IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LIGITATION	**Master File No. 1:16-md-02753-LM** **MDL No. 2753** **LANDYA B. MCCAFFERTY** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **ALL CASES**	

MOTION TO ESTABLISH A QUALIFIED SETTLEMENT FUND AND ISSUE RELATED ORDERS

Plaintiffs in the above Captioned MDL by and through Lead Counsel hereby respectfully move this Court, for the reasons specified in the attached Memorandum of Law to establish a Qualified Settlement Fund and issue related orders.

DATED: December 10, 2021

Respectfully submitted,

/s/ Jonathan D. Orent, Esq.
Jonathan D. Orent
MOTLEY RICE LLC
55 Cedar Street, Suite 100
Providence, RI 02903
401-457-7700
401-457-7708 Fax
jorent@motleyrice.com

Plaintiffs' Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has this date been filed electronically with the Clerk of Court using the CM/ECF system. Notice of these filings will be sent to all counsel of record and parties by operation of the Court's electronic filing system.

/s/ Jonathan D. Orent
Jonathan D. Orent

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IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LIGITATION	**Master File No. 1:16-md-02753-LM** **MDL No. 2753** **LANDYA B. MCCAFFERTY** **U.S. DISTRICT JUDGE**
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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS UNOPPOSED MOTION TO ESTABLISH A QUALIFIED SETTLEMENT FUND AND ISSUE RELATED ORDERS

Plaintiffs in the above Captioned MDL by and through Lead Counsel Claimants' Counsel hereby respectfully move this Court, for the reasons specified in this Memorandum of Law to establish a Qualified Settlement Fund the Fund or the QSF and issue related orders.

FACTUAL BAC GROUND

Plaintiffs are seeking damages from Atrium Medical Corp. Defendant or Atrium, and collectively with Plaintiffs, Parties , relating to the design, distribution, manufacture, testing, sale, inspection, implantation, explantation, use, promotion, advertising, administration, research, development, packaging, labeling, marketing, examining, maintenance, supplying, preparation, analy ing, recommendation, display, development, study, production, performance and warning relating to ernia Repair Products manufactured, distributed, and/or designed by Atrium collectively, the ernia Mesh Claims through various legal actions filed in this Court.

Defendant denies any and all liability to Claimants. In an effort to resolve their outstanding disputes, the Parties entered into a confidential Master Settlement Agreement between Atrium, on the one hand, and Lead Plaintiffs' Counsel on the other hand hereinafter the Master Settlement Agreement . Atrium entered into the Master Settlement Agreement solely to avoid the expense, inconvenience, and burden of litigation, and the distraction and diversion of its personnel and resources and has done so without admission of liability or wrongdoing.

At this time, the exact distribution of any settlement monies to the Plaintiffs cannot be finali ed. The Parties, therefore, ask this Court to order the establishment of the Fund to facilitate resolution of those claims through collection, allocation, final disbursement, and accounting of settlement proceeds and to appoint a fund administrator in connection with these activities. It is in the best interests of all parties that the Court establish the QSF to resolve or satisfy these ernia Mesh Claims, while allowing for the allocation, final disbursement and accounting of settlement monies to be finali ed.

All aspects of the administration of the Fund shall remain subject to the jurisdiction of the Court until such time as the Fund has settled all eligible claims according to the terms of the Master Settlement Agreement.

Only upon the satisfaction of all applicable terms, conditions and requirements set forth in the Master Settlement Agreement, the Fund shall be liable to make payments to eligible Claimants and Plaintiffs. ells Fargo shall be appointed as the Escrow Agent Escrow Agent and Peter F. augh, ead of The Legal Specialty roup shall be appointed as the Administrator of the Fund the Administrator .

ntil such time that Claimants are entitled to settlement proceeds, no settlement proceeds shall be set apart for any individual Plaintiff, or otherwise made available so that he or she may draw upon or otherwise control said settlement proceeds, until all applicable terms and conditions in the Master Settlement Agreement have been satisfied.

The Fund, by and through the Administrator, shall only make payments to the Claimants and any entities asserting a claim of subrogation, according to the terms set forth in the Master Settlement Agreement. The Fund, by and through the Administrator or its agent, may purchase and assign any structured settlements, also known as periodic payments created under any release agreements and execute any and all necessary documents related to the discharge of those liabilities. Any structured settlement shall be issued by a life insurance company that is rated A or better. The Administrator shall also be authori ed to enter into non-qualified assignments for the convenience of the Claimants to the extent that attorneys' fees are to be paid as part of the Claimants' obligations under existing contingency fee agreements.

Atrium shall have no responsibility for the expenses or administration of the Fund and shall have no liability to the Claimants in connection with such administration or decisions made by the Administrator in the discharge of any and all Administrators' duties. Said expenses, if any, may be paid out of the Settlement Amount deposited and held in the Fund. Atrium shall cooperate with the Fund Administrator to extent reasonably necessary by providing any legally required forms or data necessary, to complete the Fund's accounting. Moreover, Atrium will cooperate with its obligations under the Master Settlement Agreement relating to the release of lien holdbacks. Aside from the foregoing sentence and subject to Atrium's rights under the Master Settlement Agreement, no

relationships or responsibilities are created hereby between Atrium and the Fund and its Administrator. Atrium shall in no way be associated with the administration of the Fund or be liable in respect of any dispute between or among any Claimants and their respective counsel in respect of any costs, expenses, legal fees or litigation costs to be deducted from the Fund.

Claimants who receive periodic payments shall agree in writing to a discharge of the Fund, the Escrow Agent and the Administrator's liabilities in the making of any such structured settlement payments by executing, along with the Fund, any necessary documents required by, or related to, the discharge of those liabilities. The settlement monies are the sole property of the Fund and no portion of such monies shall be made available to Claimants except as specifically set forth in the Master Settlement Agreement and shall not be disbursed except as provided in the Master Settlement Agreement. ntil such time as monies are distributed, Claimants shall not possess any rights to demand or receive any portion of the monies or the escrowed monies or to mortgage, pledge, or encumber the same in any manner. To the extent possible, the motion to establish a QSF shall be construed so as to prevent Claimants from being in constructive receipt, as determined under federal income tax principles, of any amounts held by the Fund.

The Escrow Agent and Administrator shall be indemnified and held harmless by Claimants from any claims made by any alleged lien holder, or other person or entity that attempts to assert a right of payment, reimbursement or garnishment against the Fund. Should the Escrow Agent and/or Administrator be named as a party to, or threatened to be made a party to, any threatened, pending, or completed action, suit, or proceeding of any kind, whether civil, administrative, or arbitrative, and whether brought by or against or

otherwise involving the Fund, by reason of the Escrow Agent and/or the Administrator having served in any capacity on behalf of the Fund, the Escrow Agent and/or the Administrator shall be indemnified and held harmless by Claimants against reasonable expenses, costs, and fees including attorney fees , judgment, awards, costs, amounts paid in settlement, and liabilities of all kinds incurred by the Escrow Agent and/or the Administrator in connection with or resulting from such actual or threatened action, suit or proceeding except to the extent that it is finally determined by the Court that the Escrow Agent and/or the Administrator was grossly negligent or acted with willful misconduct in connection with the administration of the Fund. The Escrow Agent and/or the Administrator shall indemnify Claimants' Counsel, Atrium and/or its counsel from any claims that arise from the negligence or willful misconduct of the Escrow Agent and/or the Administrator as determined by the Court. Should Claimants' Counsel, Atrium and/or its counsel be named as a party to, or threatened to be made a party to, any threatened, pending, or completed action, suit, or proceeding of any kind, whether civil, administrative, or arbitrative, and whether brought by or against or otherwise involving the Fund, by reason of the Escrow Agent and/or the Administrator's negligence or willful misconduct, Claimants' Counsel, Atrium and/or its counsel shall be indemnified and held harmless by the Escrow Agent and/or the Administrator against reasonable expenses, costs and fees including attorneys' fees , judgment, awards, costs, amounts paid in settlement, and liabilities of all kinds incurred in connection with or resulting from such actual or threatened action, suit or proceeding.

The Claimants request that no bond be required, provided that all monies received by the Fund, which includes all principal and interest earned thereon, be deposited in an

investment agency account held in custody at ells Fargo ank, N.A., a financial institution doing business in Philadelphia, Pennsylvania ells Fargo , for the benefit of and titled in the legal name of the Fund according to the above terms and conditions and the Master Settlement Agreement, and said financial institution shall be responsible for any and all investment related decisions, pursuant to these terms and conditions. The settlement monies so deposited shall be invested in instruments/securities comprised of: a nited States Agency, overnment Sponsored Enterprises or Treasury debt securities or obligations maturities not to exceed five years at time of purchase or mutual funds invested solely in such instruments average maturity not to exceed 5 years and/or b cash equivalent securities including SEC registered money market funds and collaterali ed money market accounts. Such funds should be invested such that the following investment policy is implemented, as appropriate: 1 safety of principal and 2 ero sweep disbursement accounts. ells Fargo shall be responsible for any and all investment related decisions following the instructions of the Fund Administrator and/or its investment advisor, pursuant to these terms and conditions.

Notwithstanding the foregoing, ells Fargo shall not be allowed to distribute any income or principal from the Fund except upon instructions of the Administrator as authori ed by the Special Master, confirmed by Plaintiffs' Lead Counsel and the Lien Administrator, Epiq Mass Tort, or if requested, upon the order of this Court, and only upon the satisfaction of the requirements in the Master Settlement Agreement. Prior to making any distributions contemplated above, the Special Master will provide Plaintiffs' Lead Counsel, with a list of payments to be made to individual Claimants. As set forth in the Master Settlement Agreement, and assuming all obligations and requirements thereunder

have been satisfied, the Special Master and Plaintiffs' Lead Counsel will then jointly submit payment instructions to ells Fargo for implementation. In the event the Escrow Agent and/or Administrator resign, they shall designate a replacement upon the written consent of Plaintiffs' Lead Counsel and the Special Master. In addition to the forgoing, consistent with the Master Settlement Agreement, Atrium's written approval is also required for the distribution of excess monies to participating plaintiffs where those funds were previously held back for the payment of liens.

The Administrator shall be authori ed to distribute all attorney fees and litigation expenses for Claimants, consistent with existing contingency fee contracts and, to the extent required by law, upon Court approval upon the joint motion of Claimants' Counsel and the Special Master, which Atrium will not oppose. Distribution of attorneys' fees may be in lump sum or periodic payment form, with any such payments to be made for the convenience of the Claimants. All taxes on the income of the Fund and expenses and costs incurred in connection with the taxation of the Fund including, without limitation, the expenses of tax attorneys and accountants as well as any and all related administrative costs and expenses shall be paid out of the Fund in accordance with the Master Settlement Agreement, shall be considered to be a cost of administration of the settlement, and shall be paid following the Administrator's advance written notice to the Special Master, pursuant to joint instruction by Plaintiffs' Lead Counsel. The Escrow Agent will prepare and deliver monthly Fund Statements Statements to the Special Master and Plaintiffs' Lead Counsel and if specifically requested in writing, this Court. The Statements shall include, without limitation, a statement of receipts, investment earnings, disbursements, and quarter or monthly ending balance. The Escrow Agent shall provide the Statement no

later than 10 business days following the request. The Escrow Agent and/or Administrator shall have the right to rely upon any affidavit, certificate, letter, notice, electronic mail, or other document believed by the Escrow Agent and/or Administrator to be genuine and sufficient, and upon any other evidence believed by the Escrow Agent and/or Administrator, in its reasonable judgment, to be genuine and sufficient, which may be provided to the Escrow Agent and/or Administrator by the Special Master.

pon final distribution of all monies paid into the Fund, the Administrator shall take appropriate steps in conjunction with the Parties to wind down the Fund as dictated by the Master Settlement Agreement, and thereafter, in working with the Escrow Agent, both shall be discharged from any further responsibility with respect to the Fund. The Administrator will obtain a Federal Taxpayer Identification Number for the Fund upon the execution of the Order by the Court establishing the Fund.

ARGUMENT

I. T e Creatio o a Q ali ied Settleme t F d Com lies it A li a le La Permitti Its Creatio

Qualified Settlement Funds QSFs were established by Congress to enable claimants and defendants to determine how and when settlement funds are taxed and/or deductions obtained. Further, they are a valuable settlement tool whereby claimants can address critical settlement-related issues without the stress of settlement negotiations, because they release defendants from alleged tort or other liability through the doctrine of novation. QSFs, therefore, are both a useful settlement tool and asset providing unique tax benefits to claimants.

The QSF, as specified in the Master Settlement Agreement, complies with Treas. Reg. 1.4 -1c 3 by being established as an interest-bearing account, for which the

settlement funds would be segregated from the other assets of the transferor Atrium . The Master Settlement Agreement contemplates the creation of a QSF pursuant to Internal Revenue Code 4 8 and the regulations promulgated thereto. *See* Exhibits 1 and 2 2 CFR 1.4 8 -1 . The QSF in the Master Settlement Agreement is established for the principal purpose of extinguishing, resolving, and satisfying present and future claims against the taxpayer or any related person or formerly related person arising out of personal injury, death or property damage. 2 .S.C. 4 8 d 2 D .

This Court has jurisdiction over this matter pursuant to Treas. Reg. Section 1.4 8 - 1 c 1 , which states, in relevant part, that a Qualified Settlement Fund is established pursuant to an order of, or is approved by, the nited States, any state including the District of Columbia , territory, possession, or political subdivision thereof, or any agency or instrumentality including a court of law . . . and is subject to the continuing jurisdiction of that governmental authority.

This Court has the jurisdiction to establish pursuant to an order of, or is approved by, the nited States, any state including the District of Columbia , territory, possession, or political subdivision thereof, or any agency or instrumentality including a court of law of any of the foregoing. *See* 2 .S.C. 4 8 d 2 A 2 CFR 1.4 8 -1 c 1 . Moreover, in *United States v. Brown*, 348 F.3d 1200, 1208 10th Cir. 2003 , the Tenth Circuit Court of Appeals stated that a Qualified Settlement Fund satisfies subparagraph 1 of 1.4 8 -1 c if it is established pursuant to an order of a court of law. ere, this Court has jurisdiction over the underlying litigation that is currently pending before this Court. As such, this Court has jurisdiction over the establishment of a QSF to resolve settlement matters relating to these cases.

The Parties have agreed that the QSF is to be administered by an independent third party agreed-upon escrow agent. pon the satisfaction of the conditions precedent and terms specified in the Master Settlement Agreement, the funds shall be used to resolve Plaintiffs' personal injury claims and related covered costs and expenses. *See* 2 .S.C. 4 8 d 2 - E . In addition and as required by the federal tax code and accompanying regulations, the settlement amount is to be segregated and controlled by an escrow agreement. *See* 2 CFR 1.4 8 -1 c 3 . After this Order is entered by the Court and the conditions of the Master Settlement Agreement are satisfied, Defendants will make payment into the Fund as set forth in, and pursuant to the terms of the Master Settlement Agreement.

Other courts have established QSFs in other mass tort cases. For example, an appellate court noted the district court's establishment of a QSF in an alleged mass tort personal injury and property damage case arising out of the release of certain contaminants. *Burr & Forman v. Blair*, 470 F.3d 1019, 1023, 1031 n.33 11th Cir. 200 . Similarly, a QSF was established in the Fen-Phen litigation. *Middleton v. Arledge*, 3:0 -cv-303- -LRA, 2008 L 90 525, at 1 S.D. Miss. March 31, 2008 *see also Levin, Fishbein, Sedram & Berman v. Jameson*, Civ. A. No. 09-393 , 2009 L 4857434, at 2 E.D. Pa. Dec. 14, 2009 discussing the prior establishment of a QSF in the Exxon Valde oil spill Order Approving the Establishment of The Qualified Settlement Fund A' for Certain yprexa Products Claims Escrow Account dated August 17, 2005, *In re: Zyprexa Products Liability Litigation*, 04 MD 159 , Docket 251 attached hereto as Exhibit 3 Order Establishing a Qualified Settlement Fund and Appointing a Settlement Master dated May 13, 2011 in ain v. Astra eneca LP, No. C 09-4147 C , 2011 L 4827 7, at 1 N.D.

Cal. Feb. 7, 2011 establishing QSF and issuing related orders in pharmaceutical mass tort attached hereto as Exhibit 4 . The QSF is subject to the continuing jurisdiction of this Court. *See* 2 CFR 1.4 8 -1 c 1 .

II. Q ali ied Settleme t F ds Are Use l Tools i Mass Tort Settleme ts

QSFs are valuable because they provide a hosting location for the fund's assets while each of the following are done: 1 allocating the settlement proceeds among the claimants 2 verifying and negotiating liens and/or subrogation claims and 3 enabling a host of other decisions to be made relating to the settlement. Furthermore, given the concerns that lawyers have about adding unreasonable delay or expense to the transfer of settlement funds to clients, these QSFs may be created and administered: 1 to facilitate placement of a structured settlement annuity without requiring the signature and/or participation of the defendant and 2 to resolve and satisfy any and all private companies or government agencies that may have a reimbursement right or lien against a claimant's settlement amount.

As an example, utili ing a QSF in this matter facilitates the resolution of Plaintiffs' outstanding health-care related liens. For instance, upon verifying and resolving Medicare's reimbursement interest or otherwise calculating a reasonable holdback amount with the consent of Medicare , if any, in each of the Plaintiffs' claims, the Administrator here, Peter F. augh may distribute the Net Recovery as directed by the Special Master and Lead Plaintiffs' Counsel to be disbursed directly or indirectly to each Plaintiff for his or her respective claims, as a substitute party obligor pursuant to the doctrine of novation.[1]

[1] A novation has the effect of adding a new party as substitute obligor who was not a party to the action, such as the Administrator, and discharging the Defendants by agreement of all of the parties, completely extinguishing any alleged liability of the Defendants. *See* Restatement Second of Contracts 280 1981 .

CONCLUSION

For the reasons stated herein, certain Plaintiffs, by and through Lead Counsel, respectfully submit this memorandum of law in support of the motion to order the creation of a Qualified Settlement Fund and issue related orders.

DATED: December 10, 2021

Respectfully submitted,

/s/ Jonathan D. Orent, Esq.
Jonathan D. Orent
MOTLEY RICE LLC
55 Cedar Street, Suite 100
Providence, RI 02903
401-457-7700
401-457-7708 Fax
jorent@motleyrice.com

Plaintiffs' Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of this document has this date been filed electronically with the Clerk of Court using the CM/ECF system. Notice of these filings will be sent to all counsel of record and parties by operation of the Court's electronic filing system.

/s/ Jonathan D. Orent
Jonathan D. Orent

EXHIBIT 1

26 CFR 1.468B

This document is current through the Dec. 1, 2021 issue of the Federal Register, with the exception of the amendments appearing at 86 FR 68150, 86 FR 68159, and 86 FR 68389.

Code of Federal Regulations > Title 26 Internal Revenue > Chapter I — Internal Revenue Service, Department of the Treasury > Subchapter A — Income Tax > Part 1 — Income Taxes > Normal Taxes and Surtaxes > Deferred Compensation, Etc. > Methods of Accounting > Taxable Year for Which Deductions Taken

§ 1.468B Designated settlement funds.

A designated settlement fund, as defined in section 468B(d)(2) [26 USCS § 468B(d)(2)], is taxed in the manner described in § 1.468B-2. The rules for transferors to a qualified settlement fund described in § 1.468B-3 apply to transferors to a designated settlement fund. Similarly, the rules for claimants of a qualified settlement fund described in § 1.468B-4 apply to claimants of a designated settlement fund. A fund, account, or trust that does not qualify as a designated settlement fund is, however, a qualified settlement fund if it meets the requirements of a qualified settlement fund described in § 1.468B-1.

Statutory Authority

Authority Note Applicable to 26 CFR Ch. I, Subch. A, Pt. 1

History

[*57 FR 60988*, Dec. 23, 1992, Treas. Dec. 8459.; *71 FR 6197, 6200*, Feb. 7, 2006, Treas. Dec. 9249]

Annotations

Notes to Decisions

Civil Procedure: Settlements: Settlement Agreements: General Overview

Governments: Legislation: Interpretation

Tax Law: Federal Income Tax Computation: Effects of Bankruptcy: Claims Reserves & Creditor Trusts

26 CFR 1.468B

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (IRC secs. 446, 447, 451, 461, 467): Taxable Year of Deduction

Civil Procedure: Settlements: Settlement Agreements: General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B(2)* requires that a Qualified Settlement Fund be established to resolve or satisfy one or more claims. In the appellate court's view, the words "established to" are the key. When the appellate court says that a program has been "established to" do something, it does not necessarily mean that the program will fully accomplish that task, or even that it expects the task to be fully accomplished. The appellate court may be merely stating the aim, the direction, of the program. Mediation programs, even settlement conferences, can be said to be established to settle disputes; yet no one expects all disputes to be settled, and partial resolution would be welcome. Of course, an institution "established to" do something may invariably accomplish that task. Courts are established to resolve disputes; and, for better or worse, they do so. The point here is only that the phrase "established to resolve or satisfy claims" is ambiguous. It may mean that all claims are to be resolved or satisfied; or it may mean only that the institution is directed toward that end, and partial resolution or satisfaction, or even failure, is a potential result. To determine the meaning of this ambiguous language, the appellate court looks for clues elsewhere in the regulations. *Go To Headnote*

- *Treas. Reg. § 1.468B(d)(2)(D)* provides that to be a Designated Settlement Fund, a fund must both have the principal purpose of resolving and satisfying claims, and extinguish completely the taxpayer's tort liability with respect to those claims. If "extinguish completely" and "resolve and satisfy" were synonymous, there would have been no need to include both phrases in the DSF statute. And if "resolve and satisfy" does not necessarily mean "completely extinguish" in the DSF statute, it is logical to conclude that "resolve or satisfy," the phrase used in the Qualified Settlement Fund regulations, also stands for something less than complete extinguishment. *Go To Headnote*

Governments: Legislation: Interpretation

26 CFR 1.468B

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

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Tax Law: Federal Income Tax Computation: Effects of Bankruptcy: Claims Reserves & Creditor Trusts

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Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B(d)(2)(D)*provides that to be a Designated Settlement Fund, a fund must both have the principal purpose of resolving and satisfying claims, and extinguish completely the taxpayer's tort liability

with respect to those claims. If "extinguish completely" and "resolve and satisfy" were synonymous, there would have been no need to include both phrases in the DSF statute. And if "resolve and satisfy" does not necessarily mean "completely extinguish" in the DSF statute, it is logical to conclude that "resolve or satisfy," the phrase used in the Qualified Settlement Fund regulations, also stands for something less than complete extinguishment. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (*IRC secs. 446*, *447*, *451*, *461*, *467*): Taxable Year of Deduction

United States v. O'Cheskey, 100 A.F.T.R.2d (RIA) 2007-6339, 2007-2 U.S. Tax Cas. (CCH) ¶ 50756, 2007 U.S. Dist. LEXIS 74650 (N.D. Tex. Oct. 5, 2007), remanded, *310 Fed. Appx. 726, 103 A.F.T.R.2d (RIA) 2009-960, 2009 U.S. App. LEXIS 3868 (5th Cir. 2009)*.

United States v. O'Cheskey, 100 A.F.T.R.2d (RIA) 2007-6339, 2007-2 U.S. Tax Cas. (CCH) ¶ 50756, 2007 U.S. Dist. LEXIS 74650 (N.D. Tex. Oct. 5, 2007), remanded, *310 Fed. Appx. 726, 103 A.F.T.R.2d (RIA) 2009-960, 2009 U.S. App. LEXIS 3868 (5th Cir. 2009)*.

Overview: *In Chapter 11 bankruptcy litigation in which a trust recipient sued his brother for mismanaging trust assets arising from sale of debtors' property, a bankruptcy court did not err by finding that debtors were not entitled to a deduction for unpaid state income taxes, as the economic performance requirement in Treas. Reg. § 1.461-4(g)(6)(i) was met.*

- A qualified settlement fund (QSF) allows a taxpayer to establish economic performance in a current tax year by making payments to the fund. *Treas. Reg. § 1.468B(a)*. *Treas. Reg. § 1.468B-1(c)(2)* sets forth the requirements for a QSF. *Go To Headnote*

Research References & Practice Aids

Hierarchy Notes:

26 CFR Ch. I

26 CFR Ch. I, Subch. A

26 CFR Ch. I, Subch. A, Pt. 1

26 CFR 1.468B

End of Document

EXHIBIT

26 CFR 1.468B-1

This document is current through the Dec. 1, 2021 issue of the Federal Register, with the exception of the amendments appearing at 86 FR 68150, 86 FR 68159, and 86 FR 68389.

Code of Federal Regulations > *Title 26 Internal Revenue* > *Chapter I — Internal Revenue Service, Department of the Treasury* > *Subchapter A — Income Tax* > *Part 1 — Income Taxes* > *Normal Taxes and Surtaxes* > *Deferred Compensation, Etc.* > *Methods of Accounting* > *Taxable Year for Which Deductions Taken*

§ 1.468B-1 Qualified settlement funds.

(a) In general. A qualified settlement fund is a fund, account, or trust that satisfies the requirements of paragraph (c) of this section.

(b) Coordination with other entity classifications. If a fund, account, or trust that is a qualified settlement fund could be classified as a trust within the meaning of § 301.7701-4 of this chapter, it is classified as a qualified settlement fund for all purposes of the Internal Revenue Code (Code). If a fund, account, or trust, organized as a trust under applicable state law, is a qualified settlement fund, and could be classified as either an association (within the meaning of § 301.7701-2 of this chapter) or a partnership (within the meaning of § 301.7701-3 of this chapter), it is classified as a qualified settlement fund for all purposes of the Code. If a fund, account, or trust, established for contested liabilities pursuant to § 1.461-2(c)(1) is a qualified settlement fund, it is classified as a qualified settlement fund for all purposes of the Code.

(c) Requirements. A fund, account, or trust satisfies the requirements of this paragraph (c) if —

(1) It is established pursuant to an order of, or is approved by, the United States, any state (including the District of Columbia), territory, possession, or political subdivision thereof, or any agency or instrumentality (including a court of law) of any of the foregoing and is subject to the continuing jurisdiction of that governmental authority;

(2) It is established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and that has given rise to at least one claim asserting liability —

(i) Under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (hereinafter referred to as CERCLA), as amended, *42 U.S.C. 9601* et seq.; or

(ii) Arising out of a tort, breach of contract, or violation of law; or

(iii) Designated by the Commissioner in a revenue ruling or revenue procedure; and

(3) The fund, account, or trust is a trust under applicable state law, or its assets are otherwise segregated from other assets of the transferor (and related persons).

(d) Definitions. For purposes of this section —

(1) Transferor. A "transferor" is a person that transfers (or on behalf of whom an insurer or other person transfers) money or property to a qualified settlement fund to resolve or satisfy claims described in paragraph (c)(2) of this section against that person.

(2) Related person. A "related person" is any person who is related to the transferor within the meaning of sections 267(b) or 707(b)(1) [*26 USCS §§ 267(b)* or *707(b)(1)*].

(e) Governmental order or approval requirement —

(1) In general. A fund, account, or trust is "ordered by" or "approved by" a governmental authority described in paragraph (c)(1) of this section when the authority issues its initial or preliminary order to establish, or grants its initial or preliminary approval of, the fund, account, or trust, even if that order or approval may be subject to review or revision. Except as otherwise provided in paragraph (j)(2) of this section, the governmental authority's order or approval has no retroactive effect and does not permit a fund, account, or trust to be a qualified settlement fund prior to the date the order is issued or the approval is granted.

(2) Arbitration panels. An arbitration award that orders the establishment of, or approves, a fund, account, or trust is an order or approval of a governmental authority described in paragraph (c)(1) of this section if —

(i) The arbitration award is judicially enforceable;

(ii) The arbitration award is issued pursuant to a bona fide arbitration proceeding in accordance with rules that are approved by a governmental authority described in paragraph (c)(1) of this section (such as self-regulatory organization-administered arbitration proceedings in the securities industry); and

(iii) The fund, account, or trust is subject to the continuing jurisdiction of the arbitration panel, the court of law that has jurisdiction to enforce the arbitration award, or the governmental authority that approved the rules of the arbitration proceeding.

(f) Resolve or satisfy requirement —

(1) Liabilities to provide services or property. Except as otherwise provided in paragraph (f)(2) of this section, a liability is not described in paragraph (c)(2) of this section if it is a liability for the provision of services or property, unless the transferor's obligation to provide services or property is extinguished by a transfer or transfers to the fund, account, or trust.

(2) CERCLA liabilities. A transferor's liability under CERCLA to provide services or property is described in paragraph (c)(2) of this section if following its transfer to a fund, account, or trust the

transferor's only remaining liability to the Environmental Protection Agency (if any) is a remote, future obligation to provide services or property.

(g) Excluded liabilities. A liability is not described in paragraph (c)(2) of this section if it —

(1) Arises under a workers compensation act or a self-insured health plan;

(2) Is an obligation to refund the purchase price of, or to repair or replace, products regularly sold in the ordinary course of the transferor's trade or business;

(3) Is an obligation of the transferor to make payments to its general trade creditors or debtholders that relates to a title 11 or similar case (as defined in section 368(a)(3)(A) [*26 USCS § 368(a)(3)(A)*]), or a workout; or

(4) Is designated by the Commissioner in a revenue ruling or a revenue procedure (see § 601.601(d)(2)(ii)(b) of this chapter).

(h) Segregation requirement —

(1) In general. If it is not a trust under applicable state law, a fund, account, or trust satisfies the requirements of paragraph (c)(3) of this section if its assets are physically segregated from other assets of the transferor (and related persons). For example, cash held by a transferor in a separate bank account satisfies the segregation requirement of paragraph (c)(3) of this section.

(2) Classification of fund established to resolve or satisfy allowable and non-allowable claims. If a fund, account, or trust is established to resolve or satisfy claims described in paragraph (c)(2) of this section as well as other types of claims (i.e., non-allowable claims) arising from the same event or related series of events, the fund is a qualified settlement fund. However, under § 1.468B-3(c), economic performance does not occur with respect to transfers to the qualified settlement fund for non-allowable claims.

(i) [Reserved]

(j) Classification of fund prior to satisfaction of requirements in paragraph (c) of this section —

(1) In general. If a fund, account, or trust is established to resolve or satisfy claims described in paragraph (c)(2) of this section, the assets of the fund, account, or trust are treated as owned by the transferor of those assets until the fund, account, or trust also meets the requirements of paragraphs (c) (1) and (3) of this section. On the date the fund, account, or trust satisfies all the requirements of paragraph (c) of this section, the transferor is treated as transferring the assets to a qualified settlement fund.

(2) Relation-back rule —

(i) In general. If a fund, account, or trust meets the requirements of paragraphs (c)(2) and (c)(3) of this section prior to the time it meets the requirements of paragraph (c)(1) of this section, the transferor and administrator (as defined in § 1.468B-2(k)(3)) may jointly elect (a relation-back

election) to treat the fund, account, or trust as coming into existence as a qualified settlement fund on the later of the date the fund, account, or trust meets the requirements of paragraphs (c)(2) and (c)(3) of this section or January 1 of the calendar year in which all the requirements of paragraph (c) of this section are met. If a relation-back election is made, the assets held by the fund, account, or trust on the date the qualified settlement fund is treated as coming into existence are treated as transferred to the qualified settlement fund on that date.

(ii) Relation-back election. A relation-back election is made by attaching a copy of the election statement, signed by each transferor and the administrator, to (and as part of) the timely filed income tax return (including extensions) of the qualified settlement fund for the taxable year in which the fund is treated as coming into existence. A copy of the election statement must also be attached to (and as part of) the timely filed income tax return (including extensions), or an amended return that is consistent with the requirements of §§ 1.468B-1 through 1.468B-4, of each transferor for the taxable year of the transferor that includes the date on which the qualified settlement fund is treated as coming into existence. The election statement must contain —

(A) A legend, "§ 1.468B-1 Relation-Back Election", at the top of the first page;

(B) Each transferor's name, address, and taxpayer identification number;

(C) The qualified settlement fund's name, address, and employer identification number;

(D) The date as of which the qualified settlement fund is treated as coming into existence; and

(E) A schedule describing each asset treated as transferred to the qualified settlement fund on the date the fund is treated as coming into existence. The schedule of assets does not have to identify the amount of cash or the property treated as transferred by a particular transferor. If the schedule does not identify the transferor of each asset, however, each transferor must include with the copy of the election statement that is attached to its income tax return (or amended return) a schedule describing each asset the transferor is treated as transferring to the qualified settlement fund.

(k) Election to treat a qualified settlement fund as a subpart E trust —

(1) In general. If a qualified settlement fund has only one transferor (as defined in paragraph (d)(1) of this section), the transferor may make an election (grantor trust election) to treat the qualified settlement fund as a trust all of which is owned by the transferor under section 671 [*26 USCS § 671*] and the regulations thereunder. A grantor trust election may be made whether or not the qualified settlement fund would be classified, in the absence of paragraph (b) of this section, as a trust all of which is treated as owned by the transferor under section 671 [*26 USCS § 671*] and the regulations thereunder. A grantor trust election may be revoked only for compelling circumstances upon consent of the Commissioner by private letter ruling.

(2) Manner of making grantor trust election —

(i) In general. To make a grantor trust election, a transferor must attach an election statement satisfying the requirements of paragraph (k)(2)(ii) of this section to a timely filed (including extensions) Form 1041, "U.S. Income Tax Return for Estates and Trusts," that the administrator files on behalf of the qualified settlement fund for the taxable year in which the qualified settlement fund is established. However, if a Form 1041 is not otherwise required to be filed (for example, because the provisions of § 1.671-4(b) apply), then the transferor makes a grantor trust election by attaching an election statement satisfying the requirements of paragraph (k)(2)(ii) of this section to a timely filed (including extensions) income tax return of the transferor for the taxable year in which the qualified settlement fund is established. See § 1.468B-5(c)(2) for transition rules.

(ii) Requirements for election statement. The election statement must include a statement by the transferor that the transferor will treat the qualified settlement fund as a grantor trust. The election statement must include the transferor's name, address, taxpayer identification number, and the legend, "§ 1.468B-1(k) Election." The election statement and the statement described in § 1.671-4(a) may be combined into a single statement.

(3) Effect of making the election. If a grantor trust election is made —

(i) Paragraph (b) of this section, and §§ 1.468B-2, 1.468B-3, and 1.468B-5(a) and (b) do not apply to the qualified settlement fund. However, this section (except for paragraph (b) of this section) and § 1.468B-4 apply to the qualified settlement fund;

(ii) The qualified settlement fund is treated, for Federal income tax purposes, as a trust all of which is treated as owned by the transferor under section 671 [*26 USCS § 671*] and the regulations thereunder;

(iii) The transferor must take into account in computing the transferor's income tax liability all items of income, deduction, and credit (including capital gains and losses) of the qualified settlement fund in accordance with § 1.671-3(a)(1); and

(iv) The reporting obligations imposed by § 1.671-4 on the trustee of a trust apply to the administrator.

(l) Examples. The following examples illustrate the rules of this section:

Example 1. In a class action brought in a United States federal district court, the court holds that the defendant, Corporation X, violated certain securities laws and must pay damages in the amount of $ 150 million. Pursuant to an order of the court, Corporation X transfers $ 50 million in cash and transfers property with a fair market value of $ 75 million to a state law trust. The trust will liquidate the property and distribute the cash proceeds to the plaintiffs in the class action. The trust is a qualified settlement fund because it was established pursuant to the order of a federal district court to resolve or satisfy claims against Corporation X for securities law violations that have occurred.

Example 2.

(i) Assume the same facts as in Example 1, except that Corporation X and the class of plaintiffs reach an out-of-court settlement that requires Corporation X to establish and fund a state law trust before the settlement agreement is submitted to the court for approval.

(ii) The trust is not a qualified settlement fund because it neither is established pursuant to an order of, nor has it been approved by, a governmental authority described in paragraph (c)(1) of this section.

Example 3. On June 1, 1994, Corporation Y establishes a fund to resolve or satisfy claims against it arising from the violation of certain securities laws. On that date, Corporation Y transfers $ 10 million to a segregated account. On December 1, 1994, a federal district court approves the fund. Assuming Corporation Y and the administrator of the qualified settlement fund do not make a relation-back election, Corporation Y is treated as the owner of the $ 10 million, and is taxable on any income earned on that money, from June 1 through November 30, 1994. The fund is a qualified settlement fund beginning on December 1, 1994.

Example 4.

(i) On September 1, 1993, Corporation X, which has a taxable year ending on October 31, enters into a settlement agreement with a plaintiff class for asserted tort liabilities. Under the settlement agreement, Corporation X makes two $ 50 million payments into a segregated fund, one on September 1, 1993, and one on October 1, 1993, to resolve or satisfy the tort liabilities. A federal district court approves the settlement agreement on November 1, 1993.

(ii) The administrator of the fund and Corporation X elect to treat the fund as a qualified settlement fund prior to governmental approval under the relation-back rule of paragraph (j)(2) of this section. The administrator must attach the relation-back election statement to the fund's income tax return for calendar year 1993, and Corporation X must attach the election to its original or amended income tax return for its taxable year ending October 31, 1993.

(iii) Pursuant to the relation-back election, the fund begins its existence as a qualified settlement fund on September 1, 1993, and Corporation X is treated as transferring $ 50 million to the qualified settlement fund on September 1, 1993, and $ 50 million on October 1, 1993.

(iv) With respect to these transfers, Corporation X must provide the statement described in § 1.468B-3(e) to the administrator of the qualified settlement fund by February 15, 1994, and must attach a copy of this statement to its original or amended income tax return for its taxable year ending October 31, 1993.

Example 5. Assume the same facts as in Example 4, except that the court approves the settlement on May 1, 1994. The administrator must attach the relation-back election statement to the fund's income tax return for calendar year 1994, and Corporation X must attach the election statement to its original or amended income tax return for its taxable year ending October 31, 1994. Pursuant to this election, the fund begins its existence as a qualified settlement fund on January 1, 1994. In addition, Corporation X is treated as transferring to the qualified settlement fund all amounts held in the fund on January 1,

1994. With respect to the transfer, Corporation X must provide the statement described in § 1.468B-3(e) to the administrator of the qualified settlement fund by February 15, 1995, and must attach a copy of this statement to its income tax return for its taxable year ending October 31, 1994.

Example 6. Corporation Z establishes a fund that meets all the requirements of section 468B(d)(2) [26 USCS § 468B(d)(2)] for a designated settlement fund, except that Corporation Z does not make the election under section 468B(d)(2)(F) [26 USCS § 468B(d)(2)(F)]. Although the fund does not qualify as a designated settlement fund, it is a qualified settlement fund because the fund meets the requirements of paragraph (c) of this section.

Example 7. Corporation X owns and operates a landfill in State A. State A requires Corporation X to transfer money to a trust annually based on the total tonnage of material placed in the landfill during the year. Under the laws of State A, Corporation X will be required to perform (either itself or through contractors) specified closure activities when the landfill is full, and the trust assets will be used to reimburse Corporation X for those closure costs. The trust is not a qualified settlement fund because it is established to secure the liability of Corporation X to perform the closure activities.

Statutory Authority

Authority Note Applicable to 26 CFR Ch. I, Subch. A, Pt. 1

History

[*57 FR 60989*, Dec. 23, 1992, Treas. Dec. 8459.; *58 FR 7865*, Feb. 10, 1993; *71 FR 6197, 6201*, Feb. 7, 2006, Treas. Dec. 9249]

Annotations

Notes

Section 1.468B-1 also issued under *26 U.S.C. 461(h)* and 468B(g).

[EFFECTIVE DATE NOTE:

71 FR 6197, 6201, Feb. 7, 2006, amended this section, effective Feb. 3, 2006.]

Notes to Decisions

Business & Corporate Law: Agency Relationships: Causes of Action & Remedies: Breach of Contract

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Civil Procedure: Settlements: Settlement Agreements: General Overview

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Contracts Law: Sales of Goods: Damages & Remedies: General Overview

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Tax Law: Federal Income Tax Computation: General Overview

Tax Law: Federal Income Tax Computation: Deductions for Business Expenses: Business, Entertainment & Trade Expenses (IRC secs. 162, 274)

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Tax Law: Federal Income Tax Computation: Sales & Exchanges: General Overview

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (IRC secs. 446, 447, 451, 461, 467): General Overview

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (IRC secs. 446, 447, 451, 461, 467): Taxable Year of Deduction

Tax Law: Federal Tax Administration & Procedure: Settlements: Bankruptcy & Receivership (IRC secs. 6871-6873)

Tax Law: Federal Tax Administration & Procedure: Tax Credits & Liabilities: Credits, Overassessments & Refunds (IRC secs. 6401-6427): General Overview

Tax Law: Federal Taxpayer Groups: C Corporations: Recapitalizations (IRC sec. 368)

Torts: Products Liability: General Overview

Business & Corporate Law: Agency Relationships: Causes of Action & Remedies: Breach of Contract

United States v. Brown, 88 A.F.T.R.2d (RIA) 2001-7287, 2001-2 U.S. Tax Cas. (CCH) ¶ 50519, 2001 U.S. Dist. LEXIS 8064 (D. Utah May 23, 2001), remanded, *334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir. 2003)*.

United States v. Brown, 88 A.F.T.R.2d (RIA) 2001-7287, 2001-2 U.S. Tax Cas. (CCH) ¶ 50519, 2001 U.S. Dist. LEXIS 8064 (D. Utah May 23, 2001), remanded, *334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir. 2003)*.

Overview: *IRS' tax claim against receivership estate was disallowed because the estate, which was created to provide restitution to customers of companies involved in securities fraud, was not a qualified settlement fund.*

- Under the qualified settlement fund (QSF) regulations, a fund, account, or trust subject to taxation as a QSF must meet three requirements. *26 C.F.R. § 1.468B-1(a)*. First, the fund, account, or trust must be established pursuant to an order of, or be approved by, the United States or any agency or instrumentality thereof (including a court of law) and be subject to the continuing jurisdiction of that governmental authority. *26 C.F.R. § 1.468B-1(c)(1)*. Second, the fund, account, or trust must be established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and that has given rise to at least one claim asserting liability arising out of a tort, breach of contract, or violation of law. *26 C.F.R. § 1.468B-1(c)(2)*. Finally, the fund, account, or trust must be a trust under applicable state law, or its assets must be otherwise segregated from other assets of the transferor (and related persons). *26 C.F.R. § 1.468B-1(c)(3)*. *Go To Headnote*

Civil Procedure: Settlements: Settlement Agreements: General Overview

FTC v. QT, Inc., 249 F.R.D. 305, 2008 U.S. Dist. LEXIS 28395 (N.D. Ill. 2008).

FTC v. QT, Inc., 249 F.R.D. 305, 2008 U.S. Dist. LEXIS 28395 (N.D. Ill. 2008).

Overview: *Statements made in a qualified settlement fund were cumulative of other evidence in the record because similar statements were made at the oral argument and in sellers' briefs. Thus, the statements could not qualify as newly discovered under Fed. R. Civ. P. 60(b)(2), and FTC's motion for reconsideration was denied.*

- Under *26 C.F.R. § 1.468B-1*, a qualified settlement fund (QSF) is a trust, account or fund: 1) Established pursuant to an order of, among others, a Court of the United States, 2) that is established to satisfy one or more contested or uncontested claims, and 3) that is a trust under state law or has its assets segregated from other assets of the transferor. *26 C.F.R. § 1.468B-1*. A QSF must be subject to the continuing jurisdiction of the entity establishing it. *26 C.F.R. § 1.468B-1(c)(1)*. The fund is established upon the preliminary approval or order creating the fund, even if that order or approval may be subject to review or revision. *26 C.F.R. § 1.468B-1(e)*. *Go To Headnote*

- According to the Internal Revenue regulations governing the creation of a qualified settlement fund (QSF), fund, account, or trust is ordered by or approved by a governmental authority described in paragraph (c)(1) of *26 C.F.R. § 1.468B-1* when the authority issues its initial or preliminary order to establish, or grants its initial or preliminary approval of, the fund, account, or trust, even if that order or approval may be subject to

review or revision. *26 C.F.R. § 1.468B-1(e)*. Thus, a QSF can be created even if the order creating the fund might change. *Go To Headnote*

- Federal regulations are silent as to a party's continuing obligation to disclose changes to a qualified settlement fund. *26 C.F.R. § 1.468B-1*. *Go To Headnote*

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1*, entitled "Qualified settlement funds," and accompanying regulations (*Treas. Reg. §§ 1.468B-2*, -3, and -4) constitute an effort to deal with the various tax questions that arise when an independent settlement fund is created to pay a debtor's liabilities. The proper approach to taxation of financial transactions involving such a fund is not immediately apparent. The transactions could be treated as if the assets still belonged to the person who contributed the assets to the fund or as if the assets belonged to those to whom the assets would ultimately be distributed, or the fund itself could be treated as a taxpayer that owns the assets. Other questions that may arise include: When can a debtor who contributes to the fund take a tax deduction for its contribution (assuming that the contribution is otherwise deductible)—when the payment is made into the fund, when a claimant receives payment, or at some other time? Or when does the claimant recognize income? *Go To Headnote*

Contracts Law: Defenses: Fraud & Misrepresentation: General Overview

United States v. Brown, 348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003).

United States v. Brown, 348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003).

Overview: *Judgment that receivership estate was not a qualified settlement fund (QSF) was reversed; QSF regulations were not an unconstitutional delegation of legislative power and estate was a resident of U. S., not Germany, and was not exempt from taxes.*

- Under tax law with regard to a qualified settlement fund (QSF) the victims' claims result from events that have given rise to claims asserting liability arising out of a tort, breach of contract, or violation of law. *Treas. Reg. § 1.468B-1(c)(2)*. *Go To Headnote*

26 CFR 1.468B-1

Contracts Law: Sales of Goods: Damages & Remedies: General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(3)* excludes obligations of the transferor to make payments to its general trade creditors or debt-holders that relate to a title 11 or similar case. A receivership is a "similar case." *I.R.C. § 368(a)(3)(A)(ii)*. General trade creditors are those to whom a debt is owed for the provision of goods used in the conduct of one's business. And a debt-holder is not just any creditor who is owed a debt, but is one who holds a debt instrument. The final regulations exclude claims of general trade creditors and debtholders that relate to a title 11 or similar case, or to a workout. However, Qualified Settlement Fund treatment remains available for other liabilities such as tort liabilities irrespective of whether the liability, for example, relates to a title 11 case. *Go To Headnote*

Contracts Law: Types of Contracts: Personal Property

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(2)* excludes obligations to refund the purchase price of, or to repair or replace, products regularly sold in the ordinary course of the transferor's trade or business. The word "products," as used in this provision, refers to tangible goods, not intangibles like securities. This is one of the common usages of the word. And this meaning fits the context. Consider the three obligations referenced in the provision. Certainly, businesses do not "repair" intangibles, and an obligation to "replace" one is rare, if not

nonexistent. To be sure, there are occasions when a business can incur an obligation to refund the purchase price of an intangible. But this exclusion was intended to prevent taxpayers from taking advantage of favorable tax treatment of Qualified Settlement Funds when dealing with certain regularly recurring liabilities, and any enterprise that regularly incurs obligations to refund the purchase price of intangibles (obligations that are most likely to result from fraud or a statutory violation) is better referred to as a "racket" than by the regulations' terms "trade" or "business." If the intent were to include intangibles, the drafters would have used language specifically conveying that meaning. In the immediately preceding paragraph, the drafters used the word "property." Use of the word "product" suggests a narrower focus. *Go To Headnote*

Environmental Law: Hazardous Wastes & Toxic Substances: CERCLA & Superfund: Hazardous Substance Superfund

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(f)*'s general rule is that a liability cannot be the predicate liability for a Qualified Settlement Fund unless the fund extinguishes the liability, although there is a limited exception for liabilities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). That the drafters chose specifically to require extinguishment when the transferor has an obligation to provide services or property suggests that extinguishment is not generally required. Indeed, if the appellate court were to reach the opposite conclusion—that the phrase "resolve or satisfy" creates a complete-extinguishment requirement for all predicate liabilities—the specific requirement would be rendered superfluous, a result to be avoided. *Go To Headnote*

Real Property Law: Environmental Regulation: General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

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United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(f)*'s general rule is that a liability cannot be the predicate liability for a Qualified Settlement Fund unless the fund extinguishes the liability, although there is a limited exception for liabilities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). That the drafters chose specifically to require extinguishment when the transferor has an obligation to provide services or property suggests that extinguishment is not generally required. Indeed, if the appellate court were to reach the opposite conclusion—that the phrase "resolve or satisfy" creates a complete-extinguishment requirement for all predicate liabilities—the specific requirement would be rendered superfluous, a result to be avoided. *Go To Headnote*

Tax Law: Federal Income Tax Computation: General Overview

FTC v. QT, Inc., 249 F.R.D. 305, 2008 U.S. Dist. LEXIS 28395 (N.D. Ill. 2008).

FTC v. QT, Inc., 249 F.R.D. 305, 2008 U.S. Dist. LEXIS 28395 (N.D. Ill. 2008).

Overview: *Statements made in a qualified settlement fund were cumulative of other evidence in the record because similar statements were made at the oral argument and in sellers' briefs. Thus, the statements could not qualify as newly discovered under Fed. R. Civ. P. 60(b)(2), and FTC's motion for reconsideration was denied.*

- Under *26 C.F.R. § 1.468B-1*, a qualified settlement fund (QSF) is a trust, account or fund: 1) Established pursuant to an order of, among others, a Court of the United States, 2) that is established to satisfy one or more contested or uncontested claims, and 3) that is a trust under state law or has its assets segregated from other assets of the transferor. *26 C.F.R. § 1.468B-1*. A QSF must be subject to the continuing jurisdiction of the entity establishing it. *26 C.F.R. § 1.468B-1(c)(1)*. The fund is established upon the preliminary approval or order creating the fund, even if that order or approval may be subject to review or revision. *26 C.F.R. § 1.468B-1(e)*. *Go To Headnote*

- According to the Internal Revenue regulations governing the creation of a qualified settlement fund (QSF), fund, account, or trust is ordered by or approved by a governmental authority described in paragraph (c)(1) of *26 C.F.R. § 1.468B-1* when the authority issues its initial or preliminary order to establish, or grants its initial or preliminary approval of, the fund, account, or trust, even if that order or approval may be subject to review or revision. *26 C.F.R. § 1.468B-1(e)*. Thus, a QSF can be created even if the order creating the fund might change. *Go To Headnote*

• Federal regulations are silent as to a party's continuing obligation to disclose changes to a qualified settlement fund. *26 C.F.R. § 1.468B-1*. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Deductions for Business Expenses: Business, Entertainment & Trade Expenses (*IRC secs. 162*, *274*)

Suriel v. Comm'r, 141 T.C. 507, 2013 U.S. Tax Ct. LEXIS 36 (T.C. Dec. 4, 2013).

Suriel v. Comm'r, 141 T.C. 507, 2013 U.S. Tax Ct. LEXIS 36 (T.C. Dec. 4, 2013).

Overview: *Taxpayer which contractually became a tobacco product manufacturer by participating in a master tobacco settlement agreement improperly deducted payment obligations under the agreement pursuant to I.R.C. § 461(h), since economic performance with respect to the obligations could not occur until the taxpayer actually transferred funds.*

• *Treas. Reg. § 1.468B-1(c)(2)* describes several types of liabilities for which a qualified settlement fund can be established for tax purposes, including those arising out of tort, breach of contract, or violation of law. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Effects of Bankruptcy: Claims Reserves & Creditor Trusts

In re United States Mineral Prods. Co., 2005 Bankr. LEXIS 3259 (Bankr. D. Del. Nov. 29, 2005).

In re United States Mineral Prods. Co., 2005 Bankr. LEXIS 3259 (Bankr. D. Del. Nov. 29, 2005).

Overview: *Confirmation of a bankruptcy debtor's reorganization plan was warranted since the plan properly provided for funded trusts to address claims from exposure to asbestos from the debtor's products, the plan for continuing operations was feasible and in the best interests of creditors, and exculpations and releases were reasonable and necessary.*

• 26 U.S.C.S. § 468B, and regulations promulgated thereunder, provide for the creation and qualification of a qualified settlement fund, which is entitled to certain treatment under the Internal Revenue Code. A qualified settlement fund under § 468B and *Treas. Reg. § 1.468B-1* is a fund, account, or trust that is: (i) set up pursuant to a statute or court order, and would be subject to the continuing jurisdiction of that governmental authority, § 1.468B-1(c)(1); (ii) established to resolve or satisfy contested or uncontested claims arising out of a tort, among other specified bases of liability, § 1.468B-1(c)(2); and (iii) treated as a trust under applicable state law, or its assets would otherwise be segregated from the other assets of the transferor and related persons. § 1.468B-1(c). *Go To Headnote*

26 CFR 1.468B-1

- *Treas. Reg. § 1.468B-1(c)(1)* requires that settlement fund, account, or trust must be established pursuant to an order of, or is approved by, the United States, any state (including the District of Columbia), territory, possession, or political subdivision thereof, or any agency or instrumentality (including a court of law) of any of the foregoing and is subject to the continuing jurisdiction of that governmental authority. *Go To Headnote*

- *Treas. Reg. § 1.468B-1(c)(2)* requires, in part, that a settlement fund, account, or trust must be established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and that has given rise to at least one claim asserting liability arising out of a tort, breach of contract, or violation of law. *Go To Headnote*

United States v. Brown, 348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003).

Overview: *Judgment that receivership estate was not a qualified settlement fund (QSF) was reversed; QSF regulations were not an unconstitutional delegation of legislative power and estate was a resident of U. S., not Germany, and was not exempt from taxes.*

- Under the tax regulations a qualified settlement fund that can be classified as a trust within the meaning of *Treas. Reg. § 301.7701-4* (the section classifying organizations as trusts for federal tax purposes), is classified as a qualified settlement fund for all purposes of the Internal Revenue Code. *Treas. Reg. § 1.468B-1(b)*. *Go To Headnote*

In re Am. Elk Inc., 2003 Bankr. LEXIS 2292 (Bankr. N.D. Tex. Sept. 5, 2003), remanded, *96 A.F.T.R.2d (RIA) 2005-5179, 2004 U.S. Dist. LEXIS 21197 (N.D. Tex. Sept. 13, 2004)*.

Overview: *A Chapter 11 trustee was entitled to deduct contested taxes paid to a state on his federal tax return in the same year because the trustee satisfied 26 U.S.C.S. § 461(f), in part because it effectively transferred funds to pay the contested state tax liability, even though a portion of the funds transferred were refunded in the following tax year.*

- Generally, a qualified settlement fund (QSF) permits a taxpayer to deduct payments made to the fund in the year in which the QSF was established even though the payments are not made from the fund to the creditor until a subsequent tax year. However, a QSF can only be established to resolve the following allowable claims: claims under CERCLA; claims arising out of a tort, breach of contract, or violation of law; and claims designated by the Commissioner of Internal Revenue in a revenue ruling or revenue procedure. *26 C.F.R. § 1.468B-1(c)(2)*. Nevertheless, as a QSF only requires one allowable claim asserting liability under *26 C.F.R. § 1.468B-1(c)(2)* in order to be established, a QSF can also be used to satisfy non-allowable claims. *26 C.F.R. § 1.468B-1(c)(2)*, (h)(2). But, if the QSF is used to satisfy non-allowable claims, economic performance does not occur with respect to those transfers to the qualified settlement fund. *26 C.F.R. § 1.468B-1(h)(2)*. Consequently, for transfers to the QSF that do not satisfy the economic

performance requirement, those non-allowable claims are not afforded the timing benefit of the QSF and therefore cannot be deducted in the tax year the QSF is established. *26 U.S.C.S. § 461(a)*; (h); 26 U.S.C.S. § 468B(a); *26 C.F.R. § 1.468B-1(h)(2)*; *26 C.F.R. § 1.468B-3(c)*. *Go To Headnote*

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1*, entitled "Qualified settlement funds," and accompanying regulations (*Treas. Reg. §§ 1.468B-2*, -3, and -4) constitute an effort to deal with the various tax questions that arise when an independent settlement fund is created to pay a debtor's liabilities. The proper approach to taxation of financial transactions involving such a fund is not immediately apparent. The transactions could be treated as if the assets still belonged to the person who contributed the assets to the fund or as if the assets belonged to those to whom the assets would ultimately be distributed, or the fund itself could be treated as a taxpayer that owns the assets. Other questions that may arise include: When can a debtor who contributes to the fund take a tax deduction for its contribution (assuming that the contribution is otherwise deductible)—when the payment is made into the fund, when a claimant receives payment, or at some other time? Or when does the claimant recognize income? *Go To Headnote*

- *Treas. Reg. § 1.468B-1(f)*'s general rule is that a liability cannot be the predicate liability for a Qualified Settlement Fund unless the fund extinguishes the liability, although there is a limited exception for liabilities under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). That the drafters chose specifically to require extinguishment when the transferor has an obligation to provide services or property suggests that extinguishment is not generally required. Indeed, if the appellate court were to reach the opposite conclusion—that the phrase "resolve or satisfy" creates a complete-extinguishment requirement for all predicate liabilities—the specific requirement would be rendered superfluous, a result to be avoided. *Go To Headnote*

- There is a reason why the regulations distinguish between obligations to pay money and obligations to provide services or property. As the IRS explained when the final Qualified Settlement Fund regulations were promulgated, *Treas. Reg. § 1.468B-1(f)(1)* was added to maintain consistency with the general rules set forth in 26 U.S.C.S. (I.R.C.) § 461 regarding when an accrual-basis taxpayer can claim a deduction. Under § 461(h)(2)(B) a liability of the taxpayer to provide property or services is not incurred until the taxpayer provides such property or services. *Go To Headnote*

- *Treas. Reg. § 1.468B-1(f)(1)* does not speak of the source of the liability. Rather, it comes into play when the transferor has an obligation to provide services or property. *Go To Headnote*

- A transferor is a person that transfers (or on behalf of whom an insurer or other person transfers) money or property to a Qualified Settlement Fund to resolve or satisfy claims described in paragraph (c)(2) of this section against that person, *Treas. Reg. § 1.468B-1(d)(1)*. *Go To Headnote*

- Under the regulations, assets transferred to a fund for the purpose of resolving or satisfying claims are treated as owned by the transferor until the fund meets all the requirements for Qualified Settlement Fund treatment, *Treas. Reg. § 1.468B-1(j)(1)*. The tax laws do not require a person to be a true owner in order to be treated as one. *Go To Headnote*

United States v. Brown, 88 A.F.T.R.2d (RIA) 2001-7287, 2001-2 U.S. Tax Cas. (CCH) ¶ 50519, 2001 U.S. Dist. LEXIS 8064 (D. Utah May 23, 2001), remanded, *334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir. 2003)*.

Overview: *IRS' tax claim against receivership estate was disallowed because the estate, which was created to provide restitution to customers of companies involved in securities fraud, was not a qualified settlement fund.*

- Under the qualified settlement fund (QSF) regulations, a fund, account, or trust subject to taxation as a QSF must meet three requirements. *26 C.F.R. § 1.468B-1(a)*. First, the fund, account, or trust must be established pursuant to an order of, or be approved by, the United States or any agency or instrumentality thereof (including a court of law) and be subject to the continuing jurisdiction of that governmental authority. *26 C.F.R. § 1.468B-1(c)(1)*. Second, the fund, account, or trust must be established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and that has given rise to at least one claim asserting liability arising out of a tort, breach of contract, or violation of law. *26 C.F.R. § 1.468B-1(c)(2)*. Finally, the fund, account, or trust must be a trust under applicable state law, or its assets must be otherwise segregated from other assets of the transferor (and related persons). *26 C.F.R. § 1.468B-1(c)(3)*. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Retirement Plans: Tax-Sheltered Annuities (*IRC sec. 403*)

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1*, entitled "Qualified settlement funds," and accompanying regulations (*Treas. Reg. §§ 1.468B-2*, -3, and -4) constitute an effort to deal with the various tax questions that arise when an independent settlement fund is created to pay a debtor's liabilities. The proper approach to taxation of financial transactions involving such a fund is not immediately apparent. The transactions could be treated as if the assets still belonged to the person who contributed the assets to the fund or as if the assets belonged to those to whom the assets would ultimately be distributed, or the fund itself could be treated as a taxpayer that owns the assets. Other questions that may arise include: When can a debtor who contributes to the fund take a tax deduction for its contribution (assuming that the contribution is otherwise deductible)—when the payment is made into the fund, when a claimant receives payment, or at some other time? Or when does the claimant recognize income? *Go To Headnote*

Tax Law: Federal Income Tax Computation: Sales & Exchanges: General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- There is a reason why the regulations distinguish between obligations to pay money and obligations to provide services or property. As the IRS explained when the final Qualified Settlement Fund regulations were promulgated, *Treas. Reg. § 1.468B-1(f)(1)* was added to maintain consistency with the general rules set forth in 26 U.S.C.S. (I.R.C.) § 461 regarding when an accrual-basis taxpayer can claim a deduction. Under § 461(h)(2)(B) a liability of the taxpayer to provide property or services is not incurred until the taxpayer provides such property or services. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (*IRC secs. 446*, *447*, *451*, *461*, *467*): General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- There is a reason why the regulations distinguish between obligations to pay money and obligations to provide services or property. As the IRS explained when the final Qualified Settlement Fund regulations were promulgated, *Treas. Reg. § 1.468B-1(f)(1)* was added to maintain consistency with the general rules set forth in 26 U.S.C.S. (I.R.C.) § 461 regarding when an accrual-basis taxpayer can claim a deduction. Under § 461(h)(2)(B) a liability of the taxpayer to provide property or services is not incurred until the taxpayer provides such property or services. *Go To Headnote*

Tax Law: Federal Income Tax Computation: Tax Accounting: Accrual Method (*IRC secs. 446*, *447*, *451*, *461*, *467*): Taxable Year of Deduction

United States v. O'Cheskey, 100 A.F.T.R.2d (RIA) 2007-6339, 2007-2 U.S. Tax Cas. (CCH) ¶ 50756, 2007 U.S. Dist. LEXIS 74650 (N.D. Tex. Oct. 5, 2007), remanded, *310 Fed. Appx. 726, 103 A.F.T.R.2d (RIA) 2009-960, 2009 U.S. App. LEXIS 3868 (5th Cir. 2009)*.

United States v. O'Cheskey, 100 A.F.T.R.2d (RIA) 2007-6339, 2007-2 U.S. Tax Cas. (CCH) ¶ 50756, 2007 U.S. Dist. LEXIS 74650 (N.D. Tex. Oct. 5, 2007), remanded, *310 Fed. Appx. 726, 103 A.F.T.R.2d (RIA) 2009-960, 2009 U.S. App. LEXIS 3868 (5th Cir. 2009)*.

Overview: *In Chapter 11 bankruptcy litigation in which a trust recipient sued his brother for mismanaging trust assets arising from sale of debtors' property, a bankruptcy court did not err by finding that debtors were not entitled to a deduction for unpaid state income taxes, as the economic performance requirement in Treas. Reg. § 1.461-4(g)(6)(i) was met.*

- A fund qualifies as a qualified settlement fund (QSF) even if it is established to resolve or satisfy allowable claims in addition to non-allowable claims arising for the same series of events, but economic performance does not occur with respect to transfers to the QSF for the non-allowable claims. *Treas. Reg. § 1.468B-1(h)(2)*. *Go To Headnote*

- A qualified settlement fund (QSF) allows a taxpayer to establish economic performance in a current tax year by making payments to the fund. *Treas. Reg. § 1.468B(a)*. *Treas. Reg. § 1.468B-1(c)(2)* sets forth the requirements for a QSF. *Go To Headnote*

26 CFR 1.468B-1

Tax Law: Federal Tax Administration & Procedure: Settlements: Bankruptcy & Receivership (*IRC secs. 6871-6873*)

United States v. Brown, 348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003).

United States v. Brown, 348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003).

Overview: *Judgment that receivership estate was not a qualified settlement fund (QSF) was reversed; QSF regulations were not an unconstitutional delegation of legislative power and estate was a resident of U. S., not Germany, and was not exempt from taxes.*

- Under tax law, a fund satisfies subparagraph (1) of *Treas. Reg. § 1.468B-1(c)* if it is established pursuant to an order of a court of law. *Go To Headnote*

- Under tax law with regard to a qualified settlement fund (QSF) the victims' claims result from events that have given rise to claims asserting liability arising out of a tort, breach of contract, or violation of law. *Treas. Reg. § 1.468B-1(c)(2)*. *Go To Headnote*

- Under the tax regulations, assets transferred to a fund for the purpose of resolving or satisfying claims are treated as owned by the transferor until the fund meets all the requirements for qualified settlement fund (QSF) treatment. *Treas. Reg. § 1.468B-1(j)(1)*. *Go To Headnote*

- Under the tax regulations a qualified settlement fund that can be classified as a trust within the meaning of *Treas. Reg. § 301.7701-4* (the section classifying organizations as trusts for federal tax purposes), is classified as a qualified settlement fund for all purposes of the Internal Revenue Code. *Treas. Reg. § 1.468B-1(b)*. *Go To Headnote*

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(3)*excludes obligations of the transferor to make payments to its general trade creditors or debt-holders that relate to a title 11 or similar case. A receivership is a "similar case." *I.R.C. § 368(a)(3)(A)(ii)*. General trade creditors are those to whom a debt is owed for the provision of goods used in the conduct of one's business. And a debt-holder is not just any creditor who is owed a debt, but is one who holds a debt instrument. The final regulations exclude claims of general trade creditors and debtholders that relate to a title 11 or similar case, or to a workout. However, Qualified Settlement Fund

treatment remains available for other liabilities such as tort liabilities irrespective of whether the liability, for example, relates to a title 11 case. Go To Headnote

United States v. Brown, 88 A.F.T.R.2d (RIA) 2001-7287, 2001-2 U.S. Tax Cas. (CCH) ¶ 50519, 2001 U.S. Dist. LEXIS 8064 (D. Utah May 23, 2001), remanded, *334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir. 2003)*.

Overview: *IRS' tax claim against receivership estate was disallowed because the estate, which was created to provide restitution to customers of companies involved in securities fraud, was not a qualified settlement fund.*

- Under the qualified settlement fund (QSF) regulations, a fund, account, or trust subject to taxation as a QSF must meet three requirements. *26 C.F.R. § 1.468B-1(a)*. First, the fund, account, or trust must be established pursuant to an order of, or be approved by, the United States or any agency or instrumentality thereof (including a court of law) and be subject to the continuing jurisdiction of that governmental authority. *26 C.F.R. § 1.468B-1(c)(1)*. Second, the fund, account, or trust must be established to resolve or satisfy one or more contested or uncontested claims that have resulted or may result from an event (or related series of events) that has occurred and that has given rise to at least one claim asserting liability arising out of a tort, breach of contract, or violation of law. *26 C.F.R. § 1.468B-1(c)(2)*. Finally, the fund, account, or trust must be a trust under applicable state law, or its assets must be otherwise segregated from other assets of the transferor (and related persons). *26 C.F.R. § 1.468B-1(c)(3)*. Go To Headnote

- Under *26 C.F.R. § 1.468B-1(c)(2)*, "resolve or satisfy" is a phrase indicating that a qualified settlement fund must void or fully discharge the liability underlying the claims made against the settlor. Partial satisfaction of those claims will not do by the plain terms of the regulation. Go To Headnote

- The transferor is the one on behalf of whom the funds are placed in the fund and against whom the claims that are resolved or satisfied run. *26 C.F.R. § 1.468B-1(d)(1)*. Go To Headnote

Tax Law: Federal Tax Administration & Procedure: Tax Credits & Liabilities: Credits, Overassessments & Refunds (*IRC secs. 6401-6427*): General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

26 CFR 1.468B-1

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(2)* excludes obligations to refund the purchase price of, or to repair or replace, products regularly sold in the ordinary course of the transferor's trade or business. The word "products," as used in this provision, refers to tangible goods, not intangibles like securities. This is one of the common usages of the word. And this meaning fits the context. Consider the three obligations referenced in the provision. Certainly, businesses do not "repair" intangibles, and an obligation to "replace" one is rare, if not nonexistent. To be sure, there are occasions when a business can incur an obligation to refund the purchase price of an intangible. But this exclusion was intended to prevent taxpayers from taking advantage of favorable tax treatment of Qualified Settlement Funds when dealing with certain regularly recurring liabilities, and any enterprise that regularly incurs obligations to refund the purchase price of intangibles (obligations that are most likely to result from fraud or a statutory violation) is better referred to as a "racket" than by the regulations' terms "trade" or "business." If the intent were to include intangibles, the drafters would have used language specifically conveying that meaning. In the immediately preceding paragraph, the drafters used the word "property." Use of the word "product" suggests a narrower focus. *Go To Headnote*

Tax Law: Federal Taxpayer Groups: C Corporations: Recapitalizations (*IRC sec. 368*)

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(3)* excludes obligations of the transferor to make payments to its general trade creditors or debt-holders that relate to a title 11 or similar case. A receivership is a "similar case." *I.R.C. § 368(a)(3)(A)(ii)*. General trade creditors are those to whom a debt is owed for the provision of goods used in the conduct of one's business. And a debt-holder is not just any creditor who is owed a debt, but is one who holds a debt instrument. The final regulations exclude claims of general trade creditors and debtholders that relate to a title 11 or similar case, or to a workout. However, Qualified Settlement Fund treatment remains available for other liabilities such as tort liabilities irrespective of whether the liability, for example, relates to a title 11 case. *Go To Headnote*

26 CFR 1.468B-1

Torts: Products Liability: General Overview

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

United States v. Brown, 334 F.3d 1197, 92 A.F.T.R.2d (RIA) 2003-5270, 2003-2 U.S. Tax Cas. (CCH) ¶ 50559, 2003 U.S. App. LEXIS 13714 (10th Cir.), sub. op., *348 F.3d 1200, 92 A.F.T.R.2d (RIA) 2003-6826, 2003 U.S. App. LEXIS 22701 (10th Cir. 2003)*.

Overview: *The estate was subject to tax as a QSF where the estate did not have to be a transferor, and the statute authorizing the QSF regulations was not an unconstitutional delegation of legislative power.*

- *Treas. Reg. § 1.468B-1(g)(2)* excludes obligations to refund the purchase price of, or to repair or replace, products regularly sold in the ordinary course of the transferor's trade or business. The word "products," as used in this provision, refers to tangible goods, not intangibles like securities. This is one of the common usages of the word. And this meaning fits the context. Consider the three obligations referenced in the provision. Certainly, businesses do not "repair" intangibles, and an obligation to "replace" one is rare, if not nonexistent. To be sure, there are occasions when a business can incur an obligation to refund the purchase price of an intangible. But this exclusion was intended to prevent taxpayers from taking advantage of favorable tax treatment of Qualified Settlement Funds when dealing with certain regularly recurring liabilities, and any enterprise that regularly incurs obligations to refund the purchase price of intangibles (obligations that are most likely to result from fraud or a statutory violation) is better referred to as a "racket" than by the regulations' terms "trade" or "business." If the intent were to include intangibles, the drafters would have used language specifically conveying that meaning. In the immediately preceding paragraph, the drafters used the word "property." Use of the word "product" suggests a narrower focus. *Go To Headnote*

Research References & Practice Aids

Hierarchy Notes:

26 CFR Ch. I

26 CFR Ch. I, Subch. A

26 CFR Ch. I, Subch. A, Pt. 1

26 CFR 1.468B-1

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EXHIBIT

KeyCite Yellow Flag - Negative Treatment
Opinion Clarified by In re Zyprexa Products Liability Litigation, E.D.N.Y., July 9, 2008

2008 WL 2696916
Only the Westlaw citation is currently available.
United States District Court,
E.D. New York.

In re ZYPREXA PRODUCTS LIABILITY LITIGATION.
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.
v.
Eli Lilly and Company, Defendant.
Local 28 Sheet Metal Workers, on behalf of themselves and others similarly situated, Plaintiffs,
v.
Eli Lilly and Company, Defendant.
Sergeants Benevolent Association Health and Welfare **Fund**, on behalf of themselves and others similarly situated, Plaintiffs,
v.
Eli Lilly and Company, Defendant.

Nos. 04-MD-1596, 05-CV-4115, 05-CV-2948, 06-CV-0021, 06-CV-6322.
|
July 2, 2008.

Attorneys and Law Firms

Hagens Berman Sobol Shapiro LLP, by: Thomas M. Sobol, David S. Nalven, Lauren G. Barnes, Kristen A. Johnson, Cambridge, MA, Hagens Berman Sobol Shapiro LLP, by: Sleve W. Berman, Christopher O'Hara, Seattle, WA, Murray Law Firm, by: James R. Dugan, II, Doug Plymale, Ph. D., New Orleans, LA, Kenney, Egan, McCafferty & Young, by: Brian P. Kenney, Eric L. Young, Plymouth Meeting, PA, Hanly Conroy Bierstein Sheridan Fisher & Hayes LLP, by: Jayne Conroy, Paul J. Hanly, Jr., Andrea Bierstein, New York, NY, Simmons Cooper, LLC, by: Lor A. Hoerman, Greg Ertheal, East Alton, IL, Zimmerman Reed PLLP, by: Ronald S. Goldser, Stacy K. Hauer, Brian C. Gudmundson, Minneapolis, MN, Ivey & Ragsdale, by: Garve Ivey, Barry Ragsdale, Jasper, AL, Charfoos & Christensen PC, by: Ann Mandt, Dave Parker, Detroit, MI, J. Thompson & Associates LLC, by: Jason J. Thompson, Southfield, MI, Christopher A. Neal & Associates, by: Christopher A. Neal, Bedford, TX, Kahn Gauthier Law Group, L.L.C, by: Lewis Kahn, Eric O'Bell, New Orleans, LA, Murray Law Firm, by: Stephen B. Murray, Sr., Stephen Murray, Jr., New Orleans, LA, Sadin Law Firm, P .C., by: Art Sadin, Friendswood, TX, Harke & Clasby LLP, by: Lance A. Harke, Howard M. Bushman, Miami, FL, for the Plaintiffs.

Pepper Hamilton, LLP, by: Nina M. Gussak, Thomas E. Zemaitis, Anthony Vale, **Adam** B. Michaels, Kenneth J. Grunfeld, Paul V. Avelar, Philadelphia, PA, Pepper Hamilton, LLP, by: Samuel J. Abate, Jr., New York, NY, for the Defendant.

ORDER IN PREPARATION FOR CONFERENCE

JACK B. WEINSTEIN, Senior District Judge.

***1** In preparation for the July 17, 2008, 11:00 a.m. conference on the motion to certify a class action based on alleged overpricing of Zyprexa, the parties may find the attached draft in progress of the court's present tentative views useful in framing the discussion.

SO ORDERED.

Table of Contents

I. Introduction

***2** Institutions and individuals sue on behalf of a class for overpayment on purchases of Lilly's antipsychotic drug Zyprexa. Claimed is a substantive violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO") through mail fraud, predicated on overpricing supported by excessive claims of utility as well as disavowal of adverse secondary effects of the drug, primarily weight gain and diabetes. *See* 18 U.S.C. § 1964.

There is sufficient evidence of fraud under RICO to go to a jury. Proposed testimony of plaintiffs' experts would permit a jury to determine the excess price. Allocation of damages based on that excess, predicated on written receipts and other reliable information, is practicable.

State-based claims for a recovery are also made. The variations in state law make administration of state claims in this national class action too difficult. There is no need to place this burden on the parties, the court, and a jury. State causes of action would essentially be subsumed in the single federal RICO action. These state claims are not certified. *See* Parts XVIII.A.2, XVIII.C.1, XX.A, *infra.*

Certification of individual payor claims is denied. It will be difficult to obtain the necessary reliable data in most cases of payments. More important, the individual plaintiffs proposed as representatives cannot properly represent the proposed class of individual persons. They have a conflict of interest since they are suing Lilly for personal injury and may sacrifice the proposed overpayment class for a better recovery in their related individual suits. Separate releases for the two claims do not overcome this conflict. *See* affirmation of Douglas R. Plymale, June 23, 2008, at 3; Parts II.A.2.a.iv, II.A.2.b.iv, XVIII.B, *infra.*

A single price was charged for both FDA-approved (so-called "on-label") and non-FDA-approved (so called "off-label") use of the drug. Subclassing for these two categories of drug use is proposed.

There is evidence that off-label use of Zyprexa was excessive and may have been encouraged by Lilly. *See, e.g.,* Laurie Tarkan, *Doctors Say Medication [Including Zyprexa] Is Overused in Dementia,* N.Y. Times, June 24, 2008, at F1. A cause of action for Lilly's urging such off-label use may exist, but it is independent of the present case as it is now being certified based solely on overcharging for use of Zyprexa in

any form. Subclassing of on-label and off-label purchases is denied. *See* Parts XVIII.A.1 .c-d, *infra.*

Every element of Rule 23 of the Federal Rules of Civil Procedure has been satisfied. *See* Part XIX, *infra.* Appropriate certification of institutional claims under federal substantive law is appropriate.

Damages sought are limited to four years before filing. *See Agency Holding Corp. v. Malley-Duff & Associates, Inc.,* 483 U.S. 143, 107 S.Ct. 2759, 97 L.Ed.2d 121 (1987) (applying a four-year statute of limitations for civil RICO claims). They will not be allowed beyond the first date of filing, on June 20, 2005, since by that date all potential third-party payors or the doctors who prescribed Zyprexa should have been sufficiently advised of the alleged overpricing. This calculation should result in a maximum period of June 20, 2001 to June 20, 2005 for recoverable overcharges. A jury may considerably reduce or eliminate this window on finding that the third-party payors knew or should have known of Zyprexa's alleged overpricing before they commenced suit on June 20, 2005. Permitting recovery for overcharges before June 20, 2001 (four years before the suit was commenced) would be inappropriate since the specialists who are the third-party payors had a continuing duty to their clients to inquire. In these special circumstances, there are limits to awards based on passivity. The chronological issue is not free from doubt. *See* Part XIX.B.4, *infra.*

***3** A **settlement** class would be more useful than the litigation class being certified. Ideally it would include actions for overcharges brought on behalf of government entities and individual payors. With other related Zyprexa cases coming to completion, it could help end the entire Zyprexa litigation. *See* Part XXIC, *infra.*

If **settlement** is not to be effectuated, parties to the present action shall within thirty days agree on a form of order for certification, including the precise definition of the class. If they cannot agree they shall submit, based on this memorandum and without conceding its accuracy, a proposed order to be considered at a hearing at 11:00 a.m. on July 31, 2008. *See* Part XXII, *infra.*

An interlocutory appeal is certified on the defendant's motion for summary judgment. *See In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571 (E.D.N.Y.2007) (denying motion for summary judgment). Interlocutory appeal provisions of Rule 23(f) of the Federal Rules of Civil Procedure on certification of the class also apply. *See* Part XXIII, *infra.*

Details on notification and administration of the litigation as a class may await an interlocutory decision by the Court of Appeals for the Second Circuit. No substantial difficulty in providing for the particulars of administrating this class action litigation is foreseen. Federal courts have had experiences in class actions far more complex than this one. The practicality and relative ease of administration in the instant case is apparent. *See* Part XXI, *infra.*

Despite its substantive and procedural simplicity, the case comes freighted with complex medical details, economic models, and important implications for our national health care system. Allocation of scarce resources is reflected in large part by the cost of medications doctors prescribe. Drugs are primarily paid for by third-party payors ("TPPs"), rather than by the doctors who recommended them or the patients who use them. *See, e.g.,* Peter H. Schuck & Richard J. Zeckhouser, Targeting in Social Programs 56-57 (2006) ("[P]olicymakers and plan managers are relying on physicians [and HMOs] to be vigilant stewards of scarce resources," even though they are often ineffective in controlling costs). TPPs include insurance **funds** and other health management organizations ("HMOs") such as the plaintiffs in the instant action. These screeners of drug use must have reasonably accurate and transparent sources of information if they are to make reasonable medical and economic choices. So too must doctors and their patients.

The Federal Drug Administration ("FDA") is expected to guard the quality of available information about the utility and risks of pharmaceuticals by regulating drug approvals and labeling requirements, monitoring adverse side effects, and requiring warnings and "Dear Doctor" letters. Non-governmental agencies, individual expert research, publications, and meetings, and word-of-mouth supply an enormous amount of additional data on which doctors and other screeners of drug use rely. Tort law has an important function in guarding against pollution of the information the medical calling and patients receive, particularly since our federal agency, the FDA, is relatively impotent.

***4** Institutional plaintiffs-the TPPs-in the instant cases are pension **funds**, labor unions, and insurance companies. They cover members' health benefits; they have paid for Zyprexa, as well as many other pharmaceuticals upon which people rely..

Sold under the brand name Zyprexa, olanzapine is one of a class of medications known as "atypical" or "second generation" antipsychotics ("SGA"). ("Zyprexa" and "olanzapine" are used interchangeably in this memorandum.) It is a prescription drug developed and manufactured by Lilly. The FDA first approved Zyprexa in 1996 for use in treating schizophrenia, a severe mental illness; later Zyprexa was approved for treating some kinds of bipolar and other diseases. Olanzapine's main side effects appear to be weight gain, diabetes, hyperglycemia, and other metabolic problems.

Zyprexa continues to be used by, and prescribed for, large numbers of people. There is a general consensus that it is sometimes useful for both FDA-approved indications and some off-label purposes. It has substantially increased the quality of life of some sufferers from severe mental problems. *See, e.g.,* Elyn R. Saks, The Center Cannot Hold: My Journey Through Madness 303 (2008) ("I began to take Zyprexa .... The change was fast and dramatic.... I felt alert and rested, energetic in a way I hadn't felt in a long time-so long, in fact, that I'd almost forgotten what those good feelings were like.... The clinical result was, not to overstate it, like daylight dawning after a long night-I could see the world in a way I'd never seen it before.").

Beneficial effects of Zyprexa are evidenced by the fact that the institutional plaintiffs continue to reimburse or pay for Zyprexa prescriptions for their members, with few or no restrictions on its use. Many treating physicians prescribe it for their patients, despite its now well-known metabolic side effects. Nevertheless, the utility of Zyprexa does not trump plaintiffs' legal claims for fraud and overpricing.

Since this memorandum is still a draft in progress, corrections and suggestions may be freely made.

A. Plaintiffs' Claims

Plaintiffs claim overpayment through direct expenditures on Zyprexa. Individual patients buy Zyprexa for personal use pursuant to the prescriptions of their doctors, paying the market price or a portion thereof according to insurance plan. Third-party payors pay the remainder for their covered members, typically via a pharmaceutical benefit manager ("PBM"), which act as TPP agents in administering their prescription drug programs.

It is alleged that over the eleven-year period since Zyprexa's introduction in 1996 to today, Lilly has withheld information and disseminated misinformation about the safety and efficacy of Zyprexa and promoted and marketed the drug for uses for which it was not indicated and for patients who would have been better served by less expensive medications. As a result, plaintiffs contend, Zyprexa commanded a higher price than it would have had the truth been known to those who prescribed, bought or paid for the drug. The resulting alleged excess payments-estimated to range from $3.998 billion to $7.675 billion (Dr. Rosenthal) or approximate $4.9 billion (Dr. Harris)-are claimed as damages. *See* Parts XVII.A.2-3, *infra.* Having survived summary judgment, *see* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, plaintiffs now seek certification of a class of third-party and individual payors.

***5** Five causes of action are asserted: Counts I and II, violations of the Racketeer Influenced and Corrupt Organization Act ("RICO") under 18 U.S.C. §§ 1962(c) and 1962(d); Count III, violations of forty-five state consumer protection statutes; Count IV, common law fraud; and Count V, unjust enrichment. *See* First Am. Class Action Compl. (Redacted Version), Nov. 7, 2005, Docket No. 05-CV-4115, Docket Entry No. 14 ("Red.Am.Compl").

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).

B. Related Actions

Related Zyprexa actions provide the court and litigants with an extensive factual and evidentiary background. The present suit is part of a series of cases based on injuries allegedly resulting from Lilly's sale of Zyprexa. A mass tort product liability/personal injury action on behalf of approximately 30,000 private litigants against Lilly, almost all of which have now settled, was transferred to this court by the Judicial Panel on Multidistrict Litigation beginning in April 2004. *See In re Zyprexa Prods. Liab. Litig.,* No. 04-CV-1596, Docket Entry No. 1 (E.D.N.Y); 28 U.S.C. § 1407. The large

number of related individual personal injury suits necessitated administration of the litigation as a quasi-class action, with the use of matrices for **settlement** amounts, control over fees, cooperation with state courts and national **settlements** of liens. *See* *In re Zyprexa Prods. Liab. Litig.*, 451 F.Supp.2d 458, 477 (E.D.N.Y.2006) (recognizing the court's "obligation to exercise careful oversight of this national 'quasi-class action' ") (citation omitted); *In re Zyprexa Prods. Liab. Litig.*, 433 F.Supp.2d 268, 271 (E.D.N.Y.2006) (finding that the case "may be characterized properly as a quasi-class action subject to the general equitable power of the court"); *In re Zyprexa Prods. Liab. Litig.*, 424 F.Supp.2d 488, 491 (E.D.N.Y.2006) (same); *In re Zyprexa Prods. Liab. Litig.*, 233 F.R.D. 122, 122 (E.D.N.Y.2006) (same).

Various administrative measures were taken to control discovery and ensure appropriate representation for the personal injury plaintiffs. Two successive Plaintiffs' Steering Committees ("PSCs") were appointed. Multiple special masters and a magistrate judge assisted.

Extensive and coordinated discovery led to creation of a national archive available to all parties. *See* *In re Zyprexa*, 424 F.Supp.2d at 491 ("[A]ll litigants, whether in federal or any state court, have access to the materials obtained in pretrial discovery"). Over fifteen million pages of documents are available to the parties in the instant class action. Those materials, maintained initially in a depository in Denver, Colorado, and currently in Mount Pleasant, South Carolina, have been available free of charge to the multi-district litigation ("MDL") and non-MDL plaintiffs in both state and federal courts who agree to adhere to the terms of the protective and related orders issued by this court. *See also* *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, Case Mgmt. Order No. 20, at 1 (E.D.N.Y. Nov. 15, 2006) (ordering special master's discovery and trial schedule for personal injury actions); *In re Zyprexa Prods. Liab. Litig.*, 375 F.Supp.2d 190, 191 (E.D.N.Y.2005); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, at 5 (E.D.N.Y. May 15, 2006) (directing MDL counsel to use best efforts to coordinate the scheduling of depositions with state court counsel, and providing for cross-noticing of depositions in federal and state court).

***6** Because many of the personal injury suits were filed in state, not federal court, coordination with state judges was desirable. *See* *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, 2006 WL 898105, at *1 (E.D.N.Y. Apr. 16, 2006) ("Coordination and cooperation between state and federal courts has been encouraged."); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, 2006 WL 197151 (E.D.N.Y. Jan. 30, 2006) (suggesting coordination and cooperation in a letter to state judges with Zyprexa cases); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, 2004 WL 3520248, at *4 (E.D.N.Y. Aug. 18, 2004) (directing Lilly and the first PSC ("PSC I") to "confer regarding procedures for coordination of state court discovery with discovery in this MDL").

Over 8,000 personal injury claims, representing about 75% of the then-pending plaintiffs, were settled by Lilly in 2005 under the supervision of PSC I. *See* *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-01596, 2005 WL 3117302 (E.D.N.Y. Nov. 22, 2005). A complex claims processing and payment procedure was established, administered via special **settlement** masters. *See* *In re Zyprexa Prods. Liab. Litig.*, 433 F.Supp.2d 269 (E.D.N.Y.2006); *see also* *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443217 (E.D.N.Y. Aug. 24, 2006) (ordering payments to begin); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 2443249 (E .D.N.Y. Aug. 24, 2006) (establishing disbursement procedures). Another 18,000 such plaintiffs settled with Lilly in January 2007; **settlement** was largely administered by an appointed **settlement** administrator rather than the court. *See* *In re Zyprexa Prods. Liab. Litig.*, No. 04-CV-1596, 2007 WL 37736 (E.D.N.Y. Jan. 5, 2007). Since then, many more plaintiffs have settled or agreed to settle. *See e.g.*, *In re Zyprexa Prods. Liab. Litig.*, No. 04-CV-1596, 2008 WL 1827486 (E.D.N.Y. Apr. 22, 2008) (ordering the administrative closure of over a thousand cases pending reinstatement should the contemplated **settlements** not be consummated).

Summary judgment motions in several individual plaintiffs' personal injury claims were addressed in June 2007. Analysis of the summary judgment motions required review of thousands of pages of material. *See* Appendices A-D of *In re Zyprexa Prods. Liab. litig.*, 489 F.Supp.2d 230 (E.D.N.Y.2007) (including over 1500 pages of relevant depositions demonstrating doctors' awareness of Zyprexa's association with patient weight gain). In one claim, defendant's motion was granted based on statute of limitations grounds. *In re Zyprexa Prods. Liab. Litig.*, 489 F.Supp.2d 230 (memorandum and order on motions for summary judgment in individual personal injury claims). Other personal injury lawsuits set for trial in this district in June 2008 were settled before summary judgment could be rendered. *See, e.g., Godley v. Eli Lilly & Co.*, Docket No. 06-

CV-04038 (E.D.N.Y); *Smith v. Eli Lilly & Co.,* Docket No. 06-CV-04039 (E.D.N.Y.).

***7** For the personal injury **settlements**, an attorneys' fees structure was ordered. *See In re Zyprexa Prods. Liab. Litig.,* 424 F.Supp.2d 488 (capping fees at 20% of recovery for smaller, lump-sum claims, and at 35% for all other claims); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-01596, 2006 WL 2443248 (E.D.N.Y. Aug. 24, 2006) (limiting PSC costs charged to the individual settling plaintiffs); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-01596, 2006 WL 2458878 (E.D.N.Y. Aug. 22, 2006) (referring oversight of PSC I's fee claims to the magistrate judge); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MDL-0159 (E.D.N.Y. Aug. 16, 2006); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-01596, 2004 WL 3520245 (E.D.N.Y. June 17, 2004) (outlining the PSC's responsibilities).

Since many of the personal injury plaintiffs had coverage for health-related expenditures through state Medicaid and federal Medicare programs, a procedure for resolving outstanding government liens was executed. *See In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 2385230 (E.D.N.Y. Aug. 15, 2006) (describing and approving Medicaid lien agreements between states and the PSC); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 2385232 (E .D.N.Y. Aug. 16, 2006) (describing fee division issues); *In re Zyprexa Prods. Liab. Litig.,* 451 F.Supp.2d 458 (creating a national mechanism to resolve outstanding Medicare and Medicaid liens on the recoveries of settling personal injury plaintiffs); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-01596, 2006 WL 3501263, at *1 (E.D.N.Y. Dec. 4, 2006) ("In compliance with this court's instructions ... all fifty states as well as the federal government have resolved their Medicare and Medicaid liens" by agreeing to modify their lien demands to provide a national equitable system) (citation omitted); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 2443217 (E.D.N.Y. Aug. 24, 2006) (describing and approving Medicare lien agreements between certain states, the federal government, and the PSC); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 2385230 (E.D.N.Y. Aug. 15, 2006) (same); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 2095728 (E.D.N.Y. July 28, 2006) (ordering Lilly and the states to negotiate); *In re Zyprexa Prods. Liab. Litig.,* No. 04-MD-1596, 2006 WL 1662610 (E.D.N.Y. June 15, 2006) (setting initial conference regarding a possible holdback to satisfy government liens).

Non-governmental health insurance liens were dealt with on an individual basis. A private health insurance company sued the trustees of the first Zyprexa**settlementfund** for failure to resolve such liens; that matter has now been settled. *See Aetna, Inc. v. Seeger Weiss, LLP,* No. 07-CV-03559 (E.D.N.Y.).

In suits based on claims similar to those in the instant action, many State Attorneys General have sued on behalf of their states' citizens claiming reimbursement for overpayments for Zyprexa made with state and federal **funds** via state Medicaid programs. Currently pending in this court are actions on behalf of the citizens of Montana, Connecticut, New Mexico, Mississippi, West Virginia, and Louisiana. *See In re Zyprexa Prods. Liab. Litig.,* No. 07-CV1933, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008) (Montana, denying remand); *Hood ex rel. State of Mississippi v. Eli Lilly & Co.,* No. 07-CV-645, 2007 WL 1601482 (E.D.N.Y. June 5, 2007) (Mississippi, denying remand); *In Zyprexa Prods. Liab. Litig.,* 375 F.Supp.2d 170 (E.D.N.Y.2005) (Louisiana, denying remand); *State of West Virginia v. Eli Lilly & Co.,* 476 F.Supp.2d 230 (E.D.N.Y.2007) (West Virginia, denying remand); *State of Connecticut v. Eli Lilly & Co.,* No. 08-CV-955 (E.D.N.Y.); *In re Zyprexa Prods. Liab. Litig.,* No. 07-CV-1749, 2008 WL 940102 (E.D.N.Y. Apr.1, 2008) (New Mexico, scheduling discovery); *cf.* Alex Berenson, *Lilly Considers $1 Billion Fine to Settle Case,* N.Y. Times, Jan. 31, 2008 (federal and state negotiations with Lilly over a proposed fine). A putative qui tam action by a whistleblower representing California has been dismissed. *State of California ex rel. Jaydeen Vincente v. Eli Lilly & Co.,* No. 08-CV-600, Docket Entry No. 84 (dismissing action).

***8** Some of Lilly's shareholders have filed suit because of the decline in share price. *See In re Eli Lilly & Co. Securities Litig.,* No. 07-CV-1310 (E.D.N.Y.). This litigation has been dismissed on statute of limitations grounds. *See In re Zyprexa Prods. Liab. Litig.,* 549 F.Supp.2d ----, Nos. 04-MDL-1596, 07-CV-1310, 2008 WL 1923126 (E.D.N.Y. Apr.30, 2008).

Current shareholders have sued in this court in the form of three separate shareholder derivative actions. *See Waldman v. Taurel,* No. 08-CV-560 (E.D.N.Y.); *City of Taylor Employees Retirement System v. Taurel,* No. 08-CV-1554 (E.D.N.Y); *Robins v. Taurel,* No. 08-CV-1471 (E.D.N.Y.). Similar cases are pending in other courts. **Settlement** negotiations are ongoing. *See* Hr'g Tr., May 29, 2008.

The present suit must be considered in the context of the related Zyprexa actions. Materials previously submitted to the court in the MDL were, on consent of the parties, considered in deciding this class certification motion. *See* Transcript of Evidentiary Proceedings on Class Certification, March 28, 2008 through April 2, 2008 ("Tr."), at 5-6 (Mar. 28, 2008). Materials from the parties' previous summary judgment motions, *see* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, are extensively cited.

In March 2008, Lilly settled with the state of Alaska for $15 million during trial in a related case. *See* Alex Berenson, *Lilly Settles Alaska Suit over Zyprexa,* N.Y. Times, Mar. 26, 2008 (reporting the **settlement** agreement reached after three weeks of trial before the case went to the jury). That state's lawsuit sought reimbursement for the medical costs of Alaska Medicaid patients who developed diabetes while taking Zyprexa; the state's claim to recover costs associated with Lilly's off-label promotion of Zyprexa was dismissed before trial. Alex Berenson, *Lilly E-Mail Discussed Off-Label Drug Use,* N.Y. Times, Mar. 14, 2008. Some of the materials introduced in that trial are available to the court.

C. Class Certification

Plaintiffs seek to consolidate many thousands of claims in the present class action on the ground that those who paid for Zyprexa were charged more than they would have been in the absence of Lilly's fraud. Claims include those of both patients and insurance companies. Various definitions of the putative class have been proposed. As outlined in plaintiffs' papers, the class may be generally defined as:

> 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 for some or all of the purchase price.

Pfs.' Corr. Supp. Post-Hr'g Mem. on Class Cert. 32, Apr. 21, 2008 (undocketed; filed under seal); *see* Red. Am. Compl.; Class Plaintiffs' Opening Brief on Class Certification ("Pfs.' Class Cert. Br."), Aug. 3, 2007, Docket Entry No. 131 (filed under seal).

***9** Two subclasses are proposed: a Third-Party Payor Subclass and a Consumer or Direct-Payor Subclass; further subdivision into two groups, one for "on-label" (used for FDA-approved indications) purchases and the other for "off-label" (used for non FDA-approved indications) purchases has also been suggested by plaintiffs. Pfs.' Corr. Supp. Post-Hr'g Mem. on Class Cert. 33; *see* Fed.R.Civ.P. 23(c)(5); Part XVIII.A, *infra.*

The class will be certified on a more limited basis than that sought by plaintiffs. *See* Part XX, *infra.* With adequate due process protections for both plaintiffs and defendant, restrictions on the litigation will permit the jury to determine, with sufficient precision, the monetary damages, if any, to institutions which allegedly overpaid for Zyprexa as a result of Lilly's fraud. The assistance of *Daubert*-cleared experts and a plan for efficiently managing the litigation as a class action provide substantial benefits to the community, the courts and the litigants, as opposed to individual suits.

Certification will be granted to a class of Third-Party Payors on the federal RICO claims only. *See* Part XX, *infra; see also* *In re Zyprexa Prod. Liab. Litig.*, 493 F.Supp.2d 571, 577, 579 ("Based on expert reports and available modes of economic analysis, a trier could determine that Zyprexa would have ... been sold for a reasonably precise computable lesser amount than it was sold for were it not for Lilly's alleged fraud.").

Establishment of class damages is practicable based upon the admissible opinions of plaintiffs' proffered experts. In these circumstances the Constitution requires a jury disposition. *See*U.S. Const. amend. VII. For purposes of the constitutional right to a civil jury, this is essentially a "suit at common law," even though plaintiffs rely on statutory substantive law and equitable class action practice. Plaintiffs' state claims will not be certified at this time by this court because of manageability difficulties. *See* Parts XVIII.A.2, XVIII.C.1, XX.A, *infra.*

Denial of any form of certification would constitute the death knell of the action. Almost all plaintiffs' claims would be too small to individually support this costly litigation. Under such circumstances, absent an unusual situation, the rule to be applied in deciding to deny certification is essentially that for summary judgment if all the elements of Rule 23 of

the Federal Rules of Civil Procedure are satisfied-as they are here. *See* Fed. R. Civ. Proc. 23.

In arguing against class certification, defendant relies heavily on the Second Circuit Court of Appeals' reversal of *Schwab v. Philip Morris,* 449 F.Supp.2d 992 (E.D.N.Y.2006), in *McLaughlin v. American Tobacco Co.,* 522 F.3d 215 (2d Cir.2008), *subsequently placed in doubt by Bridge v. Phoenix Bond & Indemnity Co.,* No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008). Denial of some aspects of defendant's motion for summary judgment was based in part on *Schwab. See In re Zyprexa Prods. Liab. Litig .,* 493 F.Supp.2d 571. The instant action and that in *McLaughlin* superficially may appear alike: in both, consumers have sued for overpricing based on fraudulent health claims of the product-medication or cigarettes. *McLaughlin* is, as explained below, distinguishable from the present case. Assuming *McLaughlin* is still fully viable in view of the subsequent Supreme Court decision in *Phoenix Bond,* which has expanded the reach of RICO in civil prosecutions, it is not an impediment to certification in the instant *Zyprexa* case. *See* Parts XX.B-D, *infra.*

D. Interlocutory Appeal

***10** As suggested in the summary judgment opinion, *see In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d at 580-81, an interlocutory appeal from the order denying summary judgment should be, and is now, certified. *See* Part XXIII, *infra.* This will permit that issue to be considered along with any immediate appeal from the class certification order. 28 U.S.C. § 1292(b); Fed. R. Civ. Proc. 23(f).

II. Procedural History

A. Multiple Plaintiffs

1. Third-Party Payor Plaintiffs

On June 20, 2005, Mid-West National Life Insurance Company of Tennessee ("Mid-West") and Eric Tayag ("Tayag") filed a class action suit against defendant Eli Lilly and Company ("Lilly") regarding the alleged fraudulent over-promotion of olanzapine, sold under the brand name Zyprexa, and seeking economic damages. *See* Mid-West & Tayag Compl., June 20, 2005, Docket No. 05-CV-2948, Docket Entry No. 1. Similar suits were initiated by UFCW Local 1776 and Participating Employers Health and Welfare **Fund** ("UFCW"), *see* UFCW Compl., Aug. 25, 2005, Docket No. 05-CV-4115, Docket Entry No. 1, Local 28 Sheet Metal Workers ("Local 28"), *see* Local 28 Compl. (Redacted Version), Dec. 29, 2006, Docket No. 06-CV-21, Docket Entry No. 1, and Sergeants Benevolent Association Health and Welfare **Fund** ("SBA"), *see* SBA Compl., Nov. 21, 2006, Docket No. 06-CV-6322, Docket Entry No. 1. Michael Pronto ("Pronto") and Michael Vannello ("Vannello") were later added in the fall of 2006 as co-lead plaintiffs and Tayag was dropped as a class representative.

Sufficient data is available to support computations of the amounts paid for Zyprexa by these and other class members. With other information available to a trier, overpayments can be calculated.

a. UFCW

The UFCW **Fund** is a Taft-Hartley trust **fund** created to provide cost effective, comprehensive medical and prescription drug benefits to the Local 1776 members of the United Food & Commercial Workers Union ("UFCW Local 1776"), whose employers are required to contribute financially pursuant to negotiated union contracts. *See generally*29 U.S.C. §§ 141-197 *et seq.* (Taft-Hartley Act, i.e., enabling federal law pursuant to which the UFCW **Fund** was created). UFCW Local 1776 is a labor union based in Philadelphia, Pennsylvania, with over 20,000 active members, some of whom live in other states. Pfs.' Class Cert. Br. Typical of Taft-Hartley benefit trust **funds**, the UFCW **Fund** has no employees. Dep. Tr. of Regina Reardon on behalf of Plaintiff UFCW, Oct. 5, 2006, at 15 ("UFCW Dep ."). Since 1996, the UFCW **Fund** has contracted with a third-party administrator that collects employer contributions, maintains records, pays claims, and conducts the day-to-day operations of the UFCW **Fund**. *Id.* at 16. It has overall annual expenditures of $70 million, *id.* at 172-73; over the last five years, its expenditures on prescription drugs have increased almost fifty percent. *Id.* at 172-73.

***11** Like most other third-party payors, the UFCW **Fund**, with the assistance of its third-party administrator, contracts with a Pharmacy Benefit Manager ("PBM") to manage its pharmacy plan. *Id.* at 16. The UFCW **Fund** pays for eligible Zyprexa prescriptions directly through its PBM, currently National Medical Health Card ("NMHC"). *Id.* at 86, 39. To manage the UFCW **Fund's** pharmacy benefits, NMHC uses a formulary containing a list of preferred drugs. Many

of the drugs on the preferred list are those for which the NMHC has rebate contracts with the manufacturers. UFCW Dep. 91. The UFCW **Fund** pays the cost, minus a co-pay, regardless of whether the drug is included in the formulary. *Id.* at 84. The co-pay is a percentage of the drug cost or a fixed amount per prescription paid by the actual user; it may vary depending on whether the particular drug is on-formulary or off-formulary. *Id.* at 99. UFCW has no means of determining the indication for which a prescription is written and whether it is for an on-label or off-label purpose. On May 15, 2007, UFCW's PBM formally recommended that the **fund** impose prior authorization for all Zyprexa prescriptions to discourage potential off-label use of the drug.

UFCW alleges that it has suffered economic harm as a result of Lilly's false and misleading statements about the safety and efficacy of Zyprexa. Am. Compl. at ¶¶ 472, 480, 535, 54, 546. It asserts that every Zyprexa prescription for which it has paid was procured by Lilly's fraud, *id.* at No. 1; Opp'n to Eli Lilly & Co.'s Mot. to Compel Further Resps. by Pfs. to Interrogs. & Doc. Reqs. & to Compel Mid-West's Rule 30(B)(6) Witness to Answer Questions, Dec. 1, 2006 ("Opp'n to Mot. to Compel") at 7, and has produced such Zyprexa prescription information as cost, dose and date.

From January 1997 through January 2006, the UFCW **Fund** paid a total of $799,888.16 for Zyprexa. *See* UFCW 445. Between January 31, 1997 and April 10, 1997, it paid for 5,514 units; between June 9, 1999 and January 11, 2002, it paid for 3,226 units; between June 4, 2003 and June 16, 2003, it paid for 1,345 units; and between December 12, 2003 and January 5, 2006, it paid for 57,569 units. *Id.* UFCW used various PBMs between 1996 and 2000; since not all of them maintained data on Zyprexa, there are some gaps in the records.

Lilly sales representative call notes produced in discovery suggest that several physicians who prescribed Zyprexa to the UFCW **Fund's** insureds were deceived by Lilly before, or while, prescribing Zyprexa. Pfs.' Response to Def.'s Local R. 56.1 Statement of Undisputed Facts & Pfs.' Local R. 56.1 Statement of Disputed Facts, June 12, 2007, Docket No. 05-CV-4115, Docket Entry No. 113 ("Pfs.' SJ Fact Proffer"). These notes indicate that physicians who prescribed Zyprexa to UFCW **Fund's** insureds may have been falsely led into believing that Zyprexa was effective for a variety of problems for which it was not useful, including depression, mood disorders, anxiety, sleep problems, selective serotonin reuptake inhibitors ("SSRIs") failures, and dementia. *Id.*

b. Mid-West

***12** Plaintiff Mid-West National Life Insurance Company of Tennessee ("Mid-West") is an insurance company based in North Richland Hills, Texas. Texas Department of Insurance report regarding Mid-West, https:// apps.tdi.state.tx.us/pcci/pcci_search.jsp, printed May 8, 2007 ("Texas Dep't of Ins. Report"). Mid-West offers various insurance products, some of which include a prescription drug benefit. Dep. Tr. of Kip Howard on behalf of Plaintiff Mid-West, Oct. 24, 2006, at 100:8-20 ("Mid-West Dep."). The numbers of persons covered by Mid-West for pharmacy benefits for the years 1999 through 2006 are as follows: 2,356 in 1999, 1,313 in 2000, 36,244 in 2001, 138,472 in 2002, 182,847 in 2003, 197,950 in 2004, 204,096 in 2005, and 223,069 in 2006. *See* Affidavit of Mid-West, Kip Howard, Dec. 29, 2006 ("Mid-West Aff. 1") at ¶ 3. Information on the number of persons covered for the years 1996, 1997, or 1998 is not available.

Mid-West's Plan A has a $50 deductible and a maximum annual coverage of $500. *Id.* Under Plan A, the insured receives a 25% discount for payments for brand-name drugs at the point of sale; the co-pay for generic drugs is a flat rate of $20 or $10 depending on how the prescription is filled. *Id.* Plan B has a deductible of $100 and a maximum annual coverage of $1000. Under Plan B, both generic and brand drugs are covered under a tiered flat co-pay of $15, $30, or $45, depending on whether the drug is generic, brand on-formulary, or brand off-formulary. *Id.*

Wholly owned by HealthMarkets, Inc. ("HealthMarkets"), Mid-West Aff. 1 at ¶ 2, Midwest has assets in excess of $25,000. Affidavit of Mid-West, Kip Howard, Jan. 5, 2007 ("Mid-West Aff. 2") at ¶ 2; Mid-West Dep. 13; Texas Dep't of Ins. Rep. From 1996 to present, either HealthMarkets or another company it wholly owns, MEGA Life and Health Insurance ("MEGA"), has contracted with a PBM to administer pharmacy benefits for Mid-West's insureds. Mid-West Aff. 1 at ¶ 2. Pharmacy benefits are administered by the PBM pursuant to contracts between HealthMarkets (or MEGA) and the PBM. *Id.*

The PBM that administered pharmacy benefits for Mid-West's insureds from 1996 through 1999 was Advanced Paradigm, Inc. (n/k/a Caremark, Rx, Inc.). Mid-West's Obj. & Answers to Lilly's First Set of Interrogs. ("Mid-West's Resps. to Interrogs., First Set") at No. 1. From 2000 through 2002, Mid-West's PBM was MedCo Health Solutions, Inc. *See id.*

From 2003 through the present, Mid-West's PBM has been Caremark Rx, Inc. *See id.*

Mid-West always adopts the formulary of its PBMs; it does not create its own custom formulary. Mid-West Aff. 2 ¶ 7. The formulary is set and controlled by its PBM. *Id.* Mid-West does cover non-formulary drugs, but its insureds pay a higher co-pay for them. *Id.* at ¶ 5. Zyprexa has always been on the formulary of Mid-West's PBM. *Id.* at ¶ 3.

For Mid-West insureds with a prescription drug benefit, it reimburses, and has always reimbursed, eligible Zyprexa prescriptions. *Id.* at ¶ 4. It has never sought any utilization restrictions (including prior authorizations) for Zyprexa. *Id.* at ¶ 8. Since filing its complaint, it has not altered its practices or policies regarding its payment for Zyprexa. Mid-West Dep. 87-88; Mid-West's Resps. to Interrogs., First Set at No. 7. Mid-West pays a higher price for Zyprexa now than when the Amended Complaint was filed; Zyprexa's market price has steadily increased at more than the cost-of-living.

***13** Mid-West alleges that it has suffered economic harm as a result of Lilly's false and misleading statements about the safety and efficacy of Zyprexa. Am. Compl. at ¶¶ 472, 480, 535, 54, 546. It asserts that every Zyprexa prescription for which it has paid was procured by Lilly's alleged fraud. *Id.* at No. 1; Opp'n to Mot. to Compel at 7. It has produced its prescription claim data in discovery, including information such as cost, dose, date, and identity of some prescribing physicians.

From January 2000 through April 2007, Mid-West paid for 1,617 Zyprexa prescriptions for 646 of its insureds. *See* Mid-West's Resps. to Interrogs., First Set, as supplemented. Mid-West does not possess claims data prior to January 2000. *Id.* Its documented payments for Zyprexa total $32,570. *See id.*

The plaintiff has communicated neither with its insureds nor their physicians about the safety or efficacy of Zyprexa. It has not shared the allegations of this lawsuit with them.

c. Local 28

Local 28, a New York Taft-Hartley health and welfare **fund**, provides a prescription drug benefit to active and retired member of the Local 28 Sheet Metal Workers Union. It provides coverage for members living in the five boroughs of New York City as well as in Nassau and Suffolk counties. Dep. of John McGrath on behalf of Plaintiff Local 28, Nov. 10, 2006, at 13 ("Local 28 Dep."). It has 2,800 working members, 400 apprentices, and 1,800 retirees, all of whom are eligible for health benefits for themselves and their families. *Id.* In total, Local 28's Workers **Fund** provides benefits for approximately 10,000 people, *id.* at 43, 134, including eligible members in twenty-nine states. *Id.* at 13.

The pharmacy benefit plan for Local 28 is an "open plan;" payment is made for any drug as long as it is prescribed by a physician and is approved and non-experimental. *Id.* at 48-49. Since 2004, Local 28's formulary has been provided by its PBM, Specialized Pharmacy Solutions. The PBM has the exclusive authority to classify drugs in the formulary. *Id.* at 61-62. Local 28 pays any remaining balance for a prescription after a member provides the co-pay. *See also id.* at 84. It pays for Zyprexa, and has not made any Zyprexa-specific changes to its policies. *Id* . at 33.

Alleged is that Local 28 has suffered economic harm as a result of Lilly's false and misleading statements about the safety and efficacy of Zyprexa. Am. Compl. at ¶¶ 472, 480, 535, 54, 546. It claims that every Zyprexa prescription for which it had paid was procured by Lilly's fraudulent conduct. *Id.* at No. 15; Opp'n to Mot. to Compel 7. Local 28 has identified these prescriptions by producing claims data in discovery, including such information as cost, dose and date. Between 1998 and 2007, the **Fund** paid $198,906.73 for 848 Zyprexa prescriptions. Local 28 Dep. at Ex. 3.

A review of call notes produced by Lilly indicates that physicians were told that Zyprexa was effective for a variety of problems, including mood disorders, anxiety, sleep problems, SSRI failures and dementia. Lilly Physician Call Notes at ZY 1005511869, ZY 1005569827, ZY 1005599586.

d. SBA

***14** The Sergeants Benevolent Association ("SBA") provides a prescription drug benefit, as well as other health benefits to sergeants in the New York City Police Department, retirees, and dependants. Dep. of Errol Ogman on behalf of Plaintiff SBA Health & Welfare **Fund**, Jan. 24, 2007 at 9:17-20 ("SBA Dep."). It provides pharmaceutical benefits for approximately 33,000 individuals. *Id.* at 9:17-20, 11:9-19, 145:10-15.

SBA pays for prescriptions, including those for Zyprexa, of covered members. *Id.* at 105:10-106:13. It has never used a formulary; it does not distinguish between preferred and nonpreferred drugs. *Id.* at 151-52. SBA has never imposed any restrictions (including prior authorizations, step

therapy, or higher co-pays) for Zyprexa, *id.* at 150-51, 157, 159, although it has required prior authorization for other medications, including those used to treat schizophrenia. *Id.* 212-14. SBA continues to pay for Zyprexa to this day. *Id.* at 36-37.

Third-party administrators handle SBA's routine benefit management. Until October 2003, SBA used General Prescription Program as its PBM. *Id.* at 162:24-163:10. In October 2003, SBA switched to a PBM named Caremark. *Id.* at 162:24-163:10.; SBA's Response to Interrogs. Caremark was the PBM for SBA from October 1, 2003 to July 31, 2005. SBA's Objs. & Answers to Lilly's First Set of Interrogatories, Jan. 17, 2007. In July 2005, SBA started a non-profit company called True Health Benefits to handle pharmacy benefit management. True Health Benefits then contracted with Innoviant Rx as a third-party administrator to handle the tasks of a normal pharmacy benefit manager. SBA Dep. at 50:8-20. SBA, acting through True Health Benefits, encourages participants to consider cost-effectiveness by requiring members to pay a percentage of the total drug cost rather than using a formulary. *Id.* at 147:6-148:4, 151:19-22.

SBA alleges that it has suffered economic harm as a result of Lilly's false and misleading statements about the safety and efficacy of Zyprexa. *Id.* at 33, 36-37. It asserts that every Zyprexa prescription for which it has paid was procured by Lilly's alleged fraud. *Id.* at 35-36. (From July 2001 to June 2005, SBA did not pay for Zyprexa medications for non-Medicare members, because of a special New York City program that covered psychotropics for those patients. *Id.* at 152-55.) During the class period, SBA spent $87,869 for Zyprexa; it has identified these prescriptions by producing claims data in discovery.

Lilly allegedly made misleading statements to Caremark, SBA's PBM from October 2003 to July 2005. ZY204336042-043. Caremark was contacted by a Lilly representative with information downplaying Zyprexa's link with diabetes in May 2002; it was represented that Zyprexa's metabolic effects were not worse than others SGAs'. ZY203904748-ZY203904750. Lilly also used Caremark and other PBMs to communicate and market to physicians. ZY204336042-ZY2044336043. In September 2003, Lilly utilized Caremark to mail out Zyprexa marketing material to physicians. *Id.*

***15** In June 2007, SBA notified its members about the pending litigation and concerns about Zyprexa. *See* SBA's Supp. Response to Interrogs., June 1, 2007. SBA continues to communicate with its members through its delegates regarding this litigation and concerns about Zyprexa. SBA Dep. at 121:18-122:17.

e. Teachers

Based in New York, plaintiff United Federation of Teachers Welfare **Fund** ("Teachers") provides supplemental health benefits to covered members, teachers, paraprofessionals, and eligible dependents. Teachers' Objections and Resps. to Lilly' First Set of Interrogs. (Teachers' Resps. to Interrogs., First Set") at No. 1; Dep. Tr. of Arthur B. Pepper on behalf of Plaintiff Teachers, Jan. 15, 2008 ("Teachers Dep."), at 7. Teachers offers various health products to its participants, including a prescription drug benefit.

An annual $100,000 maximum on prescription drug benefits is imposed per family per calendar year. UFT Welfare **Fund** Health and Welfare Benefits for Employees and Their Families 2007 Edition, 35, 50-51. The UFT **Fund** generally does not pay for medications for eligible persons in rest homes, nursing homes, sanitaria, extended-care facilities, and like entities unless pre-authorization is applied for and granted. *Id.* at 50.

It is Teachers' policy not to pay for any medications prescribed for off-label uses. Teachers' Resps. to Interrogs., First Set at No. 27; Teachers Dep. 42. It is the responsibility of Teacher's PBM to ensure that only prescriptions for covered medications are paid for by the UFT **Fund**. The UFT **Fund** relies on its PBM for such enforcement and monitoring.

Teachers reimburses eligible Zyprexa prescriptions for its covered members, Teachers' Resps. to Interrogs., First Set at No. 7; the formulary used by its PBM actually places Zyprexa in a preferred status. Teachers Dep. 71; 2007 Express Scripts National Preferred Formulary for UFT Welfare **Fund**. Like SB A, Teachers did not pay for any Zyprexa prescriptions from July 2001 until June 2005 for non-Medicare members because of the New York City program covering psychotropics. *Id.* at 37; Teachers Dep. 79. Teachers continues to pay for Zyprexa.

Teachers alleges that it has suffered economic harm as a result of Lilly's falseand misleading statements about the safety and efficacy of Zyprexa. It claims that every reimbursed Zyprexa prescription was procured by Lilly's fraudulent conduct and has identified these prescriptions by producing claims information about cost, dose, and date in discovery.

f. DC 37

Based in New York, plaintiff ASFCME District Council 37 Health and Security **Fund** ("DC 37") provides health benefits to member employees of the City of New York and their dependants. DC 37's Objections and Resps. to Lilly's First Set of Interrogs. ("DC 37's Resps. to Interrogs., First Set") at No. 1; Dep. Tr. of Willie Chang on behalf of Plaintiff DC 37, Jan. 16 & Jan. 23, 2008 ("DC 37 Dep.") at 24-25.

***16** DC 37 offers various health products to its participants, including a prescription drug benefit. Imposed is an annual $100,000 cap on prescription drug benefits. DC 37 Dep. 241. DC 37 does not pay for medicines administered to patients in rest homes, hospitals or other in-patient facilities. *Id.* at 242-43.

DC 37 does not independently seek to impose restrictions on particular drugs or classes of drugs, but adopts its PBM's recommendations. *Id.* at 158, 237. It has required prior authorization for other medications, including those used to treat schizophrenia, upon the advice of its PBM. *Id.* at 158-59, 235-37. It is DC 37's policy not to pay for any medications prescribed for off-label uses. DC 37's Resps. to Interrogs., First Set at No. 37; DC 27 Dep. 97, 147.

For covered participants, DC 37 reimburses eligible Zyprexa prescriptions. DC 37's Resps. to Interrogs., First Set at No. 1. From July 2001 until June 2005, DC 37 did not pay for psychotropics for its non-Medicare members because the City of New York program covered those during that time, *id.;* DC 37 Dep. 136, although it did cover Zyprexa prescriptions for Medicare-eligible retirees during that period. DC 37 has not imposed or sought any restrictions (including prior authorizations, step therapy, or higher co-pays) or modifications to its formulary for Zyprexa. DC 37 Dep. 157-59, 237-38. It continues to pay for Zyprexa. DC 37's Resps. to Interrogs., First Set at No. 7; DC 37 Dep. 177.

DC 37 alleges that it has suffered economic harm as a result of Lilly's false and misleading statements about the safety and efficacy of Zyprexa. The **Fund** claims that every Zyprexa prescription which it has reimbursed was procured by Lilly's alleged fraudulent conduct. It has identified these prescriptions by producing claims data in discovery, including information such as cost, dose and date.

2. Individual Plaintiffs

a. Michael Pronto

Plaintiff Michael Pronto, age 31, is a resident of Brentwood, New York. In April 2003, he became "sad and depressed" after a romantic setback. He sought counseling, and was referred to a nurse practitioner, Florence Wissert. Dep. Tr. of Florence Wissert, Mar. 12, 2007, at 27:3-9 ("Wissert Dep.").

i. Use of Zyprexa

Pronto was first prescribed Zyprexa on April 28, 2003 through Nurse Wissert. *See* Pronto Dep. Ex. 4 at 5 (Bates No. ProntoM-HopeHouse-0005). He continued to receive prescriptions for Zyprexa from April 2003 through August 2003 and from April 2004 through the fall of 2006, at which time he stopped taking the medication. Dep. Tr. of Scott Sussman, N.P. at 79:24-80:15, April 23, 2007 ("Sussman Dep.").

Whether Pronto has bipolar disease is disputed. Nurse Wissert had no independent recollection of Pronto and her testimony was based solely on notes in his chart. Wissert Dep. at 93:18-22. Medical records indicate that she used a screening tool, Lilly's one-page "Mood Disorder Questionnaire" ("MDQ"), to find that Pronto had bipolar disease, *id.* at 29:20-30:9, but the MDQ is not intended as a diagnostic tool. *See* Part XVII. B.1. a, *infra.* Nurse Wissert also noted he had a history of alcohol abuse. Plaintiffs note that there is no evidence she performed a differential diagnosis, *see* Pronto Dep. Ex. 4 at 10 (ProntoM-HopeHouse 0001-0010), or used the criteria of the American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, 4th ed., Washington DC, American Psychiatric Press Inc., 2000 ("DSM-IV-TR"). Neither did she utilize the Young Mania Rating Scale, which Lilly uses to evaluate patient improvement and efficacy of Zyprexa in treating Bipolar I., *see* ZY205869167-ZY205869171, or the Axis V GAF. Sussman Dep. 79:24-80:15. *See generally* Pronto Dep. Ex. 4 (ProntoM_HopeHouse 0001-0020); Sussman Dep. Ex. 4 (SussmanS(CarlsonJ)-000001-000102).

***17** Pronto was not treated by Nurse Wissert after August 8, 2003. Pronto Dep. Ex. 4 at 9 (Bates No. ProntoM-HopeHouse-0009). He did not receive medical care from anyone between that date and March 31, 2004, during which time it appears that he did not take Zyprexa. *Id.* Beginning March 31, 2004, Pronto was seen at the office of Dr. James Carlson. Sussman Dep. 38:11-21. Although Pronto received some care from Dr. Carlson, he was primarily seen by Scott Sussman ("Sussman"), a nurse practitioner. *Id.* From April

26, 2004 through October 23, 2006, Pronto was prescribed Zyprexa through Dr. Carlson's office. *Id.* at 50; Pronto Med. Rec. 6, 14-15.

When Nurse Sussman began treating Pronto on March 31, 2004, he prescribed Prozac for what he diagnosed as insomnia, depression, and anxiety. Pronto Dep. Ex. 5A at 1 (ProntoM_CarlsonJ_0123-PC). At Pronto's next visit, on April 26, 2004, Sussman continued Prozac and added Ambien for insomnia. Pronto Dep. Ex. 5 at 1 (ProntoM_CarlsonJ_0121-PC). Nurse Sussman twice noted bipolar in Pronto's chart as a possible condition, but never attempted to determine whether Pronto actually had bipolar disorder. Sussman advised Pronto to see a psychiatrist, Sussman Dep. 52-53, 55, but he could not afford to do so. Dep. Tr. of Michael Pronto, March 2-3, 2007, at 127:2-128:2 ("Pronto Dep.").

Pronto's diagnoses changed over the course of his treatment with Nurse Sussman and Dr. Carlson. Pronto Dep. Ex. 5 at 1 (ProntoM_CarisonJ_0001-0123-PC). From December 17, 2004 onward, the focus of his treatment to a back and neck injury and its associated pain, Sussman Dep. 129:24-130:16, although Sussman noted Pronto's anxiety and pan ic disorder in his medical records that day. *See* Sussman Dep. Ex. 4.

In March 2006, Pronto advised Nurse Sussman that he had become aware of the Zyprexa litigation and wanted to have his blood sugar tested. Sussman Dep. 70-72. On September 25, 2006, he told a staff member in Dr. Carlson's office that he had been off Zyprexa for three months but wanted to resume treatment. *Id.* at 71-73, 146-47. On October 13, 2006, Pronto applied to Lilly's prescription drug program for free Zyprexa and received several months' supply. Pronto Dep. 149-52; Pronto Med. Rec. 12-13. It is unclear when Pronto actually last ingested Zyprexa.

ii. Payment for Zyprexa

During most of the relevant period, Pronto was insured through UFCW Local 1500, which provided a pharmacy benefit. The cost of his Zyprexa prescriptions was largely covered by insurance, except for a flat $25 co-payment per prescription. Pronto Dep. 49, 54. The total amount Pronto spent on Zyprexa is approximately $500.00. *Id* . at 19. When he lost his insurance in June 2006, *id.* at 51-52, he was able to obtain Zyprexa free from his health care providers or directly from Lilly. *Id.* at 56, 149-52; Pronto Med. Rec. 12-13.

iii. Effects of Zyprexa

Pronto claims he developed hypertension and high cholesterol and triglycerides as a result of Zyprexa. When he began the medication on April 28, 2003, Pronto weighed approximately 200 pounds. Wissert Dep. at 33:22-34:7. In the first two or three months, he reportedly experienced a rapid weight gain of approximately forty to sixty pounds, Pronto Dep. 14:4-20, 62:6-63:1, complaining about it at his September 13, 2004 visit with Nurse Sussman. Sussman Dep. Ex. 4 (SussmanS(CarlsonJ)-000032). After discontinuing Zyprexa in the fall of 2006, his weight dropped to 226 pounds by March 2, 2007. Pronto Dep. 14:19-20.

***18** Pronto's baseline laboratory values were not recorded when he started taking Zyprexa. In April 2004, his blood pressure was moderately hypertensive. *Id.* (SussmanS(CarlsonJ)-000026). A month later, blood glucose levels, cholesterol, LDL, and triglycerides were all normal. *Id.* (SussmanS(CarlsonJ)-000083). In January 2005, Nurse Sussman diagnosed him as having hypertensive heart disease, unspecified. *Id.* (SussmanS(CarlsonJ)-000018). By April 2006, Pronto's glucose level was elevated and his triglyceride levels, LDL, and cholesterol were very high. *Id.* (SussmanS(CarlsonJ)-000080).

Lilly contends that the evidence shows that Zyprexa was effective for Pronto, highlighting his positive self-reporting noted in his medical charts. *See* Pronto Med. Rec. at 1-3, 7, 8; Wissert Dep. at 51-52, 63; Sussman Dep. 65. Nurse Sussman continued to prescribe Zyprexa in April 2006 because "it was working for" Pronto. Sussman Dep. 76.

Plaintiffs allege, in contrast, that there is no evidence that Zyprexa was ever effective for Pronto. While Pronto did report he was "feeling better with his current medication," plaintiffs note that such self-reporting is often unreliable; moreover, it is difficult to determine what medication he was on at the time of these comments and whether he was referring to his pain medication. *Id.* at 131:7-13.

While this individual's case is thin, there is enough to go to a jury. The claim of overpayment, if the price charged was too high, could be accepted by a reasonable juror.

iv. Related Cases

To seek redress for his alleged physical injuries, Pronto has sued Lilly in a separate action. That case is in the process of **settlement**. *See Pronto v. Eli Lilly & Co.,* Docket No. 06-

CV-6834 (E.D.N.Y.) (administratively closed, pending final consummation of **settlement**). The general releases being used in these personal injury cases arguably prevent a case such as the instant one from being brought by this plaintiff.

> In an affirmation filed on June 23, 2008, Pronto's counsel states that the plaintiff has not settled any of his claims against Lilly and [has not] executed any release whatsoever of any claims against Lilly. Moreover, as described below, during discovery, defendant Eli Lilly and Company ("Lilly") agreed to treat Mr. Vannello's claims for economic injury, based on his purchases of Zyprexa, separately from his claims for physical injury based on his ingestion of Zyprexa. Based on this separation of the two types of claims, it is my understanding that, even if Mr. [Pronto] were to settle his physical injury claims, he would not release, and would not be asked to release, his purchase claims.

Affirmation of Douglas R. Plymale, June 23, 2008.

This portion of plaintiff's counsel's statement is contradicted by Lilly's response of June 23, 2008; Lilly indicates that Pronto is in the process of settling his case as part of a global **settlement**, with a "Master **Settlement** Agreement on behalf of ... Zyprexa clients, including plaintiffs" Michael Pronto and Michael Vannello. Def. Brief, June 23, 2008, at 2. Their cases were administratively closed by order of the court on March 18, 2008, with no objection or motion to set aside or modify the order. *Id.*

***19** The release required by the Master **Settlement** Agreement covering the Pronto and Vannello claims is broad enough to cover overcharge claims for Zyprexa. It reads:

> Claimant KNOWINGLY AND VOLUNTARILY RELEASES, ACQUITS, AND FOREVER DISCHARGES Lilly from any and all claims and/or causes of action of whatever kind or character, which have accrued or may accrue, whether known or unknown, and includes, but is not limited to, those claims which Claimant ever had, or now has, or hereafter can, shall or may have in the future against Lilly arising out of, relating to, resulting from, or in any way connected with Zyprexa, including those claims and damages of which Claimant is not aware and/or that Claimant has not yet anticipated. Claimant expressly waives the provisions of any applicable law protecting against the release of unknown or unanticipated claims.

Id. at 3. The likelihood that the **settlement** will ultimately be fully executed, making the release operative, is high; it would likely result in dismissal of plaintiffs' individual economic claims based on the general exhaustive terms of the release.

If the tentative global agreement already reached falls through, there is a conflict of interest. Plaintiff may "sell out" the proposed economic class to achieve a higher award in his personal injury claim. He cannot represent a class or subclass seeking compensation for overpayment without appearing to violate fiduciary responsibilities to the class.

In any event, the individual plaintiffs who are settling, or have settled, their personal injury claims would have to be excluded from the class, as plaintiffs' counsel practically concedes:

> Because at least some plaintiffs who have settled personal injury claims may have released their over-payment claims, however, Plaintiffs provide an adjusted definition for the Consumer Class to reflect the exclusion from the class of individuals who have released their claims. Plaintiffs had previously acknowledged that such persons would be excluded from the class; the adjusted definition merely formalizes that position and

> incorporates it into the class definition for ease of application.

Purchase Claim Pfs.'s Submission Regarding Consumer Class Members' Releases, June 23, 2008, at 2. Such a possible large carve-out of some 30,000 plaintiffs would unduly complicate administration of the litigation.

It may be that some of the third-party payors in the class will seek reimbursement from their insureds based on the personal injury recoveries. This possibility is of such minor significance as to warrant being ignored at this stage of the litigation.

b. Michael Vannello

Plaintiff Michael Vannello, aged 54, is a resident of Ridgewood, Queens, New York. In 1995, he developed pan ic attacks and fear associated with riding the subway in New York City. He left his longstanding messenger job at First Manhattan Company, Dep. Tr. of Michael Vannello, Mar. 1, 2007 ("Vannello Dep.") at 36:6-23, 80:25-81:9, and applied for and was granted Social Security Disability Insurance. *See* Dep. Tr. of Ronald Vannello, April 30, 2007 ("Ron Vannello Dep.") at 23:23-24:5. His brother, Ronald Vannello, is his representative payee for his monthly disability payments. *Id.* at 8:23-9:9.

i. Use of Zyprexa

***20** Vannello was treated with multiple medications during the 1990s, including antidepressants and anti-anxiety medication. He was initially prescribed Zyprexa by his treating psychiatrist in February 2000, and took Zyprexa almost continuously to October 2002. He did not take Zyprexa for schizophrenia or bipolar disorder.

In March 1995, Laszlo Papp, M.D., a psychiatrist and professor at Columbia University, diagnosed Vannello as having pan ic disorder and anxiety disorder. Dep. Tr. of Dr. Lazlo Papp, Apr. 24, 2007 ("Papp Dep.") at 11, 14, 16. Dr. Papp first prescribed Zyprexa on February 22, 2000 at a 5 mg level, after Vannello had complained that he was nervous and worried withmood swings and angry outbursts, and had trouble sleeping. *Id.* at 86; Select Medical Records of Michael Vannello ("Vannello Med. Rec.") at 16-17.

In March 2000, Dr. Papp referred Vannello to an intensive outpatient treatment program at Zucker Hillside Hospital, where he continued to be prescribed Zyprexa. *Id.* at 22-30. All of Vannello's Zyprexa prescriptions were for off-label uses while he was being treated at Hillside. *See* Dep. Tr. of Dr. Michael Kahan, Apr. 11, 2007, at 146:18-147:20 ("Kahan Dep."). On June 30, 2000, Dr. Michael Kahan, a psychiatrist and head of the hospital's outpatient anxiety disorder program, diagnosed Vannello with a pan ic disorder with agoraphobia and continued him on Zyprexa at 5 mg daily, along with Xanax 1 mg four times a day.

While at Hillside, Vannello attended group therapy, received individual counseling from a clinical social worker, and was prescribed medication. Kahan Dep. Ex. 2. He received a variety of medications in addition to Zyprexa. *Id.* Dr. Kahan discontinued Vannello's Zyprexa use for three months starting in January 2001, but in March he began it again at an increased dosage of 7.5 mg. *Id.* at 41-42. On June 29, 2001, Dr. Kahan further increased the dosage to 10 mg, raising it to 15 mg on August 14, 2001. *Id.* at 41-42. On September 19, 2001, Dr. Kahan again increased the dosage to 20 mg because Vannello's anxiety had been increasing. *Id.* at 41-42. Vannello took Zyprexa for general anxiety disorder and pan ic disorder with agoraphobia until September 27, 2002. Ron Vannello Dep. at 69; Vannello Med. Rec. 39-40, 53; Kahan Dep. 30-31, 44, 108.

ii. Payment for Zyprexa

Vannello paid approximately $5,932.00 in cash for his Zyprexa prescriptions. *See* Mem. Supp. of Pfs.' Mot. for Class Cert. 54; Michael Vannello Eckerd Drug Prescription Records. He also received free samples of Zyprexa from his doctors. Kahan Dep. 106; Vannello Dep. 55.

iii. Effects of Zyprexa

Before he began taking Zyprexa in 2000, Vannello had a history of obesity and diabetes. Since 1993, his doctors have recommended a weight reduction diet. Vannello Med. Rec. 5, 7-8. Vannello was first treated for hypertension in March 1991, *id.* at 1, for adult onset diabetes mellitus on March 21, 1995, Dep. Tr. of Dr. Lewis Bass, M.D., May 14, 2007 ("Bass Dep.") at 68-69; Vannello Med. Rec. at 11, and for high cholesterol in November 1996. *Id.* at 19.

***21** At the time of his initial diabetes diagnosis in 1995, Mr. Vannello weighed 293 pounds. *See* Kahan Dep. Ex. 10 at 57; Bass Dep. at 69:1-15. He was able to control his weight and diabetes without medication, Bass Dep. at 68:23-69:9, losing 90 pounds over the next two years. *See* Kahan Dep. Ex. 10 at

45. After Vannello's weight dropped, he had no symptoms of diabetes. *See id.* at 45.

When Vannello began Zyprexa in February 2000, he weighed 240 pounds, *see* Papp. Dep. Ex. 3 at 5, and he was not taking any diabetes medications. Bass Dep. 68:23-69:9. By March 21, 2000, Vannello had gained 16 pounds. *See* Papp. Dep. Ex. 3 at 6. Over the next two years while on Zyprexa, his weight increased dramatically, reaching 314 pounds by August 2002. *See* Kahan Dep. Ex. 10 at 36. Vannello's Zyprexa treatment was discontinued in October 2002, around the time he reached his peak weight. Bass Dep. Ex. 3.

Vannello was again diagnosed with diabetes mellitus in May 2003. Bass Dep. 54. His fasting blood glucose levels peaked at 388 mg/dl around this time. *See* Kahan Dep. Ex. 10 at 32. Similarly, Vannello's triglycerides were measured at 404 in early 2004, *see id.* at 21; he had no previous record of triglycerides or total cholesterol elevation prior to this time. It took almost three years to drop to his pre-Zyprexa weight of 242 pounds. *Id.* He currently takes Metformin to treat his diabetes. Vannello Dep. 10, 167.

Vannello underwent a number of echocardiograms before, during, and after his Zyprexa treatment. A pre-Zyprexa echocardiogram on November 9, 1999, showed evidence of left atrial dilation and left ventricular hypertrophy. *See* Bass Dep. Ex. 3. A post-Zyprexa echocardiogram on May 12, 2001, revealed a dilated left ventricle in addition to left atrial dilation and left ventricular hypertrophy. Bass Dep. Ex. 4. EKGs in December 3, 2002, *see* Bass Dep. 43, and 2006 suggest continuing ischemic heart disease. Bass Dep. Ex. 6. Vannello's obesity, combined with pre-existing hypertension, may have caused excess strain on the heart muscle, possibly resulting in permanent damage. Bass Dep. 100:23-102:3; Decl. of William Wirshing, M.D. ("Wirshing Decl."), Jan. 31, 2007, at 6-7, 16, 48-49; Expert Witness Rep. & Decl. of David Allison, Ph.D., Feb. 12, 2007, at 10; 23-24 ("Allison Rep.").

Lilly maintains that the evidence shows that Zyprexa was effective for Mr. Vannello, citing positive self-reports noted in his medical charts, such as feeling less irritable, under better control, less anxious, improved mood, and getting out more. Vannello Med. Rec. 17, 31-33, 37-38, 56; Vannello Dep. 99-100; Papp Dep. 47-48. Vannello's symptoms worsened when Dr. Kahan tried to take him off Zyprexa in January 2001, and that he reported feeling better after restarting Zyprexa in March 2001. Kahan Dep. 31-32.

Plaintiffs note there is no objective medical evidence-as opposed to Vannello's own self-reports-to indicate that Zyprexa was efficacious in treating him. *See*Fed.R.Evid. 702. During the course of his treatment at Hillside, his diagnoses remained consistent. Kahan Dep. Ex. 2 at 55, 71, 90, 130-31, 166, 173, 187, 190, 199, 205, 214, 251, 288, 299. At the time of Vannello's discharge in November 2002, his diagnoses were still pan ic disorder with agoraphobia and general anxiety disorder. *Id.* at 210-12. None of the treating doctors prescribing Zyprexa used the Young Mania Ratings Scale ("Y-MRS"). On Axis V of the DSM-IV-TR, another standard measure of mental/emotional function, Vannello showed no improvement; his Global Assessment of Functioning Scale ("GAF") was 50/60 when admitted on March 20, 2000 to Hillside Hospital. Kahan Dep. at 12 (Ex. 2) (Bates No. VannelloM_ZuckerHH_0299_PC).

iv. Related Cases

***22** Vannello has filed a separate personal injury action against Lilly claiming a diabetes injury as a result of Zyprexa ingestion. *See Vannello v. Eli Lilly & Co.,* Docket No. 06-CV-6839 (E.D.N.Y .) (administratively closed, pending final consummation of **settlement**). For the same reason as in Mr. Pronto's case, *see* Part II.A.2.a.iv, *supra,* Mr. Vannello cannot represent the proposed class or subclass.

B. Prior Submissions

Multiple prior submissions define the facts of the dispute. Except for the plaintiffs' original individual complaints, all submissions are docketed under Docket Number 05-cv-4115 (E.D.N.Y). *See* First Am. Class Action Compl. & Demand for Jury Trial, Nov. 7, 2005, Docket Entry No. 14 (redacted); Def.'s Answer, Apr. 26, 2007, Docket Entry No. 107; Def.'s Mot. to Dismiss First Am. Compl., Jan. 12, 2006, Docket Entry No. 22; Pfs.' Mem. of Law in Opp. to Def .'s Mot. to Dismiss, Feb. 23, 2006, Docket Entry No. 27; Def.'s Reply Mem. of Law in Further Support of Mot. to Dismiss, Mar. 24, 2006, Docket Entry No. 31; Def.'s Mot. for Summary J., May 29, 2007, Docket Entry No. 109; Pfs.' Mem. of Law in Opposition to Def.'s Mot. for Summary J., June 12, 2007, Docket Entry No. 113; Def.'s Reply Mem. in Support of Def.'s Mot. for Summary J., June 18, 2007, Docket Entry No. 121; Defendant's Local Rule 56.1 Statement of Undisputed Facts, Def.'s Local R. 56.1 Statement of Undisputed Facts, May 29, 2007, Docket Entry No. 109; and Pfs.' SJ Fact Proffer.

C. Dispositive Motions

1. Motion to Dismiss

On January 12, 2006, Lilly filed a Rule 12 motion to dismiss plaintiffs' Amended Complaint on the grounds that plaintiffs could not satisfy the causation element of their claims, that they lack standing, and that they suffered no direct injury. Def.'s Mot. to Dismiss First Am. Compl.; Def.'s Reply Mem. of Law in Further Support of Mot. to Dismiss. In response, plaintiffs assured the court that they would offer evidence that would demonstrate causation and reliance, Apr. 21, 2006 Hr'g Tr. on Def.'s Mot. to Dismiss 27, Docket Entry No. 36, and alleged as follows:

> [I]t will be proven as fact not presumption, that every influential sector of the mental health community was subjected to Defendant's misrepresentations and omissions, and that the broad-based fraudulent conduct had real-world, significant effect that was intended by the program.

Pfs.' Mem. of Law in Opp. to Def.'s Mot. to Dismiss 30.

Lilly's Motion to Dismiss was denied on April 21, 2006. *See* Minute Entry, Apr. 21, 2006, Docket Entry No. 36.

2. Summary Judgment

The court preferred instead to rule on a summary judgment motion. It directed the parties to work with the Special Master to establish a limited discovery plan. Apr. 21, 2006 Hr'g Tr. 43-49; *see* Am. Case Mgmt. Order No. 1, June 19, 2006, Docket Entry No. 39. Discovery was confined to the grounds for summary judgment. *Id.* at 3-6; Apr. 21, 2006 Hr'g Tr. 43-49. The discovery undertaken by both parties is discussed at length in Lilly's May 29, 2007 Memorandum of Law in Support of its Motion for Summary Judgment. Plaintiffs were given access to all of the discovery taken in the personal injury litigation, which comprised over fifteen million pages of records and included the depositions of fifty-eight current and former Lilly employees.

***23** Lilly conducted Rule 30(b)(6) depositions of the four original named payor plaintiffs UFCW, Mid-West, Local 28 and SBA. It also undertook discovery regarding the two individual plaintiffs, deposing them, their family members, and prescribers. *See* Kahan Dep.; Papp. Dep. Lilly also obtained testimony from the four PBMs who provide pharmacy benefit advice to the named plaintiffs.

Both parties produced a number of expert witness reports and deposed the experts. Plaintiffs submitted expert reports by Meredith Rosenthal, Ph.D.; Jeffrey E. Harris, M.D., Ph.D.; John Abramson, M.D.; Steven G. Klotz, M.D.; Lon Schneider, M.D., and Robert Rosenheck, M.D. *See* Pfs.' Disclosure of Expert Testimony Pursuant to Fed.R.Civ.P. 26(a)(2), Feb. 27, 2007, Docket Entry No. 87 (designating plaintiffs' experts). Two plaintiffs' experts, Myron Winkelman, R.Ph., and Terry D. Leach, Pharm.D, proposed to testify about how PBMs function from economic and clinical perspectives. *Id.* Plaintiffs also relied on the following experts, previously disclosed in the personal injury litigation: David Goff, Jr., M.D.; David B. Allison, Ph.D.; Frederick Brancati, M.D., MHS; William Wirshing, M.D.; John L. Guerigian, M.D.; and Laura Plunkett, Ph.D., D.A.B.T. *Id; see* Part XVII, *infra.*

In support of its summary judgment motion, Lilly relied on five experts: Ernest R. Berndt, Ph.D.; Iain M. Cockburn, Ph.D.; David F. Feigal, Jr., M.D.; David Kahn, M.D.; and Jeffrey S. McCombs, Ph.D.

With a record developed in May of 2007, Lilly filed a motion for summary judgment on grounds similar to those in its motion to dismiss. Plaintiffs also filed a summary judgment motion. *See* Part II.C.2, *infra.* On June 28, 2007, the court denied both summary judgment motions and all of the various *Dauber* t challenges to expert testimony. *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, 579 (E.D.N.Y.2007) ("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.").

Recognizing that the law underlying its decision was "in a state of flux and not free from doubt," the court declined to certify its summary judgment order for immediate interlocutory appeal pursuant to 28 U.S.C. § 1292(b), but noted that it would do so after deciding whether the case should proceed as a class action. *Id.* at 580-81.

D. Class Certification

On August 3, 2007, plaintiffs filed a motion for class certification. They proposed two subclasses: a nationwide third-party payor class of institutions that have paid for the cost of Zyprexa prescriptions, and a nationwide patient class of individuals who have paid out-of-pocket for some or all of the cost of Zyprexa prescriptions. Pfs.' Class Cert. Br. 58-59.

1. Briefing

Both parties filed extensive briefing. *See id.;* Class Plaintiffs' Proposed Trial and Apportionment Plan and Statement of State Law ("Pfs.' Trial Plan"), Dec. 4, 2007, Docket Entry No. 144; Defendant's Memorandum of Law in Opposition to Plaintiffs' Motion for Class Certification ("Def.'s Mem. of Law in Opp. to Class Cert."), Feb. 22, 2008, Docket Entry No. 150 (filed under seal); Defendant's Statement of Facts in Support of Defendant's Opposition to Plaintiff's Motion for Class Certification ("Def.'s Fact Proffer"), Def.'s Local R. 56.1 Statement of Undisputed Facts, Feb. 22, 2008, Docket Entry No. 150; Plaintiffs' Reply Memorandum of Law in Further Support of Purchase Claim Plaintiffs' Motion for Class Certification (Pfs.' Reply Mem. of Law in Further Support of Purchase Claim Pfs.' Mot. for Class Cert.), Mar. 21, 2008; Plaintiffs' Response to Defendant's Local Rule 56.1 Statement of Undisputed Facts (Pfs.' Response to Def.'s Fact Proffer"), Mar. 21, 2008, Docket Entry No. 165; Plaintiffs' Post-Hearing Memorandum on Class Certification, ("Pfs.' Post-Hr'g Mem. on Class Cert."), Apr. 9, 2008, Docket Entry No. 176; and Defendant's Post-Hearing Memorandum Opposing Class Certification, ("Def.'s Post-Hr'g Mem. Opp. Class Cert."), Apr. 9, 2008, Docket Entry No. 177.

2. Discovery

***24** In filing their motion for class certification shortly after summary judgment was denied, plaintiffs indicated they did not believe additional discovery on class certification was necessary. *See* Pfs.' Class Cert. Br., Aug. 3, 2007. In response, Lilly moved for additional discovery on class certification. At a hearing on Lilly's motion on September 21, 2007, the court agreed that the record contained little evidence regarding differences in the ways that third-party payors in the putative class develop and maintain their formularies:

> What concerns me is the differences in the nature of these insurers and now how they went about doing their research, putting their formularies together, using experts, what their insurance plans called for in connection with reimbursement, whether they were reimbursing fully or whether there was also a requirement that the insured paid a portion.

Sept. 21, 2007 Hr'g Tr. 18-19. More information in these areas was necessary to determine whether the class was sufficiently homogenous. *Id.* at 29.

On November 30, 2007, a conference was held to discuss the scope of additional class certification discovery, including the depositions of the named payors' insureds' prescribers. *See* Nov. 30, 2007 Hr'g Tr. While it was willing to permit the limited class certification discovery previously ordered by the Special Master to go forward as contemplated, *id.* at 35, the court also suggested that the information sought by the plaintiffs was not necessary for class certification. *Id.* at 23 ("So, I'm very skeptical about whether we need [additional call note and database production]"). Instead, the court recommended that the parties "just close [discovery] out at this stage and go forward with certification based on the enormous amount of papers and other material that we have in this case and in other cases." *Id.* at 35. Both parties agreed; the only further discovery undertaken was Lilly's depositions of newly identified class representatives and one of UFCW's PBMs. *Id.* at 37-38. Depositions previously taken in this and other matters were to be used to present the class certification issue. *Id.* at 37 (reserving their right to challenge the depositions' admissibility at a trial). Case Management Order No. 9 reflected this agreement and was entered on December 21, 2007. *See* CMO 9, Nov. 21, 2007, Docket Entry No. 146.

3. Expert Reports

Preparing for an evidentiary hearing on class certification, both parties relied on the same experts presented to the court on the issue of summary judgment. *See* Part XVII, *infra.* Defendants also presented a new expert, Dr. Eugene Kolassa. Additional expert reports were submitted on the issue of class certification.

All *Daubert* motions as to proposed expert witnesses, whether made as part of the class certification motion or in earlier proceedings, have been denied.

> Each of the challenged experts meets *Daubert* requirements. Each is a distinguished scientist whose expertise probably will be helpful in deciding relevant scientific and economic issues. Attacks on them ... 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.

***25** *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

Four days before the hearing, on March 24, 2008, Lilly filed a Motion to Strike as untimely and prejudicial the Supplemental Declaration of Robert Rosenheck, M.D., the Supplemental Declaration of William Wirshing, M.D. and the Second Supplemental Declaration of Meredith Rosenthal, Ph.D. *See* Def's Mot. to Strike, Mar. 24, 2008, Docket Entry Nos. 160, 161. At the March 29, 2008 hearing, defendant's motion was denied. *See* Transcript of Evidentiary Proceedings on Class Certification, March 28, 2008 through April 2, 2008 ("Tr."); *see also* Pfs.' Mot. to Strike Decl. of Alan G. White, Ph.D., June 12, 2007, Docket Entry Nos. 114, 115.

4. Evidentiary Hearing

On March 28, 29, 31 and April 1 and 2, 2008 an extensive evidentiary hearing was conducted to comply with the certification standards set by the Court of Appeals for the Second Circuit. *See* *In re Initial Public Offering Securities Litigation ("In re IPO")*, 471 F.3d 24, 41 (2d Cir.2006) (noting that even when there is overlap between a Rule 23 requirement and a merits issue, "the district judge must receive enough evidence, by affidavits, documents, or testimony, to be satisfied that each Rule 23 requirement has been met."). Extensive oral and written expert testimony was considered. More than 1,000 exhibits, the majority of which had been previously submitted, were admitted.

On April 2, 2008, the court granted leave to the parties to file post-hearing memoranda. *See* Pfs.' Post-Hr'g Mem. on Class Cert.; Def's Post-Hr'g Mem. Opp. Class Cert. Further argument was heard on April 10, 2008. Additional submissions were requested and received. *See* Pfs.' Corr. Supp. Post-Hr'g Mem. on Class Cert.; Affirm. of Andrea Bierstein in Support of Purchase Claim Pfs.' Supp. Post-Hr'g Mem. on Class Cert (undocketed); Affirm. of Thomas Sobol in Connection with Damages Calculations, Apr. 24, 2008, Docket Entry No. 180; Def.'s Supp. Post-Hr'g Mem. of Law, Apr. 24, 2008, Docket Entry No. 181. Supplemental authority letters were submitted. *See* Letter from Lauren G. Barnes, May 20, 2008, Docket Entry No. 189 (noting *New England Carpenters Health Benefits* ***Fund*** *v. First Databank, Inc.*, 248 F.R.D. 363 (D.Mass.2008); Lilly Letter, May 22, 2008, Docket Entry No. 190 (same); Pfs.' Notice of Supp. Authority, June 9, 2008, Docket Entry No. 191 (noting *Bridge v. Phoenix Bond & Indemnity Co.*, No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008)); Def.'s Mem. in Opp. to Notice of Supp. Authority, June 10, 2008, Docket Entry No. 192; Pfs.' Reply in Support of Notice of Supp. Authority, June 11, 2008, Docket Entry No. 193. Further information about the status of the two individual plaintiffs' personal injury lawsuits against Lilly and their proposed **settlement** releases was requested and received. *See* Purchase Claim Pfs.' Submission Regarding Consumer Class Members' Releases, June 23, 2008, Docket Entry No. 196; Def.'s Response Regarding Information on **Settlement** of Sub-Class Representatives' Claims, June 23, 2008, Docket Entry No. 198 (sealed); Pfs.' Reply Submission Regarding Consumer Class Members' Releases, June 25, 2008, Docket Entry No. 199; Pfs.' Reply Affirmation of Kevin L. Oufnac, June 25, 2008, Docket Entry No. 200; Affirmation of Dr. Douglas R. Plymale, June 19, 2008, Docket Entry No. 197. Additional briefing has been requested on the combined impact of the Second Circuit Court of Appeals decision in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir.2008), and the Supreme Court's recent opinion in *Bridge v. Phoenix Bond & Indemnity Co.*, No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008), on the pending motion for class certification. *See* Order, June 16, 2008, Docket Entry No. 195.

***26** The expert reports and testimony considered by the court and contested by the parties in the instant motion are individually discussed in Part XVII, *infra.* The following Parts III-XVI present the background information necessary to understand the context in which the motion for class certification lies.

III. Anti-Psychotic Medications

Lilly's prescription medicine Zyprexa, with a chemical name of olanzapine, is one of a class of medications known as "atypical" or "second generation" antipsychotics ("SGA") that treat schizophrenia and bipolar disease. Schizophrenia is a severe, debilitating mental illness that afflicts over one percent of the general population-2.5 million Americans-often beginning in late adolescence or early adulthood. *See* Robert Freedman, *Schizophrenia,* 349(18) New Eng. J. Med. 1738, 1738 (2003); Gary D. Tollefson & Cindy C. Taylor, *Olanzapine: Preclinical and Clinical Profiles of a Novel Antipsychotic Agent,* 6(4) CNS Drug Reviews 303, 304 (2000); U.S. Dep't of Health & Human Servs., Mental Health: A Report of the Surgeon General 273 (1999), http://www.mentalhealth.org/features/surgeongeneralreport/home.asp; DSM-IV-TR 308. One of the most complex and challenging of psychiatric disorders, schizophrenia is a heterogeneous syndrome of disorganized and bizarre thoughts, delusions, hallucinations, inappropriate affect and impaired psycho-social functioning. *See* DSM-IV-TR 298-302. The illness occurs when a patient suffers two or more of the following characteristic symptoms: (1) delusions, (2) hallucinations, (3) disorganized speech, (4) grossly disorganized or catatonic behavior, and (5) negative symptoms, *see id.,* or has bizarre delusions or hallucinations of voices commenting on the person's behavior or thoughts. Research has shown a variety of abnormalities in schizophrenic brain structure and function, *Pharmacotherapy: A Pathophysiologic Approach* (Joseph T. Dipiro et al., eds., 5th ed.2002) (hereinafter "Pharmacotherapy") at 1219; *see* DSM-IV-TR 299; causation is believed to be multi-factorial. Pharmacotherapy at 121; *see* DSM-IV-TR 305-06, 309-11.

Bipolar disorder is a serious, lifelong mental illness marked by dramatic shifts in mood, from abnormally elevated, expansive, or irritable moods to states of extreme sadness and hopelessness, often with periods of normal mood in between. Nat'l Inst. of Mental Health, Bipolar Disorder, *available at* http://www.nimh.nih.gov/publicat/bipolar.cfm (last visited June 30, 2008); *see* Decl. of Steven Klotz, M.D. 2, Feb. 22, 2007, Docket Entry No. 99 ("Klotz Decl."). Bipolar I, characterized by the occurrence of one of more manic episodes or mixed episodes, often with major depressive episodes, and Bipolar II, characterized by one or more major depressive episodes accompanied by at least one hypomanic episode, are separate disease states. *See* DSM-IV-TR 382-92. Because of its complexity, bipolar disease can be difficult to diagnose; between seven and ten years of mis-diagnoses and incorrect treatment is typical for bipolar patients. Klotz Decl. 6. "[U]ntreated bipolar disorder can be disastrous; 10 percent of sufferers commit suicide." Mary Carmichael, *Welcome to Max's World,* Newsweek, May 26, 2008.

***27** In the past five years there has been an extensive amount of research into diagnosing and recommending treatments for bipolar disorder, **funded** in part by pharmaceutical manufacturers. Klotz Decl. 3. There has been a corresponding growth of bipolar diagnoses-correct *and* incorrect-leading to an increase in patients and greater awareness of the disease, *id.;* many patients labeled "bipolar" are mentally ill but, upon detailed psychiatric exam, not bipolar. *Id.* at 4. An estimated 5.7 million American adults are affected by the disorder, and "at least 800,000 children in the United States have been diagnosed as bipolar, no doubt some of them wrongly. The disease is hard to pin down." *See* Carmichael, *supra.*

Both schizophrenia and bipolar disorder, like many mental illnesses, display considerable biological and symptomatic heterogeneity. *See* Decl. of Richard G. Frank, Ph.D. at ¶ 7, Jan. 8, 2008, Docket Entry No. 148 ("Frank Decl."). Often, patients with these disorders have other psychiatric and physical problems. *Id.* Because of the illnesses' heterogeneity, different people respond differently to different psychotropic drugs. Which drug will work best for a new patient is often unknown until it is tried on particular patients; thus clinical decision-making about psychotropic medications almost inevitably is based on "trial and error." *Id.* at 3-4 (citing H.A. Huskamp, *Managing Psychotropic Drug Costs: Will Formularies Work?,* Health Affairs 22(5): 84-96 (2003)). As a result, third-party payors prefer not to place strong restrictions on the use antipsychotic medications. *Id.* at 4.

A. First-Generation or "Typical" Anti-Psychotics ("FGAs")

Zyprexa is generally known as a "second generation antipsychotic" or "SGA" to differentiate it from older, first-generation antipsychotics ("FGAs"), which were the common drug therapy for schizophrenia until the 1990s. FGAs include chlorpromazine (Thorazine), fluphenzine (Proxilin), haloperidol (Haldol), molindone (Moban), thioridazine (Mellaril), loxapine (Loxitane), mesoridazine (Serentil), perphenazine (Trilafon), thiothixene (Navane), and trifluoperazine (Stelazine), some of which have been in use since the 1950s. Pharmacotherapy 1224. FGAs are sometimes referred to as "typical" antipsychotics and SGAs "atypical."

Although many different FGAs exist, they share similar levels of efficacy. They are, generally speaking, post-synaptic dopamine-receptor antagonists, i.e., they target dopamine receptors in the brain. *Id.* at 1220. A troubling side effect of typical antipsychotics is that the blockage of dopaminergic neurotransmission causes extrapyramidal syndromes ("EPS") such as Parkinsonian effects or tremors. *Id.* at 1223. Tardive Dyskinesia ("TD"), a long-lasting movement disorder, also frequently occurs with prolonged treatment. *Id.*

B. Second-Generation or "Atypical" Anti-Psychotics ("SGAs")

***28** Because of FGAs' potential for severe side effects and their limited efficacy, many pharmaceutical companies searched for new drugs that would be more effective and cause less movement disorder. By the 1980s, clozapine, the first SGA, was being investigated on that hypothesis. As it had an "atypical index" when measuring its effect on different parts of the brain, clozapine became known an "atypical" antipsychotic. 2007 Physicians Desk Reference at 2184-89. Since clozapine has different effects than FGAs on areas of the brain that control movement, it was hoped that it would cause less movement disorder than other antipsychotics. *Id.* While clozapine turned out to be effective, its toxic side effects, including agranulocytosis (dramatic loss of white blood cells), limited its use to about ten percent of persons with schizophrenia. *Id.;* Decl. of Meredith Rosenthal at 6, Feb. 27, 2007, Docket Entry No. 101 ("Rosenthal Decl."). Although clozapine was the first atypical antipsychotic, it tends to stand on its own between FGAs and SGAs. Clozapine was approved by the FDA in September 1989, *id.* at Decl. 5, and until 1993 it was the only SGA available in the United States, but due to its potential toxicity it had very little market share.

During the 1990s pharmaceutical companies, building on the "atypical" hypothesis, developed newer, second-generation antipsychotic drugs ("SGAs") attempting to capture the enhanced therapeutic effect of clozapine without its toxicity and, they hoped, without the side effects, such as EPS and TD, caused by traditional antipsychotics. "The introduction of atypical antipsychotic medications was trumpeted by the manufacturers of these pharmaceutical agents as a major advance in the treatment of schizophrenia with improved symptomatic control of the psychosis and a reduction in both tardive dyskinesia and extra pyramidal side effects." Wirshing Decl. 7.

In late 1993, risperidone became the first non-clozapine SGA to receive Food and Drug Administration ("FDA") approval. In early 1994, Janssen, a subsidiary of Johnson & Johnson, began marketing and selling risperidone under the brand name Risperdal. During the next two years, Janssen heavily marketed and promoted Risperdal for its approved indication, management of the manifestation of psychotic disorders, and, allegedly, for multiple non-approved purposes of the drug, including, for example, attention deficit-hyperactivity disorder, bipolar disorder, and aggression associated with late-onset dementia. By late 1996, Janssen had significant market share of United States antipsychotic drug use, and had demonstrated the sales potential of marketing SGAs for non-approved indications. When Zyprexa entered the market in 1996, Risperdal was seen as the primary competition. *See* Pfs.' Ex. 405 at ZY203452995.

The FDA first approved Zyprexa on September 30, 1996, for use in treating schizophrenia. FDA Sept. 30, 1996 Approval Letter. Thereafter, the FDA approved Zyprexa for maintenance treatment of schizophrenia, FDA Nov. 9, 2000 Approval Letter; for the short-term treatment of acute manic episodes associated with bipolar I disorder as monotherapy, FDA May 17, 2000 Approval Letter; in combination with lithium or valproate, FDA July 10, 2003 Approval Letter; and for maintenance in the treatment of bipolar disorder. FDA Jan. 14, 2004 Approval Letter.

***29** Multiple other second-generation antipsychotic drugs have been introduced since 1996. Atypical SGAs, in addition to clozapine (Clozaril), olanzapine (Zyprexa), and risperidone (Risperdal), now include quetiapine (Seroquel), aripiprazole (Abilify), and ziprasidone (Geodon). Pharmacotherapy 1224. Seroquel has been approved since 1998. Indicated for schizophrenia and acute manic or mixed episodes associated with bipolar disorder, Geodon entered the marketplace in March of 2001, Abilify in November 2002. Abilify is also approved for treatment of depression. Tr. 827.

SGAs now account for about ninety percent of all antipsychotics drugs prescribed for all psychiatric purposes, regardless of whether they were approved for those indications or not. *See* Jeffrey A. Lieberman, *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia,* 353 N. Eng. J. of Medicine 1209, 1210 (2005). While the two primary uses of second-generation antipsychotics remain the treatment of schizophrenia and bipolar disorder, *see* Frank Decl. at 3 (citing Agency of Health Research and Quality, Off Label Use of Atypical Antipsychotic

Drugs, *available at* http:// effe ctivehealthcare.ahrq.gov/ reports/topic.cfm?topic=8 & sid=34 & rType=10), SGAs are prescribed "off label" to treat symptoms related to agitation, anxiety, psychotic episodes, obsessive behavior, behaviors related to dementia, depression, obsessive compulsive disorder ("OCD"), Post Traumatic Stress Disorder ("PTSD"), personality disorders and Tourette's Syndrome. Although there is only mixed evidence about their efficacy for these purposes (as well as for their indications), *id.,* antipsychotics have become a booming business.

C. Rapid Growth of Pharmaceuticals and SGAs

The overall costs of prescription drugs have risen dramatically over the past decade. SGAs make up a large proportion of increased national spending on medication. In 2004, for instance, prescription drug expenditures in the United States were estimated at $188.5 billion, nearly five times the $40.3 billion the nation spent fourteen years earlier. Prescription Drug Trends, Kaiser Family Foundation (June 2006). "Sales of newer antipsychotics like Risperdal, Seroquel and Zyprexa totaled $13.1 billion in 2007, up from $4 billion in 2000." Laurie Tarkan, *Doctors Say Medication [Including Zyprexa] Is Overused in Dementia,* N.Y. Times, June 24, 2008, at F1; *see* Alex Berenson, *Lilly Adds Strong Warning Label to Zyprexa, a Schizophrenia Drug,* N.Y. Times, Oct. 6, 2007.

SGAs were and are marketed as providing more effective treatment with fewer side effects and better symptom reduction than the older-and far less expensive off-patent-FGAs. Expert Rep. of John Abramson, M.D., at 7, Feb. 28, 2007, Docket Entry No. 97 ("Abramson Rep."). Because of the severe and costly-in both human and economic terms-nature of the illnesses SGAs treat, insurance companies believing them to be more effective have been willing to spend billions of dollars on the new drugs, despite the fact that they can cost up to 100 times more than the older antipsychotic medications. *Id.* (noting that, for example, Zyprexa costs more than twenty times the cost of Haldol, an FGA).

***30** In 1994, when Risperdal, the second SGA after clonzapine, was introduced, only five percent of schizophrenic patients were being prescribed an SGA; national spending on antipsychotic medications was $1.4 billion. *Id.* Ten years later, about ninety percent of schizophrenic patients nationally were being treated with SGAs rather than FGAs, and $10 billion was spent annually on antipsychotic medications. *Id.; see* Frank Decl. 4 (noting that in 2003, IMS Health estimated United States antipsychotic drugs sales to total $8.1 billion).

Because many patients treated with antipsychotics are severely disabled, Medicare and Medicaid, as public health insurance companies, are the largest buyers of the drugs. Between 1994 and 2003, total Medicaid spending on all prescription drugs increased by $25.9 billion, quadrupling from $8.4 billion to $34.3 billion; one-third of the increase, $8.5 billion, went towards increased expenditures on SGAs. Abramson Rep. 8. In 2003, three out of the top four drugs that Medicaid purchased were SGAs. *Id.*Zyprexa headed this list: Medicaid paid over $1.8 billion for olanzapine in each of 2003 and 2004, $500 million more than for any other single drug. *Id.; see* CMS Medicaid Drug Utilization data, ranked by Drug, 2003-2006. In 2005, the most recent year for which data is available, Medicaid paid over $1.6 billion for Zyprexa.

Off-label prescriptions account for a substantial proportion of SGA sales. For instance, Zyprexa's "unapproved [off-label] uses represent an average of 31% of Zyprexa mentions in the National Disease and Therapeutic Index (NDTI) database." Rosenthal Decl. 26. In particular, "[t]he use of antipsychotic drugs to tamp down the agitation, combative behavior and outbursts of dementia patients has soared, especially in the elderly." Laurie Tarkan, *Doctors Say Medication [Including Zyprexa] Is Overused in Dementia,* N.Y. Times, June 24, 2008, at F1. Use of the medications are particularly high in short-staffed nursing homes, where sedatives and antipsychotics-despite their potentially severe side effects, including increased risk of death-present a tempting option. About a third of all nursing home patients have been given antipsychotic drugs. *Id.*

D. Lilly, with Zyprexa, Has Been Successful

Zyprexa has been a phenomenal success for Eli Lilly. Approved in more than 80 countries, it now has been prescribed to more than 23 million people since 1996. Lisa Demer, *State Claims Drug Maker Hid Data,* Anchorage Daily News, Mar. 6, 2008. Over 73 million Zyprexa and Zyprexa Zydis prescriptions had been written by the end of 2006, *see* Rosenthal Decl., Ex. E.1 (citing IMS Health TRx Data).

From its launch, Zyprexa rapidly cut into Risperdal and Clozaril's market shares, while the overall market for atypical antipsychotics grew substantially. Rosenthal Decl. 6. For both FDA-approved and off-label indications, Zyprexa has the largest market share for SGAs in the United States, *see* Lieberman, *supra,* at 1210, and in 2003, was the seventh

best-selling drug in the country with sales of $3.3 billion. Rosenthal Decl. 6. Although 2005 sales dropped to $2.5 billion, *id.,*Zyprexa sales now total $4.2 billion annually. Abramson Rep. 8. During the class period cited by the Plaintiffs, Zyprexa sales exceeded $22 billion. *See* Pfs.' Mem. in Opp. to Def.'s Mot. for Summary J., June 12, 2007 (filed under seal).

***31** Zyprexa now accounts for approximately 27 percent of Lilly's total revenues, down from a high of 33 percent in 2002, *Fitch Affirms Eli Lilly & Co.'s IDR at 'AA',* Business Wire, Sept. 26, 2007, but constitutes nearly fifty percent of the company's profits; pretax profits from Zyprexa total $2 billion annually. J.K. Wall, *$2 Billion Challenge: Lilly Under Gun to Replace Aging Blockbuster Zyprexa,* Indianapolis Business J., Nov. 3, 2007. The average cost per prescription-roughly a month's supply-ranges from $250 to $350. *See* Summary J. Hr'g Tr. 74, June 22, 2007. At commonly prescribed doses, Zyprexa now costs about $8,000 per year. Alex Berenson, *Lilly E-Mail Discussed Off-Label Drug Use,* N.Y. Times, Mar. 14, 2008. Its costs, along with Lilly's profits, will undoubtedly sharply decrease when its patent expires in 2011.

IV. Pharmaceutical Industry

A. Pricing

Unlike those of the typical consumer good, sales of most branded pharmaceuticals are not sensitive to prices or price changes. Such an inelastic market is behaves differently from the classic elastic market described by the sloping price and demand curves. Even when there is a wide variation in prices between competing pharmaceuticals, these price differences tend not to affect the unit sales of the products. Especially when a drug treats as serious a disease as a psychiatric disorder, the relative price of an agent has little, if any, affect on product use. Kolassa Decl. 10.

The pharmaceutical market's unique price stability results from the limited monopoly protection afford by patents, and, where patents have expired, a reluctance to switch to generic drugs by patients and to require such a switch by physicians and third-party payors:

> [O]nce launched, prices are unlikely to decline in the face of new warnings or other information because of the presence of brand loyalty. That is, once a drug has been on the market, there will be a segment of patients and physicians that believe that it works for them and will not switch even if significant risks are discovered .... When there are significant numbers of brand-loyal customers, a manufacturer in this situation may rationally maintain a high price and capture only the segment of the market that values the product most highly.

Rosenthal Decl. 38-39. Even when negative information about a medication is released, manufacturers are reluctant to reduce prices; such a move could "signal the market or the courts that the manufacturer accedes to the allegations that the drug is worth less than was initially promised." *Id.*

Due to this price rigidity, pharmaceutical companies are thus able to independently fix and routinely to raise their prices. Kolassa Decl 10. Lilly, like other firms, is free to set the price it chooses for its products. *Id.;* Harris Rep. ¶ 17. Competing medicines can somewhat limit a manufacturer's pricing freedom; Zyprexa's price growth, for example, has been consistent and generally paralleled that of most of the other SGAs. Kolassa Decl. 8; *see id.* at tbl. 1.

B. Marketing

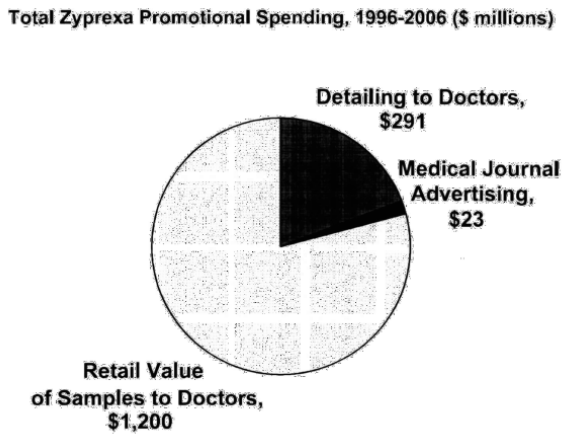
***32** Marketing and advertising have been critical to the success of the pharmaceutical industry in the last two decades. Whether via increasingly common direct-to-consumer ("DTC") advertising or one-on-one physician detailing, drug companies spend billions. Gardiner Harris, *Group Urges Ban on Medical Giveaways,* N.Y. Times, Apr. 28, 2008; *see also* Rosenthal Decl. 15. In 2000, for example, total national prescription drug promotion expenditures totaled more than $15.7 billion. *See* Adriane Fugh-Berman & Shahram Ahari, *Following the Script: How Drug Reps Make Friends and Influence Doctors,* 4(4) PLoS Medicine 621, 621 (April 2007).

Of that amount, $4.8 billion is spent on drug detailing alone. *Id.* "Detailing" is the one-on-one promotion of drugs to physicians by pharmaceutical sales representatives, usually through regular office visits, free gifts, and friendly advice, when "drug reps go to doctors' offices to describe the benefits of a specific drug." Daniel Carlat, *Dr. Drug Rep.,* N.Y. Times.

Mag., Nov. 25, 2007, at 67; *see also* Rosenthal Decl. 15. Drug companies hope that drug representatives will increase the sale of a particular drug by influencing physicians with "finely titrated doses of friendship." *Id.*

Like many other pharmaceutical campaigns, detailing-through which free samples are directly distributed to doctors-was the backbone of Lilly's marketing of Zyprexa. Over plaintiffs' putative class period Lilly spent about $291 million on detailing (more than any other SGA) out of a total marketing budget of $1.5 billion, with an additional $1.2 billion going towards drug samples distributed primarily through detailers. *See* Rosenthal Decl. 25. Its Zyprexa sales representatives wrote over fourteen million call notes, each describing doctor interactions; Tr. 744 (Abramson testimony); two thousand detailers were employed just for the primary care market alone. (Lilly did not-as do many drug manufacturers-condescend to advertising and marketing its drug directly to gullible lay consumers through maddeningly battological television and other media. Tr. 832-33 (Cockburn testimony). See the below chart and table showing Lilly's overall promotional spending on Zyprexa from 1996 through 2006.

Total Zyprexa Promotional Spending, 1996-2006 ($ millions)



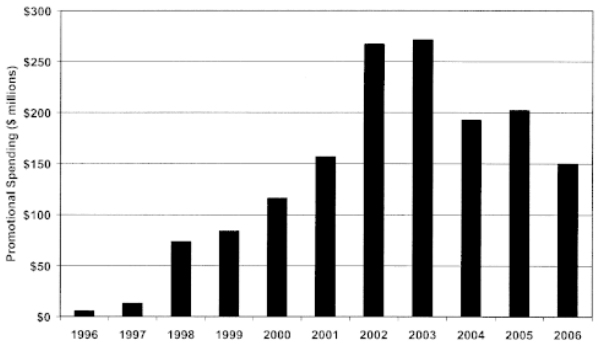
Pfs. Corr. Response 340.

Lilly's expensive promotional effects were driven by a sense of urgency: with its patent for former bestseller Prozac running out, Zyprexa's success was crucial to Lilly's future. *See* Elizabeth Lopatto & Allan Dodds Frank, *Lechleiter, Replacing Taurel as Lilly Chief, Pushes Pipeline,* Bloomberg.com, Dec. 19, 2007, http://www.bloomberg.com/app s/news?pid=20601087 & sid=aKo2Xxlu2bNg & refer=home ("Prozac generated $2.6 billion in annual sales before a U.S. appeals court stripped the drug of patent protection in 2001."). In 1995, Lilly valued the market for schizophrenia drugs at $1 billion, but believed it to have "the potential to be an estimated $3.5 billion market by 2000," Ex. 528 at ZY3971084, possibly reaching $6 billion by 2006. Ex. 338 at ZY95201325.

***33** Its promotional expenditures began low, then rapidly increased until 2003, when they dropped almost as quickly. At the peak in 2003, Lilly spent approximately $275 million per year marketing Zyprexa, declining to $150 million by 2006. Spending on detailing peaked earlier, at $60 million in 2001, although its effects lasted for some time longer. (The "stock of detailing" can be thought of as slowly accumulating, and then depreciating, over time. Tr. 889 (Cockburn testimony). Promotional effects are long-lived; once physicians and or patients are motivated to try a drug, they tend to stay with it. Rosenthal Decl. 20-21.)

The table and graph below, based on EVIS Health data, show Lilly's total promotional spending as well as its combined expenditures on Zyprexa detailing and sampling alone, broken down by year.

Total Zyprexa Promotional Spending, 1996-2006



Year	Combined Nominal Expenditures on Detailing and Sampling of Zyprexa ($millions)
1998	71.5

1999	82.2
2000	114.1
2001	151.6
2002	262.4
2003	256.2
2004	177.5
2005	194.1
2006 *	170.2

Harris Rebuttal 11 tbl. 1.

Lilly's advertising and detailing budget was not unusual. Other companies spent similar amounts promoting their SGAs. Detailing expenditures for Abilify, for example, have risen to at least $40 million, Tr. 831 (Cockburn testimony); its DTC advertising budget in 2001 totaled about $40 million per quarter. *Id.* at 832-33.

C. Wholesale Influence of Drug Marketing

It is undisputable that expenditures for drug marketing increase sales. The billions spent by the pharmaceutical industry attests to that. Physicians, despite what most claim, *are* influenced both consciously and unconsciously by commercial promotional messages. Scientific knowledge and judgment are not impervious shields against fraudulent product claims. Rosenthal Decl. 18; *see id.* at 16 (noting recent studies demonstrating that "despite their extensive training, physicians are influenced by marketing messages even when they are flawed or contradicted by scientific evidence."). One study, for instance, showed that the majority of doctors held beliefs about two classes of drugs that were consistent with the detailing message but at odds with the scientific evidence, even though the same physicians reported that commercial sources of information had little influence on their prescribing. *Id.* at 17 (also noting that doctors deny that gifts and payments have any effect on their own prescribing behavior).

The medical community appears to be only beginning to grasp the extent and influence of pharmaceutical companies over the medical system and prescribing decisions. The American Medical Student Association, for instance, found that most medical schools in the U.S. do not adequately restrict the money, gifts, and free drug samples that drug companies routinely shower on doctors and trainees). Gardiner Harris, *Survey of Medical Schools Is Critical of Perks,* N.Y. Times, June 3, 2008, at A20. A new model policy by the Association of American Medical College governing interactions between medical schools and the drug industry "recommended that gifts of free food and gifts to students and teachers be banned and that schools discourage faculty involvement in industry-sponsored speakers' bureaus." Gardiner Harris, *Group Urges Ban on Medical Giveaways,* N.Y. Times, Apr. 28, 2008.

***34** Plaintiffs allege that Lilly began its pattern of misleading the public and the health care community, minimizing the known side effects of Zyprexa and overstating its efficacy, as soon as the drug was launched. Pfs.' Mot. for Class Cert. In addition, they claim, to Lilly's falsely promoting Zyprexa as superior for the treatment of schizophrenia, defendant also fraudulently and illegally promoted Zyprexa for off-label use.

Intense pharmaceutical marketing does saturate the industry and appears in many forms-some of which some people would call disguised. To accomplish these goals and raise sales, plaintiffs allege that Lilly utilized all the various channels of information through which pharmaceutical

companies can market their products to propel Zyprexa's brand message. Those channels-today highly susceptible to industry influence-are described below.

1. Drug Labels

The most obvious source of information about a medication is its own prescription label. Abramson Rep. 9. Although a pharmaceutical company must obtain the FDA's approval for its drug's label, the label is the property of the manufacturer, not the FDA. *Id.* Initially drafted by the manufacturer, labels are then subject to negotiations between the federal agency and the manufacturer. *Id.* Because the FDA, however, depends solely on drug safety and efficacy information provided by pharmaceutical companies, it cannot object to a label's shortcomings if it never received the data from the manufacturer showing the drug's drawbacks. *See* Part V, *infra.*

2. Clinical Trials

Clinical trials provide the empirical data upon which the FDA determines a drug's safety and efficacy and doctors make professional judgments about the relative risks and benefits of a drug-and whether it is appropriate to prescribe it for their patients. The pervasive commercial bias found in today's research laboratories, however, means studies are often lacking in essential objectivity, with the potential to lead to misinformation, skewed results, or cover-ups. One of the plaintiffs' experts described how he saw as this situation:

> [C]orporate influence now permeates every aspect of this process, from the design of clinical studies (including the population included in the trial, the choice of drugs, doses, and duration of the trial, and the outcome and safety measures to be tracked), to control of the data, data analysis, the writing the manuscripts for articles, and publication decisions.

Abramson Rep. 14.

Such bias is a recent phenomenon. Before 1980, the National Institute of Health ("NTH") **funded** most clinical trials. During the 1980s, its budget was slashed; in response, drug industry **funding** went up six-fold from 1977 to 1990. *Id.;* Tr. 722. By 1991, drug companies **funded** 70% of all clinical trials, though 80% of commercially **funded** trials were still performed at universities. Abramson Rep. 14; Tr. 723. By 2004, only 26% of commercially **funded** trials took place at universities. Abramson Rep. 15. Today 80% to 90% of all trials are commercially **funded**, *id;* between 66% and 75% of the clinical studies published in the most prestigious medical journals are commercially **funded**. *Id.* at 16. Study design and control are increasingly in the hands of drug companies. Tr. 727. Published studies often do not, however, reflect their commercial ties or authorship; they may be "ghostwritten" by company employees, use proprietary data not accessible to the scientific community, or simply not acknowledge their authors' financial ties to drugmakers.

***35** Sponsorship is not insignificant. Even those trials performed at academic institutions are often partly to almost wholly controlled by the sponsor. *See* Abramson Rep. at 15. Sponsorship significantly affects chance whether trial will support drug; the odds are 5.3 times greater that commercially **funded** studies will conclude that the sponsor's drug is the treatment of choice compared to non-commercially **funded** studies of exactly the same drug. Tr. 724; Abramson Rep. 16. Odds of a trial favoring a drug also greatly increase if the trial's researchers had a financial conflict of interest with manufacturer. Abramson Rep. 18. "For those studies that had both industry sponsorship and at least one author with a conflict of interest the odds were 8.4 times higher that the study would favor the sponsor's drug." *Id.*

Not only does commercial bias affect the probable outcome of a study, but it also often controls whether and when a study is published. Because drug manufacturers often delay or suppress negative results from clinical trials they or their affiliated research institutions conduct, "doctors, formulary committees, and policy makers had based their decisions on an unrepresentative fraction of the available scientific evidence" when deciding if antidepressants in children were safe (only six out of the fifteen studies completed until then had been published). *Id.* at 19; *see* Benedict Carey, *Researchers Find Bias in Drug Trial Reporting,* N.Y. Times, Jan. 17, 2008, at A20 ("The makers of antidepressants like Prozac and Paxil never published the results of about a third of the drug trials that they conducted to win government approval, misleading doctors and consumers about the drugs' true effectiveness, a new analysis has shown."); Alex Berenson, *Accusations of Delays in Releasing Drug Results,* N.Y. Times, Apr. 1, 2008, at C7 (reporting a lead investigator's accusations against his study's commercial sponsors of

deliberately delaying the release of his trial results, which reflected substantially negatively for the sponsor's drug, for two years "to hide something.").

3. Journal Articles

Clinical trials are published via research and review articles in medical journals. Doctors value keeping up-to-date with medical literature, as journal articles are their primary source of best practices and current developments. Tr. 721, 718. Research articles describe individual primary clinical trials; review articles summarize results from multiple trials on the same subject. *Id.* at 721. Both are subject to systemic industry bias. Abramson Rep. at. 20. Because of the increase in commercially-**funded** trials, the number of commercially **funded** journal publications has likewise dramatically increased. Today, two-thirds to three quarters of trials published in the four most respected medical journals are commercially **funded**. *Id.* at 725; Abramson Rep. 16. Several editors of preeminent medical journals have gone so far as to say that their publications "have devolved into information-laundering operations for the pharmaceutical industry." *Id.* at 728; Abramson Rep. 20. For example, by April 16, 2002, the Zyprexa product team had already published 125 full manuscripts and submitted an additional 100 for publication. Tr. 731.

4. Drug Detailing

***36** As discussed above, *see supra,* medical detailing is a large field, employing over 90,000 sales representatives, or one detailer for every 4.5 doctors. Abramson Rep. 10. The vast majority of doctors-eighty-five to ninety percent-do speak with drug detailers, and most consider them and the information they provide helpful and accurate. Tr. 743; Abramson Rep. 10. Drug representatives ostensibly provide useful information for physicians as they address "difficult problems in treating patients." Jonna Perala et al., *Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population,* 64 Archives of Gen. Psychiatry 19, 1892 (2007).

But company-controlled and produced information has great potential to mislead: one "article published in the Journal of General Internal Medicine shows that nearly half (forty-two percent) of the material given to doctors by drug reps made claims in violations of FDA regulations. And only thirty-nine percent of the material provided by drug reps provided scientific evidence to back up claims." Abramson Rep. 25. Drug reps are prohibited from promoting off-label uses; they may only provide information about off-label uses if a physician specifically requests the information. *See* Part V.E, *infra.*

5. CME Course and "Thought Leaders"

Another key source of drug information for doctors is continuing medical education ("CME") courses, usually medical lectures held locally featuring prominent "thought leaders" as speakers. *See id.* at Rep. 21-22; Schneider Rep. 12. Required to maintain medical licenses and to stay current with new developments to give patients the best medical care, Tr. 735; Abramson Rep. 21, many CME courses provide expert syntheses of clinical trial information. Tr. 736.

Like clinical trials themselves, the percentage of CMEs that are commercially **funded** has increased sharply, from 48% in 1998 to 58% in 2002. Abramson Rep. 22; *see* Tr. 736. Sixty percent of CMEs have direct commercial sponsorship; indirect sponsorship (e.g., via non-profits **funded** by company money) account for a large portion of the remainder. Total industry contributions towards continuing medical education is estimated to be 70% or higher and in the hundreds of millions of dollars. Abramson Rep. 22 (noting that commercial sponsorship grew from $400 million in 1998 to $700 million in 2002).

Recognized clinical experts, well-known and respected in their field and referred to as "thought leaders" or "key opinion leaders" are recruited to join company "speakers bureaus" and conduct CMEs in exchange for lecture fees. *Id.* at 21. "[O]ne recent study indicates that at least 25 percent of all doctors in the United States [approximately 200,000 physicians] receive drug money for lecturing to physicians or for helping to market the drugs in other ways." Daniel Carlat, *Dr. Drug Rep,* N.Y. Times Mag., at 67; *see also* Gina Kolata, *Citing Ethics, Some Doctors Are Rejecting Industry Pay,* N.Y. Times, Apr. 15, 2008 (reporting that a small number of prominent academic scientists have decided to stop accepting payments from food, drug and medical device companies in response to accusations of ethical conflicts inherent in these arrangements). In many of these presentations, the slides used have been "created by drug makers, not the speakers. That's like ghost-talking." Gardiner Harris, *Group Urges Ban on Medical Giveaways,* N.Y. Times, Apr. 28, 2008 ("Speakers' bureaus and drug samples are pillars of the industry's marketing operations").

***37** Studies have shown that commercial sponsorship does result in biased CMEs. Tr. 737; *see* Abramson Rep. 10. "Drug company-sponsored lectures are two-and-a-half to three times

more likely to mention the sponsor's drug in a positive light and the competitors' drugs in a neutral or negative light than are non-commercially sponsored lectures." *Id.* at 22-23;*cf.* Rob Waters, *Harvard Doctors Failed to Disclose Fees, Senate Says,* Bloomberg.com, June 9, 2008 (reporting that Harvard Medical School doctors who helped pioneer the use of psychiatric drugs in children violated federal and school rules by failing to disclose at lease $3.2 million from drug makers, including Lilly). Increased formulary requests, the prescribing of new brand-name drugs instead of older generic products, and the prescribing of the specific product promoted have all been demonstrated to increase after exposure to pharmaceutical promotion and company-sponsored CMEs. *See id.* at 26 (effect of drug detailing).

6. Clinical Practice Guidelines and Nonprofit Organizations

Clinical Practice Guidelines ("CPGs")-summaries of expert opinion and often used to identify the standard of care-are an important source of drug information for physicians. Tr. 765, 766. For medical malpractice reasons; prescribers prefer not to depart from standards of care. Abramson Rep. at 25-26.

CPGs are typically formulated by panels of experts under the auspices of medical professional societies, non-profit organizations, or quasi-governmental organizations like the National Alliance of the Mentally Ill ("NAMI") and the American Psychiatric Association. Such organizations "have been particularly active in promoting treatment of the mentally ill with atypical antipsychotics. Guidelines and algorithms advanced by these organizations have a significant effect on the standard of care and the prescribing decisions of doctors." Abramson Rep. 68.

Many of these organizations, however, are partially or fully financially supported by pharmaceutical manufacturers, *id.* at 26, which may accompany favorable drug recommendations or guidelines:

> A host of practice guidelines and algorithms drafted before the publishing of many of the recent, independent studies on atypical antipsychotics advanced the idea that SGAs should be used as first line treatment for schizophrenia and bipolar disorder. For example, the Expert Consensus Guideline Series, Treatment of Schizophrenia 1999 recommended SGAs for first line treatment, acute exacerbation, failure of FGA at low doses, and failure of another SGA. The American Psychiatric Association instituted the second edition of its Practice Guideline for the Treatment of Patients with Schizophrenia in 2004 and recommended SGAs as first line treatment for patients in the acute phase of schizophrenia. The Texas Medication Algorithm Project ("TMAP") recommend [ed] SGAs rather than FGAs for Stage 1 and 2 of antipsychotic treatment.

***38** *Id.* at 68 (footnotes omitted). (In November 2007, TMAP reversed its earlier judgment on the basis of CATIE and other studies and issued a revised consensus judgment by leading experts suggesting that there is no advantage for chronic schizophrenics of SGAs over FGAs. *See* Rosenheck Supp. Decl. 7.)

Panel experts, moreover, often have economic ties to the industry via research grants or speaker fees. Every single expert, for example, who worked on the sections devoted to severe mental illness, including schizophrenia, in the 1994 DSM-IV edition had financial links to drug makers. Tara Parker-Pope, *Psychiatry Handbook Linked to Drug Industry,* N.Y. Times Blog, May 6, 2008, http://well.blogs.nytimes.co m/2008/05/06/psychiatry-handbook-linked-to-drug-industry/ (reporting that "[m]ore than half of the task force members who will oversee the next edition of the American Psychiatric Association's most important diagnostic handbook [the DSM] have ties to the drug industry").

V. Role of the Federal Drug Administration

A. Approval Process

Under the Food, Drug, and Cosmetics Act ("FDCA"), new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C.

§§ 355(a), (d). A drug receives FDA approval only for treatment of specified conditions, referred to as "indications." 21 U.S.C. §§ 352, 355(d). For each indication sought a manufacturer must provide condition-specific safety and efficacy information. *Id.* The FDA also determines the particular dosage (or range of dosages) considered safe and effective for each indication.

To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355(b)(1)(A). FDA approval of prescription drugs is wholly dependent upon the accuracy of information provided by drug manufacturers. *See* Abramson Rep. 11. *See generally* Wayne A. Ray & Michael Stein, *Reform of Drug Regulation-Beyond an Independent Drug-Safety Board,* 354(2) NEJM 194 (Jan. 12, 2006).

Not only does the FDA depend upon industry-supplied data, but it also relies on direct financial support from the industry. "[S]ince the enactment of the Prescription Drug User Fee Act of 1992 ... the pharmaceutical industry provides between twenty to fifty percent of the **funding** for the FDA's activities. The regulating agency is therefore dependent on those it is supposed to be regulating." Karen Baswell, Note, *Time for a Change: Why the FDA Should Require Greater Disclosure of Differences of Opinion on the Safety and Efficacy of Approved Drugs,* 35 Hofstra L.Rev. 1799, 1828 (2007). As a result, some have alleged that the FDA and the pharmaceutical industry have too many close ties:

> ***39** [F]ederal drug policy seems to currently favor the commercial pharmaceutical industry. Differences of opinion regarding drug safety and efficacy in a new drug application seem to be decided in favor of the manufacturer (at least initially). After approval, challenges to a drug's safety or to the adequateness of the drug's label regarding risks are seemingly set aside until the effects of the risks become so egregious that the manufacturer or the FDA is forced to address them. This set-aside period allows the manufacturer to maximize profits before removing either an indication for a drug or the drug itself.

Id. at 1829; *see also* Gardiner Harris, *Potentially Incompatible Goals at F.D.A.: Critics Say a Push to Approve Drugs Is Compromising Safety,* N.Y. Times, June 11, 2007, at A14 (reporting that "several F.D.A. safety reviewers in recent years have been punished or discouraged after uncovering similar drug dangers").

FDA approval does not require that a new drug be more effective or safer than other drugs approved to treat the same condition. Neither does it require that the drug be cost-effective. *See* Robert Rosenheck, *The Growth of Psychopharmacology in the 1990s: Evidence-Based Practice of Irrational Exuberance,* 28 Int'l J. Law & Psychiatry 467 (2005). A drug must only be shown to be more effective than a placebo in treating a particular condition, without any statistically significant safety findings. *See* Abramson Rep. 11-13; Ray & Stein, *supra,* at 194. Comparative data showing performance as compared to existing drugs is not required; the FDA has no basis for determining that one drug is better than another drug. *See* Ray & Stein, *supra,* at 194.

Because short-term studies are accepted, drug applications often do not contain long term data on the safety or efficiency of the drug. Abramson Rep. 11. Approval of a new drug generally contains a requirement that the manufacturer pursue further long-term studies, but two-thirds of the promised studies never materialize and the FDA lacks any enforcement authority. *Id.* at 12-13. Many of the effects of newly approved drugs could not possibly be known at the time of FDA approval, particularly the long-term effects of taking a medication, given the short length of and relatively few participants in the clinical trials conducted for approval. *See AP Analysis: How a Drug's Risks Emerge,* N.Y. Times, May 23, 2007. There is no systematic provision requiring drug companies to conduct-or provide results from-post-marketing studies. *Id.*

As the gatekeeper of drugs with potentially life-saving or life-changing effects, the FDA often finds itself between a rock and a hard place: "Safety and speed are the yin and yang of drug regulation. Patients want immediate access to breakthrough medicines but also want to believe the drugs

are safe. These goals can be incompatible." Gardiner Harris, *Potentially Incompatible Goals at F.D.A.: Critics Say a Push to Approve Drugs Is Compromising Safety,* N.Y. Times, June 11,2007, at A14.

B. Drug Labeling

***40** The drug's label, included as a printed insert in the drug's packaging, must also be approved by the FDA as part of the original application. The approved indications and respective dosage information appear on the label. 21 U.S.C. §§ 352, 355(d). "[L]abels are the primary means of providing prescribing physicians and their patients with important information on a drug's risks and benefits." Baswell, *supra,* at 1803; *see* Part IV.C.1, *supra.*

After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See*21 C.F.R. § 201.57(3); Abramson Rep. 13. Generally the manufacturer will attempt to negotiate over the FDA-proposed modifications, *see* 21 U.S.C. § 355(d); Ray & Stein, *supra,* at 194-95, and compromise often results. Raymond L. Woosley, *Drug Labeling Revisions-Guaranteed to Fail?,* 284(23) JAMA 3047 (Dec. 20, 2000). A manufacturer may also independently change its product label upon learning new safety information.

C. Drug Marketing

FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels-"labels" includes all marketing and promotional materials relating to the drug-may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* § 333. The Justice Department has reached a number of legal **settlements**, for example, with drug companies accused of off-label marketing. Anna Wilde Mathews & Avery Johnson, *FDA to Propose Guidelines for 'Off-Label' Drug Use,* Wall St. J., Feb. 15, 2008.

The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. Rosenthal Decl. 15. In particular, promotional materials may only make claims that are supported by scientific evidence (according to strict scientific procedures) and they may not be false or misleading. *Id.* FDA oversight helps ensure a "fair balance" in all promotional claims and materials, *id;* federal regulations require that the risks as well as the benefits must be clearly identified and given appropriate prominence. *Id.* at 14-15. Promotional materials must be consistent with the FDA-approved product labeling. *Id.* at 15. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy. *Id.*

A manufacturer wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also*21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

***41** Currently off-label information can only be distributed at the request of a health care provider. 21 U.S.C. §§ 360aaa-366. In a move welcomed by the drug industry, the FDA is now developing guidelines on how drug and medical-device manufacturers can provide doctors with reprints of medical journal articles that deal with uses of drugs and devices that have not won FDA approval. Mathews & Johnson, *supra.*

The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D. (Director Center for Drug Evaluation and Research ("CDER"), FDA) Before the Senate Special Committee on Aging. DDMAC's effectiveness in regulating off-label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible

for reviewing all drug advertisements and promotional materials. *Id.;* Abramson Rep. 12. Moreover, drug materials do not have to be pre-approved, ZY203727500; FDA review of promotional materials occurs, if it does at all, after the materials have already appeared in public. Woodcock Statement, *supra.* Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

D. Monitoring of Adverse Side Effects

Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Ray & Stein, *supra,* at 195. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard. "Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box,"21 C.F.R. § 201.57(e), commonly known as a "black box" warning..

The FDA's Office of Surveillance and Epidemiology ("OSE") is responsible for overseeing the safety of approved drugs. Abramson Rep. 12. Like DDMAC, OSE is underfunded and understaffed. *Id.; see* Marcia Coyle, *FDA-Regulated Officials Face Tougher Penalties,* Nat'l L.J., May 12, 2008, at 7 ("Underfunded, undermanned and under criticism for its enforcement effort in recent years, the agency has sought a broad range of [sentencing] guideline changes which, if approved, would have stiffened sentences dramatically .... 12 years ago, the FDA sought wholesale revisions to the guideline covering nonfraud violations of the FD & CA, but the [sentencing] commission withdrew the proposals after negative industry reaction."); Gardiner Harris, *Advisers Say F.D.A.'s Flaws Put Lives at Risk,* N.Y. Times, Dec. 11, 2007, at A12 (reporting that an FDA Advisory Board report had just concluded that the "FDA is falling further and farther behind in carrying out its responsibilities and understanding the science it needs to do its many jobs."); Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials,* N.Y. Times, Sept. 28, 2007, at A1 ("The F.D.A. has 200 inspectors, some of whom audit clinical trials part time, to police an estimated 35,000 testing sites," and noting that the government report concluded that "the agency's oversight of clinical trials is disorganized and underfinanced" and "federal health officials did not know how many clinical trials were being conducted, audited fewer than 1 percent of all testing sites and, on the rare occasions when inspectors did appear, generally showed up long after the tests had been completed."); *see* Gardiner Harris, *Tainted Drugs Put Focus on the F.D.A.,* N.Y. Times, Mar. 17, 2008, at A13 (discussing recent deaths from tainted heparin produced in China and the FDA's inability to conduct inspections of foreign manufacturing plants). *But see* Gardiner Harris, *F.D.A. to Expand Scrutiny of Risks from Drugs After They're Approved for Sale,* N.Y. Times, May 23, 2008, at A17 (reporting that the FDA has announced a new system, called the Sentinel Initiative, to allow FDA officials to, for the first time, almost immediately monitor how drugs affect health using Medicare claims data. "The agency now relies on an unsystematic system in which doctors, patients, and manufacturers report problems with drugs and medical devices when they deem them important.... The agency estimates that it receives reports for only a fraction of actual drug effects); Gardiner Harris, *More Money for Food Safety Is Sought: After Outbreak of Salmonella, Department Asks for $275 Million,* N.Y. Times, June 10, 2008, at A17 (reporting that the Bush Administration has requested an additional $275 million for the FDA to open more international offices for overseas inspections and to expand the workforce to 1500 people).

***42** Although drug companies are under a continuing obligation to report serious adverse events, with required safety reports to be filed every three months during the first few years of marketing of a drug, the FDA's adverse event reporting system is largely voluntary. *See* Phil B. Fontanarosa et al., *Postmarketing Surveillance-Lack of Vigilance, Lack of Trust,* 292 JAMA 2647, 2647 (2004). Through the FDA Safety Information and Adverse Event Reporting Program ("MedWatch"), consumers and healthcare professionals may voluntarily report "serious problems that they suspect are associated with drugs."*See* FDA MedWatch Homepage.

There was some evidence presented at the evidentiary hearing that a major problem with this country's system of ensuring postmarketing drug safety is that it is "the drug makers themselves who are largely responsible for collecting, evaluating and reporting data from postmarketing studies of their own products." Abramson Rep. 13 (quoting 2004 JAMA article).

> Perhaps the most terrifying aspect of the aforementioned 'bad drug' cases [referring to Avandia, Vioxx, Fen-phen, Parlodel, DES, Ortho Evra, Paxil] is not that negative or harmful side effects were ultimately linked to the drugs, but the amount of time the drugs remained on the market *without adequate warning to the consumers,* after the manufacturers knew (or had reason to know) of either the dangerous risks or the general ineffectiveness of the drugs.

Baswell, *supra,* at 1803 (original emphasis) (arguing for a change in federal drug policy, for the FDA to provide or require drug companies to provide all scientifically supported interpretations to doctors and consumers so that consumers may make a truly educated choice).

For a variety of reasons, adverse events are significantly underreported. *See* A.S. Rogers et al., *Physician Knowledge, Attitudes, and Behavior Related to Reporting Adverse Drug Events,* 148(7) JAMA (July 1, 1988); Lots La Grenade et al., *Underreporting of Hemorrhagic Stroke Associated with Phenylpropanolamine,* 286(24) JAMA 3081, 84-86 (Dec. 26, 2001). Health care professionals, for example, are not required to report serious adverse events suspected to be caused by medications, and are not even encouraged to report adverse events other than those classified as "serious." *See* Timothy Brewer, *Postmarketing Surveillance and Adverse Drug Reactions,* 281(9) JAMA 824 (Mar. 3, 1999). Drug companies are incentivized to minimize reporting. Doctors may not easily or immediately recognize a causal connection between a new drug and a deleterious side effect. As a result, adverse drug event reports are thought to represent only 1% to 10% of the total population of all complications. Rogers, *supra;* La Grenade, *supra; see also* Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality (K.G. Shojania et al., eds., 2001), at chap 4: Evidence Report/ Technology Assessment No. 43, AHRQ publication 01-E058 (finding that only 1.5% of all adverse events result in an incident report, and only 6% of adverse drug events are identified properly).

E. Monitoring of "Off-Label" Use

***43** Any use of an approved drug for a purpose other than those indicated in the labeling is considered to be "off-label." *See* David C. Radley, *Off-Label Prescribing Among Office-Based Physicians,* 166 Archives of Internal Medicine 1021 (May 8, 2006). Physicians may prescribe drugs for off-label uses at their discretion. It is generally agreed that "off-label prescribing can benefit both individual patients and patient populations as clinical experience leads to the formation of hypotheses to be tested in structured clinical trials." Rosenthal Decl. at 11. The FDA does regulate, however, off-label promotion by drug manufacturers. *See* Part V.C, *supra.*

" 'Off-Label' prescriptions are a mainstay of the drug industry-an estimated 21% of drug use overall." Mathews & Johnson, *supra.* Examples of off-label use include using a drug to treat a condition for which it is not indicated, treating an indicated condition with different doses than those specified on the label, and using a drug to treat a different patient population (such as using a drug to treat children when it is approved to treat adults). Off-label uses of approved medications have not been subjected to the baseline FDA scrutiny that approved uses, and are thus considered riskier. *See id.* at 1021.

> The lack of an indication in the label should not be an issue, however, in the concerned physician's managing of patients and prescribing a medication "off-label." Physicians and the community recognize that many drugs effective for a condition may not be labeled for that condition and may not have a strong body of evidence for or against their use. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his problems, the successfulness of prior treatment, and the risks of not treating.
>
> Whether contemplating on- or off-label use, physicians also rely on personal experience, recommendations from colleagues and academics, educational seminars, and clinical trials evidence. This of course requires that they have access to that evidence....

Schneider Decl. 11-12.

VI. FDA Approval and Regulation of Zyprexa

A. Pre-Approval Studies

In the early 1990s, Lilly began seeking FDA approval of olanzapine for use in treatment of psychotic disorders. Before applying for FDA approval of Zyprexa for treatment of schizophrenia in 1996, Lilly performed a variety of studies to test the drug's safety and efficacy. Early studies revealed Zyprexa was associated with weight gain. Lilly's 1993 HGAV study, for example, reported that "weight gain was evident and uniform in all subjects, with an average gain of nearly 9 pounds." ZY621218-1427. Statistical analysis of HGAV data in performed April 1995 noted that "weight gain was evident and uniform in all subjects, with an average gain of nearly 9 pounds over the study duration," or approximately one and a half pounds per week. *Id.* at ZY621264, ZY621218-ZY621427.

***44** In August 1995, in the "Olanzapine Integrated Summary of Safety" report prepared for submission to the FDA, which included data from 3201 patients involved in approximately fifty worldwide olanzapine studies, Lilly noted that nearly 30% of patients on olanzapine in those trials reported incidences of weight gain. Ex. 544 at ZY203550835-1150; see Wirshing Decl. 36. Compared with Haldol, "Weight gain occurred more frequently in patients treated with Zyprexa. *Id.* ("A potentially clinically significant weight gain (>7% from baseline) was experienced by 20.3% of olanzapine-treated patients compared with 5.0% of haloperidol patients.")

B. Initial Approval for Schizophrenia

Lilly was not required to, and did not, show that Zyprexa was better than, or even as good as, existing antipsychotics, or that it was safer or had fewer side effects than drugs already available to treat psychotic disorders. In seeking FDA approval, Lilly relied on two controlled studies showing Zyprexa to be superior to a placebo in the management of the symptoms of psychotic disorders in patients with schizophrenia during short term, six-week-long studies. Ex. 321 at ZY 9063679. "[F]or a drug anticipated to be used for lifetime treatment of an incurable disease, only 301 patients received at least 1 year of treatment while only 876 received at least 6 months of treatment." Wirshing Decl. 36 (citing C.M. Beasley et al., *Efficacy of Olanzapine: An Overview of Pivotal Clinical Trials,* J. Clin. Psychiatry 1997;58[suppl. 10] 7-12).

Before approving Zyprexa, the FDA expressed some concerns about both the long-term effectiveness and Lilly's claims of the comparative efficacy of Zyprexa. Regarding the former issue, Paul Leber, M.D., Director of the FDA's Division of Neuropharmacological Drug Products, remarked in an August 18, 1996 Memorandum to the NDA file for Zyprexa:

> The evidence adduced in the sponsor's short term (nominally 6 week long) studies, although it unquestionably provides compelling proof in principle of olanzapine's acute antipsychotic action, does not, because of 1) the highly selected nature of the patients admitted to study, 2) the high incidence of censored observations in the controlled trials, and 3) the indirect means used to assess the product's antipsychotic effects, provide a useful quantitative estimate of how effective (even in the short run) olanzapine actually will be in the population for whom it is likely to be prescribed upon marketing.
>
> The relatively short duration of the controlled clinical trials the sponsor relies upon, as might be anticipated, leaves us largely uninformed both about how effective a "maintenance" treatment olanzapine will be in extended use, and how best to administer it (i .e., dose and regimen) for that use.

Leber Memo, Aug. 18, 1996 (citation omitted).

As to comparative efficacy claims, Dr. Leber believed "the data adduced in the Zyprexa NDA is ... insufficient to permit the sponsor to make claims asserting the product's superiority to haloperidol." While offering criticisms of some of the studies offered in support of the assertion, Dr. Leber specifically noted:

> ***45** The problem in schizophrenia outcome assessment is that some of the so-called "negative" signs and symptoms of that illness are indistinguishable from the pseudoparkinsonian signs and symptoms that are known side effects of antipsychotic drugs like haloperidol. It would be reckless, therefore, to assume that a drug-haloperidol difference detected on an instrument that registers negative symptoms is actually measuring a difference in antipsychotic effectiveness.

Leber Mem., Aug. 30, 1996, at 3; *see also* Leber Mem., Aug. 18, 1996, at 5-7.

Before approving Zyprexa, the FDA made several recommendations regarding the placement and prominence of warnings about weight gain in the planned labeling for Zyprexa. The FDA proposed placing weight gain in the "Precautions" section. Lilly did not agree, arguing that the side effect be included instead in the "Adverse Reactions" section, further down the label: "In light of the additional supporting data ... that demonstrates that a significant portion of patients who experienced a weight increase on olanzapine started out with a low body mass index at baseline, we feel weight gain is improperly placed as a precaution". An Adverse Reaction listing would signify that weight gain was an observed adverse event in clinical trials, but need not raise a concern for most patients.

By the time the FDA approved Zyprexa for use in treatment of schizophrenia on September 30, 1996, *see* FDA Approval Letter (Sept. 30, 1996), Lilly's argument had been persuasive: weight gain was listed under the "Other Adverse Events Observed During the Premarketing Evaluation of Olanzapine" on the Zyprexa label. Specifically, the approved labeling noted that "olanzapine patients gained an average of 2.8 kg [~6*l*bs], compared to an average 0.4 kg [~1lb] weight loss in placebo patients" during short-term, six-week-long studies. Zyprexa package insert (10/02/96). Moreover, weight loss was listed as a frequent metabolic and nutritional disorder. ZY621218-1427. Diabetes mellitus, hyperglycemia, ketosis and diabetic acidosis were listed among the infrequent (i.e., 1/100-1/1000 patients) or rare (i.e., fewer than 1/1000 patients) adverse reactions observed in patients during clinical trials. *Id* .

C. Warning Letter

On October 1, 1996, one day after the FDA's approval of Zyprexa, Lilly Research Laboratories Vice President Dr. Gary Tollefson led an interactive teleconference. Because the FDA found its contents to be "false and misleading and in violation of the [Federal Food, Drug, and Cosmetic] Act," it subsequently issued Lilly a warning-the only warning from the FDA Lilly ever received about Zyprexa. Letter from Kenneth R. Feather, Senior Advisor, DDMAC, to Charles R. Perry, Jrr., Director, Pharmaceutical Communications and Compliance, Eli Lilly & Co., at 5; Tr. 800 (Abramson).

In the November 14, 1996 letter, the FDA chastised Lilly that its whole promotional campaign seemed to be "lacking in appropriate balance, thereby creating a misleading message about Zyprexa." Letter from Kenneth R. Feather, Senior Advisor, DDMAC, to Charles R. Perry, Jr., Director, Pharmaceutical Communications and Compliance, Eli Lilly & Co., at 1.

***46** In particular, the FDA highlighted Dr. Tollefson's response to a question about weight gains, along with certain other statements and promotional and labeling materials made or used during the teleconference:

> When asked a question about weight gain, Dr. Tollefson's response turned an adverse event into a therapeutic benefit. He states, "So we went back and analyzed our data and saw that the vast majority of weight gain reported initially as an adverse event, in fact, was weight gain occurring in patients who had baseline before starting treatment, had been below their ideal body weight. **So we really look at this, with the majority of patients, as being a therapeutic recovery rather than an adverse event. And that data, I think is fairly compelling, because it was included in our labeling.** (Emphasis added)."
>
> The information on weight gain was indeed included in the approved labeling, but as an adverse event, not a therapeutic benefit. Since the product was approved at the time of this teleconference, Dr. Tollefson knew or should have known what information the approved labeling contained and in what section it appeared. His statements were therefore, false and misleading.

Id. at 5 (emphasis in original). The agency also warned that,

> The promotional materials emphasize efficacy data but do not provide sufficient balance relating to adverse events and cautionary information. Further, they do not adequately or prominently discuss several important adverse events specifically selected for emphasis in the approved labeling. These events include orthostatic hypotension, seizures, transaminase elevations, weight gain, dizziness, and akathisia.

Id. at 1.

Other promotional materials were considered to include "implications of superiority over other antipsychotic products that are unsubstantiated" and "present a misleading impression of Zyprexa as a superior, highly effective, virtually free of side effects, easy to use product .... contrary to the approved labeling." *Id.* at 2-3. Further, the FDA noted, "[t]he entire thrust of [Lilly's promotional] campaign is to point out that Zyprexa is different and safer than older antipsychotic drugs. Therefore, it is necessary to properly emphasize those adverse events that do occur, that require caution when using Zyprexa." *Id.* at 2.

The DDMAC letter specifically forbid Lilly from making four claims about Zyprexa: that Zyprexa caused fewer EPS side effects, that Zyprexa was superior for schizophrenia, that Zyprexa did not cause TD; and that Zyprexa did not lead to Parkinson's disease. Tr. 745 (Abramson).

Part of Lilly's message of Zyprexa's alleged superiority was, as the FDA noted, its lack of side effects. Specifically, from the launch of the drug, despite knowledge of its metabolic effects, Lilly publicized the fact that Zyprexa had "no requirement for blood monitoring" as a benefit. Ex. 321 at ZY9063679. In his October 1, 1996 teleconference, referenced above, Dr. Tollefson stated:

> ***47** With some of the other agents, such as Clozapine or Clozaril that you may be familiar with, of course there are prerequisites for blood monitoring on a weekly basis because of some of the safety concerns with those drugs. Of course this is very troublesome to patients and very costly. We're very pleased that we have no requirements for any type of blood monitoring with Zyprexa.

Ex. 320 at ZY9063656. The assertion was reemphasized in a press release on the FDA's approval of Zyprexa offered the same day. *Id* . at ZY9063679. Although not part of the FDA's warning letter, this assertion that Zyprexa required no blood monitoring turned out to be completely false.

VII. Events from 1996 to 2000

Zyprexa sales grew substantially from 1996 to 2000, despite the introduction of Seroquel in 1998, another SGA. Throughout this time period, the numbers of adverse event reports or "AERs" submitted to the FDA and made available to Lilly through the MedWatch database grew substantially. For example, in one Periodic Adverse Drug Event Report, Lilly reported five instances of diabetic acidosis and two instances of diabetic coma between September 30 and December 30, 1997. Ex. 307 at ZY6462389-ZY6462666. Another NDA Periodic Report listed three incidents of ketoacidosis from April 1 to June 30, 1998. Ex. 306 at ZY6451475-ZY6451587. By the end of 1998, after two years on the market, the diabetes-related AERs for Zyprexa totaled nearly 200. By the end of 2000, that number was approximately 600.

Recognizing that under-reporting of adverse drug events is prevalent and that the number of reported events typically reflects 1% to 10% of the total estimated population of all complications, the diabetes-related AERs for Zyprexa were much higher. Yet Zyprexa's label from October 1996 to April 12, 2000 only mentioned any diabetes-related conditions in its Adverse Events section, also including such conditions as "chills and fever," "heart arrest," and an "infrequent" number of pre-market diabetes and hyperglycemia adverse events and a "rare" number of pre-market cases of diabetic ketoacidosis.

VIII. Events in 2000

A. FDA Approval for Manic or Mixed Bipolar

In 2000, Lilly sought to increase sales of Zyprexa by obtaining FDA approval to treat additional indications, including bipolar mania, maintenance of treatment response in schizophrenia, psychotic disorders, and adolescents. *See* NDA 20-592; Letter from Russell Katz to Gregory Brophy (Oct. 12, 2000); ZY22261666. Early that year, the FDA approved the use of Zyprexa in the treatment of manic or mixed episodes of bipolar disorder. ZY22261666.

B. European Investigation

By 2000, European officials were expressing concern about the risks and side effects of Zyprexa. On February 21, 2000, the European Agency for the Evaluation of Medicinal Products ("EAEMP") contacted Eli Lilly Ltd. UK and ordered the company to step up its review of risk factors and provide that information to the EAEMP: "Reports of myocarditis,

cardiac failure, cardiomyopathy and eosinophilia should be reviewed cumulatively for the next PSUR [Periodic Safety Update Report] and the increase in triglyceride levels and reports of hyperlipidemia are potential signals which should be reviewed thoroughly for the next PSUR, including possible risk factors such as diabetes and weight gain." Ex. 284 at ZY994701.

***48** The EAEMP also requested full review of all known cases of diabetic ketoacidosis:

> We would like to inform you that CPMP [the EU's Committee for Proprietary Medicinal Products] ... concluded that there have been several reports of diabetic ketoacidosis, some with fatal outcome and a cumulative review should be provided of all known or suspected cases as soon as possible.

Id. Because of its Adverse Events Reports, Lilly was apparently aware of numerous instances of diabetic ketoacidosis.

C. Lilly Debates Label Change

In February 2000, Lilly debated whether-but ultimately chose not-to change Zyprexa's labeling and acknowledge the risk of hyperglycemia. While perhaps somewhat puzzled by the mechanism by which Zyprexa was causing hyperglycemia, Lilly did understand the drug's link to weight gain.

> It is not immediate [sic] apparent, based on the known pharmacology of olanzapine why it would cause hyperglycemia. The blockade of serotonin receptors by olanzapine along with its antihistaminic activity can explain associated weight gain .... Glucose levels greater than 600 mg/dL was reported in half of the spontaneous reports of hyperglycemia.

Id. at ZY207868094.

In a confidential internal document, Lilly observed that patients taking Zyprexa were three and a half times as likely to develop high blood sugar as those who took nothing: "[r]ecent review of random glucose levels of patients in olanzapine clinical trials revealed that the incidence of treatment-emergent hyperglycemia in olanzapine group (3.6%) was higher than that in the placebo group (1.05%)." Ex. 495 as ZY207868092. The company was also aware that hyperglycemia has been reported uniformly since the introduction of Zyprexa: "The first report of hyperglycemia associated with olanzapine was received in October of 1996 and the last report was received in September of 1999. The reporting frequency of the hyperglycemia has not changed over the 36 months of marketing (September 1996 through 1999) olanzapine." Ex. 495 at ZY207868093. While Lilly publicly asserted that Zyprexa only poses a risk for patients with pre-existing risk factors, the documents acknowledge that "[t]he spontaneous safety database also has a number of hyperglycemia cases in which the patient has no history or known risk factors for diabetes." *Id.*

Lilly did not provide this information to the FDA. In documents later submitted to the regulatory agency, Lilly narrowed the gap between the populations, stating that 3.1% of Zyprexa patients developed high blood sugar while 2.5% of patients taking a placebo developed the same.

In October 2000, following a meeting with members of one of Lilly's academic advisory boards, Lilly executives discussed the reactions of the endocrinologists on the board to the company's data on Zyprexa and weight gain, hyperglycemia, and diabetes. Ex. 293 at ZY2224230-ZY2224233; Ex. 303 at ZY5029906-ZY5029908. Dr. Robert Baker, then Lilly's Medical Advisor and Senior Clinical Research Physician, expressed some concern:

> ***49** Unfortunately, this consultation reinforced my impression that hyperglycemia remains quite a threat for olanzapine and may merit increasing even further medical attention and marketing focus on the topic.... They were however concerned by our spontaneous AE reports, and quite impressed by the magnitude of weight gain on olanzapine and implications

> for glucose.... Disconcertingly, one member compared our approach to Warner-Lambert's reported argument that Rezulin did not cause more hepatic problems than other drugs in its class.

Ex. 293 at ZY2224230. In response, Dr. Thomas Bro die reiterated that "clearly, this group of endocrinologists ... are very concerned with the approach Lilly is taking towards the issue that Zyprexia [sic] leads to diabetes." *Id.* at ZY2224232. Continuing, he added "I do believe they made a very strong point that unless we come clean on this, it could get much more serious than we might anticipate." *Id.*

Dr. Charles Beasley, a former Senior Research Physician and Lilly Advisor on the olanzapine team, responded at length, acknowledging the side effects and concerns about how to deal with them.

> There is the marketing approach and then the scientific analyses approach. There are 2 issues-weight gain and hyperglycemia.
>
> These guys were really concerned about the weight gain, not only because of a diabetes risk but all the other potential health risks .... When they understood ... that olanzapine is the worst offender, other than clozapine, they advocated a different marketing strategy than we are taking. They believe we should "aggressively face the issue" and work with physicians to address methods of reducing weight gain ... There does not seem much to say about scientific analyses of weight gain, we know it's a weighty problem. When you translate 1-2% gain of 40+ kilos into the absolute number based on 5 million patients, the number is 50,000 to 100,000. 100,000 people putting on 90 pounds of weight is a lot....
>
> With regard to the marketing side of this issue of impaired glucose tolerance [sic] / diabetes, the message was clear. Don't get too aggressive about denial, blaming it on schizophrenia, or claiming no worse than other agents until we are sure of the facts and sure that we can convince regulators and academicians. W-L [Warner-Lambert] with Resulin [sic] was the example.

Ex. 502 at ZY5029906-ZY5029907.

D. FDA Requests Information on Hyperglycemia and Diabetes

As noted above, on May 1, 2000, the FDA sent Lilly a letter requesting that they "investigate the possibility of collaborating with organizations having large pools of patients treated with atypical antipsychotics to examine the evidence of hyperglycemia or new-onset diabetes mellitus temporally associated with olanzapine." Ex. 298 at ZY4018143. Specifically, the FDA asked for:

> A thorough assessment of all Phase 1, 2, and 3 studies in the olanzapine NDA and any subsequent supplements for evidence of new-onset diabetes mellitus, hyperosmolar coma, diabetic ketoacidosis, weight gain, and hyperglycemia. This should include the frequency of deaths, serious adverse events, total adverse events, and dropouts due to events related to abnormalities of glucose metabolism listed above, data regarding mean changes from baseline in plasma glucose level, and the percentage of patients meeting criteria for a markedly abnormal plasma glucose concentration from an appropriate pool of placebo-controlled Phase 2/3 studies. Any deaths, dropouts, or serious adverse events should have an accompanying detailed narrative summary.

***50** Ex. 280 at ZY994158. In addition, the FDA required a "review of spontaneous postmarketing reports for new-onset diabetes mellitus, hyperosmolar coma, diabetic ketoacidosis, weight gain, and hyperglycemia" as well as "a comprehensive review of all preclinical data pertaining to hyperglycemia." *Id.*

Three months later, on July 31, 2000, Lilly submitted a partial response to the FDA's May 1st request. Lilly's submission included an analysis of seventy-eight controlled trials as well as "a review of published literature, a historical review of preclinical data and previously submitted Phase I, II and III studies, and analysis of current, complete clinical trial database, a review of spontaneous postmarketing reports with

an estimate of patient exposure, and copies of correspondence with foreign regulatory agencies." Ex. 281 at ZY994178. However, most of the information was misleading, especially as it pertained to full disclosure of the risks of prolactin, weight gain, and hyperglycemia.

In "Section 1, Introduction" of the "Note to Reviewer," Lilly suggested that Zyprexa did not elevate prolactin levels, writing "[M]ost atypical antipsychotics, in contrast to typical antipsychotics, have not been associated with significant hyperprolactinemia. Risperidone is the one atypical antipsychotic associated with sustained prolactin elevations above the upper limit of normal (Chung and Eun 1998)" *Id.* at ZY994178-ZY994182. Despite this assurance, Lilly's own proposed label of October 2000 admitted the risk of heightened prolactin: "As with other drugs that antagonize dopamine D2 receptors, olanzapine elevates prolactin levels, and a modest elevation persists during chronic administration."

In "Section 2, Literature Review" of the "Note to Reviewer" submitted on July 31, 2000, Lilly dispersed blame about weight gain among antipsychotics generally, stating that "[w]eight gain has been reported during treatment with nearly every antipsychotic drug on the market ... Weight gain occurs during treatment no matter what the patient's age, sex, or race and is seen with both oral and depot drug formulations." *Id.*

Further, in "Section 4, Phase I Historical Data" of its July 31, 2000 attachment, Lilly told the FDA that "the average weight gain observed in the clinical pharmacology studies was 8.9 +7.1 pounds (mean +standard deviation)." Ex. 282 at ZY994210. Lilly downplayed the results, suggesting that all patients enrolled in studies gain weight and thus the fact of weight gain could not be attributed to olanzapine:

> The clinical meaning of the weight gain is difficult to assess, since in the experience of the investigator over 20 years, patients generally tend to gain weight while enrolled in studies at the Lilly Clinic. The reasons for weight gain may be attributed to lack of exercise and liberal access to high fat meals.

Id.

Lilly did not mention that its own 1993 study had shown "uniform" and consistent weight gain among olanzapine patients. Ex. 276 at ZY621218-ZY621427.

***51** Similarly, Lilly tried to hide the incidence of hyperglycemia, blaming it on pre-disposed factors among schizophrenic patients. In the "Section 2, Literature Review" attached to its July 31, 2000 letter, Lilly told the FDA:

> On the basis of [ ] case studies it appears as though patients that may develop hyperglycemia in temporal association with olanzapine are patients that are typically at risk for DM-II based on race, obesity, or family history. It is unclear at this point whether or not the number of cases of olanzapine in temporal association with DM-II exceeds the expected incidence for the development of DM-II in patients with schizophrenia.

This explanation overlooks the fact that increased incidence of diabetes in Zyprexa users appears in studies in which all subjects are diagnosed schizophrenics.

E. FDA Approval for Schizophrenia Maintenance

On October 12, 2000, the FDA approved the use of Zyprexa for the maintenance of treatment response in schizophrenia. Letter from Russell Katz to Gregory Brophy (Oct. 12, 2000). The FDA only agreed to approve this new indication on the condition that Lilly adopt the FDA's proposed labeling revisions. *Id.* One of these revisions included greater emphasis on the narrow indication for which Zyprexa was approved, using the phrases "treatment of schizophrenia" and "in schizophrenia" and eliminating any reference to the broader category of psychosis or psychotic disorders. Of course, the narrow label language did not stop Lilly from continuing to use its sales representatives, network of enterprises, and influence for off-label promotion of those indications.

Another of these revisions concerned the communication of information about Zyprexa's effect on plasma glucose levels and the risk of diabetic coma. On May 9, 2000, Lilly proposed

making a change to the Zyprexa label to include data from the olanzapine clinical trial database that would list effects on random plasma glucose levels as an adverse reaction in the Laboratory Changes section and diabetic coma as an adverse reaction in the Postintroduction Reports section. Ex. 280 at ZY994158; Ex. 359 at ZY200367530-ZY 200367531. Lilly claimed that this label change was based on "[t]he results from the analysis of our clinical trial safety database ... and review of our spontaneous case reports," and not in response to May 1, 2000 letter the company had received from the FDA requesting information on "hyperglycemia or new-onset diabetes mellitus temporally associated with olanzapine." Ex. 280 at ZY994158; Ex. 281 at ZY994178.

F. "Diabetic Coma" Added to Label

The FDA approved the addition of the phrase "diabetic coma" to the label via a letter to Lilly dated October 11, 2000. However, the FDA rejected Lilly's proposed "inclusion of data from the olanzapine clinical trial database with respect to random plasma glucose levels." The FDA based its rejection on the grounds that Lilly's proposed revision was misleading; Lilly's proposed text stated:

> ***52** In the olanzapine clinical trial database, as of September 30, 1999, 4577 olanzapine-treated patients (representing approximately 2255 patient-years of exposure) and 445 placebo-treated patients who had no history of diabetes mellitus and whose baseline random plasma glucose levels were 140 mg/dL or lower were identified. Persistent random glucose levels >= 200 mg/dL (suggestive of possible diabetes) were observed in 0.8% of olanzapine-treated patients (placebo 0.7%). Transient (i.e., resolved while the patients remained on treatment) random glucose levels >= 200 mg/dL were found in 0.3% of olanzapine-treated patients (placebo 0.2%). Persistent random glucose levels >= 160 mg/dL but <200 mg/dL (possibly hyperglycemia, not necessarily diabetes) were observed in 1.0% of olanzapine-treated patients (placebo 1.1%). Transient random glucose levels >= 160 mg/dL but <200 mg/dL were found in 1.0% of olanzapine-treated patients (placebo 0.4%).

Id. This language suggests that random glucose levels were the same for patients taking olanzapine and patients taking a placebo. On October 11, 2000, Dr. Russell Katz of the FDA wrote to Gregory T. Brophy of Eli Lilly expressing his opinion that the proposed label change was misleading:

> The descriptive data that is provided expresses a certain level of implied safety with respect to treatment emergent hyperglycemia. This reassuring language is not appropriate for submission under 21 CFR 314.70(c) as a 'Special Supplement-Changes Being Effected' (CBE). A more complete submission of glucose data, and additional discussion of pooling and analysis of this data is necessary before an appropriate review of treatment emergent hyperglycemia and diabetes can take place.

To Dr. Katz and the FDA, olanzapine was not as safe as Lilly made it out to be. Because there was not enough data to support Lilly's proposed revision to the label, the FDA would not permit Lilly to use the label as a marketing device to infer "a certain level of implied safety" that was not proven to exist.

G. Malaysian "Dear Doctor" Letter

During this same time period, other countries requested or required Lilly to make changes to the Zyprexa label. In November 2000, at the request of the Malaysian Regulatory Authority, Lilly sent a "Dear Doctor" letter to Malaysian physicians advising them of a change in Zyprexa's package insert and an increased risk of hyperglycemia and/or diabetes as it relates to Zyprexa use. The "Dear Doctor" letter also advised Malaysian physicians to monitor patients with risk factors for the development of diabetes. Ex. 530 at ZY8492254-ZY8492254.

IX. Events of 2001

A. Marketing Campaign to Primary Care Doctors

At a national sales meeting in March 2001, Lilly launched its "Viva Zyprexa" marketing campaign targeted at primacy care doctors. Tr. 754 (Abramson).

B. Japan Launch

In preparation for Zyprexa's launch in Japan in or about June 2001, Lilly attempted to persuade Japan's Ministry of Health and Welfare ("MHW") that the Zyprexa package insert did not need to include a requirement that blood glucose monitoring should be conducted in certain patients due to the reports of diabetes and hyperglycemia. Ex. 351 at ZY200284418-ZY200284425. Lilly's concern was that such a disclosure would drive down demand for the drug. In fact, in an email dated October 5, 2000, Masashi Takahashi, a Lilly representative in Japan, discussed the MHW's request "to rank weight gain (and hyperglycemia) issues higher in the safety section of the package insert because MHW recognizes that olanzapine causes weight gain more than other [antipsychotics] and weight gain is a widely accepted risk factor for diabetes". Mr. Takahashi went on to state that "we want to avoid a request from MHW of forced blood glucose monitoring at launch. So, team thinks, it would be clever to make a deal with MHW by ranking weight gain and hyperglycemia at higher places so as to avoid the possibility of forced blood glucose monitoring." *Id.*

X. Events of 2002

A. Japanese Label Change

***53** In March 2002, in response to a request from the Japanese Ministry of Health, Labor, and Welfare ("MHLW") for an "analysis of Eli Lilly global trial data on weight gain and hyperglycemia associated with the use of olanzapine," Lilly prepared a report entitled "Review of Glycemic Related Studies." Ex. 378 at ZY201585170-ZY201585179. In the "Conclusions" section the report, the company stated

> An increased risk of developing diabetes compared to a general reference population was observed in the AdvancePCS prescription database cohorts during treatment with either conventional or atypical antipsychotics. Though the risk of developing diabetes was significantly greater for patients in the Risperidone [Risperdal] cohort than in the Haloperidol cohort, this analysis did not demonstrate a generally elevated risk between the atypical and conventional antipsychotic cohorts. It remains unclear whether the observed increases are related to factors intrinsic or extrinsic to those psychotic conditions commonly treated with antipsychotic drugs.

Id. Despite Lilly's attempts to convince the MHLW of the safety of atypical antipsychotics, Japanese regulators required a label change shortly thereafter.

Following the initial Japanese approval of Zyprexa, Lilly learned that the Japanese government was going to require Zyprexa's label to be changed to include precautions and warnings about the potential for diabetes and/or hyperglycemia. Lilly immediately set about reconciling the Japanese label change with its sales pitch that Zyprexa does not cause diabetes. In response to the forced Zyprexa label change in Japan, on or about April 15, 2002, Lilly's Kristen Lynn Anderson and Ashish Kalgaonkar authored a memorandum to all Business to Business Internal and External Lilly Personnel regarding how to "proactively" discuss with "formulary decision makers" Japan's decision to force a Zyprexa label change. ZY200117576. Lilly's message was that it "strongly disagreed" with the conclusion drawn by the Japanese regulators notwithstanding reports of several deaths in connection with Zyprexa use and severe hyperglycemia. *Id.* Further, the memorandum emphasized that "we expect this outcome in Japan will not affect the Zyprexa label in the United States. It is important to keep in perspective the benefits of Zyprexa to patients with schizophrenia and bipolar mania ." *Id.* The Lilly memorandum also highlighted six "points to note" while emphasizing the safety and cost effectiveness of Zyprexa and that the label change in Japan "does not affect the value of Zyprexa." *Id.* (emphasis added). Finally, the Lilly memorandum affirmed that "Lilly stands by its science, and is exploring several options to correct this regulatory injustice." *Id.* (emphasis added).

B. Mexican and Australian Label Changes

On or about July 1, 2002, the Mexican government requests that Eli Lilly revise its package insert regarding hyperglycemia for Zyprexa. Ex. 362 at ZY200371124-ZY200371125. Shortly thereafter, in or about August 2002, Lilly completed negotiations with the Australian Regulatory Board about a required label change for Zyprexa in Australia. The label change required Lilly to disclose, "that clinical trials revealed that Zyprexa use can cause hyperglycemia." Ex. 358 at ZY200310611-ZY200310617.

C. Lilly's Response to Foreign Label Changes

***54** The foreign label changes, in particular that of Japan, were serious challenges to Zyprexa's future. Following the announcement of that label change, at the request of the FDA, Lilly performed an "Analysis of Japanese Data on Hyperglycemic and Diabetic Spontaneous Serious Adverse Events Associated with Use of Zyprexa." The analysis was based upon thirteen serious adverse event reports of hyperglycemia, including two deaths from diabetic coma, in patients taking Zyprexa in Japan. Rather than taking responsibility for properly investigating these serious adverse events in order to prevent future tragedies, in an effort to save Zyprexa's brand image, Lilly continued discrediting and dismissing these reports while claiming that the Japanese cases were anecdotal, the Japanese patients were injured due to other pre-existing risk factors, and the events in Japan were due to unspecified confounding causation factors. In addition, Lilly took the extraordinary step of claiming that because the Japanese Zyprexa package insert had a stronger warning regarding diabetes than in the United States, Japanese physicians were, therefore, more likely to blame glucose-related adverse events on Zyprexa than American doctors. Ex. 531 at ZY30432362.

On or about October 15, 2002, Dr. Russell Katz and Steve Hardeman of the FDA took part in a conference call with Lilly representatives Alan Breier (Vice President and Zyprexa Team Leader), Gregory Brophy (Director, U.S. Regulatory Affairs), Melanie Bruno (Senior Regulatory Research Scientist) and Patrizia Cavazzoni (Medical Director). Ex. 357 at ZY200310451-ZY200310452. The purpose of the conference call was to discuss the FDA's concerns about glucose "dysregulation" connected with Zyprexa use. *Id.* Dr. Katz noted that the FDA has concerns about Lilly's use of data and methodologies with regard to reports of treatment emergent diabetes and informed Lilly that the FDA was awaiting the results of a VA study in its efforts to determine its position with regard to glucose dysregulation and Zyprexa. *Id.*

Handwritten notes on a document prepared for the meeting note that "John Buse has seen around 20 cases DKA that just appeared w/o patient having been identified as diabetic I or II type. Concerned about good drug/bad drug perception by prescribers and patients if drugs are labeled individually and differently." Ex. 529 at ZY8023602-ZY8023608. The document coached Lilly officials on how to respond to FDA inquiries about label changes in other countries. Lilly officials are told that the FDA might ask, "Are you going to change your label in the U.S. since the labeling has been changed in Japan, Australia, New Zealand and potentially Canada and there is already more information in the EU label than the U.S. label?" As detailed in the Preparation Document, Lilly officials are supposed to tell the FDA that "labeling changes in Japan and other countries has not been based [sic] full consideration of the available data, but rather forced upon Zyprexa." *Id.*

XI. Events of 2003

A. Pancreatitis Added to Label

***55** Early in 2003, the FDA agreed that Lilly should include pan creatitis as an adverse event in the Postintroduction Reports section of the Zyprexa label.

B. Canadian Approval

On March 17, 2003, Canadian regulators approved olanzapine for the treatment of bipolar mania. In the "Precautions" section of the product monograph, however, the Canadian regulatory agency forced Lilly to add language warning of the risks of the drug in worsening pre-existing diabetes or other metabolic concerns:

> As with some other antipsychotics, exacerbation of pre-existing diabetes, hyperglycemia, diabetic ketoacidosis, and diabetic coma including some fatal cases have been reported very rarely during the use of ZYPREXA, sometimes in patients with no reported history of hyperglycemia ... In some cases, a prior increase in body weight has been reported which may be a pre-disposing factor. Appropriate clinical

> monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus.

Lilly was also required to include the following language about the incidence of weight gain among patients taking Zyprexa, acknowledging here that nearly ten times as many patients on Zyprexa as opposed to placebo gained clinically significant amounts of weight (more than seven percent of baseline body weight) in six weeks:

> During acute therapy (up to 6 weeks) in controlled clinical trials comparing ZYPREXA with placebo in the treatment of schizophrenia, the percentages of patients with weight gain >= 7% of baseline body weight at any time were 29% for ZYPREXA and 3% for placebo, which was a statistically significant difference. The average weight gain during acute therapy in patients treated with ZYPREXA was 2.8 kg.

C. European Label Change

European regulators, in a May 26, 2003 Assessment Report, highlighted a number of problems they had with Lilly's analysis of and explanation for various side effects of Zyprexa. They further required the addition of several warnings to the product information. First, regulators informed Lilly that it would need to change its label to reflect the risk of tardive dyskinesia. Ex. 388 at ZY202360928-ZY202361006. In response to Lilly's claim that tardive dyskinesia tremors were not the fault of Zyprexa but were instead "confounded by recent antipsychotic use or pre-existing EPS, were mild, or were transient," the regulators observed that whether "events were mild and transient is not a reason to conclude that these events were not clinically significant enough to be mentioned in the SmPC." *Id.*

Second, regarding weight gain, the European regulators concluded that Zyprexa's product labeling "must be revised to highlight the high percentage of patients experiencing clinically significant weight gain during olanzapine treatment." *Id.* Third, after a back and forth on treatment-emergent diabetes and possible explanations for the occurrence of such in nine patients lacking risk factors for the disease, the regulators chided Lilly for an inappropriate analysis and refused to accept the company's rationale for the problems:

> ***56** The further analysis of the 9 patients in the schizophrenia database who appeared to lack risk factors for diabetes and who experienced treatment-emergent diabetes is not reassuring. It is not considered appropriate to label a patient as having hypertension based on isolated hypertensive blood pressure and, therefore, having a risk factor for diabetes. Similarly, the approach taken to consider isolated total cholesterol values as risk factors for diabetes is not considered appropriate. These new analyses do not change the conclusion that treatment-emergent diabetes has been observed in cases with no definite risk factors.

Id.

Consequently, European regulators required the following warning to be added to the European label:

> Hyperglycemia and/or development or exacerbation of diabetes occasionally associated with ketoacidosis or coma, has been reported very rarely, including some fatal cases. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable particularly in diabetic patients and in patients with risk factors for the development of diabetes mellitus.

Id.

The regulators dropped the first several words of this warning, which had been proposed by Lilly: "As with some other antipsychotics ..." *Id.* Lilly had been able to keep this blame-the-class language in its FDA-approved labels but it was rejected by European regulators who said that their cleaner version "must be implemented." *Id.* In choosing this warning, the regulators rejected Lilly's watered-down suggestions and blame-the-class language. In fact, the regulators directly pointed out a link between weight gain and diabetes that Lilly had been loathe to admit:

> The Rapporteurs strongly disagree with the wording proposed by the MAH to be included in SmPC section 4.4. In fact, olanzapine treatment-induced weight gain is a risk factor for the development of diabetes! It is important to emphasize the development of diabetes in the wording. Otherwise the message is diluted. What the MAH is now proposing is a step backwards. Furthermore, it does not add any relevant information to draw the attention to other neuroleptics in the beginning of the sentence, it merely shifts the focus from the important message.

Id.

D. FDA Class-Wide Diabetes Label Change

In September 2003, the FDA required Lilly and all other SGA manufacturers to add a warning about treatment-emergent diabetes and hyperglycemia to the labels for those drugs. The FDA informed Lilly that after "an extensive review of data available for patients treated with atypical antipsychotics over a number of years," it had concluded that "epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics." Ex. 365 at ZY200429111-ZY200429115. As a result, the FDA requested "class-labeling for all atypical antipsychotics to include a warning about hyperglycemia-related adverse events." *Id.*

***57** On September 15, 2003, the FDA advised Lilly and the other SGA manufacturers that they would be required to change their labeling to include warnings about diabetes and hyperglycemia. Ex. 273 at ZY30658-ZY30659. The FDA "requested" that Lilly "add a WARNING with regard to Hyperglycemia and Diabetes Mellitus" as a "labeling revision" to NDAs 20-592 and 21-086. *Id.* (emphasis in original). The FDA did not require Lilly to make an Zyprexa-specific change as regards to diabetes or hyperglycemia; the FDA had determined that there was not enough evidence to conclude that there was a difference in rates of diabetes or hyperglycemia among the various atypical antipsychotics, and indicated that comparisons between drugs as to weight gain were inappropriate. Tr. at 393 (March 31, 2008: Wirshing).

The FDA included certain "recommendations" of language to be included in the revised labels but negotiated with Lilly about the actual language to be used. Ex. 365 at ZY200429111-ZY200429115. Lilly hoped to include a sentence stating that the FDA had not ranked the comparative risk of the atypical antipsychotics in this regard: "The available data are insufficient to provide reliable estimates of differences in hyperglycemia related adverse event risk among the marketed atypical antipsychotics."

The FDA, however, required Lilly to omit that sentence from its warning and avoid an implication that all atypical antipsychotic medications carried an equal risk of treatment-emergent diabetes and hyperglycemia. Letter, Dec. 23, 2003, Dr. Russell Katz, FDA to Michele Sharp, Lilly. Similarly, the FDA required Lilly to include language in the new warning about the necessity of conducting blood glucose testing "at the beginning of treatment" for "[p]atients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics." Ex. 300 at ZY4099534-ZY4099536.

After all the revisions were taken into account, the FDA required Lilly to adopt the following "WARNING" about hyperglycemia and diabetes mellitus in its label:

> Hyperglycemia and Diabetes Mellitus
>
> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics

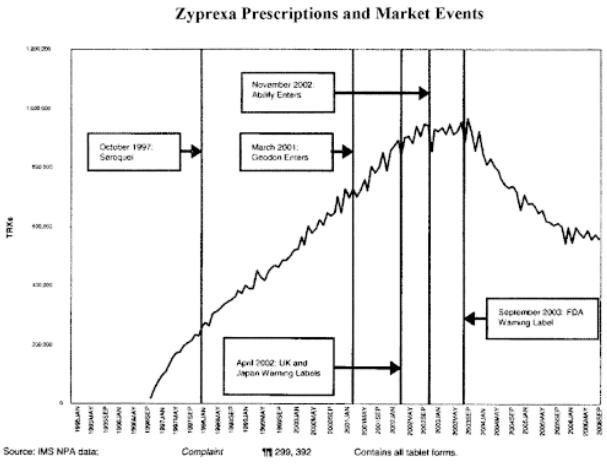
including Zyprexa. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. 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. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

***58** Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. 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.

Ex. 300 at ZY4099534-ZY4099536.

The September 2003 label change required by the FDA apparently had a profound influence on forcing down sales of Zyprexa compared to those of other antipsychotics. *See also* analyses of Dr. Harris' reports, Part XVII. A3, *infra.*

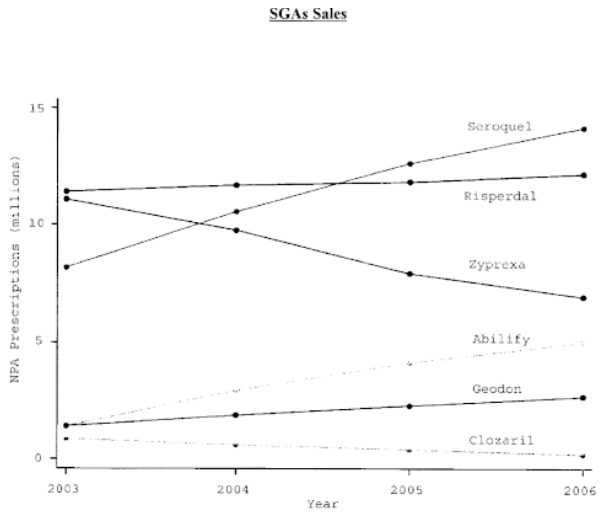
Zyprexa Prescriptions and Market Events



Zyprexa TRXs [Prescriptions] and Market Events; Rosenthal Rep. at Ex. 8, attch. C.1.b

"The only other brand-name atypical antipsychotic to decline after 2003 was Clozaril, approved by the FDA in September 1989, which was also identified by clinicians as more prone to induce weight gain and increase diabetes risk, and which had been available as a generic clozapine since December 1997." *Id.*

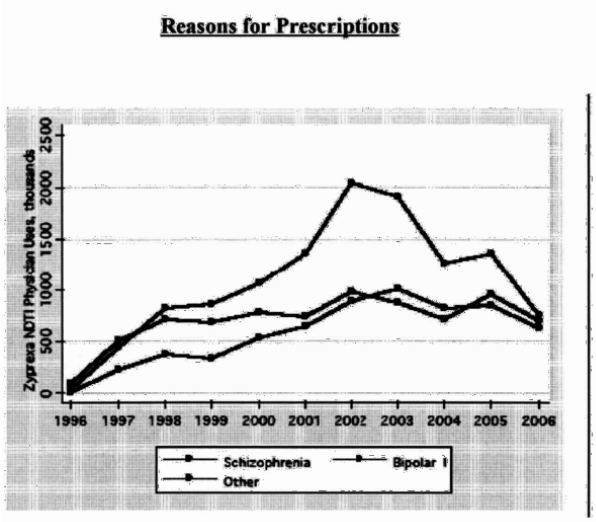
SGAs Sales



Harris Rep. Ex. 2.

"[T]he overall decline in Zyprexa use since the peak of 2002-2003 corresponded almost entirely to a decrease in prescriptions written for diagnoses other than Schizophrenia and Bipolar I disorder." *Id.* at ¶ 24.

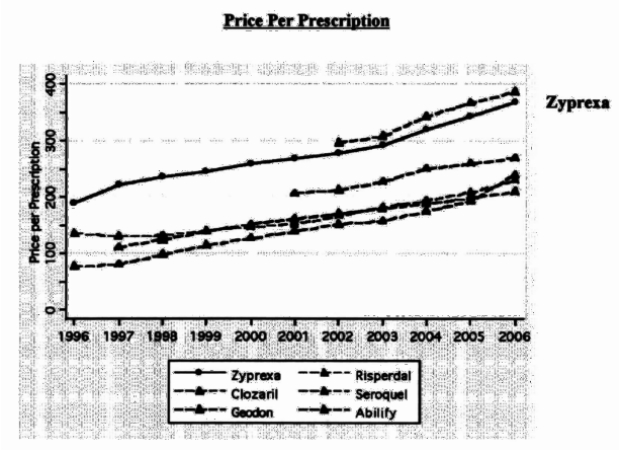
Reasons for Prescriptions



Because of Lilly's monopoly control over the price of its patented drug, decreased demand after 2003 did not lead to a price reduction relative to other atypical antipsychotics.

"Lilly maintained the price differential between Zyprexa and the three comparison drugs Seroquel, Risperdal and Clozaril even after the introduction of Geodon and Abilify. Even after the FDA-mandated change in warning label in 2003 and the consensus report of the American Diabetes Association in 2004, there was little change in the relative prices of the six branded atypical antipsychotics." Harris Rep. ¶ 32, Ex. 3.

Price Per Prescription



E. VA Cooperative Study 451

The Department of Veterans Affairs Cooperative Study Group on the Cost-Effectiveness of Olanzapine ("VA Cooperative Study 451") was a large multi-site trial evaluating the cost-effectiveness of Zyprexa as compared to Haldol. *See* Rosenheck et. al., *Effectiveness and Cost of Olanzapine and Haloperidol in the Treatment of Schizophrenia,* 290 J.A.M.A. 2693 (2003); Rosenheck Decl. 6; Abramson Rep. 33-33. Although the study was **funded** with $5 million from Lilly, Dr. Rosenheck deems the study independent. *See* Tr. 11, Mar. 28, 2008.

***59** Initiated in 1997 and published in November 2003, the results showed no advantage for Zyprexa over Haldol on any measure of symptoms, social functioning, or quality of life, no superiority on measures of tardive dyskinesia or higher abstract cognitive functions, but a small benefit for Zyprexa on measures of akithesia, fine motor movement, and memory. The study also showed Zyprexa was associated with significantly higher risk of weight gain, and $3,000-4000 to $9,000-$10,000 greater annual costs due to the greater price of the medication. Rosenheck Decl. 6; see Abramson Rep. 33. Unlike the ICT study, however, the VA study found "no statistically or clinically significant advantages of olanzapine for schizophrenia on measures of compliance, symptoms or overall quality of life, nor did it find evidence of reduced inpatient use or total cost." *Id.* Further, the study noted, "[p]erhaps the most unexpected difference was the lack of any significant advantage for olanzapine on measures of retention, termination due to adverse effects, or EPS other than akathisia." *Id.*

XII. Events of 2004

A. American Diabetes Association Consensus Statement

In February 2004, the American Diabetes Association ("ADA"), the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity collectively issued a Consensus Development Statement on the interplay between antipsychotic medications, obesity, and diabetes, published in the ADA's official journal, Diabetes Care. *Diabetes Consensus Statement,* 27(2) Diabetes Care 596 (February 2004). The consensus statement concluded in part that clozapine is clearly the most effective antipsychotic. *Id.*

The consensus suggested that both hunger and satiety may be altered in people taking olanzapine and clozapine because of their known affinities to serotonin, norepinephrine,

dopamine, and particularly histamine-H1 receptors, all of which have been implicated in the control of body weight." Wirshing Decl. 14 (citing Eder at 598).

The statement noted that there was "considerable evidence" that atypical antipsychotics can cause a rapid increase in body weight and that olanzapine was one of the worst offenders.

Additionally, the consensus statement found that despite the shortcomings in studies examining the relationships between atypicals and obesity and diabetes, "clear-cut trends can be identified." *Id.* at 597. These trends include that second generation antipsychotics can cause a rapid increase in body weight in the first few months of therapy that may not reach a plateau even after one year of treatment, and that data consistently show an increased risk for diabetes in patients treated with clozapine or olanzapine compared with other antipsychotics. *Id.* at 598. The consensus statement also states that among the atypicals, olanzapine and clozapine had the greatest risk of weight gain, diabetes, and worsening lipid profile. The Consensus Statement concluded:

> ***60** [T]he data consistently show an increased risk for diabetes in patients treated with clozapine or olanzapine ...
>
> Patients treated with olanzapine and clozapine have higher fasting and post-prandial insulin levels than patients treated with FGAs, even after adjusting for body weight.

The Consensus Statement observed that the risks of these side effects "have considerable clinical implications in this patient population and should ... influence drug choice." Figure R4, below, reproduces a table from the Consensus Statement comparing the metabolic effects of SGAs.

SGAs' Metabolic Abnormalities

Drug	Weight gain	Risk for diabetes	Worsening lipid profile	
Clozapine	+++	+	+	
Olanzapine	+++	+	+	[Zyprexa]
Risperidone	++	D	D	
Quetiapine	++	D	D	
Aripipmzole*	+/-	-	-	
Ziprasidone*	+/-	-	-	

+ = increase effect;-= no effect; D = discrepant results. *Newer drugs with limited long-term data

Figure R4.

Source: American Diabetes Association & American Psychiatric Association [38].

Clozapine = Clozaril; Olanzapine = Zyprexa; Risperidone = Risperdal; Quetiapine = Seroquel, Aripiprazole = Abilify; Ziprasidone = Geodon

Harris Rebuttal Rep. 19.

In response to the ADA Consensus statement, Lilly issued a press release is titled "Lilly Expresses Concern with Opinion of ADA Panel On Antipsychotic Drug and Obesity and Diabetes: Company Reaffirms 2004 Earnings Guidance." In the release, Lilly states, "Eli Lilly and Company does not agree with a controversial conclusion of an opinion paper issued by an American Diabetes Association-sponsored panel, which states that second generation antipsychotics (SGAs) differ in their diabetes risk profiles." Lilly refers to the ADA paper as "controversial," even though such consensus statements "have to be regarded as ... powerful and distinct," and (as Lilly's own expert recognized), "the publication of a consensus statement ... often represents the culmination of a process, not the beginning of one." Tr. at 249 (March 29, 2008: Harris); *id.* at 825 (March 31, 2008: Cockburn). Lilly also states that "these findings [are] not supported by the

total body of evidence available on the subject," implying that if these psychiatrists were to look at all of the evidence, including evidence in Lilly's possession, they would have reached a different conclusion.

B. "Dear Doctor" Letter

Despite the FDA's mandate that Lilly immediately warn physicians about the new label change, Lilly waited six additional months-until March 1, 2004-to send out a "Dear Doctor Letter" advising of the new warnings for diabetes and hyperglycemia. ZY4099534-ZY4099536. The letter told physicians about the increased risk of hyperglycemia and diabetes in patients taking atypical antipsychotics and stated:

> Eli Lilly and Company would like to inform you of important labeling changes regarding Zyprexa (olanzapine). The Food and Drug Administration (FDA) has asked all manufacturers of atypical antipsychotic medications, including Lilly to add a Warning statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including Zyprexa.

***61** ZY200427046-ZY200427047; ZY200622359-ZY200622360.

When the FDA notified Lilly that it sought "updated product labeling for all atypical antipsychotics to include a warning about additional information on hyperglycemia and diabetes," Lilly tried to downplay the seriousness of the new warnings, responding that "The requested labeling echoes what Lilly has said for several years: that the risk of diabetes in patients with schizophrenia is greater along with ever increasing incidence of diabetes in the general population." ZY200038429-ZY200038431. Yet, Lilly had worked for years to prevent such warnings from being added to the Zyprexa label.

Various exchanges with the FDA lead up to this critical label change. On February 24, 2003, Steven Hardeman of the FDA sent an email to John Roth of Lilly requesting further information about the risks that olanzapine posed for treatment-emergent diabetes. ZY200307548-ZY200307551. Mr. Hardeman noted that the FDA "has been reviewing the analysis of treatment emergent diabetes (TED) with olanzapine (submitted 10/2/02)." The FDA figured out the misleading manner in which Lilly had been comparing itself to clozapine instead of simply describing the effects of olanzapine. The FDA asked them to stop:

> Your proportional hazards analysis relied on comparison or risk with olanzapine to the pooled risk with other antipsychotics. Table 3.5 (p.31) suggests that clozapine may be different, that is, it appears to have a higher risk for glucose elevations, when compared to the rest of the non-olanzapine antipsychotics. We are interested in viewing the results of an analysis that compares olanzapine to non-olanzapine antipsychotics excluding the clozapine data.

Id. at ZY200307550. This was not the first time the FDA had asked for data excluding clozapine as Mr. Hardeman wrote, "This is the same question Russell Katz asked during our tc [telephone conference] in October, and I had clarified it for him verbally."

On June 20, 2003, in a document titled "Update to Olanzapine and Glucose Homeostasis (Prepared for FDA)" and submitted to the FDA, Lilly noted that since the FDA's letter of inquiry [in 2002], Lilly's "researchers and clinicians have been focusing increased attention on the topic of serious mental illness and diabetes." Lilly reviewed some recent studies including the one with "1362 patients not known to be diabetic," and found that 1.6% of the olanzapine patients developed treatment-emergent diabetes as opposed to .59% of the haloperidol patients and .95% of the divalproex patients. ZY200285790-ZY200285864.

Despite the increased percentage of treatment emergent diabetes associated with olanzapine, Lilly discouraged the FDA from singling out Zyprexa, stating that "[d]ifferential labeling would ultimately not be in the best interest of patients and caregivers," using the following rationale:

> It is the opinion of Eli Lilly and Company that the cumulative data currently available, representing multiple lines of evidence, do not demonstrate clinically relevant or consistent differences in the risk for diabetes, or in changes in markers of glucose regulation, in patients treated with olanzapine compared with other atypical antipsychotics.

***62** *Id.*

Even at this late stage in 2003, Lilly continued to try to convince prescribers that Zyprexa's adverse effects were no different from those in the class of atypical antipsychotics at large. It also continued to deny any link to diabetes whatsoever: "At the same time, the cumulative data do not currently allow us to establish whether treatment with antipsychotic mediation contributes to the increased risk of diabetes observed in the seriously mentally ill." *Id.*

Prior to the September 2003/March 2004 label change, Zyprexa's label did not warn of diabetes or hyperglycemia. Despite having the ethical obligation to make label changes as more data emerged regarding side effects and adverse events, this change was only made after the FDA required Lilly to include in the Zyprexa label a warning about the risk of developing diabetes and hyperglycemia and the need for baseline screening and glucose monitoring. *See*21 CFR § 201.57.

Despite Lilly's adamant denial of any link between diabetes and olanzapine, data suggests that these warnings were appropriate. The American label change in September 2003/ March 2004-though far overdue-was still not adequate to warn of the significant and potentially catastrophic risks and was made far too late to affect ingrained physician prescribing habits. This is specifically supported by 21 CFR 201.57(e)'s requirement that "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with the drug; a causal relationship need not have been proved." This shift in tone coincided with the FDA's decision to require all atypical antipsychotic medications to carry a warning about the risk of treatment-emergent diabetes and hyperglycemia they carried.

The injectable form of Zyprexa (Intramuscular) was approved in March 2004 for the treatment of agitation associated with schizophrenia and bipolar I mania. Harris Rep. 10. Since then, the FDA has approved no additional indications for the drug beyond patients with schizophrenia and bipolar I disorder. Harris Rep. 10.

XIII. Events of 2005

A. Class-Wide Black Box Dementia Warning

In May of 2005, the FDA required the manufacturers of Zyprexa, Risperdal, Seroquel, and Abilify to add a black box warning to the labels advising of the increased risk of death when using these drugs in treating the elderly for dementia. *See* Lindsey Tanner, *Dementia Drugs Can Increase Death Risks in Elderly Dementia Patients,* ABC News (2005).

Lilly had initially hoped that Zyprexa would be approved to treat dementia in the elderly. Between 1996 and 2000, Lilly engaged in and submitted to the FDA the results of at least two additional studies designed to support approval of an indication for treatment of dementia in the elderly. *See* Ex. 301 at ZY4099542 (reflecting submissions of the results of the HGEU and HGGV to the FDA in 1998 and 1999). But, by 2003, Lilly admitted to the FDA that Zyprexa had no proven efficacy in treating psychosis associated with dementia. *Id.* at ZY4099543.

***63** In December of that year, Lilly requested a meeting with the FDA's Center for Drug Evaluation and Research and provided information on seven clinical studies of Zyprexa it had conducted in elderly patients with dementia. The point of the request was not to focus on Zyprexa's efficacy or lack thereof for dementia. (Most of the studies "were designed and conducted to support a clinical development plan for the treatment of psychosis associated with dementia", but Lilly acknowledge that the "efficacy results from these studies were not sufficient to support the intended new indication." Ex. 301 at ZY4099542-ZY4099543.)

Rather, Lilly wished to discuss a label change addressing the finding that in its clinical trials, elderly patients taking Zyprexa for treatment of dementia faced a much higher risk of death than those taking placebo, stating, "[i]n placebo-controlled clinical trials of elderly patients with dementia-related psychosis, the incidence of death in olanzapine-treated patients was significantly greater than placebo-treated patients (3.5% vs. 1.5%, respectively)." *Id.* at

ZY4099543. Afraid that a Zyprexa-specific "label change regarding mortality in elderly based on dementia studies ... [would] likely be disadvantageous to our positioning vs. the competition," *see* Oct. 2003 "Zyprexa Business Summary," ZY204056179-ZY204056182, Lilly encouraged the FDA to instead consider a class-wide warning for all atypical antipsychotics, rather than simply a warning on Zyprexa:

> Based on the safety comparisons of olanzapine [Zyprexa] with risperidone [Risperdal] and conventional antipsychotics in our integrated safety database, along with our understanding of the aripiprazole [Abilify] safety data, an increased risk of mortality in patients with dementia-related psychosis strongly suggests a class effect.
>
> Does the Division believe that this safety result may represent a class effect and should lead to updated antipsychotic labeling across the class?

Id. at ZY4099546. Lilly suggested that the following proposed language to be inserted in the WARNINGS section of the label:

> Safety Experience in Elderly Patients with Dementia-Related Psychosis- In elderly patients with dementia-related psychosis, the efficacy of olanzapine has not been established. In placebo-controlled clinical trials of elderly patients with dementia-related psychosis, the incidence of death in olanzapine-treated patients was significantly greater than placebo-treated patients (3.5% vs. 1.5%, respectively). After adjusting for differences in duration of treatment, the exposure-adjusted mortality rate in olanzapine-treated patients was not significantly different from placebo-treated patients ....

Id. at ZY4099543. The FDA agreed, requiring a class-wide warning in 2005, allowing Lilly to avoid increased competition in the elderly market.

Since the class action certification hearing, the FDA has imposed a new requirement for a black box warning for all antipsychotics-FGAs as well as SGAs-warning of the increased risk of death associated with prescribing antipsychotics to older people with dementia. *See Antipsychotics and the Elderly,* N.Y. Times, June 17, 2008.

B. Publication of Clinical Studies Disputing Zyprexa's Safety and Efficacy

***64** Since 2005, the results of several influential studies challenging Zyprexa's safety and efficacy have been published. Among the most significant are *Clinical Antipsychotic Trials of Intervention Effectiveness Study* ("CATIE"); J.P. McEvoy et. al. *Effectiveness of Clozapine vs Olanzapine, Quetiapine, and Risperidone in Patients with Chronic Schizophrenia Who Did Not Respond to Prior Atypical Antipsychotic Treatment,* 163 Am. J. Psychiatry 600 (2006) ("CATIE II-McEvoy"); T. Scott Stroup, *Effectiveness of Olanzapine, Quetiapine, and Risperidone in Patients With Chronic Schizophrenia After Discontinuing Perphenazine,* 164 Am. J. Psychiatry 415 (2007) ("CATIE-II Stroup"); Robert A. Rosenheck, et al., *Cost-Effectiveness of Second-Generation Antipsychotics and Perphenazine in a Randomized Trial of Treatment for Chronic Schizophrenia,* 163 Am. J. Psychiatry 2080 (2006) ("CATIE-III"); Lon Schneider et al., *Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer's Disease,* 355(15) NEJM) 1525 (Oct. 12, 2006) ("CATIE-AD"); and P.B. Jones et. al, *Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study,* 63 Arch. Gen. Psychiatry 1079 (2006) ("CUtLASS").

1. CATIE

CATIE was sponsored and **funded** by the National Institutes of Mental Health ("NIMH") and remains the single largest government **funded** clinical study to date, **funded** with $40 to $60 million. Tr. 60; *see* Rosenthal Decl. 10; Rosenheck Supp. Decl. 2-7; Abramson Rep. 34-35. NIMH initiated the study to test the relative effectiveness, side effects, and costs of atypical second-generation antipsychotic drugs ("SGAs") in treating schizophrenia and Alzheimer's disease by providing study subject with either a first generation antipsychotic ("FGA")-perphenazine-or one of four SGAs: quetiapine (Seroquel), risperidone (Risperdal), ziprasidone (Geodon), and olanzapine (Zyprexa). Jeffrey A. Lieberman, *Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia,* 353 N. Eng. J. of Medicine 1209, 1209 (2005); Rosenheck Decl. at 11; Pfs.' Slides: Hr'g on Pfs.' Mot. for Class Cert.: Robert Rosenheck, M.D. ("Rosenheck Slides"), at 13. Of the five comparators, the first four are all SGAs and currently under patent; only perphenazine,

a FGA drug, is available in generic form (and thus costs the least). Rosenheck Decl. 9. Perhenazine was chosen as the representative FGA because it "falls in the midrange of antipsychotic drug potency-lower than the high potency drugs like [Haldol], but higher than more sedating drugs like [Thorazine]." Rosenheck Decl. 11.

Conducted between January 2001 and December 2007 at fifty-seven U .S. clinical sites across twenty-three different states, patients were initially randomized to receive flexible-dose treatment double-blind conditions. Rosenheck Slides at 14. The study involved 1,493 patients who had been diagnosed with schizophrenia for the last ten to fifteen years, and lasted eighteen months. Lieberman, *supra.* A clinical team with doctors from the University of North Carolina, Yale University, Duke University and Columbia University oversaw the study and published the results in the September 22, 2005 issue of the New England Journal of Medicine. *See id.*

***65** CATIE's results were published in several phases. Released in 2005, Phase I results concluded that on CATIE's primary outcome-time to all-cause discontinuation-Zyprexa performed better than Seroquel and Risperdal, but with no statistically significant difference compared with perphenazine or Geodon. Tr. at 19; Rosenheck Decl. 12; *see also* Lieberman, *supra,* at 1209-23. (Time to all-cause discontinuation is, in other words, the amount of time a patient stays on a drug before stopping or switching to something else, is considered a surrogate measure for effectiveness.)

CATIE also found that increases in weight were substantially greater with Zyprexa than the other medications, and that the greatest increases in levels of glucose and lipid metabolism were also found in patients given Zyprexa. Rosenheck Decl. 12. CATIE reaffirmed that Zyprexa was associated with greater weight gain and increased measures of glucose and lipid metabolism (all features of metabolic syndrome) than all the other drugs. *Id.* at 1218. The study indicated that schizophrenia patients showed similar rates of extrapyramidal symptoms ("EPS") regardless of whether they took perphenazine or any of the four SGAs. This result surprised the researchers to a certain degree, given that the decreased frequency of EPS has been heralded as a significant advantage of SGAs over FGAs. CATIE further confirmed that the few limited measures in which Zyprexa scored higher than perphenazine were "moderate," and Zyprexa's greater weight gain and increase in glycosylated hemoglobin, cholesterol and triglycerides may have serious implications with respect to medical comorbidity such as the development of the metabolic syndrome. *Id.* at 1218.

2. CATIE-II: McEvoy and Stroup

CATIE II compared clozapine, the first of the SGAs, to other SGAs. McEvoy, *supra,* at 600; Stroup, *supra,* at 415. The second phase of CATIE involved 543 patients who wanted to switch from perphenazine or their initial SGA because they were dissatisfied with the results; they were then randomized to a different SGA or clozapine. *Id.* Results from CATIE II were published as two separate articles in the American Journal of Psychiatry, one regarding the efficacy pathway and the other reporting the results of the intolerability pathway. *Id.*

Clozapine performed the best in CATIE II. *See* McEvoy, *supra,* at 608. The researchers described clozapine as being remarkably effective and substantially better then all the other SGAs, including Zyprexa. *Id.* Forty-four percent of patients who received clozapine were able to stay on the drug for the remainder of the study, whereas only eighteen percent who received another SGA were able to stay on that drug to complete the study. *Id.* at 607-08. Participants taking clozapine remained on it for an average often months, compared to an average of three months for those taking any of the other three SGAs. Those taking clozapine had the greatest symptom reduction rate of any of the medications. *Id.* at 608.

***66** In an editorial in the American Journal of Psychiatry and subsequently in her deposition, Lilly's own expert, Carol A. Tamminga, M.D., agreed that clozapine was the superior medication "by far." Indeed, as Dr. Tamminga put it, CATIE "strongly confirms what we have seen before, that clozapine is our most effective drug for schizophrenic psychosis." Carol Tamminga, *Practical Treatment Information for Schizophrenia,* 163(4) Am. J. Psychiatry 563 (April 2006).

XIV. Events of 2006

A. Additional Critical Studies

1. CATIE-III

At the conclusion of the CATIE trials, Dr. Robert A. Rosenheck led a team that analyzed the results for cost effectiveness. *See* Rosenheck, *Cost-Effectiveness, supra.* His cost-effectiveness analysis of CATIE was published in 2006. Rosenheck Decl. 12; *see* Robert A. Rosenheck, et al., *Cost-Effectiveness of Second-Generation Antipsychotics*

and Perphenazine in a Randomized Trial of Treatment for Chronic Schizophrenia, 163 Am. J. Psychiatry 2080 (2006) ("Rosenheck, *Cost-Effectiveness"*). The results "showed that Zyprexa had no significant advantage over perphenazine on symptoms, but was superior to" Risperdal and Seroquel. Rosenheck Decl. 13; *see* Rosenheck Slides at 19; Tr. at 55-56. Since none of the drugs demonstrated any savings on inpatient, outpatient, or residential care, the cost-effectiveness of each treatment was primarily driven by the price of the drug; perphenazine costs $300 less per month than Zyprexa. (The overall medical costs associated with Zyprexa use were less, however, than the costs associated with Seroquel and Risperdal. Rosenheck, *Cost-Effectiveness* at 2083, tbl. 2 (2006); *see* Tr. at 565-66.)

The study found that during the eighteen months of the CATIE trial, initial assignment to perphenazine, the FGA, was less costly but not less effective than assignment to each of four SGAs. *Id.* at 2085-86. The cost of treatment during the initial treatment periods, including the costs of the drugs, was $1,404.00 per month for Zyprexa versus $960.00 per month for perphenazine, a 46% increase in costs per month for Zyprexa. *Id.* at 2086.

The researchers found no statistically significant difference in overall effectiveness between perphenazine and the SGAs, with regard to symptom relief and side effect burden. *Id.* at 2087. (Notably, the CATIE study was not long enough to detect differences in time-dependent longer-term side effects such as diabetes and cardiovascular disease. *Id.* at 2087.) The study thus cast doubt on the notion that SGAs are more effective than the FGAs; instead, the data suggest that perphenazine and other FGAs may be just as beneficial for some patients. *Id.* Rosenheck and the CATIE II authors concluded "These results should encourage consideration of older intermediate potency drugs like Perphenazine when a medication change is indicated." *Id.* at 2087.

2. CATIE-AD

***67** The CATIE-AD study was also **funded** by the NIMH, and sought to assess the effectiveness of SGAs in outpatients with Alzheimer's disease. *See* Schneider, *supra;* Abramson Rep. 35-36. More than 400 outpatients with Alzheimer's disease and psychosis, aggression, or agitation were randomly assigned to receive Zyprexa, Seroquel, Risperdal, or placebo for up to thirty-six weeks. Schneider, *supra* at 1526. No significant differences among treatments with regard to the time to discontinuation of treatment for any reason were found. CATIE-AD concluded that adverse effects offset advantages in the efficacy of SGAs for the treatment of psychosis, aggression, or agitation in patients with Alzheimer's disease. *Id.* at 1537.

3. CUtLASS

The Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study ("CUtLASS 1") was **funded** by the British National Health Service. It was designed to test the hypothesis that schizophrenic patients requiring a change in medication who were randomly assigned to take an SGA (of their doctor's choosing) would experience an improved quality of life compared to those assigned to take an FGA (of their doctor's choosing). Abramson Rep. 33.

It involved 277 people diagnosed with schizophrenia and related disorders in fourteen community psychiatric services in the United Kingdom. Jones, *supra.* Subjects were randomized between either FGAs or SGAs (other than clozapine) and measured on quality of life scores, symptoms, adverse effects, participant satisfaction, and cost of care. Abramson Rep. 33.

Participants reported no clear preference for either drug group, and costs were similar. The clinicians concluded that "the results of this pragmatic randomized trial refute the hypothesis that the use of SGAs is superior to the use of FGAs in terms of quality of life at one year," and specifically stated, "We emphasize that we do not present a null result; the hypotheses that SGAs are superior was clearly rejected." Jones, *supra,* at 1083, 1085. Further, the researchers stressed that "a range of adverse effects of FGAs and SGAs is emerging. Serious weight gain, diabetes mellitus, and hyperlipidemia may all adversely affect quality of life." *Id.* at 1086.

The authors noted "the hypothesis that SGAs are superior was clearly rejected," finding that "L[i]n people with schizophrenia whose medication is changed for clinical reasons, there is no disadvantage across 1 year in terms of quality of life, symptoms, or associated costs of care in using FGAs rather than non-clozapine SGAS." Abramson Rep. 33.

B. New York Times Articles

In December 2006, the *New York Times* published a series of articles revealing confidential information obtained illegally from the Zyprexa MDL. *See* *In re Zyprexa Injunction,* 474 F.Supp.2d 385 (E.D.N.Y.2007). The articles raised questions

about Lilly's misleading the medical profession about the efficacy and safety of Zyprexa. *See* Alex Berenson, *Eli Lilly Said to Play Down Risk of Top Pill,* N.Y. Times, Dec. 17, 2006; Alex Berenson, *Drug Files Show Maker Promoted Unapproved Use,* N.Y. Times, Dec. 18, 2006; Alex Berenson, *Disparity Emerges in Lilly Data on Schizophrenia Drug,* N.Y. Times, Dec. 21, 2006.

XV. Events of 2007

A. FDA Requests Additional Information in Response to NYT Articles

***68** A few weeks later on January 12, 2007, the FDA contacted Lilly to request additional safety information regarding Zyprexa not previously disclosed to the agency:

> Recent articles in the New York Times reported on clinical trial data from 70 clinical trials on Zyprexa that showed patients taking Zyprexa experienced high blood sugar levels and weight gain that may have differed from information Eli Lilly revealed publicly and to the FDA....
>
> [W]e further request that you submit to the agency all data and information ... that bear on the safety of Zyprexa. In particular, we are interested in receiving data and analyses bearing on these concerns about weight gain and hyperglycemia that have not already been submitted to the agency. Additionally, if you are in possession of other information not specifically required to be submitted by statute or regulation, but that would nevertheless be useful to FDA in evaluating the safety of Zyprexa regarding these concerns of weight gain and hyperglycemia, we request that you please submit this information to us as well.

Regulatory Response: Response to the FDA Query Regarding the NYT Articles, Part 2. Lilly submitted its "Response to the FDA Query Regarding the New York Times Articles" in three parts between February and July 2007.

B. FDA Requests More Information for Lilly's Symbyax Supplemental NDA

In March 2007, the FDA raised additional questions about weight gain and hyperglycemia and suggested that Lilly has not been forthcoming with additional data. Lilly had submitted to the FDA in September 2006 a supplemental New Drug Application ("NDA") for approval to market Symbyax-a combination of Zyprexa (olanzapine) and Prozac (fluoxetine)-for Treatment Resistant Depression. *See* 2006 Physicians Desk Reference at 1820 (Symbyax combines Zyprexa and Prozac and is indicated to treat depressive episodes associated with bipolar disorder). Responding to this application in March 2007, the FDA stated:

> A primary concern with this application and the primary basis for our not taking a final action is our view that we lack important safety information needed to adequately update the labeling with all relevant risk information. In particular, we are concerned that the labeling is deficient with regard to information about weight gain, hyperglycemia, and hyperlipidemia that is associated with olanzapine use ... You must fully address these concerns before we will be able to take a final action on this application.

Letter: Thomas Laughren, FDA to Robin Pitts Wojcieszek, Eli Lilly & Co., Mar. 27, 2007. Laughren also mentions that, "Your recent February 20, 2007 response to our January 12, 2007 letter regarding the New York Times story has not been particularly helpful in addressing these concerns." Laughren goes on to state, "We do not feel that current labeling for either Symbyax of Zyprexa provides sufficient information on these risks, and we fully intend to insure that these labels are enhanced with the best available information to characterize these risks."

C. FDA Directs Zyprexa-Specific Label Change

***69** On August 28, 2007, the FDA directed Lilly to "make the labeling changes [delineated in the letter] pertaining to the effect of olanzapine and Symbyax on body weight, lipids, and glucose." The changes would affect labels for both Zyprexa and Symbyax. Continuing, the agency indicated that these would likely not be the last changes mandated:

> We anticipate that additional labeling changes will be necessary when we have reviewed the results of the additional analyses that we have requested. Given that your completing these analyses and our review of

> them will take some time, we believe that it is in the best interest of the public health to make interim labeling changes now based on the data that we already have available.

Letter: FDA to Robin Wojcieszek, Eli Lilly & Company, Aug. 28, 2007, labeled "ZYAK-AG20030164" and submitted in *State of Alaska v. Eli Lilly & Co.,* 3AN-06-06530, in March 2008.

The specified changes included adding information about hyperglycemia, weight gain, and hyperlipidemia to the WARNINGS section of the Zyprexa label. The FDA's proposed language regarding hyperglycemia focused on the risk:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including olanzapine.... Olanzapine (and clozapine) treatments have been associated with a greater potential to induce hyperglycemia than other atypical antipsychotics.

Id.

In response, Lilly proposed language that eliminated any reference to a causal relationship between olanzapine and hyperglycemia. The current Zyprexa label contains no reference to such a causal relationship:

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including Zyprexa.
>
> While relative risk estimates are inconsistent, the association between atypical antipsychotics and increases in glucose levels appears to fall on a continuum and olanzapine appears to have a greater association than some other atypical antipsychotics.

Letter from Eli Lilly, Oct. 8, 2007, *In re Zyprexa Prod. Liab. Litig.,* Docket No. 04-MD-1596,

Docket Entry No. 1424. For the first time, Zyprexa's label now acknowledges that the drug is associated with high blood sugar *more than* other SGAs, but it does not appear to note that the drug is associated with diabetes more than other SGAs. *See* Alex Berenson, *Lilly Adds Strong Warning Label to Zyprexa, a Schizophrenia Drug,* N.Y. Times, Oct. 6, 2007.

Lilly continues to deny a causal relationship exists between Zyprexa and high blood sugar and Zyprexa and diabetes. As the company's Director of United States Regulatory Affairs testified in March 2008,

> Q: But you took about-you took out any reference to language that indicates a causal relationship?
>
> A: We-we did not include that in our proposal.
>
> ***70** Q: Okay. And, in fact, to this day, Lilly denies that olanzapine can induce or cause hyperglycemia, correct?
>
> A: We don't feel that the-that we have data to support that particular statement FDA included.

Testimony of Robin Wojcieszek, R.Ph., Assoc. Director of U.S. Regulatory Affairs for Lilly, entered into evidence on March 11, 2008 in *State of Alaska v. Eli Lilly & Co.,* 3AN-06-06530.

The new label also indicates that patients taking Zyprexa may continue to gain weight for as long as two years after starting therapy; one in six patients who take Zyprexa will gain more than 33 pounds after two years of use. *See* Alex Berenson, *Lilly Adds Strong Warning Label to Zyprexa, a Schizophrenia Drug,* N.Y. Times, Oct. 6, 2007

D. Change in TMAP Formulary

In November 2007, the Texas Medication Algorithm Project ("TMAP") issued a revised consensus judgment by leading experts suggesting that there is no advantage for chronic schizophrenics of SGAs over FGAs-reversing its earlier judgment on the basis of CATIE and other studies. *See* Rosenheck Supp. Decl. 7.

XVI. Pharmaceutical Distribution

Pharmaceutical companies often employ private manufacturers to produce medicine; collectively they provide 64% of all pharmaceuticals directly to wholesalers for distribution. Cong. Budget Office, 110th Cong., Prescription Drug Pricing in the Private Sector, 5 fig. 2 (Jan.2007) ("CBO Paper"); Kolassa Decl. 2. Wholesalers and pharmaceutical manufacturers send drugs to retail and nonretail providers, who then supply them to consumers. CBO Paper 1. (Examples of non-retail providers include hospitals, health maintenance organizations (HMOs), clinics, etc.). "Consumers obtain about three-quarters of their prescription drugs from retail pharmacies and the remainder from nonretail providers." *Id.*

In order for this system to operate, three separate sets of price negotiations must take place: (1) retail pharmacies and nonretail providers negotiate with pharmaceutical manufacturers and wholesalers, (2) payors (often through PBMs) negotiate with pharmaceutical manufacturers and wholesalers, and (3) payors negotiate with retail pharmacies and nonretail providers. *See id.* at 2. PBMs pass through or share the rebate negotiated with the manufacturers with their clients, in accordance to the terms of their contracts. Decl. of Edward Adamcik ("Admacik Decl.") ¶ 18; Decl. of Myron D. Winkelman, R.Ph. ¶ 38, Feb. 7, 2007, Docket Entry No. 90 ("Winkelman Decl."). Manufacturers pay rebates based on the volume of the medications reimbursed. Adamcik Decl. ¶¶ 11-12; CBO Paper 7.

For Zyprexa the matter was simpler, since there were relatively few rebates available. Records will permit computation of what "overcharges" found by the jury involved those standard rebates.

A. Pharmacy Benefit Managers ("PBMs")

Plaintiffs tendered two expert witnesses concerning PBMs, Terry D. Leach and Myron D. Winkelman. Decl. of Terry D. Leach, Pharm.D., Jan. 11, 2007, Docket Entry No. 89 ("Leach Decl."); Dep. of Terry Leach, Apr. 4, 2007 ("Leach Dep"); Winkelman Decl. ¶ 8; Dep. Tr. of Myron D. Winkelman, R.Ph., Apr. 12, 2007 ("Winkelman Dep"). Additionally, Plaintiffs' expert Richard G. Frank described how PBMs fit into the overall scheme of institutions that influence prescribing of anti-psychotic medications. *See* Decl. of Richard G. Frank, Ph.D., Jan. 8, 2008, Docket Entry No. 148 ("Frank Decl").

1. Expert Witnesses

a. Myron Winkelman, R.Ph.

***71** Plaintiffs' expert Mr. Winkelman is a registered pharmacist with over eighteen years of service as a Senior Pharmacy Executive for a large retail drug store chain, eight years of MIS experience with retail pharmacies and experience working directly as a Senior Manager with a large PBM. *See* Winkelman Decl.

Mr. Winkelman opined that: (i) PBMs do not influence physicians to prescribe any particular drug for a specific condition; (ii) PBM formularies generally include atypical antipsychotic drugs such as Zyprexa because PBM Pharmacy & Therapeutics ("P & T") Committees are loath to interfere with the plan of care for plan recipients with severe, persistent mental illness; (iii) Pharmaceutical and Therapeutics Committees of PBMs do not place drugs on their formularies for therapeutic uses that are not approved by the FDA; and (iv) P & T Committees are reactive and not proactive in their deliberations-they perform no independent clinical or laboratory work; their deliberations are based on the information provided by the drug manufacturers about their products. *See id.*

Lilly did not file a *Daubert* motion with respect to Mr. Winkelman. In any event, he met *Daubert* standards. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

b. Terry D. Leach, Pharm.D.

Plaintiffs' expert Dr. Terry D. Leach, Pharm.D, has had key roles throughout his career in formulary management and on the P & T Committees of PBMs. He has held senior management positions in managed care pharmacy at firms such as Horizon BlueCross and BlueShield of NewJersey and Mid Atlantic Medical Services and as a consultant. He has served as a P & T vice chairman, developed and presented drug monographs to P & T Committees, created formulary kits and dossiers, and attended major PBM P & T meetings. *See* Leach Decl. 2-3.

Dr. Leach declared that third-party payors who offer prescription drug benefits rely upon their contracted pharmacy benefit manager to develop and maintain a sound prescription drug benefit. In turn, PBMs maintain the formulary management system based upon publicly available clinical information which itself is largely derived from the drug manufacturers. As a result, in situations where relevant

accurate clinical data are not made available by the drug manufacturers, the P & T committee formulary decisions recommending covering of medications may not be in the best interests of the TPP or the beneficiaries. *See id.*

Lilly did not file a *Daubert* motion with respect to Dr. Leach. He met *Daubert* standards. *See* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

c. Richard G. Frank, Ph.D.

Plaintiffs expert Dr. Richard Frank is the Margaret T. Morris Professor of Health Economics at Harvard University Medical School. *See* Frank Decl. He provided an overview of the institutions that influence prescribing of anti-psychotic medications, focusing on how institutions such as PBMs and public and private health insurance institutions affect the prescribing of antipsychotic agents. Included in his expert opinion was the role of formularies and physician prescribing practices. *See id.* at 2.

***72** People with major mental disorders such as schizophrenia and bipolar disorder are often disabled from work. Many are eligible for public health insurance. *Id.* at 4. As a result, a large percentage-70% to 80%-of sales of antipsychotic drugs in the United States are to Medicaid and Medicare. *Id.* at 4 (citing R.G. Frank, R.M. Conti & H.H. Goldman, *Mental Health Policy and Psychotropic Drugs,* Milbank Quarterly 83(2):271-298 (2005)). Thus, most patients prescribed antipsychotic medications pay little or no out-of-pocket costs; drug choice is driven by physician advice based on information that flows to doctors rather than patients. *Id.* at 5.

The ultimate consumer's role in mental health care is especially weak, either through inability to participate in decision-making or because of influence or coercion by others. *Id.* at 5 (citing Institute of Medicine, Improving the Quality of Health Care for Mental and Substance-Use Conditions (2006)). Moreover, little information about comparative effectiveness is readily available in a user-friendly form. *Id.* (citing S.J. Tannenbaum, *Evidence-Based Practice as Mental Health Policy: Three Controversies and a Caveat,* Health Affairs 24(1): 163-73 (2005)).

The terms of drug coverage as defined by health insurance plans and utilization controls potentially affect most consumer choices of antipsychotic drugs-to the extent that patients really choose. *Id.* at 6. As noted earlier, most public and private health insurance plans are reluctant to place effective restrictions on the ability of physicians to prescribe particular antipsychotic medications. As a result, third-party payors, including Medicare and Medicaid, do not place strong restrictions on the use antipsychotic medications. *Id.* at 4. State Medicaid plans, for example, frequently exempt antipsychotic drugs from preferred drug lists and prior authorization provisions. *Id.* at 7 (citing C. Koyanagi, S. Forquer, & E. Alfano, *Medicaid Policies to Contain Psychiatric Drug Costs,* Health Affairs 24(2):536-44 (2005)). While most physicians-especially those providing Medicaid and Medicare services-may more or less freely choose among SGAs, this unfettered discretion, when combined with the preservers' difficulty in obtaining reliable information about new drugs, has led to overprescribing, particularly among such patient populations as children and the elderly. *Id.* at 8-9.

Dr. Frank summarized the effect of lack of candid information to the prescriber who can be influenced by inappropriate and incomplete anecdotal information:

> Because schizophrenia and bipolar disorders are severe illnesses and create much disability, large portions of the people that suffer from these illnesses are supported by public programs (SSI/DI). This means that antipsychotic medications are overwhelmingly purchased by public health insurance programs. The vulnerability of people with severe mental illnesses has led policy makers to exercise great caution in the application of utilization and cost controls to the treatments for schizophrenia and bipolar disorders. The result is that formulary designs and utilization controls under the Medicare and Medicaid programs allow for a great deal more flexibility in clinical decision making than occurs for many other illnesses. The implication of this flexibility is that physicians treating severe mental disorders have relatively wide discretion in making treatment recommendations.

***73** Obtaining information on the range of new treatments has long been a difficult task for most physicians. The physician's practice environment has only become more complex over time. Psychiatrists, it appears, rely little on decision supports such as guidelines and electronic prescribing to aid them in making therapeutic choices. Thus, it appears that they rely on less systematic influences in making choices. This may result in raising the importance of casual recommendations from colleagues, past experiences with drugs, promotional information from companies and their own trial and error. Thus, in the area of antipsychotic medications, there is a wide set of influences

that may drive treatment choices and these extend beyond institutions that can apply evidence based principles to the management of care.

Id. at 9-10 (internal citation omitted).

2. Generally

Plaintiffs' experts offered only general, and not case-specific, testimony about the PBM industry and how PBMs operate. Leach Dep. 27, 202-06, 224-25, 236-41, 264-67; Winkelman Dep. 17-19, 24. Both agreed that the descriptions of PBM operations presented in the affidavits and deposition from the PBMs for the payors in this case are consistent with their understanding of how PBMs operate. Winkelman Dep. 23; Leach Dep. 170-71.

Many health insurance plans contract with companies known as Pharmacy Benefit Managers ("PBMs"). Winkelman Decl. ¶ 8. "PBMs manage pharmacy benefits on behalf of their clients, which include health plans, HMOs, and self-insured employer-based plans." CBO Paper 10. PBMs handle such tasks as collecting **funds** from health plans and using those **funds** to pay network pharmacies, process claims, answer questions as to coverage parameters, and negotiate with drug companies. Winkelman Decl. ¶ 9; *see also* Leach Dep. at 32-34. PBM services include the management of formularies and rebates.

PBMs administer drug plans for more than 210 million Americans. Br. for Pharm. Care Mgmt. Ass'n as Amicus Curiae Opposing Proposed **Settlement** 5, *New England Carpenters Health Benefits **Fund** v. First Databank, Inc.*, No. 05-CV-11148 (D.Mass. Dec.20, 2007). They exert a major influence on the economics of the pharmaceutical industry. Winkelman Dep. 80-85. "PBMs are the 800-pound gorillas of pharmaceutical reimbursement." *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 71 (D.Mass.2005).

Offered by PBMs are expertise in the management of pharmacy benefits, providing services such as formulary development, negotiations with pharmaceutical companies, rebate management, and claims processing. Winkelman Decl. ¶¶ 9, 11-12. They are essentially administrators of prescription drug benefits. Through their contracts with companies and **funds** offering healthcare plans they cover millions of patient "lives" and manage about seventy-five percent of all outpatient drug claims. *Id.* at ¶¶ 9, 11. They create and maintain a preferred drug list known as a formulary. A formulary is a list of drugs that are covered under the benefit provided by the health plan. *Id.* at ¶ 13; *see also* Dep. of Raulo Frear (on behalf of PBM Express Scripts), Nov. 18, 2006 ("Express Scripts Dep.") 36:23-37:13; *see also* Leach Decl. 1-2.

***74** The process for selecting drugs for placement on a formulary begins with a PBM's P & T Committee. Winkelman Decl. ¶ 14. P & T Committee members include physicians and clinical pharmacists. *Id* . The P & T Committee makes recommendations concerning which drugs should be included or excluded from the PBM's formulary. *Id.* PBM P & T Committees do not place drugs on their formularies for therapeutic uses that are not approved by the FDA. *See id.* at ¶ 3.

Theoretically, the P & T Committee acts to ensure the drug's safety and efficacy; their primary focus, however, remains on rebates and economic efficiency. *See* Winkelman Dep. 71-72. The health plan sponsors, or TPPS, that contract with the PBMs for prescription benefit management generally have little expertise in this complex area and tend to rely fully on the PBM and its formulary decisions. *See* Winkelman Decl., ¶ 20; *see also* Local 28 Dep. 61:17-62:4; UFCW Dep. 90:24-91:19; *see also* Leach Dep. 33:19-34:24. They tend to adopt without question or change the formulary recommendations provided to them by their PBM and indeed did so in this case. *See* Winkelman Decl., ¶ 20; *see also* Local 28 Dep. 61:17-62:4; UFCW Dep. 90:24-91:19. While TPPs do have the authority to decide which drugs they will cover and to reject the suggestions of their PBM, this power is almost never used given that TPPs rely upon their PBMs to offer guidance. *See* Decl. of Keith Bradbury (on behalf of PBM Medco) ("Medco Decl.") ¶¶ 8-10; *see also* Decl. of Marsha Moore (on behalf of PBM Caremark) ("Caremark Decl.") ¶¶ 7-8; Leach Dep. 33:19-34:24.

Even where a TPP chooses to customize its formulary, it typically does so in consultation with the PBM's P & T Committee. *See* Medco Decl. at ¶ 9; *see also* Caremark Decl. ¶ 8. TPPs that do some customization generally rely on the PBM's existing relations for rebates with drug manufacturers. *See* Winkelman Decl. ¶ 20. It is typical for the terms in the agreements between PBMs and their client TPPs to prevent the client TPP from negotiating on its own with drug manufacturers. *See id.* When developing a drug formulary, P & T Committees do not conduct clinical research, review

or laboratory analysis on drugs. *See* Leach Decl. 2; *see also* Winkelman Decl. ¶ 32.

In short, although PBMs administer prescription drug benefits, including processing prescriptions, they act as middlemen in the prescription drug benefit process, *see* Winkelman Dep. 122:25-123:3, and do not influence the prescribing of particular drugs to particular patients. *See* Winkelman Decl. ¶ 1.

As a result of this passivity, doctors can prescribe for a condition whatever medication they think fit, with no input from the PBM. *See id.* at ¶ 43. Once a drug is on the formulary, the PBM exerts no control over whether a particular drug is used for any particular condition. *See id.* PBMs have insufficient control to permit their limiting the use of a particular medication to FDA-approved uses. *See* Winkelman Dep. 15:1-12. When considering formulary placement of a particular prescription drug, P & T Committees generally limit their discussions to approved uses of a drug. *See* Medco Decl. ¶¶ 18, 37, 48; *see also* Caremark Decl. ¶¶ 37, 38, 40, 47; Winkelman Dep. 103:14-23. Moreover, once a drug is on the formulary, a PBM will take no position on whether one drug is better than another. *See* Express Scripts Dep. 46:18-22. While PBM P & T Committees do not place drugs on their formularies for therapeutic uses that are not approved by the FDA, *see* Winkelman Decl. ¶ 32; Leach Decl. 2, once on their list of drugs the TPP will pay for, P & T Committees do not make determinations of appropriate off-label drug uses. *See* Leach Decl. 2.

***75** PBM P & T Committees rely on the clinical pharmacy departments of PBMs to present the most up-to-date information available to the public. *See id.* This publicly available clinical information is derived from the drug manufacturers, who are generally the only elements of the industry other than the FDA that have all such data. *See id.*

As with all new drug launches, there is rarely any information available in the public domain-journal articles, abstracts from professional meetings, and the product's label, which is typically limited to information that the drug company chooses to share. *See id.* This clinical information, primarily provided by the drug manufacturers, sets the foundation for sound formulary development and management. *See id.; see also* Winkelman Decl. ¶¶ 30-32.

PBM formularies generally include atypical antipsychotic drugs such as Zyprexa because PBM P & T Committees are unwilling to interfere with the plan of care for individuals with severe, persistent mental illness. *See* Winkelman Decl. ¶ 19. PBMs generally believe that all atypicals should be available for patients for whom this class of drugs may be prescribed. *See* Medco Decl. ¶ 49; *see also* Caremark Decl. ¶ 48; Express Scripts Dep. 74:10-12.

Other rationales for providing access to all available drugs in a class is that the diseases they treat are serious; most prescribing for these drugs is done by highly trained and board certified specialists; results are highly variable; and even small deviations in drug therapy can be either harmful or helpful to patients. Winkelman Decl. ¶ 19. The nature of atypical antipsychotic medicine and the diseases for which they are prescribed have led to an industry-wide consensus that the formulary include all such drugs, with no hindrances, such as prior approval or step therapy, leaving doctors' with the widest discretion to prescribe the drug they deem most appropriate. *See* Winkelman Dep. 82.

There are limited occasions where PBM P & T Committees approve a therapeutic interchange program for a particular pharmaceutical. A therapeutic interchange program requires that one drug of a class is preferred over a different pharmaceutical in the same class. *See* Winkelman Decl. ¶ 24. A PBM may then suggest an alternative pharmaceutical to a physician who prescribes a prescription drug that is the subject of a therapeutic interchange program. *See* Medco Decl. ¶ 14; Caremark Decl. ¶ 14.

"Step therapy" is another possible limitation a PBM may rarely place upon a prescription. Rules are established by the PBM that mandate the sequence in which patients must try drugs. *See* Winkelman Decl. ¶ 28. If the clinical results are not satisfactory with the first alternative drug, the patient is then allowed access to another prescribed drug. *See id.* Step therapy programs are not, however, used for atypicals. *See* Express Scripts Dep. 104:25-105:3; *see also* Winkelman Dep. 111:7-l 12:10. Express Scripts never had a step therapy for any atypical antipsychotic. Express Scripts Dep. 104:20-24. Mr. Winkelman testified he has never seen a client implement a prior authorization or step therapy program for an atypical. *See* Winkelman Dep. 116-19:-117:3.

***76** Neither the P & T Committee nor the PBM tracks "off-label" use of a drug or has the ability to do so. *See* Medco Decl. ¶ 19; *see also* Caremark Decl. ¶¶ 17, 19; Winkelman Dep. 103:9-13. When a prescription is supplied to a retail pharmacist or a PBM mail-order facility, the information

provided is limited and generally includes only the drug, dose, and other limited information about the prescription. *See* Medco Decl. ¶ 19; *see also* Caremark Decl. ¶¶ 17, 19. The prescription does not contain a diagnostic code. *See* Express Scripts Dep. 86:18-87:18, 90-17:22. Because there is no diagnosis provided with the prescription information, PBMs are unable to record the indication for which a drug is prescribed. *See id.* The individual physician who prescribed the drug alone knows why the particular drug was prescribed. *See* Medco Decl. ¶ 20; *see also* Caremark Decl. ¶ 18; Winkelman Dep. 103:24-104:2.

A PBM can follow off-label use of a drug only when it is prescribed pursuant to a prior authorization program. *See* Winkelman Dep. 15:11-17. A prior authorization program requires approval of a prescription by the PBM before a prescription is filled. *See* Express Scripts Dep. 99:9-19; *see also* Winkelman Decl. ¶ 24. Prior authorization programs have little overall impact on the number of additional off label prescriptions written for Zyprexa because they are limited to less than two percent of prescriptions. *See* Winkelman Dep. 106:25-107:8. A prior authorization process is quite burdensome so it is utilized judiciously. Winkelman Decl. ¶ 25. In the real world, the process is impractical. *See* Winkelman Dep. 107:21-108:5. All major PBMs agree that prior authorization programs for atypicals are not appropriate. Medco Decl. ¶¶ 44, 49-50; *see also* Caremark Decl. ¶ 48; Express Scripts Dep. 101: 12-20.

At the end of the day, it is the manufacturer who decides what their drug is going to be sold for. *See* Winkelman Dep. 118:22-24. The relationship between their the Plaintiff TPP and the PBMs is that of contracting out a service, with the TPPs remaining ultimately responsible for the cost of prescriptions and for looking out for the well-being of their members, but relying totally on the expertise of the PBMs for the activities of creating the formularies and operation of the P & T committees in so doing. *See* Winkelman Decl. ¶ 20; *see also* Local 28 Dep. 59:10-24; UFCW Dep. 84:12-85: 3; Midwest Dep. 111:7-14.

3. Plaintiffs'PBMs

During the relevant time period, each of the named payor plaintiffs engaged PBMs to administer the prescription drug benefit they provide to their insureds. *See, e.g.,* Mid-West's Resps. to Interrogs., First Set at No. 1; UFCW's Resps. to Interrogs., First Set at No. 1; Local 28's Resps. to Interrogs., First Set at No. 1; SBA's Resps. to Interrogs., First Set at No. 1. These PBMs include Caremark, Inc. ("Caremark"), used by Mid-West and SB A; Express Scripts, Inc. ("Express Scripts"), used by UFCW; and Medco Health Solutions, Inc. ("Medco"), used by Mid-West. Mid-West's Resps. to Interrogs., First Set at No. 1; UFCW's Resps. to Interrogs., First Set at No. 1; Local 28's Resps. to Interrogas., First Set at No. 1. These three PBMs dominate the industry and manage over half of all retail prescriptions. Winkelman Decl. ¶ 11.

***77** During the instant litigation, both parties conducted discovery of these three PBMs. Each PBM produced documents related to Zyprexa. Caremark provided an affidavit, Caremark Decl., Express Scripts provided deposition testimony and an affidavit, Express Scripts Dep.; Affidavit of Rodney Gerald Wilson ("Wilson Aff."), and Medco provided two affidavits. Adamcik Decl.; Medco Decl. Lilly also conducted two depositions of National Medical Healthcard Systems, Inc., which provides PBM services to UFCW.

For Zyprexa, Caremark, Express Scripts and Medco each reviewed the medicine soon after its entry onto the market and each placed it on their respective formularies. Medco Decl. ¶ 41; Caremark Decl. ¶ 41; Express Scripts Dep. 40-41. Zyprexa was subject to later review by each PBM. Medco Decl. ¶¶ 43-44; Caremark Decl. ¶¶ 42, 49; Express Scripts Dep. 133-35. Each PBM considered and was aware of the side effect profile of Zyprexa and other atypical antipsychotics well before the September 2003 label change. Medco Decl. ¶¶ 43-44; Caremark Decl. ¶¶ 42, 49; Express Scripts Dep. 133-35. In fact, Caremark sent communications to physicians addressing topics related to the side effects of atypical antipsychotics. Caremark Decl. ¶ 49.

In addition to removing a medicine from the formulary, a P & T Committee may remove it from "preferred" status, impose prior authorization or initiate step therapy. Leach Dep. 148-50; Winkelman Dep. 73-74. For example, Express Scripts addressed safety concerns with Geodon by determining that it was not required to be listed on the formulary. Express Scripts Dep. 22, 46.

Zyprexa was on all the major PBM standard formularies. *See* Medco Decl. ¶ 41; *see also* Caremark Decl. ¶¶ 41, 44; Express Scripts Dep. 41:6-18; Rosenthal Decl. 13. Because Zyprexa is an atypical antipsychotic, most P & T Committees added the medication to their PBM's drug formularies, with or without restrictions, based solely upon the drug's classification and the information provided by Lilly. *See* Leach Decl. 7. Dr. Frear

testified that, to his knowledge, all his clients had Zyprexa on their formularies. Express Scripts Dep. 42:23-43:3, 60:9-14.

None of the nation's largest PBMs has a therapeutic interchange program for Zyprexa. *See* Medco Decl. ¶ 49; *see also* Caremark Decl. ¶ 48; Express Scripts Dep. 74:10-12. The P & T Committee never considered a therapeutic interchange program for Zyprexa. *See* Medco Decl. ¶ 49; *see also* Caremark Decl. ¶ 48; Express Scripts Dep. 74:10-12. Dr. Frear, of Express Scripts, testified that he did not recall any conversations among the clinical group about off-label uses of atypical drugs. *See* Express Scripts Dep. 132:23-133:1. None had a prior authorization program for Zyprexa. Medco Decl. ¶¶ 44, 49-50; *see also* Caremark Decl. ¶ 48; Express Scripts Dep. 101: 12-20. None considered a prior authorization program for any atypical or instituted a prior authorization for Zyprexa at the request of any client. Express Scripts Dep. 100: 4-11.

***78** Despite having several options to respond to safety concerns related to a medication, only one of the PBMs-Express Scripts, on behalf of plaintiff UFCW-has relatively recently taken any of these actions in regard to Zyprexa. Express Scripts now, for UFCW members, requires prior authorization, instituted at UFCW's request.

B. Health Insurance

The prescription pharmaceutical market is unique because of the widespread presence of insurance coverage. In 1996, 77% of non-elderly Americans had drug coverage, and in 2001, 64% of Medicare recipients had prescription drug coverage through either a commercial or public insurance plan (e.g., Medicaid). In 1996, nearly 70% of all prescription drug spending was paid for by insurance. Rosenthal Decl. 12.

The relatively small share of prescription drug spending that is paid for out-of-pocket by consumers reflects the prevalence of fixed dollar copayments as the most common form of cost sharing. Because copayments only represent a small share of the full retail price of a drug, patients and their physicians are relatively insensitive to the prices of prescription drug therapies. See chart below summarizing doctors' attitudes; Rosenthal Decl. 12.

Third-party payors who cover most spending for drugs, including the majority of Zyprexa costs, usually exert only indirect control over therapeutic choice. They are under pressure from patient groups and doctors to offer generous coverage for drugs that treat serious conditions such as schizophrenia and bipolar disorder, particularly in light of concerns about the potential for restrictions on access to medication to cause overall increases in medical spending.

The potential for formularies to combat or challenge the impact of high prices on spending is extremely limited. While patients may cut back on medications, switch to generics, and use mail order service in the face of higher and tiered copayments, prescription drug spending and costs are relatively inelastic. Pricing for drugs like Zyprexa is unresponsive to cost-sharing or any effective pressures of TPPs or their agents. Rosenthal Decl. 13.

While some controls have been imposed by TPP health insurers they have had little effect on doctors' prescription of antipsychotics since restrictions are minimal and do not, in general, encourage doctors to use one drug rather than another.

Tier Status of Selected Antipsychotics

	Zyprexa	Abilify	Geodon	Seroquel	Risperdal	Invega
Plan	Tier-Restrictions	Tier-Restrictions	Tier-Restrictions	Tier-Restrictions	Tier-Restrictions	Tier-Restrictions
Aetna	2nd tier-QL	3rd tier-QL	3rd tier-QL	2nd tier-QL	3r d tier-QL	3rd tier-QL / ST

Aetna: Medicare Part D	2nd tier	3rd tier-QL / ST	3rd tier-QL / ST	2nd tier-QL	2nd tier-QL	3rd tier-QL / ST*
CIGNA	2nd tier	3rd tier	3rd tier	2nd tier	2nd tier	3rd tier
Harvard Pilgrim	2nd tier	2nd tier	2nd tier	2nd tier	2nd tier	3rd tier
Humana	2nd tier / DL	2nd tier / DL	2nd tier / DL	2nd tier / DL	2nd tier / DL	2nd tier / DL
Humana: Medicare Part D	2nd tier / QL	2nd tier / QL	2nd tier / QL	2nd tier / QL	2nd tier / QL	2nd tier / QL*

KEY:

DL-Dispensing Limit (There is a limit on coverage based on the length of time or amount that can be dispensed for this medication to ensure the appropriate dose and usage based on the FDA label recommendations.)

QD-Quantity Duration

QL-Quantity Limits

ST-Step Therapy

C. Doctors

***79** The prescription pharmaceutical market is unique because the consumers of the product-patients-are not free to choose the medicines they take. Prescription drugs, unlike typical commodities, can only be purchased under a physician's oversight. Thus, physicians act as a trusted intermediary-a learned gatekeeper-in prescription drug (and all health care) decision making. While patient preferences play a role in the choice of therapy, physicians have enormous influence over health care decisions, particularly for serious medical conditions. Professional norms require physicians to use their clinical skills, knowledge and experience to make therapeutic choices that are in the best interest of their patients. Rosenthal Decl. 11.

While the pharmaceutical companies, PBMs and third-party payors play an integral role in the delivery of prescription medicine, doctors are bestowed with the last and most important judgment: whether a particular patient should be treated with a particular medicine.

Physicians obtain and review clinical information about prescription medicine from a variety of different sources, including medical literature, medical school, continuing medical education, professional meetings, guidelines, algorithms, the FDA, exchanges between colleagues, their own experience using the medication, and factors specific to their individual patients, as well as pharmaceutical marketing from manufactures and competitors. Kahn Report 5; Wirshing

Dep. 160-65; Schneider Dep. 188-90, 194-99; Klotz Dep. 197-99. In practice they face numerous constraints including limited time and cognitive ability to digest the continuous enormous flow of information about available treatments. Physicians are often not aware of the latest scientific evidence on appropriate regimes. They rely heavily on commercial sources of information, such as pharmaceutical company promotional materials. Rosenthal Decl. 11.

Doctors typically choose treatments based on what works best for each individual patient, not on the relative costs of the medications. Kahn Report 8; Schneider Dep. 190-94; Harris Dep. 93-95; Rosenthal Dep. 93. The price of a medicine plays little role in the prescription decision. Kolassa Decl. 9. Physicians are generally unaware of the price of the products they prescribe. *Id.* at 10 (citing various research studies).

They are expressly granted freedom to prescribe medication as they deem appropriate. *See* Food & Drug Admin., *Use of Approved Drugs for Unlabeled Indications,* 12 FDA Drug Bulletin 4, 5 (1982); *Washington Legal Found.,* 202 F.3d at 333 (D.C.Cir.2000); Expert Rep. of John Abramson ¶ 65, M.D., Feb. 28, 2007, Docket Entry No. 97 ("Abramson Rep"). Off-label prescribing is an important function of a physician, and can benefit both individual patients and patient populations as clinical experience leads to the formation of hypotheses to be tested in structured clinical trials. There is justified concern over the extent of off-label prescribing and the potential for waste or even patient harm that may result when drugs are prescribed for uses with little or no scientific support. Rosenthal Decl. 11. FDA regulations attempt to protect off-label prescribing from commercial influences because of the potential conflict between what is best for the patient and what is best for the pharmaceutical manufacturer. *Id; see* Part V.E, *supra.*

***80** Physicians are reluctant to change a patient's medication in light of safety concerns if the medication appears to be helping the patient, as Dr. Harris testified regarding this phenomenon of persistence:

> [T]he clinical community doesn't immediately adopt or discontinue-a recommendation or immediately discontinue a drug, although these consensus or blue ribbon reports can sometimes have a great impact. And one of the reasons is a well-known phenomenon which is basically called persistence. There are patients and doctors who believe that a drug is working and they stay with the drug. There are some doctors who may have heard about the report, but they are busy and maybe they read an article, maybe a colleague has mentioned it to it. But the idea of instantaneously changing clinical practice does occur in some cases, but in many cases it's gradual as the information continues to diffuse.

Tr. at 250 (Mar. 29, 2008: Harris)

Analysis of Zyprexa Prescriber Depositions

Type of Doctor	Total Number of Doctors in Sample	"I weigh the risks and benefits of drugs when making prescription decisions"	"I rely on multiple sources of information about drugs when making prescription decisions."	"I am visited by Zyprexa sales representatives	"My decisions to prescribe is not impacted by price."		"My decision to prescribe is not impacted by PBMs, formularies, and/or health plans."
					Yes	No	

Psychiatrist	46	45	45	42	42	4	46
Primary Care	15	13	11	13	15	0	15
Nurse Practitioner	1	1	1	1	1	0	1
Other (Physician's Assistant, Psychopharmacologist)	2	2	2	2	2	0	1
Family Practitioner	4	2	2	2	4	0	4
TOTAL	68	63	61	60	64	4	68

Analysis of Sales Representative Depositions

Type of Sales Rep	Total Number of Sales Reps in Sample	Promoted Zyprexa as a Mood Stabilizer	Told doctors the risks of diabetes/ weight gain are the same for all atypicals	Told prescribers Zyprexa treats symptoms of anxiety, agitation, and/ or irritability	Used patient profiles, including Donna, Marty, Melvin	Used the MDQ, help to rule out bipolar first (ROBF)	Told prescribers about Lilly weight loss tools, such as "Solutions for Wellness"	Only gave prescribers information that came directly from Lilly
Primary Care & Pediatrician	5	1	3	2	5	5	4	4
Psychiatrists	11	9	9	6	7	0	9	11
TOTAL	16	10	12	8	12	5	13	13

Analysis of Prescriber-Specific Zyprexa Call Notes

Type of Prescriber	Total Number of Prescribers in Sample	Lilly Promoted Zyprexa as a Mood Stabilizer	Lilly said the risks of diabetes/ weight gain	Told prescribers Zyprexa treats symptoms of anxiety, agitation,	Used patient profiles, including Donna, Marty, Melvin	Used the MDQ of DIGFAST, encouraged me to	Lilly Told prescribers about Lilly weight loss tools,

			are the same for all atypicals	and/or irritability		rule out bipolar first (ROBF)	such as "Solutions for Wellness"
Primary Care & Pediatrician	7	7	0	5	7	7	1
Psychiatrists	30	26	19	14	19	4	23
TOTAL	37	33	19	19	26	11	24

D. Patients

***81** It is axiomatic that in the community treating psychiatric disorders that "different people respond differently to different psychotropic drugs." Frank Decl. ¶ 7. The different antipsychotic medications work differently for different patients. *Id.* ("different people respond differently to different psychotropic drugs"); Kahn Report 8; Harris Dep. 66, 79-80. This variation in reactions is particularly important with respect to patients suffering from schizophrenia and bipolar disorder, where psychiatrists often employ "trial and error" to determine the best medication for the patient. Frank Decl. ¶¶ 7, 18. For some patients, Zyprexa is the most effective medication. Kahn Report 8; Wirshing Dep. 156-58, 160-62; *see, e.g.,* Elyn R. Saks, The Center Cannot Hold: My Journey Through Madness 303 (2008).

XVII. Evidentiary Hearing Expert Testimony

A. Plaintiffs' Witnesses at Hearing

Plaintiffs proffered six witnesses at the evidentiary hearing on the certification issue: (1) Dr. Robert Rosenheck, *In re Zyprexa Prods. Liab. Litig.* Transcript of Evidentiary Proceedings on Class Certification ("Tr."), March 28, 2008 through April 2, 2008 at 7-80; (2) Dr. Meredith Rosenthal, Tr. at 82-191 (Mar. 28, 2008); (3) Dr. Jeffrey Harris, *id.* at 204-343 (Mar. 29, 2008); (4) Dr. William Wirshing, *id.* at 349-463 (Mar. 31, 2008); (5) Dr. Lon S. Schneider, *id.* at 464-549 (Mar. 31, 2008); and (6) Dr. John Abramson, *id.* at 708-806 (Apr. 1, 2008). All met *Daubert* and Federal Rule of Evidence 702 standards: "(1) the[ir] testimony is based upon sufficient facts or data, (2) the[ir] testimony is a product of reliable principles and methods, and (3) [they] ha[ve] applied the principles and methods reliability to the facts of the case." Fed.R.Evid. 702; *see* *Daubert v. MerrellDow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); *see also* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571 (E.D.N.Y.2007) (denying summary judgment); *In re ZyprexaProds. Liab. Litig.,* 493 F.Supp.2d 571 (E.D.N.Y.2007) (at Part IV, outlining criteria for meeting *Daubert* requirements).

1. Robert Rosenheck, M.D.

Dr. Rosenheck is a Professor of Psychiatry, Epidemiology and Public Health at Yale University School of Medicine and the Yale Child's Study Center. Decl. of Robert Rosenheck, M.D., at 2, Jan. 9, 2007, Docket Entry No. 87 Ex. 5 ("Rosenheck Decl"). For twenty years, he has been the Director of the Department of Veterans Affairs ("VA") Northeast Program Evaluation Center ("NEPEC"), a national arm of the VA Central Office in Washington. *Id.* at 3. In that capacity, he is responsible for monitoring and evaluating mental health initiatives in the United States Veterans Health Administration, which provides mental health services to 900,000 veterans annually. *Id.*

Board-certified in psychiatry, Dr. Rosenheck has devoted himself full-time since 1988 to mental health services research focusing "on the evaluation of treatments used in 'real world' clinical settings and their implications on policy." *Id.* He has authored or coauthored over 400 articles, *id.,* and published the results from three major studies of the cost-effectiveness of antipsychotic medications, including the VA Cooperative Study 451 and CATIE, which he conducted and oversaw as lead investigator. *Id* . at 5.

***82** At the evidentiary hearing, Dr. Rosenheck testified substantially as set forth in his three previous declarations. Tr. 8 ff. (Mar. 28, 2008); *see* Rosenheck Decl.; Rebuttal Decl. of Robert Rosenheck, M.D., Apr. 5, 2007, Docket Entry No. 164 attmt. B ("Rosenheck Rebuttal"); Supp. Decl. of Robert Rosenheck, M.D., Mar. 17, 2008, Docket Entry No. 161 Ex. B (Rosenheck Supp. Decl."). Lilly did not file a *Daubert* motion with respect to Dr. Rosenheck.

To a reasonable degree of medical and scientific certainty, it is Dr. Rosenheck's view that: (i) the current state of research shows little independent evidence of superiority of Zyprexa as compared to other first-generation antipsychotics ("FGAs") or second generation antipsychotics ("SGAs") in the treatment of schizophrenia, Rosenheck Decl. 2(ii) manufacturer-sponsored trials that attempt to show superiority of Zyprexa are methodologically biased, *id.;* and (iii) there is no credible evidence that Zyprexa is more cost-effective in the treatment of schizophrenia than any other antipsychotic medication and some evidence that it is less cost-effective than some earlier drugs. *See id.* at 2; *see also* Rosenheck Rebuttal. While earlier randomized trials suggested that Zyprexa was superior to FGAs and had fewer effects, more recent studies, including his own VA Cooperative Study 451 and CATIE, have found no advantages for Zyprexa on symptom measures or quality of life, minimal advantages on neurological side effects, and greater risk of obesity and metabolic disorder. *Id.* at 5; *see* Tr. at 24, 38 (Mar. 28, 2008: Rosenheck testimony); Troy Moore et al., *The Texas Medication Algorithm Project Antipsychotic Algorithm for Schizophrenia: 2006 Update Journal of Clinical Psychiatry,* J. Clin. Psychiatry 1751-1762 (November 2007) (noting that the Texas Medication Algorithm Project ("TMAP"), for example, stated in November 2007 that for chronic schizophrenics there is no reason to prefer SGAs to FGAs). These recent studies have also demonstrated that higher Zyprexa drug costs result in greater annual total health costs by $2,400 to $6,000 per patient. Rosenheck Decl. 5. "[A] consensus has also emerged that olanzapine causes weight gain and probably diabetes." *Id.*

a. Independent Study Results Found No Advantage for Zyprexa

Dr. Rosenheck testified at length about the results of the VA Cooperative Study 451 and the CATIE cost-effectiveness study which he oversaw. Both found no advantages for Zyprexa. Tr. 11, 16 ff Mar. 28, 2008; *see* Parts XI.E, "VA Cooperative Study 451," "CATIE," *supra* at XIII.B-XIV. A. The VA study compared Zyprexa with Haldol, an older FGA, and showed "no advantage for olanzapine over haloperidol on any measure of symptoms, social functioning, or quality of life; no superiority on pseudoparkinsonian symptoms; and no advantage on measures of tardive dyskinesia ...." While a small benefit for Zyprexa was found "on measures of akithesia, fine motor movement, and memory[, t]he study also showed olanzapine to be associated with significantly greater risk of weight gain, and $4,000-$ 10,000 greater annual costs." Rosenthal Decl. 6. The CATIE cost-effectiveness study found that "1) olanzapine showed no significant advantage over perphenazine [a low-cost generic FGA] on symptoms as measure by the most widely used measure of schizophrenia symptoms (the PAN SS total score), but was superior to [Risperdal] and [Seroquel]; and 2) olanzapine had no significant advantage on total days of hospitalization or any of four measures of quality of life." Rosenthal Decl. 13. He emphasized that "[a]ll publications completed thus far [have] found no statistically significant advantage for [Zyprexa] over perphenazine on any outcome." Rosenheck Slides at 15; Rosenheck Decl. 12; Rosenheck Supp. Decl. 5; Tr. 34, 10 ("[T]he research of the last five years, which has been large independent studies, suggests that there is no net clinical benefit" of Zyprexa as compared to perphenazine). Dr. Rosenheck now believes that Zyprexa should be the last option for schizophrenic patients because of its metabolic risks; Risperdal would be the first-line treatment. *See* Tr. Ex. 742.

***83** At the time of their publication, the results of both the VA Cooperative Study 451 and the CATIE trial were surprising. They conflicted with the outcome of other earlier studies, most of which were designed and authored by Lilly employees, concluding that Zyprexa was superior to conventional antipsychotics. Rosenthal Decl. 6-9; *see* Tr. at 13 (discussing the 1997 Lilly-sponsored International Collaborative Trial ("ICT") study showing improvement over Haldol); *see also id.* at 10, 19, 34, 40, and 42. Dr. Rosenheck opines that these Lilly studies and reviews were biased.

b. Deficiencies of Lilly-Sponsored Trials

The unanticipated results obtained in the VA study arose from the study's use-as would be typical in clinical practice-of prophylactic anticholinergic medication to counter Haldol's side effects *before* they occurred. Rosenthal Decl. 7. In the VA study, Zyprexa performed the same, but Haldol performed much better than in Lilly-sponsored studies administered without prophylactics. *Id.* at 7, 8 (noting that his 2005 summary of research literature revealed that the vast majority of favorable studies of atypical antipsychotics, including

Zyprexa, used Haldol without prophylactics); Tr. at 13; *see also id.* at 10, 19, 34, 40, and 42; Rosenheck Decl. 8-9 (describing ICT study analysis and results). "[T]he vast majority of favorable studies of atypical antipsychotics, including olanzapine, used haloperidol*without* preventative side effect medicines." Rosenthal Decl. 8.

Lilly's International Collaborative Trial ("ICT"), the source of data for numerous publications by Lilly employees, suffered from significant flaws, both by not using preventative side effect medication, stopping data collection at early points, analytic and statistical methods. In reviewing the ICT, the Director of the Division of Neuropharmacological Drug Products of the FDA concluded that "... the data adduced in the Zyprexa NDA [New Drug Application] is ... insufficient to permit the sponsor to make claims asserting the product's superiority to haloperidol." Rosenthal Decl. 9. A subsequent memo by the same person said:

> The problem in schizophrenia outcome assessment is that some of the so-called "negative" signs and symptoms of that illness are indistinguishable from the pseudoparkinsonian signs and symptoms that are known side effects of antipsychotic drugs like haloperidol. It would be reckless, therefore, to assume that a drughaloperidol difference detected on an instrument that registers negative symptoms is actually measuring a difference in antipsychotic effectiveness.

Rosenthal Decl. 10. But two Lilly publications subsequently asserted Zyprexa's superiority over Haldol. Rosenthal Decl. 10.

Dr. Rosenheck's rebuttal and supplement reports respond to Dr. Kahn's, Dr. McCombs', and Dr. Kolassa's criticisms of CATIE. The jury can resolve the scientific issues between the parties with the assistance of good advocacy.

2. Meredith Rosenthal. Ph.D.

***84** Dr. Rosenthal, an Associate Professor of Health Economics and Policy at the Harvard School of Public Health, has done research and written extensively in the area of the impact of pharmaceutical marketing and promotion on pharmaceutical sales and the economics of the health care industry. *See* Decl. of Meredith Rosenthal at 3-4, Feb. 27, 2007, Docket Entry No. 101 ("Rosenthal Decl."). She is also an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. *Id.* at 3. In her reports, she describes the extensive body of health care economics that she has studied, how pharmaceutical marketing causes increases in drug sales, and how that impact can be measured and quantified over time and by different type of marketing effort.

Dr. Rosenthal worked independently from Dr. Harris. *See id.; see also* Rosenthal Rebuttal.

At the evidentiary hearing, Dr. Rosenthal testified substantially as set forth in her previous reports. *See* Rosenthal Decl. 11; Rebuttal Decl. of Meredith Rosenthal, Apr. 5, 2007 ("Rosenthal Rebuttal"); Supp. Decl. of Meredith Rosenthal in Support of Plaintiffs' Motion for Class Certification, Jan. 8, 2008, Docket Entry No. 147 ("Rosenthal Supp. Decl."); Second Supp. Rep. of Meredith Rosenthal, Mar. 20, 2008, Docket Entry No. 161 Ex. D ("Rosenthal Supp. Rep."); Dep. of Meredith Rosenthal, Apr. 12, 2007 ("Rosenthal Dep."); Second Supp. Dep. of Meredith Rosenthal, Mar. 21, 2008 ("Rosenthal Second Supp. Dep."). Lilly's *Daubert* motion with respect to Dr. Rosenthal was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

At the direction of plaintiffs' counsel, Dr. Rosenthal undertook to: (1) examine whether economic theory and evidence suggest that Lilly's allegedly unlawful Zyprexa sales, marketing, and promotional practices resulted in common economic impact to the putative class; (2) quantify damages to the class based on a "loss-of-value" theory, i.e., as the difference in economic value that class members were allegedly led to believe they would obtain from Zyprexa and the actual economic value of the drug in light of limitations known to Lilly; (3) estimate the number of units sold of Zyprexa that resulted from Lilly's alleged promotion of Zyprexa for off-label uses and apply the "loss-of-value" approach to estimated damages associated with these units; and (4) quantify the amount by which Lilly incrementally profited from the allegedly unlawful practices. Rosenthal Decl. 1.

Dr. Rosenthal concluded that the alleged unlawful conduct regarding Lilly's marketing and lack of disclosure of complete information about product risks and efficacy of Zyprexa did result in economic harm to the putative class. *Id.* at 2. Her conclusion was based on two key ideas supported by standard economic theory, empirical studies, and academic literature: (1) promotion positively affects sales, *see id.* at 16-18; and (2) prices of prescription drugs are influenced by product characteristics including the perceived value of the drug relative to alternative therapies. *Id.* at 2, 28-30.

***85** After finding that economic analysis to quantify the effect of the alleged wrongful conduct using a class-wide "loss-of-value" approach is feasible, Dr. Rosenthal conducted such an analysis, identifying and quantifying a significant amount of damages. Her work suggests that the lower- and upper-bound estimates for nominal "loss-of-value" for the putative class period proposed by plaintiffs often years-September 1, 1996 to December 31, 2006-are $4.0 billion and $7.7 billion respectively. *Id.* at 2; *see* Part XVII.A.2.c.ii, Table, "Summary of 'Loss-of-Value' Damages" and Table, "Dr. Rosenthal's "Yardstick" Model Damage Estimate, *infra.* Since this period is greater than will be allowed by the court-four years-*see* Parts I, *supra,* and XIX.B.4, *infra,* the damages that might be proved by her approach are less than half.

a. Damage Model Assumptions

To determine these figures, Dr. Rosenthal assumed that the following allegations were true:

a) From the time of launch, Lilly obscured and downplayed serious side effects associated with Zyprexa. In particular, Lilly failed to adequately test Zyprexa despite knowing of a well-established effect for increasing the risk of hypoglycemia and diabetes. In the limited testing conducted by Lilly, it failed to inform the medical community that Zyprexa was especially insidious with respect to these side effects. Zyprexa's original label, and all label changes until 2004, did not adequately warn of these adverse effects.

(b) Most seriously, until required to do so by the FDA in September 2003, Lilly failed to adequately warn the public, including Class members and their physicians, about the increased risk of diabetes and hyperglycemia and of the related need to provide baseline diabetes screening and ongoing glucose monitoring for patients treated with Zyprexa.

(c) Lilly's strategy to maximize the market potential of Zyprexa relied on targeted research and marketing efforts that would establish the drug as a relatively safe and effective alternative that could be used to treat not only approved indications but also "mood and thought disorder" symptoms of other mental health and neurological problems for which the drug had not been approved (nor in many cases studied).

(d) Beginning in 1996, Lilly's marketing and promotional campaign, planned and executed by its own staff and a wide range of collaborating organizations and consultants: "(i) falsely and deceptively oversold the efficacy of Zyprexa as compared to other antipsychotics, (ii) failed to adequately warn of, and affirmatively mislead the medical community regarding the severe side effects of Zyprexa such as weight gain, hyperglycemia, diabetes and cardiovascular effects, and (iii) unlawfully promoted Zyprexa for usage in populations for which it had not received FDA approval and for which the efficacy and side effects had not been established through adequate clinical evidence."

(e) The specific tactics Lilly used in its campaign to promote Zyprexa included supporting the production of articles favorable to Zyprexa, disseminating biased information through continuing medical education programs, and paying physician thought leaders to represent Zyprexa favorably to their colleagues. In addition, given the central role Medicaid financing plays in the reimbursement of antipsychotics, Lilly manipulated and paid state agencies to promote the use of Zyprexa in the Medicaid population.

***86** (f) Lilly's efforts to misrepresent the safety and efficacy of Zyprexa thus were delivered not only through traditional pharmaceutical promotional strategies such as detailing and sampling, but also through channels that have the appearance of independence and legitimacy, including scientific journals, continuing medical education programs, and state agencies. All of these efforts reinforced Lilly's strategy of positioning Zyprexa to appear higher-value to physicians, patients, and payers than Lilly knew the drug to be.

(g) In addition to overstating Zyprexa's value for approved indications, Lilly sought to expand Zyprexa's use in patients with symptoms and conditions that were completely unrelated to schizophrenia (and, later, to bipolar mania, for which Zyprexa was approved).

For many of these off-label indications, Lilly's efforts involved promoting Zyprexa to primary care physicians, who are generally less familiar with antipsychotic medications.

(h) Lilly "sought to position Zyprexa as a 'foundational mood stabilizer' by focusing on 'behavior treatment' and 'reducing symptoms associated with mood, thought, and behavioral disturbances.' " Sales of Zyprexa associated with treatment of depression, for which it has never been approved, are estimated to have reached nearly $3 billion from 1999 to 2005. In addition, Lilly promoted the utilization of Zyprexa in the elderly for symptoms of dementia, a use for which a black box warning was ultimately added to Zyprexa's label due to an increased mortality risk. Finally, Lilly promoted the use of Zyprexa in children for a wide range of indications including Tourettes Syndrome, poor impulse control, bipolar disorder and stuttering.

(i) In summary, Lilly failed to adequately warn about Zyprexa's known association with diabetes and diabetes-related injuries and of the need to provide baseline screening and monitoring to prevent such complications from occurring, while overselling the comparative effectiveness of the drug. Moreover, Lilly undertook promotion and sales of Zyprexa for unapproved uses, many of which were unsupported by clinical evidence.

Rosenthal Decl. 7-9 (footnotes omitted). A jury could find these assumptions, findings and calculations and those of the other plaintiffs' expert, accurate.

Assuming the allegations described above are true, Dr. Rosenthal found the economic impacts to the putative class would be the following:

a) the economic value of Zyprexa to the class is less than that conveyed by Lilly's sales, marketing and promotional efforts; that is, there is a difference between the economic welfare of the class in reality compared with the perception Lilly allegedly created; and

b) the prices and quantities of Zyprexa sold during the class period were higher than they would be absent the allegedly unlawful practices.

Id. at 10.

b. Lilly's Unlawful Marketing Increased Sales: The "Quantity Effect"

Dr. Rosenthal found that the data showed a clear relationship between Lilly's promotional spending and numbers of Zyprexa prescriptions. She concluded that the allegedly unlawful off-label promotion likewise increased the quantity of Zyprexa consumed by the putative class. Her examination of off-label promotion patterns reveals an association with off-label use; she found that a substantial share of Zyprexa prescriptions were for unapproved uses by demonstrating on an aggregate basis that supposed off-label promotional activities resulted in more off-label prescriptions of Zyprexa than would have occurred absent promotion. Rosenthal Decl. 27. She then performed a regression analysis to quantify the impact of Lilly's off-label marketing on sales. *See id.* at 20-28.

***87** The impact of promotion on pharmaceutical sales is well-documented. *Id.* at 20; Tr. at 95-96, 134; *see* Part IV.B, *supra.* To demonstrate that defendant's alleged unlawful marketing efforts impacted costs to the putative class, Dr. Rosenthal undertook an econometric analysis using data on Lilly's promotional expenditures as well as the prices and promotional spending, based on IMS data, of the other SGAs (not including clozapine). Rosenthal Decl. 22-28. Her analysis included data from the 1996 launch through October 2006.

Dr. Rosenthal used Lilly's own strategic marketing documents to identify its investments in off-label promotion, and found that these documents also supported the conclusion that these efforts yielded substantial financial returns. *Id.* at 33. To calculate the number of prescriptions of Zyprexa caused by the off-label marketing, she used Lilly's marketing documents to identify the percentage of salesforce spending (13.7%) for long-term care and primary care targets in 2002 and 2003 as her primary measures of the challenged promotions. *Id.* at 34. Data from years other than 2002 and 2003 was not accessible. Because only limited marketing data was available to her, Dr. Rosenthal then computed a lower and an upper bound of damages. *Id.* at 35.

Her assumption that all Lilly sales representatives in 2002 and 2003 for primary and longterm care markets were promoting off-label uses is untenable. But a jury could, based on the evidence available, discount her computations by reliably estimating how much of the marketing costs should be attributable to on-label and off-label expenditures. For the lower bound, she assumed that plaintiffs would be able to prove the allegations *only* with regard to pediatric and long-

term care uses-not other alleged off-label uses, like primary care-and that Lilly's off-label promotion occurred *only* during 2002 and 2003. By taking the average percentage (13.7%) of salesforce spending associated with the pediatric and long-term care markets, she computes fraud-free spending. *Id.* at 36.

In contrast, the upper bound computations assume that essentially *all* salesforce efforts to target all long-term care doctors and physicians in all subgroups of primary care-a far greater number than just pediatric and long-term care doctors-can be proved to be illegal and that the 2002 and 2003 promotional spending data applies to the entire class period. Rosenthal Decl. 36. In this scenario, she computes fraud-free promotional spending as actual promotional spending less the average share (50.3%) of salesforce spending identified as targeting primary and long-term care physicians and applied this average share (50.3%) throughout the class period. Rosenthal Decl. 36.

Using regression analysis, she estimated that approximately every $200 spent promoting Zyprexa resulted in one extra prescription. Tr. at 134; Rosenthal Decl. 26. She then applies the $200 per prescription ratio to derive the number of "extra" off-label prescriptions caused by Lilly's alleged off-label promotion. For each "extra" prescription derived using this methodology, Dr. Rosenthal assigns zero value to the prescription, and therefore, the entire cost of the prescription as damages. Tr. at 187. Her methodology thus concludes that the entire prescription price is the measure of damages for each "extra" off-label prescription. Tr. at 186-88. Dr. Rosenthal chose the entire prescription price as the measure of damages based on her understanding that "the evidence suggests that there was no effectiveness for off-label uses." All these figures and computations are subject to decrement by the jury.

***88** Lilly offers substantial criticism of Dr. Rosenthal's model. Her key assumptions, they note, are debatable: (1) that actual expenditures matched the budgeted expenditures shown on Lilly documents produced in discovery; (2) that all expenditures for marketing to long term care facilities and primary care practitioners were for the promotion of off-label use of Zyprexa; and (3) that, for the higher range of her damage estimate, those same long-term and primary care marketing expenditures in 2002 and 2003 occurred every year of the class period (though plaintiffs themselves allege that marketing to primary care practitioners did not begin in earnest until September 2000, Am. Compl. at ¶ 155). By assuming that the *entire* prescription price is the measure of damages for each "extra" off-label prescription, Dr. Rosenthal ignores the possibilities that even if a prescription was induced by off-label promotion, (a) the medication may have conferred a benefit or value on the patient; (b) the use of Zyprexa may have reduced other costs incurred by the payor, such as hospital costs; and (c) had that prescription not been written, the physician would likely have written a prescription for another medication, possibly even more expensive. The jury can accept much of this criticism as valid while giving substantial weight to her analyses and attenuated damage estimates.

c. "Loss of Value" Pricing Theory

Dr. Rosenthal also provided an opinion on the value of Zyprexa and how the class received less than what was represented and paid for. *See* Rosenthal Decl. 28 ff. She begins with basic premise of health economics that people are willing to pay higher prices for high-quality health care than for lower-quality health care. Rosenthal Decl. 28. She notes that Dr. Kolassa, one of own Lilly's experts, describes pharmaceutical pricing is just that way:

> "The primary principle that should guide every pricing decision is that the price should reflect the value of the product to the customer."
>
> "When a product delivers better outcomes, it deserves to be priced at a premium relative to competitors. Should the outcomes not differ from competitive products, a parity price is in order. Worse relative outcomes should be reflected by a price that is lower than prevailing levels."

Rosenthal Decl. 29 (quoting E.M. Kolassa, *Pharmaceutical Pricing Principles, in* Pharmaceutical Marketing: Principles, Environment, and Practice (M.C. Smith & E.M. Kolassa, et al., eds.2002) at 189, 212). Although the pharmaceutical market is unique in many ways, *see* Part IV.A, *supra,* "this basic premise has been shown to hold true in pharmaceutical pricing as well." Rosenthal Decl. 28.

Dr. Rosenthal "loss of value" methodology attempts to demonstrate that the expected value of Zyprexa to patients was inflated by Lilly's allegedly fraudulent behavior. (A "loss of value" damage model is different from a but-for calculation of the effect of Lilly's alleged fraud on Zyprexa's prices. Tr. at 162.) To determine the extent of loss of value for each prescription, she compared the price of Zyprexa to that of two other antipsychotic medications she

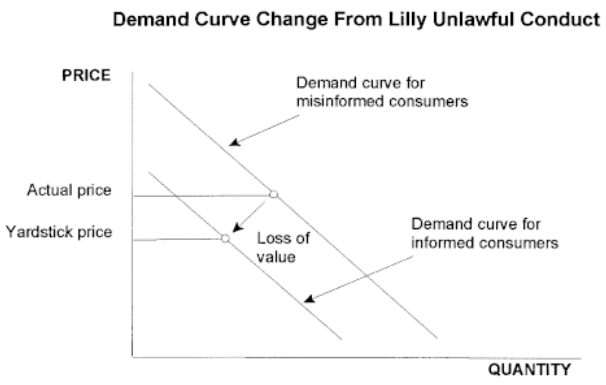
determined to be appropriate "yardsticks" for the actual value of Zyprexa: Seroquel, a branded SGA launched in 1998, and perphenazine, a generic off-patent FGA. Tr. at 115, 121, 125.

***89** Dr. Rosenthal does not claim that Zyprexa's actual price would have been the same as the other medications had Lilly provided different information about side effects and effectiveness. Instead, she uses price as a proxy for the loss of value, or disappointment of consumer expectations, that occurred as a result of Lilly's alleged fraud. Tr. at 176. Her analysis may assist the jury in analyzing the overpricing claim based on competitive and fraud aspect of the case.

The value of a product to patients relates to manufacturer strategic pricing decisions. A text on pharmaceutical pricing clearly recognizes that drug launch prices reflect the value that customers can expect from the drug (as offset by possible adverse effects) compared to what is charged for competitive drugs. Lilly itself recognizes the interrelationships between pricing and comparative expected value to the consumer.

In quantifying the "impact of allegations that Eli Lilly and Co .... engaged in fraudulent statements and conduct in its sales, marketing and promotion of Zyprexa" on the class of consumers and third-party payors, Dr. Rosenthal implemented a "loss of value" approach, utilizing Seroquel and perphenazine as yardsticks reflecting "class members' willingness-to-pay for Zyprexa had Lilly warned them of the true risks of weight gain and the associated health problems." Rosenthal Dep. at 1, 37; *see* Rosenthal Decl. 30-33.

Demand Curve Change From Lilly Unlawful Conduct



Pfs.' Reply Mem.

Lilly relied on Dr. Rosenthal's recognition that willingness to pay will vary: "I don't contest that there's a range of willingness-to-pays among class member, that there's some variation and that while there's an effect over all class members, it will differ." Lilly Mem. 20-21 (quoting Rosenthal Dep. 229). This variation in value among members of the class does not negate overpricing to all. Dr. Rosenthal convincingly testified that all class members experience an effect; even those who are still willing to pay the current price for Zyprexa experienced a loss of value because they did not get what they thought they were getting out of their purchase of Zyprexa:

> [T]o the extent that there have been adjustments in the market over the last several years, they have come in the form of reductions in quantity which could be expected to reflect the fact that those individuals who, once the information was revealed about the risks-the true risks and comparative effectiveness of Zyprexa, chose not to purchase it. And so those were individuals whose willingness-to-pay was substantially high enough to-to make it still worth their while. It's still true that those individuals in the past, what they thought they were getting out of the purchase was greater than what, in fact, they ended up getting, so those same individuals would still have had a loss-of-value in the past.

Rosenthal Dep. at 227-28. As she summarized: "again, the aggregate is the sum of the parts. It will reflect those specific differences, but I did not estimate any specific differences." *Id.* at 298-99.

i. Price "Yardsticks"

***90** Dr. Rosenthal selected Seroquel and perphenazine as yardsticks because, according to her, they are of "equal economic value" based on QALY scores reported in Dr. Rosenheck's CATIE cost-effectiveness paper in December 2006. Tr. at 115. She applied the QALY results to all Zyprexa prescriptions, irrespective of diagnoses or conditions. Tr. at 167.

After considering and rejecting as less valid other possible sources of willingness-to-pay estimates, Dr. Rosenthal selected these yardsticks on the basis, in part, of results of the CATIE trial, a large, national, publicly-**funded** and unbiased randomized controlled trial examining the comparative value of atypical antipsychotic medications and one typical antipsychotic medication (perphenazine). *See* Rosenthal Decl. 37-31.

Employing standard "yardstick" techniques used by healthcare economists, she establishes the value of Zyprexa as measured against the prices of two comparators: Seroquel and perphenazine. Among other things, her choice was grounded in independent NIMH studies including the outcomes from the CATIE study, published in recent years.

Dr. Rosenthal testified that, based on her price methodology, "Zyprexa's price should have some value premium over Risperdal's." Tr. at 169.

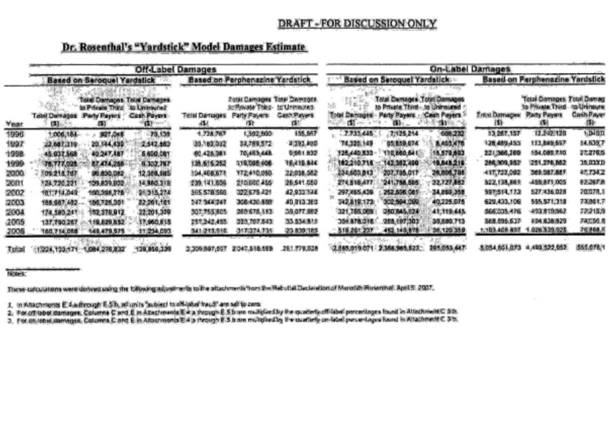
ii. Damage Calculations

Dr. Rosenthal's estimate of damages for the class period sought by the plaintiff ranges from $3,998 billion to $7,675 billion, i.e., approximately 25% of the total dollars spent by endpayers for Zyprexa over the class period. *See* Rosenthal Decl. 41-43. The below table shows a summary of total loss-of-value damages for Zyprexa and Zyprexa Zydis.

Summary of "Loss-of-Value" Damages ($ millions)

	Lower Bound	***Upper Bound***
Using Seroquel as a Yardstick:		
Third-Party Payeos	$3,541	$4,214
Cash Payeos	$447	$529
Total	**$3,988**	**$4,743**
Using Perphenazine as a Yardstick:		
Third-Party Payors	$6,581	$6,822
Cash Payors	$821	$853
Total	**$7,403**	**$7,675**

Id. at 43.


DRAFT - FOR DISCUSSION ONLY

Dr. Rosenthal's "Yardstick" Model Damages Estimate

	Off-Label Damages						On-Label Damages					
	Based on Seroquel Yardstick			Based on Perphenazine Yardstick			Based on Seroquel Yardstick			Based on Perphenazine Yardstick		
Year	Total Damages ($)	Total Damages to Private Third Party Payers ($)	Total Damages to Uninsured Cash Payers ($)	Total Damages ($)	Total Damages to Private Third Party Payers ($)	Total Damages to Uninsured Cash Payers ($)	Total Damages ($)	Total Damages to Private Third Party Payers ($)	Total Damages to Uninsured Cash Payers ($)	Total Damages ($)	Total Damages to Private Third Party Payers ($)	Total Damages to Uninsured Cash Payer ($)
1996	1,006,184	927,048	79,139	1,728,767	1,392,800	135,967	7,733,446	7,125,214	608,232	13,287,157	12,242,120	[illegible]
1997	22,687,319	20,144,439	2,542,880	30,183,032	34,789,572	4,393,400	74,325,149	65,859,674	8,465,476	128,489,453	113,849,697	[illegible]
1998	45,937,568	40,247,487	5,690,081	80,425,381	70,463,448	9,961,932	126,440,533	110,860,641	15,579,893	221,366,269	194,089,730	[illegible]
1999	76,777,025	67,474,258	9,302,767	135,515,252	119,095,408	16,419,844	162,210,718	142,362,499	19,848,219	286,309,952	251,276,862	[illegible]
2000	109,218,767	96,830,082	12,388,685	194,468,671	172,410,090	22,058,582	234,603,813	207,795,017	26,808,796	417,722,092	369,987,887	[illegible]
2001	124,720,221	109,839,902	14,880,319	239,141,505	210,600,455	28,541,050	274,516,477	241,788,595	32,727,882	522,138,861	459,871,005	[illegible]
2002	181,714,049	160,398,776	21,315,274	365,578,566	322,675,421	42,933,144	297,465,439	262,596,081	34,869,358	597,514,173	527,436,028	[illegible]
2003	188,987,482	166,726,301	22,261,161	347,344,247	306,430,888	40,913,360	342,819,173	302,594,099	40,225,075	629,433,106	555,571,318	[illegible]
2004	174,580,241	152,378,912	22,201,329	307,755,805	269,678,113	38,077,692	321,765,069	280,845,624	41,119,445	566,035,476	493,810,962	[illegible]
2005	137,790,267	119,829,652	17,960,615	257,242,455	223,707,643	33,534,813	304,878,016	265,197,303	39,680,713	568,595,637	494,838,820	[illegible]
2006	160,714,068	149,479,975	11,234,093	341,213,916	317,374,731	23,839,185	518,261,237	482,140,878	36,120,359	1,103,408,897	1,026,539,925	[illegible]
Total	1,224,133,171	1,084,276,832	139,856,339	2,309,397,597	2,047,618,569	261,779,028	2,665,019,071	2,368,965,623	295,053,447	5,054,601,073	4,490,522,052	555,078,[illegible]

Notes:

These calculations were derived using the following adjustments to the attachments from the Rebuttal Declaration of Meredith Rosenthal, April 5, 2007.

1. In Attachments E.4.a through E.5.b, all units "subject to off-label fraud" are set to zero.
2. For off-label damages, Columns C and E in Attachments E.4.a through E.5.b are multiplied by the quarterly off-label percentages found in Attachment C.3.b.
3. For on-label damages, Columns C and E in Attachments E.4.a through E.5.b are multiplied by the quarterly on-label percentages found in Attachment C.3.b.

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Dr. Rosenthal also estimated unjust enrichment damages-with lower- and upper-bound estimates of $3.7 billion and $7.1 billion-over the class period. *See id.* at 44-47. Her calculations are not discussed further here since the unjust enrichment cause of action has been rejected. Unjust enrichment is not available under the civil RICO statute's definition. *See* 18 U.S.C. § 1964(c) ("damages he sustains").

Among Dr. Rosenthal's comments supporting her conclusions were the following: "my analysis of the loss of value to the Class is based on standard microeconomic theories, including welfare theory and hedonic analysis, as noted in my original report." Rosenthal Second. Supp. Rep. 2. "Value is inherently subjective but this does not mean that it cannot be

ascertained or measured. The theory of demand rests on the premise that consumers reveal their (inherently subjective) preferences through their purchasing behavior." Rosenthal Second Supp. Dep. 5. Her analysis considered dosing regimes of competitive drugs. Tr. at 170.

3. Jeffrey E. Harris, M.D., Ph.D.

***91** Dr. Harris is a professor of economics at the Massachusetts Institute of Technology and at the Harvard Medical School-MIT Program in Health Sciences and Technology. He is also a practicing physician, now at the Providence Community Health Center having previously spent almost thirty years as an attending doctor at the Massachusetts General Hospital. Among other subjects, he teaches health economics and the economics of the pharmaceutical industry. At the evidentiary hearing, he testified substantially as set forth in his previous reports, focusing on explaining his assumptions and damage calculations. *See* Expert Report Dr. Jeffrey Harris M.D., Ph.D., Feb. 20, 2007, Docket Entry No. 98 ("Harris Rep."); Rebuttal Expert Rep. of Jeffrey Harris, Apr. 4, 2007 ("Harris Rebuttal"). Dr. Harris offered no opinion on causation. Tr. at 304-05, 309-10; Harris Rebuttal 2. Lilly's *Daubert* motion to exclude Dr. Harris' testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

Dr. Harris was asked by plaintiffs' counsel to address the extent of aggregate economic damages, if any, suffered by the putative class as a result of defendant's alleged misconduct, during the proposed class period from 1996 to the present, under the following two assumptions:

> (1) But for Defendant Lilly's misconduct, the total nationwide number of Zyprexa prescriptions would not have exceeded its projected 2006 level.
>
> (2) But for its misconduct, Defendant Lilly would not have raised the price of a Zyprexa prescription beyond the average price per prescription charged for Seroquel, Risperdal, and Clozaril, which were its three principal competitors in the therapeutic category of atypical antipsychotics during the class period.

Harris Rep. 3-4; Harris Rebuttal 3; Tr. at 207. His damages estimate does not include any government (Medicaid or Medicare) payments. *Id.* at 4.

a. Damages Estimate

Dr. Harris first estimated the total nationwide increase in expenditures for Zyprexa attributable to defendant's alleged misconduct during 1996-2006 to be $11.342 billion. Excluding the government-paid fraction (estimated to be 56.5 percent of the total, *see* Harris Rep. App'x 3, Dr. Harris found total economic damages to be $4,926 billion during the class period, or somewhat less than 25% of what endpayers had paid for Zyprexa during the class period. Harris Rep. 4.

In calculating damages, he distinguished between two groups of consumers: (1) those patients who, but for Lilly's alleged misconduct, would not have purchased Zyprexa at all (Quantity or "Excess Prescription Theory"); and (2) those patients who, but for Lilly's alleged misconduct, would still have purchased Zyprexa, but at a lower price ("Excess Price Theory"). *Id.* at 5.

b. Data Sources

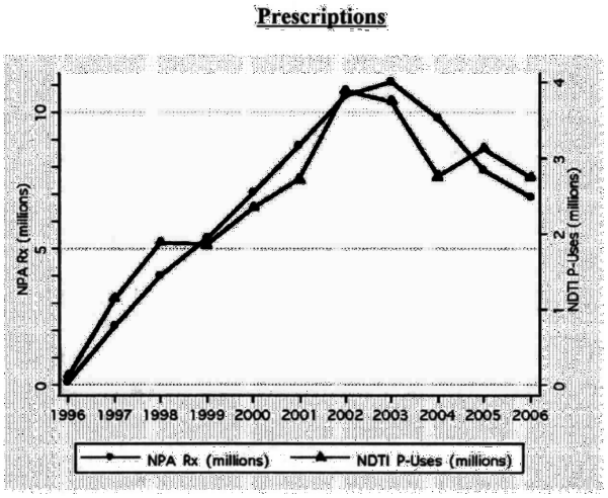
To quantify his theories, Dr. Harris acquired Zyprexa expenditure data from two different data sources (the National Prescription Audit ("NPA") and the National Disease and Therapeutic Index ("NDTI")). *Id.* at 6-7. Both data sources originated from IMS Health and are frequently used in scholarly analyses of the pharmaceutical industry. *Id.* at 7. Of defendant's two economic experts, Drs. Cockburn and Berndt, the former relied on IMS Health data for his own calculations and both have relied upon data from FMS Health in their published research. Harris Rebuttal 6.

***92** The NPA is derived from prescription records of a large, representative panel of retail, chain, hospital and mail service pharmacies throughout the United States. The basic unit of analysis in the NPA is the prescription ("Rx"). Harris Rep. 7. The NDTI is derived from a large, representative panel of office-based physicians nationwide. The unit of analysis in the NDTI is a physician-reported drug use ("P-Use"), which includes patient encounters in which a drug was newly prescribed and encounters in which a previously ordered drug was continued. *Id.* The NDTI estimates of physician drug use were further broken down by widely-employed primary diagnostic codes, allowing Dr. Harris to track trends in Zyprexa use with respect to FDA-approved indications and off-label use. *Id.* at 11.

c. Prescription Trends

Although there is "sampling variability," the two sources of information present a consistent picture of the trends in Zyprexa use. The consumption of Zyprexa in the United States reached a peak in 2002-2003, and then declined in 2004 and thereafter. *See also* charts Part VI. C, "FDA Warning Letter," *supra.* Based on NPA data, the number of Zyprexa prescriptions reached a maximum of 11.092 million in 2003; by 2004, Zyprexa prescriptions had fallen to 9.765 million; 2006 was projected to be 6.901 million, a 38% decrease from 2003. Harris Rep. 8.

Prescriptions



The above graph, *see* Harris Rep. fig. R1, shows trends in the quantity of Zyprexa consumed nationwide during 1996-2006. The circles, connected by the lines and calibrated on the left-hand axis, represent the estimated number of prescriptions written for Zyprexa nationwide, based upon the NPA. The triangles, connected by the lines and calibrated on the right-hand axis, represent the estimated number of physician uses of Zyprexa, based upon the NDTI.

Dr. Harris credited the decline to the contemporaneous publication of information concerning the adverse effects of the drug, especially weight gain and the increased risk of diabetes. He noted that a warning for hyperglycemia and diabetes was first placed on Zyprexa's label in September 2003, followed up by Lilly's "Dear Doctor" letter in March 2004. Harris Rep. 8; *see* Parts XI.D, XII.B, *infra.* Although the warning was required for all SGA labels, it negatively impacted Zyprexa in particular because of the perception of the drug's greater metabolic risks, reinforced by the February 2004 ADA consensus statement. *See* Harris Rep. 9 (noting that after the ADA Consensus, prescriptions for all other SGAs except clonzapine (identified with Zyprexa as having the worst metabolic side effects) increased).

Using the NDTI data broken down by diagnostic code, Dr. Harris was able to also determine the trends in Zyprexa's on- and off-label prescriptions. Dr. Rosenthal had found that overall, "unapproved uses represent an average of 31 % of Zyprexa mentions" in the NDTI database. Rosenthal Decl. 26. Off-label use was particularly prevalent among conditions commonly diagnosed in children and for dementia, beginning with an upward trend beginning to accelerate around 2001. Rosenthal Decl. 26-27. In late 2002 and early 2003, there were increases in prescribing for pediatric conditions; off-label prescribing for dementia also experienced an increased trend beginning in 2001 to an apex in mid-2002. Use for dementia did not begin to decline until early 2006, many months after the FDA's decision in April 2005 to require a "black box" warning for all SGAs for elderly patients. Rosenthal Decl. 27.

***93** Demonstrated by Dr. Harris was that the overall decline in Zyprexa use since its peak of 2002-2003 corresponded almost entirely to a decrease in prescriptions written for diagnoses other than the approved indications for schizophrenia and bipolar I disorder. *See* Graph, "Reasons for Prescriptions," at Part VI.C, *supra; see* Harris Rep.; *see also* Harris Rebuttal at Ex. 2 & 3.

Dr. Harris also examined trends in Zyprexa pricing during the class period. His analysis revealed that Zyprexa was consistently priced higher than the other three principal competitor antipsychotic drugs throughout the class period. The per-prescription price differential increased from $77 in 1996 to $150 in 2006. At the peak level of Zyprexa consumption in 2003, the difference in price per prescription was $113. *See* Graph, "Price Per Prescription," at Part VI.C, *supra;* Harris Rep. App'x B (explaining price-per-prescription calculations).

Dr. Harris' graph "Price Per Prescription," *see* Part VI.C, *supra,* is based on IMS Health data and shows trends in the estimated retail price per prescription of Zyprexa compared to the prices of the branded SGAs Risperdal, Clozaril, Seroquel, Geodon and Abilify during 1996-2006. Harris Rebuttal 16 fig. R3. Risperdal and Clozaril were already on the market in 1996, when Zyprexa was introduced. Seroquel, Geodon, and Abilify were later introduced in 1997, 2001, and 2002, respectively. From its launch in 1996, Zyprexa was priced higher than Risperdal and Clozaril. During 1997-2000, Zyprexa remained at a consistently higher

price than Risperdal, Clozaril and Seroquel, the three branded atypical antipsychotics that were on the market at the time. Price differentials between Zyprexa and its competitors remained the same over the class period; all prices increased at the same rate. *See* Harris Rep. 10 (noting the average price of a Zyprexa prescription rose by 26 percent during 2003 to 2006, while average price per prescription of all other brand-name atypical antipsychotics rose by 30 percent during the same period).

d. Damage Theory & Calculations

To calculate his Quantity or Excess Prescription Theory and identify those patients who, but for Lilly's alleged misconduct, would not have purchased Zyprexa at all, Dr. Harris assumed that Zyprexa's price, but for Lilly's alleged misconduct, would not have exceeded the average price per prescription charged for Seroquel, Risperdal, and Clozaril.

To calculate his "Excess Price Theory" and identify those patients who, but for Lilly's alleged misconduct, would still have purchased Zyprexa, but at a lower price, Dr. Harris determined the quantity of Zyprexa sold and the price charged, with the alleged misconduct, on an annual basis for the class period and compared those quantities with the total nationwide number of Zyprexa prescriptions in 2006.

Those assumptions include: (1) Lilly suppressed the truth about Zyprexa's side effects from the time of launch until the end of 2003, Tr. at 210, 260, 309-10, 320-21; (2) beginning in late 2003, the truth about these side-effects was revealed to the market through the class-wide FDA label change, the ADA Panel Consensus Statement, and Lilly's "Dear Doctor" letter; (3) a reduction in Zyprexa prescriptions after 2003 was caused by these "revelations," Tr. at 254-55, 325; (4) therefore, in the years 2000 to 2005, the number of Zyprexa prescriptions per year would never have exceeded the projected total for 2006. Tr. at 308. Finally, Dr. Harris assumed that plaintiffs were entitled to a 100% refund for the "excess scripts" written in 2000 to 2005. Tr. at 312 ("Q: ... [T]he basic theory there is that the people that paid for all of those so-called excess prescriptions should get their money back in full? A: Yes.").

***94** Dr. Harris also depended on assumptions by plaintiffs' counsel when making his price theory calculations. Tr. at 309-10. The assumptions were: (1) that Lilly suppressed information about Zyprexa's side effects from the time of launch, Tr. at 210, 260, 309-10, 321; and (2) that, but for this suppression, the price of Zyprexa "would have been the same as a combination or average of Risperdal, Seroquel, and Clozaril." Tr. at 333. Given these two assumptions, Dr. Harris took the average "price per prescription" for the other three medications and subtracted that figure from the price per prescription for Zyprexa to obtain his damage estimate. Tr. at 335.

e. Criticisms

Dr. Harris' theory assumes that every one of the "excess" prescriptions from 2000-05 was written by a physician who was deceived by Lilly and who would not have written the prescription but for Lilly's alleged fraud. Dr. Harris claimed that 100% of the decline in Zyprexa prescriptions was due to the September 2003 class-wide label change and subsequent events. This assumption is 100% gullibility is contradicted by the many depositions read by the court showing that some doctors were not misled. See attached deposition exhibits to *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571 (E.D.N.Y.2007) (denying summary judgment). Nevertheless, the analysis can be reduced in force by discounting the percentage of misled doctors without negating the theory and by permitting the jury to reduce the computed damages based on those doctors who were misled; recalculation for trial can be permitted.

Dr. Harris himself acknowledged that "there was clearly information about potential risks [of Zyprexa] that was in the published referee literature" before the consensus statement was published"; there had been an "accumulation of articles" of this very subject. Tr. at 249. Lilly's competitors would "very typical[ly]" have counter-detailed Zyprexa, serving as "another channel by which information about the side-effects of Zyprexa," *id.* at 328, would have been made known to prescribing physicians in advance of the supposedly watershed consensus statement. *Id.* at 249, 324 (knowledge previously available to prescribing physicians); *see also id.* at 835 ("The notion this was a bolt from the blue or a surprise or an earthshaking event or a watershed which suddenly started to have an impact with a publication of this ADA Consensus Statement is entirely unreasonable."). "Put differently, the ADA, American Diabetes Association, didn't invent for the first time the relationship between Zyprexa and these side-effects," *id.* at 249, nor would it have been the first time that most physicians had heard of that relationship.

Dr. Harris supported his excess prescription theory by concluding that "those physicians who were using the drug for off-label purposes became the most influenced by the information about the side-effects" and that "the quantity

effect is primarily an effect on off-label uses." *Id.* at 267. He testified that antipsychotics have been prescribed off-label at Massachusetts General Hospital, including by him, for many years. *Id.* at 337:10-38:13. At plaintiffs' counsel's directive, Dr. Harris assumed that "the people that paid for all of the so-called excess scripts should get their money back in full." *Id.* at 312.

***95** This concept of finding different damages for different class members will not be allowed at trial. It would complicate proof excessively. Plaintiffs as a class will be permitted to proceed only on a theory of an excessive computed price for all payors which may vary over time.

Dr. Harris's price theory results in recovery no matter what a payor or patient knew about Zyprexa, *id.* at 306, and does not depend on any deception of doctors by Lilly. *Id.* at 310-11. Dr. Harris used an average price-per-prescription to set a "but for" aggregate price.

Dr. Harris did not examine individual prescribing decisions. *Id.* at 312. He was asked to make certain assumptions and calculate damages on an aggregate basis. *Id.* Dr. Harris' approach does not depend on what a payor or patient knew about Zyprexa, *id.* at 306, and on whether some or all doctors were deceived by Lilly. *Id.* at 310-11. He did not address reliance on either an individual or an aggregate basis.

Two of plaintiff's experts, Dr. Berndt and Dr. Cockburn, criticized the soundness of Dr. Harris's two main assumptions, deeming his report as having "no economic basis" and "no credible economic foundation." *See* Harris Rebuttal 3-4. Despite their criticisms, Dr. Harris insists that "as an economist and physician, [he] find[s] both assumptions to be entirely consistent with well-founded principles of economic analysis and to adhere to the methodological standards employed by scholarly and professional analysts of the pharmaceutical industry, including Professors Cockburn and Berndt themselves." *Id.* at 3. The assumptions "were not arbitrary and were in fact based on objective evidence of the kind normally relied upon by economists, physicians and other analysts of the pharmaceutical industry." *Id.* at 4. The jury will be in a position to accept part of Dr. Harris' analysis, permitting its computation of a pricing overcharge for all class payors.

Defendant's two experts believe Dr. Harris's model to impute the but-for changes in price and quantity does not take "other factors" into account, although complex multivariate statistical methods-which Dr. Harris did not use-would. *Id.* Dr. Harris agrees that "[i]n principle, complex multivariate statistical methods, including hedonic price analysis, might be useful and reliable in computing damages," but that here "such statistical methods constitute a type of retrospective non-blinded analysis of the data and are highly susceptible to biases that may be difficult even for a professional audience to detect." *Id.* at 5-6.

Such "other factors" cited by Dr. Cockburn as possible explanations for the decline in Zyprexa use, including Abilify's introduction and attorney advertising for Zyprexa product liability suits, are not significant factors: Market shares of Risperdal and Seroquel, unlike Zyprexa, continued to rise after Abilify and Geodon were introduced. Harris also estimated that the 20,000 individuals with pending Zyprexa personal injury claims against Lilly comprised only one percent of total Zyprexa prescriptions for non-governmentally covered patients since 1996. *Id.* at 9. These disagreements among competent experts are best left for jury resolution.

4. William Wirshing, M.D.

***96** Dr. Wirshing is a professor of clinical psychiatry in the Department of Psychiatry and Behavioral Sciences at UCLA School of Medicine. For almost fifteen years he has been the Chief of the Schizophrenia Treatment Unit at the West Los Angeles VA Medical Center, Brentwood Division, California, and Co-Chief of the Schizophrenia Outpatient Research Clinic during the last ten years. *See* Decl. of William Wirshing, M.D. ("Wirshing Decl."), Jan. 31, 2007, at 2-3. In those positions, he regularly treats patients with mental illnesses, using medication when required. *Id.* at 5. Dr. Wirshing has authored many articles, presentations, and other publications in the fields of schizophrenia and the effects on patients with this illness of the administration of various antipsychotic medications, including Zyprexa. *See id.* at 48.

His position in clinical research has allowed Dr. Wirshing to "test" potential medications in his patients under controlled protocol conditions from the beginning of their development by industry; he has tested every antipsychotic medication that did receive FDA approval, including Risperdal, Zyprexa, Geodon, Abilify, and Seroquel. *Id.* at 4. He has consulted and worked as a clinical investigator for Lilly (as well as other pharmaceutical companies, *id.* at 48) during clinical trials of Zyprexa. *Id.* at 4-5.

Dr. Wirshing was "among the very first to report on the curious metabolic effects" of the new SGAs in the early to mid 1990s. *Id* . at 5. He and his group noticed, in particular:

> [T]hat many of our patients gained weight when first begun on these drugs and at a rate that was, on occasion, singular in our experience. We also noted that these patients soon began to suffer the usual downstream consequences of gaining weight (e.g., glucose intolerance, frank diabetes ... [W]e described our experience in the peer-reviewed literature, reported it at any number of scientific meetings, and discussed it with the manufacturers.

Wirshing Decl. 5.

In his expert reports, Dr. Wirshing supplied strong evidence supporting the plaintiffs' position. *See* Wirshing Decl.; Supp. Decl. of William Wirshing, M.D., Mar. 20, 2008, Docket Entry No. 161 Ex. C ("Wirshing Supp. Decl."). His testimony is likely to be impressive to a jury on key issues of fraud and damages, Dr. Wirshing described at length the issue of weight gain and its associated increased morbidity vis-a-vis Zyprexa: overweight and obesity are widely accepted as causal factors to increase the risk for a number of diseases including diabetes, cardiovascular disease (heart attacks and strokes) and hypertension. Marked weight gain and obesity are associated with abnormal metabolic changes such as insulin resistance and dyslipidemia, which are themselves risk factors for cardiovascular disease and diabetes. *See* Wirshing Decl. 6-7. Weight gain as a side effect will cause some patients to discontinue a medication. *Id.* at 8. Certain atypical antipsychotics are associated with greater weight gain than others. *Id.*Olanzapine and clozapine was associated with the most weight gain (citing numerous studies). One study, for instance, found that over 10 weeks patients on Zyprexa gained 9 pounds, an "astounding amount." *Id.* at 10. "Weight gain of 5% or greater in adults area associated with important increases in risk." *Id.* Dr. Wirshing highlighted the studies and case reports linking diabetes, ketoacidosis, hyperglycemia and dyslipidemia with olanzapine. *Id.* at 17-28. "Coming together, the case reports, the vast majority of the retrospective database analyses, and controlled experimental studies including randomized clinical trials consistently demonstrate that olanzapine treatment increases the risk of significant weight gain, insulin resistance, hyperglycemia, and/or diabetes mellitus. *Id.* at 28-29.

***97** Dr. Wirshing reported that olanzapine is also associated with pancreatitis, an acute or chronic inflammation of the pancreas resulting in autodigestion of the organ. *Id.* at 34.

Dr. Wirshing also analyzed the efficacy of Zyprexa through a review of the medical literature. *Id.* at 36. He first examined the clinical trials upon which Lilly based its initial FDA New Drug Application for schizophrenia, including the U.S. Clinical Trial (six weeks' duration), the North American Clinical Trial (primarily six weeks duration, with up to 12 months option), the Eastern Hemisphere Clinical Trial (six weeks duration), and the International Clinical Trial ("ICT") (six week active phase).

Dr. Wirshing then concluded, inter alia, that: (i) information released by pharmaceutical companies can substantially affect the decisions of treating doctors and their choice of drugs for the treatment of certain psychiatric disorders and in turn substantially affect the outcome of the treatment efforts; (ii) there is a direct and indirect causal connection between the administration of olanzapine and certain adverse effects including significant weight gain, hyperlipedemia, hyperglycemia, pancreatitis, and the development of diabetes, *id.* at 48; (iii) the degree of the adverse effect on some patients using Zyprexa is substantially greater than the adverse effects observed in patients on other atypical antipsychotic medications, *id.* at 49; (iv) there is no credible evidence that olanzapine is more efficacious than typical and other atypical antipsychotic medications, *id.* at 49; (v) Lilly had a duty to notify health care providers and consumers when it knew or had reason to know of the clinically significant increase of weight gain to patients who had been prescribed Zyprexa, and to warn physicians that Zyprexa carries greater risk of diabetes than typical antipsychotics and all antipsychotic drugs other than clozapine, *id.;* (vi) Zyprexa should not be used as the first line drug of choice in the treatment of disorders for which it has been marketed, *id.;* (vii) had Lilly provided full disclosure to treating physicians of the actual potential consequences to their patients of the use of Zyprexa over other atypical antipsychotic medications, and of Zyprexa's lack of enhanced efficacy to justify the increased serious risk, a reasonably prudent doctor would not, given the fact that there are choices of typical antipsychotics and other atypical antipsychotics available to treat the illness for which Zyprexa is used, choose Zyprexa as the drug of first choice for

treatment of any illness for which the drug has been marketed, *id.* at 49-50; Wirshing Supp. Decl. 2-3; and (viii) Lilly was grossly negligent in allowing physicians to prescribe this drug without necessary and essential information about serious medical complications to a patient population already at an elevated risk for the development of diabetes or pancreatitis. Wirshing Decl. 50.

***98** Moreover, Dr. Wirshing opined that "[a]ccording to [his] personal consulting work for [Lilly], including clinical trial investigator, the considerable risk of significant weight gain and its potential adverse effects on patients being given olanzapine was known to Lilly as early as 1995." *Id.* at 49.

Lilly did not file a *Daubert* motion with respect to Dr. Wirshing. At the evidentiary hearing, Dr. Wirshing's testimony focused on two issues: 1) the clinical utility of Zyprexa and 2) what Lilly knew at time of launch.

a. Clinical Utility of Zyprexa

The positive impact of Zyprexa on a severally ill population was described by Dr. Wirshing: "Zyprexa ... clearly is useful and indeed, for certain patients, life-altering to a positive degree." Tr. at 401 (Mar. 31 & Apr. 1, 2008: Wirshing). He acknowledged that those patients' quality of life is dramatically enhanced by using Zyprexa. *Id.* at 430 ("[F]or that individual patient, it is potentially irreplaceable and crucial").

> I described to my students, I describe the selected serotonin reuptake inhibitors as slightly different shades of green of the same Chevy Caprice classic. I mean, okay, they are a little different, but its not really anything to write home about. But for these, the antipsychotic drugs for a given patient, one drug can work magnificently and another drug not work at all. They aren't fungible ....

Id. 409-10.

When a medication is working with a patient Dr. Wirshing sticks with that treatment like "a pit bull with lockjaw," Tr. at 391, notwithstanding side effects, considering it "tantamount to malpractice" to stop using a medication successfully treating a patient's psychosis. *Id.* at 401. Testifying that "there's almost on one hand I can tell you the side effects that I will stop a drug that's working because of toxicity .... I will stick with it because that's the right thing for that patient." Tr. at 391.

Dr. Wirshing explained that: "[p]atients that are treated on olanzapine .... are not the same patients that are necessarily being treated with quetiapine [Seroquel] .... So, it's a bit like comparing apples and oranges." Tr. at 407. He also testified that he used Seroquel and perphenazine much less than Zyprexa because they are less effective, Tr. at 434 (conventional drugs); 436-37 (perphenazine); 436 (Seroquel), and because perphenazine has side effects that are more difficult to manage than those he associates with Zyprexa. Tr. at 432.

Dr. Wirshing testified that Seroquel cost more than Zyprexa for patients with schizophrenia. Tr. at 407-08, 436 (Seroquel "is more expensive than clozapine" Risperdal and Zyprexa when dosed at high enough levels to "achieve an antipsychotic effect.").

Although Zyprexa might be more expensive for some prescriptions, successful treatment may result in total cost savings:

> THE COURT: So, within the class then, of bi-polar and schizophrenic people, some would be better treated if they were using Zyprexa. Would have better results on a per-cost basis.
>
> ***99** THE WITNESS: Absolutely. Despite what's enormously expensive technology, I mean literally hundreds of times the cost of generic haloperidol, if it works, it will wipe out the other costs. And is a perfectly prudent and defensible thing to do.

Tr. at 407-08.

b. Lilly's Knowledge at Launch

Dr. Wirshing testified that he was aware of the Zyprexa's association with weight gain at Zyprexa's launch. Tr. at 396. He knew that "[t]he contributed risk of significant weight gain and its potential adverse effects on patients being given olanzapine was known to Lilly as early as 1995." Tr. at 363. "The available evidence then ... was that you can't demonstrate a clear superior efficacy for olanzapine." *Id.* at

385; *see also id.* at 362, 384-86. Continuing, Dr. Wirshing stated, "There is a direct and indirect causal connection between the administration of olanzapine and certain adverse effects observed in some patients treated with this drug. These adverse events include, among other things, significant weight gain, hyperlipidemia, hyperglycemia, pancreatitis, and the development of diabetes." Tr. at 363.

In support of his opinions, Dr. Wirshing discussed a 1995 review of Lilly's preclinical data that concluded Zyprexa showed a lack of neurotoxicity but causes significant weight gain. *See* Pfs.' Slides: Hr'g on Pfs.' Mot. for Class Cert.: William Wirshing M.D. at 7. He also described an "extremely large, indeed the largest study, carried out at the time involving schizophrenic patients involving 1,996 patients with schizophrenia across the world," conducted by Lilly, that included 335 patients on olanzapine in a one-year extension of the study and who yielded an average weight shift of 24 pounds in one year's time. Tr. at 370-72. Despite knowing this information, Lilly only reported to the FDA the average weight shift at six months, which was approximately half of that observed at a year (5.8 kg vs. 24vs. 24 lbs). *Id.* at 379-80; *see also* Pfs.' Slides: Hr'g on Pfs.' Mot. for Class Cert.: William Wirshing M.D. at 2-12. Referring to a 1999 article about weight gain associated with Zyprexa, Dr. Wirshing noted that it confirmed what "[t]hose of us in the field had been discussing ... for years at that point." Tr. at 451.

Dr. Wirshing testified that the information made available on the Zyprexa label in October 2007 consisted of the kind of data known to Lilly in 1996:

> It was completely in keeping with the work that we've talked about that we did dating back to 1994. So the drug has not changed in terms of the metabolic consequences it causes....
>
> [T]he information contained in the 2007 label could have been-I can go back to the 1996 data set and pull out those numbers and arrive at numbers that are within a fraction of a pound of the numbers that are listed in the current product labeling. There's been no evolution of [Lilly's] understanding about the temporal relationship between weight gain and the use of olanzapine. It's not like those data have been elaborated recently. Those data have been known since before the drug was marketed.

***100** Tr. at 395-96.

At the time of Zyprexa's launch, the only SGAs available in the market were Risperdal and Clozaril. Moreover, "[a]t the doses clinically used, Risperdal clearly has more incidence of EPS" than do the other SGAs. *Id.* at 443. Clozapine, on the other hand has the distinction of being the "most powerful antipsychotic on the planet earth" and "without question the most toxic," with "potentially fatal" side-effects. *Id.* at 442-43.

Dr. Wirshing, who discussed original pricing with Lilly representatives, testified that Lilly had a "good faith" belief in that Zyprexa justified a price-premium over Risperdal:

> THE COURT: But was there at least, in your opinion, in your discussions with Lilly, a good faith marketing effort to price the drug at what they thought the value would be in the marketplace?
>
> THE WITNESS: In my opinion, absolutely. I mean, they were-were trying to price a drug which they felt, clearly felt, and I think they believed this, to be superior to the available technology at the time, which was risperidone. I didn't happen to share that opinion, but it's my belief that they had that opinion.

Tr. at 402-03

As Dr. Wirshing testified, at the time of the class-wide label change in 2003, the FDA determined that there was not enough evidence to conclude that there was a difference in rates of diabetes or hyperglycemia among the various atypical antipsychotics, and indicated that comparisons between drugs as to weight gain were inappropriate. *Id.* at 393. Nonetheless, Lilly unleashed "a virtual tsunami of marketing reaction from Lilly ... heralding the class uniformity of that particular toxicity." *Id.* at 393-94.

5. Lon S. Schneider, M.D.

Dr. Schneider is a professor of psychiatry and behavioral sciences at the University of Southern California ("USC") Keck School of Medicine, where he has taught psychiatry and behavior sciences, neurology and gerontology for over twenty years. He is also a professor of gerontology at the USC Leonard Davis School of Gerontology. Decl. of Lon S. Schneider, M.D., at 3, Feb. 21, 2007, Docket Entry No. 100 ("Schneider Decl."). Dr. Schneider is a practicing geriatric psychiatrist; his clinical practice includes the diagnosis and treatment of patients with dementia of various types, including Alzheimer's disease, behavior disorders, and

psychosis. *Id.* He has published almost 200 peer-reviewed articles and many more academic writings. *Id.*

Dr. Schneider is presently the director of the psychiatry department at the Geriatric Studies Center; vice chief of psychiatry services at USC University Hospital; director and principal investigator of the USC Alzheimer's Disease Research and Clinical Center of California; and the clinical core director at USC Alzheimer's Disease Research Center. *Id.* He was the principal investigator in the Alzheimer's disease trial portion of CATIE ("CATTE-AD"), in which Zyprexa and other SGAs were evaluated for treatment of psychosis and agitation in Alzheimer's disease. *Id.;* Rosenheck Decl. 3. He has received consulting fees from Lilly and other manufacturers of antipsychotic medications. Schneider Decl. 6. Lilly paid him to participate in various meetings and advisory boards with respect to drugs in development for Alzheimer's disease, and to consult on design of and investigator training for two ZyprexaAlzheimer disease clinical trials. *Id.*

***101** Dr. Schneider was asked by the plaintiffs to opine on the use of Zyprexa in elderly patients and efforts by Lilly to promote prescribing to elderly people and people with dementia. *Id.* at 2. At the evidentiary hearing, Dr. Schneider testified substantially as set forth in his previous report. *See id.* Lilly did not file a *Daubert* motion with respect to Dr. Schneider.

Based on his knowledge, experience, and review of the materials, Dr. Schneider opined that: (i) Lilly promoted evidence of efficacy and safety of Zyprexa for treating behavioral signs and symptoms in people with Alzheimer's disease and dementia that was misleading, *see* Schneider Decl. 14 ff; (ii) despite knowing that its clinical trial results could not support a therapeutic claim in the FDA-approved label for efficacy for behavioral signs and symptoms associated with Alzheimer's disease, Lilly continued to advertise, promote and personally detail physicians that the drug was effective for such purposes, using the "Martha" patient profile toward these efforts, *id.* at 21 ff.; (iii) between at least 1997 and 2003, Lilly published advertisements in geriatric medicine journals that advocated the use of Zyprexa, falsely and misleadingly implying its efficacy and safety for Alzheimer's disease, dementia, and behavioral symptoms in elderly patients, *see id.* at 30-38; and (iv) Lilly sponsored medical education meetings where the speakers were biased in favor of Zyprexa, touted its use for patients with dementia based on the results of a single positive trial, suppressed results of other negative trials, minimized adverse effects, and did not provide balance. *See id.* at 38-41; *see also* Abramson Rep. 62-66 (analyzing Lilly's marketing to the geriatric market).

a. Use of Antipsychotics for Dementia and Alzheimer's

The majority of people with dementia, including Alzheimer's Disease, develop behavioral symptoms during the course of their illness, including agitation, aggression, delusions, and hallucinations. Schneider Decl. 7-8. Treatment of such people "is a difficult and challenging clinical problem for which there are no satisfactory pharmacological or non-pharmacological approaches that work for most people so afflicted."*Id.* at 8. Doctors use multiple medications to try to treat symptoms, including FGAs, SGAs, anti-anxiety, and anti-convulsants. *Id.* at 8. As Dr. Schneider noted,

> [That] so many medications have been used for this purpose demonstrates that there are no clearly good or universal choices. So does the fact that when these medications are used in attempts to treat behavioral signs and symptoms of dementia, they are being prescribed by physicians for "off-label" indications. If any of these medications could be shown to be safe and effective for this population of patients are adequate and well-controlled studies, then that medication's prescribing label most likely would contain that indication.

***102** *Id.* at 8. Zyprexa's label currently carries a black box warning on its stating that it "is not approved for treatment of patients with dementia-related psychosis."

This is not for lack of trying; pharmaceutical companies, Lilly included, have sponsored trials intended to provide efficacy evidence for the FDA, but most results were not statistically significant. *Id.* at 11.

By 2000, Risperdal and Zyprexa became the dominant antipsychotics prescribed to nursing home patients, displacing FGAs, despite the limited efficacy. Schneider Decl. 12 (from July 1994 to March 2001, FGA market share

dropped from 92% to 21%; in March 2001, SGAs had 79% market share). "The vast majority of nursing home residents prescribed these drugs did not have schizophrenia or bipolar disorder," and the vast majority-90%-of prescribing doctors were not psychiatrists, but generalists. *Id.* at 12-13.

b. Lilly's Misleading Marketing to Alzheimer's Patients

Dr. Schneider testified that "Lilly promoted misleading evidence of Zyprexa's efficacy and safety for treating behavioral signs and symptoms of Alzheimer's Disease by delaying or failing to publish results of clinical trials and through the Martha patient profile." Tr. at 484, 491; Schneider Decl. 15 ff; *see also id.* at 493, 494, 495, 499, 505.

His opinions support Dr. Abramson's testimony; Dr. Abramson analyzed Lilly's internal marketing documents on geriatric use as supporting Dr. Schneider's conclusion about a program of Lilly to mislead. *See* Abramson Rep. 62-67; Part XVII.A.6, *supra.*

At the evidentiary hearing, Dr. Schneider testified that at the time Zyprexa was launched "[t]here was no evidence known and I don't think there was evidence [that Zyprexa was effective in treating dementia]." Tr. at 484, 491 (Mar. 31, 2008: Schneider testimony); *see also id.* at 493, 494, 495, 499, 505. He further testified that despite a lack of evidence supporting the claim, "[Lilly] prepared materials suggesting that olanzapine was cognitively improving in, of patients with Alzheimer's disease." Tr. at 501.

i. Delay of Clinical Trial Results

For example, Dr. Schneider noted that although Lilly's HGAO study on use of olanzapine for Alzheimer's disease or dementia-apparently the first drug-company-sponsored trial of its kind-was completed in 1994, "[t]he results of that study still had yet to be published in the peer review journal" as of the writing of his report in early 2007, although a brief abstract had been published in a journal in 1995. Tr. at 490; Schneider Decl. 14; *see* Abramson Rep. 64. In that trial, Zyprexa was not effective compared to a placebo. Schneider Decl. 15. Until 1999 there were no peer-reviewed published trials results available on the efficacy of SGAs in elderly people with dementia or Alzheimer's disease. *Id.* In October 2002, Lilly published the results of its HGEU Zyprexa trial for patients with Alzheimer's disease, with statistically significant results in favor of Zyprexa compared to a placebo. *Id* . at 15.

***103** Because of the lack of availability of all clinical trial results, the entire geriatric community came to conclusions other than they would have had Lilly ensured full publication. As a member of the panel that drafted the 1997 *Practice Guidelines for the Treatment of Patients with Alzheimer's Disease and Other Dementias of Late Life,* Dr. Schneider declared that the recommendations were made without knowledge of Lilly's negative HGAO trial despite the trial having concluded in 1994:

> Q: So if I understand it then, the negative HGAO study, at least the data for that, had been available for almost two years before this guideline was relegated, correct?
>
> A: Yes.
>
> Q: And the people, all of the people set forth in this practice guideline, none of them had available that data and that information for purposes of formulating guidelines that would be used for the treatment of those people, correct?
>
> A: No-yes, we did not have that information ...
>
> ...
>
> Q: So if I understand it then ... many doctors from around the country getting together, at least electronically, if not otherwise, trying to formulate guidelines for the treatment of Alzheimer's disease and other dementia items late-life seeking to get a hold of the best scientific information did not have access to the data from the HGAO study that had been around for two years at Lilly?
>
> A: I believe that's the case.

Tr. at 548-49.

ii. Formation of "Martha" Patient Profile

The "Martha" patient profile was one of the ways, according to Dr. Schneider, how Lilly promoted misleading evidence of Zyprexa's efficacy and safety for treating behavioral signs and symptoms of Alzheimer's Disease. Schneider Decl. 21 ff. Lilly used "patient profiles" and gave them to their sales representatives for help detailing the product to doctors. *See* Part XVII.B.1.b, *infra* (describing the hypothetical patient profile of "Donna"). She is presented as a widow living independently, but at risk for nursing home placement because of agitation, restlessness and paranoia.

> In sum, with the Martha spread, Lilly conflates various pieces of evidence-selected trials and evidence from patients with schizophrenia-to make up a story that Zyprexa is safe and effective for treating various behavioral symptoms in the elderly, including Alzheimer's disease, and improving the patients' cognitive function. In the spread, they show their intention to market this drug broadly to primary care physicians and elderly people generally. The primary care physician would interpret the Martha Spread as a claim that Zyprexa is effective for Alzheimer's disease and behavioral symptoms in old age.

Schneider Decl. 28-29.

iii. Ads in Geriatric Journals

The second branch of Dr. Schneider's opinion is that during the late 1990s and early 2002, Lilly published Zyprexa advertisements in geriatric medicine medical journals that were false and misleading and that suggest its use for elderly people with dementia and people with behavioral signs and symptoms that have not been diagnosed. *Id.* at 30-38. Specifically, they "were intended to encourage geriatricians to prescribe Zyprexa for elderly patients with dementia and patients with undiagnosed behavior problems. The advertisements were not aimed at treating schizophrenia or bipolar illness." *Id.* at 30. He points to ten advertisements as examples, one of which being the following:

> ***104** Advertisement # 3 states, "For your patients with SYMPTOMS and BEHAVIORS related to Psychotic Disorders ..." and then follows with, "Goals of Therapy: symptoms and behaviors STABILIZE hostility, hallucinations, delusions; the Zyprexa Profile MAXIMIZE tolerability, ease of use, safety; on additional benefits CAPITALIZE benefits for depression, anxiety, social withdrawal, cognition." The front page goes on to say in small print, "In 6-week acute phase trials, the most common treatment emergent adverse events associated with Zyprexa was somnolence ..." The second page with fine print on prescribing information under Indications and Uses is only that Zyprexa is "for the management of the manifestations of psychotic disorder." Advertisement # 3 ran in *Journal of American Geriatrics Society Clinical Geriatrics* on a nearly monthly basis from July 1999 to August 2000. In October and November 1999, and July and August 2000, the advertisement appeared in *Annuals of Long-Term Care: Clinical Care and Aging.*

Dr. Schneider's final conclusion was that:

> Taken together, these advertisements were meant to sell Zyprexa to nursing home physicians for nursing home patients and to encourage the prescribing of Zyprexa for elderly patients with nonspecific behavioral problems and dementia. The advertisements were important components of a "Long Term Care: Zyprexa Marketing Strategy7" (Plaintiffs' Exhibit No. 05843, Bates ZY1 00174845) that promoted Zyprexa for off-label uses in elderly people including a "wide range of symptoms, control of agitation and aggression, control of dangerous and inappropriate behaviors, does not impair cognition, [has] long term efficacy, ... helps patients think more clearly (cognition story), patients interested in activities ...," and without scientific evidence for any of this.

This and other testimony and physical exhibits would support a finding that Lilly deliberately misled debtors and others, leading to overpayments by class members.

iv. Geriatric CMEs

Dr. Schneider's third point was that Lilly sponsored Continuing Medical Education ("CME") meetings to inappropriately promote Zyprexa for use in the elderly to physicians and pharmacists by highlighting the drug, talking more about it and less about alternatives, and not providing fair balance. A physician attending these sessions would gain a misleading impression of Zyprexa's efficacy and safety. Schneider Decl. 38-41.

Dr. Abramson's report noted Lilly's marketing materials included "Strategy 1 in accomplishing this goal is to 'Establish Zyprexa as a first line choice in the treatment of the adult patient who is experiencing behavioral or cognitive symptoms-but is functioning well enough to live independently.' Handwritten on this document: 'Need to balance off label/symptoms and behaviors,' clearly showing that Lilly was aware that its 'Strategy 1" involves active marketing of Zyprexa off-label." Abramson Rep. 63. Only

"[t]wo studies [HGAO and HGEU] of the efficacy of Zyprexa in treating behavioral disorders in the elderly had been completed at that point ." *Id.*

***105** Since the class action certification hearing, the FDA has warned about the dangers of prescribing antipsychotic drugs to older people with dementia, that could increase the risk of death. The drugs include Zyprexa and Risperdal. *Antipsychotics and the Elderly,* N .Y. Times, June 17, 2008 (noting the FDA's new requirement for a black box warning for all antipsychotics describing their risks to dementia patients).

> The use of antipsychotic drugs to tamp down the agitation, combative behavior and outbursts of dementia patients has soared, especially in the elderly. Sales of newer antipsychotics like Risperdal, Seroquel and Zyprexa totaled $13.1 billion in 2007, up from $4 billion in 2000, according to IMS Health, a health care information company. Part of this increase can be traced to prescriptions in nursing homes. Researchers estimate that about a third of all nursing home patients have been given antipsychotic drugs.

Laurie Tarkan, *Doctors Say Medication [Including Zyprexa] Is Overused in Dementia,* N.Y. Times, June 24, 2008, at F1.

> [D]rugs carry a 'black box' label warning of an increased risk of death. Last week, the FDA required a similar warning on the labels of older antipsychotics. The agency has not approved marketing of these drugs for older people with dementia, but they are commonly prescribed to these patients 'off label.' Several states are suing the top sellers of antipsychotics on charges of false and misleading marketing.... Nursing homes are short staffed, and insurers do not generally pay for the attentive medical care and hands-on psychosocial therapy that advocates recommend. It is much easier to use sedatives and antipsychotics, despite their side effects.

Id. at F2.

6. John Abramson, M.D.

Dr. Abramson is a medical doctor and clinical instructor at Harvard Medical School. He is board-certified in Family Medicine and also has a Master of Sciences degree in Family Practice. Pfs.' Witness Statements; Expert Rep. of John Abramson, M.D., Feb. 28, 2007, Docket Entry No. 97 ("Abramson Rep."), at 4. For twenty years he practiced family medicine, and from 1994 to 2001, he was Chair of the Department of Family Practice at the Lahey Clinic in Massachusetts. *Id.* Between 1986 and 1993, he served as Associate Medical Director of Pru-Care of Massachusetts, and is currently the Executive Director of Health Management for Acordia Complete Health, a Wells Fargo Company, where he designs health benefits for self-insured companies. *Id.* at 5. Since 2002, Dr. Abramson has concentrated full time on his research, which focuses on "the information and misinformation about drugs and other medical products available to practicing physicians impacts their medical decisions and the overall quality, effectiveness, and cost of American health care," and has published multiple works on the subject. *Id.* at 6.

Dr. Abramson testified substantially as forth in his previous report. *See* Abramson Rep. Lilly's *Daubert* motion to exclude Dr. Abramson's report and testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

***106** He addressed the issue of how pharmaceutical-sponsored research and marketing affects doctors' decisions, patients' expectations and the overall quality and effectiveness of medical care. His opinion was that: (i) Lilly systematically maximized Zyprexa sales by influencing the sources of information that doctors are trained to trust, including scientific research, guidelines, continuing medical education, "thought leaders" and public advocacy groups, and marketing through drug representatives, (ii) much of Lilly's off-label marketing campaign was informed not by sound scientific studies of the benefits of Zyprexa, but by marketing studies

designed to determine the most effective ways to convince doctors to prescribe Zyprexa rather than the most effective ways to treat patients, and (iii) Lilly influenced purchasers and policy makers with claims of clinical and economic superiority, neither of which have stood up to non-Lilly sponsored scrutiny. *See* Abramson Rep.

In sum, it was Dr. Abramson's view that in the current commercially-dominated pharmaceutical arena, drug companies are able to turn medical data into brand messages. *See* Part IV.C, *supra* (describing drug company marketing influence over many sources of information). Because medical education gets mixed with drug marketing, the scientific message is corrupted. Tr. 740 (Apr. 1, 2008: Abramson testimony). Doctors themselves are often unaware of the extent of commercial influence over information they believe to be objective and subsequently find is biased and misleading.

a. Lilly's Influence over All Sources of Drug Information

Dr. Abramson testified that "Lilly systematically maximized Zyprexa sales by influencing the sources of information that doctors are trained to trust, including scientific research, guidelines, continuing medical education, "thought leaders," and public advocacy groups and marketing through drug representatives." Tr. at 715; *see also* Pfs' Slides: Hr'g on Pfs.' Mot. for Class Cert.: John Abramson, M.D. at 2 ("Abramson Slides"). During direct questioning, he stated:

> Q: And you've identified here today the various channels of information that have been available to physicians to acquire information about the use of olanzapine, correct?
>
> A: Correct.
>
> Q: And didn't you reach an opinion that every area of information that might be available to physicians, whether they're psychiatrists or primary care physicians, ... geriatric practitioners, was subject to the influence by Lilly?
>
> A: I did reach that opinion.

Tr. at 768-69 (Apr. 1, 2008: Abramson testimony).

Many sources of information contribute to the decision making of doctors. But over the past thirty years, the production and dissemination of medical knowledge about drugs and medical devices has been largely privatized. Tr. 716. Doctors should be, but often are not, aware of this commercial filter. *Id.* at 729. The system now depends on fair balance from, and truthfulness of, pharmaceutical companies themselves. *Id.* In sum, "Health policy decisions can be no better than the scientific evidence available to decision-makers. As shown above, it can no longer be assumed that the 'scientific evidence' is complete, unbiased, or represents the best possible information." Abramson Rep. 21.

b. Off-Label Promotion Informed by Marketing Studies

***107** Dr. Abramson testified, "[m]uch of Lilly's off-label marketing campaign was informed not by sound scientific studies of the benefits of Zyprexa, but by marketing studies designed to determine the most effective ways to convince doctors to prescribe Zyprexa rather than the most effective ways to treat patients." *See* Abramson Slides at 2; *see also* Tr. at 715 (Abramson). In Dr. Abramson's opinion, Lilly engaged in campaign of off-label marketing to primary care doctors, including Alzheimer's doctors, which was driven by marketing, not scientific research. Tr. 749. Primary care doctors are particularly vulnerable to such marketing campaigns. *Id.* at 750. The marketing was designed to convince doctors that Zyprexa would enhance the doctor-patient relationship. *Id.* at 752. The marketing also targeted symptoms. *Id.*

In particular, Dr. Abramson analyzed Lilly's "Viva Zyprexa" marketing campaign targeted at primacy care doctors, which was launched at a national sales meeting in March 2001. Tr. 754. The focus of the campaign was to target symptoms, not diagnoses. *See* Tr. 756 (quoting Lilly's "Zyprexa Implementation Guide" as stating that "in order to succeed in the primary care market we must focus on symptoms and behaviors that are found with mood, thought and behavioral disturbances."). After reviewing the marketing documents produced during discovery, including Zyprexa Implementation Guide, the "Zyprexa Surround Sound Marketing" document, Tr. 738; Abramson Rep. 41, multi-page detail aids, Stat-Grams, and John Q. Public letters, Tr. 747, he opined that the Viva Zyprexa drug detailers had been trained to provide information that is not honest and masked real risks. *Id.* at 761. The campaign exploited doctors who desperately wanted to help patients in difficult circumstances for which there is no good solution and held out false hope. *Id.* at. 759. Lilly first educated doctors on schizophrenia and bipolar treatment, and then switched to ordinary symptoms to enormously expand the potential range of customers for Zyprexa. *Id.* at 753-54.

On cross examination, Abramson said that for each new indication, the FDA must receive a supplemental NDA.

Tr. 776. The dramatic expansion he referred to in 2000 occurred right after Zyprexa's indication for bipolar mania was approved. *Id.* at 777. According to Lilly's own market research, 100% of doctors associated Zyprexa with diabetes by 2001. *Id.* at 789. Lilly justified emphasis on prescribing for symptoms by its contention that it often takes seven to ten years for bipolar patients to be correctly diagnosed and that marketing to primary care doctors was required since psychiatrists are not always easily available to diagnose bipolar and schizophrenia diseases. *Id.* at 800.

c. Lilly's Claims of Zyprexa Superiority Have Been Proven False

Dr. Abramson's view was that Lilly influenced purchasers and policymakers with claims of clinical and economic superiority, neither of which have stood up to non-Lilly sponsored scrutiny. Tr. 715 (Abramson). He highlighted the fact that Lilly misrepresented information about Zyprexa for years despite warnings from the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC"):

> ***108** And they describe three properties of atypicals including Zyprexa, of course. One is broad efficacy in treating negative as well as positive symptoms. DDMAC has said that they can't make comparative claims .... DDMAC has objected to comparative claims.
>
> One is greatly reduced risk of extrapyramidal side-effects and tardive dyskinesia. And DDMAC has taken exception to that claim.
>
> ... the third point that's made in the primary care implementation guide is "neutral clinical impact on prolactin." And that claim is disallowed or not substantiated by the information about prolactin in the label.

Tr. at 748 (Apr. 1, 2008: Abramson testimony).

It was Dr. Abramson's testimony that "Lilly created articles and marketing materials that made Zyprexa appear cost effective for managed care organizations and formularies." Abramson Slides at 5. In support of this opinion, he referred to two studies published in 1999 that "created a knowledge base that showed that using Zyprexa is cost effective compared to using first generation antipsychotics." Tr. at 732 (Abramson testimony). These two publications, based on the same study (Lilly's ICT study, *see* Rosenheck Decl. 8-9), suffered from methodological problems that were not known to the public until years later, in 2006, when a review article was published in the American Journal of Psychiatry. Tr. at 732-733. The 2006 article determined that "there is no clear evidence that atypical antipsychotics generate cost savings or are cost-effective in general use among all schizophrenia patients." *See* Abramson Slides at 30.

As of 2000, the "Zyprexa Product Team," with a "commercialization focus," had already published "over 125 full length manuscripts" in medical journals and in addition there were more than "100 recent manuscripts currently in play (i.e., under review ready for submission, etc) including proposed data mining papers." Abramson Rep. 30.

1999 Lilly studies showed Zyprexa to be cost-effective. Tr. 723. Formulary committees from 1999 to 2006 would have thought Zyprexa was cost-effective based on these reports. *Id.* at 733. "The three earliest studies of Zyprexa versus a first generation antipsychotic (FGA) [including the North American Double-Blind Olanzapine Trial and the International Collaborative Trial ("ICT")], all **funded** by Lilly, showed significant advantage of Zyprexa over haloperidol." Abramson Rep. 27. These studies were misleading according to plaintiffs' experts. *See* Rosenheck Decl. 8 ff.

B. Other Plaintiffs' Experts

1. Steven Klotz, M.D.

Dr. Klotz is a private practice psychiatrist, board-certified in Psychiatry, whose practice focuses on adult, child, and adolescent psychiatry. *See* Decl. of Steven Klotz, M.D. 4, Feb. 22, 2007, Docket Entry No. 99 ("Klotz Decl."). Lilly's *Daubert* motion to exclude Dr. Klotz as an expert was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007). Dr. Klotz reviewed the marketing materials and "diagnostic" instruments distributed by Lilly sales representatives to primary care doctors ("PCPs"). He then analyzed whether those materials conformed to and were appropriate diagnostic tools for Zyprexa's FDA-approved indications and found them misleading. *See* Klotz Decl. at 2.

***109** Lilly marketed Zyprexa to PCPs as well as to psychiatrists to reach a greater number of potential prescription writers, *id.* at 5; many people, in fact, are given antipsychotic medications without a psychiatric examination. The accuracy of mental health diagnoses made by primary care doctors without specialized training and experience of psychiatrists, however, often is questionable, as Dr. Klotz

noted. Lilly's marketing documents took advantage of this lack of studied expertise, in Dr. Klotz's opinion, leading PCPs to prescribe Zyprexa to patients for whom the antipsychotic was not appropriate. *Id.* at 7.

In Dr. Klotz's opinion, Lilly's PCP marketing campaign was designed to encourage primary care physicians to overdiagnose bipolar disease and to prescribe Zyprexa for symptoms-not FDA-indicated diagnoses-while minimizing Zyprexa's severe side effects. *Id.* at 8. As examples, Dr. Klotz points to Lilly's Mood Disorder Questionnaire ("MDQ"), a screening instrument offered to PCPs, and to sales representatives' use of the "Donna" patient profile when detailing PCPs. *Id.* at 7.

a. Lilly's Mood Disorder Questionnaire ("MDQ")

To encourage prescriptions of Zyprexa, Lilly distributed the MDQ, originally designed by Dr. R. Hirschfeld, to primary care physicians. The hand-out contained a series of questions Lilly indicated were to help diagnose the person filling out the questionnaire. ZY206449170-ZY 206449171. The MDQ instructed physicians they "have a positive screen if the patient answers ... 'Yes' to seven or more of the 13 items in question 1 AND ... 'Yes' to question 2." *Id.* at ZY206449171.

In Dr. Klotz's view, Lilly's promotion of the MDQ as Zyprexa prescription aid was misleading: "Screening instruments are not diagnostic instruments. They suggest that a patient in a selection group should receive further evaluation or referral to a specialist if the diagnosis is outside the realm of expertise of the clinician. Screening instruments in no way suggest treatment." Klotz Decl. 11. The MDQ "does not discriminate between subtypes of bipolar disorder" and "is insufficient to differentially diagnose active bipolar mania from phenotypically similar illnesses." *Id.* at 10-12. Although Zyprexa is only FDA-approved for certain types of bipolar disorder, the MDQ implies that Zyprexa is appropriate for all bipolar types. Assuming Lilly's marketing materials promoted the message that if you have the disease, you need the medicine, that would be "unsupported in the literature and medically inappropriate." *Id.* at 12. Dr. Klotz went as far as calling use of the MDQ "dangerous." *See id.*

These limitations on the sensitivity and applicability of the MDQ did not stop Lilly from encouraging primary care physicians to diagnose serious psychiatric illnesses using this thumbnail questionnaire: of the 100,000 call notes produced in this litigation (0.7% or less of the total number of call notes Lilly has for Zyprexa), approximately 3,000 entries mention the MDQ. *See* Ex. 510 at ZY100551-ZY10055100000.

b. Lilly's "Donna" Patient Profile

***110** Lilly's marketing materials also present a patient profile of an abstract "Donna," which was constructed to exemplify and detail the symptoms and history of a hypothetical patient who was suffering from a mental illness that should be treated with Zyprexa. *See also* Part XVII.A.5.b.ii, *supra* (describing the hypothetical older widow "Martha" profile used to market to the geriatric market). Lilly's marketing materials described "Donna" as a mother of two children in her early 30s who is "unable to focus," has "depressive symptoms" and cannot "get on with her life." She chiefly complained of sleeping too much and having trouble concentrating at work and home. Donna had been on SSRIs for depression in the past but has never been prescribed an antipsychotic. Primary care physicians were encouraged to prescribe Zyprexa to help people like Donna deal with symptoms of mood, anxiety, and disrupted sleep. Ex. 345 at ZY200061996-ZY200062011.

In Dr. Klotz's opinion, Lilly's patient profiles, including Donna, "lack sufficient information to suggest a treatment trial that begins with Zyprexa." Klotz Decl. 13-14. Using only the information in the Donna profile would be "medically insufficient to determine that Zyprexa, or any antipsychotic, were indicated." *Id.* at 13. Moreover, there is no evidence that Zyprexa has any mood-stabilizing effects. *Id.* at 12. (A mood stabilizer is "a compound that when taken prevents both depressed mood and mania or euphoric mood elevations." *Id.*)

In sum, Dr. Klotz concluded that: (i) Lilly's marketing to primary care physicians fostered a variety of misconceptions which would have led to the inappropriate treatment by primary care physicians with Zyprexa; (ii) the promotion of Zyprexa for use in the bipolar depressed phase was not indicated and Lilly utilized a variety of misleading marketing materials that would have encouraged that use; and (iii) "the use of Zyprexa in children is not warranted, supported or necessary," *see id.* at 16; moreover, the incidence of schizophrenia and bipolar in children is actually very low. *Id.* at 15.

2. Plaintiffs' Medical Experts

Plaintiffs also relied upon the following reports submitted in other phases of the Zyprexa litigation:

a. David B. Allison, Ph.D.

Plaintiffs' expert Dr. Allison is a professor in the department of biostatistics, head of the section of statistical genetics and director of the National Institute of Health-**funded** Clinical Nutrition Research Center at the University of Alabama in Birmingham, Alabama. In his report, Dr. Allison presented his opinion that: (i) antipsychotic drugs and especially the atypical agents generally induce significant weight gain after only a few months of treatment; (ii) among atypical antipsychotics, olanzapine produces more weight gain than all other drugs with the exception of clozapine; (iii) there are FDA-approved atypical antipsychotic drugs that cause little to no weight gain; (iv) the antipsychotic-induced or olanzapine-induced weight gain is at least deleterious as other weight gain; and (v) it is a misapprehension to believe that weight gain response to olanzapine is correlated with a therapeutic response. *See* Expert Witness Rep. & Decl. of David Allison, Ph.D., Feb. 12, 2007 ("Allison Decl.").

***111** Lilly did not file a *Daubert* motion with respect to Dr. Allison.

b. Fredrick Brancati, M.D., M.H.S.

Plaintiffs' expert Dr. Brancati is a professor of medicine and the director of the Division of General Internal Medicine at the John Hopkins School of Medicine, holding a joint appointment in epidemiology in the John Hopkins University Bloomberg School of Public Health. Dr. Brancati opines that: (i) the available peer-reviewed scientific evidence demonstrates that Zyprexa and a number of other atypical antipsychotic medications are associated with an increased risk of type II diabetes; and (ii) the propensity of individual atypical antipsychotic agents to cause weight gain (in order: clozapine, Zyprexa, Risperdal, Seroquel, Abilify, Geodon) appears to mirror their risk for glucose dysregulation and type II diabetes. *See* Expert Witness Rep. & Decl. of Frederick Brancati, M.D., M.H.S., Feb. 12, 2007.

Lilly did not file a *Daubert* motion with respect to Dr. Brancati.

c. David Goff, Jr., M.D., Ph.D.

Plaintiff's expert Dr. Goff is a professor in the Division of Public Health Sciences, Department on Epidemiology and Prevention in the Department of Internal Medicine at Wake Forest University School of Medicine in Winston-Salem, North Carolina. He is also the director of the schizophrenia program at Massachusetts General Hospital. Dep. of Donald C. Goff at 9, Nov. 14, 2006 ("Goff Dep."). He is a clinician who prescribes atypical antipsychotics and testified that he prescribes a pharmaceutical every time he sees a patient. *Id.* at 11-12. Dr. Goff found that: (i) the use of olanzapine is specifically associated with an increased risk for diabetes; (ii) the strength and consistency of this evidence is striking; and (iii) there is evidence showing that correct temporality, a dose-response relationship and potential mechanisms of action demonstrate that olanzapine can cause diabetes mellitus. *See* Expert Report of David C. Goff, Jr., M.D., Ph.D., Feb. 12, 2007 ("Goff Rep.").

Lilly did not file a *Daubert* motion with respect to Dr. Goff.

d. John L. Guerigian, M.D.

Dr. Guerigian is a medical doctor, currently employed at PharmaGenesis, Inc., a pharmaceutical consultancy in which he works with pharmaceutical experts worldwide. Previously he was a medical officer for twenty years at the FDA assisting in the discovery, development, and/or market introduction of a number of important drugs. In his report, Dr. Guerigian concludes that: (i) olanzapine can cause diabetes and its consequences or be a substantial contributing factor in the development of diabetes in some individuals; (ii) olanzapine increases the risk of diabetes and its consequences more than other atypical antipsychotics (other than clozapine) and thus the risk of diabetes with olanzapine is not "comparable" with other atypical antipsychotic drugs as claims by Lilly; (iii) internal Lilly documents demonstrate the company had credible scientific evidence in its possession since at least 1995 that the use of olanzapine was correlated with both weight gain and hyperglycemia; (iv) internal Lilly documents demonstrate the company had credible scientific evidence in its possession that weight gain and diabetes were inter-related and would thus act concurrently to increase the frequency of diabetes, its complications, and cardiovascular disease (which happens to be the number one cause of death in patients with diabetics); (v) Lilly's clinical studies were flawed by the use of imperfect methodologies, in particular the use of random blood glucose tests as opposed to the use of other more reliable methods of resting for hyperglycemia; (vi) internal Lilly documents demonstrate that the company delayed communicating essential data to regulatory agencies and resisted their requests to change the olanzapine label; (vii) internal Lilly documents demonstrate that the company did not act as a reasonably prudent manufacturer in that Lilly did not take the initiative of voluntarily adding to the label information needed by prescribers and indeed

ignored internal and external expert advice to warn physicians about the risks of diabetes; (viii) internal Lilly documents demonstrate that the company trained its representatives to mislead prescribers about the risks and benefits of olanzapine; (ix) Lilly failed to adequately warn physicians of critically important information regarding the risks of olanzapine that were reflected in its own internal documents and in published medical literature; and (x) Lilly compounded the danger of failing to adequately warn prescribing doctors about the risks of olanzapine by over-promoting the drug. *See* Rep. of John L. Gueriguian, Feb. 12, 2007.

***112** Lilly's *Daubert* motion with respect to Dr. Guerigian was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

e. Laura Plunkett, Ph.D., D.A.B.D.

Plaintiffs' expert Dr. Plunkett is a pharmacologist, toxicologist, FDA regulatory specialist and principal of a consulting company known as Integrative BioStrategies, LLC. In her report, she declared that: (i) it is clear that Zyprexa use is associated with an increased risk of adverse metabolic effects that include clinically significant weight gain and diabetes; (ii) these effects of Zyprexa were predictable based on the pharmacological profile of the drug; (iii) adverse metabolic effects can be pronounced with both short and longer term use of the drug; and (iv) at the time that Lilly failed to change its labeling language to warn of risks it was aware of to patients for hyperglycemia and potentially diabetes, Lilly was widening its marketing of the drug from psychiatrists to general medicine physicians. *See* Expert Statement of Laura M. Plunkett, Ph.D., DABT.

Lilly's *Daubert* motion with respect to Dr. Plunkett was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

C. Defense Witnesses at Hearing

Defendant Lilly proffered two witnesses at the certification hearing: Dr. Eugene M. Kolassa, Tr. at 553-707 (Apr. 1, 2008), and Dr. Iain M. Cockburn, *id.* at 811-925 (Apr. 2, 2008). Both defendant's experts met *Daubert* and Rule 702 standards.

1. Eugene M. Kolassa, Ph.D.

Dr. Kolassa is a health economist with thirty years of experience in the field of pharmaceutical marketing and economics. He is the Chief Executive Officer and Managing Partner of Medical Marketing Economics, LLC, a consulting firm providing advice and training in the fields of pricing, marketing, and market analysis in health care markets. Dr. Kolassa also serves as Adjunct Professor of Pharmacy Administration at the University of Mississippi and as Adjunct Professor of Pharmaceutical Business at the University of the Sciences in Philadelphia He has written and lectured extensively on the topics of pharmaceutical marketing and pricing, and the value of pharmaceuticals in the health care system, including authoring the book *Elements of Pharmaceutical Pricing* (1997), and coauthoring *Pharmaceutical Marketing: Principles, Environment, and Practice* (2002). *See* Kolassa Decl. 1.

In his declaration and at the evidentiary hearing, Dr. Kolassa presented his conclusions on several different issues, including: 1) the unusual nature of the pharmaceutical market; 2) the commonality of the proposed subclasses; 3) plaintiff's experts' determination of loss; 4) general rules of pharmaceutical pricing; 5) pharmaceutical price elasticity;

a. Nature of the Pharmaceutical Market

Dr. Kolassa pointed out that the pharmaceutical market operates very differently than other markets and involves unique distribution and financial aspects. Typically, a consumer purchases a product from either the manufacturer itself or a distributor; in contrast, a consumer *cannot* purchase a prescription drug directly from the manufacturer. The patient must obtain the drug from a pharmacy or its equivalent and only then with a valid prescription from a licensed physician. Each physician makes clinical decisions regarding the appropriateness of a specific medicine based on that patient's individual needs and expected response to the agent selected, which varies considerably in the case of antipsychotic agents. *Id.* at 2.

b. The Commonality of the Proposed Subclasses

***113** Dr. Kolassa also opined that the proposed consumer and third-party subclasses are lacking in commonality. Among third-party payors, access to and use of information about Zyprexa differs substantially, as does the degree to which they, individually, made any decisions regarding reimbursement for antipsychotics. *Id.* Patients also differ substantially and cannot be viewed as a group of similarly situated individuals. Differences in diagnoses, treatment

history, insurance coverage, co-payments make a common measure of "damages" impossible to quantity. In addition, prescribing physicians differ in knowledge levels and treatment approaches to mental illnesses. *Id.* at 2-3.

c. Plaintiff's Experts' Determination of "Loss"

Plaintiffs' methods for establishing "value," "actual worth" or "willingness to pay" were criticized by Dr. Kolassa. *See id.* at 3 ff. He believes that Dr. Rosenthal's determinations of loss of value for Zyprexa, computations of "excess sales" of Zyprexa caused by Lilly's alleged conduct, and calculation of damages "are neither consistent with marketplace realities nor the application of rigorous and accepted analytical techniques." *Id.* at 3. Her reliance on the CATIE study for comparative information "is totally inappropriate." Moreover, Dr. Kolassa takes issue with the plaintiffs' global approach to damages, opining that a "loss of value" approach requires individual damages assessment for each patient and payor.

d. General Rules of Pharmaceutical Pricing

Dr. Kolassa has established a set of pricing guidelines that have been widely adopted in the pharmaceutical marketplace. *Id.* at 4 (citing E.M. Kolassa, *The Elements of Pharmaceutical Pricing* (1997)). In setting the price for a prescription drug, manufacturers consider a variety of factors, including:

1. The existence and price of competitive product and the pricing behavior of the firms that sell them (i.e., how competitor respond to pricing actions).

2. The clinical, economic and social value offered by the medicine, both substantively as in economic terms.

3. Plaintiff population characteristics, such as age, common co-morbidities, and prescription drug coverage.

4. The factors that physicians will likely consider in determining whether to prescribe the medicine, and the degree to which the price may affect that decision.

5. Disease characteristics (e.g., chronic or acute; debilitating or cosmetic).

6. The reimbursement environment-how a product is likely to be reimbursed by payeos-and issues in the specific market for the product.

7. Public relations and public policy concerns over pricing.

8. The needs and ability of the manufacturer, including overall corporate strategy, market positioning for future performance, and the availability of internal resources to support its pricing strategy.

See id. at 4-5.

e. Pharmaceutical Price Elasticity

Dr. Kolassa described the wide discretion pharmaceutical companies have in the United States for setting and maintaining prices of their patented products. Because most pharmaceutical markets, including the market for antipsychotic medications, are relatively inelastic (unit sales are not responsive to most price changes), manufacturers almost never lower a drug's wholesale price, even when new information, positive or negative, is revealed; rather, they generally increase the prices of their products. *Id.* at 7 ("When a manufacturer learns that unexpected safety issues or other negative factors for their products emerge, the manufacturer does not lower the price to reflect a change in value. In fact, if such information is expected to result in a decrease in unit sales, the result is often more aggressive price increases, to compensate for that decrease and to protect revenue."). A change in value of a product does not usually result in a change in its price. Because medicines offer economic value considerably higher than the prices that are charged for them, Dr. Rosenthal's analysis, rooted in the hypothesis that the price of a medicine bears a direct and close correlation to its value, is "fundamentally unsound." *Id.* at 3.

***114** The price of Zyprexa was set upon its launch into the marketplace and was increased regularly, according to Lilly's internal policies that were applied to the majority of its products. The price of Zyprexa increased more rapidly after the September 2003 label change and the publication of the CATIE study. Kolassa Decl. 8.

Dr. Kolassa acknowledged, during questioning by the court, that

> A: ... these products differ so much that generally the payor is going to say that I can't just automatically exclude one because the patients need that and, so, it really has to do with the therapeutic aspects and the clinical aspects of that market. Whereas in others, they're freer to [distinguish between drugs and impose restrictions].
>
> ...

> The Court: In effect, these third-party payors are saying it's up to the doctor to decide with the patients we're just going to go along, right? ...
>
> A: Yes, pretty much, because and, again, because they see the products as different and they don't want to deny that. I've actually spoken with P and T committee directors specifically about this in this category and he [sic] said our belief was every one of these products needs to be made available.

Tr. at 695 (Apr. 1, 2008: Kolassa testimony).

As Dr. Kolassa explained, new indications for competitor drugs can create a 'halo effect,' which is a "signal to the marketplace that they might be comfortable in trying these products in other [off-label] areas as well." Tr. at 601.

For Dr. Kolossa, "the primary principle that should guide every pricing decision is that the price should reflect the value of the product to the customer ... The physical product itself should have clinical and economic value." His chapter "Pharmaceutical Pricing Principles" in "Pharmaceutical Marketing: Principles, Environment, and Practice" then goes on to discuss "the factors that should be considered when making pricing decisions" which include "the economic and social value of the therapy itself." *Id.* at 189. And Dr. Kolassa acknowledges that simply because a product is new, or because it has some different mechanism of action, does not necessarily mean that the product has a greater value or should be priced at a higher level. Dr. Kolassa, a recent lecturer to Lilly's "senior pricing people," summarized the pricing issue well:

> But what the market values, and what should be priced, is not the mechanism of action or unique chemical structure, but the outcome of the therapy, the end result, and how that differs from competitive products. When a product delivers better outcomes, it deserves to be priced at a premium relative to competitors. Should the outcomes not differ from competitive products, a parity price is in order. Worse relative outcomes should be reflected by a price that is lower than prevailing levels.
>
> Setting the price according to the relative value of the product is pricing at its most basic and most logical.

***115** E.M. Kolassa, *Pharmaceutical Pricing Principles, in* Pharmaceutical Marketing: Principles, Environment, and Practice (M.C. Smith & E.M. Kolassa, et al., eds.2002) at 211-12; *see also* Tr. at 649 (Apr. 1, 2008: Kolassa testimony). Dr. Kolassa has made the same point elsewhere. *See, e.g.,* Slides of E.M. Kolassa "Eli Lilly Comprehensive Strategic Pricing" MME00861-2, Kolassa Dep. Ex. 5 ("Understanding Value ... Value-based pricing is more than a buzzword; it is an important business tool and the most profitable method for reaching pricing decisions."); Slides of E.M. Kolassa "Eli Lilly Comprehensive Strategic Pricing" MME00864, Kolassa Dep. Ex. 5 ("Value Comparisons ... The value in which we should be most interested is the incremental value a new product will bring to the market"); E.M. Kolassa, Elements of Pharmaceutical Pricing 88 (1997) ("The economic value of the new product is the difference between the two treatment approaches: the cost of the original treatment minus the cost of treatment with the new product. Ideally, the treatment with the new product results in lower costs than treatment without it. The alternative, that treatment with the new product is more costly than treatment without, requires serious decisions about the launch of the product.").

In emphasizing value to the consumer as the basis for pricing, Dr. Kolassa joins issue with plaintiffs' experts who also made this same assumption about principles, but then conclude that Lilly's estimate of value, compared to other drugs of the same class, was grossly excessive.

2. Iain M. Cockburn, Ph.D.

Defense expert Dr. Iain Cockburn is a Professor of Finance and Economics at the School of Management at Boston University and experienced in the field of pharmaceutical pricing and delivery. He has a Ph.D. in economics from Harvard University.

Dr. Cockburn was asked to review the work and analysis of plaintiff's economic experts, Dr. Rosenthal and Dr. Harris. Specifically, he addressed the question of the reasonableness of their analysis and conclusions. He did not himself conduct any econometric studies of the price and quantities in the antipsychotic market. Tr. at 814. He submitted an expert report, then supplemented it. *See* Cockburn Rep.; Cockburn Supp. Rep.; Tr. at 815.

Like Dr. Berndt, Dr. Cockburn agrees that the statistical and health economics methodologies used by Dr. Rosenthal and Dr. Harris are well-accepted in the field of health economics. Among other criteria, a "willingness to pay" approach is a proper method to perform damage calculations. Although Dr. Cockburn attempted to criticize the implementation of econometrics by Dr. Rosenthal and Dr. Harris in their price

analyses, Dr. Cockburn conceded that, at the direction of Lilly's lawyers, he had performed no damage analysis of his own. As a result, because he had been instructed not to perform any calculations in order to determine whether or not his criticisms of Dr. Rosenthal and Dr. Harris supported Lilly's position, his opinion (that different results might be reached with the tweaks he suggests) is speculative. Nevertheless, plaintiffs' *Daubert* motion to exclude Dr. Cockburn's expert report and testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

***116** At the evidentiary hearing, Dr. Cockburn testified that he believed Dr. Harris and Dr. Rosenthal's price comparators are unreasonable and arbitrary, Tr. 838; they did not model price setting behavior; manufacturers have wide latitude in setting price; and pricing of Zyprexa and Risperdal have not changed relative to each other since launch. *Id.* at 840. If Lilly had known of the adverse side effects in 1996, Zyprexa might have been priced even higher because of the smaller target group. *Id.* at 841. Dr. Cockburn summed up his view of why the market is so complex: the diseases it is designed for are hard-to-diagnose and treat, and the market has changed constantly with new entrants and new labels. *Id.* at 818.

Dr. Cockburn noted that any analysis of what was causing the change in Zyprexa off-label use would require studying not just other drugs in the antipsychotic class, but "what is going on in other drug classes" where there are alternatives (including on-label alternatives) to off-label prescribing of an antipsychotic. Tr. at 867.

a. Criticism of Dr. Rosenthal's Analysis

In criticizing Dr. Rosenthal's off-label quantity theory, Dr. Cockburn emphasized the impact of promotion on sales. Dr. Rosenthal is wrong to assume that all the promotional effort directed at, for example, primary care doctors were attempts to persuade write off-label prescriptions, *id.* at 852, and that all the money in draft budget was actually spent; she assigns a value of zero for use of Zyprexa off-label, *id.* at 853, but off-label use is quite widespread since doctors prescribe off-label because they see some benefit in doing so, *id.* at 854; yardstick methodology or pricing is used only in a specific context relating to utility regulation, *id.* at 842, and he has never seen it used in a similar context to the instant case and believes it is unreliable, *id.* at 842; her yardstick comparators are very different products, which are not identical or interchangeable, *id.* at 843; she should not rely only on CATIE to establish equivalence of products, *id.* at 843-44; QALY is only one aspect of a drug's impact; dosing frequency is another, and very important, *id.* at 845; there is no evidence that prices have a clear relationship to QALYs, *id.* at 845; and hedonic price analysis is a methodology which is being quite widely used in economics to try to understand differences in pricing, *id.* at 846, but neither Dr. Harris nor Dr. Rosenthal used hedonic price analysis. *Id.* at 847.

Also contended by Dr. Cockburn is that Dr. Rosenthal's loss of value theory did not use any standard tools of economic analysis, *id.* at 847, and included no detailed, quantitative empirical work. *Id.* at 848. Dr. Rosenthal was using welfare analysis to capture the difference in consumer surplus were the demand curve to shift, but she never measured the slope of the curve, *id.* at 850; the area of consumer surplus will depend on the curve and the price elasticity, *id.* at 850, there is no way of knowing the slope of the curve or extent of the demand shift. *Id.* at 851.

b. Criticism of Dr. Harris' Analysis

***117** Dr. Cockburn testified that Dr. Harris's assumptions are not reasonable. Tr. 817. He contended that the Harris opinion is not standard, but is "very different from the approach that would be normally taken by an economist which will be to look at a range of hypotheses, a full range of the factors that might affect pricing or sales, and then to conduct an statistical or econometric testing of such hypotheses rather than to assume these factors away." *id.* at 820. Cockburn would draw a much steeper demand curve because of price inelasticity, *id.* at 822, and Harris did not try to calculate the slope of demand curve.

This defense expert asserted that Dr. Harris attributed 100% of the decline in sales post 2003 to revelation of weight information. *Id.* at 824. According to Dr. Cockburn, Dr. Harris's model is too simplistic-there are in fact many factors. He says that CATIE was not a watershed event. *Id.* at 835. The evidence of weight relationships had been building up to support a consensus statement over some time. *Id.* at 825 (2003 label change was for all SGAs, and weight gain on Zyprexa's label had existed for years). The 2003 label change did not mention weight, *id.* at 826, and other factors that should be considered in decline, including: 1) competition-of Geodon in March of 2001 and of Abilify in November of 2002, *id.* at 827; and 2) promotion effort differences among competing drugs. *Id.* at 830.

Dr. Cockburn stated that Zyprexa detailing fell in 2001, declining from $60 million per year to $30 million, while

Abilify detailing went from $5 million to $40 million. Tr. 831. Other criticisms were based on the fact that direct-to-consumer advertising for Abilify was substantial during 2005-$40 million per quarter, Tr. 832-33, while Zyprexa did not rely on direct advertising; personal injury litigation advertising began extensively in 2004 by personal injury lawyers, Tr. 833; and reaction to information about metabolic issues may have caused doctors to change their prescribing behavior. Tr. 834. He would have modeled these five potential causes in analyzing the decline in Zyprexa sales. *Id.* at 834-35. Dr. Harris' assumption that sales in the years 2000 to 2005 would not have exceeded 2006 levels is invalid and unreasonable, *id.* at 836, since the weight issues were already known so they already had had an effect; Harris should have done empirical, quantitative investigation into competing explanations, and that plaintiffs were relying on "armchair economics" instead of field research. *Id.*

Dr. Cockburn emphasized that Lilly marketing document from 2001 reported 100% doctors in a survey were aware of Zyprexa-related weight gain, metabolic issues, and diabetes. *Id.* at 835. He also explained that NDTI data is not reliable for measuring off-label prescriptions. *Id.* at 855 ff. NDTI data does not link individual prescriptions with a diagnosis code. *Id.* at 861. Most doctors who participate are primary care doctors. *Id.* at 862. NDTI data are reported quarterly with the possibility of substantial fluctuations within and between quarters, *id.* at 863, and what is on-label changes over time. *Id.* at 865. Off-label use could have fallen because the doctors were prescribing some other drug off-label. *Id.* at 867.

***118** Dr. Cockburn noted that NDTI data does not track any individual prescriptions, but is based on "mentions" that certain office-based physicians enter on the survey form. *Id.* at 855-64. Linking the "mention" with the approved indication for the drug is an inexact science, and the substantial fluctuations in the data from quarter to quarter make NDTI a "noisy source." *Id.* at 863. "[T]here are multiple potential causative factors" that can drive NDTI data. *Id.* at 866. "You'd have to rule out a lot of other factors before you could necessarily attribute changes in prescribing these particular drugs to something such as, you know, these concerns about metabolic problems." *Id.* at 867. Any useful model of this market should look at market share. *Id.* at 868. There is a reliably fixed set of patients that have to be treated. Zyprexa fell and Abilify increased. *See also* Tr. at 866-67, 884, 889, 892, 897, 904, 926. As Dr. Cockburn testified, increased advertising by plaintiffs' attorneys about Zyprexa personal injury litigation might have frightened some number of physicians, as they moved away from using Zyprexa to other medications. *Id.* at 833.

Dr. Cockburn's Exhibit A showed that: "there were over 200 clinical trial studies published on antipsychotics between the period 1996 and 2005 ... Approximately half of these were published prior to the label change in 2003." In rebuttal, plaintiffs point out that some publications may be far more influential than others, *see* Harris Rebuttal 8, and that many of these articles may have been written, produced, or influenced by Lilly, resulting in a positive, not negative, influence on Zyprexa. *Id.*

D. Other Defense Experts

Four of Lilly experts, upon whom Lilly relied during summary judgment proceedings, did not testify at the evidentiary hearing.

1. Ernest R. Berndt, Ph.D.

Defendant's expert, Dr. Ernest Berndt, is a professor of economics at the Massachusetts Institute of Technology. He has co-authored with Plaintiff's expert Dr. Rosenthal various articles that are a part of basic health economics literature applying accepted statistical and regression analysis quantifying the impact of various types of marketing efforts on pharmaceutical sales. He criticized Dr. Rosenthal's implementation of econometrics to estimate marketing impact on sales. Plaintiffs' *Daubert* motion to exclude Dr. Berndt's testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

2. David W. Feigal, Jr., M.D.

Defendant's Dr. Feigal is an employee with a pharmaceutical company although he once worked for the FDA. Dr. Feigal proffers the opinion that Lilly provided the FDA with comprehensive and appropriate information to evaluate the potential association between Zyprexa and glucose dysregulation and pancreatitis. He did not review Lilly's internal analysis of its own data or other available data or information concerning the safety profile of Zyprexa or any internal Lilly correspondence on the subject. His opinions are based solely on his review of Lilly's final submission to the FDA. Plaintiffs' *Daubert* motion to exclude Dr. Feigal's testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

3. David Kahn, M.D.

***119** Defendant's Dr. David Kahn is a clinical professor of psychiatry at the Columbia University College of Physicians and Surgeons. Dr. Kahn was a part of the "consensus" panel for the Texas Medication Algorithm Project, a project largely **funded** by the makers of psychotropic and atypical antipsychotics drugs. Dr. Kahn points out that results for Zyprexa in CATIE were not uniformly negative: "olanzapine had a statistically significant advantage over perphenazine for discontinuation due to lack of efficacy, and duration of successful treatment." Kahn Rep. 6

Dr. Kahn favors off-label use of medications, including Alzheimer's disease and especially in psychiatry. He proffered several opinions in an effort to rebut the sweeping cost-effectiveness studies, including CATIE, released in recent years. *See* Rosenheck Rebuttal Decl. (rebutting Dr. Kahn's comments on CATIE). In doing so Dr. Kahn contradicted another one of Lilly's proposed experts, Carol Tamminga, M.D. Plaintiffs' *Daubert* motion to exclude Dr. Kahn's testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

4. Jeffrey S. McCombs, Ph.D.

Defendant's Dr. McCombs is a professor at the School of Pharmacy at the University of Southern California. Dr. McCombs and his department have a long-standing relationship with Lilly; most of his grants are **funded** by the company. Dr. McCombs proffered an opinion that CATIE's results are inconsistent with McCombs's own Lilly-sponsored and unpublished retrospective findings based on underlying data and analysis Lilly has refused to produce. At the request of Lilly's counsel, Dr. McCombs did not undertake a review of all appropriate scientific evidence regarding Zyprexa cost-effectiveness. *See* Pfs.' Fact Proffer at II. Plaintiffs' *Daubert* motion to exclude Dr. McCombs' testimony was denied. *See* *In re Zyprexa Prods. Liab. Litig.,* 493 F.Supp.2d 571, 580 (E.D.N.Y.2007).

Dr. McCombs expressed concern about the loss of data in CATIE and representativeness of CATIE patient sample. He used an analysis of 2000-2002 data from the California Medicaid program. For purposes of the present analysis this evidence suffices.

XVIII. ***Proposed Class, Class Representatives, and Claims***

A. Proposed Class

Plaintiffs propose one class, a Purchase Claim Plaintiff Class, with two subclasses: the Third-Party Payor Subclass and the Consumer or Direct Payor Subclass. These two subclasses could be further subdivided into classes for on-label purchases and off-label purchases. Plaintiffs seek class certification under two different legal causes of action: state consumer fraud statutes and the federal civil RICO statute.

Counsel for plaintiffs claim to represent the entirety of third-party payors. According to plaintiffs' counsel Mr. Sobol, "approximately 25,000 third party payers in the United States, i.e., for-profit and not-for-profit insurers, health and welfare **funds**, self-insured employers that routinely are that class." Sept. 21, 2006 Hr' g Tr. at 16.

***120** As outlined in Plaintiffs' First Amended Complaint and the Memorandum of Law in Support of Purchase Claim Plaintiffs' Motion for Class Certification ("Plaintiffs' Class Certification Brief"), the Purchase Claim Plaintiff Class is defined as:

> 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 for some or all of the purchase price.

Pfs.' Corr. Supp. Post-Hr' g Mem. on Class Cert. 32.

1. Proposed Class Definitions

In Plaintiffs' Class Certification Brief, plaintiffs subdivided the definition into the Third-Party Payor Class and the Consumer Class.

a. Third-Party Payor Subclass

The Third-Party Payor Subclass is defined as:

> All private, non-government entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of Zyprexa prescribed, provided, or administered to natural persons covered by such contract, policy, or plan during the period from January 1, 1996 to the present. Such entities include, but are not limited to, insurance companies, union health and welfare benefit plans, entities with self-**funded** plans that contract with a health insurance company or other entity to serve as a third-party claims administrator to administer their prescription drug benefits, private entities paid by any governmental entity (including a state Medicaid program), and other organizations that paid for all or part of a Zyprexa prescription since January 1, 1996.

Id. Alternatively, Plaintiffs propose the following, slightly revised definition for the Third-Party Payor Subclass:

> All entities in the United States and its territories, except Medicare, Medicaid and the Veterans Administration, that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of Zyprexa prescribed, provided, or administered to natural persons covered by such contract, policy, or plan during the period from January 1, 1996 to the present.

Id. at 32 n. 90.

b. Direct Payor Subclass

The Direct Payor Subclass is proposed to be defined as:

> All individuals in the United States and its territories who, for purposes other than resale, purchased, reimbursed, or paid for some or all of the price of Zyprexa during the period from January 1, 1996 to the present.

Id. at 33. Alternatively, Plaintiffs propose the following, slightly revised definition for the Direct Payor Subclass:

> All natural persons in the United States and its territories who paid, either in cash or as a percentage co-pay, all or part of the cost of Zyprexa prescribed, provided, or administered to natural persons during the period from September 30, 1996 to the present.

***121** *Id.* Only consumers who paid for their entire prescriptions or whose insurance plans require variable co-payments are in the Direct Payor subclass. Individuals with flat co-pay plans are not included.

c. On-Label Sub-Subclass

Within the Direct Payor Subclass, Plaintiffs seek certification of two further subclasses: on-label and off-label. The proposed definition of the On-Label Direct Payor Subclass is as follows:

> All natural persons in the Consumer Class who paid for prescriptions of Zyprexa, as set forth in the Consumer Class definition, which were for diagnoses of schizophrenia, acute mixed or manic episodes associated with Bipolar I Disorder, or agitation associated with schizophrenia and bipolar I mania.

Id.

d. Off-Label Sub-Subclass

The proposed definition of the Off-Label Direct Payor Subclass is as follows:

> All natural persons in the Consumer Class who paid for prescriptions of Zyprexa, as set forth in the Consumer Class definition, which were for diagnoses other than schizophrenia, acute mixed or manic episodes associated with Bipolar I Disorder, or agitation associated with schizophrenia and bipolar I mania.

Id.

2. Proposed Multi-State Class

Plaintiffs request certification of these four classes/subclasses under a state law consumer fraud theory. Under that theory, the Direct Payor Class would consist of a class of consumers in forty-one jurisdictions, including: Alaska, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, **NewJersey**, New Mexico, New York, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin. Ten states are not listed because they require individualized reliance, expressly preclude class actions, or have uniquely onerous elements that would make trial of class claims. The third-party payor class would consist of a class of third-party payors in thirty-two jurisdictions, including: Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, **NewJersey**, New Mexico, New York, North Dakota, Oregon, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. In addition to the ten states excluded from the Direct Payor Class, nine additional states have been removed from this class because their statutes prohibit standing by third-party payors.

Alternatively as to state law claims, Plaintiffs seek certification of an exemplar New York state only class for each of the four subclasses. Six of the eight named class representatives are from New York, made their purchases in New York and invoke New York state substantive law for their claims. (The named plaintiffs' claims are governed by Pennsylvania (UFCW), Texas (Mid-West), and New York (SBA, Local 28, Teachers **Fund**, DC 37, Mr. Pronto and Mr. Vannello) law.) Certifying an exemplar New York state only class avoids, contends plaintiffs' counsel, arguments of complexity from multistate proceedings.

3. Proposed National Class

***122** As to the federal RICO claim, Plaintiffs seek certification nationwide on behalf of all four subclasses on liability, causation and damages. They contend that *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir.2008), *subsequently requiring modification by Bridge v. Phoenix Bond & Indemnity Co.*, No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008), does not bar this class action.

B. Proposed Class Representatives

Plaintiffs' counsel has selected as representative payor plaintiffs six small entities that pay for prescription drugs under pharmacy benefit plans: Mid-West National Life Insurance Company of Tennessee; UFCW Local 1776 and Participating Employers Health and Welfare **Fund**; Local 28 Sheet Metal Workers; and Sergeants Benevolent Association Health and Welfare **Fund**. Five of the entities are Taft-Hartley or similar **funds**, and one is an insurance company. Additionally, Michael Pronto and Michael Vannello are co-lead plaintiff patients representing individual consumers who paid in part or in whole for their own individual Zyprexa prescriptions.

UFCW Local 1776

UFCW Local 1776 is a small labor union based in Philadelphia with over 20,000 active members. Services: Provides, through a trust **fund**, pharmacy benefits for employees and their family members. Payments for Zyprexa were $800,000, with plaintiff's estimated damages of $264,000.

Mid-West Life Insurance
Mid-West Life Insurance is a small life and health insurance company providing health and pharmacy benefits to beneficiaries throughout the United States, with payments for Zyprexa of $32,570 and estimated damages of $10,000.

Sheet Metal Workers Local 28
Sheet Metal Workers Local 28 operates its program through a Taft-Hartley trust **fund**. It provides coverage for members living in the five boroughs of New York as well as Nassau and Suffolk Counties in New York. Payments for Zyprexa were $200,000, with estimated damages of $66,000.

Sergeants Benevolent Association
Sergeants Benevolent Association has a Health and Welfare **Fund**. Provided are pharmaceutical benefits for approximately 33,000 individuals, including New York City police officers who have been promoted to the rank of Sergeant as well as line of duty widows, their dependents, and retiree sergeants. Its payments for Zyprexa were $87,869, with estimated damages of $28,996.

Michael Vannello
Michael Vannello is an individual payor and former messenger for the First Manhattan Company. He took Zyprexa from February 23, 2000 to October, 2002. His payments for Zyprexa were $5,932 out of pocket, with estimated damages of $1,957. As already noted, he cannot represent the class. *See* Part III.2.b.iv, *supra.*

Michael Pronto
Michael Pronto is an individual payor from New York that felt sad and depressed after breaking up with his girlfriend. He took Zyprexa from April 28, 2003 through October, 2006. His payments for Zyprexa were $500 in out-of-pocket copayments, with estimated damages of $165. As already noted, he cannot represent the class. *See* Part III.2.a.iv, *supra.* He is in the process of settling his claim for personal injuries due to Zyprexa and, having recovered for this use, would not be a suitable class representative.

C. Causes of Action

1. State Consumer Fraud Statutes

***123** Plaintiffs have submitted a proposed trial plan and analysis of relevant state laws. *See* Class Plaintiffs' Proposed Trial and Apportionment Plan and Statement of State Law in Support of Class Certification ("Proposed Trial Plan").

2. Federal Civil RICO Claim

Section 1964(c) of Title 18 ("civil RICO") gives private citizens a federal substantive cause of action under the Racketeer Influenced and Corrupt Organizations ("RICO") statute and the federal mail fraud statute. 18 U.S.C. §§ 1341 *et seq.* It provides that "[a]ny person injured in his business or property by reason of a violation of [RICO's substantive provisions] may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." 18 U.S.C. § 1964(c). To succeed on a civil RICO claim, a plaintiff must be able to prove (1) a RICO violation, (2) injury, and (3) transaction and loss causation. *McLaughlin v. American Tobacco Co.,* 522 F.3d 215, 222 (2d Cir.2008); *Bridge v. Phoenix Bond & Indemnity Co.,* No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008) (holding that the persons injured by the fraud need not be the persons to whom the false statements were directed).

D. Proposed Class Damages Estimate the Total Out-of-Pocket Losses with Sufficient Precision

To certify a damages claim in this case (whether under RICO or state law), plaintiffs must propose one or more methods by which to reasonably estimate damages to class members in a manner consistent with the flexibility and efficacy permitted by Rule 23 of the Federal Rules of Civil Procedure, and with appropriate consideration of defendants' and individual plaintiffs' due process rights. Plaintiffs claim to have done so; Lilly disagrees. In resolving factual disputes as to certification, the court "should be persuaded that [each] fact [relevant to Rule 23] at issue has been established." *In re Initial Public Offering Securities Litigation,* 483 F.3d 70 (2d Cir.2007).

Assuming fraud leading to a price differential has been established, damages may be estimated based on the difference between what was paid for Zyprexa and the actual value of the product. The computation requires (i) estimating

the total out-of-pocket expenditures for the class members and (ii) using well-accepted techniques in applied economics to determine the actual value, or appropriate launch price, plus minor increases, of Zyprexa.

The evidence shows that reasonably accurate estimates can be made of the total out-of-pocket payments made by the class for Zyprexa over the class period. Lilly did not dispute at the evidentiary hearing (or in its prior submissions) that in the "data rich" pharmaceutical field, expenditure information by year, by source of payment (*e.g.,* third-party payors; government payors; insurance copay or cash consumers), and by state are available. Plaintiffs' experts Drs. Rosenthal and Harris used widely available expenditure data to estimate expenditures by the class. Internal Lilly documents also show Lilly coming to similar estimates of expenditures by source of payment at various times. In short, the question "what was paid?" for Zyprexa during the class period is readily determined.

***124** The methodology for determining actual economic value, or true launch price of Zyprexa, is an issue a jury can determine. Evidence could be relied upon by a jury to determine that, but for Lilly's misconduct, the launch price of Zyprexa would have been set at markedly lower levels than its major competitors. Lilly's own experts both opined that pharmaceutical launch prices are in large part set by the clinical attributes that distinguish the product. Better products suggest better launch prices. Internal Lilly documents confirm this methodology. And plaintiffs' experts persuasively testified that comparables with other competing pharmaceuticals are routinely used in applied microeconomics.

The implementation of comparative value is well-documented on this record. Two economists for plaintiffs, working independently, each chose and implemented a comparative methodology for determining the value of Zyprexa for damage purposes, both at launch and during the class period. The soundness of their comparative analysis was bolstered by the testimony of two of the nation's leading psychiatrists, along with the conclusions of an expansive clinical trial conducted by the NIMH. The CATIE study, bolstered by CUtLASS, the VA Cooperative Study, and many others, along with the testimony of Drs. Rosenheck and Schneider, supported the comparative use by Drs. Rosenthal and Harris of other, markedly less expensive, second generation and even first generation antipsychotics. Specific arguments raised by Lilly regarding the comparative analysis were rebutted by plaintiffs' experts, providing a jury issue.

McLaughlin does not bar the methodology for determining class members' damages here. Unlike plaintiffs' damages model used in the instant case, the plaintiffs in *McLaughlin* had not developed a manner by which a standardized overcharge based on the actual out-of-pocket losses caused by the defendants' conduct could be determined.

The plaintiffs in *McLaughlin* posited two methods of calculating damages: (i) the loss of value method, assuming that plaintiffs should have paid less for light cigarettes because they did not receive the benefit of their bargain over their out-of-pocket expenditures, to wit, healthier cigarettes, *McLaughlin,* 522 F.3d at 228-29; and (ii) the price impact method, asserting that defendants would have been required to reduce their prices if the truth about their products had been known and the concomitant demand had been reduced. *Id.* at 299-30. The *McLaughlin* court found that an unacceptable level of speculation was inherent in both proposed methodologies.

In the loss of value method, the plaintiffs would have had to estimate what a consumer would have paid for a healthy cigarette. Plaintiffs' experts were, however, according to the appellate court, unable to establish the purported loss of value. One expert asked consumers to compare between a "genuine" light cigarette that reduced health risk and a "misrepresented" light cigarette that was no different than conventional cigarettes, and survey respondents reported a "non-zero" loss in value, leading the appellate court to conclude that plaintiffs' theory was "pure speculation." *Id.* at *9.

***125** In the price impact method of evaluating damages, the *McLaughlin* plaintiffs would have had to estimate how much class members would have been willing to pay for light cigarettes had the truth been known. But the plaintiffs had failed, according to the appellate court, to provide a reasonable means of estimating that price because (i) light cigarettes had always been priced the same as regular cigarettes, and (ii) no drop in demand or price for light cigarettes occurred once a monograph was published reporting that light cigarettes did not reduce the risks of smoking. *Id.* at *9-10.

In both proposed *McLaughlin* methodologies, the appellate court held that there was no method for determining an actual overcharge. It rejected the plaintiffs' proposed method of determining a hypothetical overcharge and method by which those with varying degrees of strengths of claims might make claims for damages at the claims stage, leading to the payment of damages that would not reflect the defendants' actual liability or, worse, would "bear[ ] little or no relationship to the amount of economic harm actually caused by defendants." *Id.* at *11.

Contrary to the salient flaws present found by the appellate court in the causation and damages model presented by the plaintiffs in *McLaughlin,* plaintiffs' Zyprexa model reflects actual overcharges and actual harm caused by Defendant. A jury could find that Drs. Rosenthal and Harris's calculations of aggregate damages for the class are sufficiently reliable and appropriate based on the record.

The economic analyses undertaken in the instant case are supported by the fact that they have the features of reliability lacking in *McLaughlin.* For example, in *McLaughlin* there was the "lack of an appreciable drop in the demand ... of light cigarettes after the truth about lights was revealed...." *McLaughlin,* 522 F.3d at 227. Here, however, there is a remarkable decline in the demand for Zyprexa after only some of the truth was revealed, and despite Lilly's counter-offensive to ameliorate the impacts of truth creep. *See* charts and graphs, *supra.* Unlike the tobacco companies in *McLaughlin,* here Lilly itself ascribed the diminution in demand for Zyprexa to the disclosures of opinions by the American Diabetes Association's consensus statement in late 2003 and early 2004. And, of course, significant truths were yet to be revealed-e.g., the lack of comparative cost effectiveness of Zyprexa to perphenazine or other antipsychotics, as revealed in CATIE and later trials; the FDA's eventual acquisition of data (previously undisclosed by Lilly) leading up to the label change in October 2007; and analyses regarding the lack of efficacy and safety issues posed by treating elderly persons with dementia by prescribing Zyprexa.

McLaughlin affirmatively ruled that in RICO cases the "acceptable measure of injury [is] out-of-pocket damages ...." *Id.* Unlike *McLaughlin* (where different types of cigarette purchasers might seek different levels of percentage recovery), in this case all purchasers seek the same level of recovery-the difference between what they paid and what the product should have been priced at.

***126** Finally, in *McLaughlin,* the estimate of aggregate damages would "not accurately reflect the number of plaintiffs actually injured by defendants" and would bear "little or no relationship to the amount of economic harm actually caused by defendants." *McLaughlin,* 522 F.3d at 231. But there is no rough estimation of gross damages proposed in the instant case. The present overcharge case may be likened to garden-variety antitrust claims. Indeed, in this case even more so than in many such anti-trust cases, a highly accurate estimation of the class members' damages can be determined for the class, because of the "data rich" environment of pharmaceuticals.

It is important to note that *Bridge v. Phoenix Bond & Indemnity Co.,* No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008), decided subsequent to *McLaughlin,* supports directly plaintiffs' theory of causation. It held that the person who suffered the loss need not be the one to whom the fraudulent words were directed. *Phoenix Bond,* 553 U.S. 639 at ----, 128 S.Ct. 2131, 170 L.Ed.2d 1012 at ----, 2008 WL 2329761 at *12 ("[W]e hold that a plaintiff asserting a RICO claim predicated on mail fraud need not show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations."); *id.* at 10 ("Petitioners' contention that proximate cause has traditionally incorporated a first-party reliance requirement for claims based on fraud cannot be reconciled with these authorities."); *id.* at 11 ("Accordingly, it may well be that a RICO plaintiff alleging injury by reason of a pattern of mail fraud must establish at least third-party reliance in order to prove causation."); *id.* at 11 ("Proof that the plaintiff relied on the defendant's misrepresentations may in some cases be sufficient to establish proximate cause, but there is no sound reason to conclude that such proof is always necessary."). The instant case is a perfect example of that proposition. The fraud was directed to prescribing doctors. The overpayments were made by third-party and individual payors.

In *McLaughlin,* the Court of Appeals for the Second Circuit rejected the district court's proposal to allocate damages: "the plaintiffs could prove collective damages on a class-wide basis, and individual plaintiffs would then claim shares of this **fund**." *McLaughlin v. American Tobacco Co.,* 522 F.3d 215, 231 (2d Cir.2008). The appellate court based its rejection in the fact that the circuit does not allow "fluid recovery" because it offends both the Rule Enabling Act and the Due Process Clause. Damages that are too speculative and bear

little relationship to the actual amount of economic harm offend the REA, which provides that Rule 23 cannot be used to abridge, enlarge, or modify any substantive right. The defendants have a substantive right to pay damages reflective of their actual liability. *Id.* at 231. Even if defendants pay individuals correctly, money left over distributed through cy pres might result in overpaying a total amount. "When fluid recovery is used to permit the mass aggregation of claims, the right of defendants to challenge the allegations of individual plaintiffs is lost, resulting in a due process violation." *Id.* at 232.

***127** Assuming that this their recovery objection to fluid recovery of the Court of Appeals for the Second Circuit applies to some class actions, it has no bearing on the instant action. Each plaintiff can prove the amount it paid, the percentage overcharge can be computed by the jury and an amount can be allocated to individuals with no need for the *cy pres* doctrine.

> 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.

In re Zyprexa Prods. Liab. Litig., 493 F.Supp.2d 571, 578 (E.D.N.Y.2007) (denying summary judgment).

XIX. Class Certification

A. Burden of Proof

As the party seeking certification of the class, plaintiffs bear the burden of proving that all of the Rule 23 requirements are met." *Amchem Prods., Inc. v. Windsor,* 521 U.S. 591, 614, 117 S.Ct. 2231, 138 L.Ed.2d 689 (1997); *Caridad v. Metro-North Commuter R.R.,* 191 F.3d 283, 291 (2d Cir.1999), *overruled on other grounds by In re Initial Public Offering Securities Litigation* (*"In re IPO"*), 471 F.3d at 42. Thus, where disputed issues of fact implicate Rule 23 issues, it is the plaintiffs' burden to prove that those facts are established. *In re IPO,* 471 F.3d at 40. This is no *pro forma* burden. After *In re IPO,* it is no longer the case that "an expert's report will sustain a plaintiff's burden so long as it is not 'fatally flawed.' " *Id.* (quoting *In re Visa Check/ Master Money,* 280 F.3d 124, 135 (2d Cir.2001). Instead, "the district judge must receive enough evidence by affidavits, documents, or testimony, to be satisfied that each Rule 23 requirement has been met." *Id.* at 41. Moreover, "[a] district judge is to assess *all* of the relevant evidence admitted at the class certification stage and determine whether each Rule 23 requirement has been met, just as the judge would resolve a dispute about any other threshold prerequisite for continuing a lawsuit." *Id.* at 42 (emphasis added). Thus, a court may not leave for the jury's consideration flaws in plaintiffs' experts' opinions that bear on Rule 23 considerations. *Id.* at 41.

***128** As the Court of Appeals for the Second Circuit made clear in *In re IPO,* 471 F.3d 24 (2d Cir.2006), the time when plaintiffs seeking class certification can rely on the pleadings and unscrutinized expert reports have passed. It is the plaintiffs' burden to produce sufficient evidence from which the court can conclude that all the requirements of Rule 23 have been met. The *In re IPO* court made three conclusions applicable to the instant case:

> We conclude (1) that a district judge may not certify a class without making a ruling that each Rule 23 requirement is met and that a lesser standard such as "some showing" for satisfying each requirement will not suffice, (2) that all of the evidence must be assessed as with any other threshold issue, (3) that the fact that a Rule 23 requirement might overlap with an issue on the merits does not avoid the court's obligation to make a ruling as to whether the requirement is met, although such a circumstance might appropriately limit the scope of the court's inquiry at the class certification stage.

In re IPO, 471 F.3d 24, 27 (2d Cir.2006) (rejecting former obtuse standards such as "some showing" of meeting Rule 23 requirements or an expert's report will sustain a plaintiff's burden so long as it is not "fatally flawed.").

But the Court of Appeals for the Second Circuit "resist[ed] saying that what are required are 'findings' because that word usually implies that a district judge is resolving a disputed issue of fact." *Id.* at 40. "The ultimate issue as to each requirement is really a mixed question of fact and law." Rule 23 requirements are threshold issues-district court must make a ruling or a determination (not a finding) as to whether they are met.

> In light of the foregoing discussion, we reach the following conclusions: (1) a district judge may certify a class only after making determinations that each of the Rule 23 requirements has been met; (2) such determinations can be made only if the judge resolves factual disputes relevant to each Rule 23 requirement and finds that whatever underlying facts are relevant to a particular Rule 23 requirement have been established and is persuaded to rule, based on the relevant facts and the applicable legal standard, that the requirement is met; (3) the obligation to make such determinations is not lessened by overlap between a Rule 23 requirement and a merits issue, even a merits issue that is identical with a Rule 23 requirement; (4) in making such determinations, a district judge should not assess any aspect of the merits unrelated to a Rule 23 requirement; and (5) a district judge has ample discretion to circumscribe both the extent of discovery concerning Rule 23 requirements and the extent of a hearing to determine whether such requirements are met in order to assure that a class certification motion does not become a pretext for a partial trial of the merits.
>
> In drawing these conclusions, we add three observations. First, our conclusions necessarily preclude the use of a "some showing" standard, and to whatever extent *Caridad* might have implied such a standard for a Rule 23 requirement, that implication is disavowed. Second, we also disavow the suggestion in *Visa Check* that an expert's testimony may establish a component of a Rule 23 requirement simply by being not fatally flawed. A district judge is to assess all of the relevant evidence admitted at the class certification stage and determine whether each Rule 23 requirement has been met, just as the judge would resolve a dispute about any other threshold prerequisite for continuing a lawsuit. Finally, we decline to follow the dictum in *Heerwagen* suggesting that a district judge may not weigh conflicting evidence and determine the existence of a Rule 23 requirement just because that requirement is identical to an issue on the merits.

***129** *In re IPO,* 471 F.3d 24, 27 (2d Cir.2006). Following *In re IPO,* this court considered a huge amount of evidence in this and related Zyprexa cases on the viability issues, held extensive evidentiary hearings, and had briefed and argued all RICO and Rule 23 issues at great length.

B. RICO Claims

The Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968, provides a private right of action for treble damages to "[a]ny person injured in his business or property by reason of a violation" of the Act's criminal prohibitions. § 1964(c).

> RICO provides a private right of action for treble damages to any person injured in his business or property by reason of the conduct of a qualifying enterprise's affairs through a pattern of acts indictable as mail fraud. Mail fraud, in turn, occurs whenever a person, "having devised or intending to devise any scheme or artifice to defraud," uses the mail "for the purpose of executing such scheme or artifice or attempting so to do." § 1341. The gravamen of the offense is the scheme to defraud, and any "mailing that is incident to an essential part of the scheme satisfies the mailing element," *Schmuck v. United States,* 489 U.S. 705, 712, 109 S.Ct. 1443, 103 L.Ed.2d 734 (1989) (citation and internal quotation marks omitted), even if the mailing itself "contain[s] no false information," *id.,* at 715.

Bridge v. Phoenix Bond & Indemnity Co., No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008).

1. Causation

a. Reliance

McLaughlin stated that where "mail or wire fraud is the predicate act for a civil RICO claim, the transaction or 'but for' causation element *requires the plaintiff to demonstrate that he relied* on the defendant's misrepresentation." 522 F.3d at 222 (emphasis added). The first "half of the equation," involves proving widespread and uniform misrepresentation; the "other half" requires proving reliance on that misrepresentation. *Id.* As to this point, *McLaughlin* was subsequently placed in doubt by the Supreme Court's decision in *Bridge v. Phoenix Bond & Indemnity Co.,* No. 07-210, --- S.Ct. ----, 2008 WL 2329761 (June 9, 2008). It held "that a plaintiff asserting a RICO claim predicated on mail fraud need *not* show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations" (emphasis added). There is ample evidence that fraud was directed through mailings and otherwise at doctors who relied, causing damages in overpayments by plaintiffs.

b. Proof of Uniform Misrepresentation

The evidence showed misrepresentation leading to uniform overcharge per prescription paid for by plaintiffs.

c. Proof of Reliance on Misrepresentation

Evidence of doctors' reliance on the misrepresentation in prescribing Zyprexa supported the excessive price. The Second Circuit Court of Appeals in *McLaughlin* held that "reliance on the misrepresentation[ ] cannot be the subject of general proof. Individualized proof is needed to overcome the possibility that a member of the purported class purchased Lights for some reason other than the belief that Lights were a healthier alternative .... " *McLaughlin,* 522 F.3d at 223.

***130** *McLaughlin* is distinguishable. In *McLaughlin,* the appellate court declared:

> Plaintiffs and the district court suggest that defendants distorted the body of public information and that, in purchasing Lights, plaintiffs relied upon the public's general sense that Lights were healthier than full-flavored cigarettes, whether or not individual plaintiffs were actually aware of defendants' alleged misrepresentation. *Cf. Falise v. Am. Tobacco Co.,* 94 F.Supp.2d 316, 335 (E.D.N.Y.2000) ("Where ... the fraudulent scheme is targeted broadly at a large proportion of the American public[,] the requisite showing of reliance is less demanding. Such sophisticated, broad-based fraudulent schemes by their very nature are likely to be designed to distort the entire body of public knowledge ..."). Their argument invokes the fraud-on-the-market presumption set forth in *Basic Inc. v. Levinson,* 485 U.S. 224, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988), which concerned fraud claims in the securities context. "The fraud-on-the market doctrine ... creates a rebuttable presumption that (1) misrepresentations by an issuer affect the price of securities traded in the open market, and (2) investors rely on the market price of securities as an accurate measure of their intrinsic value." *Hevesi v. Citigroup Inc.,* 366 F.3d 70, 77 (2d Cir.2004). Thus, a plaintiff alleging securities fraud may establish reliance simply by virtue of the defendant's public dissemination of misleading information. *See Basic,* 485 U.S. at 241-42 (noting that because the price of stock in an efficient market reflects all publicly available information, "[m]isleading statements will ... defraud purchasers of stock even if the purchasers do not directly rely on the misstatements").
>
> We do not think that the *Basic* presumption, or the district court's variation of it, applies in this case; we cannot assume that, regardless of whether individual smokers were

aware of defendants' misrepresentation, the market at large internalized the misrepresentation to such an extent that all plaintiffs can be said to have relied on it. Basic involved an efficient market-the market in securities traded on the New York Stock Exchange-capable of rapidly assimilating public information into stock prices, *see id.* at 247, 249 n. 29 (describing the securities market as "impersonal, well-developed," and "information-hungry"); the market for consumer goods, however, is anything but efficient, *cf.* *Sikes v. Teleline, Inc.*, 281 F.3d 1350, 1364 (5th Cir.2002) ("[E]ach individual plaintiff is the only person with information about the content of the advertisement upon which he relied."). Indeed, the fact that the publication of Monograph 13 produced no change in either the sales or the price of Lights shows just how unresponsive the consumer market in Light cigarettes is to the advent of new information. *See* *In re IPO,* 471 F.3d at 43 ("Plaintiffs' own allegations as to how slow the market was to correct the alleged price inflation despite what they also allege was widespread knowledge of the scheme indicate the very antithesis of an efficient market."). As we stated in *In re IPO,* "[w]ithout the Basic presumption, individual questions of reliance would predominate over common questions."*Id.; see also Gunnells,* 348 F.3d at 435 (noting that Basic's presumption of actual reliance was based on the efficiency of capital markets, which did not apply to plaintiffs' purchase of health care plans, and that therefore actual reliance could not be presumed and individualized inquiry was required).

***131** *McLaughlin,* 522 F.3d at 233-34 (footnote omitted); *see* *id.* at 226 ("Indeed, the fact that the market did not shift away from light cigarettes after the publication of Monograph 13 is compelling evidence that plaintiffs had other, non-health related reasons for purchasing Lights.").

Unlike *McLaughlin,* here the evidence supported a finding of an overcharge based on the fraud of doctors and others. The overcharge resulted in specific damages to the plaintiffs who overpaid for Zyprexa.

McLaughlin found that "differences in plaintiffs' knowledge and levels of awareness also defeat the presumption of reliance" in cigarette cases. *Id.* at 226. Here the total fraud resulted in an increased price as in securities cases, so the fact that some doctors, patients or others were aware of the fraud is irrelevant. Without the fraud the price would have been lower to all payors.

2. Loss Causation

Loss causation means that the defendant's misrepresentations must have caused the plaintiff to "suffer economic loss." Did the alleged violation, in other words, lead directly to the plaintiff's injuries? *See* *Anza v. Ideal Steel Supply Corp.,* 547 U.S. 451, 126 S.Ct. 1991, 164 L.Ed.2d 720 (2006). In *McLaughlin,*

> In this case, plaintiffs' theory is that they suffered an economic loss because they were overcharged for Lights. Plaintiffs argue that defendants' misrepresentation that Lights were healthier led to an increased market demand for light cigarettes, which drove up the price of Lights. Thus, plaintiffs contend that they paid more for Lights than they otherwise would have had the truth been known. As with reliance, plaintiffs claim that they can establish loss causation on a class-wide basis.

McLaughlin, 522 F.3d at 226. The Court of Appeals for the Second Circuit rejected this argument by holding that "the issue of loss causation, much like the issue of reliance, cannot be resolved by way of generalized proof." *Id.* at 226. Proof in the instant case is not generalized. The plaintiffs were directly injured by Lilly when each was overcharged a fixed computable amount for each prescription.

3. Injury

"Only by showing that the plaintiffs paid more for [Zyprexa] than they would have but for defendant's misrepresentation can plaintiffs establish the requisite injury under civil RICO." *Id.* at 227. *McLaughlin* rejected the plaintiffs' two theories of injury: the loss of value theory and the price impact theory. The "acceptable measure of injury"-out-of-pocket damages-requires individualized proof. *Id.* As already indicated in Parts XVII.A.2-3, *supra,* plaintiffs have supported their theory of price impact sufficiently to go to the jury.

4. Claim Period

a. Statute of Limitations

Although the RICO statute does not contain a statute of limitations for civil claims brought under its provisions, the Supreme Court has applied a four-year limit to such actions. *Agency Holding Corp. v. Malley-Duff & Associates, Inc.,* 483 U.S. 143, 107 S.Ct. 2759, 97 L.Ed.2d 121 (1987). The Court has "not settle[d] upon a final rule" regarding when the statute begins to run, *Rotella v. Wood,* 528 U.S. 549, 554 n. 2, 120 S.Ct. 1075, 145 L.Ed.2d 1047 (2000), but the Second Circuit Court of Appeals, along with the majority, if not all, of the appellate courts, now applies "an injury discovery accrual rule starting the clock when a plaintiff knew or should have known of his injury." *See McLaughlin v. American Tobacco Co.,* 522 F.3d 215, 233 (2d Cir.2008); *In re Merrill Lynch Ltd. Partnerships Litig.,* 154 F.3d 56, 60 (2d Cir.1998); *see also Rotella,* 528 U.S. 549, 120 S.Ct. 1075, 145 L.Ed.2d 1047 (rejecting the "injury and pattern discovery rule," under which a civil RICO claim accrued only when the claimant discovered, or should have discovered, *both* the injury and pattern of RICO activity).

***132** A federal rule of equitable tolling may be applied in the case of fraudulent concealment in civil RICO actions as well as in litigation generally. *See, e.g., Griffin v. McNiff,* 744 F.Supp. 1237 (S.D.N.Y.1990), *aff'd,*996 F.2d 303 (2d Cir.1993); *Camotex, S.R.L. v. Hunt,* 741 F.Supp. 1086 (S.D.N.Y.1990). Whatever efforts Lilly may have made to conceal its fraud, it was not in a position to have misled the class certified sufficiently to allow for the twelve-year class period claimed, or anything near that, in view of the third-party payors' expertise in merchandising of pharmaceuticals and fiduciary responsibilities to their clients.

There is no basis in the instant case for tolling a statute (or caselaw rule) limiting the time to commence this RICO action on equitable grounds. At some point sufficient information was available to put potential claimants on notice of a possible claim. Since the case was first filed on June 20, 2005, no damages for overpayment can be recovered for any purchases of Zyprexa prior to June 20, 2001. *See* Part I, *supra.*

b. End of Claim Period

At the latest, once the suit was first commenced on June 20, 2005, all members of the class (or their representatives and advisors) knew or should have known of the claimed overcharge. No damages can be recovered for any purchases after that date.

c. Certified Period

The temporal period for the class will be from June 20, 2001 to June 20, 2005. The jury may, on the present record, decide that plaintiffs should have known enough to sue before June 20, 2005. If it does, the temporal damage period will be shortened, or entirely eliminated.

C. The Class Satisfies the Requirements Imposed by Rule 23(a)

To pursue their claims as a class action, plaintiffs must satisfy the four prerequisites of Federal Rule of Civil Procedure 23(a):

> (1) the class is so numerous that joinder of all members is impracticable; (2) there are questions of law or fact common to the class; (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and (4) the representative parties will fairly and adequately protect the interests of the class.

Fed.R.Crim.P. 23(a).

1. Class Is So Numerous that Joinder of All Members Is Impracticable

Rule 23(a)(1) requires that the proposed class be so numerous that joinder of all members is impracticable. Fed.R.Civ.P. 23(a) (1). Impracticability does not mean impossibility of joinder, but refers to the difficulty of joinder. *Robidoux v. Celani,* 987 F.2d 931, 935 (2d Cir.1993).

> Determination of practicability depends on all the circumstances surrounding a case, not on mere numbers. Relevant considerations

include judicial economy arising from the avoidance of a multiplicity of actions, geographic dispersions of class member, financial resources of class members, the ability of claimants to institute individual suits, and requests for prospective injunctive relief which would involve future class members.

***133** *Id.* at 936. Precise quantification of class members is not necessary, so long plaintiffs reasonably estimate the number as substantial. *See id.* at 935; *McNeil v. New York City Hous. Auth.,* 719 F.Supp. 233, 252 (S.D.N.Y.1989). The Court of Appeals for the Second Circuit has held that a prospective class of forty or more raises a presumption of numerosity. *See* *Consol. Rail Corp. v. Hyde Park,* 47 F.3d 473, 483 (2d Cir.1995); *Trinidad v. Breakaway Courier Sys., Inc.,* 2007 U.S. Dist. LEXIS 2914, 2007 WL 103073 (S.D.N.Y. Jan. 12, 2007).

Numerosity of the class cannot reasonably be contested here. There are thousands of third-party payors in the United States. *See, e.g.,* *In re Lupron Mktg. and Sales Practices Litig.,* 228 F.R.D. 75 (D.Mass.2005) ("the class includes thousands of TPPs"). Given the overwhelming number of Zyprexa prescriptions during the class period, it stands to reason that most, if not all, TPPs have paid or reimbursed the cost of Zyprexa prescriptions. Accordingly, the numerosity requirement is easily satisfied.

2. Questions of Law and Fact Common to the Class

The single federal RICO statute and common factual background are common to each member of the class since each overpaid the same excess charge in each prescription. *See* Parts XVII.A.2-3, *supra.*

There is too much variation among state claims. Therefore only the federal RICO claim will be certified. *See* Part XX, *infra.*

3. Claims of the Representative Parties Are Typical of the Claims of the Class

The claims of the third-party payors are typical of the claims of the class. *See* Part XVIII.B, *supra.* The claims of the individual payors are not. *See id.* Only the Third-Party Payor class will be certified.

4. Representative Parties Will Fairly and Adequately Protect the Interests of the Class

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed.R.Civ.P. 23(a)(4). This requirement is satisfied when the class representatives have no interests conflicting with the class. *See* *Sosna v. Iowa,* 419 U.S. 393, 403, 95 S.Ct. 553, 42 L.Ed.2d 532 (1975); *Marisol A.,* 126 F.3d at 378. "The question of whether the named plaintiffs can fairly and adequately represent the class is one committed to the sound discretion of the district court." *County of Suffolk v. Long Island Lighting Co.,* 710 F.Supp. 1407, 1413 (E.D.N.Y.1989) (internal quotation omitted), *aff'd* 907 F.2d 1295 (1990).

"Representative plaintiffs must not have interests that are antagonistic to or in conflict with those of the class as a whole," yet only a fundamental conflict will defeat the adequacy of representation requirement. *Schwab,* 449 F.Supp.2d at 1107;*see also* *In re Visa Check,* 280 F.3d at 145. The inquiry into adequacy "serves to uncover conflicts of interest between named parties and the class they seek to represent. A class representative must be part of the class and possess the same interest and suffer the same injury as the class members." *Amchem,* 521 U.S. at 625-26.

***134** While some courts have considered the representative plaintiff's knowledge of the case, representative plaintiffs are only required to know enough about the case to "serve the interests of the class and ensure that they are not simply lending their names to a suit controlled entirely by the attorneys for the benefit of counsel." *Schwab,* 449 F.Supp.2d at 1108;*see also* *Baffa v. Donaldson, Lufkin & Jenrette Sec. Corp.,* 222 F.3d 52, 61 (2d. Cir.2000); *In re Frontier Ins. Group Secs. Litig.,* 172 F.R.D. 31 (E.D.N.Y.1997). The Court of Appeals for the Second Circuit has concluded: "The Supreme Court has expressly disapproved of attacks on the adequacy of a class representative based on the representative's ignorance." *Baffa,* 222 F.3d at 61 (2d. Cir.2000) (citing

Surowitz v. Hilton Hotels Corp., 383 U.S. 363, 370-74, 86 S.Ct. 845, 15 L.Ed.2d 807 (1966)).

The credibility of the class representatives should only come into play during the class certification process if they "are so lacking in credibility that they are likely to harm their case." *In re Frontiers Ins. Group Secs. Litig.*, 172 F.R.D. 31 at 47. Courts have only held that class representatives were inadequate due to credibility concerns in extreme situations, including plaintiffs that gave inconsistent accounts of conversations or repeatedly changed their positions. *See* *Panzirer v. Wolf*, 663 F.2d 365, 368 (2d Cir.1981) (Plaintiff gave no less than four versions of her conversation with her broker). "Where the individual claims are not based on credibility of individual [plaintiffs], but on the characteristics of a universe to be determined with the aid of experts, the candor of one representative plaintiff among many is not decisive." *Schwab*, 449 F.Supp.2d at 1109.

The named third-party plaintiffs are adequate representatives of the putative class. They are typical payors. There is no indication that their interests are antagonistic to the class, let alone represent a fundamental conflict with other class members.

As to their knowledge about the case, the named plaintiffs have participated in the litigation to date, in part by answering interrogatories and having their depositions taken. Additionally, the third-party payors have informed members of the ongoing litigation (Sergeants Benevolence Association) and taken steps to require prior authorization of Zyprexa largely in part because of the same issues raised in this lawsuit (UFCW Local 1776). *See* Frontline Newsletter: Official Publication of the Sergeants Benevolent Association, Police Department, City of New York, Summer 2007. Plaintiffs are not merely lending their names to the case, but are aware of the particular allegations involved in this litigation and have participated to the best of their ability. *See* *Bqffa*, 222 F.3d at 61. There is no indication that the named plaintiffs are anything but credible.

The individual named plaintiffs cannot represent the class. *See* Part XVIII.B, *supra.* An individual payors class will not be certified.

D. Class Satisfies the Requirements for Certification Under Rule 23(b)(3)

***135** In addition to satisfying the four Rule 23(a) requirements, plaintiffs must satisfy one of the subsections of Rule 23(b). Fed.R.Crim.P. 23(b). Here, plaintiffs assert that their class is certifiable under Rule 23(b)(3), which requires that the court find that "the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed.R.Crim.P. 23(b)(3). Also pertinent to the Rule 23(b)(3) inquiry are "the class members' interests in individually controlling the prosecution or defense of separate actions; the extent and nature of any litigation concerning the controversy already begun by or against class members; the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and the likely difficulties in managing a class action." Fed.R.Crim.P. 23(b)(3)(A)-(D).

1. Questions of Law or Fact Common to Class Members Predominate over Questions Affecting Only Individual Members

Here both questions of law and fact are common to class members. *See* Part XIX.C.2, *supra.* The only difference among class third-party payors is how much of the total overcharge each shall receive in damages. That can be readily computed based on available payment records of responsible entities. *See* Part XVIII.D, *supra.*

2. Class Action Is Superior to Other Available Methods for Fairly and Efficiently Adjudicating the Controversy

Rule 23(b)(3) requires consideration of whether class action is superior to alternate methods of adjudication. Factors relevant to the inquiry include the interest of members of the class in individually controlling the prosecution or defense of separate actions, the extent and nature of any litigation concerning the controversy already commenced by or against members of the class, the desirability or undesirability of concentrating the litigation of the claims in the particular forum, and the difficulties likely to be encountered in the management of a class action. *See* Fed.R.Civ.P. 23(b)(3).

The difficulties likely to be encountered in the management of this RICO class action with respect to individual

reliance and damages issues are not significant. Given the evidence available, there should be no serious problems in administration. "[F]ailure to certify an action under Rule 23(b)(3) on the sole ground that it would be unmanageable is disfavored and should be the exception rather than the rule." *In re Visa Check,* 280 F.3d at 140.

In *Parker v. Time Warner Entertainment Co., L.P.,* the Court of Appeals for the Second Circuit held that the district court must revisit its refusal to certify a class under Rule 23(b)(3) because it lacked sufficient information to determine if certification of a class would raise, amongst other things, issues of due process on account of the size of the class and its largely technical and statutory damage claims. 331 F.3d at 21-22 (2d. Cir.2003). "[T]he Court's conclusion that the size of the class would inevitably lead to 'the financial demise' of Time Warner, or even to significant manageability provisions, was speculative." *Id.* at 22. In the instant action there is no risk that the size of any recovery or its distribution will put defendant's economic viability at issue or would create serious management problems.

***136** "[T]he courts are arguably in the strongest position to effectively enforce appropriate standards protecting the public from fraudulent merchandising of drugs." Ct.'s Mem. & Order re Mot. for Summary J., July 3, 2007, Docket Entry No. 129. Without certification, this litigation will result in thousands of individual trials with overlap in scope, issues, testimony, and experts. Certifying a class provides an efficient and manageable means of litigating this matter.

3. Class Members' Interests in Individually Controlling the Prosecution Are Not Substantial and Can Be Fully Protected by Opt-Out Rights

Since the third-party payors are largely institutions with fiduciary obligations to manage resources and reduce costs, there is no reason to suggest that any will have due process qualms about recovery in the class litigation.

4. Litigation Already Conducted on Behalf of the Class Is Substantial

The parties have thoroughly explored legal and factual issues and **settlement** and other dispositions of tens of thousands of other Zyprexa cases supply full assurance that little additional effort will be required to try the class action.

5. Desirable to Concentrate the Claims of the Class in One Forum

The fact that the Multidistrict Panel concentrated Zyprexa claims in one court, as well as procedures in related cases and extensive discovery, strong suggest that third-party payor cases should be in one court.

6. No Substantial Difficulties in Managing a Class Action

No substantial difficulties in managing this class action are likely. While the evidence is extensive, the legal and factual issues are of a garden-variety that have been thoroughly rehearsed in many federal courts.

E. Adequate Class Counsel Appointed

A court that certifies a class must ensure adequate class counsel. *See* Fed.R.Civ.P. 23(g). It "must consider:

> (i) the work counsel has done in identifying or investigating potential claims in the action;
>
> (ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action;
>
> (iii) counsel's knowledge of the applicable law; and
>
> (iv) the resources that counsel will commit to representing the class;

Fed.R.Civ.P. Rule 23(g)(1)(A)(i)-(iv). The court also "may consider any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class." Fed.R.Civ.P. Rule 23(g)(1)(B). "[The Adequacy of Counsel requirement] is satisfied where the class attorneys are experienced in the field or have demonstrated professional competence in other ways, such as by the quality of the briefs and the arguments during the early stages of the case." *Schwab,* 449 F.Supp.2d at 1106 (E.D.N.Y.2006) (citing *Klein v. A.G. Becker Paribus Inc.,* 109 F.R.D. 646 (S.D.N.Y.1986) and *Bacon v. Toia,* 437 F.Supp. 1371 (S.D.N.Y.1977)), *rev'd on other grounds sub. nom, McLaughlin v. American Tobacco Co. .,* 522 F.3d 215 (2d Cir.2008).

1. Class Counsel Is Adequate Under Rule 23(g)(1) & (2)

***137** Thomas M. Sobol of Hagens Berman Sobol Shapiro, LLP and James Dugan, formerly with Dugan & Browne and now with the Murray Law Firm, has previously been appointed interim class counsel in this matter. *See* Case Mgmt. Order 1, Feb. 1, 2006. Plaintiffs' counsel have fully demonstrated their competency during the progress of this now three-year-old case. Class counsel is adequate.

2. Class Counsel Will Fairly and Adequately Represent the Interests of the Class Pursuant to Rule 23(g)(4)

Present class counsel can represent fairly and adequately the class as limited, by excluding individual payors, eliminating state causes of action, and limiting the period for which damages may be imposed.

F. Prosecuting Separate Actions Would Substantially Impede the Ability of Other Potential Claimants under Rule 23(b)(1)(B) to Protect Their Interests.

Were class certification granted, no potential plaintiffs' ability to opt out and conduct an individual litigation would be impaired.

XX. Conclusion as to Plaintiffs' Motion for Class Certification

Plaintiffs' motion for class certification is granted, subject to the limitations already outlined above and those stated below.

A. State Consumer Protection Claims Not Certified

Plaintiffs claim that multi-state classes are manageable. A jury's tasks would be so complicated by multiple state causes of action as to make the case too difficult to control. Unpersuasive is the contention of plaintiffs that most state consumer fraud statutes draw on language from the Federal Trade Commission, so that nearly all of them proscribe conduct in somewhat the same terms: "unfair practices," "deceptive practices," "unconscionable practices," and that they generally use the same definitions for these common terms. The "minor" differences in state substantive law would have to be clearly charged and understood by the jury-a daunting task.

Even if the class were subdivided only on the issue of applicable state law for the class members, insurmountable manageability problems might well be present because of differences among the laws of the forty-one states at issue. State consumer protection laws vary on a range of fundamental substantive and procedural issues. Plaintiffs' attempt to group them into four general categories is "overly simplistic in light of the nuances and differences presented by the consumer fraud acts," *Tylka v. Gerber Prod. Co.*, 178 F.R.D. 493, 498 (N.D.111.1998) (rejecting plaintiff's attempts to group various states' consumer fraud acts into four subclasses); *see also Carpenter v. BMW of N. Am., Inc.*, No. 99-CV-214, 1999 WL 415390, at *3 (E.D. Pa. June 21, 1999) (rejecting plaintiffs attempts to group all 50 states' consumer fraud acts into three subclasses, noting that plaintiffs' position that consumer subclasses "can easily be divided into subclasses and cha[r]ged to the jury ... is overly simplistic") (internal citations omitted). 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, **NewJersey**, or Louisiana).

***138** The application of various state laws to a class, which would be required here, presents both predominance and manageability issues. *See, e.g., Schwab v. Philip Morris USA, Inc.*, 449 F.Supp.2d 992, 1019 (E.D.N.Y.2006) ("[T]he tort law in the fifty states is not uniform" and creates commonality, typicality, and predominance "difficulties"), *rev'd on other grounds sub. nom, McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir.2008), *subsequently placed in doubt by Bridge v. Phoenix Bond & Indemnity Co.*, No. 07-210, ---S.Ct. ----, 2008 WL 2329761 (June 9, 2008); *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 82-86 (D.Mass.2005) (refusing to certify a nationwide class of third-party payors and consumers because varying state laws preclude a finding of commonality, typicality, and predominance).

Plaintiffs argue that there are no material differences among the majority of state laws. In support of this claim, they have

submitted an ingenious Trial Plan and Statement of State Law organized around broad statutory language and propose to argue their case to the jury using "broad" jury instructions that sweep together the law of up to forty-one states. *See* Class Pfs.' Proposed Trial & Apportionment Plan & Statement of State Law in Support of Class Cert., Dec. 4, 2007, Docket Entry No. 144. Even if the various states recognize similar cases of action with similar elements, it does not follow that the laws are in fact the same, especially in regard to novel claims with novel proofs. Differences among applicable state laws are barrier to class certification. *See, e.g., Castano,* 84 F.3d at 741; *In re Rhone-Poulenc Rorer, Inc.,* 51 F.3d 1293, 1301-02 (7th Cir.1995); *In re AWP,* 230 F.R.D. at 82.

Plaintiffs' analysis of state laws does not carry their burden under *IPO.* The application of the various state laws precludes a determination that, in this proposed nationwide class action, common state law issues predominate or that proceeding as a state law class action is manageable.

B. Limited Class Certified on RICO Claim

The certified class should be limited, as already described, to a single class of third-party payors for Zyprexa under RICO for the period June 20, 2001 to June 20, 2005. Overpayments shall be computed for all purchases whether on or off label.

The parties shall attempt to agree on a class definition that follows the analysis in this memorandum. They shall submit an agreed-upon definition within ten days or separate definitions if they cannot agree. They shall appear with the proposed definitions on July 31, 2008 at 11:00 a.m. with briefs supporting their proposals. Submission of a proposal shall not constitute agreement with any findings now being made.

XXI. Administration, Damages, and Fees

A. Administration

Administration of this class litigation should be simple. A single substantive rule-RICO-applies. There are no subclasses.

***139** Plaintiffs should have written receipts or other data indicating what was prescribed and the sales price. The available data is sufficiently accurate and complete to go to the jury. *See Schwab,* 449 F.Supp.2d at 1065 (E.D.N.Y.2006) ("Where injury is established, damages need not be demonstrated with precision."); *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).

The evidence, including that of experts suffices to prove a cause of action for the class.

A simple method of computing individual class action members' damages will be available. Distribution of damages to individual payors should present no serious problem. A special master or magistrate judge will be appointed to determine whether damages have been proved with sufficient affidavits and supporting documentation as to each claimant's payments and overpayments.

B. Notice and Claims Procedures

Examples of notice and claims procedures undertaken in other pharmaceutical matters, including participation rates of consumers and third-party payors and efforts taken to increase such rates have been furnished by plaintiffs' counsel and are set forth below for litigations involving ten different pharmaceuticals. Notice and claims procedures are available to ensure widespread class participation. *See* Todd B. Hilsee, *Notice Expert Shines a Light on (Another) Bad Nationwide Class Action Notice,* Product Safety & Liab. Reporter, Vol. 36, No. 14, p. 346 (Apr. 7, 2008). The fact that a class action is settled does not detract from its relevance as to practicality. The instances relied upon by plaintiffs demonstrate that distribution of **funds** and allocation of damages would not present substantial problems in an action tried by a jury.

1. Paxil

In *Nichols v. SmithKline Beecham,* No. 00-cv-622 (E.D.Pa.2005), class plaintiffs brought suit against GlaxoSmithKline, alleging the company violated antitrust and consumer protection laws by unlawfully seeking to keep lower cost generic versions of Paxil off the market. The Eastern District of Pennsylvania certified a national **settlement** class of all consumers and third-party payors who purchases and paid for Paxil or its general equivalent during a six-year period. *See* Ct.'s Order Certifying **Settlement** Class

& Preliminarily Approving **Settlement**, Oct. 18, 2004; Order, Apr. 22, 2005.

The parties and the court distributed notice of the proposed **settlement** class through national consumer publications focusing on the appropriate target demographic, first class mailings to ascertainable potential class members, and a website. In order to facilitate consumer claims, the widely published summary notice even included a simple claim form that could be detached and returned by consumers. *See*Paxil Summary Notice Form 2. Through several **settlements** have adopted this method of notice publishing since then, the inclusion of a simply claim form in the widely published summary notice forms in the Paxil litigation was a first at that time. In total, administrators received 65,088 consumer claims and paid out more than 61,000 claims.

YOUR LEGAL RIGHTS AND OPTIONS IN THIS SETTLEMENT:

Submit a Claim Form	The only way to get a payment.
Exclude Yourself	Get no payment. This is the only option that allows you to be part of any other lawsuit against GlaxoSmithKline about the legal claims in this case.
Object	Write to the Court about why you don't like the **settlement**.
Go to a Hearing	Ask to speak in Court about the **settlement**.
Do Nothing	Get no payment. Give up rights to be part of any other lawsuit against GlaxoSmithKline about the legal claims in this case.

2. Relafen

***140** *In re Relafen Antitrust Litigation,* CA No. 01-cv-12239 (D.Mass.2001), involved antitrust claims brought by putative classes of consumers and third-party payors against GlaxoSmithKline, manufacturer of the drug Relafen (nabumatone), on behalf of purchases of Relafen or its generic equivalent. The District of Massachusetts certified an exemplar litigation class of consumers and the parties thereafter entered into a nationwide **settlement** for $75 million. Order Approving **Settlement**, *In re Relafen Antitrust Litigation,* 231 F.R.D. 52 (D.Mass.2005).

The notice program to consumers involved many traditional avenues, including publication in many national newspapers and magazines as well as the use of a **settlement** website. *Id.* Yet plaintiffs' counsel also subpoenaed data from ten of the largest retail chain pharmacies as well as the five largest pharmacy benefit managers in the United States to get contact and payment information for individual consumers for whom the entities had filled a prescription. Because of the reliability of the data, checks were sent ton consumers without the need for a claims process. Thus, in addition to paying the claims of individuals who submitted traditional claim forms as a result of seeing a notice publication, the claims administrator mailed unsolicited checks, totaling more than $14 million, to more than 250,000 consumers whose information appeared in the subpoenaed data.

3. AWP

The *In re Pharmaceutical Industry Average Wholesale Price Litigation,* MDL 1456 (D.Mass), involves RICO and state law claims against seventeen of the largest pharmaceutical manufacturers in the United States. Claims against five defendants were “fast-tracked” and three initial classes certified: a national subclass of Medicaid recipients who

made or incurred an obligation to make percentage co-payment for drugs at issue, a national subclass of third-party payors who provide supplemental Medicare insurance, and a Massachusetts state-wide subclass of third-party payors and consumers who made payments for the same drugs based on AWP but outside the Medicare context. Order Certifying Class, MDL 1456, No. 01-12257, Jan. 30, 2006.

Claims against several of the "fast-tracked" defendants culminated in a nine week bench trial in late 2006 and a finding of liability against three of those defendants. Many of the claims against many of the defendants have settled, however, and the notice and claims provisions are described briefly below.

GlaxoSmithKline ***Settlement****:* The parties settled claims against GlaxoSmithKline prior to trial for $75 million. *See* Order Approving GSK **Settlement**, Docket No. 01-cv-12257, Docket Entry No. 4619, Aug. 7, 2007, Pfs.' Ex. 13 to the Bierstein Aff. The notice program for third-party payors used traditional direct mail but the consumer notice program involved an extensive national publication program, claims website, press releases, and a direct mail notice program directed at Medicare enrollees. Plaintiffs' counsel subpoenaed electronic data from the Centers for Medicare and Medicaid Services ("CMS") and generated a list of all individual consumers who incurred an obligation to make a percentage co-payment for the drugs at issue in the **settlement** for the entire class period. As a result, more than two million notices were sent via first class mail to potential Medicare consumer class members. No claims have yet been paid due to the pending appeal of the court's final approval order.

141** ***AstraZenecaSettlement*:* The District of Massachusetts preliminarily approved a **settlement** between **AstraZeneca** and the plaintiffs in 2007. *See* Order Approving **AstraZenecaSettlement**, Docket No. 01-cv-12257, Docket Entry No. 4879, Nov. 1, 2007, Pfs.' Ex. 14 to the Bierstein Aff. Because this **settlement** involves only the Medicare subclass and a single drug, the parties accomplished notice of the **settlement** primarily through direct mail using data from CMS like that used in the GlaxoSmithKline **settlement**. As a result of this data, approximately 450,000 consumers received mailed notice of the **settlement**. In addition, as a supplement to direct mailing, the notice program also included publication of notice in a number of national publications and the creation of a **settlement** website.

"Track Two" ***Settlement****:* Finally, the court preliminarily approved a $125 million **settlement** with eleven remaining defendants including all three subclasses. The proposed notice program in this **settlement** built on that approved in the GlaxoSmithKline **Settlement**, including mailed notice to third-party payors, mailed notice to Medicare recipients through data obtained from CMS, and an extensive national publication program. Like the **AstraZenecasettlement**, this data will be used not just to send direct mail notice, but to calculate Medicare consumer's potential claim amounts, thus making it easier for consumers to collect from the **settlement**.

In addition, the notice program also included outreach to potential consumer class members through various consumer organizations, use of television cable advertisement, and internet banner advertisement directed to health related websites. Further, in order to try to increase participation of consumers who made payments for the drugs at issue through private insurance, plaintiffs counsel have been working with counsel representing most of the largest third-party payors in the United States to provide data identifying consumer class members from their active membership databases. These third-party payors will provide this data to the claims administrator who will use it to send direct mail notice to consumers who paid outside of the Medicare context.

4. Lorazepam-Clorazepate

In *State of Connecticut v. Mylan Laboratories, Inc.,* class plaintiffs brought suit against Mylan Laboratories, alleging violations of antitrust and consumer protection laws related to an exclusive agreement entered into by the defendants pertaining to the drugs lorazepam and clorazepate. *See State of Connecticut v. Mylan Laboratories, Inc.,* M.D.L. 1290, Misc. No. 99-276 (D.D.C.2002). The court certified a national **settlement** class of consumers and, in 2002, approved the **settlement** for $100 million. *See* Ct.'s Order (granting final approval of the **settlement**), 205 F.R.D. 369 (D.D.C.2002).

The notice program for the proposed **settlement** utilized national consumer publications, targeting the appropriate demographic and a website that included answers to commonly asked questions, allowed consumers to download the claim form, and contained an email link for consumers to ask additional questions. In order to facilitate consumer claims, fifteen national pharmacy chains agreed to mail **settlement** notices directly to over 1,000,000 consumers who purchased lorazepam and/or clorazepate, thus ensuring

confidentiality of prescription data. All told, nearly 251,000 consumers received reimbursements totaling over $42 million.

5. Synthroid

***142** In *In re Synthroid Marketing Litigation,* class plaintiffs brought suit against the various manufacturers of Synthroid, alleging violations of antitrust, RICO, and consumer protection statutes. *In re Synthroid Marketing Litig.,* MDL No. 1182, No. 97 C 6017, (N.D. IL 1999). The Northern District of Illinois certified two national **settlement** classes-one for consumers and one for third-party payors-of those who purchased or paid for Synthroid. Notice of the proposed **settlement** included publication of ads (often full-page in size) in hundreds of newspapers and magazines and a website on the internet was maintained.

6. Sereno

In the *Serono* litigation, plaintiffs claimed that Defendants violated both RICO and consumer protection statutes by encouraging doctors to prescribe Serostim, a growth hormone approved by the FDA to treat HIV/AIDS patients, based on diagnostic criteria that were not approved by the FDA, and for purposes other than those indicated. *Government Employees Hospital Association, et al. v. Serono,* C .A. No. 05-cv-11935 (D.Mass.), and *Eugene Francis v. Serono Laboratories, Inc.,* C.A. No. 06-cv-10613 (D.Mass.). There was a proposed **settlement**, and the court certified a national **settlement** class of all consumers and third-party payors who purchased or paid for Serostim during the ten year class period and approved a **settlement** in the amount of $24 million. *See* Order Granting Preliminary Approval of **Settlement**, Docket No. 83, Pfs.' Ex. 15 to the Bierstein Aff.

Because an estimated 70% of third-party payors that had paid for Serostim were represented in the litigation, mass mailings were relied on to reach the remaining third-party payors. Notice to consumers included the traditional aspects, such as publication in newspapers and magazines and a HIV + website. In order to better facilitate consumer claims, the parties three novel notice techniques. First, every physician that had prescribed Serostim received direct mailings, in the hopes that they would pass the notice along to their patients. (This information was in the defendant's possession.) Second, the claims administrator reached out to various activist and charitable groups so that they might provide notice to the potential claimants they worked with. Third, counsel for plaintiffs subpoenaed certain pharmacies with the highest dispensing rates of Serostim for the names, last known addresses, and amounts paid by consumers who had purchased Serostim. The court and attorneys were extremely cognizant of privacy concerns, particularly in light of the fact that potential claimants all suffered from HIV and/or AIDS. Privacy issues were addressed through the use of appropriate protective orders, as well as having the names, addresses, and amounts paid sent directly to the claims administrator, forbidding the claims administrator to share that information with anyone (including the attorneys), and ensuring that all such information will be destroyed as soon as the consumer claims are paid. *See* Order Requiring Class Counsel to Serve Subpoenas in Furtherance of Class Claims, Docket No. 05-cv-11935-PBS, Docket Entry No. 89, Ex. 16 to the Bierstein Aff.

7. Buspar

***143** In *In re Buspirone Antitrust Litigation,* class plaintiffs brought an antitrust suit against Bristol Myers Squibb, alleging that the defendant acted illegally in order to prevent the availability of less expensive, generic brands of BuSpar from coming to market. *In re Buspirone Antitrust Litig.,* 01-MDL-1413 (S.D.N .Y.2001). The court certified a nationwide class of approximately 119-169 million consumers who had purchased or paid for Buspar and approved a $42 million **settlement**.

The notice program for the proposed **settlement** used national consumer publications focusing on the appropriate target demographic, nearly 200 thirty-second spots aired on broadcast and cable networks, press releases, as well as audio and video news releases that were distributed to news outlets, and a website with claims information. In order to facilitate consumer claims, notice also included the involvement of certain advocacy groups: several organizations with relationships with the target audience assisted in disseminating notice of the claim through articles and providing links to the claims website.

8. Lupron

In *In re Lupron Marketing and Sales Practices Litigation,* class plaintiffs brought a suit against TAP, Abbott Laboratories, and Takeda Pharmaceuticals, alleging that they manipulated the average wholesale price of the drug Lupron and actively marketed the resulting profit doctors could make as a result, thus increasing the price paid by consumers and third-party payors. *In re Lupron Marketing and Sales Practices Litig.,* MDL No. 1430, Master File

No. 01-cv-10861 (D.Mass.2001). The court approved a proposed **settlement** of $150 million, and certified a national **settlement** class of all consumers and third-party payors who purchased and paid for Lupron during a twenty-year time period. *See* Order Granting Preliminary Approval of **Settlement**, Certifying Class For Purposes of **Settlement**, Directing Notice to the Class and Scheduling Fairness Hearing, Nov. 24, 2004, Ex. 17 to the Bierstein Aff.; Mem. & Order Approving **Settlement** & Certifying the Class, May 12, 2005, Ex. 29 to the Bierstein Aff.

"TPP Notice Packets" were mailed to 235,480 potential third-party payor class members. For consumers, individual notice was given where practicable, but the notice program also included nationwide publication notice, solicitation of public service radio announcements and mainstream news coverage, the posting of court-approved notices on Lupron-related websites, establishment of an interactive claims information website, and a toll-free telephone number to take questions from class members. In order to increase consumer claims, notice also included a court-approved informational release issued to news wires reaching more than 450 health and medical publications, as well as 4,200 press outlets throughout the country. The informational release was also sent to sixty-eight support groups for the diseases treated by Lupron in the hopes that the groups would inform their members.

9. Remeron

***144** In *In re Remeron End Payer Antitrust Litigation,* class plaintiffs brought an antitrust suit against Organon USA Inc. and Akzo Nobel N.V., alleging the companies had improperly monopolized the United States market for Remeron® and mirtazapine. *In re Remeron End Payer Antitrust Litigation,* Master File No. 02-cv-2007 (D.N.J.2002). The court approved a proposed **settlement** in the amount of $36 million, and certified a nationwide class of consumers and third-party purchasers that had purchased or paid for Remeron or its generic equivalents. *See* Order Conditionally Certifying **Settlement** Class, Approving Representation of Attorneys General and Preliminarily Approving Proposed **Settlement**, June 25, 2005, Pfs.' Ex. 18 to the Bierstein Aff; Final J. & Order Certifying **Settlement** Class, Approving Proposed **Settlement** and Dismissing Actions, Aug. 31, 2005, Pfs.' Ex. 19 to the Bierstein Aff.

The parties used traditional measures of notifying class members of the **settlement**-such as press releases and Radio public service announcements-but also utilized additional types of notice. First, website banner advertising brought individuals to the **settlement** website, where they could submit a claim. (The target demographic for these class members was known to be heavy with Internet users.) The claims administrator and state Attorneys General also solicited the help of chain pharmacies, third-party payors, senior citizen organizations, mental health organizations, psychiatrists, and women's organizations is spreading word to the target demographic for consumer class members. *See* Sample Letter from Pharmacies, Pfs.' Ex. 20 to the Bierstein Aff; Sample Letter to Psychiatrists, Pfs.' Ex. 21 to the Bierstein Aff. Nearly 70,000 consumer claims were paid out.

10. Hytrin

In *In re Terazosin Hydrochloride Antitrust Litigation,* plaintiffs brought suit against Abbott Laboratories and Geneva Pharmaceuticals, alleging defendants had violated antitrust and consumer protection laws in marketing Terazosin products (including Hytrin). *In re Terazosin Hydrochloride Antitrust Litigation,* MDL 1317 (S.D. FL 1999). The court approved a **settlement** in the amount of $30.7 million, and certified a class of all consumers and TPPs in eighteen states who paid for all or part of the purchase price of Hytrin or its generic equivalents over a ten year period. *See* Order Prelim. Approving the Indirect Purchaser Pf. **Settlement**, MDL 1317, Mar. 7, 2005, Pfs.' Ex. 24 to the Bierstein Aff.

Notice to third-party payor class members included direct mailing and publication. Notice to consumers included direct mailings to chain pharmacies asking them to display Point of Sale ("POS") placards on their counters, which demonstrably increased the number of claims filed. *See* Order Approving Form & Language of Point-Of-Sale Placard, MDL 1317, July 8, 2005, Pfs.' Ex. 25 to the Bierstein Aff; Hytrin Point of Sale Placard and Letter to Pharmacies, Pfs.' Ex. 26 to the Bierstein Aff.; Aff. of Thomas R. Glenn re: Consumer Claim Submissions as a Result of the Point-Of-Sale Placard Project, MDL 1317.

C. Damages

***145** Damages will not be speculative. They will be based on proven payments by plaintiffs. Fluid recovery will not be relied upon. It has no bearing on the instant case. *See* *McLaughlin v. American Tobacco Co.,* 522 F.3d 215 (2d Cir.2008), *subsequently placed in doubt by* *Bridge v. Phoenix Bond & Indemnity Co.,* No. 07-210, --- S.Ct. ----,

2008 WL 2329761 (June 9, 2008). Because of Lilly's patent monopoly for Zyprexa, while sales have decreased, the price remained essentially the same, increasingly slightly in parallel with competing drugs. A price differential can be validly determined by the jury year by year for the few years in which damages are permitted under the temporal definition of the class.

Since under plaintiffs' theory a single amount of overcharge is attributable to each prescription, a subclass for an award for off-label use is not required. No other subclass is required.

XXII. Certification Order

A. Rule 23(c)

The parties shall submit an appropriate form of certification order fulfilling the requirements of Rule 23(c), consistent with and incorporating the analysis and findings in this memorandum and order. *See* Fed.R.Civ.P. 23(c). The order shall include such matters as the notification procedures to be used under Rule 23(c) (2), opt-out provisions, and the like. If they cannot agree, each side may submit a proposed order. Submission of such an order shall not constitute agreement with any portion of this memorandum.

A briefing schedule shall be agreed upon by the parties, of if they cannot agree, by the magistrate judge. A hearing is scheduled for July 31, 2008 at 11:00 a.m. on the form of the certification order.

B. Rule 23(d)

The court will also consider on July 31, 2008, at 11:00 a.m., any proposed order under Rule 23(d), particularly under Rule 23(d)(1) (B)(iii). *See* Fed.R.Civ.P. 23(d)(1)(B)(iii) ("In conducting an action under this rule, the court may issue orders that: ... require-to protect class members and fairly conduct the action-giving appropriate notice to some or all class members of ... (iii) the members' opportunity to signify whether they consider the representation fair and adequate, to intervene and present claims or defenses, or to otherwise come into the action."). Submission of such an order does not constitute agreement with any portion of this memorandum.

C. Other Matters

The parties shall propose any other relevant orders or raise any other appropriate issues at the July 31, 2008 hearing.

XXIII. Interlocutory Appeal

When denying summary judgment in *In re Zyprexa Prods. Liab. Litig.*, 493 F.Supp.2d 571 (E.D.N.Y.2007), this court noted that:

> [A]n 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 [18 U.S.C.] § 1292(b) so the class-procedural and substantive merits can be considered together by the appellate court.

***146** 493 F.Supp.2d at 580-81. Rule 23(f) of the Federal Rules of Civil Procedure states that:

> A court of appeals may permit an appeal from an order granting or denying class-action certification under this rule if a petition for permission to appeal is filed with the circuit clerk within 10 days after the order is entered. An appeal does not stay proceedings in the district court unless the district judge or the court of appeals so orders.

Fed.R.Civ.P. 23(f).

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). A delay in certification was designed to avoid unnecessary separate applications to the Court of Appeals for the Second Circuit.

The proceedings in this court are stayed pending any possible remand by the Court of Appeals for the Second Circuit or refusal to hear an interlocutory appeal under section 1292(b) or Rule 23(f). *See* Fed.R.Civ.P. 23(f) ("An appeal does not stay proceedings in the district court unless the district court of appeals so orders.").

XXIV. Settlement Class

Were the parties to choose to settle instead of proceeding to trial as currently proposed, a motion to certify a **settlement** class would be entertained. **Settlement** masters could be appointed to work out the details. Even though the court has in the instant decision certified only plaintiffs' RICO claims, a **settlement** class would ideally include all state consumer fraud claims and individual payor claims. Plaintiffs may not receive damages based on state as well as RICO claims because of the prohibition against double recovery. Should a **settlement** class be certified, it should include both off-label and on-label claims. The class definition could be amended to include all of the state and federal claims in their positions as third-party payors.

States (as well as the federal government) have already received substantial payments from Lilly for Zyprexa through liens placed on the recoveries of personal injury litigants. *See In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596, 2006 WL 3501263, at *1 (E.D.N .Y. Dec. 4, 2006) ("In compliance with this court's instructions ... all fifty states as well as the federal government have resolved their Medicare and Medicaid liens."); *In re Zyprexa Prods. Liab. Litig.*, 451 F.Supp.2d 458 (E.D.N.Y.2006) (Memorandum Order & Judgment Regarding Liens and Disbursement Procedures).

A global **settlement** for the overpricing claims and any other claims is desirable. Legal disputes of this nature should be resolved as quickly and comprehensively as possible so that government, the medical profession, and drug manufacturers can get on with their main job-protecting the people's health effectively at the cheapest practicable cost.

XXV. Conclusion

***147** Plaintiffs' motion to certify is granted in part and denied in part, subject to the hearing on July 31, 2008. A certification order consistent with this memorandum and the results of that hearing will follow.

SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2008 WL 2696916

Footnotes

* Projected to full year, based on first 10 months.

EXHIBIT

2011 WL 482767
Only the Westlaw citation is currently available.

This decision was reviewed by West editorial staff and not assigned editorial enhancements.

United States District Court,
N.D. California.

Lisa BAIN, et al., Plaintiffs,
v.
ASTRAZENECA LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Lisa Saunders, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Kimberly Kessler, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Cynthia Arnold, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Angel Colon, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Mark Coffey, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Sharon Diston, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Damon Brown, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.
Dennis O'Brien, et al., Plaintiffs,
v.
AstraZeneca LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation, Defendants.

Nos. C 09–4147 CW, C 09–4148 CW, C 09–4149 CW, C 09–4157 CW, C 09–4158 CW, C 09–4161 CW, C 09–4165 CW, C 10–0288 CW, C 10–0289 CW.
|
Feb. 7, 2011.

Attorneys and Law Firms

David Christian Andersen, The Miller Firm, LLC, Orange, VA, for Plaintiffs.

Lee Leonard Kaster, Oliver Quinn Dunlap, Peter Auguste Strotz, William Edward Steimle, Filice Brown Eassa & McLeod LLP, Oakland, CA, for Defendants.

ORDER GRANTING IN PART AND DENYING IN PART WITHOUT PREJUDICE JOINT MOTION FOR LEAVE TO FILE UNDER SEAL

CLAUDIA WILKEN, District Judge.

***1** Plaintiffs in these related cases and Defendants **AstraZeneca** LP, **AstraZeneca** Pharmaceuticals LP and McKesson Corporation jointly move for leave to file under seal documents related to their stipulated motion for an "Order Establishing a **Qualified** **Settlement** **Fund** and Appointing **Fund** Administrator" (Stipulated Motion).

Because the public interest favors filing all court documents in the public record, any party seeking to file a document under seal must demonstrate good cause to do so. *Pintos v. Pac. Creditors Ass'n,* 565 F.3d 1106, 1115 (9th Cir.2009). This cannot be established simply by showing that the document is subject to a protective order or by stating in general terms that the material is considered to be confidential, but rather must be supported by a sworn declaration demonstrating with particularity the need to file each document under seal. *See* Civil L.R. 79–5(a).

In the declaration supporting their motion to seal, the parties indicate that they have entered into a **Master** **Settlement** Agreement (MSA), which involves the establishment of a **Qualified** **Settlement** **Fund** (QSF). They assert that both "the MSA and the QSF contain and concern confidential, private and sensitive **settlement** information." Dunlap Decl. ¶ 3.

Not all of the documents the parties seek to file under seal appear to implicate information regarding the MSA and the QSF. The stipulation filed in support of the motion contains specific, detailed information about the **settlement**. However, the Stipulated Motion does not appear to contain such information. Requests for leave to file documents under seal must be narrowly tailored. *See* Civ. L.R. 79–5(a).

Accordingly, the parties' motion to seal is GRANTED in part and DENIED in part without prejudice. The "Stipulation with Respect to Motion Regarding Plaintiffs' Request for Administrative Relief and for Order Establishing a **Qualified Settlement Fund** and Appointing **Fund** Administrator" may be filed under seal. Within three days of the date of this Order, the parties may renew their motion for leave to file their Stipulated Motion under seal, so long as they proffer a declaration establishing the Stipulated Motion's sealability. In the alternative, they shall file the Stipulated Motion in the public record within three days.

IT IS SO ORDERED.

All Citations

Not Reported in F.Supp.2d, 2011 WL 482767

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