Title

Assessing Patterns of Noncompliance with Multistate Settlement in the Pharmaceutical Industry

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Publication Date

2024

ASSESSING PATTERNS OF NONCOMPLIANCE WITH MULTISTATE SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY

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February 21, 2024
Law 696 – Final Paper (SAW) Revised

I. INTRODUCTION

Multistate litigation, a system in which a number of state attorneys general file parallel and closely coordinated actions, has arisen as a powerful means of curtailing powerful corporate actors. Under both state and federal law, coalitions of state attorneys general have pursued multibillion dollar corporations for activities that harm the physical and financial welfare of the people, including pollution, monopolization, fraudulent marketing, and restraints on trade. Multistate litigation has generally proven incredibly effective; the crowning achievement of the practice is the 1998 Master Settlement Agreement with four major tobacco companies, which fundamentally and permanently changed the way that tobacco was sold and marketed in the U.S., saving thousands of lives.[1] However, one incredibly profitable and powerful industry has remained seemingly immune to the multistate litigation model: the pharmaceutical industry.

In this paper, I will first provide a brief overview of multistate settlements with pharmaceutical companies over the past four decades. Next, I will evaluate a number of multistate settlement agreements between state attorneys general and major pharmaceutical companies, identifying the enforcement mechanisms incorporated into the governing documents and discussing their limitations. I will then evaluate the role of external market forces on pharmaceutical companies' compliance with multistate settlements, arguing that limited customer influence and powerful profit drives create little incentive for compliance. I will conclude with a few broad recommendations for improving future compliance in multistate settlements.

[1] Tamara Schlinger, *The MSA – 20 Years Later,* National Association of Attorneys General, Jan. 2, 2019, https://www.naag.org/attorney-general-journal/tobacco-master-settlement-agreement-msa-20-years-later/

II. BACKGROUND

The practice of multistate litigation among state attorneys general began in earnest in the 1980s.[2] The shift from single state to multistate litigation was driven in part by necessity, as individual attorneys general, with their limited resources, faced extreme logistical difficulties in bringing solo suits against incredibly wealthy and powerful companies.[3]

From 1980 through 2019, over 600 corporations entered into multistate settlements with two or more state attorneys general.[4] These settlements cover a wide range of industries, from farming to manufacturing to banking to insurance. Of these more than 600 companies, approximately 130 have entered into more than one multistate settlement. Even this group is fairly diverse, though tobacco, energy, and pharmaceutical companies combined make up over a third of the companies with two or more multistate settlements.

The outsized role of pharmaceutical companies in multistate litigation is unmistakable when examining the handful of companies that have entered into four or more multistate settlements. Out of more than 600 companies that have entered into multistate settlements in the past 40 years, only 24 have entered into four or more multistate settlements. 13 of those companies are in the pharmaceutical industry.

At first glance, the dynamics of multistate settlements with pharmaceutical companies suggest that the commonly cited benefits of the multistate litigation model are less applicable when dealing with the pharmaceutical industry. One proposed benefit of multistate litigation is

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[2] Jason Lynch, *Federalism, Separation of Powers, and the Role of State Attorneys General in Multistate Litigation* (2001) 101 Colum. L. Rev. 1998.

[3] Id.

[4] The following statistics in this section all derive from the Dr. Paul Nolette's Multistate Settlement Database, available at https://attorneysgeneral.org/settlements-and-enforcement-actions/searchable-list-of-settlements-1980-present/. For the sake of clarity and consistency, I have treated both entities which underwent mergers and acquisitions between 1980 and 2019 and as well subsidiary entities as separate entities for the purpose of the following totals. Additionally, to account for the potential of my own personal error in combing through the database, I have provided approximations for larger totals.

the ability of state attorneys general to fill gaps created by weak or nonexistent federal regulations and general federal disinterest in some areas of enforcement.[5] However, the dynamics of multistate settlements entered into by the 13 pharmaceutical companies with four or more settlements indicate high levels of federal involvement. Of the whopping 84 multistate settlements entered into by those 13 companies, exactly 50% saw at least one federal department or agency join in the suit. The federal government therefore plays a significant role in multistate litigation against pharmaceutical companies, suggesting that state attorneys general do not have as many federal gaps to fill when it comes to the pharmaceutical industry.

A second commonly cited benefit of multistate litigation is the increased influence and enforcement power that multistate actions have compared to individual suits, in which individual state attorneys general offices are dwarfed by corporations' armies of private counsel.[6] The theory is that by combining tens of parallel actions, multistate litigation enhances the coercive power of the state attorneys general and therefore forces greater cooperation by corporate defendants.[7] However, the settlement patterns within the pharmaceutical industry suggest that the coercive powers of the states have been less than successful in multistate settlements with pharmaceutical companies. The 13 pharmaceutical companies in question have entered into an average of six settlements with state attorneys general. Both Pfizer and Omnicare have entered into nine multistate settlements, while GlaxoSmithKline entered into 11 settlements in as many years. Additionally, while the role of mergers in compliance with settlements will not be explored in this paper, it is worth noting that at least three of the pharmaceutical companies with four or more settlements are the product of a merger wherein one or more company party to the

[5] Lynch, *Federalism, Separation of Powers, and the Role of State Attorneys General in Multistate Litigation* at 2005.
[6] Id. at 2009.
[7] Id.

merger had previously entered into their own settlements with state attorneys general.[8] A further three pharmaceutical companies with four or more settlements have a subsidiary with at least one multistate settlement of its own.[9]

III. AUTHORITY

Multistate litigation with pharmaceutical companies over the past 40 years can be broadly divided into three categories: consumer protection, antitrust, and Medicaid fraud. In bringing these types of claims, state attorneys general draw on a range of legal authorities.

1. Statutory Authority

The first category of multistate pharmaceutical litigation is consumer protection litigation, which makes up approximately 33% of the multistate suits against major pharmaceutical companies over the past 40 years.[10] State attorneys general are entitled to bring consumer protection claims under both state and federal consumer protection legislation. The movement to introduce consumer protection statutes at the state level began in earnest in the late 1960s with the introduction of the Uniform Deceptive Trade Practices Act; by 1981, every state had some form of consumer protection legislation on the books.[11]

These state consumer protection statutes, known as Unfair and Deceptive Acts and Practices (UDAP) laws, differ in scope between states but generally bar companies from engaging in a range of deceptive, unfair, or unconscionable trade practices.[12] In multistate pharmaceutical litigation, the deceptive trade practices in question tend to be misleading

[8] The three companies I identified that fit this pattern are Aventis, AstraZeneca, and GlaxoSmithKline.
[9] The three companies I identified that fit this pattern are CVS, Johnson & Johnson, and Omnicare.
[10] Nolette, Multistate Settlement Database, *supra* note 4.
[11] Henry Butler and Joshua Wright, *Are State Consumer Protection Acts Really Little-FTC Acts?* (2011), 63 Fla. L. Rev. 163.
[12] *Consumer Protection in the States*, National Consumer Law Center, Mar. 2018, https://filearchive.nclc.org/udap/udap-report.pdf.

marketing and advertisement campaigns, which falls squarely in the purview of UDAP laws.[13] The state attorney general office is typically the state agency charged with enforcement of UDAP laws.[14]

State attorneys general are also permitted to bring claims under a range of federal consumer protection laws; however, state attorneys general typically only invoke more niche federal statutes, such as antispam laws.[15] This dynamic might be explained in part by the fact that state UDAP laws are generally understood to be more powerful enforcement mechanisms than their federal counterparts. For one, many state UDAP laws call for more relaxed legal standards, broadly doing away with the requirement of evidence of reliance on deceptive practices; the lessened standards of state UDAP laws lighten the plaintiffs' burden of proof.[16] Additionally, state UDAP laws generally allow for punitive and treble damages.[17] These advantages may drive state attorneys general to rely primarily on state consumer protection laws, invoking federal authority only in certain types of claims.

The next category of multistate pharmaceutical litigation is antitrust litigation, which makes up the smallest portion of multistate actions; approximately 12% of the claims brought against major pharmaceutical companies by state attorneys general in the past 40 years have been antitrust claims.[18] State attorneys general again derive their authority to bring antitrust suits from federal and state law. At the federal level, state attorneys general are empowered to bring a range of antitrust claims under major federal antitrust legislation. The Clayton Act of 1914 permits

[13] Nolette, Multistate Settlement Database, *supra* note 4.
[14] *Consumer Protection in the States*, National Consumer Law Center, Mar. 2018, https://filearchive.nclc.org/udap/udap-report.pdf.
[15] Amy Widman and Prentiss Cox, *State Attorneys General's Use of Concurrent Public Enforcement Authority in Federal Consumer Protection Laws*, (2001), 33 Cardozo L. Rev. 53.
[16] Butler and Wright, *Are State Consumer Protection Acts Really Little-FTC Acts?* at 175.
[17] Id. at 174
[18] Nolette, Multistate Settlement Database, *supra* note 4.

state attorneys general to bring suits for economic damage to the state itself as a consumer, and the Hart-Scott-Rodino Antitrust Act of 1976 allows state attorneys general to bring antitrust suits on behalf of state citizens economically injured by unfair trade practices.[19]

State attorneys general are further authorized to bring antitrust suits by state statutes. The trend towards state antitrust laws began in the 1970s, and now all 50 states have adopted some form of antitrust statute.[20] State antitrust statutes broadly outlaw unfair competition or manufactured restraints on trade.[21] Further, the majority of states single out the health care industry in their antitrust legislation, with almost every state code including statutes that specifically address healthcare providers or "health maintenance organizations."[22] The state attorney general is granted statutory authority to pursue antitrust violations in every state.[23] In fact, in a number of states, the attorney general has the exclusive authority to litigate violations of state antitrust law.[24]

Lastly, Medicaid fraud makes up the majority of multistate pharmaceutical settlements, accounting for approximately 55% of settlements in the past 40 years.[25] States have adopted statutes targeting fraud within state Medicaid programs, which are in turn funded by the federal Medicaid program.[26] Courts have held that these state Medicaid fraud laws are not preempted by federal statute, instead finding evidence of congressional support for state prosecution of Medicaid fraud cases.[27] Additionally, many states have adopted statutes which bar specific

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[19] Emily Myers, "Chapter 15: Antitrust" in *State Attorneys General Powers and Responsibilities, 4th Ed.*, National Association of Attorneys General.
[20] Id.
[21] "State Antitrust Laws" in *50 State Statutory Surveys: Health Care*, Thompson Reuters, Aug. 2022.
[22] Id. *See eg.* Colo. Rev. Stat. Ann. § 10-16-421.5, Haw. Rev. Stat. Ann. § 432D-22.
[23] Emily Myers, "Chapter 15: Antitrust" in *State Attorneys General Powers and Responsibilities, 4th Ed.*
[24] *See eg.* Conn. Gen. Stat. Ann. § 35-32, Fla. Stat. Ann. § 542.22.
[25] Nolette, Multistate Settlement Database, *supra* note 4.
[26] State exclusion and civil money penalty statutes, Medicare and Medicaid Fraud and Abuse § 4:16 (2023).
[27] *People v. Kanaan*, 278 Mich. App. 594, 751 N.W.2d 57, 69-70 (2008).

fraudulent acts that fall under the umbrella of Medicaid fraud; for example, several states have adopted legislation explicitly barring under-the-table payments for patient referrals, known as "kickbacks," within the health care industry.[28] Further, a number of states have passed statutes modeled on the federal False Claims Act which allow state attorneys general, and in some cases private citizens, to file civil suits related to fraud of a state healthcare program.[29]

The federal government has routinely encouraged the involvement of state attorneys in Medicaid fraud enforcement. Under the State Medicaid Fraud Control Unit Program, first enacted by Congress in 1977 and rendered effectively mandatory by Congress in 1980, state attorneys general offices have been deputized into the fight against Medicaid fraud.[30] Historically, the vast majority of Medicaid fraud control units have been located inside state attorneys general offices.[31]

2. Parens Patriae

Though state attorneys general have generally relied on robust state and federal statutes in their multistate litigation of pharmaceutical corporations, it is worth briefly examining the role of doctrine of parens patriae in this arena, especially given the dynamics of ongoing opioid litigation. The parens patriae doctrine, imported from historical English jurisprudence, affords the state attorney general standing to bring claims which involve the state's "quasi-sovereign interest" in the physical and economic health of its citizens.[32] Though the theory of parens patriae has been enshrined in many state constitutions, parens patriae standing is primarily rooted

[28] Medicaid fraud control units (MFCUs), Medicare and Medicaid Fraud and Abuse § 6:12 (2023).
[29] Id.
[30] Id.
[31] Mark Schlein et. al., *State Attorneys General: A Dynamic Force in Health Care Fraud Enforcement*, Sept. 2004, AHLA-PAPERS P09260418.
[32] Richard Ieyoub and Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of Parens Patriae* (2000), 74 Tul. L. Rev. 1859.

in common law, not constitutional or statutory authority; therefore, it is theoretically available to any state attorney general, perhaps only limited by legal creativity and judicial flexibility.[33]

As the tobacco litigation of the 1990s demonstrates, parens patriae can be a powerful tool in pursuing massive corporations with deep pockets. After decades of largely unsuccessful lawsuits against tobacco companies, a coalition of state attorneys general forged a revolutionary settlement with major tobacco corporations, with parens patriae operating as the lynchpin in their legal arguments.[34] In an attempt to secure their standing in court, several state attorneys general advanced a theory of standing rooted in parens patriae, arguing that their respective states had a right to defend the health and welfare of their citizens against the damage done by tobacco sales and marketing.[35] Though this argument was only expressly supported by one court, it was compelling enough to drive the tobacco companies to the negotiation table.[36]

Clearly, then, the doctrine of parens patriae can be incredibly useful in advancing powerful claims and establishing a state's standing where it is otherwise questionable. Further, it has proven incredibly effective in curtailing powerful industries. That said, I do not believe that the parens patriae doctrine is necessary or even appropriate in most multistate pharmaceutical litigation. Even in the burgeoning arena of opioid litigation, I believe that the parens patriae doctrine should be introduced with caution.

My concern with the use of parens patriae doctrine in pharmaceutical litigation comes down to three points: a lack of necessity, heightened risk, and the unique nature of the pharmaceutical industry. First, the deployment of parens patriae doctrine is not necessary in the

[33] Id. at 1870.
[34] Michelle L. Richards, Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation (2020), 54 U. Rich. L. Rev. 405.
[35] Richard Ieyoub and Theodore Eisenberg, *State Attorney General Actions, the Tobacco Litigation, and the Doctrine of Parens Patriae* at 1866.
[36] Id. at 1870.

vast majority of pharmaceutical cases. As discussed above, state attorneys general can rely on a range of state and federal statutes when pursuing consumer protection, antitrust, and Medicaid fraud claims against pharmaceutical companies. Even in opioid litigation, public nuisance law has proven a viable avenue for standing.[37] Second, these laws are better defined in terms of their applicability and potential remedies because they have been more thoroughly litigated, whereas there is little relevant precedent on the potential scope of parens patriae doctrine.[38] This lack of information creates a great deal of risk in advancing a parens patriae claim.

Finally, there is a genuine argument to be made that parens patriae is not an appropriate doctrine to wield against the pharmaceutical industry. In a sense, tobacco was the ideal testing ground for applying parens patriae doctrine on a large scale. Though the scale of evidence was surely daunting, the tobacco litigation was ultimately quite straightforward. There were a finite number of defendants, and the product in question had no tangible benefit and was effectively unregulated.[39] By contrast, the ongoing opioid litigation has a huge cast of defendants and revolves around a heavily regulated and debatably life-saving product.[40] Thus, though the plaintiff cities and states have compelling legal and moral arguments, opioid litigation will be far more complex and less clear-cut than tobacco litigation. The pharmaceutical companies may very well be willing to gamble on a trial, where the application of the parens patriae doctrine will face heavy scrutiny. Given the other complexities involved in the opioid cases, I am unconvinced that parens patriae is the best fit.

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[37] Michelle L. Richards, *Pills, Public Nuisance, and Parens Patriae: Questioning the Propriety of the Posture of the Opioid Litigation* at 440-42.
[38] Id. at 447-48.
[39] Mason A. Leichhardt, *Big Tobacco's Big Settlement: What Pharmaceutical Companies Can Learn to Protect Themselves in Opioid Litigation* (2021), 60 U. Louisville L. Rev. 161, 192-93.
[40] Id.

IV. EXAMINING PATTERNS OF NONCOMPLIANCE

1. Corporate Integrity Agreements

Corporate Integrity Agreements (CIAs) are documents accompanying civil settlements which include the federal government as a party.[41] CIAs set out the obligations agreed on by the settling parties, which typically entail the creation of a compliance regime with regulatory and reporting requirements, as well as the creation of enforcement mechanisms for those obligations.[42] In pharmaceutical settlements, CIAs are governed by the Department of Health and Human Services.[43] Though CIAs are agreements between the federal government and corporations, state attorneys general sometimes incorporate the existing CIAs into their own settlement agreements, making CIAs the primary enforcement mechanism available in those cases.

OMNICARE

In 2006, Omnicare faced allegations of Medicaid price fraud, as details emerged of a scheme in which the pharmaceutical company switched nursing home patients from generic drugs to more expensive name brand alternatives in order to collect higher rebate rates.[44] The company ultimately entered into a settlement with the federal government and 43 states for a

[41] *Corporate Integrity Agreement FAQs*, U.S. Department of Health and Human Services Officer of the Inspector General, https://oig.hhs.gov/faqs/corporate-integrity-agreement-faq/.
[42] *Corporate Integrity Agreements*, U.S. Department of Health and Human Services Officer of the Inspector General, https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp
[43] Id.
[44] *Drug Provider Settles Medicaid Case*, The New York Times, Nov. 15, 2006, https://www.nytimes.com/2006/11/15/business/15healths.html

total of $49.5 million.[45] In addition, Omnicare entered the first of several CIAs with the United States Department of Health and Human Services, Office of Inspector General (OIG-HHS).[46] The CIA barred Omnicare from switching medications or doses if it would create additional third-party costs, namely superfluous Medicaid payments.[47] The CIA further established a reporting and certification regime requiring Omnicare to report its pricing mechanisms and certify their accuracy.[48] The CIA established a $5,000 penalty for each false certification, as well as an accruing penalty of $2,500 for every day of noncompliance.[49]

Omnicare's activities in the years following this initial CIA demonstrate one shortcoming of CIAs as an enforcement mechanism. Later court filings revealed that after adopting the CIA, Omnicare continued to operate a similar kickback scheme, violating federal law and the terms of the CIA in the process.[50] However, Omnicare repeatedly filed false certifications, obscuring its pricing scheme.[51] Omnicare received internal reports from employees alleging fraud by its customers, which Omnicare did not report.[52] Because Omnicare presented a cooperative front through false certifications, it evaded any penalties under the CIA for over three years.[53]

Then, in 2009, Omnicare once again found itself in hot water for its continued use of kickbacks, with the U.S. Department of Justice (DOJ) and numerous state governments alleging that Omnicare not only sought kickbacks from drug suppliers but also provided customer nursing

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[45] Press Release, Illinois Office of the Attorney General, *Madigan Announces Agreement with Kentucky-Based Omnicare, Illinois to Receive over $2.5 Million*, Nov. 14, 2006, https://ag.state.il.us/pressroom/2006_11/20061114.html

[46] John Allen, , *Annual Report for the Office of Inspector General for Calendar Year 2006*, Illinois Department of Healthcare and Family Services, March 30, 2007.

[47] Press Release, Illinois Office of the Attorney General, *supra* note 14.

[48] *Ruscher v. Omnicare Inc.*, 2014 WL 4388726 at 2 (S.D. Tex., 2014).

[49] Id.

[50] Id.

[51] Id.

[52] Id.

[53] Id.

homes with significant kickbacks in return for their continued business.[54] In addition to paying $98 million to participating governments, Omnicare entered an amended CIA with HHS-OIG as part of the settlement.[55] The federal government opted to enter an amended CIA with Omnicare despite the company's repeated, flagrant violations of its 2006 CIA, with the participating states apparently endorsing this move.

The 2009 CIA, which was in effect until November 2, 2014, subjected Omnicare to "greater federal scrutiny."[56] The CIA expressly required compliance with the Anti-Kickback Statute, the legislation that Omnicare's pricing schemes ran afoul of, stating that "Omnicare shall create procedures to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute."[57] Extending the reporting requirements established in the initial agreement, the 2009 CIA called on Omnicare to report any "reportable events" to the relevant authorities; reportable events were defined broadly, including any "matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized."[58] In addition to Omnicare's reporting requirements, the CIA allowed for the possibility of external inquiries at the government's discretion.[59]

The 2009 CIA further established a range of penalties for noncompliance. Much like the 2006 CIA, the new agreement set out monetary penalties for false certifications and failure to

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[54] *Omnicare Will Settle Kickback Cases for $98 Million,* Cleveland.com, Nov. 3, 2009, https://www.cleveland.com/business/2009/11/omnicare_will_settle_kickback.html
[55] Omnicare, Inc., *Form 10-Q, Note 17 – Commitments and Contingencies,* Dec. 31, 2010, retrieved from SEC EDGAR website at ://www.sec.gov/Archives/edgar/data/353230/000144264311000043/R22.htm
[56] Id.
[57] *Amended And Restated Corporate Integrity Agreement Between The Office Of Inspector General Of The Department Of Health And Human Services And Omnicare, Inc.*, page 12, Nov. 2, 2009, https://www.justice.gov/sites/default/files/elderjustice/legacy/2015/07/12/omnicare_inc_11022009.pdf.
[58] Id. at 27.
[59] Id. at 47, 59.

comply with a series of internal oversight reforms.[60] However, the amended CIA also introduced the possibility of a much more severe penalty: exclusion from Medicaid and Medicare programs.[61] Per the CIA, a material breach, which included a failure to disclose "reportable events," would be grounds for exclusion, again at the discretion of the federal government.[62] In an apparent show of its seriousness, the federal government explicitly reserved the right to exclude Omnicare from Medicaid and Medicare in its own settlement agreement with the company.[63]

However, the federal government demonstrated a fairly limited willingness to impose the CIA's penalties in 2014. When Omnicare reported its employment of an excluded individual under the terms of the CIA, the federal government responded by fining the company $138,000.[64] However, in response to more severe and material violations, the federal government elected not to invoke the CIA. In June of 2014, the federal government entered another settlement agreement with Omnicare, resolving allegations with obvious parallels to those giving rise to the 2009 CIA. The DOJ yet again uncovered a series of kickback schemes by Omnicare, claiming that the company submitted inflated Medicaid and Medicare claims and provided several facilities with financial incentives for their continued patronage.[65] These activities were

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[60] Id. at 35-6.
[61] Id. at 38.
[62] Id.
[63] *Settlement Agreement Among (A) United States, (B) Omnicare, and (C) Adam Resnick, David Kammerer, Deborah Maguire, and Bernard Lisitza*, page 10, Nov. 2, 2009, https://www.phillipsandcohen.com/wp-content/uploads/Omnicare-Kickbacks-Federal-Settlement.pdf
[64] *Omnicare Agreed to Pay $138,000 for Allegedly Violating the Civil Monetary Penalties Law by Employing an Excluded Individual*, U.S. Department of Health and Human Services, Officer of the Inspector General, Jul. 10, 2014, https://oig.hhs.gov/fraud/enforcement/omnicare-agreed-to-pay-138000-for-allegedly-violating-the-civil-monetary-penalties-law-by-employing-an-excluded-individual/

[65] Press Release, U.S. Department of Justice, *Nation's Largest Nursing Home Pharmacy Company to Pay $124 Million to Settle Allegations Involving False Billings to Federal Health Care Programs*, Jun. 25, 2014, https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving

seemingly a clear-cut material breach of the 2009 CIA; Omnicare's pricing and incentive schemes violated the Anti-Kickback Statute, expressly incorporated into the CIA. Further, Omnicare's failure to report these activities constituted a failure to disclose a "reportable event" by the CIA's terms, outlined above. However, the 2014 settlement made no reference to the 2009 CIA, and the federal government did not pursue exclusion measures, though the 2009 CIA and accompanying settlement introduced such measures as a real possibility.[66] Thus, the federal government, which had the sole discretion to pursue penalties under the 2009 CIA, demonstrated a clear unwillingness to fully enforce the agreement.

Furthermore, a series of court cases made clear that third-party efforts to hold Omnicare accountable for its violations of its CIAs faced an uphill battle. In 2014, a district court in Illinois set a high bar for one former employee suing Omnicare under the False Claims Act for violations of its 2009 CIA.[67] The former employee alleged that despite the provisions of the 2009 CIA, Omnicare continued to offer unlawful incentives to retain customers and file false certifications.[68] Though the employee claimed that Omnicare consistently disregarded the terms of its 2009 CIA for almost the entire duration of the agreement, the federal government declined to intervene in the suit, leaving the employee to fight his case alone.[69] Though the Court granted the employee leave to amend several complaints related to Omnicare's misconduct, the Court's requirements effectively blocked the lawsuit.[70] Due to jurisdictional bars in the False Claims Act, the employee's claims could only survive if he could demonstrate that he was an "original source of the information."[71] Though the employee alleged personal knowledge of various violations of

[66] Id.
[67] *United States v. Omnicare, Inc*., 2014 WL 1458443 (N.D.Ill., 2014).
[68] Id. at 1.
[69] Id.
[70] Id. at 9.
[71] Id. 8-9.

the CIA, his claims would be barred under this requirement if he could not demonstrate that he "voluntarily disclosed the information underlying his allegations to the government at any time."[72] Effectively, the employee's failure to directly report the violations to the government barred his independent claim; the employee never filed an amended complaint.

In 2016, the Fifth Circuit similarly prevented another former employee's case alleging violations of the 2006 CIA to move forward. In this case, a different employee made very similar claims, alleging she had personal knowledge of Medicaid fraud perpetuated by Omnicare in violation of its original 2006 CIA.[73] Further, the employee claimed that she had sent an internal email in 2007 alerting Omnicare to Medicaid fraud by its customers.[74] However, the Court held that the 2007 email did not constitute a "reportable event" under the CIA; therefore, the employee had not alleged a breach of the agreement.[75] Though the employee reported evidence that Omnicare customers were not making payments in violation of Medicaid law, the Court reasoned that the employee could not know that those customers would not remedy their violations by preparing a particular form.[76] Further, the Court declined to grant the employee's discovery motion to compel further documents related to Omnicare's CIA violations, finding that the employee had not sufficiently articulated the evidence she hoped to uncover.[77] As a result, the Court affirmed a prior decision granting summary judgment, putting an end to the case.[78]

Two former Omnicare employees filed federal lawsuits alleging personal knowledge of Omnicare's violations with little success; Omnicare's shareholders fared similarly. In 2014, the Sixth Circuit dismissed a case brought against Omnicare by an asset management firm on behalf

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[72] Id. at 8.
[73] *United States ex rel. Ruscher v. Omnicare, Inc*., 663 Fed.Appx. 368, 371 (5th Cir. 2016).
[74] Id. at 376.
[75] Id.
[76] Id.
[77] Id. at 372.
[78] Id. at 377.

of several Omnicare stakeholders.[79] The firm alleged that Omnicare had repeatedly made misrepresentations in its public filings in violation of Medicaid and Medicare law, citing the terms of the 2009 CIA.[80] However, the Court dismissed any reference to the CIA for a procedural failure to properly incorporate the CIA in the initial complaint.[81] The Court then proceeded to dismiss the claims, pointing to a failure to adequately allege the facts.[82]

The outcomes of these cases demonstrate the difficulties third parties face in suing pharmaceutical companies for CIA violations when the federal government declines to participate. Because the plaintiffs are restricted to their own personal knowledge of corporate malfeasance, it can be incredibly difficult for them to meet the evidentiary standards necessary to progress their cases. Further, various jurisdictional bars designed to prevent abuse of *qui tam* actions can prevent well-founded claims from moving forward. Therefore, if the federal government refuses to pursue violations of a CIA, which it regularly did in the case of Omnicare, there are few viable alternatives to penalizing noncompliance.

GLAXOSMITHKLINE

In 2003, GlaxoSmithKline (GSK) entered into a settlement agreement with the federal government and 50 state governments over an alleged Medicaid fraud scheme.[83] The agreement resolved allegations that GSK sold Paxil, its top-selling antidepressant, and Flonase at a discounted rate but reported full price sales to Medicaid in order to profit off of the higher

[79] *In re Omnicare, Inc. Securities Litigation,* 769 F.3d 455 (6th Cir. 2014).
[80] Id. at 466.
[81] Id.
[82] Id. at 483-4.
[83] Denise Lavoie, *Drug Makers to Pay Medicaid Settlement*, Midland Daily News, Apr. 15, 2003, https://www.ourmidland.com/news/article/Drug-Makers-to-Pay-Medicaid-Settlement-7138324.php

rebates.[84] Along with an $87.6 million settlement payment, GSK entered into a CIA, requiring them to certify their price methodology with HHS-OIG.[85] Additionally, the CIA established an internal compliance program at GSK and called for independent pricing reviews.[86]

In a close parallel to the Omnicare cases, GSK then faced another round of scrutiny for their continued fraudulent pricing in 2005. In response to allegations that the company improperly priced and marketed two drugs used in cancer treatment, GSK entered a second settlement with federal and state governments, this time for $150 million.[87] Just as with Omnicare, the DOJ and the states agreed to a five-year addendum to GSK's existing CIA.[88] This 2005 addendum once again required GSK to accurately report their prices.[89] Thus, as in the case of Omnicare, despite the fact that GSK clearly and habitually violated their first CIA, the federal and state governments relied on an addendum to correct GSK's noncompliance. The press releases accompanying the settlement make no reference to the 2003 CIA, highlighting the regulatory requirements established in the new addendum without addressing GSK's past CIA violations.[90]

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[84] Press Release, Hawaii Office of the Governor, *State Reaches Settlement Agreements With Bayer Corporation And GlaxoSmithKline For "Lick And Stick" Fraud Scheme*, May 12, 2003, https://ag.hawaii.gov/wp-content/uploads/2012/12/2003-20.pdf
[85] Id.
[86] Jonathan Henderson and Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 Annals of Health 107 (2006), https://lawecommons.luc.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1188&context=annals

[87] Press Release, U.S. Department of Justice, *GlaxoSmithKline Pays $150 Million To Settle Drug Pricing Fraud Case*, Sept. 20, 2005, https://www.justice.gov/archive/opa/pr/2005/September/05_civ_489.html. Dr. Nolette's Multistate Settlement Database, *supra* note 4, indicates that fifty state attorney generals as well as the DOJ were party to this settlement.

[88] U.S. Department of Health and Human Services Office of Inspector General, *Semiannual Report to Congress*, 2006, https://oig.hhs.gov/publications/docs/semiannual/2006/semiannualspring2006.pdf
[89] Press Release, U.S. Department of Justice, *GlaxoSmithKline Pays $150 Million To Settle Drug Pricing Fraud Case*, Sept. 20, 2005.
[90] Id.

Then, in 2012, the tides seemingly turned. A coalition of 45 states joined with the DOJ in entering into a record-breaking $3 billion settlement with GSK.[91] The largest healthcare fraud settlement in United States history, this agreement saw federal and state Medicaid programs recover $2 billion in civil penalties.[92] In addition to the civil settlement, GSK pled guilty to three criminal counts for misbranding drugs and failing to report safety data.[93] In addition to the hefty financial penalties, this settlement also saw GSK enter into its most restrictive CIA yet. The 2012 CIA, which came in at a remarkable 122 pages, introduced an extensive range of measures to promote transparency and limit incentives for misconduct in marketing.[94] Much like Omnicare's 2009 CIA, GSK's 2012 CIA both established a system of penalties for noncompliance and introduced the threat of exclusion as a consequence for material breach, which could stem from a failure to meet any number of settlement obligations or Food and Drug Administration (FDA) and Medicaid requirements.[95] The stringent CIA requirements, in concert with the historic civil and criminal penalties, were accompanied by messages of optimism and determination from the settlement parties. Connecticut Attorney General George Jepsen claimed that the settlement would "shut down a practice by one of the largest drug manufacturers of marketing drugs for uses not approved by the federal Food and Drug Administration."[96] Similarly, California

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[91] Press Release, California Office of the Attorney General, *Attorney General Kamala D. Harris Joins Nationwide $3 Billion Settlement with GlaxoSmithKline to Resolve Fraud Allegations*, Jul. 2, 2012, https://oag.ca.gov/news/press-releases/attorney-general-kamala-d-harris-joins-nationwide-3-billion-settlement

[92] Press Release, U.S. Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data*, Jul. 2, 2012, https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

[93] Id.

[94] Ben Comer, *Comply or Die: Introducing GSK's New Corporate Integrity Agreement*, PharmaExec.com, Jul. 5, 2012, https://www.pharmexec.com/view/comply-or-die-introducing-gsks-new-corporate-integrity-agreement

[95] *Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline L.L.C.,* Jun. 28, 2012, https://www.justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-ex-d.pdf

[96] Press Release, Connecticut Office of the Attorney General, *Connecticut Joins Federal-State Settlement with GlaxoSmithKline to Resolve Drug Marketing and Pricing Claims*, Jul 2, 2012, https://portal.ct.gov/AG/Press-Releases-Archived/2012-Press-Releases/Connecticut-Joins-FederalState-Settlement-With-GlaxoSmithKline-To-Resolve-Drug-Marketing-and-Pricing

Attorney General Kamala Harris assured consumers that this settlement "puts an end to unscrupulous marketing practices, kickbacks and illegal labeling of prescription drugs."[97]

In one sense, the 2012 CIA has shown signs of success. Though several multistate settlements have been filed since its effective date, all of these settlements relate to misconduct predating the CIA. In fact, GSK has not been targeted in multistate litigation since 2015, breaking a cycle of repeated settlements and violations in the early 2000s.[98]

However, several developments emerging after the 2012 settlement suggest that even the most stringent CIA cannot generate complete compliance. In 2014, GSK entered a $489 million settlement with the Chinese government over allegations that the company had been bribing doctors in the country to use its drugs.[99] Further evidence of bribes to foreign officials from 2010 to 2013 then sparked investigations in the United States, with GSK ultimately entering into a $20 million settlement with the Securities and Exchange Commission, which alleged that GSK's actions in China violated the Foreign Corrupt Practices Act.[100] These allegations of bribery, as well as claims of record falsification ,immediately raised questions related to the 2012 CIA; HHS-OIG left open the possibility that GSK's foreign conduct may have violated the CIA, despite the agreement's domestic framing.[101] Though the CIA limited the scope of reportable events to potential violations of US health care law, the agreement is internally referred to as a

[97] Press Release, California Office of the Attorney General, *supra* note 60.
[98] Dr. Paul Nolette, Multistate Settlement Database, *supra* note 4.
[99] Adam Jourdan and Ben Hirschler, *China Hands Drugmaker GSK Record $489 Million Fine for Paying Bribes*, Reuters, Sept. 19, 2014, https://www.reuters.com/article/us-gsk-china/china-hands-drugmaker-gsk-record-489-million-fine-for-paying-bribes-idUSKBN0HE0TC20140919
[100] Sarah Lynch, *GlaxoSmithKline to Pay $20 Million to Settle U.S. Foreign Bribery Case*, Reuters, Sept. 30, 2016, https://www.reuters.com/article/us-sec-glaxosmithkline-corruption/glaxosmithkline-to-pay-20-million-to-settle-u-s-foreign-bribery-case-idUSKCN1202F3
[101] Ed Silverman, *Did Glaxo Violate its Corporate Integrity Agreement?*, Forbes, Jul 24, 2013, https://www.forbes.com/sites/edsilverman/2013/07/24/did-glaxo-violate-its-corporate-integrity-agreement/?sh=74a646d1399c

"global civil, criminal, and administrative settlement."[102] Further, the drafters of the CIA foresaw an international reach, with certain provisions such as Appendices D and E explicitly allowing for responses to certain international misconduct under the CIA.[103] While the Chinese bribery scandal was by no means a clear-cut violation of the CIA, it demonstrated that GSK was willing to test the boundaries of the agreement and face investigative scrutiny in the US and abroad as a result.

In a more recent scandal that clearly implicates the 2012 CIA, GSK recalled Zantac, a heartburn medication that was a long-time best seller for the company, in 2020.[104] The recall followed an FDA finding that the drug contained a probable carcinogen which was dangerous in large quantities.[105] GSK cooperated immediately with the FDA's recall order, adhering to the terms of the CIA.[106] However, a recent Bloomberg investigation seemingly uncovered evidence that GSK was aware of the heightened cancer risks long before the FDA.[107] Based on court filings, FDA transcripts, and FOIA requests, Bloomberg alleges that GSK withheld a critical 1982 report detailing the high levels of carcinogenic compounds in GSK's drug samples.[108] GSK then allegedly kept secret this report for almost forty years, including almost the entire duration of its 2012 CIA, despite obligations to adhere to FDA requirements.[109]

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[102] *Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and GlaxoSmithKline L.L.C., supra* note 64, page 45.
[103] Id. at Appendix D, Appendix E.
[104] Robert Hart, *GSK Settles Zantac Cases After Claims Popular Heartburn Drug Causes Cancer*, Forbes, Oct. 11, 2023, https://www.forbes.com/sites/roberthart/2023/10/11/gsk-settles-zantac-cases-after-claims-popular-heartburn-drug-causes-cancer/?sh=653e137b6cb4
[105] Id.
[106] Anna Edney et. al., *Zantac Cancer Risk Data Was Kept Quiet by Manufacturer Glaxo for 40 Years*, Bloomberg, Feb. 14, 2023, https://www.bloomberglaw.com/product/blaw/bloombergterminalnews/bloomberg-terminal-news/RQ3VAFDWX2PT?bc=W1siQmxvb21iZXJnIExhdyIsIi9wcm9kdWN0L2JsYXcvbm90aWZpY2F0aW9ucy9pdGVtcy9SRVNFQVJDSF9UUkFJTCJdXQ--7d97e0814b01f2a467dfe0a55cca64ed76649c62
[107] Id.
[108] Id.
[109] Id.

Compliance with federal health care law and FDA regulations was at the heart of the regulatory regime instituted by the 2012 CIA. The drop in both multistate and federal litigation against GSK following the 2012 CIA's introduction indicates that its stringent requirements have had a beneficial impact on compliance and transparency. However, the alleged cover-up of carcinogens in one of GSK's best-selling drugs suggests that even the strictest regulatory regime has its limits when it comes to highly damaging information and highly profitable goods.

STRENGTHS AND LIMITATIONS OF CIAS

An examination of patterns of noncompliance with CIAs by both Omnicare and GSK reveals insights into the successes and limitations of the incorporation of CIAs in multistate settlements. To some extent, the regulatory regimes imposed by CIAs have been effective in curtailing illegal behavior. Under its 2009 CIA, Omnicare was compelled to report its employment of an excluded individual, a measure which the company very likely would not have taken absent the agreement. Further, the steep drop-off in multistate litigation against GSK following the institution of its comprehensive 2012 CIA indicates that the implementation of extensive reporting and disclosure requirements has real potential to curb illicit activity. Ultimately, any additional compliance that comes as a result of the CIAs is a real victory in an industry fraught with bad behavior.

However, the cases of Omnicare and GSK also demonstrate the dearth of effective enforcement mechanisms. On one hand, the system of penalties for noncompliance set out in the CIAs did little to deter repeated violations. As Omnicare's activities following its 2006 CIA demonstrate, companies under CIAs can also evade penalties to some extent through false reporting. Additionally, if the federal government elects not to pursue violations of CIAs,

unsupported third parties have limited recourse given restrictive statutory bars on *qui tam* actions.

On the other hand, the more severe enforcement mechanism of exclusion from Medicare and Medicaid has never been implemented, for fairly obvious reasons. Excluding a massive pharmaceutical company from Medicare and Medicaid would have disastrous economic impacts, putting the company in dire financial straits and wreaking havoc on the stock market. Further, exclusion would ultimately put millions of consumers at risk of losing access to their medications, some of which might be lifesaving. The severe consequences of exclusion of a major pharmaceutical company mean that the federal government will likely never implement this mechanism in the event of a material breach of a CIA; it is a bluff, and based on Omnicare and GSK's repeated breaches, they know it. This leaves monetary penalties, however ineffective, as the only practical enforcement mechanism under the CIA.

2. Consent Decrees

A second, more common settlement mechanism used in multistate litigation of pharmaceutical companies is the consent decree. A consent decree embodies the terms of a settlement agreement and provides enforcement mechanisms in the event of noncompliance.[110] Though the terms of a consent decree are negotiated by the parties, a consent decree is a judicial act which is issued and governed by the court.[111]

[110] *Consent decree*, Federal Control of Business §183.
[111] Id.

BAYER

The year 2000 saw the first of many multistate settlements with Bayer over false or misleading advertising. The attorneys general of New York and Connecticut, joined by the Federal Trade Commission and FDA, alleged that Bayer had made unsubstantiated claims in marketing aspirin; Bayer claimed that taking aspirin regularly was a safe and effective way to reduce the risk of heart attack and stroke, while evidence suggested that regularly consuming aspirin could be dangerous for some adults.[112] The penalties were fairly conservative, with each state receiving $30,000.[113] The settlement also required Bayer to "possess and rely upon competent and reliable scientific evidence to substantiate any claims about regular aspirin use."[114] Further, Bayer agreed to conduct a $1 million consumer education campaign, informing customers of the potential risks of regular aspirin use and encouraging them to consult a doctor before taking aspirin.[115] The terms of the settlement were therefore limited to Bayer's marketing of its aspirin medication, not incorporating its marketing practices more generally.

Less than a decade later, a coalition of 30 states sought much more comprehensive injunctions in an $8 million settlement with Bayer over its similarly misleading marketing of a different drug, Baycol.[116] Just as in 2000, the states alleged that Bayer failed to disclose the safety risks associated with the drug to consumers.[117] This 2007 settlement sought to increase

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[112] Press Release, Federal Trade Commission, *Bayer Settles FTC Charges*, Jan11., 200. https://www.ftc.gov/news-events/news/press-releases/2000/01/bayer-settles-ftc-charges
[113] Deborah Josefson, *Bayer Made to Tone Down Aspirin Advertisements*, 173 Western Journal of Medicine 154 (2000), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1070790/
[114] Press Release, Federal Trade Commission, *supra* note 81.
[115] Id.
[116] Press Release, Delaware Department of Justice, *Attorney General Announces 30-State Settlement with Bayer Corporation*, Jan. 23, 2007, https://news.delaware.gov/2007/01/23/attorney-general-announces-30-state-settlement-with-bayer-corporation/
[117] Press Release, Washington State Office of the Attorney General, *McKenna Announces $8 Million Settlement with Bayer Corporation*, Jan. 24, 2007, https://www.atg.wa.gov/news/news-releases/mckenna-announces-8-million-settlement-bayer-corporation

transparency, requiring Bayer to register all clinical studies and include links to the results of those studies on their website.[118] The settlement also introduced broader injunctions, barring Bayer from making "any false, misleading, or deceptive representation regarding any of its products."[119] Failure to comply with the settlement terms would allow the states to pursue "separate civil action to enforce [the] Consent, or to seek any other relief afforded by law."[120] The settlement did not outline any further penalties or enforcement mechanisms.

This agreement was put to the test less than two years later, when 27 state attorneys general pursued Bayer for violations of the 2007 settlement. The state attorneys general alleged that Bayer's marketing of the contraceptive Yaz as a treatment for premenstrual symptoms and acne misrepresented the drug's federal approval status.[121] They therefore argued that Bayer had violated the 2007 settlement's bar on "false, misleading, or deceptive representations."[122] To resolve the allegations, Bayer yet again agreed to undertake a corrective campaign, committing $20 million to a new advertising program accurately detailing the scope of Yaz's efficacy.[123] This 2009 settlement agreement also introduced an especially paternalistic form of oversight, requiring Bayer to submit its future Yaz advertisements to the FDA for pre-approval.[124]

Just one year later, Bayer would reach a separate, smaller settlement with three states claiming that until mid-2009, the company had similarly marketed its One-a-Day Men's

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[118] Consent Decree and Judgement Resolving State's Claims Violations of the Consumer Protection Act, *State of Washington v. Bayer Corp.*, No. 07-2-03323-8SEA (King County Sup. Ct., Washington).
[119] Id.
[120] Id.
[121] Robbie DiMesio, *Oregon AG, Bayer Reach Settlement Over Yaz Ads*, The Oregonian, Feb 10, 2009, https://www.oregonlive.com/business/2009/02/oregon_ag_bayer_reach_settleme.html
[122] Press Release, Illinois Office of the Attorney General, *Madigan Reaches Settlement with Bayer for Violating 2007 Agreement to Cease Deceptive Marketing Practices*, Feb. 9, 2009, https://ag.state.il.us/pressroom/2009_02/20090209.html
[123] Press Release, Connecticut Office of the Attorney General, *Attorney General Announces New Terms to 2009 Bayer Judgment Involving Direct-To-Consumer Marketing*, 2009, https://portal.ct.gov/AG/Press-Releases-Archived/2009-Press-Releases/Attorney-General-Announces-New-Terms-To-2007-Bayer-Judgment-Involving-Direct-To-Consumer-Marketing
[124] Id.

medication in a misleading fashion.[125] According to the state attorneys general, Bayer made claims suggesting that its multivitamin could reduce the risk of prostate cancer, despite the lack of evidence suggesting its efficacy in cancer prevention.[126] Echoing past settlements, this 2010 settlement barred Bayer from claiming that One-a-Day could prevent cancer or any other disease without sufficient scientific evidence.[127]

2010 marked Bayer's final multistate settlement, but it was not the end of Bayer's misleading advertising. In 2013, a public interest group put Bayer on notice of misleading claims in its marketing for One-a-Day Women's, alleging that much like in the 2010 case, several of Bayer's claims implied that the multivitamins reduced cancer rates.[128] Additionally, in 2019, the Kentucky Attorney General settled a suit with Bayer over its continued misinformation in the marketing of Yaz, the very subject of the multistate 2009 settlement.[129] The Kentucky Attorney General, noting the terms of the 2007 and 2009 consent decrees, alleged that Bayer had hidden significant risks of clotting associated with Yaz from consumers.[130]

PFIZER

In 2003, Pfizer entered a settlement with 19 states to resolve allegations that it improperly marketed its best-selling antibiotic Zithromax.[131] The states claimed that Pfizer misrepresented

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[125] *U.S. States Settle with Bayer over Vitamin Claims*, Reuters, Oct. 26, 2010, https://www.reuters.com/article/bayer-vitamin-settlement/u-s-states-settle-with-bayer-over-vitamin-claims-idUSN2616819120101026
[126] Duff Wilson, *Bayer Settles One-A-Day Claims Case,* The New York Times, Oct. 27, 2010, https://archive.nytimes.com/prescriptions.blogs.nytimes.com/2010/10/27/bayer-settles-one-a-day-claims-case/
[127] *U.S. States Settle with Bayer over Vitamin Claims*, *supra* note 94.
[128] *Re: Bayer's deceptive trade practices based on unsubstantiated and illegal claims found on multiple varieties of Bayer One A Day multivitamins*, Center for Science in the Public Interest, May 6, 2013,://www.cspinet.org/sites/default/files/media/documents/resource/bayer_demand_letter_050613.pdf
[129] Press Release, Kentucky Office of the Attorney General, *Beshear Secures $17 Million Settlement with Bayer Corporation*, Oct. 23, 2019, https://www.kentucky.gov/Pages/Activity-stream.aspx?n=AttorneyGeneral&prId=848
[130] Id.
[131] *Pfizer Settles Over Antibiotic*, The Washington Post, Jan. 07, 2003, https://www.washingtonpost.com/archive/business/2003/01/07/pfizer-settles-over-antibiotic/f8d39390-d4d0-4ec7-b5cc-32a1ae565811/

the efficacy of the drug by suggesting that Zithromax was inherently superior to competitor's antibiotics due to its lower number of doses.[132] In addition to paying $6 million in penalties, the company agreed to initiate a $2 million corrective campaign, advising consumers of the relative efficacy of the drug compared to its competitors' products..[133]

In 2008, 34 state attorneys general entered into another settlement with Pfizer related to its misleading promotion of the pain medication Bextra.[134] After a five-year investigation, the attorneys general determined that despite clear advisal from the FDA, Pfizer had engaged in an "aggressive, deceptive and unlawful campaign" to promote off-label uses of the drug, despite the drug's severe side effects.[135] The resulting consent decree introduced a series of injunctions related to Pfizer's marketing practices. Notably, the decree bans the use of internal financial incentives for off-label marketing by the company's sales force.[136] Additionally, much like the Bayer settlement, which would be finalized the following year, this decree requires that Pfizer submit all television advertisements to the FDA for pre-approval.[137] In one curiously permissive term, the decree requires that Pfizer "not market two or more Products in a manner that falsely or misleadingly conflates the various properties of the respective Products."[138] In the event of noncompliance, the decree provides that any state attorney general may serve Pfizer with a notification outlining her concerns; after providing Pfizer 30 days to correct the issue, the state attorney general may initiate a separate civil action.[139] The decree notes explicitly that it does not

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[132] *Nevada and Other States Settle with Pfizer over Antibiotic Ads*, Nevada Appeal, Jan. 7, 2003, https://www.nevadaappeal.com/news/2003/jan/07/nevada-and-other-states-settle-with-pfizer-over-an/
[133] Melody Peterson, *Pfizer Settles an Inquiry into Ads for an Antibiotic*, The New York Times, Jan. 7, 2003, https://www.nytimes.com/2003/01/07/business/pfizer-settles-an-inquiry-into-ads-for-an-antibiotic.html
[134] Press Release, Illinois Office of the Attorney General, *Madigan, 33 AGs Reach $60 Million Settlement with Pfizer*, Oct. 22, 2008, https://ag.state.il.us/pressroom/2008_10/20081022.html
[135] Id.
[136] *State v. Pfizer Inc*, No. C20087337, 2008 WL 5478266 (Ariz. Super. 2008).
[137] Id.
[138] Id.
[139] Id.

"create a private cause of action or confer any right to any third party for violation of any federal or state statute."[140]

In 2009, Pfizer entered another multistate settlement, this time for a total of $33 million.[141] Here, 43 state attorneys general alleged that Pfizer marketed the antipsychotic Geodon for off-label uses, which troublingly included pediatric use.[142] The terms of this decree are generally narrower than those of the 2008 settlement, as the majority of the injunctive language relating to Pfizer's marketing practices only introduces limitations related to Geodon.[143] An additional goal of the decree appears to be disclosure and transparency; it includes provisions requiring Pfizer to publicize grants, physician payments, and clinical research.[144] The section on noncompliance closely mirrors the language of the 2008 settlement, providing the states a right of action following 30 days' notice.[145] Again, this decree bars private rights of action against Pfizer for any future violations.[146]

In 2012, Pfizer yet again settled with 34 states over familiar claims of misleading marketing. The attorneys general alleged that in promoting the antibiotic Zyvox, Pfizer repeatedly emphasized its superiority over competing products, despite a lack of evidence indicating that Zyvox was a more effective product in treating infection.[147] Further, Pfizer allegedly continued to assert the superiority of Zyvox in its marketing even after it received a

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[140] Id.
[141] Press Release, Arizona Office of the Attorney General, *Goddard Announces $33 Million Drug Marketing Settlement with Pfizer*, Sept. 2, 2009, https://www.azag.gov/press-release/goddard-announces-33-million-drug-marketing-settlement-pfizer
[142] Id.
[143] Consent Decree, *State of Washington v. Pfizer, Inc.*., No. 09-2-33085-9SEA (King County Sup. Ct., Washington).
[144] Id.
[145] Id.
[146] Id.
[147] Press Release, Ohio Office of the Attorney General, *DeWine, 32 Attorneys General Reach a $43 Million Settlement with Pfize*r, Dec. 12, 2012, https://www.ohioattorneygeneral.gov/Media/News-Releases/December-2012/DeWine-32-Attorneys-General-Reach-a-$43-Million-Se

warning letter from the FDA[148] Additionally, the attorneys general claimed that Pfizer promoted off-label uses, including common migraine treatment, for Lyrica, a drug approved to treat limited neuropathic conditions.[149] The resulting consent decree barred Pfizer from promoting any off-label uses for its medications and from continuing its Zyvox superiority claims.[150]

LIMITATIONS OF CONSENT DECREES

Reviewing the cases of Bayer and Pfizer reveals the trends and shortcomings of consent decrees. The consent decrees discussed above outline an even more limited array of enforcement mechanisms than are available through CIAs, though perhaps to similar effect. The only enforcement mechanism discussed in the Bayer and Pfizer decrees was the initiation of separate civil action by the states. The consent decrees did not incorporate a system of penalties; additionally, because the consent decrees reviewed did not bind federal parties, exclusion from Medicare and Medicaid was not available as an enforcement mechanism. However, as the review of CIA compliance demonstrated, neither structured penalties nor exclusion provided a viable deterrent to continued noncompliance. Further, the consent decrees generally explicitly barred third party rights of action for violation of the terms. Conversely, third party rights of action were available under the laws governing the CIAs, though unsupported whistle blowers struggled to bring successful claims in federal court.

Again, the patterns of noncompliance outlined above indicate that the threat of future civil actions has been a weak deterrent for future violations. Both Bayer and Pfizer persisted in

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[148] Press Release, Delaware Department of Justice, *Biden Reaches Settlement with Pfizer over Improper Marketing Practices*, Dec. 12, 2012, https://news.delaware.gov/2012/12/12/biden-reaches-settlement-with-pfizer-over-improper-marketing-practices/

[149] Id.

[150] Press Release, Ohio Office of the Attorney General, *DeWine, 32 Attorneys General Reach a $43 Million Settlement with Pfize*r, *supra* note 116.

the improper marketing of a range of drugs despite a series of consent decrees designed to halt the practice. In the case of Bayer, the company allegedly violated its 2007 settlement within a year; then, after reaching another settlement in 2009, Bayer allegedly continued to violate the terms of that second settlement for years. Though Pfizer's settlements did not refer to each other internally, Pfizer's marketing of Zyvox and Lyrica was a clear violation of its 2008 settlement, which barred the company from marketing two or more drugs in a false or misleading fashion. Clearly, the threat of future litigation did not have a significant impact on the marketing practices of either company.

The consent decrees binding Bayer and Pfizer introduced a novel type of relief in the form of corrective advertising campaigns; Bayer was required to carry out corrective campaigns in 2000 and 2009, and Pfizer was required to carry out a corrective campaign in 2003. These corrective campaigns reflect the decrees' broader emphasis on transparency and seemingly invoke the notion that some degree of public humiliation can serve as an additional deterrent. This notion is well-founded, though as discussed in the following section, its impacts are limited by the pharmaceutical industry's unique relationship with its customers.

V. EXTERNAL FACTORS

1. The Reduced Role of the Consumer

One general benefit of high-profile corporate settlements is the threat of diminished public perception. This 'naming and shaming' theory of settlements holds that when settlements damage a corporation's reputation by forcing a public apology or retraction or by generally drawing negative publicity, the resulting damage to the corporation's public image can serve as a

powerful deterrent for future bad behavior.[151] Psychological research suggests that even when a defendant in a settlement does not admit to any wrongdoing or offer an apology, the public generally infers the defendant's responsibility, which can impact that defendant's reputation.[152]

However, the pharmaceutical industry's consistently negative public perception minimizes the impact that high-profile settlements can have on the reputations of pharmaceutical companies. Since 2001, Americans have almost exclusively held net negative views of the pharmaceutical industry, with Gallup polls finding that those with positive views of the industry outnumbered those with negative ones in only three years across the last two decades.[153] Further, in part due to rising prices, public perceptions have only worsened in recent years.[154] In fact, in 2019, the pharmaceutical industry became the most "poorly regarded industry in Americans' eyes," ranking behind oil and gas companies as well as the federal government in an assessment of 25 sectors.[155]

The COVID-19 pandemic and the pharmaceutical industry's quick response in manufacturing vaccines benefitted the industry's levels of public trust, but Americans continue to distrust the industry more than other major markets. In a 2021 study, while participants from other nations including the United Kingdom, India, and South Africa reported relatively high levels of trust in the pharmaceutical industry, 50% of American respondents indicated a serious distrust towards biopharmaceutical companies; Americans primarily cited high prices and a view

[151] Joshua Andrix, *Negotiated Shame: An Inquiry into the Efficacy of Settlement in Imposing Publicity Sanctions on Corporations* (2007) 28 Cardozo L. Rev. 1857.
[152] Jennifer Robbennolt et. al., *The Psychology Behind How the Public Assigns Fault and Responsibility*, 54 Judicial Notebook 35 (2023).
[153] Justin McCarthy, *Big Pharma Sinks to the Bottom of U.S. Industry Rankings*, Gallup, Sept. 3, 2019, https://news.gallup.com/poll/266060/big-pharma-sinks-bottom-industry-rankings.aspx
[154] Id.
[155] Id.

of pharmaceutical companies as profit-focused ventures as the sources for their distrust.[156] Notably, individuals suffering from or at high risk of serious disease, a key market for the pharmaceutical industry, reported the highest levels of distrust.[157]

Because Americans have a consistently negative view of the pharmaceutical industry, deeming pharmaceutical companies as more interested in profit than patient care, the potential reputational damage of high-profile settlements is diminished. Americans expect pharmaceutical companies to behave in profit-seeking and unpalatable ways. Therefore, when state attorneys general announce yet another settlement in response to the industry's bad behavior, consumers are not surprised. Public perception the pharmaceutical industry is so consistently negative that high-profile settlements are unlikely to shame those companies into future compliance; in terms of reputation, pharmaceutical companies have little to lose.

Furthermore, even if consumers felt compelled to switch from brand-name to generic drugs in response to allegations of unlawful activity by drug manufacturers, they would face logistical, financial, and psychological hurdles, many of which have been crafted by the pharmaceutical industry. The generic drug market, the only viable alternative to taking a name-brand drug, is fraught with problems that prevent customers from making the switch. For one, the generic drug market is vulnerable to price spikes, due in great part to the fact that the majority of generic drugs have two or less suppliers in the U.S. market.[158] Additionally, pharmaceutical companies regularly interfere in the generic market, preventing suppliers from

[156] Greg Reh et. al., *Overcoming Biopharma's Trust Deficit*, Deloitte Insights, May 6, 2021, https://www2.deloitte.com/us/en/insights/industry/life-sciences/trust-in-biopharmaceutical-companies-covid.html
[157] Yashaswini Singh et. al, *Factors Associated with Public Trust in Pharmaceutical Manufacturers*, JAMA Network Open, Mar. 14, 2023, doi:10.1001/jamanetworkopen.2023.3002
[158] *Competition in Generic Drug Markets*, National Bureau of Economic Research, Nov. 2017, https://www.nber.org/digest/nov17/competition-generic-drug-markets

accessing name-brand drug samples or entering into "pay to delay" agreements wherein would-be generic competitors agree to keep out of the market.[159]

Pharmaceutical companies also offer incentives to customers to discourage them from switching to more affordable alternatives. For one, pharmaceutical companies regularly offer general copay assistance, which reduces insured patients' personal costs; as of now, this practice remains legal in 31 states.[160] Pharmaceutical companies also target generic competitors specifically by offering customers "copay coupons," which cover the difference in cost between generic and brand-name products.[161] So far, only California and Massachusetts have outlawed copay coupons, though other states have considered similar bans.[162]

Finally, aggressive advertising by pharmaceutical companies, paired with a general lack of knowledge about the generic market, prevent consumers from pursuing generic alternatives. A 2021 study found that while consumers are generally aware of lower-priced generic options for over-the-counter medications, they tend to associate generic drugs with greater risk and lower quality.[163] Consumers continue to place greater trust in the brands they know and recognize and are generally more suspicious of generic labels, despite significantly lower prices.[164] Therefore, a lack of familiarity with and knowledge of generic medications creates a psychological disincentive for forgoing brand names for generics.

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[159] *Ten challenges in the prescription drug market – and ten solutions*, Brookings Institute, May 2, 2017, https://www.brookings.edu/articles/ten-challenges-in-the-prescription-drug-market-and-ten-solutions/
[160] *State Copay Accumulator Bans Will Affect 19% of US Commercial Lives*, Avalere, May 13, 2022, updated Jun 22, 2023, https://avalere.com/insights/state-copay-accumulator-bans-impact-11-of-us-commercial-lives
[161] *Ten challenges in the prescription drug market – and ten solutions*, Brookings Institute, *supra* note 128
[162] Leemore Dafny et. al., *Eliminating Prescription Drug Copay Coupons*, 1% Steps for Health Care Reform Project, https://onepercentsteps.com/policy-briefs/eliminating-prescription-drug-copay-coupons/
[163] Lisa Aufegger et. al., *The Risk-Value Trade-Off: Price and Brand Information Impact Consumers' Intentions to Purchase OTC Drugs*, 14 Journal of Pharmaceutical Policy and Practice 11 (2021), https://doi.org/10.1186/s40545-020-00293-5
[164] Id.

2. Economic Incentives

While already poor public perception and difficulties in accessing the generic market provide weak disincentives for repeated unlawful behavior by pharmaceutical companies, the harsh reality is that pharmaceutical companies have incredibly strong economic incentives for noncompliance. An examination of reported profits for drugs that have been the subject of multistate settlements demonstrates that revenues far outweigh the related penalties.

For example, as outlined above, in 2003 Pfizer paid a total of $8 million between civil penalties and a corrective advertising campaign over allegations that the company improperly marketed the anti-biotic Zithromax. In 2002, Zithromax earned Pfizer over $1 billion.[165] Similarly, Bayer pledged $20 million to a corrective campaign over allegations that in violation of a prior settlement, the company had marketed the contraceptive Yaz for off-label uses in 2008. A best-seller for Bayer, Yaz earned the company €602 million globally in the first half of 2008, a marked increase from 2007.[166]

In 2011, AstraZeneca entered into a $68.5 million settlement with 38 states over allegations that the company had promoted off-label uses for the anti-psychotic Seroquel.[167] AstraZeneca's profit report for the first half of 2009, a period during which AstraZeneca was allegedly engaging in improper marketing of Seroquel, indicates that Seroquel sales in the U.S. alone brought in approximately $1.6 billion, an increase over the previous year.[168] Therefore, the

[165] Melody Peterson, *Pfizer Settles an Inquiry into Ads for an Antibiotic*, *supra* note 102.
[166] *Stockholder's Letter: Half-Year Financial Report as of June 30, 2008*, Bayer Corporation, https://www.bayer.com/sites/default/files/2020-04/ab-q2-2008-en.pdf
[167] Press Release, Washington Office of the Attorney General, *States Reach Record $68.5 Million Settlement with Seroquel Maker*, Mar. 9, 2011, https://www.atg.wa.gov/news/news-releases/states-reach-record-685-million-settlement-seroquel-maker
[168] *Second Quarter and Half Year Results 2009*, AstraZeneca PLC, Jul. 30, 2009, https://www.astrazeneca.com/content/dam/az/media-centre-docs/press-releases/2009/Q2/Narrative.pdf

settlement amount negotiated by the state attorneys general represented less than 5% of the drug's profits over the course of just six months.

Even in the case of GSK, a record-breaking settlement amount of $3 billion in 2012 did not truly stagger the corporation. In its 2012 annual report, GSK noted that though "free cash flow was adversely impacted by legal settlements," it netted a free cash flow of over £2 billion in 2012.[169] The report proudly relayed that in the US, its "operating profit increased 1% to £4.8 billion as a result of our continuing efforts to simplify our processes and produce efficiencies in our operations."[170] GSK was ultimately able to return £6.2 billion to its shareholders in 2012.[171]

Further, pharmaceutical companies limit the financial impact of settlements by setting aside litigation reserves in their annual budget. For example, in 2022, Pfizer's litigation reserve contained $385 million.[172] In 2016, in anticipation of large settlements with the DOJ and SEC, Teva Pharmaceutical Industries established a reserve of $520 million.[173] Though litigation is inherently unpredictable, such reserves allow pharmaceutical companies to weather the storm of multimillion dollar settlements more effectively.

VI. BROAD RECOMMENDATIONS FOR STATE ATTORNEYS GENERAL

In light of the patterns of noncompliance with multistate settlements by pharmaceutical companies and the balance of incentives and disincentives driving continued noncompliance, this section offers several broad recommendations for state attorneys general engaging in multistate

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[169] *Annual Report 2012*, GlaxoSmithKline PLC, https://www.gsk.com/media/8077/annual-report-2012.pdf, page 69
[170] Id. at 20.
[171] Id. at 7.
[172] Pfizer, Inc., *Form 10-K,* Dec. 31, 2022, https://s28.q4cdn.com/781576035/files/doc_financials/2022/ar/PFE-2022-Form-10K-FINAL-(without-Exhibits).pdf
[173] Gary Giampetruzzi et. al., *Teva Pharmaceuticals Announces a Reserve of $520M in View of What Stand to Be the Fourth Largest FCPA Resolution to Date*, Paul Hastings, Nov. 17, 2016, https://www.paulhastings.com/insights/client-alerts/teva-pharmaceuticals-announces-a-reserve-of-520m-in-view-of-what-stands-to-be-the-fourth-largest-fcpa-resolution-to-date

litigation within the pharmaceutical industry. The first recommendation relates directly to the scope and enforcement of future multistate settlements with pharmaceutical companies, while the second and third recommendations relate to broader actions state attorneys general might take to diminish the power of major pharmaceutical companies outside of litigation.

1. Consider Alternative Forms of Penalties and Enforcement

As examined in Section V, monetary damages of any amount tend to be an ineffective deterrent for the pharmaceutical industry. The true power of multistate suits against pharmaceutical companies is the potential for wide-ranging injunctive relief embodied in consent decrees or CIAs. As the various settlement terms cited in Section IV indicate, injunctions can increase transparency within pharmaceutical companies by compelling mandatory reporting and publication, corrective advertising, and disclaimers. Further, as the cases of Omnicare and GSK indicate, such injunctive relief can create genuine reform.

As it stands, the greatest obstacle to the efficacy of such injunctive terms is the lack of viable enforcement mechanisms. The threat of monetary penalties or future suits has proven to be a weak deterrent due to the immense financial resources of major pharmaceutical companies. On the other end of the spectrum, the very severity of the threat of exclusion renders it impractical. The exclusion of a major pharmaceutical company from Medicare and Medicaid, even temporarily, is unprecedented and could have devastating effects on the health of consumers as well as the economy, given the potential for repercussions in the stock market as well as massive layoffs. Since such consequences would be politically disastrous, any elected official is unlikely to pursue exclusion. Ultimately, as the discussion in Section III indicates, if

injunctive measures cannot be effectively enforced, pharmaceutical corporations will almost inevitably skirt them.

Therefore, state attorneys general should pursue alternative means of enforcement, namely civil contempt citations. When a court retains jurisdiction over a consent decree, it may issue a civil contempt citation, accompanied with sanctions, to force compliance with the terms of the consent decree.[174] One benefit of contempt proceedings in this context is the relative ease of constructing a prima facie case. As outlined in Section IV, state attorneys general have repeatedly responded to violations of an existing consent decree by effectively relitigating the matter, building a new case against the pharmaceutical companies based on the violating actions. These cases tend to be quite complex and demand a great deal of investigation, requiring state attorneys general offices to dedicate significant portions of their time, personnel, and budget to the matter. On the other hand, civil contempt proceedings are fairly streamlined. A prima facie showing generally requires a party to demonstrate that a valid and clear court order was violated and that the violating party had the initial ability to comply with the order.[175] The investigation into violations of specific consent decree terms would be far more targeted than the investigation demanded by a complex antitrust or consumer protection suit, making it a more efficient choice for state attorneys general offices.

A second benefit of civil contempt citations is that the governing court has broad discretion in assessing and fashioning appropriate sanctions. Courts may consider not only the harm of the noncompliance in question, but also the financial resources of the violating party and the willfulness of the violation.[176] Therefore, a court presiding over a multistate pharmaceutical

[174] *Can a district court hold a party in civil contempt for failing to comply with provisions of a settlement agreement?*, Larsen, Navigating the Federal Trial § 21:27 (2023 ed.).
[175] C*ontempt Proceedings*, Rutter Group Practice Guide: Fed. Civil Trials & Evidence, Chapter 13-E.
[176] Id.

settlement could consider not only the seriousness of the violation but also the resources available to the corporation in crafting an appropriately coercive penalty. Furthermore, courts have broad discretion in fashioning sanctions when issuing a contempt citation. Financially, a court can order either monetary penalties or the sequestration of property to compel compliance with settlement terms.[177] As an additional penalty, the court can reward attorney's fees for the cost of the contempt proceedings, which would be valuable for some underfunded state attorneys general offices.[178] Further, limited case law suggests that in extreme circumstances of repeated failure to comply, corporate representatives can be imprisoned in connection with corporate civil contempt citations.[179] The flexibility and discretion permitted by civil contempt citations renders them a viable alternative to the enforcement mechanisms previously contemplated in multistate settlements with pharmaceutical companies.

Additionally, in future multistate litigation of pharmaceutical companies, state attorneys general should pursue individual penalties in addition to corporate penalties. This approach has already shown success, with the Securities and Exchange Commission announcing in 2020 that three executives from Valeant Pharmaceuticals would pay penalties as part of a broader settlement resolving allegations of misleading disclosures to the agency.[180] Given that the imbalance of incentives discussed in Section IV makes it unlikely that corporate penalties will ever prove an effective disincentive, individual penalties may be the most direct mechanism to discourage pharmaceutical higher-ups from participating in or encouraging unlawful schemes.

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[177] *Fiedler v. Bambrick Bros. Const. Co.,* 142 S.W. 1111, 1113-14 (1912).
[178] *Chambers v. NASCO, Inc*., 501 U.S. 32, 55-58 (1991).
[179] *Anthony Marano Co. v. A. Stallone, Inc.*, 2002 WL 31875471 (N.D. Ill. Dec. 24, 2002). In this case, the court held that after failing to appear on behalf the defendant corporation at both discovery and citation proceedings, a named corporate representative could be imprisoned to compel both her personal obligations as well as the corporate defendant's obligations. The court noted that a warrant for imprisonment was appropriate where "additional monetary sanctions are unlikely to be effective."
[180] Press Release, Securities and Exchange Commission, *Pharmaceutical Company and Former Executives Charged with Misleading Financial Disclosures*, Jul. 31, 2020, https://www.sec.gov/news/press-release/2020-169

Further, in select, fact-dependent circumstances, state attorneys general should consider seeking criminal charges against responsible individuals within pharmaceutical companies. As the case of *Friedman v. Sebelius* demonstrates, criminal charges for corporate officers within pharmaceutical companies are a viable enforcement mechanism.[181] Criminal charges under the responsible corporate office doctrine are an extreme penalty, and they would not be feasible in every case. However, the patterns of noncompliance outlined in Section III detail blatant disregard for federal and state law as well as court ordered settlement terms; where other enforcement mechanisms have failed to adequately deter noncompliance, extreme measures may be appropriate. The potential for criminal charges creates a strong disincentive for individual complicity. For one, as noted above, the fear of personal financial penalties is more powerful than the fear of broader corporate penalties when it comes to corporations with deep pockets. Additionally, as *Friedman* demonstrates, even a criminal misdemeanor charge can derail a pharmaceutical executive's career by opening them up to personal exclusion. I suspect that corporate executives would be far less complacent with profitable but illicit practices if their personal finances and careers could be at stake.

2. Use the Bully Pulpit

As addressed in Section IV, the pharmaceutical industry has manipulated the drug market in a number of ways to prevent its customers from switching from name-brand to generic drugs, thereby assuring their continued dominance of the marketplace. Outside of litigation, state attorneys general can take broader steps to further curtail pharmaceutical companies and reduce

[181] *Friedman v. Sebelius*, 686 F.3d 813 (D.C. Cir. 2012).

their relative power in the marketplace. As a result, pharmaceutical companies may not be in the same financial position to flaunt settlement agreements.

State attorneys general, in addition to their investigative and litigative powers, have a number of soft law powers that allow them to shape regulations and mold public discourse. For one, state attorneys general have a powerful platform from which they can lobby for much-needed changes to state and federal laws. Given this, I would recommend that state attorneys general advocate for legislation which would curtail domineering practices in the pharmaceutical industry.

For one, state attorneys general can advocate for bans on copay assistance and coupons, which disincentive consumers from pursuing generic alternatives. As noted in Section IV, only 19 states have banned copay assistance, and only two have banned copay coupons. State attorneys general in states that have not pursued such laws can work with state legislatures and encourage their adoption.

Further, at the federal level, state attorneys general can advocate for federal policies that would allow generic competitors greater access the market. Would-be generic competitors currently face difficulties in accessing brand-name formulas and getting approval for generic manufacturing; these difficulties could be alleviated through more transparent and streamlined FDA regulations.[182] Many state attorneys general have developed close working relationships with the FDA through a number of collaborative settlements, as outlined in Section III. State attorneys general should capitalize on this relationship and call for the adoption of new regulations to reduce the burden of generic competitors.

[182] *Ten challenges in the prescription drug market – and ten solutions*, Brookings Institute, *supra* note 128.

State attorneys general should also advocate for changes to federal legislation which would make violation of CIAs a more costly venture for pharmaceutical companies. As discussed in Section III, unsupported third parties face extreme difficulties in bringing *qui tam* actions under the False Claims Act against pharmaceutical companies committing fraudulent activity in violation of CIAs. State attorneys general should call for amendments to the legislation which lower the burden for *qui tam* actions, thereby exposing pharmaceutical companies to greater liability for CIA violations.

In a similar vein, state attorneys general should more comprehensively engage their constituents on the issues of illicit activity by pharmaceutical companies and the availability of generic alternatives. Because of its unique oversight capabilities, the FDA is typically the first party to become aware of illicit activity in the pharmaceutical industry. However, state attorneys general can also contribute to the awareness of illicit activity in the industry by encouraging constituents to reach out and report any concerns they may have with the ways that their drugs are being priced or marketed. Some individuals may fail to report concerns to the FDA due to concerns over federal red tape or a general distrust of the administration or the federal government as a whole. State attorneys general could fill this gap by creating points of contact, such as phone numbers or website links, through which their constituents could easily report their concerns.

Further, state attorneys general should take a leading role in educating the public on the generic drug market. As Section IV outlined, some individuals are unaware of the viability of generic alternatives and believe that the lower generic prices reflect poorer quality. State attorneys general can use their platforms to provide resources on generic alternatives and highlight their viability.

3. Targeted Use of Funds

Finally, state attorneys general should make the most of their settlement funds. Indiana Attorney General Greg Zoeller received wide-spread praise for his approach to public health crises during his tenure, using pharmaceutical settlement funds to purchase Narcan and rally resources to combat the spread of opioids.[183] So long as pharmaceutical companies continue to enter and violate multistate settlements, state attorneys general should use the funds to combat and reverse the damage done by pharmaceutical companies in their states. State attorneys general can lead the charge in their home states to purchase and distribute Narcan, establish educational platforms and offer trainings, and further fund opioid litigation.

As the tobacco litigation demonstrated, securing settlement funds is easier said than done. However, state attorneys general should make a concerted effort to retain and direct pharmaceutical settlement funds. They can potentially leverage the political popularity of an anti-pharma stance to get the governors and state legislators on board. As addressed above, the pharmaceutical industry is widely distrusted in the US, and communities across the country are all too familiar with the fatal consequences of the industry's reckless practices.

VII. CONCLUSION

Over the past four decades, pharmaceutical companies have entered into multistate settlements at an alarming high rate. Of the 24 corporations which have entered into four or more

[183] Maureen Hayden, *State of the Statehouse: Zoeller Leaves Attorney General Role with Legacy in Public Health*, Tribune-Star, Dec. 25, 2016, https://www.tribstar.com/news/news_columns/state-of-the-statehouse-zoeller-leaves-attorney-general-role-with-legacy-in-public-health/article_6f7b63a4-cb0e-11e6-988b-bfc9cd01005b.html.

multistate settlements, 13 are pharmaceutical companies. On average, those 13 companies have entered into six multistate settlement agreements.

These statistics suggest that multistate litigation has been somewhat ineffective in curbing illegal activity within the pharmaceutical industry, a conclusion which is supported by an examination of several case studies. The settlement patterns of Omnicare and GSK indicate that though CIAs can introduce valuable regulatory requirements, they lack sufficient enforcement mechanisms to ensure full compliance. The settlement patterns of Bayer and Pfizer demonstrate that consent decrees are similarly ineffective in deterring noncompliance, as both companies repeatedly violated the terms of their multistate settlements, often soon after their effective dates.

Failures in compliance can in part be explained by the balance of incentives and disincentives created in the marketplace. Because public perception of the pharmaceutical industry is consistently poor, multistate settlements do not carry the additional deterrent of tarnishing a given company's reputation. Further, the pharmaceutical industry's manipulation of the drug market has ensured that customers are unlikely to pursue generic alternatives to name-brand drugs, allowing major pharmaceutical companies to dominate the market and retain customers even in the face of startling allegations. On the other hand, remarkably high profits from drug sales provide a strong incentive for pharmaceutical companies to flaunt the terms of their settlement agreements, and their litigation reserve funds dampen the sting of large payouts.

In light of these factors, my broad recommendations for state attorneys general include alternative enforcement mechanisms. State attorneys general should pursue contempt citations for settlement violations due to the efficiency of contempt proceedings as well as the court's flexibility in crafting contempt sanctions. Furthermore, state attorneys general should pursue individual penalties under the responsible corporate officers doctrine to create a stronger

personal disincentive for corporate executives' involvement in, or tacit sponsorship of, illegal activities.

Additionally, I recommend that state attorneys general capitalize on their unique platform to encourage reforms which would diminish the role of major pharmaceutical companies in the drug market. State attorneys general should also engage directly with their constituents on the topic and provide reporting mechanisms and educational resources to the citizens of their states.

Finally, I recommend that state attorneys general steer pharmaceutical settlement funds towards causes which will directly address and correct the damage wrought by the pharmaceutical industry's reckless business tactics. State attorneys general should use money from pharmaceutical settlements to combat opioid addiction and overdoses and to fuel opioid litigation.