id.*¶ 12.

A little over a year and a half later, on December 6, 2002, a case alleging diabetes-related injuries was filed in the District Court for the District of Columbia. The complaint, filed on behalf of Barry McClamrock, contained allegations made under eight causes of action: (1) strict products liability—failure to warn; (2) strict products liability under Restatement Second Torts § 402A; (3) negligence; (4) breach of implied warranty; (5) breach of express warranty; (6) fraud; (7) negligent misrepresentation; and (8) fraud by concealment. Complaint, *McClamrock v. Eli Lilly and Company*, No. 1:02-CV-02383 (D.D.C. Dec. 6, 2002), attached as Ex. 227 to Lilly's Motion. The complaint alleged that Lilly, "beginning in 1996, aggressively marketed and sold Zyprexa by falsely misleading potential users about the products and by failing to protect users from serious dangers which [Lilly] knew or should have known to result from use of Zyprexa." *Id.* ¶ 11. The *McClamrock* complaint, soon to be followed by several others, provided detailed descriptions of Lilly's alleged failure to warn and promotion of Zyprexa for unapproved uses.

2. 2003

In the early months of 2003, the news of Zyprexa's legal troubles garnered wider public attention. On February 27, 2003, Hersh & Hersh, a San Francisco, California, law firm, issued a press release announcing that it had filed "several" lawsuits on behalf of plaintiffs pursuing product liability claims related to Zyprexa. Press Release, Hersh & Hersh, *Hersh & Hersh Targets Eli Lilly's Most Profitable Anti-Psychotic Drug* (Feb. 27, 2003) (Business Newswire), attached as Ex. 219 to Lilly's Motion. According to the press release, the firm intended to file "numerous other complaints" and planned "to prove that as a result of taking Zyprexa, . . . their clients [had] sustained life-threatening or fatal injuries, including diabetes mellitus, hyperglycemia and pancreatitis." *Id.* The press release proclaimed that "patients are being kept in the dark about [Zyprexa's] damaging side effects. We believe Eli Lilly is culpable in heavily promoting Zyprexa as a safe and effective drug for psychotic disorders, yet virtually concealing the risks to doctors and their patients." *Id.* The announcement caught national attention, and was distributed through nationwide newswires, including PR Newswire, Business Wire, and EPIS.com Business Intelligence. Lilly reported the Hersh press release in its 10-Q for the first quarter of 2003. Lilly 1Q 2003 Form 10-Q (filed 5/8/03), at 14, attached as Ex. 4 to Lilly's Motion.

In addition to allegations surrounding Zyprexa's association with diabetes-related conditions, Hersh & Hersh made clear its contention that Lilly was illegally promoting Zyprexa for non-FDA-approved uses. The press release stated:

> "To boost sales and circumvent the FDA approval process drug manufacturers like Eli Lilly are actually encouraging their sales reps to push secondary uses of these anti-psychotic drugs and regularly review reports of the frequency of doctors prescribing these meds for off-label uses[.]" "[O]ur intention in the case against Eli Lilly is to also shine a light on the severe damage caused by this kind of dubious sales and marketing practice."

Press Release, Hersh & Hersh, *Hersh & Hersh Targets Eli Lilly's*, *supra*. The firm followed its announcement by filing several complaints within the next year.

In these complaints, filed as public documents, allegations of fraud by concealment, negligence, negligent misrepresentation, failure to warn, strict products liability, and breach of implied and express warranties were detailed. Plaintiffs alleged that Lilly:

> purposefully minimized and understated health hazards and risks associated with ZYPREXA. The DEFENDANTS, through promotional literature, deceived potential users of ZYPREXA and their physicians by relaying positive information, including testimonials from satisfied users and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects of the drug. The DEFENDANTS, falsely and fraudulently withheld relevant information from potential users of Zyprexa.

Complaint ¶ 16, *Wilson v. Eli Lilly and Company*, No. CIO200302374 (Oh. Ct. Com. Pl. Mar. 28, 2003), attached as Ex. 228 to Lilly's Motion. These general allegations of malfeasance were coupled with more specific charges detailing what plaintiffs believed to be the misstatements and illegal actions of Lilly:

> The true facts were that the products [Zyprexa] were not adequately tested, that there were frequent, severe, protracted, debilitating, difficult, life threatening and disabling side effects and adverse effects of the products, including but not limited to the development of diabetes, ketoacidosis and pancreatitis, that the products caused injuries including but not limited to diabetes, ketoacidosis and pancreatitis, and Defendants did not disclose or warn users and their physicians about the known risk of injury in using the products. Defendants misrepresented the safety of the products, represented that the products marketed were safe for use in bipolar disorder and schizophrenia treatment, and concealed warnings of the known or knowable risks of injury in using the products.

Id. ¶ 55.

The complaints cited numerous instances of medical literature, which plaintiffs alleged "conclusively revealed data . . . [linking] ZYPREXA with causing diabetes and other injuries." *Id.* ¶ 18. Included among the documents cited was an article published in *Society of Biological Psychiatry* in 1998. *Id.* ¶ 18.

Additional attention was brought to Zyprexa litigation when, on April 11, 2003, *The Wall Street Journal* published an article highlighting Hersh & Hersh's clients in a story challenging Zyprexa's safety profile and raising concerns about off-label use of Zyprexa. Anand & Burton, *Drug Debate: New Antipsychotics Pose a Quandary, supra*, at A1. The front page story contained discussions of medical literature purporting to find some association between Zyprexa and diabetes-related conditions. It recounted allegations of plaintiffs who were prescribed Zyprexa for off-label conditions or were injured by Zyprexa use. When comparing Zyprexa to other atypical antipsychotic agents, the article described Zyprexa as "the one most frequently associated with serious side effects." *Id.*

Hersh & Hersh provided an "Advisory" to inform the public about the article, explaining that "Hersh & Hersh attorneys are reviewing 30 additional cases and are available for comment on the Zyprexa lawsuits and the need for enforcement of prominent labeling of acute side effects linked to ingestion of Zyprexa." Press Release, Hersh & Hersh, *Advisory/Hersh & Hersh Attorneys Available to Comment on Eli Lilly Zyprexa Lawsuits; Attorneys Push for Prominent Labeling That Warns of Acute Side Effects Linked to Drug's Use* (Apr. 11, 2003) (Business Wire), attached as Ex. 220 to Lilly's Motion. On April 16, 2003, *The Indianapolis Star* reported that the Hersh firm had filed five lawsuits against Lilly. *See* Jeff Swiatek, *Eli Lilly Confronts Medical Lawsuits Stemming from Popular Schizophrenia Drug*, Indianapolis Star, April 16, 2003, attached as Ex. 161 to Lilly's Motion. On May 8, 2003, Lilly reported in an SEC filing that it had been served with four suits. Lilly 1Q 2003 Form 10-Q (filed 5/8/03), at 14, attached as Ex. 4 to Lilly's Motion.

Other law firms were simultaneously publicizing allegations that Lilly hid information about Zyprexa's association with weight gain and diabetes-related conditions. On May 1, 2003,

the law firm of Lopez, Hodes, Restaino, Milman & Skikos filed the first of many complaints on behalf of plaintiffs alleging fault with Zyprexa and Lilly's marketing. Complaint, *Rodriguez v. Eli Lilly and Company*, No. RIC-392629 (Cal. Super. Ct. May 1, 2003), attached as Ex. 230 to Lilly's Motion. The *Rodriguez* complaint, representative of many complaints to follow from this firm, made allegations against Lilly. *Id.* Similar to those allegations in complaints filed by Hersh & Hersh, the plaintiff alleged that Lilly deceived plaintiffs by:

> (1) making false and fraudulent misrepresentations in magazine advertisements and in products' package inserts, all of which advised the plaintiff, his physicians and the general public that said pharmaceutical product was safe and not capable of causing adverse health effects and was fit and effective for human consumption; and (2) concealing from the plaintiff, his physicians and the general public the true fact that defendants' drugs were known by defendants to cause serious complications in persons who used the drug, including but not limited to diabetes and the resultant life threatening complications associated with that illness.

Id. ¶ 28.

By late summer 2003, plaintiff law firms had erected billboards in several states, "soliciting" Zyprexa users to become plaintiffs. *See, e.g.*, Alpert, *Tech Trader, supra*, at T1 (describing "ominous billboard" in Texas, asking travelers "if they've taken the drug Zyprexa and suffered diabetes"). Hersh & Hersh also had been joined by several other law firms advertising plans to pursue claims against Lilly and "soliciting" new plaintiffs via the internet. The North Carolina law firm, Duffus & Associates, P.A., website included a statement that "Zyprexa . . . has been linked to dangerous side effects that may lead to the development of diabetes, hyperglycemia, and ketoacidosis." Duffus & Associates, www.zyprexa-lawyer.com/ (Sept. 14, 2004), attached as Ex. 252 to Lilly's Motion. The website of a Nevada law firm, Bourgault & Hardin, advertised: "Zyprexa is known to cause unhealthy changes to the patient's blood sugar level." Bourgault & Harding, www.lvjustice.com/areas_drugs_zyprexa.html (last visited Oct. 2, 2007), attached as Ex. 256 to Lilly's Motion. The website of a Florida law firm,

Berke Lubell, P.A., told readers if they or a loved one has taken Zyprexa and suffered "diabetes mellitus, diabetic coma, diabetic ketoacidosis or fatal complications," they may have a case against Lilly. Berke Lubell, PA, www.defective-drugs.com/Zyprexa (June 27, 2005), attached as Ex. 254 to Lilly's Motion.

The broadening litigation gained the attention of legal publications. Mealey's provided commentary on the Zyprexa litigation in its "Emerging Drug and Devices" and "Mass Tort Pleadings" publications. *See, e.g., Celexa/Zyprexa Interaction Wrongful Death Complaint*, 8 Mealey's Emerg. Drugs & Devices 18 (Nov. 13, 2003), attached as Ex. 264 to Lilly's Motion; *Zyprexa Diabetes Complaint*, 8 Mealey's Emerg. Drugs & Devices 20 (Aug. 21, 2003). These publications provided a synopsis of newly filed Zyprexa-related complaints, summarized Zyprexa legal proceedings, provided copies of pleadings, and tracked the growth and development of the litigation beginning with the filing of the *McClamrock* case.

On December 23, 2003, with the number of lawsuits growing and solicitation for Zyprexa plaintiffs on the rise, Lilly filed a motion with the Judicial Panel on Multidistrict Litigation ("JPML") to transfer the then-pending federal actions (and future federal cases) to a single federal district court for consolidated and coordinated pre-trial proceedings pursuant to 28 U.S.C. § 1407(a). The brief in support of the motion explained that "Plaintiffs in seven federal districts [had] filed eight product liability actions alleging that the FDA-approved prescription medication Zyprexa . . . has caused death or serious bodily injuries." Brief in Support of Defendant's Motion Pursuant to 28 U.S.C. §1407(a), at 1, *In re Zyprexa Prod. Liab. Litig.*, MDL No. 1596 (Dec. 23, 2003), attached as Ex. 236 to Lilly's Motion. Lilly's motion also outlined the allegations of each of the eight then-pending federal cases, noting "all plaintiffs have alleged that

Lilly failed to warn of Zyprexa's alleged side effects" and the majority of plaintiffs alleged diabetes-related injuries. *Id.* at 3.

3. 2004

a. Formation of the Zyprexa MDL

In 2004, the Zyprexa litigation grew exponentially. On April 14, 2004, the JPML entered an order transferring six federal actions to this court in a consolidated proceeding to be known as MDL 1596, *In re Zyprexa Products Liability Litigation* ("Zyprexa MDL"). Order Forming MDL 1596, *In re Zyprexa Prod. Liab. Litig.*, MDL No. 1596 (Apr. 14, 2004), attached as Ex. 237 to Lilly's Motion. On the same day, a preliminary hearing was held in this court to discuss coordinating discovery between the Zyprexa MDL and state court proceedings. During the hearing, Lilly admitted that it "fully expect[ed] that there [were] going to be dozens, if not hundreds, of more cases that [would] be filed in the next several months." *Zyprexa MDL Created, . . . Lilly Sees 'Cascade' of Cases*, 4 Mealey's Litig. Rep. Class Actions 24 (May 20, 2004), attached as Ex. 266 to Lilly's Motion. Counsel for Lilly predicted on the record that "the cases are going to start cascading in over the next several months." *Id.*

b. Litigation and Government Investigations Expand

As predicted by Lilly at the first Zyprexa MDL hearing in 2004, the litigation had grown considerably. On February 18, 2004, Jacoby & Meyers aired the first television advertisement regarding Zyprexa and diabetes-related injuries. Plaintiff-lawyer "solicitation" of Zyprexa patients expanded as firms across the country used the internet to broadcast statements about Zyprexa's alleged causal relationship with diabetes-related conditions. *See, e.g.*, Ashcraft & Gerel, LLP, www.ashcraftandgerel.com/zyprexa.html (Aug. 31, 2004), attached as Ex. 251 to Lilly's Motion. In its 2003 Form 10-K, filed on March 15, 2004, Lilly reported that it had been

named in approximately fifteen Zyprexa-related product liability cases in the United States, "involving plaintiffs claiming a variety of injuries from the administration of Zyprexa," and that "[m]ost of the cases allege[d] that the product caused or contributed to diabetes or high blood glucose levels." Lilly 2003 Form 10-K (filed 03/15/04), at 12, attached as Ex. 7 to Lilly's Motion.

Although these product liability suits primarily alleged diabetes-related injuries, plaintiffs also alleged that Lilly promoted Zyprexa for off-label uses. For example, on July 6, 2004, the law firm of Waite, Schneider, Bayless, & Chesley Co., LPA alleged in *Kovach v. Eli Lilly and Company* that, in addition to hiding the risks of diabetes-related conditions associated with Zyprexa, "Defendant, LILLY, promoted, marketed and sold its Zyprexa for 'off-label' uses to the detriment of the Plaintiffs." Complaint ¶ 34, *Kovach v. Eli Lilly and Company*, No. 1:04-CV-02931 (E.D.N.Y. July 6, 2004), attached as Ex. 241 to Lilly's Motion.

On March 9, 2004, Lilly reported in a Form 8-K that other pharmaceutical companies had recently received subpoenas from government agencies regarding their marketing and promotion of various products. Lilly Form 8-K (filed 3/9/04), at 14, Ex. 99, attached as Ex. 6 to Lilly's Motion. The report warned that it was "possible that other Lilly products, including Zyprexa, could become subject to investigation." *Id.* On March 15, 2004, Lilly repeated this information in its Form 10-K for 2003. Lilly 2003 Form 10-K (filed 3/15/04), at 14, attached as Ex. 7 to Lilly's Motion. This warning became headline news in the drug industry. *See, e.g., DOJ Probing Pfizer Sales Practices; Lilly Says Zyprexa May Be Next*, Drug Indus. Daily, Mar. 12, 2004, attached as Ex. 182 to Lilly's Motion. Investment analysts reported it as well. *See, e.g.*, Goldman Sachs, *Eli Lilly & Company: Marketing Investigation May Reach Lilly* (Mar. 9, 2004);

SG Cowen, *Eli Lilly: New Information in Recently-Issued 10K* (Mar. 17, 2004), attached as Ex. 59 to Lilly's Motion.

On March 25, Lilly reported that the United States Attorney's Office for the Eastern District of Pennsylvania had notified the Company that it had "commenced a civil investigation relating to the company's marketing and promotional practices." Press Release, Lilly, *U.S. Attorney's Office in Pennsylvania Investigating Lilly's Marketing Practices* (Mar. 25, 2004), attached as Ex. 210 to Lilly's Motion; *see also* Lilly 1Q 2004 Form 10-Q (filed 5/7/04), at 7; Lilly 3Q 2004 Form 10-Q (filed 11/5/04), at 23, attached as Ex. 8 to Lilly's Motion. In its press release, Lilly explained that, based on information received from the United States Attorney's office, the company believed that the Lilly products "likely to be involved include[d] . . . Zyprexa." Press Release, Lilly, U.S. Attorney's Office, *supra*. The news of this investigation was widely covered by the press. *See, e.g.*, *Lilly Facing Federal Probe of Drug Marketing Practices*, Drug Indus. Daily, Mar. 26, 2004, attached as Ex. 185 to Lilly's Motion.

In the spring of 2004, plaintiffs' attorneys filed the first two class-action lawsuits alleging diabetes and weight-gain related injuries from the use of Zyprexa. On April 16, 2004, attorneys for Hersh & Hersh and Parker & Waichman LLP filed *Ortiz v. Eli Lilly and Company*, a class action alleging products liability and fraud claims on behalf of named plaintiffs and all others similarly situated. Complaint, *Ortiz v. Eli Lilly and Company*, No. 04-CV-1587 (E.D.N.Y. Apr. 16, 2004), attached as Ex. 238 to Lilly's Motion. Plaintiffs made clear that they suspected that Lilly knew and concealed Zyprexa's effects on blood sugars: "Defendant failed to appropriately warn Plaintiffs, their psychiatrists, physicians . . . of the dangerous risk of developing diabetes mellitus, pancreatitis, hyperglycemia, diabetic ketoacidosis, and diabetic coma, as well as other severe and permanent health consequences from their use of Zyprexa." *Id.* ¶ 50.

In addition to citing medical literature which allegedly supported a link between Zyprexa and diabetes, the complaints referenced the hyperglycemia and diabetes-related label changes in Japan and the U.K. as further evidence of Lilly's failure to be forthcoming with United States physicians and patients regarding the alleged true risks of Zyprexa. *Id.*¶ 44-49. The *Ortiz* class sought compensatory and punitive damages as well as the costs of counseling for emotional distress, compensation for medical monitoring for future illnesses caused by their ingestion of Zyprexa, and other costs. *Id.* ¶ 9; *see also Proposed Class Action Filed Against Manufacturer of Medicine Used To Treat Schizophrenia*, 1 Mealey's Mass Tort Pleadings 6 (Apr. 29, 2004), attached as Ex. 265 to Lilly's Motion.

The filing of the *Ortiz* class action attracted national attention. Press releases were distributed through PR Newswires and PrimeZone Media Network, while industry and legal publications distributed information about the lawsuit and the firm's press release. *See, e.g.*, Press Release, Parker & Waichman LLP, *Parker & Waichman and Douglas & London File First Nationwide Class Action Lawsuit Against Eli Lilly and Company on Behalf of All Persons Residing in the United States Who Used Zyprexa* (Apr. 19, 2004), attached as Ex. 222 to Lilly's Motion; *Class Action Filed over Zyprexa Side Effects*, Pharma Marketletter, Apr. 19, 2004, attached as Ex. 187 to Lilly's Motion. These publications provided a summary of the allegations. Press releases distributed through PR Newswire and PrimeZone Media solicited potential plaintiffs for a "free legal evaluation," provided contact information for class counsel, and referred anyone with an interest to www.zyprexa-side-effects.com for more information.

Approximately one month later, on May 19, 2004, the law firm of Gilman and Pastor filed the second class-action lawsuit asserting Zyprexa-related product liability claims. In *Tringali v. Eli Lilly and Company*, plaintiffs made similar allegations to those made in the *Ortiz*

complaint, but they added more detail. In addition to criticizing Lilly for its promotion of Zyprexa, plaintiffs alleged members of the potential class had available "numerous alternatives [to taking Zyprexa], including but not limited to other atypical antipsychotic medications, such as Risperdal, Quetiapine, Ziprasidone, and Clozapine, as well as other, older, antipsychotic medications, including but not limited to Haldol." Complaint ¶ 12, *Tringali v. Eli Lilly and Company*, No. 04-CV-2104 (E.D.N.Y. May 19, 2004), attached as Ex. 239 to Lilly's Motion. The complaint provided details about the medical literature discussed in the *Ortiz* complaint. It cited research published in August 2003 studying antipsychotic use and diabetes in schizophrenic veteran patients, and the January 2004 statement of the ADA Consensus Panel.

On September 15, 2004, Lilly and plaintiffs' attorneys in the two potential class actions, *Ortiz* and *Tringali*, reached an agreement to execute stipulations of dismissal and toll the statute of limitations on plaintiffs' claims. Joint Memorandum of the Parties Regarding Stipulation of Voluntary Dismissal of Certain Claims, *In re Zyprexa Prod. Liab. Litig.*, MDL No. 1596 (Sept. 15, 2004), attached as Ex. 242 to Lilly's Motion. Lilly's agreement to enter tolling agreements was reported in *The Indianapolis Star* as a "legal tactic to stall the filing of potentially hundreds of new lawsuits" related to Zyprexa. Jeff Swiatek, *Lilly Adds Weapon in Zyprexa Suits; "Tolling Agreements" Aimed at Limiting Cases that Come to Trial*, Indianapolis Star, Nov. 7, 2004, at 1D, attached as Ex. 188 to Lilly's Motion. The article reported that Lilly was facing 125 Zyprexa-related lawsuits and the tolling agreements "delay the filing of lawsuits on behalf of more than 1,800 potential claimants." *Id.* Lilly reported its pursuit of tolling agreements in its SEC filing. Lilly Q3 2004 Form 10-Q (filed 11/5/04), at 20, attached as Ex. 9 to Lilly's Motion.

By the end of September 2004, approximately 125 lawsuits, involving some 340 claimants, had been filed throughout the United States in both state and federal court alleging

that Zyprexa had caused diabetes-related injuries. *Id. See also* SG Cowen, *Eli Lilly: What's New In The 10-Q* (Nov. 9, 2004), attached as Ex. 65 to Lilly's Motion.

State governments had also begun to challenge Lilly's marketing practices. On September 16, 2004, attorneys from Morrow, Morrow, Ryan, and Bassett, in conjunction with other law firms, filed suit on behalf of the Attorney General of the State of Louisiana alleging that Lilly illegally promoted Zyprexa for pediatric use and that:

> [Louisiana] has suffered harm and has incurred medical expenses associated with providing health care and other necessary assistance under various state programs to eligible citizens suffering from Zyprexa related illnesses.
>
> [ ]
>
> Defendant, ELI LILLY . . . has promoted and distributed Zyprexa for off-label usage through Louisiana, including in St. Landry Parish. For many years the State has paid out large sums of money for health care for citizens of Louisiana and citizens of St. Landry Parish, Louisiana.

Complaint ¶¶ 9-10, *Foti* ex. rel. *Louisiana v. Eli Lilly and Company*, No. 04-1-3965-A (La. 27th Jud. Dis. Ct. Sept. 16, 2004), attached as Ex. 243 to Lilly's Motion.

In an amended complaint filed December 14, 2004, the Louisiana Attorney General's complaint provided a more detailed account of Lilly's alleged improper marketing. For example, in its amendment to paragraph 5, the State asserted:

> Despite the fact that Zyprexa has not been approved for off-label usage for treatment of illnesses such as depression, anxiety, ADD, ADHD, sleep disorders, anger management and mood disorders, ELI LILLY has promoted the drug for these and other off-label usages among adults and children. Adults in Louisiana taking Zyprexa off-label have also suffered from Zyprexa-related injuries and illnesses such as diabetes, pancreatitis, and seizures.[]

Id. Am. Complaint ¶ 5. The case is currently pending in the Zyprexa MDL.

The litigation continued to expand. On November 5, 2004, Lilly reported in its 10-Q for the third quarter of 2004 that the Company "had been named in approximately 125 product liability cases in the United States involving approximately 340 claimants alleging a variety of

injuries from the administration of Zyprexa." Lilly 3Q 2004 Form 10-Q (filed 11/5/04), at 20, attached as Ex. 9 to Lilly's Motion. The company further explained:

> Most of the cases allege that the product caused or contributed to diabetes or high blood-glucose levels. The suits seek substantial compensatory and punitive damages and typically accuse us of inadequately testing for and warning about side effects of Zyprexa, and many of the suits also allege that we improperly promoted the drug.

Id.

On November 15, 2004, *Forbes* named Zyprexa as "Lilly's Big Fat Risk." Herper, *Lilly's Big Fat Risk, supra*. The article explained that in a number of recent studies, Zyprexa's weight gain and diabetes profile were different from those of other atypical antipsychotic agents, and "[t]he message is starting to stick. Zyprexa growth has stalled, and the trial lawyers are calling. A hundred cases have been filed, some alleging death resulting from Zyprexa, with hundreds more on the way." *Id.*

c. Zyprexa Litigation Garners Heightened Attention From the Plaintiff's Bar

In November 2004, a leading litigation reporting association sponsored a Continuing Legal Education ("CLE") program devoted to educating plaintiffs' attorneys about the Zyprexa litigation and how they could become involved. The Mealey's Drug and Litigation Conference, held November 9, 2004 featured presentations from members of the Zyprexa MDL's Plaintiff's Steering Committee ("PSC") and other prominent plaintiffs' attorneys. The brochure describes the focus of the Zyprexa Litigation Conference:

> Zyprexa . . . has become a target of trial attorneys representing patients who claim the drug caused serious effects, including severe diabetic conditions . . . . With 14 million prescriptions written and much off-label prescribing, some believe Zyprexa lawsuits could result in one of the largest class actions.
>
> **Mealey's Zyprexa Litigation Conference** is a one-day program for plaintiff attorneys that will help you get in on the ground floor of this emerging litigation.

Brochure, *Mealey's Drug Litigation Conferences: Zyprexa Litigation, Hormone Therapy Litigation, Ephedra Update* (Nov. 8-9, 2004) (bold in original), attached as Ex. 268 to Lilly's Motion. The program included a detailed overview of the Zyprexa MDL and lectures on the learned intermediary defense, "building a case against Lilly," and "managing a Zyprexa case" (including copies of the Plaintiff's Fact Sheet and instructions on managing medical records). *Id.*

In one presentation, entitled "Zyprexa: The Legal Issues – analysis and debate of the areas of liability," the panelists explained in detail the theories of liability, including failure to warn, design defect, breach of express and implied warranties, and challenges to Zyprexa's efficacy and Lilly's marketing practices. Similar to many of the complaints filed against Lilly, the presentation noted that the litigation was based on the theory that "Lilly failed to adequately warn of the risk of diabetes mellitus and related conditions[, and] . . . . Lilly's promotional efforts diluted the benefit of the warnings that were provided." Slide Presentation, Melvyn I. Weiss, et al., *Zyprexa: Legal Issues – Analysis and Debate of Various Areas of Liability Including Failure to Warn and Design Defect* (Nov. 8, 2004), attached as Ex. 267 to Lilly's Motion. In the discussion of Lilly's marketing of Zyprexa, the presentation claimed that "Lilly promoted off-label use to maximize profits[, and] . . . . Lilly's extensive off-label promotion efforts have made Zyprexa the company's most profitable drug." *Id.*

4. 2005

Increased government involvement and changes in the composition of the group of litigants was seen in 2005. In January 2005, the Canadian law firm of Stevenson & Associates filed a potential class-action claim against Eli Lilly Canada alleging that Zyprexa caused diabetes-related injuries. Press Release, Stevenson & Associates, *Zyprexa/Diabetes Canadian Class Action Lawsuit Issued Against Eli Lilly* (Feb. 4, 2005) (Market News Publishing), attached

as Ex. 223 to Lilly's Motion. According to a press release issued by the firm and distributed in Canada and the United States on February 4, 2005, "[t]he action has been brought on behalf of all persons in Canada who were prescribed Zyprexa and who became diabetic as a result of taking that drug." *Id.* It also explained that lawyers for the plaintiffs "intend to work with law firms across Canada and the United States in pursuing this claim and other similar claims against the manufacturers and distributors of Zyprexa, Eli Lilly and Company and Eli Lilly Canada Inc." *Id.*

On January 27, 2005—two months before the March 28, 2005 statute of limitations cut-off date in the instant case—the law firm of Schiffrin Barroway Topaz and Kessler, LLP (co-lead counsel for current plaintiffs) filed a product liability and fraud action against Lilly, *Frye v. Eli Lilly and Co.*, alleging that Lilly misrepresented Zyprexa's comparative side-effect profile. Complaint ¶ 14, *Frye v. Eli Lilly & Co.*, No. 3:05 CV 053 (E.D. Va. Jan. 27, 2005), attached as Ex. 288 to Lilly's Reply Memorandum dated March 21, 2008 ("Lilly's Reply"); Complaint ¶ 15, *Banks v. Eli Lilly & Co.*, No. 1:05-cv-0452 (S.D. Ind. Mar. 29, 2005), attached as Ex. 289 to Lilly's Reply. In its complaint, the Schiffrin firm specifically averred that Lilly's alleged advertising of Zyprexa "*falsely and fraudulently* created the image and impression that the use of Zyprexa was safe for human consumption and *had fewer side-effects and adverse reactions than other medications used to treat both bipolar disorder and schizophrenia.*" Complaint ¶ 14 (emphasis added), *Frye*, No. 3:05 CV 053.

Less than a month later, the Association of Trial Lawyers of America ("ATLA") announced at its 2005 Winter Convention that it established a "Zyprexa Litigation Group" to "provide education and support to members and act as an information clearinghouse with a document library and list server." Press Release, Association of Trial Lawyers of America, *New*

ATLA Litigation Group Takes on Zyprexa (Apr. 1, 2005) (Gale Group, Inc.), attached as Ex. 224 to Lilly's Motion.

By March 31, 2005, there were approximately 140 Zyprexa-related product liability suits pending against Lilly, representing approximately 360 plaintiffs, and 330 of those plaintiffs' cases were pending in the Zyprexa MDL. Lilly 2004 Form 10-K (filed 3/8/05), at 13, attached as Ex. 10 to Lilly's Motion. Additionally, several plaintiff law firms had identified thousands of potential Zyprexa plaintiffs interested in pursing claims against Lilly.

The Florida Attorney General's Office in June 2005 commenced an investigation of Lilly's Zyprexa marketing practices. As Lilly reported in its 10-Q for that quarter, the Florida Medicaid Fraud Control Unit had served the Company with a subpoena, "seeking production of documents relating to sales of Zyprexa and [Lilly's] marketing and promotional practices with respect to Zyprexa." Lilly 2Q 2005 Form 10-Q (filed 8/3/05), at 7-8, attached as Ex. 11 to Lilly's Motion; Lilly 3Q 2005 Form 10-Q (filed 11/3/05), at 8, Ex. 10.2, attached as Ex. 12 to Lilly's Motion.

On June 9, 2005, Lilly announced that it had reached an agreement in principle with plaintiffs' lawyers to settle approximately 8000 Zyprexa-related product liability claims. Press Release, Lilly, *Lilly and Plaintiffs' Attorneys Enter into an Agreement in Principle to Settle Majority of Zyprexa Product Liability Litigation* (June 9, 2005) (PR Newswire), attached as Ex. 214 to Lilly's Motion. The settlement resolved approximately 75% of the then-pending claims, but the litigation continued to expand with individual, state governments, and third-party payer plaintiffs.

F. New York Times Articles

In December 2006, the Zyprexa litigation was highlighted on the front page of the *The New York Times* in a series of articles based on excerpts taken from confidential, internal Lilly documents produced to plaintiffs during discovery in the Zyprexa MDL. *Eli Lilly Said to Play Down Risks of Top Pill*, N.Y. Times, Dec. 17, 2006, at A1, attached as Ex. 201 to Lilly's Motion; *Drug Files Show Maker Promoted Unapproved Use*, N.Y. Times, Dec. 18, 2006, at A1, attached as Ex. 202 to Lilly's Motion; *Disparity Emerges in Lilly Data on Schizophrenia Drug*, N.Y. Times, Dec. 21, 2006, at A1, attached as Ex. 203 to Lilly's Motion. These allegations against Lilly had been current in the medical, legal and investment worlds since at least 2001.

The December 17, 2006 article stated that "Lilly has engaged in a decade-long effort to play down the health risks of Zyprexa . . . according to hundreds of internal Lilly documents and e-mail messages among top company managers." *Eli Lilly Said to Play Down Risks*, *supra*. The article claimed that Lilly had knowledge of clinical trials and other information demonstrating strong evidence of a causal link between taking Zyprexa and diabetes. *Id.* The article quoted Lilly's response:

> On Friday, in its written response, Lilly said that it believed that Zyprexa remained an important treatment for patients with schizophrenia and bipolar disorder. The company said it had given the Food and Drug Administration all its data from clinical trials and reports of adverse events, as it is legally required to do. Lilly also said it shared data from literature reviews and large studies of Zyprexa's real-world use.
>
> "In summary, there is no scientific evidence establishing that Zyprexa causes diabetes," the company said.

Id. The article also reported that, by mid-2003, Lilly was "publicly acknowledging that Zyprexa can cause severe obesity." *Id.*

The December 18, 2006 article indicated that Lilly withheld information about the risk of Zyprexa in causing diabetes. *See Disparity Emerges*, *supra*. It noted that Lilly engaged in a

campaign to mislead the public about the link between Zyprexa and heightened glucose levels and diabetes as compared to other atypical antipsychotics. *Id.*

G. Procedural History of this Action

A class action complaint alleging violations of securities law was filed in this court in March 28, 2007. *See* Complaint, *Smith v. Eli Lilly & Co.*, No. 07-CV-1310 (E.D.N.Y.). On April 5, 2007, a similar complaint was filed in this court. *See* Complaint, *Valentine v. Eli Lilly & Co.*, No. 07-CV-1428 (E.D.N.Y.). The actions were consolidated on June 11, 2007. *See* Order, *In re: Eli Lilly & Co. Sec. Litig.*, 07-CV-1310 (E.D.N.Y. Jun. 11, 2007). A consolidated complaint was then filed under seal on August 1, 2007; it was ordered redacted and refilled on August 21, 2007.

Defendants moved to dismiss the complaint, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, on October 9, 2007. By order dated October 11, 2007, the court informed the parties that it preferred to convert the motion directed to the pleadings into one for summary judgment:

> The court has received Defendants' Motion to Dismiss Plaintiffs' Consolidated Securities Class Action Complaint, dated October 9, 2007. While the court appreciates that the motion is principally based on an alleged failure "to satisfy the heightened pleading requirements" mandated by the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4(b), as well as the statute of limitations, the substantial Appendices and other material already before the court suggest that a summary judgment motion would be more efficacious in bringing the case to a speedy conclusion. Even if the motion based on the pleadings were granted, an opportunity to replead would almost certainly follow, leading to further delay. The court has no view on whether the present motion or a converted summary judgment motion should be granted.
>
> While the defendants are free under the Federal Rules of Civil Procedure to bring a motion based on the pleadings, the parties may wish to consult with each other on the question of whether the present motion should be converted to a rule for summary judgment under Federal Rule 12(c) ("If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment

> and disposed of as provided in Rule 56"). Whether the extensive Appendices supplied by defendants to support their motion are characterized as "matters outside the pleadings" is not decisive, since the court can hardly be expected to put out of mind the extensive evidentiary materials it has examined in related Zyprexa matters.
>
> If the motion is converted, the parties will be given "reasonable opportunity to present all material made pertinent to such a motion by Rule 56." Fed. R. Civ. P. 12(c).

Order, *In re: Eli Lilly & Co. Sec. Litig.*, 07-CV-1310 (E.D.N.Y. Oct. 11, 2007) (case citations omitted). The parties submitted written responses. A hearing was held on November 1, 2007.

By order dated November 2, 2007, the court converted defendants' motion to dismiss into a motion for summary judgment "solely on the issue of statute of limitations." Order, *In re: Eli Lilly & Co. Sec. Litig.*, 07-CV-1310 (E.D.N.Y. Nov. 2, 2007). The court ruled that conversion was appropriate "in light of the extensive Appendices supplied by Defendants in support of their motion to dismiss, this court's past review of other evidentiary materials in related Zyprexa matters, and the complex fact-specific nature of a statute of limitations and inquiry notice defense." *Id.* The court ordered particularized discovery on the statute of limitations issue "to prevent undue prejudice to the parties." *Id.* Scope and timeframe for the parties to conduct discovery relating to the statute of limitations issue was left to the discretion of the magistrate judge. After holding argument on the scope and timing of discovery on November 7, 2007, by order dated November 8, 2007, the magistrate judge set February 15, 2008, as the close of discovery on the inquiry notice issue.

A hearing on the motion for summary judgment on the statute of limitations ground and the motion to dismiss for failure to state a claim was held on March 27, 2008. At the hearing, the parties were asked if they agreed that the court could rely upon extensive discovery and other material produced in the related Zyprexa multidistrict litigation before the court. *See* Transcript

of March 27, 2008 Hearing at 3-4. Lead plaintiffs notified the court that they wanted the court to solely rely on the record created in this securities case: "[w]e believe it makes the most sense, given the hundreds of pages of briefing and thousands of documents identified and submitted by the parties, for the Court to rely solely on the enormous record that has been created in the securities case in resolving the pending motion." *See* Letter dated April 4, 2008. Defendants agreed. *See* Letter dated April 7, 2008.

The present decision is based upon matters submitted by the parties. To the extent that judicial notice was taken of any evidence, the court complied with Rule 201 of the Federal Rules of Evidence. Were such judicial notice not taken the court's rulings would be unchanged.

III. Conversion of Motion and Standard on Summary Judgment

A. Conversion

"[W]hen matters outside the pleadings are presented in response to a 12(b)(6) motion, a district court must either exclude the additional material and decide the motion on the complaint alone or convert the motion to one for summary judgment under Fed. R. Civ. P. 56 and afford all parties the opportunity to present supporting material." *Friedl v. City of New York*, 210 F.3d 79, 83 (2d Cir. 2000) (quotation marks and citation omitted). District courts have "complete discretion in determining whether to convert the motion to one for summary judgment; '[t]his discretion generally will be exercised on the basis of the district court's determination of whether or not the proffered material, and the resulting conversion from the Rule 12(b)(6) to the Rule 56 procedure, is likely to facilitate the disposition of the action.' " *Carione v. United States*, 368 F. Supp. 2d 186, 191 (E.D.N.Y. 2005) (quoting 5C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure, Civil § 1366 (3d ed. 2004). A district court gives notice to the parties before it converts a motion to dismiss into one for summary judgment. *See Kopec v. Coughlin*, 922 F.2d 152, 154-55 (2d Cir. 1991).

Conversion on the statute of limitations issue in this case is appropriate in light of the extensive appendices supplied by defendants to support their motion to dismiss and the complex fact-specific nature of a statute of limitations and inquiry notice defense. *See Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 169 (2d Cir. 2005); *LC Capital Partners, L.P. v. Frontier Ins. Group, Inc.*, 318 F.3d 148, 156 (2d Cir. 2003). The parties were given advance notice of the desirability of conversion when the motion to dismiss was filed. They agreed to proceed under Rule 56 of the Federal Rules of Civil Procedure. Discovery on the statute of limitations issue by both sides was permitted. The motion for summary judgment was fully briefed and argued.

B. Summary Judgment Standard

Summary judgment is appropriate only if "there is no genuine issue as to any material fact . . . [in which case] the moving party is entitled to a judgment as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *see also Mitchell v. Washingtonville Central School District*, 190 F.3d 1, 5 (2d Cir. 1999). "[O]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248.

The court's responsibility on summary judgment is not to resolve disputed issues of fact but to assess whether there are factual issues to be tried. *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 11 (2d Cir. 1986). Critical is recognition of the jury's fact-finding primacy:

> It is well established that credibility assessments, choices between conflicting versions of the events, and the weighing of evidence are matters for the jury, not for the court on a motion for summary judgment. If, as to the issue on which summary judgment is sought, there is any evidence in the record from which a reasonable inference could be drawn in favor of the opposing party, summary judgment is improper.

Curry v. City of Syracuse, 316 F.3d 324, 333 (2d Cir. 2003) (quotation marks omitted).

IV. Federal Securities Claims

A. Law on Statute of Limitations

Federal securities fraud claims should be dismissed where the statute of limitations has run. *See, e.g., LC Capital Partners*, 318 F.3d 148 (affirming dismissal of securities fraud action on statute of limitations grounds). Section 804 of the Public Company Accounting Reform and Investor Protection Act of 2002 extended the statute of limitations period applicable to section 10(b) of the Securities Exchange Act and Rule 10b-5 to the earlier of "(1) two years after the discovery of the facts constituting the violation; or (2) 5 years after such violation." 28 U.S.C. § 1658(b).

The two-year limitations period, usually referred to as the "inquiry notice" period, begins when "circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded." *Dodds v. Cigna Sec., Inc.*, 12 F.3d 346, 350 (2d Cir. 1993) ("Discovery . . . [under the two-year period] includes constructive and inquiry notice as well as actual notice. A plaintiff . . . will be deemed to have discovered fraud for purposes of triggering the statute of limitations when a reasonable investor of ordinary intelligence would have discovered the existence of the fraud."); *LC Capital Partners*, 318 F.3d at 154 ("The [statute of] limitations period applicable to discovery of the violation begins to run after the plaintiff obtains actual knowledge of the facts giving rise to the action *or notice of the facts, which in the exercise of reasonable diligence, would have led to actual knowledge*.") (emphasis in original; citations and quotation marks omitted); *Masters v. GlaxoSmithKline*, No. 06-5140-cv, 2008 WL 83305, at *1 (2d Cir. March 26, 2008) (summary order) ("The two-year limitations period—referred to as the "inquiry notice" period—is triggered when circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded.") (quotation marks and citations omitted). As the Court of Appeals for the Seventh Circuit has noted, "if the stock

rebounded from the cellar [investors] would have investment profits, and if it stayed in the cellar they would have legal damages. Heads I win, tails you lose. This tactic is discouraged by the doctrine of inquiry notice . . . ." *Tregenza v. Great Am. Commc'ns Co.*, 12 F.3d 717, 722 (7th Cir. 1993).

Courts in the Second Circuit have referred to the circumstances giving rise to inquiry notice as "storm warnings." *Lentell*, 396 F.3d at 168 ; *but see Law v. Medco Research, Inc.*, 113 F.3d 781, 784 (7th Cir. 1997) (criticizing excessive reliance on the phrase). A simile or metaphor like "storm warnings" is not the rule of law; and in *Lentell*, the Court of Appeals for the Second Circuit encapsulated its inquiry notice standard as follows:

> The limitations period begins to run after the plaintiff obtains actual knowledge of the facts giving rise to the action or notice of the facts, which in the exercise of reasonable diligence, would have led to actual knowledge.
>
> *Inquiry notice—often called "storm warnings" in the securities context—gives rise to a duty of inquiry when the circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded.* In such circumstances, the imputation of knowledge will be timed in one of two ways: (i) if the investor makes no inquiry once the duty arises, knowledge will be imputed as of the date the duty arose; and (ii) if some inquiry is made, we will impute knowledge of what an investor in the exercise of reasonable diligence should have discovered concerning the fraud, and in such cases the limitations period begins to run from the date such inquiry should have revealed the fraud.

Lentell, 396 F.3d at 167-68 (emphasis added; quotation marks and citations omitted).

In applying this rule, an untutored individual investor's arguably reasonable reliance on the corporation's excessive optimism and false assurances is ignored. *Id.* He cannot sue on the ground that he was not aware of facts substantially relevant to purchase and long term value when that information was widely bruited about by the cognoscente on the Rialto before the statute of limitations began to run.

"Undergirding the inquiry notice analysis is the assumption that a plaintiff either was or should have been able, in the exercise of reasonable diligence, to file an adequately pled

securities fraud complaint as of an earlier date." *Benak v. Alliance Capital Mgmt. L.P.*, 435 F.3d 396, 401 (3d Cir. 2006). "If the investor makes no inquiry once the duty [of inquiry] arises, knowledge will be imputed as of the date the duty arose." *LC Capital Partners*, 318 F.3d at 154 (citation omitted). If "the investor makes some inquiry once the duty arises, we will impute knowledge of what an investor in the exercise of reasonable diligence, should have discovered concerning the fraud, and in such cases the limitations period begins to run from the date such inquiry should have revealed the fraud." *Id.* (internal quotation marks and citation omitted). Knowledge of the fraud is imputed to a plaintiff who fails to allege that he or she undertook any inquiry subsequent to inquiry notice. *See Dodds*, 12 F.3d at 350 ("when circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded, a duty of inquiry arises, and knowledge will be imputed to the investor who does not make such an inquiry."); *Shah v. Morgan Stanley*, No. 03-CV-8761, 2004 WL 2346716, at *8 (S.D.N.Y. Sept. 29, 2004) ("Since plaintiff does not allege that he undertook any inquiry after that date, knowledge of the alleged fraud is imputed to plaintiff . . . and accordingly his complaint is untimely.").

Notice to the market that inquiry is needed can be based on a wide variety of public documents and other sources. *See In re Ultrafem, Inc. Sec. Litig.*, 91 F. Supp. 2d 678, 692 (S.D.N.Y. 2000). For these purposes, information that may be held to constitute inquiry notice includes:

> any financial, legal, or other data, including public disclosures in the media about the financial condition of the corporation and other lawsuits alleging fraud committed by the defendants, available to the plaintiff providing him with sufficient storm warnings to alert a reasonable person to the probability that there were either misleading statements or significant omissions involved in the sale of the securities.

Dietrich v. Bauer, 76 F. Supp. 2d 312, 343 (S.D.N.Y.1999) (quotation marks, brackets and citation omitted).

To determine whether an investor was on notice to inquire, the circumstances as a whole will be evaluated. *In re Salomon Analyst Winstar Litig.*, No. 02-CV-6171, 2006 WL 510526, at *5 (S.D.N.Y. Feb. 28, 2006) ("Whether or not any of these facts or statements taken in isolation would have been sufficient to give rise to inquiry notice, the circumstances as a whole should have alerted reasonable investors . . . to the probability that they had been defrauded.") (footnote omitted). Need to inquire need not be triggered by revelation of all aspects of the alleged fraud or substantiation of all elements of plaintiffs' claim. *See Ohio v. Peterson, Lowry, Rall Barber & Ross,* 651 F.2d 687, 695 (10th Cir. 1981). "Inquiry notice is triggered by evidence of the *possibility* of fraud, not full exposition of the scam itself." *Theoharous v. Fong*, 256 F.3d 1219, 1228 (11th Cir. 2001) (quoting *Sterlin v. Biomune Sys.*, 154 F.3d 1191, 1203 (10th Cir. 1998)) (emphasis in original).

Even a single news article can provide sufficiently strong omens to place a plaintiff on notice of the need for investigation. *See LC Capital Partners*, 318 F.3d at 155 (affirming dismissal because one press article and one lawsuit triggered inquiry notice); *In re Global Crossing, Ltd. Sec. Litig.*, 313 F. Supp. 2d 189, 200 (S.D.N.Y. 2003) (ruling that a *Fortune* magazine article was enough to put plaintiff investors on inquiry notice); *In re Ultrafem, Inc. Sec. Litig.*, 91 F. Supp. 2d at 692 (dismissing complaint as time-barred because one article and one public filing triggered inquiry notice). Vigilance may be particularly necessary in an industry where new developments often turn out to be less favorable than was hoped. *See, e.g.*, *Masters v. GlaxoSmithKline*, 2008 WL 83305, at *1 (Paxil); *In re Merck & Co., Inc. Sec., Derivative & "Erisa" Litig.*, 483 F. Supp. 2d at 420 (Vioxx); *U.S. Asks for Cholesterol Data,*

N.Y. Times, April 26, 2008, at C3 (mipomersen); Editorial, *Overpromoted Cholesterol Drugs*, N.Y. Times, April 2, 2008, at A26 (Vytorin and Zetia); *Law*, 113 F.3d 781 (Adenoscan); *In re Amgen Inc. Sec. Litig.*, __ F. Supp. 2d __, 2008 WL 999058, (C.D. Cal. Feb. 1, 2008) (Epogen and Aranesp); *In re Pozen Sec. Litig.*, 386 F. Supp. 2d 641 (M.D.N.C. 2005) (MT 300 and MT 100); *In re Genta, Inc., Sec. Litig.* No. 04-CV-2123 (JAG), 2005 WL 2416970 (D.N.J. Sept. 30, 2005) (Genasense); *Noble Asset Mgmt. v. Allos Therapeutics, Inc.*, No. 04-CV-1030 (RPM), 2005 WL 4161977 (D. Col. Oct. 20, 2005) (efaproxiral); *In re Pharmaceuticals, Inc. Sec. Litig.*, No. 04-CV-12581 (GAO), 2007 WL 951695 (D. Mass. March 28, 2007) (Plenaxis); *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434 (S.D.N.Y. 2006) (Mucotrol); *In re Chiron Corp. Sec. Litig.*, No. 04-CV-4293 (VRW), 2007 WL 4249902 (N.D. Cal. Nov. 30, 2007) (Fluvirin); *In re Bayer AG Sec. Litig.* No. 03-CV-1546 (WHP), 2004 WL 2190357 (S.D.N.Y. Sept. 30, 2004) (Baycol).

B. Application of Law to Facts

Plaintiffs filed their initial complaint on March 28, 2007. Numerous and substantial publicly available warnings about the facts and theories underlying plaintiffs' claims were present for *years* before March 2005, when the two-year statute of limitations began to run. Based on extensive available medical research, media coverage, court filings, regulatory decisions and securities analyst reports, an investor of ordinary intelligence should have been aware of: (1) Zyprexa's substantial potential to cause diabetes and other diseases; (2) Zyprexa's substantial potential for having a "greater likelihood" of causing diabetes than other atypical antipsychotics; (3) Lilly's substantial off-label illicit marketing to promote Zyprexa; and (4) the substantial potential of a sharp drop in Zyprexa sales when the facts known to Lilly became known to prescribers generally.

Considering the vast number of alarms, plaintiffs were placed on notice of investment dangers long before March 2005. Their late-filed federal securities claims alleging securities fraud are time-barred. *See In re Merck & Co., Inc. Sec., Derivative & "Erisa" Litig.*, 483 F. Supp. 2d 407, 425 (D.N.J. Apr. 12, 2007) (dismissing Rule 10b-5 claims on statute of limitations grounds because plaintiffs were on inquiry notice of their claims more than two years before the action was filed). The constructive reasonably intelligent and informed investor could not ignore Zyprexa's problems and their likely effects on the value of Lilly stock.

1. Inquiry Notice of Zyprexa's Link to Diabetes

a. Public Documents and News Article

The Zyprexa-diabetes debate before March 2005 was conducted in numerous articles and other public documents. The problems that Zyprexa faced were so well-publicized that it was "more akin to thunder, lightning and pouring rain than subtle warnings of a coming storm." *Id.* at 423 (discussing warnings in the public realm concerning Merck's drug Vioxx and its link to heart attacks). Plaintiffs were placed on inquiry notice of Zyprexa's alleged potential to cause diabetes and other diseases long before March 28, 2005.

According to plaintiffs themselves, "*the first publicly reported potential link between Zyprexa and diabetes came on January 6, 2001*, when *The Indianapolis Star* reported that Lilly was reanalyzing data from thousands of patients to determine if Zyprexa caused high blood sugar." Complaint ¶ 70 (emphasis added). The article which plaintiffs cite states that the study in question was precipitated by the death of a man during a clinical trial of Zyprexa being run by a competitor, Abbott Laboratories. It quotes an Abbott spokesman as contending that "*the possibility that Zyprexa can cause high blood sugar needs to be studied.*" Jeff Swiatek, *Indiana-Based Lilly Discounts Possible Zyprexa Link to High Blood Sugar*, Knight Ridder Tribune

Business News, Jan. 6, 2001 (emphasis added), attached as Ex. 142 to Lilly's Motion. This article represents an early portent of a potential link between Zyprexa and diabetes. Various other public disclosures recognized by plaintiffs made during 2002, 2003, and 2004 provided them with strong notice of possible connections between Zyprexa and diabetes. *See* Complaint ¶¶ 71-75, 154, 254.

Without substance is plaintiffs' response that although they recognize the abundant information about the link between Zyprexa and diabetes, they did not have sufficient notice of the potential that Lilly committed any fraud—that is, that Lilly was taking measures to conceal a link between Zyprexa and diabetes. For example, plaintiffs rely upon a February 2003 news article disclosing that plaintiffs in products liability lawsuits against Lilly were alleging that Lilly had concealed the Zyprexa-diabetes connection. According to plaintiffs:

> The first *report of a lawsuit* being filed against Lilly alleging that the Company failed to warn about the dangers of Zyprexa was on February 28, 2003. *See San Francisco Law Firm Targets Lilly's Zyprexa Over Side Effects*, Datamonitor, *Feb. 28, 2003*. The lawsuits alleged that Lilly failed to adequately warn about the danger of Zyprexa and concealed information proving that Zyprexa causes diabetes.

Id. ¶ 153 (emphasis added).

If other plaintiffs had access to sufficient information in February 2003 to allege fraud and complain of Lilly's failure to warn about Zyprexa's alleged dangers, then a reasonable investor with access to this publicly available information had a duty to inquire by that date. *See, e.g., In re Merck & Co., Inc. Sec., Derivative & "Erisa" Litig.*, 483 F. Supp. 2d at 420 ("While not conclusive of knowing misrepresentations or omissions by Merck with regard to VIOXX, the product liability litigation must be recognized as a sign of the brewing storm.").

Apart from the many documents that plaintiffs relied upon in support of their complaint, the wider world of readily available documents provides plentiful information demonstrating the

existence of a looming danger that investors ignored at their peril. Plaintiffs were placed on inquiry notice when the "plethora of public information would have required even a *blind, deaf, or indifferent* investor to take notice of the purported alleged 'fraud.' " *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 273 F. Supp. 2d 351, 389 (S.D.N.Y. 2003) (emphasis in original). A frenzy of publicity surrounding Zyprexa's alleged link to diabetes and the contentions that Lilly had concealed the link was created by publicly filed litigation, news articles and analyst reports. Given this overwhelming presence of publicly available information well before March 2005, plaintiffs' claims of fraud relating to an alleged link between Zyprexa and diabetes are barred by the statute of limitations.

b. Court Documents

Court documents are "inherently public information." *See White v. H&R Block, Inc.*, No. 02-CV-8965, 2004 WL 1698628, at *6 (S.D.N.Y. July 28, 2004) (dismissing claims premised on theory that company "concealed" the existence of litigation in violation of securities laws). Judicial notice is taken of other litigations relating to Zyprexa in this court, as public information supporting a motion for summary judgment on statute of limitations grounds. Lawsuits alleging similar fraud (even without assessment of their factual sufficiency) serve as a public event for the purpose of putting a plaintiff on inquiry notice. *See, e.g., Benak*, 435 F.3d at 403 n.20. In conducting inquiry notice analysis on the basis of these public filings, a court is not barred by the truth of the detailed matters asserted in previously filed litigation. *Staehr v. Hartford Fin. Serus. Group, Inc.*, 460 F. Supp. 2d 329, 335 (D. Conn. 2006).

There was widespread awareness of the allegations in the many Zyprexa-related lawsuits filed before March 2005 that Lilly concealed a causal connection between Zyprexa and diabetes. Many lawsuits were filed before March 2005 that raised the very same Zyprexa-diabetes claims

that plaintiffs now put forward in their complaint. *See* Part II.E., *supra*. The number of state and federal complaints that alleged fraud, which are nearly identical to those that plaintiffs raise in the instant case, compel the conclusion that plaintiffs were placed on inquiry notice well before March 2005. *See Masters v. GlaxoSmithKline*, 2008 WL 833085, at *2 ("Notwithstanding [investor's] assertion that the [consumer class action alleging pharmaceutical company's failure to disclose the drug's adverse effects], . . . the complaints in the class actions sufficiently made known the underlying factual allegations forming the basis of Masters' securities fraud claim..").

Securities claims have been dismissed under similar circumstances. For example, in dismissing a securities action on statute of limitations grounds in the Vioxx litigation, the district court viewed previously filed products-liability actions as relevant for inquiry notice purposes:

> [A] class action product liability suit was filed against Merck in the spring of 2001. The complaint in that case alleged that VIOXX was not safe, that patients taking the medication were subject to an increased risk of suffering a heart attack and that Merck's research bore this out. While not conclusive of knowing misrepresentations or omissions by Merck with regard to VIOXX, the product liability litigation must be recognized as a sign of the brewing storm.

In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig., 483 F. Supp. 2d at 420. The court noted in detail:

> Add to this body of information . . . the initiation of law suits related to VIOXX's alleged propensity for increasing a patient's risk of heart attack. . . . [A]lthough they plead for relief under different legal theories than those at issue here—namely, under products liability and consumer fraud causes of action rather than securities fraud—*the lawsuits are predicated upon the same alleged wrongdoing as the allegations on which plaintiffs base their securities fraud claims*. The suits revolve around Merck's alleged misrepresentations and omissions regarding the known possibility that Vioxx increased a patient's risk of a thrombotic event . . . The fact that the information available by the end of September 2001 would give those plaintiffs sufficient notice to file statutory and common law fraud claims as well as failure to warn claims against Merck reinforces the Court's conclusion that *a reasonable investor of ordinary intelligence would have recognized, no later than early October 2001, warnings of troubles at Merck bearing upon his or her investments.*

Id. at 421 (emphasis added).

Because of the public nature of these court filings and the extensive media coverage they received, there is no need to ask whether plaintiffs actually obtained and examined the court papers. "[A] diligent plaintiff would obtain such documents and scrutinize them." *Ohio*, 651 F.2d at 695.

Plaintiffs as investors should have been aware of the existence of the many Zyprexa suits filed well before March 2005. Lilly disclosed the existence of Zyprexa-related lawsuits in its 2002 annual report filed with the SEC and made a similar disclosure to the SEC in 2003. The statements in Lilly's public SEC filings put plaintiffs on notice of a need to inquire further. Statements in public documents such as SEC filings that disclose the existence of lawsuits raising allegations concerning the same type of fraud as the securities action alleges serve to provide inquiry notice. *See Menowitz v. Brown,* 991 F.2d 36, 42 (2d Cir. 1993); *see also In re JWP Inc. Sec. Litig.*, 928 F. Supp. 1239, 1250 (S.D.N.Y. 1996).

2. *Inquiry Notice of Zyprexa's Potential for Having "Greater Likelihood" Of Causing Diabetes Than Other Atypical Antipsychotics*

According to plaintiffs, Zyprexa is more prone to cause diabetes than other drugs in its class, and this alleged relative difference is the critical piece of information that Lilly concealed from the marketplace. They claim that they first learned of the existence of this concealment from reports in the *New York Times* of confidential internal Lilly documents. The *New York Times* story was, so far as investors and the statute of limitations, irrelevant. For instance, in paragraph 73 of the complaint, plaintiffs rely upon an article by Geeta Anand and Thomas Burton, published in *The Wall Street Journal* on April 11, 2003. Anand and Burton wrote that "[a]mong the most widely prescribed versions of these [atypical antipsychotics] medications, Zyprexa, made by Eli Lilly & Co, *is the one most frequently associated with serious side effects*." Anand & Burton, *Drug Debate: New Antipsychotics Pose a Quandary for FDA, supra,*

Al (emphasis added). The authors observed that market competitors interpreted the available scientific data to support their position that competing medications were safer than Zyprexa: "Based on this and other research, *Johnson & Johnson says Risperdal has a lower risk of diabetes than Zyprexa.*" *Id.* (emphasis added).

By 2003 and early 2004, plaintiffs should have been on notice of the possibility that Zyprexa could be more harmful than other similar medications, and that at least some scientific findings refuted Lilly's "reassurances" to the market. In February 2004, the ADA, the APA, the American College of Clinical Endocrinologists, and the North American Association for the Study of Obesity published the results of their consensus development conference on the subject of antipsychotic drugs and diabetes. *See* Complaint ¶ 147 (citing American Diabetes Association. et al., 9 *Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes*, 27 Diabetes Care 596 (2004)). According to plaintiffs, "*[a]fter considering all of that scientific evidence, the consensus panel issued a statement that was contrary to Lilly's "comparable rates" message. Of the six atypical antipsychotics discussed in the census statement, only Clozapine and Olanzapine were found to increase the risk of diabetes.*" *Id.* (emphasis added, citations to the Consensus Statement omitted).

Just as the Zyprexa-related lawsuits filed in the years before 2005 provided warnings of a purported Zyprexa-diabetes link, there were compelling notices that Zyprexa might be relatively more dangerous or harmful than other antipsychotic drugs, and that Lilly had failed to disclose this information. For example, one lawsuit filed in December 2003 alleged that Lilly "*failed to warn that the risks associated with the ingestion of Zyprexa exceeded the risks of other comparable forms of medication for schizophrenia.*" Amended Complaint ¶ 48(e), *Phillips v. Fribley,* No. 03-04884-C (Tex. Dist. Ct. Dec. 12, 2003) (emphasis added), attached as Ex. 278 to

Lilly's Reply. Many other publicly filed lawsuits in 2003 and 2004 raised nearly identical claims of fraud and concealment.

Unconvincing is plaintiffs' argument that they did not have knowledge of the differential risk diabetes claim: plaintiffs' co-lead counsel in the present case filed a product liability and fraud lawsuit against Lilly before March 28, 2005. *See* Complaint ¶ 14, *Frye v. Eli Lilly & Co.*, No. 3:05-CV-053 (E.D. Va. Jan. 27, 2005). In *Frye*, counsel specifically averred that Lilly's alleged advertising of Zyprexa "falsely and fraudulently created the image and impression that the use of Zyprexa was safe for human consumption and had fewer side-effects and adverse reactions than other medications used to treat both bipolar disorder and schizophrenia." *Id.* This assertion of differential risk diabetes claim is strong evidence that the stock market had knowledge of such a claim prior to the statute of limitations date. *See In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 483 F. Supp. 2d at 421 ("The fact that the information available by the end of September 2001 would give those plaintiffs sufficient notice to file statutory and common law fraud claims as well as failure to warn claims against Merck reinforces the Court's conclusion that a reasonable investor of ordinary intelligence would have recognized, no later than early October 2001, warnings of troubles at Merck bearing on his or her investments."); *In re Exxon Mobil Corp. Sec. Litig.*, 387 F. Supp. 2d 407, 419 (D.N.J. 2005) ("Because the . . . plaintiff [in a previously filed securities action] must have known about the existence of certain facts suggesting fraudulent conduct on part of Defendants prior to the filing of the complaint in March 2004, the same information was available to plaintiffs in this matter.").

Lilly's public statements that the product liability and fraud actions were "without merit" are not of a kind that "an investor of ordinary intelligence would reasonably rely on . . . to allay

the investor's concern." *LC Capital Partners*, 318 F.3d at 155. Such boiler plate denials in response to pending litigation are insufficient to undermine the warnings provided by the filing of similar litigation. *See In re MBIA, Inc. Securities Litig.*, 2007 WL 473708, at *8 (finding that although MBIA denied all allegations of fraud, its "blanket response was no more than the 'mere expressions of hope, devoid of any specific steps taken to avoid' " future problems that have been routinely rejected by courts as insufficient reassurances) (citations omitted).

Plaintiffs also had inquiry notice of their claims concerning the alleged comparative risks associated with Zyprexa based on many news articles and analyst reports published long before March 2005. For example, as early as August 2002, an article appearing in Barron's encapsulating the specific issue underlying plaintiffs' "greater likelihood" claims. *See* Alpert, *Tech Trader, supra*, at T1. Alpert noted that the market was aware of the potential for a Zyprexa-diabetes link, and that Lilly denied that any alleged dangers posed by the drug were worse than those posed by other atypical antipsychotics:

> [I]nvestors have struggled this month with reports that link Zyprexa to diabetes. . .
>
> > [L]illy itself has studied the issue, and company researchers say that blood-sugar problems also accompany other schizophrenia drugs—and indeed, accompany schizophrenia itself. Any diabetes issue should therefore not affect Zyprexa's market share, Lilly tells doctors and investors.

Id. The article explicitly questioned Lilly's position on the issue: "*But the evidence to date convinces leading psychiatry researchers that Zyprexa does pose a greater risk of diabetes than other widely prescribed—and equally effective—schizophrenia drugs.*" *Id.* (emphasis added).

Analysts' reports addressed the issue in detail in the months and years before March 2005. For instance, in March 2004, a Prudential Equity Group report discussed the fact that Zyprexa's competitors contended that Zyprexa is comparatively less safe than other atypicals. "One of Abilify's key marketing messages (mainly directed at Eli Lilly's Zyprexa) has been that

Abilify has a better side effect profile." Prudential Equity Group, LLC, *Warning Added to Abilify Label* (Mar. 25, 2004), at 6, attached as Ex. 60 Lilly's Motion. A broader allegation about Zyprexa's comparative safety profile was made: "on the issue of weight gain (unrelated to diabetes), Zyprexa still has the worst profile." *Id.*

3. Inquiry Notice of Zyprexa's Off-Label Marketing

Plaintiffs claim that they could not have been aware that Lilly engaged in a covert "scheme" to promote off-label usage of Zyprexa. Complaint ¶¶ 186-213. They contend that they had no notice of this issue before December 2006: "Prior to the release of a December 18, 2006 article in the New York Times, the public at large had no knowledge of the lengths to which Lilly had gone to promote the off-label use of Zyprexa." *Id.* ¶ 206. This claim is belied by the evidence; plaintiffs were placed on inquiry notice of these alleged marketing practices long before March 2005.

For instance, in their complaint plaintiffs reference a 2003 article discussing a lawsuit raising claims by an individual who had been prescribed Zyprexa for "off-label" use:

> "FDA has approved Zyprexa to treat schizophrenia and bipolar disorder. *But in December 2000, Frank Olenick's doctors prescribed the drug to help him with sleeplessness and confusion* he suffered while withdrawing from painkillers, says his wife. . . . Such '*off label*' prescriptions are legal and not unusual with some drugs."

Anand & Burton, *Drug Debate: New Antipsychotics Pose a Quandary for FDA, supra*, at A1 (emphasis added) (cited at Complaint ¶ 73). Plaintiffs admit that "beginning in 2004, accusations began to surface that Lilly had engaged in the off-label marketing of Zyprexa." Complaint ¶ 211. Given plaintiffs' presumptive knowledge of these off-label marketing charges, inquiry notice of this issue existed well before March 2005.

Numerous Zyprexa-related lawsuits that were filed well before March 2005 also raised claims similar to plaintiffs' "off-label marketing" theory. The existence of these lawsuits provided plaintiffs with multiple warnings of their claims well before March 2005. *See* Parts II.D. and E., *supra*.

Widely discussed in the press was Lilly's off-label marketing. For example, a March 15, 2004 article in *Drug Industry Daily* revealed that Pfizer was the subject of investigation by the Department of Justice for off-label marketing practices, and noted that Lilly could be the next off-label marketing investigation target. *DOJ Probing Pfizer Sales Practices; Lilly Says Zyprexa May Be Next, supra*, at 50. According to the author, "Eli Lilly has announced that legal difficulties may be on the horizon for its top-selling drug. Already facing scrutiny for possible improper marketing . . . the company said in a regulatory filing this week that Zyprexa (olanzapine), as well as other company drugs, could come under investigation." *Id.* Just over a week later, the same publication announced that the government had initiated such an investigation into Zyprexa marketing practices: "Justice Department officials have notified Eli Lilly that they have begun a civil investigation into the way the drugmaker markets and promotes its products, Lilly announced yesterday." *Lilly Facing Federal Probe, supra*, at 60. Faced with the large number of public reports of allegations concerning off-label marketing, it is evident that plaintiffs had received sufficient "storm warnings" of their claims long before the applicable two-year inquiry notice period ran. In short, for years before the statute of limitations barred this suit, the red triangular flags of an incipient hurricane had been figuratively hoisted over Lilly and Zyprexa. The reasonable investor cannot blink away what the market sees.

C. Equitable Tolling

Plaintiffs argue that the statute of limitations should be tolled. The Supreme Court has recognized that equitable tolling is "fundamentally inconsistent" with the structure of the statute of limitations in federal securities cases. *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350, 363 (1991).

> Equitable tolling is inconsistent with the [two-year] discovery period because if a defendant actively conceals a fraud, then plaintiff will not discover the facts suggesting the violation and the statute will not begin to run, making tolling unnecessary. Equitable tolling is also fundamentally inconsistent with the [five-year] repose period because that limit is 'clearly to serve as a cutoff' and it would have no significance as an outside limit if it could be tolled.

In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig., 289 F. Supp. 2d at 426 (citations omitted).

Equitable tolling may apply in some limited situations where an investor inquires about a probable fraud but is frustrated in that inquiry by a defendant's deliberate concealment of the violation. *Id.* at 426 n.17; *Dodds*, 12 F.3d at 350 ("The doctrine of equitable tolling is . . . limited. Equitable tolling will stay the running of the statute of limitations only so long as the plaintiff has exercised reasonable care and diligence in seeking to learn the facts which would disclose fraud.") (quotation marks and citations omitted). In the instant case plaintiffs have not alleged any attempt to undertake an investigation once they were placed on inquiry notice.

According to the plaintiffs "[d]efendants' seemingly reliable statements of reassurance to the marketplace served to dissipate any and all storm warnings which may have appeared during the Class Period." Complaint ¶ 351. Plaintiffs contend that these "reassurances" attenuated their duty to inquire into the allegations underlying the complaint. Given the continuing warnings raising allegations of fraud beginning in 2002, plaintiffs have no reasonable basis for relying on so-called "reassurances" from management as an excuse for failing to inquire. "[A]n investor may not reasonably rely on words of comfort from management 'when there are direct

contradictions between defendant's representations and the other materials available to plaintiffs regarding the possibility of fraud.' " *In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 483 F. Supp. 2d at 421 (quoting *In re Exxon Mobil Corp. Sec. Litig.*, 387 F. Supp. 2d at 418). Plaintiffs' "duty to inquire is not dissipated merely because of a defendant's later refusal to acknowledge or own up to the alleged fraud." *In re Merrill Lynch & Co., Inc. Research Reports Sec. Litig.*, 289 F. Supp. 2d at 425. Because public documents raised the specter of Lilly's fraud, plaintiffs—as reasonable investors—had a duty make a contemporaneous inquiry.

An August 2002 article appearing in Barron's summarized one of the primary issues underlying plaintiffs' claims and gave notice of possible false reassurances by Lilly. It noted that the market was aware of the potential for a Zyprexa-diabetes link, and that Lilly denied that any alleged dangers posed by the drug were worse than for other atypical antipsychotics:

> [I]nvestors have struggled this month with reports that link Zyprexa to diabetes. . .
>
> Wall Street's latest Zyprexa worries were fanned by the Boston-based broker Leerink Swann, which publicized recent medical reports of diabetes incidence among Zyprexa patients. Lilly itself has studied the issue, and company researchers say that blood-sugar problems also accompany other schizophrenia drugs—and indeed, accompany schizophrenia itself. Any diabetes issue should therefore not affect Zyprexa's market share, Lilly tells doctors and investors.

Alpert, *Tech Trader, supra*, at T1. The article explicitly raised questions about the legitimacy of Lilly's position: "But the evidence to date convinces leading psychiatry researchers that Zyprexa does pose a greater risk of diabetes than other widely prescribed—and equally effective—schizophrenia drugs." *Id.* As a result of these issues, "Lilly shares faltered on Zyprexa worries . . . ." *Id.*

There can be no reasonable doubt that the market received strong warnings to question Lilly's "reassurances." "[R]eassuring statements will prevent the emergence of a duty to inquire

or dissipate such a duty only if an investor of ordinary intelligence would reasonably rely on the statements to allay the investor's concern." *LC Capital Partners*, 318 F.3d at 155.

By delaying suit for years, when a reasonable investor would not have done so in light of the publicity that the Zyprexa-related issues received, plaintiffs are barred from raising their fraud claims at this juncture. Even were equitable tolling legally available in securities cases like the present one, there is no factual basis for tolling.

D. Section 20(a) Claims

Plaintiffs assert a claim under Section 20(a) of the Exchange Act against individual defendants Taurel, Breier, Lechleiter, Beasley, Mayr and Tollefson. *See* Complaint ¶¶ 315-33. To state a claim under Section 20(a), plaintiffs must show "(1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful sense a culpable participant in the primary violation." *Boguslavsky v. Kaplan*, 159 F.3d 715, 720 (2d Cir. 1998) (internal quotation marks and citation omitted).

Claims against Lilly employees and managers under Section 20(a) are derivative. Absent an underlying violation of the securities laws, there can be no controlling-person liability. *See, e.g., Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1132 (2d Cir. 1994) ("[B]ecause we find that the primary violation asserted by [plaintiff] is . . . properly dismissed by the district court, we also find no error in the district court's dismissal of the claims of secondary liability under § 20 of the 1934 Act against" individual defendants). Because plaintiffs cannot prove a primary violation of Section 10(b), their derivative claim under Section 20(a) against the individual defendants fails. *Id.*

V. Maine Securities Claims

The complaint alleges various state law claims on behalf of the Maine State Retirement System ("MSRS") and the putative subclass that MSRS purports to represent—"a subclass of state and municipal pension plans that purchased Lilly securities during the Class Period." *See* Compliant ¶ 361. MSRS appears to be making claims under the laws of all fifty states, on behalf of all the states, against each of the defendants for: common law fraud (counts III and IV); negligent misrepresentation (counts V and VI), and unspecified "state securities law violations" (count VII). Count VII is limited to claims "pursuant to those state securities laws that have a private right of action of each of the states in which the members of the Subclass are located." *Id.* ¶ 430.

Plaintiffs have not identified which states they contend are suing. Nor do they assert that any state but Maine has authorized a suit. For purposes of this suit, the only authorized plaintiff with standing is MSRS.

A. Law on Statute of Limitations

The statute of limitations under Maine's Uniform Securities Act mirrors the statute of limitation that applies to plaintiffs' federal securities claims. "[U]nless the action is instituted within the earlier of 2 years after discovery of the facts constituting the violation or 5 years after the violation," Me. Rev. Stat. Ann. tit. 32, § 16509(10)(B) (2005), it is barred.

Although it appears that there is no Maine case law interpreting the current statute, comment 14 to the statutory notes explains that the federal statute of limitations provides guidance on interpretation of Maine's statute of limitations:

> Section 509(j)(2) . . . generally follows the federal securities law model. An action must be brought within the earlier of two years after discovery or five years after the violation. As with federal courts construing the statute of limitations under Rule 10b-5, it is intended that the plaintiff's right to proceed is limited to two years after actual discovery "or after such discovery should have been made

> by the exercise of reasonable diligence" (inquiry notice), *see, e.g.*, *Law v. Medco Research, Inc.*, 113 F.3d 781 (7th Cir. 1997), or five years after the violation."

Me. Rev. Stat. Ann. tit. 32, § 16509 cmt. 14 (2005). As with plaintiffs' federal securities law claims, the "inquiry notice" standard applies.

B. Application of Law to Facts

As demonstrated in part IV, *supra*, plaintiffs were placed on inquiry notice for all of their claims long before March 2005, when the applicable Maine two-year statute of limitations began to run. Frequent and strong warnings appeared in the public domain—in news articles, analyst reports, and lawsuits—in 2002, 2003 and 2004. *See* Parts II.C., D., E., and IV.B., *supra*. These warnings triggered plaintiffs' duty to investigate the issues that underlie their claims. Comment 14 to the Maine statutory notes references *Law v. Medco Research, Inc.*, 113 F.3d 781 (7th Cir. 1997) which noted that "too much emphasis on the statute of limitations can precipitate premature and groundless suits, as plaintiffs rush to beat the deadline without being able to obtain good evidence of fraud." *Id.* at 786. Even after applying a standard which might require investors to be in possession of or have ready access to essential facts that they need in order to be able to sue, it has been demonstrated beyond any reasonable doubt by the evidence in the instant case that—well before March 2005—there was ample, publicly available, Lilly-specific information that directly related to whether Zyprexa was associated with higher rates of diabetes and whether Lilly promoted Zyprexa off-label. *Cf. Menowitz v. Brown*, 991 F.2d 36, 40-41 (2d Cir. 1993) ("a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of transferor circuit.").

Plaintiffs' claims under the Maine Uniform Securities Act are dismissed as time-barred. No other state claims are before the court.

VI. Conclusion

Summary judgment is granted to the defendants on statute of limitations ground. *See* Parts III.B., IV.B. and V.B., *supra*. An amendment to the complaint could not alter this judgment. *See In re "Agent Orange" Prod. Liab.*, 517 F.3d 76, 103-04 (2d Cir. 2008) (opportunity to amend before a responsive pleading is filed is not needed if amendment cannot change result); *Yerdon v. Henry*, 91 F.3d 370, 378 (2d Cir. 1996) ("Where it appears that granting leave to amend is unlikely to be productive, it is not an abuse of discretion to deny leave to amend.").

The case is dismissed. Costs and disbursements to defendants.

SO ORDERED.

Jack B. Weinstein
Senior United States District Judge

Date: April 30, 2008
Brooklyn, New York