

The New AG Case:

*Defending Cases Where There Is an Alliance between
an Attorney General and the Plaintiffs' Bar*

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I. Introduction

As state budgets were strained under increasing Medicaid costs, targeting pharmaceutical companies became a method to alleviate fiscal shortfalls. Vioxx®, Zyprexa®, Risperdal®, and Seroquel® (for example) have recently been caught in the cross hairs of lawsuits by multiple state attorneys general. *See, e.g.*, Press Release, Merck, Merck Wins Summary Judgment in Texas Attorney General's Lawsuit Involving Vioxx (Nov. 23, 2009), http://www.merck.com/newsroom/news-release-archive/corporate/2009_1123.html (last visited Feb. 16, 2010) (noting that Vioxx was the subject of 12 attorney-general suits); Margaret Cronin Fisk, *J&J Improperly Marketed Drug, South Carolina Says*, Bloomberg News, May 24, 2007, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=alrVtPufft4A> (noting South Carolina's suit was one of at least 12 state claims against manufacturers of atypical antipsychotics); *State of Utah Sues Zyprexa Maker*, Sale Lake Tribune, May 18, 2007 (noting that Utah was the eighth state to file a Medicaid lawsuit against Eli Lilly and Company); Steve Korris, *McGraw's Zyprexa Case Sent to Federal Court in Brooklyn*, Legal NewsLine, Mar. 13, 2007, <http://www.legal-newsline.com/printer/article.asp?c=186941> (discussing West Virginia's suit against Eli Lilly and Company); Margaret Cronin Fisk, *Pa. Sues Eli Lilly, AstraZeneca over Antipsychotic Medications*, Bloomberg News, Mar. 3, 2007; Jim Rosack, *Company Accused of Improprieties in Marketing Risperdal*, Psychiatric News 42 (3), Feb. 2, 2007, at 30, available at <http://pn.psychiatryonline.org/cgi/content/full/42/3/30> (noting Texas AG joined whistleblower suit against Johnson and Johnson).

In general, plaintiffs' attorneys present opportunities for various types of litigation to state attorneys general. States then hire the private plaintiffs' attorneys to bring cases on their behalf, in lieu of managing the litigation with their own staff. Attorneys general eager to defend their decision to subcontract large and potentially lucrative pieces of litigation to private plaintiffs' attorneys, often on contingency, say that they needed the expertise that private counsel offer or that the state simply could not afford to bring litigation through the AG's office. *See, e.g.*, *McGraw Has Taken Outside Counsel Idea to New Heights*, West Virginia Record (Aug. 1, 2008). Although New York's Eliot Spitzer is credited with "perfect[ing]" the use of outside counsel to aggressively pursue lawsuits, "other AGs are catching up fast." *See id.* The circumstances under which state AGs retain private counsel have come under increased scrutiny. In some instances, greater accountability and transparency have resulted. *See, e.g.*, Office of the Attorney General of Florida: Government Accountability Project, <http://myfloridalegal.com/pages.nsf/Main/20AB6480E324FC5885257297006997E7> (promoting transparency in AG/private attorney contracting and outlining the steps the Florida AG must take to retain private counsel).

The coordination between AGs and the plaintiffs' bar makes these cases an increasingly common threat. This article first discusses theories of recovery that states have used (*e.g.*, consumer protection and unfair trade practices acts, and Medicaid fraud acts), and the types of damages they have sought (*e.g.*, treatment costs, overpricing damages, and civil penalties). The article continues with a discussion of potential lines of defense. Such defenses include separation of powers and due process arguments, the learned intermediary doctrine, challenges to the manner in which states attempt to prove causation and reliance in fraud-based claims, the remoteness doctrine, preemption, and attacks on a state's ability to calculate an appropriate penalty.

II. Theories of Recovery

States, in conjunction with private plaintiffs' attorneys, have employed a variety of legal theories against pharmaceutical companies. Those theories include violation of state consumer protection laws and unfair trade practices acts, Medicaid fraud statutes, state products' liability acts, common-law fraud and negligence, and RICO. This section provides an overview of these theories.

A. Consumer Protection Statutes

States have used state consumer protection or unfair trade practices acts in suits against pharmaceutical companies. These statutes often allow for civil penalties in addition to actual damages. States have argued that they need not show reliance and causation to obtain penalties. See, e.g., *State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General v. Johnson & Johnson*, No. 04-C-156, *slip op.* (Cir. Ct. Brooke Cty, Feb. 25, 2009).

Unfair trade practice and consumer fraud acts vary by jurisdiction. Because the acts are generally based on the Federal Trade Commission Act, they share some similarities. (For a thorough overview of the development of state unfair competition and consumer protection laws, see Sheila B. Scheuerman, *The Consumer Fraud Class Action: Reining in Abuse by Requiring Plaintiffs to Allege Reliance as an Essential Element*, 43 Harv. J. on Legis. 1, *14 (2006)). In general, state unfair trade practices acts and consumer protection laws prohibit

- 1) unfair methods of competition,
- 2) false or misleading acts or practices, and/or
- 3) "unfair" or deceptive acts or practices.

See *id.* at *17-*18.

When considering potential defenses to consumer protection actions, one should evaluate the specific nature of an AG's allegations. Upon first receiving a complaint, it can be difficult to divine who was allegedly defrauded. Allegations that the defendant-company committed fraud must be fleshed out: fraud on whom (the state itself, physicians practicing in the state, patients? all three?), when, how? Questions of reliance and causation (*who* is supposed to have relied on *what* alleged misstatement) and whether but-for an allegedly fraudulent statement "someone" would have acted differently affect both discovery strategy and legal theories.

As further discussed below, allegations regarding fraud on doctors raise issues related to the learned intermediary doctrine, as well as questions of proximate causation. Because the learned intermediary doctrine shifts a company's duty to warn from patients to physicians, physicians hold an important position in both negligence- and fraud-based theories of recovery. Where a state alleges that it was damaged by having to pay treatment costs for adverse events purportedly caused by a particular medication, the issues of what physicians knew about a medication's safety profile and whether a different or stronger warning would have deterred the physician from prescribing the medication become paramount. Similarly, if a state alleges that a company communicated a misleading or fraudulent promotional message to doctors, the question of whether physicians received and relied on such communications takes center stage.

B. State Medicaid Fraud Statutes

States often rely on state Medicaid fraud statutes to recover moneys the state spent on certain medications through its Medicaid program.

Under the federal Medicaid statute, states are permitted, but not required, to offer a pharmacy benefit to Medicaid-eligible citizens. 42 U.S.C. §1396a(a)(10); see also 42 U.S.C. §1396d(a)(12). Once a state elects to participate in the Medicaid program, it must reimburse for "medically accepted" indications of medica-

tions. Medically accepted indications include the FDA-approved uses *and* any of the off-label uses supported by three compendia: the DRUGDEX Information System, the United States Pharmacopeia Drug Information, and the American Hospital Formulary Service Drug Information. 42 U.S.C. §1396r-8(k)(6); 42 U.S.C. §1396r-8(g)(1)(B)(i). A state “*may* exclude or otherwise restrict coverage of a covered outpatient drug if . . . the prescribed use is not for a medically accepted indication,” but it is not required to do so. 42 U.S.C. §1396r-8(d)(1)(B) [emphasis added].

States have several tools with which they can influence the use and cost of medications under the Medicaid program. These include state drug utilization review (“DUR”) boards, pharmacy and therapeutics (“P&T”) committees, preferred drug lists (“PDL”), prior authorization requirements, and communications to physicians who participate in the Medicaid program. Each of these provides important territory to investigate during discovery. Depositions of DUR boards and P&T committee members can show that a state was aware of purported safety and efficacy issues with a particular medication. Evaluation of PDL or prior authorization programs can show that a state did not change reimbursement policies for a particular medication, even after learning of an alleged fraud.

Because of the complexities of the Medicaid system and the highly state-specific facts related to open formularies, PDLs, and prior authorization requirements, this area should be a focus of discovery in AG actions where Medicaid fraud is alleged.

C. Common-Law Fraud and Negligence

States have also pursued theories of common-law fraud and negligence. In addition to common-law fraud, states may bring fraud-related claims under the federal RICO statute, as RICO provides for treble damages. *See* 18 U.S.C. §§1962 and 1964(c). Because a RICO claim creates federal question jurisdiction, however, states’ use of RICO is rare.

III. Types of Damages

This section reviews the types of damages states can pursue. Because states aggregate damages and penalties across their citizenry or Medicaid population, damage amounts in these cases can be substantial. For example, in *State of Connecticut v. Eli Lilly and Co.*, the State sued under the federal RICO statute and the Connecticut Unfair Trade Practice Act, seeking a refund of the amount paid for Zyprexa through public assistance programs, the costs incurred to treat Medicaid recipients whose diabetes was allegedly caused by Zyprexa, as well as statutory penalties up to \$5000 for every Zyprexa prescription written to a Connecticut resident since Zyprexa’s launch in October 1996. The resulting damage award would have reached the hundreds of millions of dollars. Because companies frequently face suits from more than one state simultaneously, potential damages can be astronomical.

A lawsuit by a state on behalf of its Medicaid agency or patients generally is a structural or *de facto* class action. Even though a state-plaintiff is not a class of multiple plaintiffs, courts have applied the logic and reasoning of class action jurisprudence to state cases. *See, e.g., State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289 (E.D.N.Y. 2009). In the Mississippi Zyprexa litigation, these issues proved fatal to many of the State’s claims.

A. Treatment Costs

Through the Medicaid system, states cover the costs associated with medical treatment and prescription medications of Medicaid-eligible individuals. As a result, states have sought costs that they paid to treat

illnesses purportedly caused by the targeted drug. See, e.g., *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289 at *83 (E.D.N.Y. 2009).

B. Economic Damages

Plaintiffs also seek several types of damages for economic loss in pharmaceutical litigation. These include pricing (e.g., loss-of-value, price inflation, and launch-price inflation) and quantity (e.g., excess prescription) theories.

1. Pricing damages

Loss-of-value is a measure of damages based on the theory that plaintiffs did not receive the benefit of their bargain. This theory does not require a showing of but-for causation. The theory turns on the value that a plaintiff attached to a certain medication and whether the medication lived up to the plaintiff's expectation. Price inflation claims are based on the theory that a company's misrepresentations regarding a drug *caused* the price to be too high by inflating demand over time. In other words, *but for* a defendant's fraud, a drug would not have commanded a premium price. Price inflation claims in pharmaceutical litigation are usually unsuccessful, because drug prices generally do not decrease after disclosure of adverse information. See, e.g., *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. Lexis 58900, *77-*80 (D.N.J. 2009) (rejecting fraud-on-market theory). The patent-holder has considerable power to set prices and is unlikely to reduce the price if adverse information develops. In contrast, the market sets the price of publicly traded securities, and adverse information will lower the price. In the launch-price inflation theory, plaintiffs allege that a defendant's misrepresentations (or planned misrepresentations) enabled the defendant to set the launch price artificially high. In other words, but for the defendant's fraud, a drug's launch price would not have been set at a premium.

In the Zyprexa litigation, states claimed that Zyprexa was overpriced. This theory was first deployed in the Zyprexa *private* payor litigation. As the state cases evolved, overpricing emerged as the main theory of relief, but its viability is questionable and currently on appeal before the Second Circuit in the Zyprexa third party payor litigation. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *154-*155. In the Zyprexa third party payor litigation, the plaintiffs first used a loss-of-value theory. This theory was not viable under RICO, however. The plaintiffs then alleged that Zyprexa's price at launch had been set too high relative to its actual value because of Lilly's purported misrepresentations regarding Zyprexa's safety and efficacy profile. See *In re Zyprexa Prods. Liab. Litig.*, 235 F.R.D. 69 (E.D.N.Y. 2008). By borrowing and applying garden variety antitrust law, the court determined that an overpricing claim could be viable, assuming that a pharmaceutical's price is a proxy for its value (a matter of heated debate between the parties). See *id.* at 159-61, 190. Because this theory was deemed viable by Judge Weinstein in the TPP litigation, states followed the same theory in the Zyprexa litigation.

For example, in *State of Connecticut v. Eli Lilly & Co.*, the State asserted that it overpaid for Zyprexa prescriptions in an amount ranging from \$31 million to \$145 million as a result of Lilly's alleged improper marketing and lack of disclosure regarding Zyprexa's risks and efficacy. These proposed damages were generated by the State's expert, Professor Meredith Rosenthal. (The same methodology was offered by plaintiffs in the Zyprexa third party payor litigation.) The overpayment calculus for *all* on-label Zyprexa prescriptions was based on price differences between Zyprexa and either Seroquel (another second-generation antipsychotic) or perphenazine (a generic, first-generation antipsychotic). The State claimed these two "yard sticks" were cheaper but equally safe. The State argued off-label prescriptions had *no* value. Thus it claimed Zyprexa's full prescription price for off-label damages.

2. Quantity damages

Quantity or excess prescription damages are based on the theory that a defendant's fraudulent or misleading communications caused a greater number of prescriptions to be written (or more units of a medical device to be used) than otherwise would have absent the fraud. See, e.g., *In re Neurontin Mktg. & Sales Prac. Litig.*, 2010 U.S. Dist. Lexis 1756 (D. Mass. Jan. 8, 2010). In the Zyprexa third party payor litigation, Judge Weinstein said individual issues would predominate in an excess scripts case. Thus, plaintiffs abandoned that theory in favor of an overpricing theory. See *supra*. Because the Zyprexa state cases followed the third party payor case, the states abandoned their excess prescription theories as well.

C. Civil Penalties

State consumer fraud, unfair competition, and Medicaid fraud statutes often allow for civil penalties. Unlike damages related to treatment costs, states argue that penalties may be imposed without establishing reliance or causation. Proof of reliance and causation is usually required in fraud-based cases. Compare *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008) (finding that individualized proof was required to show causation in a consumer class action against tobacco manufacturers under RICO) with *In re Tobacco II Cases*, 207 P.3d 20, 35 (Cal. 2009) (holding that, in a consumer class action under California's unfair competition law, absent class members need not show that they have "lost money or property as a result of the unfair competition" on an individualized basis).

With civil penalties, however, some courts have found that proof of reliance and causation is not required. Penalties are intended to penalize and deter inappropriate conduct. Penalties are not designed to compensate parties for actual damages. Thus, once a court determines an appropriate amount for each *per*-violation penalty and the number of violations, the total penalty amount is based on simple arithmetic. Jansen faced this issue in a suit brought by the attorney general for West Virginia over the antipsychotic Risperdal. See *State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General v. Johnson & Johnson*, No. 04-C-156, *slip op.* (Cir. Ct. Brooke Cty, Feb. 25, 2009). In this case, West Virginia sought civil penalties under the West Virginia Consumer Credit and Protection Act, W. Va. Code, §§46A-1-101, *et seq.*, for allegedly fraudulent statements in promotional materials for Risperdal and Duragesic. See *id.* at 3. The court observed that the State of West Virginia did not need to establish reliance and causation to receive civil penalties. *Id.* at 61. Depending on how many violations are found and the amount of each *per*-violation penalty, the threat of civil penalties across a company's statewide conduct can be significant.

IV. Potential Lines of Defense

Before attacking the legal theories and factual underpinnings of a state's case, a defendant can challenge the *relationship* between the state and its private attorneys. Such attempts have met with varying levels of success. The theories underlying such challenges range from separation of powers and due process considerations, to violations of state laws that govern an attorney general's ability to retain private counsel.

A. Constitutional Issues: Separation of Powers and Due Process Challenges Where Cronyism Trumps Competitive Bidding

Where a state retains private counsel pursuant to a contingency fee arrangement, separation of powers and due process issues arise. State constitutions are often modeled on the U.S. Constitution and provide for a system of checks and balances through a tripartite government. Like the U.S. federal government, the power of the purse is supposed to reside with the legislature, not the executive branch (of which the attorney general's

office is a member). See Andrew Spiropoulos, *State AGs Hiring Private Attorneys to Assist in Government Lawsuits*, The Federalist Soc’y, Jan. 10, 2009 (observing that a state legislature’s primary check on the attorney general is its control of the office’s appropriations). Where state attorneys general enter into retainer agreements that provide for private plaintiffs’ attorneys to receive a percentage of any award or settlement, without that money flowing into the state’s coffers, the arrangement arguably violates separation of powers principles.

Similarly, a contingency fee arrangement between a state and private plaintiffs’ attorneys violates a defendant’s due process rights. The nature of the contingency payment makes the private plaintiffs’ attorneys self-interested parties to the litigation. Because the size of their fee is married to the amount that the state recovers, the private plaintiffs’ attorneys have “skin in the game.” The attorney general’s office is a governmental position, and private plaintiffs’ attorneys should not wield that power when they themselves have a personal, private interest in the outcome of the litigation. The separation of powers and due process issues come more acutely into focus where, as is often the case, the plaintiffs’ attorneys have contributed to the attorney general’s campaign fund. Where cronyism replaces competitive bidding, the specter of pay-to-play supplements the underlying constitutional concerns. Indeed, a former attorney general for the state of Alabama went so far as to say that contingency fee contracts create the potential for “outright corruption.” See E. Berton Spence, *Alabama AG Uses Contingency Fee Agreements to Sue Drug Manufacturers*, State AG Tracker (produced by The Federalist Society’s State Courts Project), 2009, http://www.fed-soc.org/publications/pubid.1567/pub_detail.asp.

States’ elected officials, including attorneys general, have come under increased scrutiny for the campaign contributions that they have received from private plaintiffs’ attorneys. See, e.g., Molly Parker, *Group: Lawsuit Process Unfair: AG’s Contracts with Campaign Donors Called into Question*, Clarion Ledger, Feb. 14, 2010, available at <http://www.clarionledger.com/article/20100214/NEWS01/2140353/Group++Lawsuit+process+unfair> (hereinafter “Molly Parker”). In some states, like Mississippi, the issue has become a “well-worn saga” that “goes on and on and on.” See *id.* Issues regarding campaign contributions and pay-to-play controversies that appear in the media have recently generated negative press. For example, in the wake of the announcement of the Mississippi settlement in the Zyprexa litigation for \$18.5 million, the *Clarion Ledger* probed into issues concerning Texas attorney Ken Bailey’s contributions to Mississippi Attorney General Jim Hood and to the Democratic Attorneys General Association (“DAGA”), another major Hood donor. See Molly Parker. The article reported that Bailey, personally and through his firm, had contributed \$75,000 to Hood directly, as well as \$110,000 in contributions to the DAGA. See *id.* Interviewed for the article, AG Hood defended the contract with Bailey Perrin by saying that his contract award system is “first come, first serve” and that he’s “done everything he knows to do short of banning attorneys with contracts from contributing to his campaign fund.” See *id.* Lisa Rickard, president of the Washington-based U.S. Chamber Institute for Legal Reform noted, “Pay-to-play might be good for (Attorney) General Hood and the law firms, but it is bad for the people of Mississippi to have their legal system tainted in this way.” See *id.*

The extant and growing hostility toward the pay-to-play issue, combined with the sometimes speedy and poorly documented manner in which AGs retain private counsel without legislative oversight, afford defense attorneys several ways to challenge the relationship.

B. Contingency Fee Agreements Can Be Challenged on Separation of Powers and Due Process Grounds

Despite the constitutional problems and growing public hostility toward noncompetitively bid contingency fee arrangements, separation of powers challenges to contingency fee agreements have met with varying levels of success.

In the Zyprexa MDL, Lilly first tested this strategy in the cases brought by the State of Louisiana. In 2005, Eli Lilly and Company filed a motion to dismiss two cases brought by the Louisiana AG on the grounds that (1) the private counsel retained by the State did not have expressed or implied authority to file the suits on behalf of the State; (2) the contingency fee agreement between the private attorneys and the AG was prohibited under Louisiana law as a violation of separation of powers; (3) the agreement did not meet Louisiana's requirements for a professional services contract; and (4) the arrangement between the private counsel and the AG had not been approved by the Louisiana Office of Contractual Review. See *State of Louisiana, ex rel. Charles C. Foti, Jr., Attorney General v. Eli Lilly and Co.*, Memorandum & Order dated July 1, 2005) at 2. Judge Weinstein denied the motion, finding that the capacity of the Louisiana attorney general to employ private counsel was "not contestable." See *id.*

Noting that the AG's ability to authorize payment of private counsel was a question of Louisiana law, the court stated that counsel, not Lilly, had assumed the risk of nonpayment of fees. If the cases were to result in a recovery, the court would determine whether counsel was entitled to a fee that was authorized under Louisiana law. See *id.*; see also *State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General v. Johnson & Johnson*, No. 04-C-156 (Cir. Ct. Brooke Cty. Feb. 25, 2009) (noting that in October 2005, the court found defendant lacked standing to enjoin the AG's use of nongovernmental, private practice attorneys).

Several years later, in the Zyprexa case brought by the State of South Carolina, which was pending in state court, Lilly again challenged a state's ability to retain private counsel using a contingency fee. Lilly also questioned the legality of the agreement where the appointed counsel had contributed to Attorney General McMaster's campaign fund. Lilly moved to disqualify the State's special counsel on separation of powers and due process grounds. The company also argued that the contingency fee agreement violated the South Carolina Ethics, Government Accountability, and Campaign Reform Acts, because the private attorneys had contributed to the AG's reelection campaign. See Brief of Defendant, *State of South Carolina ex rel. Henry McMaster, in his capacity as Attorney General of the State of South Carolina v. Eli Lilly & Co.*, No. 2007-CP-42-1855 (7th Judicial Cir. Aug. 21, 2009).

The South Carolina court rejected Lilly's challenge. Public hostility to campaign donations and perceived pay-to-play issues flared up, however. After initially trying to defend the legality of the campaign contributions, Attorney General McMaster, who was seeking the Republican nomination for governor, relented and agreed to return the suspect donations. See, e.g., *McMaster Accepted Campaign Cash from Lawyers He Hired*, Sept. 25, 2009, available at www.TheItem.com; Meg Kinnard, *SC AG Won't Return Questioned Campaign Cash*, Citizen-Times, Sept. 25, 2009; Travis Medlock, *Medlock: Campaign Donations to McMaster Perfectly Legal*, The State, Oct. 1, 2009; *South Carolina AG to Return Questioned Donations*, Associated Press, Oct. 2, 2009). Less than a month later, on October 23, 2009, Attorney General McMaster issued a press release announcing that a settlement had been reached. (See Press Release, Office of the Attorney General Henry McMaster, \$45 Million Eli Lilly Settlement Nations Largest (Oct. 23, 2009), http://www.scattorneygeneral.org/newsroom/pdf/2009/elilily_pressrelease.pdf).

Recently, in a suit against Janssen Pharmaceutica regarding the antipsychotic Risperdal, the pharmaceutical manufacturer asked a Pennsylvania court to invalidate the contingency fee agreement between the Commonwealth and the law firm of Bailey Perrin. Although the motion was denied without opinion at the trial court level, Janssen petitioned the Pennsylvania Supreme Court for extraordinary review on January 6, 2009. On June 30, 2009, the Pennsylvania Supreme Court granted Janssen's application and requested briefing on several issues. These issues included whether Janssen lacked standing to seek disqualification of Bailey Perrin; whether the Pennsylvania Attorneys Act authorized the Office of General Counsel's contingency fee arrangement; whether the contingency fee arrangement violated the separation of powers doctrine under the Penn-

sylvania Constitution; and whether Bailey Perrin should be disqualified because the delegation of sovereign powers to private attorneys with an interest in the litigation's outcome violated the due process guarantees of the U.S. and Pennsylvania Constitutions. See Brief of Petitioner at 4, *Commonwealth of Pennsylvania v. Janssen Pharmaceutica, Inc.*, No. 24 EAP 2009 (Pa. Aug. 11, 2009).

Critical to Janssen's challenge was the manner in which Bailey Perrin had been awarded the contract. In 2005, two years before the Commonwealth filed suit, Ken Bailey met with Pennsylvania Attorney General Tom Corbett to market the idea of a Risperdal lawsuit. Corbett was "not impressed with the presentation Bailey made, or the evidence Bailey presented" and Corbett decided not to retain the firm. See Brad Bumsted, *Rendell Defends Contract with Houston Law Firm That Made Donation*, Pittsburgh Tribune-Review, Apr. 10, 2009. A year later, however, Governor Rendell's General Counsel Barbara Adams asked Corbett to delegate to her office the power to pursue the suit. See *id.* In the interim, Ken Bailey had contributed nearly \$100,000 to Rendell's campaign. Absent any competitive bidding process or legislative approval, Rendell's Office of General Counsel awarded the contingency fee contract to Bailey Perrin. Pay-to-play allegations arose when Ken Bailey's political contributions to Rendell came to light. See *id.* (reporting that Ken Bailey had donated \$59,200 in cash and air-fare to Rendell in the seven months before the Risperdal contract was awarded and \$31,900 after the agreement was signed).

Janssen's challenge garnered national attention when the *Wall Street Journal* used the motion as the basis for an article on the "State Lawsuit Racket." See *The State Lawsuit Racket*, Wall St. J., Apr. 8, 2009, at A12. Condemning the cozy relationship between the trial bar and state office holders, *WSJ* highlighted the "inherent conflicts of interest and questionable ethics" of the practice whereby state AGs hire private plaintiffs' lawyers on a contingency-fee basis, and the trial bar "returns the favor" with campaign donations. See *id.* "State prosecutors are supposed to be motivated by a sense of public responsibility for the interests of justice. Law firms have other motivations, and no-bid contingency-fee deals encourage lawyers with a financial stake in a case to try meritless claims or ask for exorbitant rewards." See *id.* *WSJ* revisited the issue several months later, after the Pennsylvania Supreme Court granted Janssen's petition for extraordinary review, heralding the court's decision as "good news." See *Pay to Sue on the Docket: The Trial Bar on Trial in Pennsylvania*, Wall St. J., July 28, 2009, available at <http://online.wsj.com/article/SB10001424052970203946904574300053629391052.html#printMode>.

The Pennsylvania Supreme Court heard argument on Janssen's petition on October 21, 2009. As March 8, 2010, however, no opinion had been issued.

C. Medicaid Fraud Statutes Are Not Intended to Reach Pharmaceutical Companies

Medicaid fraud statutes are designed to punish providers who submit false claims. Depending on the wording of a particular state's Medicaid fraud act and whether the act defines the term *provider*, defendants can argue that a pharmaceutical or medical device manufacturer is not a provider under the relevant statute. Janssen Pharmaceutica and AstraZeneca Pharmaceuticals were successful in challenging claims under the Pennsylvania Medicaid and PACE Programs using this reasoning. See *Commonwealth of Pennsylvania v. Ortho-McNeil-Janssen Pharm. Inc.*, No. 2181 (Ct. Com. Pl. Phila. Jan. 5, 2010) (order granting defendant's motion for judgment on the pleadings and dismissing counts regarding submission of false and fraudulent claims under the Pennsylvania Medicaid and PACE Programs); *Commonwealth of Pennsylvania v. AstraZeneca Pharm. LP*, No. 2178 (Ct. Com. Pl. Phila. Dec. 10, 2008) (order granting defendant's motion to determine preliminary objections and dismissing counts regarding submission of false and fraudulent claims under the Pennsylvania Medicaid and PACE Programs).

In the *AstraZeneca* case, the court noted that the Pennsylvania Medicaid statute, 62 P.S. §§1401, *et seq.*, defines the terms *Provider*, *Medical Facility*, and *Purveyor*. Based on their plain language, none of these definitions seemed to apply to AstraZeneca. The court determined that AstraZeneca is not an individual, medical facility, or purveyor as defined by the statute. See *id.* [citation omitted].

D. Attacking the Causal Chain Offers Several Viable Challenges to a State Attorney General's Case

1. Learned intermediaries break the causal chain

One tool for attacking a state AG's causation argument is the learned intermediary doctrine. Physicians who have prescribed a medication, together with state medical experts who formulate the medication's reimbursement policy for the state's medication assistance programs, are independent intervenors that break the causal chain between a company's alleged conduct and the state's alleged injury. As in traditional products liability cases, where the actions of learned intermediaries foreclose a finding of proximate causation, the independent judgments of such physicians preclude a finding of causation in a state AG case.

This argument succeeded in the *Seroquel* private payor litigation, where the district court dismissed a RICO claim seeking to recover for purchases of Seroquel, because physicians' decisions to prescribe Seroquel were an intervening factor between the alleged misrepresentations and payments. Thus, the allegations did not sufficiently plead proximate causation.

This case raises serious concerns regarding the ascertainment of damages caused by Defendants' alleged fraudulent conduct, as opposed to damages by other, independent, factors. The key independent factor in this case stems from the fact that consumers may only obtain Seroquel through a prescription from a physician. Presumably, these physicians use their independent medical judgment to decide whether Seroquel is the best treatment for a given patient. This independent judgment can be influenced by a number of things, only one of which may be representations by a manufacturer as to a particular drug's relative safety and efficacy. Thus, in the context of this case, establishing that Plaintiffs' injuries were caused by Defendants' misconduct would require an inquiry into the specifics of each doctor-patient relationship implicated by the lawsuit. In other words, each physician who prescribed Seroquel to an individual consumer or health and welfare fund member would have to be questioned as to whether his or her independent medical judgment was influenced by Defendants' misrepresentations, and to what extent.

Local Union No. 68 v. AstraZeneca Pharm. LP, 585 F. Supp. 2d 1339, 1334 (M.D. Fla. 2008).

Similarly, in the *Risperdal* private payor litigation, the court dismissed RICO claims noting the "substantial question" of whether "the independent and individualized decision making of physicians prescribing Risperdal breaks any chain of causation between Defendants' alleged misconduct and Plaintiffs' payment for the medication." See *District 1199 Health & Welfare Plan v. Janssen, L.P.*, 208 WL 5413105, at *9 (D.N.J. 2008).

Even if the learned intermediary defense fails to carry a motion to dismiss, it is important to develop the defense during discovery. The presence of learned intermediaries may be used to challenge a state's theory of aggregate proof at the summary judgment state or at trial.

2. States cannot use aggregate proof to show causation

As further discussed below, plaintiffs may not use aggregate data to establish reliance and causation in fraud-based class actions. See, *e.g.*, *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008). Where

a single state brings suit, however, it acts as a single plaintiff, not a class. As recent case law illustrates, this distinction is one of form but not substance.

In the Zyprexa Mississippi case, Judge Weinstein noted the existence of a single plaintiff but analogized the case to a class action and characterized the suit as a “structural class action.” *Jim Hood, Attorney General of the State of Mississippi, ex rel. the State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289 (E.D.N.Y. 2009) at *96-97 (hereinafter, *State of Mississippi v. Eli Lilly*). As a result of this “structural” similarity, key points from class action jurisprudence came into play.

Mississippi alleged that Lilly’s purportedly fraudulent promotional message had misled prescribing physicians (as opposed to the State itself). Thus, the court found, the State’s claims rested upon a series of underlying acts of fraud:

The present case is not a Rule 23 class action or a quasi-class action Mississippi brings suit individually. In this respect, decisions in class actions concerning the use of statistical or aggregate evidence are not directly on point. Conceptually and structurally, however, the State’s suit is predicated on numerous acts of fraud and other delicts alleged to have affected a statewide population of prescribing physicians and patients. In effect, Mississippi’s individual claim is structured on the foundation of many thousands of conceptually separate claims, coordinated and aggregated by the State for purposes of recovering a portion of its overall Zyprexa-related costs through its Medicaid reimbursement program. The court will refer to an individual claim structured in this way as a “structural” class action.

Id. at *96-97. But see *State of Missouri, ex rel. Chris Koster, Attorney General v. Portfolio Recovery Assoc., Inc.*, 2010 U.S. Dist. Lexis 16596 (Feb. 24, 2010) (finding an AG consumer fraud case was neither a class action nor a mass action for removal under the Class Action Fairness Act).

Upon reaching this conclusion, Judge Weinstein determined that the extensive case law regarding the uses and limitations of aggregate evidence in Rule 23 class actions would be applicable to Mississippi’s case. See *id.* at *97-98. As a result, the State of Mississippi could not use aggregated data to prove reliance, causation, and injury on a populationwide basis. See *id.* *97.

Plaintiffs’ attorneys in state cases (*e.g.*, the State of Mississippi in the Zyprexa litigation) often try to establish causation using an expert’s *ipse dixit* opinions based on aggregated data. As Judge Weinstein determined in the Mississippi case regarding Zyprexa, a state’s reliance on such aggregated proof to establish causation is barred by the Second Circuit’s decision in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008), as well as a host of similar decisions across other circuits. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *98 (citing *Fotta v. Trustees of United Mine Workers of Am.*, 319 F.3d 612, 619 (3d Cir. 2003); *Doe v. Chao*, 306 F.3d 170, 183-84 (4th Cir. 2002); *McManus v. Fleetwood Enters., Inc.*, 320 F.3d 545, 549 (5th Cir. 2003); *Oshana v. Coca-Cola Co.*, 472 F.3d 506, 513-14 (7th Cir. 2006); *St. Jude Med., Inc.*, 522 F.3d 836, 838-39 (8th Cir. 2008); *Poulos v. Caesars World, Inc.*, 379 F.3d 654, 658, 666 (9th Cir. 2004); *Heffner v. Blue Cross & Blue Shield of Ala., Inc.*, 443 F.3d 1330, 1344 (11th Cir. 2006)); see also, *e.g.*, *In re Neurontin Marketing, Sales Practices, & Liab. Litig.*, 257 F.R.D. 315, 322-27 (D. Mass. 2009).

Because the Zyprexa MDL and the Mississippi case were presided over by Judge Weinstein in the Eastern District of New York, the *McLaughlin* case was the controlling precedent and is discussed in greater detail below. Judge Weinstein also characterized the Second Circuit’s case law on the aggregate proof issue as “the most detailed and well-developed . . . of any jurisdiction.” See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *122. Nevertheless, Judge Weinstein’s opinion also provided a multicircuit overview

of similar decisions in accord with *McLaughlin*. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at **99-*122.

In *McLaughlin*, the Second Circuit reversed the trial court's (Judge Weinstein's) decision, in *Schwab v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 992 (E.D.N.Y. 2006), to certify a class of smokers who alleged that cigarette manufacturers had deceived the public as to the healthier quality of light cigarettes. The trial court had found that plaintiffs could prove reliance on a classwide basis using statistical methods of analysis applied to determine the effects of defendant's nationwide campaign to promote light cigarettes. That theory was rejected on appeal.

The *McLaughlin* case involved a class action civil RICO case brought by consumers of light cigarettes. In that case, the injured plaintiffs (the smokers) were the direct targets of the alleged fraudulent promotion by light cigarette manufacturers. To prevail in their civil RICO claim, plaintiffs had to prove that the RICO violation was both a but-for and a proximate cause of their injuries. See *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 452, 461 (2006). In *McLaughlin*, the Second Circuit evaluated these requirements in the context of allegations of fraud in terms of "transaction causation" (whether the alleged fraud caused the transaction to occur, or reliance) and "loss causation" (whether the alleged fraud caused the loss at issue, or proximate cause). See *McLaughlin*, 522 F.3d at 223. For both transaction and loss causation, the court held that individualized proof is required. See *id.* at 225, 226.

Judge Weinstein, analyzing *McLaughlin* and similar cases, noted the existence of an "individualized proof rule" that barred a plaintiff's ability to use aggregate proof of reliance and causation. The application of this individualized proof rule proved fatal to the majority of Mississippi's claims. Subsequently, at least one other court elected to adopt Judge Weinstein's reasoning regarding *McLaughlin* and the requirement for individualized proof in a state case, for claims other than overpricing. See *Charles Foti, Attorney General ex rel. State of Louisiana v. Janssen Pharmaceutica, Inc.*, No. 04-C-03967-D and No. 04-C-3977-D (27th Judicial Dist. Ct., St. Landry Parish, Jan. 7, 2010) (order granting in part defendant's motion for summary judgment and holding that the individualized proof requirement was inapplicable to Louisiana's redhibition, fraud, negligence, unfair trade practices, and Medicaid fraud claims to the extent that the State was seeking to recover overpricing damages).

a. *McLaughlin* was fatal to Mississippi's treatment cost claims, which required individualized proof

Under its Products Liability Act ("PLA"), the State of Mississippi sought to recover the costs of treating illnesses allegedly caused by Zyprexa. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289 at *157. Because Mississippi's claim rested on the prescription decisions and treatment results of thousands of patients, individual issues were insurmountable. Judge Weinstein recognized that, for Mississippi's PLA claim to succeed, the State would need to show that physicians had relied uniformly on Lilly's warnings and express warranties and representations in prescribing Zyprexa, which resulted in metabolic diseases for which the State paid treatment costs. *Id.* at *158-159. Individualized proof would, therefore, be needed to overcome the possibility that a Mississippi patient was prescribed Zyprexa for a reason other than the physician's belief in the accuracy of Lilly's warnings or representations. *Id.* at *159.

Whether a more adequate warning by Lilly would have prevented any particular patient's injuries requires consideration of what the prescribing physician knew and the cost-benefit analysis that applied to the individual patient suffering from a variety of serious mental problems observed by the physician to be affected by the drug to varying degrees. The same analysis requires individualized proof[.] Each individual patient's metabolic condition would have to be shown to have resulted from Zyprexa, rather than other supervening causal factors. Any damages would similarly have to be calculated on an individualized basis.

State of Mississippi v. Eli Lilly & Co., 2009 U.S. Dist. Lexis 113289, at *159-*160.

The State of Mississippi had offered only the expert reports of Drs. Abramson and Rosenthal to address reliance and causation issues; therefore, the claim for treatment costs under the PLA failed. Because of his experience overseeing the individual products liability cases in the Zyprexa MDL, Judge Weinstein was already aware of the highly fact-specific nature of a particular prescribing physician's treatment decision. Thus, Judge Weinstein determined that broad categorization across thousands of patients would be "almost impossible." See *id.* at *161-62.

b. The individualized proof requirement was also fatal to the Medicaid fraud claims

Relying on the Second Circuit's reasoning in *McLaughlin*, Judge Weinstein also granted Lilly's request for summary judgment on Mississippi's claims under the Medicaid Fraud Control Act. The State had alleged two types of false claims: those resulting from Lilly's purported failure to warn and those for uses not medically necessary. See *id.* at *162. The court determined that Mississippi would need to prove how fraudulent claims resulted from physicians' reliance on the lack of appropriate warnings. Because aggregate proof of reliance was not permitted, the claims failed.

The claims for false and non-medically-necessary prescriptions met a similar fate but under somewhat different reasoning. After all, *McLaughlin* discussed aggregate proof as it related to reliance, loss causation, and injury, not whether a particular prescription was medically necessary. Nevertheless, the court determined that individualized proof would be required. The Mississippi Division of Medicaid's own materials provided seven "complex factors" in the concept of medical necessity. *Id.* at *164-*165. Several of the criteria were deemed to be "context-sensitive, rather than one-size-fits-all." *Id.* at *165.

Whether a prescription of Zyprexa, or any medical intervention is 'medically necessary' must take into account all the information available to the prescribing physician about the risks and benefits with respect to the individual patient in question and the myriad vectors affecting the presenting person, his family, and his associates. Whether, for example, to risk weight gain to effect relief from dreadful mental disease to obtain a livable lifestyle, requires exquisitely balanced judgment of the prescribing physician. The concept of "medical necessity" therefore does not operate in a mechanical way.

Id. at *166.

Because of the necessarily individualized nature of the determination of medical necessity, individualized proof was required. Because Mississippi had provided none, the Medicaid fraud claims failed as well. Thus, the Mississippi case in the Zyprexa litigation illustrates the power of the individualized proof requirement in defending against these types of cases. Following Judge Weinstein's application of the individualized proof rule, only Mississippi's overpricing claim survived. The viability of this theory is questionable, given the pendency of the same issue before the Second Circuit in the Zyprexa third party payor litigation.

c. Despite *McLaughlin* and *Mississippi v. Lilly*, could plaintiffs find support for aggregate proof?

Judge Weinstein and others have lamented that a state's inability to use aggregate proof of reliance and causation would seem, functionally, to deprive a state of its ability to litigate these types of large "structural class actions." See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113286 at *143-*145; see also *State of Louisiana v. Janssen Pharmaceutica, Inc.*, Nos. 04-C-3967-D, 04-C-3977-D (27th Judicial Dist. Ct., St. Landry Parish, Jan. 7, 2010) at 6 (order granting in part and denying in part defendant's motion for summary judgment). Considering Janssen's motion for summary judgment in a case brought by the State of Louisiana for

consumer fraud and Medicaid fraud violations allegedly related to the atypical antipsychotic Risperdal (a case similar to the Mississippi Zyprexa case), the district court in St. Landry Parish observed that

Precluding the use of aggregate or statistical proof in a case such as this one, in which there are allegations of pervasive and widespread deception of the public and their health care providers, might be a death knell for this type of litigation. Without the use of aggregate proof, this litigation could result in thousands of individual trials with overlap in scope, issues, testimony, and experts, while permitting aggregate proof of causation might afford an efficient and manageable means of litigating this matter.

State of Louisiana v. Janssen Pharm. Inc., Nos. 04-C-3967-D, 04-C-3977-D (27th Judicial Dist. Ct., St. Landry Parish, Jan. 7, 2010) at 6-7.

Such judicial lamentations notwithstanding, however, *McLaughlin* and its application in *State of Mississippi v. Eli Lilly* illustrate that a party's proof must conform to the law (not *vice versa*). As the Second Circuit observed in *McLaughlin*, "[N]ot every wrong can have a legal remedy . . . at least not without causing collateral damage to the fabric of our laws." See *McLaughlin*, 522 F.3d 215, 219 (2d Cir. 2008).

Although *McLaughlin* and its sister cases would seem to sound the death knell for a state's attempt to use aggregate data to establish reliance and causation, a recent First Circuit decision suggests that the issue may not be foreclosed. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289 at *133- *145 (discussing *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009) (hereinafter "AWP litigation")).

The AWP litigation was a class action on behalf of patients and third party payors who purchased AstraZeneca's prostate cancer medication Zoladex. In that case, plaintiffs alleged that the average wholesale price ("AWP") of Zoladex published by AstraZeneca, which was used to calculate reimbursements and patient copays, did not reflect discounts and rebates offered to physician providers. The providers therefore reaped the windfall of the difference between the AWP and the actual price, and AstraZeneca marketed Zoladex to physicians on this basis (*i.e.*, the company "marketed the spread"). See *AWP Litig.*, 582 F.3d at 160-61. At the trial court level, AstraZeneca was found liable for unfair and deceptive business practices under the Massachusetts consumer protection law. AstraZeneca appealed, arguing, *inter alia*, that the trial court had erred in considering the knowledge of only the named plaintiffs and by relying on an aggregate statistical damages methodology.

The First Circuit rejected AstraZeneca's challenges. The court noted that AstraZeneca's challenge was a familiar one in the context of class actions, and the court recognized that, in some circumstances, constitutional principles prohibit reliance on proof relating to class representatives to make classwide findings. See *AWP Litig.*, 582 F.3d at 195. Nevertheless, the First Circuit stated that the very essence of class action litigation "often requires" a court to extrapolate from class representatives to the entire class. *Id.* [emphasis in original]. "[I]t would quickly undermine the class-action mechanism were we to find that a district court presiding over a class action lawsuit errs every time it allows for proof in the aggregate." *Id.* at 195.

It is important to consider the facts of *AWP Litigation's* finding. In this case, AstraZeneca and certain other defendants were allowed "ample opportunity" to depose third party payors, and the defendants did depose approximately 50 TPPs, in addition to multiple representatives of several of them. Despite this "extensive discovery," AstraZeneca could point to no specific evidence on appeal to suggest that absent class member TPPs had knowledge or expectations regarding AWP that differed substantially from the class representative. See *AWP Litig.*, 582 F.3d at 196. In addition, the trial court's conclusions about industry knowledge and expectations regarding AWP were based on a careful analysis of the class representatives and on expert testimony that was properly admitted. See *id.* at 196.

Distinguishing *McLaughlin*, the First Circuit noted that the AWP litigation did not present “intractably payor-specific issues.” *Id.* at 196. Instead, the evidence in the record regarding the knowledge and expectations about AWP inflation and Zoladex pricing about TPPs was voluminous. In addition, and important, the portions of the record cited by AstraZeneca as cause for concern contained “strikingly consistent evidence as to each of the TPPs.” See *id.* The First Circuit, therefore, was not persuaded that the evidence of the variation across the class members as to their knowledge and expectations demonstrated the existence of significant individualized issues. See *id.* at 197. In contrast, the prescribing decisions at issue in the Zyprexa Mississippi case implicated highly individualized and patient-specific issues.

E. Remoteness of a State’s Injury May Also Provide a Defense

Although perhaps conceptually indistinct from issues of proximate causation, courts have also considered the remoteness of a payor’s injury when evaluating claims. The remoteness doctrine provides that a third party payor cannot recover for economic harm arising from injuries allegedly suffered by an individual patient. States who bring suit as third party payors may, therefore, be vulnerable to similar challenges, if their claims are derivative of harm suffered by third parties (*i.e.*, citizens of a state, but not the state itself). The issue was an important defense argument in tobacco-related litigation, where payors sought to recover payments made for treatment of individual smokers’ smoking-related health problems. Such damages were at least one step removed from the alleged tort-feasor’s conduct (*i.e.*, they were indirect or derivative claims).

The common law has long been averse to awarding damages to third parties who indirectly suffer harm. Justice Holmes once noted, “the general tendency of the law, in regard to damages at least, is not to go beyond the first step.” See *Southern Pac. Co. v. Darnell Taenzer Lumber Co.*, 245 U.S. 531, 533 (1918). In the pharmaceutical context, harm for illnesses allegedly caused by medications would stop with the patient. The first step ends there.

In the context of litigation brought by a state to recover treatment costs for illnesses allegedly caused by a prescription pharmaceutical, a state is analogous to a third party payor or private insurance company. Recourse is available to the individual patient through theories of product liability and to the payor through subrogation. Under the remoteness doctrine, if a plaintiff (*e.g.*, a state) complains of injuries that are derivative of harm to a third party (*e.g.*, Medicaid patients who took a prescription medication and purportedly developed an adverse event for which the state paid treatment costs), those injuries are generally deemed indirect and, as a consequence, too remote, as a matter of law, to support recovery. See *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229, 236 (2d Cir. 1999) (citing *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258, 268-69 (1992)).

In *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, the Second Circuit dismissed RICO claims by several union health and welfare funds that sought reimbursement of the costs they incurred treating tobacco-related illnesses. The claim failed because the funds’ alleged economic injuries were purely derivative of the physical injuries suffered by the plan participants, and thus too remote to satisfy RICO’s proximate causation standing requirement:

[Plaintiffs’] damages are entirely derivative of the harm suffered by plan participants as a result of using tobacco products. Without injury to the individual smokers, the Funds would not have incurred any increased costs in the form of the payment of benefits, nor would they have experienced the difficulties of cost prediction and control that constituted the crux of their infrastructure harms. Being purely contingent on the harm to third parties, these injuries are indirect. Consequently, because defendants’ alleged misconduct did not proximately cause the injuries alleged, plaintiffs lack standing to bring RICO claims against defendants.

Id. at 239.

The Second Circuit went on to explain that the only avenue for recovery of treatment costs would be a subrogation action. *Id.* at 241; *c.f. National Asbestos Workers Med. Fund v. Philip Morris, Inc.*, 74 F. Supp. 2d 221, 228 (E.D.N.Y. 1999) (distinguishing the Plans from the health care insurers involved in *Laborers Local 17*, and explaining that the Plans had amended their complaint to assert a subrogation claim as an alternative basis for recovery). Courts across the nation agree that the cost of disease treatment is too remote an injury to confer RICO standing on a payor. See, e.g., *Service Employees Int'l Union Health & Welfare Fund v. Philip Morris, Inc.*, 249 F.3d 1068, 1073 (D.C. Cir. 2001); *Lyons v. Philip Morris, Inc.*, 225 F.3d 909 (8th Cir. 2000); *United Food & Commercial Workers Unions, Employers Health & Welfare Fund v. Philip Morris, Inc.*, 223 F.3d 1271 (11th Cir. 2000); *Texas Carpenters Health Benefit Fund v. Philip Morris, Inc.*, 199 F.3d 788 (5th Cir. 2000); *International Bhd. of Teamsters, Local 734 Health & Welfare Trust Fund v. Philip Morris, Inc.*, 196 F.3d 818 (7th Cir. 1999); *Oregon Laborers-Employers Health & Welfare Trust Fund v. Philip Morris, Inc.*, 185 F.3d 957 (9th Cir. 1999), *cert. denied*, 528 U.S. 1075 (2000); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912 (3d Cir. 1999); see also *Association of Wash. Pub. Hosp. Dists. v. Philip Morris, Inc.*, 241 F.3d 696 (9th Cir. 2001); *Allegheny Gen. Hosp. v. Philip Morris, Inc.*, 228 F.3d 429 (3d Cir. 2000); *Williams & Drake, Inc. v. American Tobacco Co.*, No. 98-553, 1998 U.S. Dist. Lexis 21917, at *2 (W.D. Pa. Dec. 21, 1998).

Arguments regarding remoteness of injury, while accepted in the treatment-cost context, have been less successful in cases where the injury relates to overpricing. Subsequent case law on the remoteness issue illustrates the importance of determining whom a plaintiff claims a defendant defrauded (*i.e.*, prescribing physicians or the payor itself). The importance of this distinction was considered by the Second Circuit in a Rezulin-related case, *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2003). The *Desiano* case arose from plaintiff-insurers' appeal from the Southern District of New York's granting of a motion to dismiss claims of consumer fraud, breach of warranty, and unjust enrichment under New Jersey law. In that case, plaintiff-insurers claimed that, but for Warner Lambert's misrepresentations about the safety of Rezulin, they would have taken steps so as not to purchase the medications at the prices set by Warner-Lambert. Instead, the plaintiffs would have excluded it from their formularies, set a low reimbursement value, set a high copay, and otherwise dissuaded doctors from prescribing the drug. *Id.* at 349. The Second Circuit determined that the plaintiff's claims were directly tied to Warner-Lambert's marketing and promotion of Rezulin, and therefore not derivative of any injuries to a third party. *Id.* at 340, 350.

In *Desiano*, the third party payors alleged that Warner-Lambert had misrepresented Rezulin's risks and benefits *directly* to the payors *themselves*. The payors' claim did not depend on whether prescribing physicians had been misled.

In the instant case, instead, Plaintiffs allege an injury directly to themselves; an injury, moreover, that is unaffected by whether any given patient who ingested Rezulin became ill. Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers, since they would not have bought Defendant's product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations. Thus the damages--the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased "but for" Defendants' fraud--were in no way "derivative of damages to a third party."

Id. at 349.

Thus, *Desiano* illustrates that, although indirect treatment costs are too remote, a direct economic loss independent of any injury to a third party is less susceptible to a remoteness challenge. See also *In re Neurontin Mktg. & Sales Prac. Litig.*, 2010 U.S. Dist. Lexis 1756 at *82-*83 (D. Mass. Jan. 8., 2010) (denying Pfizer's motion

for summary judgment against Kaiser where plaintiff-Kaiser showed that it reduced payments for Neurontin through an information campaign regarding off-label use after news reports of Pfizer's fraudulent activities began to surface).

A recent case in the District of Minnesota that relies on (and arguably misapplies) *Desiano* may enlarge the concept of a direct injury. See *Kinetic Co. v. Medtronic, Inc.*, 2009 U.S. Dist. Lexis 112918 (D. Minn. 2009). In *Kinetic v. Medtronic*, plaintiff Kinetic, a self-insured employer that pays its employees' medical expenses, sought to represent a class of third party payors for medical services. Kinetic brought suit for reimbursement of medical expenses that resulted from the recall of implantable cardiac defibrillators manufactured by Medtronic. *Id.* Possible battery defects in Medtronic's original defibrillators resulted in much shorter battery service life than expected. Kinetic's alleged damages included the costs associated with the implantation, the subsequent explantation, and reimplantation of defibrillators with longer battery life. Medtronic had provided Kinetic's employee with a free replacement device, but the company did not reimburse plaintiff for the cost of the defective device or the second surgery. *Id.* at *3. Kinetic alleged violations of the Minnesota False Statements in Advertising Act, the Minnesota Deceptive Trade Practices Act, the Minnesota Prevention of Consumer Fraud Act, and various unfair and deceptive trade practices statutes of other states.

Relying on the logic of *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, which found that third party payors lack standing to seek reimbursement of medical expenses, Medtronic challenged Kinetic's standing to bring suit. See *Kinetic v. Medtronic, Inc.*, 2009 U.S. Dist. Lexis 112918, at *6 (citing *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 484 F. Supp. 2d 973, 983 (D. Minn. 2007)). The *Kinetic* court, analogizing the facts at issue to those in *Desiano*, declined to follow the *Guidant* logic. See *id.* at *12-*13. Noting that Kinetic's claim was unaffected by whether its employee had suffered physical or emotional injury in connection with the Medtronic defibrillator, the court observed that "[w]hat matters" was that Kinetic was required to pay prematurely for replacement surgery. *Id.* at *13. If Medtronic had timely disclosed the problems associated with the first device, "Kinetic—like the insurers in *Desiano*—might have taken steps to avoid paying for it in the first place." *Id.*

The court was openly hostile to Medtronic's argument that the plaintiff's class's injuries were indirect. The court observed that there is "virtually no such person in the United States today" who would have directly purchased from and directly paid Medtronic for his own defibrillator. *Id.* at *10. "As Medtronic had every reason to know, these employers or their insurers are the parties bearing the actual economic injury." *Id.*

In the face of this reality, it is neither fair nor just to hold . . . that third party payors, which have paid for the same procedure on behalf of their insureds, lack . . . standing . . . [W]hen Medtronic blithely asserts that the third-party payors—which ultimately reimbursed the physicians or hospitals which held the device in inventory—are barred from any recovery, it is wrong. It is wrong, because this cost is simply the last falling domino in a long line started by Medtronic. And when it falls, it injures the third-party payors. Medtronic cannot be protected against its own harm by marketing its products through intermediaries. Each intermediary player has been made whole. It ill-befits Medtronic—and the law will not allow it—to attempt to shield itself from its ultimate and true financial victim.

Id. at *10-*11.

Thus, the *Kinetic* case would seem to be at odds with the long line of common law that rejects looking past the "first step" in a transaction or tort.

F. Even in a Post-Wyeth World, State Law Unfair Trade Practices Claims Are Preempted

Allowing an AG to regulate and police pharmaceuticals under consumer or Medicaid fraud acts is preempted. Congress has granted the FDA authority over the content of prescription drug labels, and the FDA oversees the national regulatory structure establishing “detailed labeling requirements which dictate virtually every aspect of a [drug’s] label.” See *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 309 (E.D. Pa. 2007); see also 21 U.S.C. §§352, 353. Pursuant to statutory authority, the FDA conducts a detailed review and approval process of the information manufacturers must include in their products’ labeling. See 21 C.F.R. §§201.56, 201.57; *Sykes*, 484 F. Supp. 20 at 308. A state attorney general’s attempt to punish a company for the content of a product’s FDA-approved label impedes Congress’s objective of empowering one centralized agency (*i.e.*, the FDA), not 50 disparate states, to determine the warnings accompanying prescription medicines sold throughout the country.

The Supremacy Clause preempts every state law that interferes with the exercise of federal power in this area. See *Fidelity Fed. Sav. & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982). Even where Congress has not explicitly stated that state law is preempted, a court should infer preemption when federal and state law conflict. See *Schneidewand v. ANR Pipeline Co.*, 485 U.S. 293, 299-300 (1988). Such conflict preemption applies, according to the Supreme Court, where either (1) it is “impossible for a . . . party to comply with both state and federal law”; or (2) the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” See *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 899 (2000) [citation omitted].

The Supreme Court’s recent decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), does not contradict these principles. The *Wyeth* Court held that state *tort* law suits seeking recovery for personal injuries to individual patients were not preempted, but the Court did not purport to authorize imposition of civil penalties for violations of state consumer protection statutes. *Id.* at 1199-1200. Unlike individuals who bring common-law causes of action, states who pursue civil penalties claim they need not show causation or reliance. If that is so, the civil penalties would act as a quasi-criminal penalty for the content of FDA-approved labeling or promotional materials, without regard to whether some deficiency in the label caused any individual’s injury. Thus, if this form of action were permitted, state attorneys general would enjoy unfettered discretion to dictate the content of medication labels, which is only degrees removed from a state statute simply prescribing the content of an FDA-approved product label, which the Supreme Court has prohibited. See, *e.g.*, *McDermott v. Wisconsin*, 228 U.S. 115 (1913) (prohibiting state statute requiring labeling language different from FDA).

Thus, companies should consider a preemption defense in state AG suits.

G. Some State Unfair Trade Practices Acts Contain Safe Harbors for Regulated Activities

The statutory language of individual states’ consumer protection or unfair trade practices acts will vary. In some instances, an unfair trade practices act may contain a safe harbor provision that shields heavily regulated industries from liability. Because pharmaceutical companies are regulated by FDA—both in terms of product labeling and review of promotional materials—such safe harbor provisions offer another argument to challenge such claims.

For example, the Connecticut Unfair Trade Practices Act (“CUTPA”) contains such an exemption.

Nothing in this chapter shall apply to . . . [t]ransactions or actions otherwise permitted under law as administered by any regulatory board or officer acting under statutory authority of the state or of the United States.

Conn. Gen. Stat. §42-110c.

Applying this exemption, Connecticut courts consider four factors to determine whether CUTPA's safe harbor exempts challenged conduct from the Act: "(1) the applicability of Federal Trade Commission rules to the suspect conduct and the absence of any Federal Trade Commission regulatory activity over industry practices; (2) the existence and scope of an alternate comprehensive regulatory scheme or system; (3) the absence of any activity by the commissioner of consumer protection within this area; and (4) the case law of other jurisdictions." See *Normand Josef Enter., Inc. v. Connecticut Nat'l Bank*, 646 A.2d 1289, 1302 (Conn. 1994). In the prescription pharmaceutical context, the application of these four factors suggests that the exemption applies. Regarding the first two factors, the FDA, not the FTC, is responsible for regulating prescription drugs. FDA takes an active role in reviewing clinical data on a product's safety and efficacy and approving promotional materials and product labeling. For the third factor, in the Connecticut Zyprexa AG case, there was no evidence that the commissioner of consumer protection in Connecticut ever attempted to subject a pharmaceutical company to CUTPA penalties.

Regarding the fourth factor, courts in other jurisdictions interpreting substantively identical safe harbor provisions of unfair trade practice and consumer protection statutes have dismissed claims based on conduct regulated by the FDA. In *Prohias v. Pfizer, Inc.*, a case involving Pfizer's advertisements for Lipitor, the court held that the safe harbor provisions of the Massachusetts and Florida consumer protection statutes barred such claims because Pfizer's advertisements complied with the FDA-approved label. See *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1234-35 (S.D. Fla. 2007). Similarly, in *Bober v. Glaxo Wellcome PLC*, the Seventh Circuit affirmed dismissal of an Illinois Consumer Protection Act claim because Glaxo's statements regarding Zantac were "authorized by federal law." See *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 942 (7th Cir. 2001). As the Seventh Circuit explained in *Bober*:

The pharmaceutical industry is highly regulated, both at the federal level and internationally. Technical requirements abound, and it is not only possible but likely that ordinary consumers will find some of them confusing, or possibly misleading as the term is used in statutes like Illinois's [Consumer Fraud Act]. But, recognizing the primacy of federal law in this field, the Illinois statute itself protects companies from liability if their actions are authorized by federal law. (Such protection would amount to nothing if it applied only to statements that were not susceptible to misunderstanding; those statements would escape liability under the CFA in any event.)

Id. at 942-43.

In *American Home Products Corp. v. Johnson & Johnson*, the Southern District of New York federal court dismissed a New York consumer protection statute claim because the defendant's compliance with FDA's labeling requirements triggered the statute's safe harbor provision, which provided a complete defense. See *American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 144 (S.D.N.Y. 1987) ("[t]he rationale underlying the exemptive provisions of all of these statutes is the need for uniformity in the regulation of advertising and labeling and a deference to the expertise of the responsible regulatory agency."). In *Duriono v. Merck & Co.*, the court affirmed the dismissal of Michigan Consumer Protection Act claim because "general marketing and advertising activities underlying plaintiff's MCPA claim are authorized and regulated under laws administered by FDA." See *Duriono v. Merck & Co.*, No. 267003, 2006 WL 1628516, at *7 (Mich. Ct. App. June 13, 2006).

Although individual state laws may differ, a company in a highly regulated industry, such as the pharmaceutical sector, should evaluate whether the statutes at issue contain safe harbor language that may shield them from liability.

H. A State Is Not a Consumer under a Consumer Fraud Act or Unfair Trade Practices Act

Depending on how a particular state statute is worded, defendants should consider challenging whether a state is a “consumer.” This theory is particularly useful where the state-payor claims it was *directly* defrauded (*i.e.*, the alleged injuries do not depend on physical harm to underlying patients).

Again, it is instructive to consider case law involving private third party payors. For example, in *In re Rezulin Products Liability Litigation*, the District Court for the Southern District of New York considered whether a third party payor could bring an action under section 349 of New York’s General Business Law. See *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597, 612315 (S. D.N.Y. 2005). Under New York law, a plaintiff had to show that the challenged act or practice was “consumer-oriented”; that it was misleading in a material way; and that the plaintiff suffered injury as a result of the deceptive act. *Id.* at 612. The court observed that the conduct for which the third party payor plaintiff sought to hold Warner-Lambert liable was directed at a pharmacy benefits manager, “not at diabetes patients.” *Id.* at 613. It is important that communication from “one sophisticated business” (*i.e.*, Warner-Lambert) to another (*i.e.*, the PBM, Medco) was “quite different from that of any promotion aimed directly at diabetes patients.” *Id.* (The record did not discuss any direct-to-consumer advertising, and the injury at issue was alleged to have resulted from communications to Medco.)

The court noted that because the injury alleged was economic, it “did not have any broad impact . . . on diabetes patients at large.” *Id.* at 614. Because the third party payors had alleged that the fraudulent communications had directly injured them, they were the “true targets” of the harm. *Id.* The court stated, however, that “[third party payors] are not consumers.” *Id.* (noting that consumers are “those who purchase goods and services for personal, family or household use”) [citations omitted]. The *Rezulin* court reached similar conclusions when considering Louisiana and New Jersey law. *Id.* at 615-17; see also *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 U.S. Dist. Lexis 58900 (D.N.J. 2009) at *116 (finding that third party payor plaintiffs were not consumers entitled to bring suit under New Jersey’s consumer protection law).

Because states act as third party payors, attorneys general (and their private plaintiffs’ attorneys cohort) who sue under consumer fraud acts are vulnerable to similar attacks.

I. Look at the Facts: Has the State Taken No Steps to Change Reimbursement Policy, Despite the Alleged Fraud?

As previously discussed, issues of causation provide key defense points in cases where states (or other payors) bring suit. In addition to considering challenges to aggregate proofs or remote injuries, it is important to evaluate what actions the state itself has taken before and after filing suit. A state’s own actions may provide opportunities to challenge its ability to establish reliance and causation.

One would expect that a party who believes it was defrauded and damaged in an amount that exceeds several hundred million dollars would, upon learning of the fraud, take steps to mitigate the effects of the fraud, such as limiting the use of (and payment for) the allegedly offending product. In the Zyprexa AG cases, however, the opposite was generally true. Although the states alleged that Lilly lied about the benefits and risks of Zyprexa and that the company promoted the allegedly sub-par and harmful product for off-label uses, discovery repeatedly revealed that the states had taken no steps to change the formulary status of the product or to stop paying for off-label prescriptions. Because the states failed to change their reimbursement and/or formulary policies in response to Lilly’s purported fraud, the door was opened to challenge the states’ claim that they had relied on Lilly’s promotional messages or that Lilly’s conduct was the but-for cause of any harm. See also, *e.g.*, *Ironworkers Local Union No. 68 v. AstraZeneca Pharm. LP*, 585 F. Supp. 2d 1339, 1345 (M. D. Fla. 2008) (not-

ing that the alleged causal nexus between AstraZeneca's purported fraud and plaintiffs' injuries is "even further attenuated" by plaintiffs' affirmations that they continued to pay for Seroquel even after defendants' alleged misconduct was uncovered).

Although it did not rely on Mississippi's post-alleged-fraud-discovery actions in reaching its summary judgment decision, the court in *State of Mississippi v. Eli Lilly & Co.* did comment on the State's actions. In that case, the State continued to approve and pay for Zyprexa prescriptions even after filing its claims for fraud and lack of efficacy. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *180. The court stated that Mississippi's role and responsibilities with respect to a widely prescribed medication such as Zyprexa were worthy of consideration. "The State has a special opportunity, and, arguably, a special obligation to understand the benefits and dangers of widely prescribed drugs, including their appropriate off-label uses and potential adverse side effects, in order to effectively administer State programs and manage government expenditures." *Id.* at *181.

As a company considers its legal defenses, it is critical not to lose sight of discovering what steps, if any, a state took after learning of an alleged fraud. The answer may be none.

J. Civil Penalties

1. Claims for exorbitant, and potentially ruinous, damages or penalties violate due process

Where states and their private plaintiffs' attorneys seek exorbitant damage amounts, due process defenses are available. Courts have recognized the potentially ruinous effects of aggregated civil penalties or statutory damages and the due process issues that may arise. See, e.g., *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, * 183-* 187 (citing *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003), and *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996)), and noting that Mississippi's request for penalties on a *per-violation* basis was grossly disproportionate to its injury and that courts cannot be used as an engine of an industry's destruction); cf. *Parker v. Time Warner Entmt Co.*, 331 F.3d 13, 22 (2d Cir. 2003) (acknowledging district court's concern that "potential for a devastatingly large damages award, out of all proportion to the actual harm suffered" by class members could raise due process issues if \$1000 *per* consumer statutory damage under Cable Communications Policy Act of 1984 were to be applied across 12-million-member class).

Courts may be more likely to recognize the unjust result of the application of such aggregated penalties in the pharmaceutical context, because medications provide a benefit to patients. In granting summary judgment in part in *State of Mississippi v. Eli Lilly and Co.*, Judge Jack Weinstein noted the benefits that Zyprexa gives patients.

Lilly ... has created a product with substantial benefits that even now—after many years of litigation, research, testing, and controversy—is still favored by many physicians and patients ... for some of the most serious psychological conditions that afflict millions of people worldwide. Courts cannot ignore the substantial benefits accruing to the State of Mississippi and its citizens from the use of Zyprexa. The State arguably saved large sums through use of Zyprexa by preventing users with serious mental problems from requiring hospitalization in State facilities, and allowing them to become productive taxpayers and participants in the economy.

See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *181-*182.

In situations where state-AG actions arise in a mature MDL, defendants can build on a court's existing knowledge of a medication's or device's therapeutic benefits. The penal nature of a large civil penalty is more palpable where purportedly harmful or fraudulent conduct conveyed a benefit.

2. The punishment must fit the tort: defendants should also consider challenging a state's ability to calculate the number of violations or the appropriate penalty based on the proofs it has provided

Unlike actual damages, which are intended to address a harm to a plaintiff that was caused by the actions of a defendant, civil penalties (as the name suggests) are meant to penalize and/or deter behavior that a legislative body has deemed inappropriate. Because they are not meant to make a plaintiff whole for conduct that caused a harm, an award of penalties for fraud-based conduct does not necessarily require a showing of reliance or causation.

For example, in *State of West Virginia v. Johnson & Johnson*, the Circuit Court of Brooke County determined that the attorney general was not required to show direct or specific harm to consumers as a required element of proof in a case brought under West Virginia Code section 46A-7-111(2). See *State of West Virginia, ex rel. Darrell V. McGraw, Jr., Attorney General v. Johnson & Johnson*, No. 04-C-156 (Cir. Ct. Brooke Cty. Feb. 25, 2009) at 61. The West Virginia Consumer Credit and Protection Act defined unfair or deceptive acts as those containing a false statement or material omission made “with intent that other rely upon such concealment, suppression or omission, . . . whether or not any person has in fact been misled, deceived or damaged thereby[.]” See *id.* That the materials at issue had reached the public and had the capacity to deceive was sufficient to support the award of civil penalties. See *id.* at 62.

In *West Virginia v. Johnson & Johnson*, the parties had stipulated to the number of sales calls that had occurred and Dear HCP Letters that had been issued. Thus, the court had a firm number of violations with which to work. Because a civil penalty award is based on number of violations multiplied by amount of each penalty, the court had half of the information it needed to complete the equation. Because the punishment must fit the tort, however, Judge Gaughan needed to set the individual penalty amount.

In *West Virginia v. Johnson & Johnson*, the West Virginia Consumer Credit and Protection Act provided that “interpreting and defining” the act should conform with the manner and method in which the Federal Trade Commission interprets the FTC Act. See *id.* at 57. Thus, the court was constrained to consider five specific factors in determining the amount of the *per*-violation penalty. Those five factors were

- 1) the good faith or bad faith of the defendant;
- 2) injury to the public;
- 3) the defendant's ability to pay;
- 4) the desire to eliminate the benefits derived by a violation;
- 5) the necessity of vindicating the authority of the agency involved.

See *id.* at 57 (citing *United States v. Reader's Digest Ass'n*, 662 F.2d 955 (3d Cir. 1981)).

Applying these factors, the court awarded a penalty of \$5000 for each Duragesic and Risperdal sales call and \$500 for each Duragesic file card and Risperdal Dear HCP Letter. The total penalty award was \$4,475,000. This amount was considerably less than what the penalty award could have been, if the statutory maximum of \$5000 *per* violation had been applied across the board (\$22,250,000). See *id.* at 69.

In the Zyprexa Mississippi action, however, counsel for the State said at oral argument that, assuming a knowing and willful violation of the consumer protect act were found, the appropriate penalty (up to \$10,000 *per* violation) was *entirely in the discretion of the court*. See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *91. Judge Weinstein then observed that exercising discretion in determining the proper amount of the fines that would attach to each of almost one million Zyprexa prescriptions, or more than

100,000 “episodes of care” (depending on which measure was used) would “necessarily require individualized consideration of the circumstances of each case.” See *id.* at *156.

Musing on which factors the court might wish to evaluate in determining an appropriate *per*-violation penalty, Judge Weinstein enumerated a nonexhaustive litany of possible considerations:

- 1) whether the prescription was for an on-label or off-label use;
- 2) whether the prescription was medically necessary;
- 3) whether the patient received any benefit from Zyprexa;
- 4) whether and the extent to which the patient experienced any of Zyprexa’s potential metabolic side effects;
- 5) information about Zyprexa available to the medical community at the time the prescription was written;
- 6) times of the various alleged instances of misconduct by Lilly;
- 7) whether and to what extent each instance may have effected the prescription in question.

See *State of Mississippi v. Eli Lilly & Co.*, 2009 U.S. Dist. Lexis 113289, at *171-*172.

The court determined that such an inquiry would be “administratively impossible” and “beyond the capacity of the court.” *Id.* at *156-*157, *172-*173. More important, however, Judge Weinstein stated that “the aggregate proof proffered by the State is insufficient to properly inform an exercise of that nature.” *Id.* at *156-*157. As a result, Mississippi’s claim for civil penalties under the State’s consumer protection act was dismissed.

V. Conclusions

The governmental authority of a state attorney general’s office can pose a formidable challenge to the defense. Nevertheless, recent developments in the case law related to third party payors, of which states are a subtype, provide strong arguments for attacking a state’s case. To conserve resources, private plaintiffs’ attorneys often attempt to offer proof of reliance, causation, and injury based on aggregated data or single expert reports. As recent case law illustrates, such attempts are generally futile. In addition, the very nature of the relationship between state attorneys general and private plaintiffs may offend state constitutional principles or ethics laws. Much can be at stake in cases where states bring suit, because of the additive effect of damages and penalties across an entire state-payor. However, states and the private plaintiffs’ attorneys with whom they contract face significant challenges in persuading a court that the maximum allowable penalty is the appropriate or just penalty. Lastly, a state’s own actions in managing its Medicaid formulary and drug approval process may cause a court to question the merits of a state’s case.

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