UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA PRODUCTS LIABILITY LITIGATION	MEMORANDUM & ORDER MOTIONS FOR SUMMARY JUDGMENT 04-MD-1596
UFCW LOCAL 1776 AND PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, ERIC TAYAG, and MID-WEST NATIONAL LIFE INSURANCE COMPANY OF TENNESSEE, on behalf of themselves and others similarly situated, Plaintiffs, vs. ELI LILLY AND COMPANY, Defendant.	05-CV-4115 05-CV-2948
LOCAL 28 SHEET METAL WORKERS, on behalf of themselves and others similarly situated, Plaintiffs, vs. ELI LILLY AND COMPANY, Defendant.	06-CV-0021
SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, on behalf of themselves and others similarly situated, Plaintiffs, vs. ELI LILLY AND COMPANY, Defendant.	06-CV-6322

JACK B. WEINSTEIN, Senior United States District Judge:

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I. Introduction

These are part of a series of cases based on injuries allegedly resulting from sale of the drug Zyprexa, manufactured by Eli Lilly & Company ("Lilly"). *See, e.g., In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2007 WL 1678078 (E.D.N.Y. June 11, 2007) (memorandum and order on motions for summary judgment in individual personal injury claims).

In June of 2005, Mid-West National Life Insurance Company of Tennessee filed a class action suit against Lilly seeking economic damages. Similar suits were initiated by UFCW Local 1776 and Participating Employers Health and Welfare Fund, and Eric Tayag, in August of 2005 (Michael Pronto and Michael Vanello were later added as co-lead plaintiffs); Local 28 Sheet Metal Workers in January of 2006; and Sergeants Benevolent Association Health and Welfare Fund in November of 2006. Institutional plaintiffs in the instant cases are pension funds, labor unions, and insurance companies who cover members' health benefits and have paid for the drug Zyprexa when it was prescribed by physicians for their individual members or clients. An individual Zyprexa user who made co-payments is also named as a plaintiff.

Plaintiffs claim overpayment through direct purchase of Zyprexa. They allege that over an eleven-year period continuing to today Lilly withheld information, and disseminated misinformation, about the safety and efficacy of Zyprexa, and promoted and marketed it for uses

for which it was not indicated, and for patients who would have been better served by less expensive medications. The consequence, it is contended, was pricing of the drug at more than it would have sold for had the truth been known. The resulting excess payments are claimed as damages.

Five causes of action are asserted: violation of 18 U.S.C. 1962(c) (Racketeer Influenced and Corrupt Organization Act (RICO)); 18 U.S.C. 1962(d) (RICO); various state consumer protection statutes; common law fraud; and unjust enrichment.

Class certification is sought on the ground that anyone who paid for Zyprexa was charged more than they would have been in the absence of Lilly's fraud. The proposed class is defined as follows:

> All individuals and entities in the United States and its territories who, for purposes other than resale, purchased, reimbursed, and/or paid for Zyprexa during the period from September 1996 through the present. For purposes of the class definition, individuals and entities purchased Zyprexa if they paid all or some of the purchase price.

Subject matter jurisdiction is based upon 28 U.S.C. § 1331 (action arising under the laws of the United States) and 18 U.S.C. §§ 1962 and 1964(c) (RICO). Plaintiffs also invoke jurisdiction pursuant to 28 U.S.C. § 1332(d)(2) (Class Action Fairness Act). Venue is placed in the Eastern District of New York pursuant to 28 U.S.C. § 1391(b) and (c) (requiring that a substantial portion of the alleged improper conduct took place in the district where suit is commenced) and 18 U.S.C. § 1965 (RICO).

Under the present organization of the pharmaceutical industry, the official federal Food and Drug Administration (FDA), and the plaintiffs' bar, the courts are arguably in the strongest position to effectively enforce appropriate standards protecting the public from fraudulent

merchandising of drugs. *See, e.g.*, James Surowiecki, *A Drug on the Market*, The New Yorker, June 25, 2007, at 40 ("The U.S. has no rational system for 'post market surveillance' — the evaluation of drugs after they're approved. Instead, oversight is left to a motley collection of altruists, academics, lawyers, self-publicists, and drug companies . . . . Somehow, the truth is expected to rise to the surface from among all these competing interests and random decisions."). As Drs. Kesselheim and Avorn put it:

> [C]ase studies [of major pharmaceutical litigations, including Zyprexa] indicate that clinical trials and routine regulatory oversight as currently practiced often fail to uncover important adverse effects for widely marketed products. In each instance, the litigation process revealed new data on the incidence of adverse events, enabled reassessments of drug risks through better evaluation of data, and influenced corporate and regulatory behavior. In performing these tasks, lawyers and their clients often find themselves serving as drug safety researchers of last resort.

Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, Journal of the American Medical Association, January 17, 2007, at 308; *see also, e.g.*, Janet L. Dolgin & Joel Weintraub, *Biomedical Research and the Law: The Pharmaceutical Industry and its Relationship with Government, Academia, Physicians, and Consumers*, 35 Hofstra L. Rev. 681 (2006).

There is little doubt about the usefulness of Zyprexa for both on-label and some off-label purposes. It assists many people with serious debilitating diseases. It has substantially increased the quality of life of many thousands of people. Its salutary effect is evidenced by the fact that there have been no changes in plaintiffs' formularies which continue to include Zyprexa without restrictions. Many treating physicians continue to rely on it after what is by now extensive revelation of information about Zyprexa's risks and benefits. Nevertheless, the utility of Zyprexa does not trump plaintiffs' legal claims for fraud and overpricing.

This turns out to be incorrect although it is easy to see how the judge would draw this erroneous conclusion. Jim Gottstein

II. Summary Judgment Law

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, 106 S. Ct. 2505 (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.

"In considering the motion, the court's responsibility 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).

III. Plaintiffs' Motion for Partial Summary Judgment

Plaintiffs' motion for partial summary judgment is based upon the following proposed findings: (1) third party payers ("TPPs") are purchasers of prescription drugs, and pharmaceutical benefit managers ("PBMs") act as agents for TPPs; (2) PBMs exercise no effective influence on the prescribing habits of physicians with regard to Zyprexa; (3) preemption is not applicable to or an issue in this litigation; (4) Zyprexa is not superior in efficacy to conventional antipsychotic medications or other atypical antipsychotic drugs; and (5) damages to the proposed class are at

least $3.7 billion.

The motion is without merit. (1) The relation of TPPs to PBMs in the case is unclear. (2) Determination of how Lilly's actions influenced what physicians prescribed will require a trial. (3) The court has already ruled that preemption does not apply, *In re Zyprexa, supra*, at Part III.A.6.a; a separate ruling is not required. (4) Zyprexa may be found by a jury to be considered preferable to other medications by knowledgeable prescribing physicians in specific cases, *see id.* at Part III.B. (5) It is not clear that plaintiffs can prove any damages, whether they attempt to prove overpayment on a case-by-case basis for each insured or through statistical analysis. *See id.; Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris USA, Inc.*, 3 N.Y.3d 200 (N.Y. 2004) (finding statistical proof acceptable); *Empire Healthchoice, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 211 (2d Cir. 2003)(same).

IV. Conclusion as to Plaintiffs' Motion for Partial Summary Judgment

Plaintiffs' motion for partial summary judgment is denied.

V. Defendant's Motion for Summary Judgment

Defendant moves for summary judgment on the ground that plaintiffs cannot satisfy the elements of any of their claims. Strength of proof is not the appropriate standard for a summary judgment decision. *See* Part II, *supra*. While the case is close, plaintiffs have sufficiently demonstrated for purposes of this motion that genuine issues of material fact exist with respect to their RICO and state substantive law claims.

A. Injury and Causation

As purchasers of Zyprexa, consumers and third party payers have standing to sue for economic damages; they have demonstrated a sufficient causal nexus between Lilly's alleged

fraud and their own claimed economic injuries. The Court of Appeals for the Second Circuit "and other courts have long recognized the right of [health care benefit providers] to recover from drug companies amounts that were overpaid due to illegal or deceptive marketing practices." *Desiano v. Warner-Lambert* Co., 326 F.3d 339, 350 (2d Cir. 2003).

Boiled down, this is an overpricing claim. The alleged injury is direct: plaintiffs overpaid from their own funds for Zyprexa because of Lilly's fraud. The case is distinguishable from a RICO suit by an insurance company dismissed by the Court of Appeals for the Second Circuit for failure to satisfying proximate cause requirements in *Laborers Loc. 17 Health & Benefits Fund v. Philip Morris*, 191 F. 3d 229 (2d Cir. 1999).

> In *Laborers Local 17*, the tobacco companies' alleged tort directly harmed only the smokers, who suffered both a health injury (smoking-related illness) and an economic injury (the purchase price of the fraudulently marketed cigarettes). The smokers' health injuries, in turn, caused economic losses to the insurance companies, who had to reimburse patients for the cost of their smoking-related illnesses. That case was therefore clearly one in which the plaintiffs' damages were entirely derivative of the injuries to their insured. For . . . without injury to the individual smokers, the plaintiffs would not have incurred any increased costs.

Desiano, 326 F.3d at 349 (quotation and citation omitted).

As purchasers of Zyprexa — i.e., those who paid for the product in whole or in part out of their personal funds — plaintiffs here allege a direct injury to themselves that is not dependent on any physician's decision or injury suffered by those who ultimately ingested Zyprexa. This case falls within the category of suits approved in *Desiano*:

> Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers, since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendant's misrepresentations. Thus the damages — the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased 'but for' Defendants'

fraud — were in no way derivative of damages to a third party.

Desiano, 326 F.3d at 349 (quotation omitted).

In attempting to distinguish *Desiano*, Lilly emphasizes the fact that third party payer plaintiffs continue to include Zyprexa in their approved formularies. This fact has evidentiary relevance to the central claim of overpayment due to fraudulently-inflated prices, but it is not decisive. Probative force of this and other evidence of fraud and overpricing — or their contrary — present jury questions. Based on expert reports and available modes of economic analysis, a trier could determine that Zyprexa would have — or would not have — been sold for a reasonably precise computable lesser amount than it was sold for were it not for Lilly's alleged fraud. *See Schwab v. Philip Morris*, 449 F. Supp. 2d 992, 1065 (E.D.N.Y. 2006).

The allegation of economic harm in *Schwab* was structured in a manner similar to the instant plaintiffs' allegations:

> Plaintiffs here allege a simple and short chain of causation: defendants represented that 'light' cigarettes provided health benefits that they knew these cigarettes did not provide; plaintiffs believed the misrepresentation and so continued to buy 'light' cigarettes in larger numbers than they would have absent the fraud; this kept demand for 'light' cigarettes at a much higher level than it otherwise would have been; elevated demand allowed defendants to keep prices higher than they otherwise would have; and plaintiffs paid more for 'light' cigarettes than they otherwise would have.

Id. at 1049.

Present plaintiffs allege that Lilly represented that Zyprexa was safer and more efficacious than other available drugs; Lilly in fact knew this to be untrue; the misrepresentation led doctors to continue to prescribe, and plaintiffs to continue to pay for, greater amounts of Zyprexa than they would have absent the fraud; this kept demand for Zyprexa at a higher level than it otherwise would have been; elevated demand allowed Lilly to keep prices higher than they

otherwise would have been; and plaintiffs paid more for Zyprexa than they otherwise would have.

Non-pharmaceutical treatment, while of proven efficacy is not paid for. Jim Gottstein

The economic analysis may be more difficult in this case than in *Schwab* because of the monopoly status provided by the patent laws to Lilly. In addition, the many competing modes of treatment available — other atypical antipsychotic drugs, first generation antipsychotic drugs, and non-pharmaceutical treatment — complicate the question of damages computation. While the required economic analysis may be somewhat more sophisticated than that required in *Schwab*, it appears to be within the competence of econometricians on both sides. *See Blue Cross & Blue Shield v. Philip Morris*, 344 F.3d 211, 222-28 (2d Cir. 2003) (finding statistical and aggregate proof appropriate and not in violation of right to jury and due process); *Blue Cross & Blue Shield of N.J. v. Philip Morris*, 3 N.Y.3d 200, 204 (N.Y. 2004) ("aggregate proof on issues of causation and damages was legally sufficient").

Once fraud has been proven, the burden of proving specifics of damages by the claimant is reduced. "Where injury is established, damages need not be demonstrated with precision." *Schwab*, 449 F. Supp. 2d at 1065 (E.D.N.Y. 2006); *see Blue Cross*, 344 F.3d at 224-25; *cf. Lee v. Joseph E. Seagram & Sons, Inc.*, 552 F.2d 447, 456 (2d Cir. 1977) ("When it is certain that damages have been caused by a breach of contract, and the only uncertainty is as to their amount, there can rarely be good reason for refusing, on account of such uncertainty, any damages whatever for the breach. A person violating his contract should not be permitted entirely to escape liability because the amount of damages which he has caused is uncertain.") (quotation and citation omitted).

Both the individual and institutional plaintiffs have laid out their own money for Zyprexa.

While it can be assumed for purposes of this motion that the drug was properly prescribed, payers may recover the difference between the price they paid for Zyprexa and the price they would have paid for Zyprexa but for Lilly's alleged fraud. *See, e.g., Schwab,* 449 F. Supp. 2d at 1065 (approving use of price impact model to calculate damages). The questions of damages and their allocation is in some respects simpler here than in *Schwab* since the institutional and individual claimants can probably trace their own payments through contemporaneous writings.

B. Reliance

Where, as here, mail fraud and wire fraud are the alleged predicate acts forming the racketeering activity, justified reliance on the fraud is necessary to satisfy RICO's causation requirements. *See, e.g., Metromedia Co. v. Fugazy*, 983 F.2d 350, 368 (2d Cir. 1992). *But see Anza v. Ideal Steel Supply Corp.*, 126 S.Ct. 1991, 2008 (2006) (Thomas, J., concurring in part and dissenting in part) (reaching a question not reached by the majority — whether reliance is required in a civil RICO suit predicated on mail and wire fraud — and concluding that "[b]ecause reliance cannot be read into [the mail or wire fraud statutes], nor into RICO itself, it is not an element of a civil RICO claim").

Defendant argues that plaintiffs' use of aggregate proof, rather than individualized proof, to establish reliance is impermissible. This assertion is without merit.

Statistical proof of reliance is appropriate in the RICO context where a "sophisticated, broad-based [scheme,] by [its] very nature . . . likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people[,]" is alleged. *See Schwab*, 449 F. Supp. 2d at 1047; *id.* at 1115-17 (permitting generalized proof of reliance including "surveys, expert evidence on marketplace principles, and extrapolated and statistic

analysis of individuals and groups in the class"). Here, plaintiffs allege that Lilly intentionally engaged in a broad-based plan to misrepresent to the medical and scientific communities the nature of Zyprexa's benefits and risks, and that the scheme was successful in distorting the general body of knowledge about Zyprexa. These allegations, and the factual and expert proof that plaintiffs rely on to prove them, meet the standard for reliance established in *Falise v. American Tobacco Co.*, 94 F. Supp. 2d 316 (E.D.N.Y. 2000), and *Schwab*.

Defendant urges the court to distinguish this case from the cigarette industry cases decided in *Schwab* and *Falise* on the basis that there is no allegation that Lilly conspired with other companies within the pharmaceutical industry to distort the body of public knowledge concerning Zyprexa's risks. This distinction is of no moment: Lilly is the monopolistic purveyor of Zyprexa so there was no need for it to collaborate with any other manufacturer with respect to the dissemination of information about Zyprexa. While Lilly's competitors may have been expected to lay bare Zyprexa's flaws in the vigorous merchandising of their own products, such evidence would not be decisive on the question of reliance — rather, it would be for the trier to consider when examining the question of whether Lilly's alleged fraud was in fact successful in distorting scientific knowledge about Zyprexa. In addition, plaintiffs rely on evidence of cooperation of non-Lilly-employed experts and co-opted paid doctors to support their RICO theory.

C. Consumer Protection Statutes

Since a decision on class certification has not yet been made, it is not appropriate to now address the elements of specific state consumer protection statutes. There have been holdings in similar cases that suits by insurance companies to recover economic damages arising from the

fraudulently-inflated price of prescription drugs are not actionable under some states' consumer protection statutes. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597 (S.D.N.Y. 2005) (finding health care benefit providers could not recover from manufacturer for alleged overpayment for the prescription drug Rezulin under consumer protection statutes of New York, New Jersey, or Louisiana). If the class is certified, the substantive state law applicable under choice of law rules — as well as RICO — will be considered in defining the class.

VI. Conclusion as to Defendant's Motion for Summary Judgment

Though the question is a close one on the facts, defendant's motion for summary judgment is denied.

Allowing this and like suits to proceed may or may not increase the cost of pharmaceuticals and the efficacy of medical treatment in this country. It does, however, furnish backstop protection against under-regulated potentially dangerous activity by a market where *caveat emptor* largely rules. *Cf.*, Eric S. Lipton & David Barboza, *As More Toys are Recalled, Trail Ends in China*, N.Y. Times, June 20, 2007, at A1 ("Combined with the recent scares in the United States of Chinese-made pet food, and globally of Chinese-made pharmaceuticals and toothpaste, the string of toy recalls is inspiring new demands for stepped-up enforcement of safety by United States regulators and importers, as well as by the government and industry in China.").

Arguably, suits such as the present one do more good than harm. *See, e.g.*, authorities referred to in Part I, *supra*; *In re Zyprexa Prods. Liab. Litig.*, 2007 WL at *10 ("Whatever the advantages to available court procedures limiting the 'piling on' phenomena in mass tort cases, the process involves substantial transactional costs."). It is for the legislature, not this court, to

limit individual litigation-enforced remedies for fraud on consumers of pharmaceuticals.

VII. Daubert Motions

Plaintiffs move to exclude all or part of the proposed testimony of defendant Lilly's proffered experts, Charles M. Beasley, Jr., M.D., Ernst R. Berndt, Ph.D., Patrizia Cavazzoni, M.D., Iain Cockburn, Ph.D., David W. Feigal, Jr., M.D., William S. Gilmer, M.D., Silvio E. Inzucchi, M.D., David A. Kahn, M.D., Jeffrey S. McCombs, Ph.D., Michael A. Silver, M.D., and Gary Tollefson, M.D. The criteria for meeting *Daubert* requirements have been outlined in *In re Zyprexa Prods. Liab. Litig.*, *supra* at Part IV. Each of the challenged experts meet *Daubert* requirements. Each is a distinguished scientist whose expertise probably will be helpful in deciding relevant scientific and economic issues. Attacks on them by plaintiffs are primarily based on assessments of credibility best left for the trier. *In limine* motions respecting particular aspects of these and other experts' proposed testimony will be considered when it becomes clear what will be the detailed issues to be tried.

The court has evaluated plaintiffs' expert reports submitted on their motion by registered pharmacist Myron Winkelman; Doctor of Pharmacology Laura M. Plunkett; Master of Science in Pharmacology Terry D. Leach; Keith Bradbury; Marsha More, M.D.; Meredith Rosenthal, Ph.D.; Jeffrey E. Harris, M.D., Ph.D.; John Abramson, M.D.; Steven Klotz, M.D.; and John L. Gueriguian, M.D. All the plaintiffs' experts meet *Daubert* standards. *See id.*

VIII. Interlocutory Appeal

Section 1292(b) of title 18 of the United States Code provides that a district court judge may certify an order that is "not otherwise appealable" if the judge is "of the opinion that such order involves [1] a controlling question of law [2] as to which there is a substantial ground for

difference of opinion and [3] that an immediate appeal from the order may materially advance the ultimate termination of the litigation . . . ." 18 U.S.C. § 1292(b). Absent certification, an order denying summary judgment is not appealable. *See Sira v. Morton*, 380 F.3d 57, 66 (2d Cir. 2004) ("It is settled law that a denial of summary judgment is ordinarily not a final judgment from which an appeal will lie.").

Section 1292(b)'s requirements are not met in this case, even though both the substantive and procedural law relied upon by the parties are in a state of flux and not free from doubt. An immediate appeal might save considerable costs in discovery, preparation for trial, and trial. But an interlocutory appeal should await a decision on the critical question of class certification — an issue not yet considered by the court. When that question is decided by this court, the Court of Appeals can in its discretion decide the class certification issue under Rule 23(f) of the Federal Rules of Civil Procedure. For this reason, upon deciding on class certification this court plans to certify an interlocutory appeal under § 1292(b) so the class-procedural and substantive merits can be considered together by the appellate court. *See* Karen Schwartz et al., *Some Problems Dealing With Class Action Disputes*, 163 F.R.D. 369, 385 (1995) (recommending that merits and class certification be considered together).

SO ORDERED.

Jack B. Weinstein

Date: June 28, 2007
Brooklyn, N.Y.