A Practical Guide

Defending Against State Attorney General Litigation

By Jessica D. Miller
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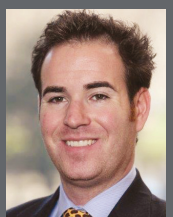
With their growing focus on civil penalty recoveries and the threat of exorbitant verdicts, these cases present real challenges to pharmaceutical companies, but they are by no means insurmountable.

One of the biggest legal challenges facing the pharmaceutical industry is the increasing volume of litigation prosecuted by state attorneys general. Most of these cases, which typically seek restitution and civil penalties, are premised on theories of economic loss under which an attorney general claims that the state or its citizens have been injured by virtue of having to pay for an allegedly defective pharmaceutical drug or device. The attorneys general in some of these lawsuits have prevailed against pharmaceutical manufacturers. For example, an attorney general lawsuit regarding the drug Risperdal resulted in a $1.2 billion penalty for nearly 240,000 alleged violations of the state's Medicaid fraud law and $11 million for alleged violations of the state deceptive practices act. A similar lawsuit by the Louisiana attorney general regarding the same drug resulted in a $257.7 million verdict after the jury found 35,542 violations of the Louisiana Medical Assistance Programs Integrity Law and penalized the company $7,250 for each one.

The good news for defendants is that they can take a series of concrete steps to challenge these cases successfully. This article examines four practical steps that pharmaceutical defendants should consider when facing such a lawsuit. First, defendants should consider removing the case to a federal court under a theory of substantial federal question jurisdiction as set forth in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308 (2005), or under the Class Action Fairness Act (CAFA). Second, defendants should move to dismiss a case asserting aggregate claims and requests for civil penalties under the individualized-proof rule or for lack of a cognizable loss, or both, as well as challenge any claims under the state false claims act or Medicaid fraud statute as not reaching drug and device manufacturers. Third, defendants should conduct their own discovery, including deposing state officials to uncover the bases of the state's claims. And fourth, defendants should determine whether an attorney general has hired outside counsel to prosecute the lawsuit—and if so—whether there is any basis to challenge such arrangement.



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Theories of Removal for State Attorney General Cases

The starting point for defending against litigation initiated by a state attorney general is removal to a federal court. A federal court is less likely to be hostile to an out-of-state defendant and is arguably more likely to embrace its substantive defenses, including those under the individualized-proof rule. Two theories of removal have been attempted when pharmaceutical companies are forced to defend against claims brought by state attorneys general: (1) substantial federal question jurisdiction under *Grable*, 545 U.S. at 308; and (2) jurisdiction under CAFA.

Grable: Substantial Federal Question Jurisdiction

In *Grable*, 545 U.S. at 308, the Supreme Court held that a quiet title claim that depended on the interpretation of a federal tax law provision was subject to substantial federal question jurisdiction, despite the fact that the claim was brought under state law. *Id.* at 312. In its holding, the Supreme Court made clear that "federal question jurisdiction will lie over state-law claims that implicate significant federal issues" because a "federal court ought to be able to hear [state-law claims] that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.*

A common characteristic of litigation brought by state attorneys general in the pharmaceutical context is the pursuit of Medicaid dollars spent on covering allegedly defective pharmaceutical products. Federal district courts are currently split on whether attorney general actions seeking to recover Medicaid dollars are subject to federal question jurisdiction under *Grable*. Judge Jack Weinstein, who oversaw the federal litigation involving the drug Zyprexa, has repeatedly held that state law claims seeking to recoup Medicaid payments for prescription drugs are subject to federal question jurisdiction under *Grable* because such claims require interpretation of federal Medicaid law. *See, e.g.*, *West Virginia ex rel. McGraw v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 476 F. Supp. 2d 230, 233 (E.D.N.Y. 2007) (denying remand where the state attorney general sought to recover Medicaid funds spent on Zyprexa); *Montana ex rel. McGrath v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 07-CV-1933 (JBW), 2008 U.S. Dist. Lexis 10355, at *8–10 (E.D.N.Y. Feb. 12, 2008) (same); *Louisiana ex rel. Foti v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 375 F. Supp. 2d 170, 172 (E.D.N.Y. 2005) (same); *New Mexico v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596,07-CV-01749 (JBW/RLM), 2009 U.S. Dist. Lexis 20768, at *71 (E.D.N.Y. Mar. 11, 2009) (same). In each of these cases, Judge Weinstein held that federal Medicaid funding provisions were integral to determining whether states were entitled to reimbursement for payments made for Zyprexa and that the states' claims therefore presented substantial federal questions regarding Medicaid law. For instance, in *McGraw* and *McGrath*, the court held that because federal Medicaid law mandates that states cover certain drugs, plaintiffs' claims would turn on whether the states were obligated to pay for Zyprexa under federal law, making federal jurisdiction appropriate.

In contrast, a number of courts, including those adjudicating claims involving the drug Risperdal, have held that federal question jurisdiction does not exist over state law claims seeking recovery of Medicaid dollars. For example, a federal court assessing jurisdiction in the Pennsylvania Risperdal case found that *Grable* did not apply because "[e]ven though 'medically accepted indication' is defined by federal law, liability under the state law claims presented here nonetheless does not depend on the violation of any federal standard or statute." *Pennsylvania v. Eli Lilly & Co.*, 511 F. Supp. 2d 576, 581 (E.D. Pa. 2007). While the court recognized that Judge Weinstein has taken the opposite approach in the Zyprexa cases, it found that Judge Weinstein's view was incorrect. *See id.* at 584 n.3. As the court explained, "[a]lthough federal regulatory schemes may be implicated" in cases seeking the return of Medicaid funds, "it takes more than a federal element to open the… door" to federal question jurisdiction. *Id.* at 584. According to the Pennsylvania federal district court, the "mere presence of a federal standard embedded in a state law cause of action is not sufficient to warrant federal subject matter jurisdiction where there is no federal remedy for a violation of the federal statute." *Id.* at 585. *See also, e.g.*, *Caldwell ex rel. Louisiana v. Bristol Myers Squibb Sanofi Pharms. Holding P'ship*, No. 2:12 CV 00443, 2012 U.S. Dist. Lexis 126039, at *5–6 (W.D. La. Sept. 4, 2012) (rejecting the "argu[ment] that the [state-law] claims arise under federal Medicaid law because the Attorney General will have to prove that the defendants caused the state to spend more money than it otherwise would have been obligated to spend under federal Medicaid regulations"); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 1871, 2012 U.S. Dist. Lexis 48319, at *9 (E.D. Pa. Apr. 4, 2012) (remanding cases by state attorneys general claiming that Medicaid funds were improperly dispersed based on defendant's alleged fraudulent marketing of Avandia because "[t]he issues of federal law do not predominate"); *Hood ex rel. Mississippi v. AstraZeneca Pharms., LP*, 744 F. Supp. 2d 590, 607 (N.D. Miss. 2010) (granting remand where the state attorney general sought reimbursement for Medicaid funds spent on Risperdal); *State ex rel. McMaster v. AstraZeneca Pharms. LP*, No. 7:09-387-HFF, 2009 U.S. Dist. Lexis 39174, at *18–*19 (D.S.C. May 5, 2009) (granting remand where the state attorney general sought reimbursement of Medicaid funds spent on Seroquel).

Federal district courts are currently split on whether attorney general actions seeking to recover Medicaid dollars are subject to federal question jurisdiction under *Grable*.

Removal of Parens Patriae Lawsuits as "Class Actions" or "Mass Actions" Under CAFA

Pharmaceutical companies should also consider removing attorney general cases as "class actions" or "mass actions"

under CAFA, Pub. L. No. 109-2, 119 Stat. 4 (2005), codified in relevant part at 28 U.S.C. §1332(d), although the viability of this removal theory will turn on how the U.S. Supreme Court rules in a case currently before it.

CAFA defines a "class action" as "any civil action filed under Rule 23 of the Federal Rules of Civil Procedure or similar State statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action." 28 U.S.C. §1332(d)(1)(B). A "mass action," which is also removable under CAFA, is defined as "any civil action… in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs' claims involve common questions of law or fact." 28 U.S.C. §1332(d)(11)(B)(i). Defendants have argued that attorney general lawsuits should be removable as "mass actions" when an attorney general seeks relief that would benefit the state's citizens—for example, by seeking damages on behalf of individual consumers. Under these circumstances, an action brought by an attorney general is essentially a representative action brought on behalf of individuals supposedly injured by the defendant's conduct, making the individuals the real parties in interest.

It bears noting that cases removed as "mass actions" may not be transferred to multidistrict litigation (MDL) proceedings "unless a majority of the plaintiffs in the action request transfer" under the MDL statute.

It bears noting that cases removed as "mass actions" may not be transferred to multidistrict litigation (MDL) proceedings "unless a majority of the plaintiffs in the action request transfer" under the MDL statute. 28 U.S.C. §1332 (d)(2)(C). This limitation is significant because more and more pharmaceutical companies face state attorney general cases that overlap with the subject matter of pending MDL proceedings. Thus, when contemplating potential removal theories, pharmaceutical defendants should not only consider the relevant case law in their jurisdictions, but also whether a case belongs in a pending MDL proceeding. Notably, defendants can avoid the limitation imposed by section 1332(d)(2)(C) by removing on more than one theory. *See In re: Darvocet*, MDL No. 2226, 2013 U.S. Dist. Lexis 54107, at *13 (J.P.M.L. Apr. 17, 2013) ("Upon review of CAFA's overall purpose and its entire legislative history, we conclude that Congress did not intend that actions removed on multiple grounds, grounds which include the mass action provision, would be restricted from Section 1407 transfer.").

The propriety of some of these removal theories is currently in a state of flux. In *State ex rel. Hood v. AU Optronics Corp.*, 701 F.3d 796 (5th Cir. 2012), the Mississippi attorney general asserted state consumer protection and antitrust claims against the manufacturers and distributors of certain liquid crystal display (LCD) panels. The defendants removed the case under both the "class action" and "mass action" provisions of CAFA. The district court remanded the case, but the appellate court reversed. The Fifth Circuit first rejected the argument that the case qualified as a "class action" under CAFA, reasoning that "[b]ecause Mississippi did not bring th[e] suit under Rule 23 or a rule of judicial procedure" and because the statutes under which the lawsuit was brought were not "similar" to Federal Rule 23, the action did not constitute a "class action" under CAFA. *Id.* at 799. However, the court of appeals did find that the action met the definition of a "mass action" under CAFA. Because the lawsuit involved "monetary relief" claims in excess of $75,000, the determinative question was whether the lawsuit involved claims of "100 or more persons." *Id.* at 799. According to the court, the answer to that question was "yes" because the state was not the only real party in interest. In addition to the state, which purchased the LCD panels, the lawsuit involved the claims of "numerous" individual Mississippi citizens who also purchased those products and "possess[ed] 'rights sought to be enforced.'" *Id.* at 800. This determination was based on several grounds: (1) the complaint itself alleged harm to both the state and to individual citizens; (2) the statutes on which the lawsuit was based did not give the "[s]tate sole authority to recover for particularized injuries suffered by consumers"; and (3) the state had not acted in the case under its *parens patriae* authority, "but essentially as a class representative." *Id.* at 800-01. For all of these reasons, the Fifth Circuit held that the lawsuit initiated by the attorney general was a "mass action" removable to a federal court under CAFA. The Supreme Court has granted a writ of certiorari in the *AU Optronics* case to determine whether state attorney general cases may qualify as "mass actions" under CAFA. Thus, the viability of this theory of removal hinges on how the Supreme Court resolves this question. *See* 2013 U.S. Lexis 4007 (U.S. May 28, 2013).

Other federal appeals courts that have addressed the "mass action" question in attorney general-initiated lawsuits have reached a contrary result. In *LG Display Co. v. Madigan*, 665 F.3d 768 (7th Cir. 2011), for example, the Illinois attorney general sued manufacturers of LCD products, alleging violations of the Illinois Antitrust Act. The complaint alleged that defendants unlawfully inflated prices on their products sold to the state and Illinois citizens and sought injunctive relief, civil penalties, and treble damages for the state as a purchaser and, as *parens patriae*, for harmed citizens. *Id.* at 770. The defendants removed the lawsuit as a "class action" and "mass action" under CAFA, but the district court remanded the case, and the Seventh Circuit affirmed. The appellate court first determined that the lawsuit was not a "disguised" "class action" under CAFA, explaining that "[a] class action must be brought under Rule 23 or the state equivalent." *Id.* at 772. Because the Illinois Antitrust Act "does not impose, for example, requirements for adequacy, numerosity, commonality or typicality," the court of appeals reasoned that a lawsuit brought under that statute did not qualify as a "class action" under CAFA. *Id.* at 772. The appellate court also rejected the defendants' argument that the lawsuit satisfied the requirements of a "mass action." According to the court, "only the Illinois Attorney General makes a claim for damages,"

and the lawsuit therefore did not involve the monetary relief claims of 100 or more persons. *Id.* Further, while the complaint also sought relief for harm allegedly caused to Illinois citizens, these claims were asserted "on behalf of the general public" rather than "individual claimants or members of a purported class." *Id.* For this reason as well, the lawsuit was not a "mass action" removable under CAFA. The Ninth Circuit reached a similar conclusion in *Nevada v. Bank of Am. Corp.*, 672 F.3d 661, 672 (9th Cir. 2012), reasoning that because "[t]he State of Nevada is the real party in interest, … the action falls 99 persons short of a 'mass action.'"

In sum, if the Supreme Court affirms the Fifth Circuit ruling in *AU Optronics* it would validate removing attorney general lawsuits seeking relief on behalf of individual consumers as "mass actions" under CAFA. Because the question presented in the Supreme Court order granting certiorari is limited to the "mass action" issue, the Court's decision may leave open the possibility of removing attorney general cases as "class actions" as well, although the adverse case law regarding this theory of removal would make removal on this basis much more difficult.

Moving to Dismiss Aggregate Claims, Requests for Penalties, and Claims Under State False Claims Acts

Once jurisdiction is determined, a defendant should next consider moving to dismiss the claims asserted by an attorney general under various theories.

First, a pharmaceutical defendant may be able to obtain dismissal under the individualized-proof rule, which bars courts from adjudicating aggregate claims with generalized proof. As some federal courts have recently recognized, attorney general litigation in which a state asserts multiple wrongful acts that allegedly affected numerous individuals cannot proceed to trial when the claims would require hundreds or thousands of causation inquiries. Two district court rulings in state attorney general cases arising from alleged misrepresentations regarding prescription drugs demonstrate how the individualized-proof rule can doom attorney general litigation.

In *Hood ex rel. Mississippi v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 453 (E.D.N.Y. 2009), the Mississippi attorney general asserted Medicaid-related claims regarding Lilly's purported off-label marketing of the drug Zyprexa, alleging that the company engaged in illegal off-label promotion of Zyprexa and failed to warn about the drug's side effects. *Id.* at 401, 453. Judge Jack Weinstein applied an "individualized proof rule" to bar one of the state's primary theories of causation, namely, that Lilly's alleged misconduct caused more Zyprexa to be prescribed to Medicaid beneficiaries, either because doctors prescribed Zyprexa for off-label use more than they otherwise would have, or because doctors would have been more hesitant to prescribe the drug if it had come with a stronger warning. *Id.* at 454. Judge Weinstein granted Lilly summary judgment on this theory, holding that the state could not prove its theory of causation on an aggregate basis. Judge Weinstein began by explaining that Mississippi's theories of relief turned the lawsuit into a functional class action even though the state itself was a single party and Federal Rule 23 had not been invoked. The court reasoned that "[c]onceptually and structurally," "the State's suit is predicated on numerous acts of fraud… alleged to have affected a statewide population of physicians [and] patients." *Id.* at 433. Judge Weinstein went on to hold that an "individualized proof rule" applies in a structural class action just as it does in a traditional class action under Federal Rule 23. Such a rule requires plaintiffs to prove causation on an individual basis and thus bars aggregate adjudication of claims that include a causation element. *Id.* at 434.

Applying the "individualized proof rule" to Mississippi's theories of relief, Judge Weinstein granted summary judgment in favor of Lilly with respect to all theories of causation that depended on individualized showings, in particular, the state's theories that it had spent money on diseases caused by Zyprexa and on prescriptions that were made as a result of Lilly's representations or warnings. *Id.* at 454–55. Judge Weinstein reasoned that

> [i]ndividualized proof is needed… to overcome the possibility that a Mississippi patient was prescribed Zyprexa for some reason other than belief in the accuracy of Lilly's warnings or representations. 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.

Id.

A pharmaceutical defendant may be able to obtain dismissal under the individualized-proof rule, which bars courts from adjudicating aggregate claims with generalized proof.

Judge Weinstein also found that an award of penalties was barred under the individualized-proof rule because the trial court "is invested with discretion to determine the appropriate amount of the penalty with respect to each violation, whether the maximum of $10,000 or some smaller amount." *Id.* at 458. Although the Mississippi statute did not articulate the specific factors that a court should consider when evaluating a request for civil penalties, Judge Weinstein found that the court would nonetheless have to consider

> a number of issues as they bear on each Zyprexa prescription, including but not limited to: whether the prescription was for an on-label or off-label use; whether the prescription was medically necessary; whether the patient received any benefit from Zyprexa; whether and the extent to which the patient experienced any of Zyprexa's potential metabolic side effects; the information about Zyprexa available to the medical community at the time the prescription was written; and the times of the various alleged instances of misconduct by Lilly,

and whether and to what extent each instance may have impacted the prescription in question.

Id. at 458–59.

The court went on to reason that [d]ue to the nature of the alleged misconduct and injuries in the instant case, and in light of the discretion invested in the court to set the amount of the CPA penalty, proper assessment of the claimed penalties would require individualized consideration of the circumstances of each prescription alleged to be in violation of the statute.

Id. at 459.

Many courts have recognized that a plaintiff suing based on an allegedly defective pharmaceutical product lacks standing to sue for purely economic losses where the plaintiff does not allege that the product was ineffective or caused the particular plaintiff physical injury.

Thus, determining the propriety of civil penalties on a "per-violation basis" would be "impractical and beyond the resources of any court." *Id.* Based on this reasoning, the court granted summary judgment in favor of the defendant with respect to the claim for statutory penalties. *Id.*

Similarly, in *Louisiana v. Merck & Co. (In re Vioxx Prods. Liab. Litig.*, No. 05-md-1657), 2010 U.S. Dist. Lexis 142767, at *23 (E.D. La. Mar. 31, 2010), Judge Eldon Fallon of the United States District Court for the Eastern District of Louisiana also applied an "individualized proof rule" to a structural class action brought by the state of Louisiana arising from alleged misrepresentations concerning the drug Vioxx. In that case, the state alleged, among other things, that fewer Vioxx prescriptions would have been written—and thus fewer Medicaid dollars spent—but for defendant Merck's alleged misrepresentations and failure to warn. *See* Louisiana Atty. Gen.'s Mem. of Law in Opp'n to Merck's Mot. to Dismiss Pl.'s Am. Compl. at 16. Judge Fallon held that such theories are foreclosed under the "individualized proof rule" because "[e]ach decision by each doctor and each patient was different," and it would be "simply impossible, or close to it, to determine the individual thought process of each of the thousands of doctors and patients involved." *In re Vioxx*, 2010 U.S. Dist. Lexis 142767, at *23-24. For this reason, the state's theory of causation that Merck's alleged misrepresentations "led to the prescription of Vioxx" failed as a matter of law, and Merck was entitled to summary judgment on that theory. *Id.*

While the *Zyprexa* and *Vioxx* courts applied the individualized-proof rule on motions for summary judgment, the reasoning underlying the decisions also supports challenging a state attorney general's case on the pleadings. After all, as the *Vioxx* court recognized in the Louisiana attorney general case, it would be "simply impossible, or close to it" for a court to assess individualized facts even if a governmental entity attempted to proffer them. 2010 U.S. Dist. Lexis 142767, at *23–24. For this reason, a number of courts have dismissed aggregate claims in pharmaceutical cases that did not involve class actions. *See, e.g.*, *United Food & Commer. Workers Cent. Pa. v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (affirming dismissal of a third-party-payor complaint for "fail[ing] to plead a cognizable theory of proximate causation" on a motion to dismiss); *Emplr. Teamsters-Local Nos. 175/505 Health & Welfare Trust Fund v. Bristol Myers Squibb Co.*, No. 3:12-0587, 2013 U.S. Dist. Lexis 21589, at *32 (S.D. W. Va. Jan. 29, 2013) (granting a motion to dismiss on causation grounds and noting that "[b]etween [d]efendants' alleged misleading marketing and [p]laintiffs' prescription reimbursements lies a vast array of intervening events, including the 'independent medical judgment' of doctors") (citation omitted); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774 (SRC), 2010 U.S. Dist. Lexis 56621, at *24–25 (D.N.J. June 9, 2010) ("Despite the unquestionable detail in the Amended Complaint concerning the tactics employed by Schering in marketing the Subject Drugs, the allegations still fail to establish that Named Plaintiffs suffered injury fairly traceable to the misconduct at issue."), *aff'd*, 678 F.3d 235 (3d Cir. 2012).

While most federal appeals courts that have addressed aggregate claims in pharmaceutical litigation in contexts other than traditional class actions have held that plaintiffs cannot prove such claims with generalized evidence, a recent decision by the First Circuit reached a contrary result. *See Harden Mfg. Corp. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.*, No. 11-1806), 2013 U.S. App. Lexis 6797 (1st Cir. Apr. 3, 2013). In that case, several third-party-payor purchasers of prescription drugs sued two pharmaceutical defendants under, among other things, the federal Racketeer Influenced and Corrupt Organizations (RICO) Act and the New Jersey Consumer Fraud Act, seeking to recover the money spent in covering Neurontin for various off-label purposes. *Id.* at *2. The district court had granted the defendants summary judgment, finding that plaintiffs' aggregate evidence of causation was improper as a matter of law. *Id.* at *3. The court of appeals reversed, however, rejecting the defendants' argument that "the individualized nature of physicians' prescribing decisions renders aggregate proof inappropriate." *Id.* at *21. According to the court, "[t]he combination of [] aggregate evidence and [] circumstantial evidence was enough for the [] plaintiffs to overcome summary judgment." *Id.* at *21–22. The defendants plan to petition the U.S. Supreme Court for certiorari review.

While the *Neurontin* ruling threatens the vitality of the individualized-proof rule within the First Circuit, that rule, as illustrated by the *Zyprexa* and *Vioxx* rulings, remains a strong weapon against attorney general litigation in most other jurisdictions. Under the *Zyprexa* and *Vioxx* line of reasoning, an attorney general seeking to recover based on multiple acts of alleged fraud against the citizens of a state cannot prove causation or entitlement to pen-

alties on an aggregate basis. Rather, issues related to causation and penalties would have to be addressed in myriad, individualized minitrials, making an aggregated trial impractical.

Second, suits by state attorneys general against pharmaceutical companies are often also subject to challenge for lack of injury—a core element of many causes of action. The attorneys general in these actions often allege that the state or its citizens were injured because they would have paid for cheaper or supposedly safer alternative medications or both. Because this is not a viable theory of economic injury, pharmaceutical companies should consider moving to dismiss an attorney general's claims on this ground as well.

Many courts have recognized that a plaintiff suing based on an allegedly defective pharmaceutical product lacks standing to sue for purely economic losses where the plaintiff does not allege that the product was ineffective or caused the particular plaintiff physical injury. *See, e.g.*, *Ironworkers Local Union 68 & Participating Emplrs. Health & Welfare Funds*, 634 F.3d 1352, 1363 (11th Cir. 2011) ("a patient suffers no economic injury merely by being prescribed and paying for a more expensive drug"); *Id.* at 1363-64 (same conclusion with respect to insurers that cover such prescriptions); *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319-20 (5th Cir. 2002) (holding that the plaintiff did not allege any cognizable injury because she does "*not* claim Duract caused [her] physical or emotional injury, was ineffective as a pain killer, or ha[d] any future health consequences to users"); *Health Care Serv. Corp. v. Pfizer, Inc.*, No. 2:10-cv-221, 2012 U.S. Dist. Lexis 89759, at *7-8 (E.D. Tex. Apr. 23, 2012) (third-party payor failed to plead injury because it "does not allege that any physician, had he or she known all the true information about Geodon or Zyvox, would not have prescribed the drugs under the standards of sound medical practice because the drugs actually were unsafe or ineffective in treating their patients' conditions"), *report and recommendation adopted by* 2012 U.S. Dist. Lexis 89758 (E.D. Tex. June 28, 2012); *In re McNeil Consumer Healthcare*, MDL No. 2190, 2011 U.S. Dist. Lexis 76800, at *45 (E.D. Pa. July 14, 2011) (dismissing claims arising from allegedly overpriced medications because the plaintiffs failed to allege that the products did not work as intended). Rather, as the Eleventh Circuit recently explained, a plaintiff must also allege that but for a defendant's alleged misconduct, physicians "would not have prescribed the drug under the standards of sound medical practice because the drug actually was unsafe or ineffective in treating the plaintiff's condition." *Ironworkers*, 634 F.3d at 1363–64.

In *Ironworkers*, several third-party payors sued AstraZeneca, alleging that the company fraudulently induced physicians to prescribe the medication Seroquel for numerous off-label uses. *Id.* at 1356. The plaintiffs claimed that AstraZeneca's allegedly fraudulent off-label marketing campaign caused them "'to unnecessarily pay for [the more expensive] Seroquel off-label prescriptions,'" and they sought to recover the difference between the price of the off-label Seroquel prescriptions and the amount that they would have paid for the less expensive alternatives. *Id.* at 1357 (quoting complaint). The district court dismissed each of the plaintiffs' claims for failing to adequately allege causation. The Eleventh Circuit affirmed, but on a different ground: failing to plead cognizable injury. The court of appeals recognized that "for tort-based causes of action, the scope of potential economic injury arising from a… health insurer's[] purchases of prescription drugs is limited." *Id.* at 1362. This is so, the court explained, because a drug prescription is based on a doctor's medical judgment that the drug will be beneficial to the patient. *Id.* As such, a plaintiff does not suffer "economic injury merely by being prescribed and paying for a more expensive drug." *Id.* at 1363. Instead, a plaintiff must also show that the drug was "unnecessary or inappropriate according to sound medical practice—*i.e.*, the drug was either ineffective or unsafe for the prescribed use." *Id.* Because the plaintiffs in *Ironworkers* did not plead any facts suggesting that the prescriptions were "unsafe or ineffective in treating the [enrollees'] condition," they had not "plausibly suffered economic injury caused by AstraZeneca's false representations." *Id.* at 1363, 1369.

Thus, depending on the precise causes of action asserted by an attorney general, lack of injury can provide pharmaceutical defendants with a means to dispose of meritless cases early in litigation.

Third, when an attorney general pursues litigation under a state's false claims act or Medicaid fraud act, a drug manufacturer should examine the particular statute carefully and consider whether it could successfully challenge the state's lawsuit on the ground that the statute does not apply to drug and device manufacturers or to the wholesale transactions involving their products.

For example, the Pennsylvania Medicaid fraud law expressly applies to "providers." *See* 62 P.S. §1407 (listing "[*p*]*rovider* prohibited acts") (emphasis added); *id.* §1407(c)(1) ("If the department determines that a *provider* has committed any prohibited act… it shall have the authority to immediately terminate, upon notice to the provider, the provider agreement and to institute a civil suit against such *provider* in the court… for twice the amount of excess benefits or payments plus legal interest from the date the violation or violations occurred.") (emphases added). The statute defines provider as "any individual or medical facility which signs an agreement with the department to participate in the medical assistance program, including, but not limited to, licensed practitioners, pharmacies, hospitals, nursing homes, clinics, home health agencies and medical purveyors." *Id.* §1401. Drug manufacturers are not included in this list.

Similarly, Missouri's Medicaid fraud statute provides that a "health care provider shall [not] knowingly make or cause to be made a false statement or false representation of a material fact in order to receive a health care payment[.]" Mo. Rev. Stat. §191.905(1) (emphasis added). A "health care provider" is defined as "any person delivering, or purporting to deliver, any health care, and including any employee, agent or other representative of such a person, and further including any employee, representative, or subcontractor of the state of Missouri delivering, purporting to deliver, or arranging for the delivery of any health care," *id.* §191.900(7); a "health care payment" is a payment made by a state medical assistance program for a health care service, *id.* §191.900(5)-(6). This language, too, likely does not reach drug manufacturers because they do not deliver or purport to deliver health care "in order

to receive a health care payment"—*i.e.*, a payment from the state.

South Carolina's Medicaid fraud statute imposes similar requirements as well. That statute limits liability to a "provider of medical assistance, goods, or services." S.C. Code Ann. §43-7-60(B). The statute defines a "provider of medical assistance" as a "person who provides goods, services, or assistance and who is entitled or claims to be entitled to receive reimbursement, payment, or benefits under the state's Medicaid program." *Id.* §43-7-60(A)(1). Drug companies are likely not covered by this language because they do not receive reimbursement or payment under South Carolina's Medicaid program.

Depending on the precise causes of action asserted by an attorney general, lack of injury can provide pharmaceutical defendants with a means to dispose of meritless cases early in litigation.

Arguments like these have already had some success before the courts. *See, e.g.*, *United States ex rel. Ramadoss v. Caremark Inc.*, No. SA-99-CA-00914, 2008 U.S. Dist. Lexis 71299, at *17–18 (W.D. Tex. Aug. 27, 2008) ("With regard to the first provision under Section 36.002(1), it appears that the language precluding the unlawful act of making a false statement or misrepresentation on an application for a benefit or payment is directed at the Texas Medicaid recipient, and was not intended to apply to" providers) (citation omitted) [The court was construing a version of the Texas Medicaid Fraud Prevention Act that has since been amended to apply more broadly.] As one commenter explained, "drug companies… sell the[ir] products to wholesale distributors… [who] in turn sell to pharmacies and other providers; and… these other providers in turn file claims with the government (*e.g.*, Medicare and Medicaid)." Fazal Khan & Justin Holloway, *Verify, Then Trust: How to Legalize Off-Label Drug Marketing*, 117 Penn St. L. Rev. 407, 414 (2012). Because drug and device manufacturers do not request payment from the state and may not be "providers" as defined under certain statutes,, they are likely outside the scope of laws like those in Pennsylvania, Missouri and South Carolina. "

More and more state attorneys general rely on their respective states' false claims acts and Medicaid fraud laws to sue pharmaceutical companies. As these officials seek to stretch these laws beyond their intended scope, pharmaceutical defendants should rebuff these efforts by relying on the plain language of the statutes in moving to dismiss these lawsuits.

Conducting Discovery Against Attorneys General

Another step that a pharmaceutical defendant should take in challenging attorney general litigation is to conduct its own discovery. This begins with propounding interrogatories, requests for admissions, and requests for production to an attorney general's office. The fruits of this initial discovery can then be used to depose representatives of the state with knowledge of the case to uncover the factual bases of a lawsuit even further. The information gleaned from these depositions can help the defendant adequately prepare its defense and formulate arguments for dispositive pre-trial motions.

Under Federal Rule of Civil Procedure 30(b)(6), a "party may name as the deponent a public or private corporation, a partnership, an association, *a government agency*, or other entity and must describe with reasonable particularity the matters for examination" and "[t]he named organization must then designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on its behalf." Fed. R. Civ. P. 30(b)(6) (emphasis added). Federal Rule 30(b)(6) does not include any exception for state attorneys general. However, attorneys general tend to resist 30(b)(6) deposition notices lodged with their offices on the grounds that the only suitable deponent is a lawyer or that a deposition would impinge on protected work product. A handful of courts have barred depositions of government agency lawyers on these bases. *See, e.g.*, *SEC v. Buntrock*, 217 F.R.D. 441, 445 (N.D. Ill. 2003) (holding that a 30(b)(6) notice was an inappropriate attempt to depose opposing counsel and to delve into the theories and opinions of the SEC attorneys); *EEOC v. HBE Corp.*, 157 F.R.D. 465, 466 (E.D. Mo. 1994) (granting a motion for a protective order barring deposition of an EEOC attorney, explaining that "it is the selection and compilation of the relevant facts that is at the heart of the work product doctrine"); *SEC v. Morelli*, 143 F.R.D. 42, 47 (S.D.N.Y. 1992) ("the Court finds that the proposed Rule 30(b)(6) deposition constitutes an impermissible attempt by defendant to inquire into the mental processes and strategies of the SEC").

While attorneys general have relied on these cases in opposing a defendant's efforts to take 30(b)(6) depositions, this caselaw represents the minority approach. Several other courts have recognized that defendants have a right to depose public agencies that sue them. *See, e.g.*, *William Beaumont Hosp. v. Medtronic, Inc.*, No. 09-CV-11941, 2010 U.S. Dist. Lexis 60370, at *22–23 (E.D. Mich. June 18, 2010) (granting a motion to compel a 30(b)(6) deposition and rejecting reliance on *Morelli* because the "[p]laintiffs should have the opportunity to more fully probe [defendant's] [interrogatory] response using the traditional method for ascertaining facts in the litigation process—examination of a witness"); *see also Serrano v. Cintas Corp.*, No. 04-40132, 2007 U.S. Dist. Lexis 66553, at *9–10 (E.D. Mich. Sept. 10, 2007) (denying the EEOC's motion for a protective order barring a 30(b)(6) deposition and noting that "[t]he arguments and caselaw cited by [d]efendant… are [more] compelling and persuasive" than *EEOC v. HBE Corp.*).

As one federal court put it, an attorney general must submit to a deposition "like any other litigant" by preparing a witness to testify on his or her behalf. *See United States ex rel. Fry v. Health Alliance of Greater Cincinnati*, No. 1:03-cv-167, 2009 WL 5227661, at *3 (S.D. Ohio Nov. 20, 2009) ("[T]he fact that government attorneys are the only individuals with the requisite knowledge to answer Defendants['] questions does not prevent them from preparing a designee to

answer the questions.… The United States, like any other litigant, has the duty to prepare a witness to testify under oath on its behalf."). *See also Town of Colorado City v. United Effort Plan Trust*, No. CV11-8037-PHX-DGC, 2012 WL 5989482, at *2 (D. Ariz. Nov. 29, 2012) (stating that the Utah Attorney General's office must submit to a representative deposition); *Oklahoma ex rel. Edmonson v. Tyson Foods, Inc.*, No. 05-CV-329-GKF-SAJ, 2007 WL 649335, at *2 (N.D. Okla. Feb. 26, 2007) ("Defendant has a method under the Federal Rules of Civil Procedure that will permit Defendant to obtain the information Defendant seeks—a Fed. R. Civ. Proc. 30(b)(6) deposition of Plaintiff [Attorney General of Oklahoma] on topics listed by Defendant."); *Brown, Rudnick, Freed & Gesmer v. Commonwealth*, 17 Mass. L. Rptr. 11 (Super. Ct. 2003) (noting that representative of Massachusetts Attorney General's office was deposed as representative of office).

In short, pharmaceutical defendants facing significant liability exposure are not powerless to uncover the facts underlying a particular set of claims just because a state attorney general has asserted them. The basic tools of civil discovery, including interrogatories, requests for admissions, and document requests, are a sensible starting point. And given the ample case law supporting the use of Federal Rule 30(b)(6) to depose representatives of a state, including government attorneys familiar with the underlying litigation, depositions remain an important and viable discovery tactic to help shape a company's defenses before trial.

Challenging Contingency Fee Arrangements Between Attorneys General and Outside Counsel

Pharmaceutical defendants can also fend off attorney general litigation by challenging questionable arrangements between an attorney general's office and outside counsel, including contingency fee agreements. As legislators cut state budgets, attorney general offices increasingly resort to attorney general-private counsel contingency fee agreements to prosecute pharmaceutical cases because they do not technically involve expending tax dollars. However, these contingency fee arrangements raise serious conflict-of-interest and other ethical questions, and they most likely violate a defendant's right to due process, at least when a state only seeks to recover civil penalties. Under these circumstances, a defendant should challenge a contingency fee arrangement between a state attorney general's office and outside counsel.

Contingency fee contracts between state attorney general offices and private counsel became popular during the landmark tobacco litigation of the 1990s. Explaining the trend, one commentator wrote, "Public officials find it easy to say yes [to these arrangements] because the deals are sold as no-win, no-fee." Walter Olson, *Tort Travesty*, Wall St. J., May 18, 2007. In other words, a state is "not on the hook for any downside, so wouldn't it practically be negligent to let a chance to sue pass by?" *Id.* However, these fee arrangements have considerable downsides as well. For one, they create an opportunity for unseemly liaisons between public enforcement officials and private, profit-motivated lawyers. As one former attorney general who has openly criticized these arrangements explained, "[t]hese contracts… create the potential for outrageous windfalls or even outright corruption for political supporters of the officials who negotiated the contracts." Adam Liptak, *If You Win, You Lose*, N.Y. Times, July 9, 2007, at A10 (quoting William H. Pryor Jr.). Critics have also condemned the practice as promoting "regulation through litigation," empowering states to attack a wide variety of behavior by corporations merely by wielding the power of private attorneys. *See* Br. of U.S. Chamber of Commerce & Am. Tort Reform Ass'n as Amici Curiae in Supp. of Mot. for J. as a Matter of Law, at 20–21; *Oklahoma v. Tyson Food, Inc.*, No. 05-cv-00329-GKF-SAJ (N.D. Okla. June 12, 2007). But perhaps the most troubling consequence of these contracts is that they violate the due process rights of defendants through lawsuits that combine the political power of the state and the financial power of plaintiffs' lawyers.

This concern was recently noted by Judge Danny Reeves in a case challenging Kentucky's retention of contingency fee counsel to sue a drug manufacturer over its marketing of the drug Vioxx. *See Merck Sharp & Dohme Corp. v. Conway*, No. 3:11-51-DCR, 2012 U.S. Dist. Lexis 40940, at *12 (E.D. Ky. Mar. 23, 2012). In that case, the Kentucky attorney general prosecuted a penalties-only enforcement action under the Kentucky Consumer Protection Act. *Id.* at *2. The attorney general alleged that Merck had misrepresented and failed to disclose the cardiovascular risks posed by the drug Vioxx. Merck filed a lawsuit in federal court in Kentucky, alleging that the attorney general had violated Merck's right to due process by engaging contingent-fee counsel to prosecute his action. *Id.* Merck contended that the arrangement violated its due process right to an impartial tribunal because it created an irresistible incentive for private counsel to seek to maximize monetary return, regardless of the public interest. *Id.* at *3–4. Judge Reeves allowed the case to proceed to discovery, holding that "[i]f there is evidence that private counsel 'have ever engaged in any conduct that invaded the sphere of control' reserved to the [attorney general's] office, then the door is opened to a conclusion that the contingency fee arrangement violated the defendant's rights." *Id.* at *12. The case advanced through discovery, and both parties filed motions for summary judgment.

As one federal court put it, an attorney general must submit to a deposition "like any other litigant" by preparing a witness to testify on his or her behalf.

Earlier this year, Judge Reeves granted summary judgment to the Kentucky attorney general, dealing a setback to defendants seeking to challenge contingency fee arrangements between state attorneys general and outside counsel in quasi-criminal enforcement proceedings. *See Merck Sharp & Dohme Corp. v. Conway*, No. 3:11-51-DCR, 2013 U.S. Dist. Lexis 73672 (E.D. Ky. May 24, 2013). In granting the attorney general's motion, Judge Reeves determined that the attorney general's office was exercising sufficient control over the underlying lawsuit and that the fee arrangement with

the outside counsel did not violate Merck's due process rights. According to the court, "the [attorney general's] office does not need to be intimately involved in all of the everyday work or decision-making that occurs in the [Vioxx] litigation to exercise meaningful control over the proceedings." *Id.* at *41. While the court rejected Merck's arguments regarding control, it did find the attorney general's office's "unfamiliarity" with certain aspects of the underlying state court litigation to be "disconcerting," and characterized the office's involvement in the action as "complacen[t] or laz[y]." *Id.* at *38–39. Merck appealed the ruling, and three amici filed briefs supporting its position, but the underlying case by the Kentucky attorney general settled shortly thereafter, mooting Merck's appeal.

Similarly, in *International Paper Co. v. Harris County*, the Texas Court of Appeals recently declined to apply "a blanket prohibition against a governmental entity's engagement of private counsel on a contingent-fee basis to pursue civil litigation in which the only remedy sought [was] civil penalties." No. 01-12-00538-CV, 2013 Tex. App. Lexis 9188, at *42 (Tex. Ct. App. July 25, 2013). There, defendants in a penalties-only environmental enforcement lawsuit moved to enjoin Harris County from using contingency fee counsel to prosecute the case. *Id.* at *7-8. The defendants urged the appellate court to apply a categorical bar on contingency fee agreements in such circumstances, arguing that "'[d]ue process cannot tolerate the pernicious influence of personal financial gain' in a case in which the only remedy sought is punitive." The Texas Court of Appeals rejected this argument, stressing that the "authorities [relied upon by defendant] do not show that due process prohibits a governmental entity from retaining contingent-fee counsel in civil-penalties-only cases." *Id.* at *23. The Texas court therefore "decline[d] [d]efendants' invitation to become the first court to hold" otherwise. *Id.* at *41-42.

A lawsuit filed by the South Carolina Attorney General against AstraZeneca in 2009 similarly challenged a contingency fee arrangement with outside counsel on due process grounds. In that case, South Carolina sued AstraZeneca for its alleged off-label marketing of the drug Seroquel. *See* David Bario, *AstraZeneca Sues South Carolina to Block Use of Private Lawyers in State's Seroquel Case*, The National Law Journal, Mar. 17, 2011, http://www.law.com/jsp/cc/PubArticleCC.jsp?id=1202486359257&Sure_You_Can_Bring_Counsel_Of_Your_Choice_IF_We_Want_Them_Too. Under the terms of the contingency fee agreement, the outside law firms would be entitled to 23 percent of any penalties awarded to the state under the South Carolina Unfair Trade Practices Act, while the attorney general's office would retain 10 percent of the contingency fee under the agreement. Because the attorney general and the state's outside counsel were apparently claiming that AstraZeneca must be penalized $5,000 for every Seroquel prescription ever written in South Carolina, the penalties could have "translate[d] into 'at least millions' for the plaintiffs' firms." *Id.*

AstraZeneca subsequently challenged the contingency fee arrangement in state court, contending that it violated the defendant's due process rights by allowing the attorney general to delegate his law enforcement function to private plaintiffs' attorneys. *Id.* The company characterized the state's lawsuit as a "'law enforcement action akin to a criminal proceeding' under the guise of a civil suit." *Id.* The South Carolina Attorney General moved to dismiss AstraZeneca's lawsuit, and the trial court denied the motion. *See AstraZeneca Pharms. LP v. Wilson* (Order Den. Mot. to Dismiss). The court did not issue a written opinion; however, the fact that the lawsuit withstood a motion to dismiss is encouraging news for defendants that face coercive, penalties-only enforcement actions tainted by contingency fee arrangements. Following the South Carolina judge's ruling, AstraZeneca decided to settle the underlying litigation for $26 million. *See* Nate Raymond, *AstraZeneca Pays $26 Million to Settle South Carolina Lawsuit*, Chicago Tribune, Aug. 24, 2012, http://articles.chicagotribune.com/2012-08-24/lifestyle/sns-rt-us-astrazeneca-settlementbre87n11o-20120824_1_seroquel-astrazeneca-plc-million-settlement.

The premise of a due process challenge similar to the ones brought by Merck, International Paper Co. and AstraZeneca is that a contingency fee arrangement gives outside counsel an improper personal financial stake in the outcome of the underlying action, making such arrangements particularly inappropriate where the State seeks penalties in what is essentially a quasi-criminal manner. In such cases, contingency fee arrangements create the risk of bias by "distracting private counsel from the singular goal of serving the public interest—an issue that is wholly absent when governmental employees pursue the same claims." Richard O. Faulk & John S. Gray, *Alchemy in the Courtroom? The Transmutation of Public Nuisance Litigation*, 2007 Mich. St. L. Rev. 941, 972 (2007). This, in turn, substantially increases the risk of overzealous prosecution. The threat to due process becomes even more pronounced in cases in which an attorney general seeks civil penalties rather than compensatory damages because in such proceedings, a defendant's due process rights correspond more closely to the rights of a criminal defendant than the rights of a defendant in ordinary civil litigation between private parties. *See* Martin H. Redish, *Constitutional and Political Implications: Private Contingent Fee lawyers and Public Power*, 18 S. Ct. Econ. Rev. 77, 80-81 (2010).

In short, delegating the coercive power of the government to private lawyers having a direct and substantial financial stake in the outcome of an enforcement action is inconsistent with the requirement of fundamental fairness embodied in the Due Process Clause of the Fourteenth Amendment. Thus, a pharmaceutical defendant sued by a state attorney general should scrutinize any retention agreement between the attorney general and outside counsel and consider challenging that arrangement in court.

Conclusion

State attorney general cases, with their growing focus on civil penalty recoveries, threaten pharmaceutical companies with potentially exorbitant jury verdicts. However, while these cases present real challenges to pharmaceutical companies, they are by no means insurmountable. In particular, pharmaceutical companies can effectively overcome these obstacles by undertaking the four steps outlined in this article: (1) removing a case to a federal court; (2) challenging the legal basis for an attorney general's claims; (3) conducting discovery, including deposing representa-

tives of an attorney general's office, to better understand the basis of the claims; and (4) challenging questionable fee arrangements between an attorney general's office and outside counsel. These steps, taken together, constitute a viable strategy for fighting back against this increasingly common type of pharmaceutical litigation. FD