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# The Newest 'War on Drugs': Regulating Pharmaceuticals through State Litigation

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# The Newest "War on Drugs": Regulating Pharmaceuticals through State Litigation

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**Abstract:** State-driven litigation has had increasing influence in the development of national policy in recent years, including in national health policy. One prominent recent example includes the efforts of several state governments to bring coordinated constitutional challenges against one of the Obama Administration's key first term achievements, the Patient Protection and Affordable Care Act. This paper examines how states have influenced health care policy influence in a more subtle but no less important litigation campaign. Over the past decade, state prosecutors have reached numerous multi-million dollar settlements with the nation's largest pharmaceutical companies imposing a variety of restrictions on prescription drug pricing and advertising. Though often relying upon state law claims, these settlements have created new *de facto* national standards covering the drug industry – frequently going beyond and even against express congressional action. Relying upon an analysis of numerous legal cases, investigations, and settlements, this paper traces the development of this persistent litigation campaign and discusses the wide policy implications state litigation has had in this area. In doing so, the paper raises important broader questions about the operation of modern American public policy.

A longstanding feature of the American political system is its remarkable fragmentation. Political power is distributed not only horizontally among the three main branches of government but vertically between the federal government and a myriad of state and local government actors. Despite increasing centralization of power in the federal government during the twentieth century, this significant structural fragmentation is kept alive by record levels of public mistrust of the federal government on both ends of the political spectrum.

As many scholars have noted, this structural fragmentation has important consequences for public policy. Perhaps most importantly, it creates special political challenges in an era in which increasing political polarization combines with public demands for the government to solve problems. There have been suggestions that this political polarization and structural fragmentation is a recipe for perpetual gridlock, demanding a radical overhaul of the structure of the system.<sup>1</sup> Other scholars have highlighted how the many veto points available to opponents of policy change have led to attempts at "unorthodox lawmaking" in various venues.<sup>2</sup> One of these methods of unorthodox lawmaking has been an increasing reliance on courts and litigation as a way to resolve disputes and implement public policy – a dynamic Robert Kagan has termed "adversarial legalism."<sup>3</sup>

This paper examines an important yet underappreciated new development in the politics of adversarial legalism, one illustrating how the fragmentation of the American political system creates not just veto points and perpetual gridlock but "opportunity points" for policy development as well.<sup>4</sup> In recent years, state prosecutors have become key opportunity points as they have increasingly turned to litigation consciously aimed at changing policy. Most famously, forty-six states negotiated a massive settlement with several tobacco firms in 1998 that included not just massive payouts to the states but a host of new

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<sup>1</sup> Sanford Levinson, *Our Democratic Constitution* (Oxford, UK: Oxford University Press, 2006).

<sup>2</sup> Barbara Sinclair, *Unorthodox Lawmaking*, 4<sup>th</sup> ed. (Washington D.C.: CQ Press, 2011).

<sup>3</sup> Robert Kagan, *Adversarial Legalism* (Cambridge, MA: Harvard University Press, 2001).

<sup>4</sup> The notion of "opportunity points" is borrowed from R. Shep Melnick, *Between the Lines: Interpreting Welfare Rights* (Washington D.C.: Brookings Instit. Press, 1994): 140-141.

regulatory requirements on the tobacco industry.<sup>5</sup> The states' more recent litigation campaigns have been at least as consequential as this earlier tobacco litigation. Several states have filed challenges to a variety of Obama Administration priorities, including most prominently the signature achievement of the Obama presidency to date – the Patient Protection and Affordable Care Act (PPACA). During the George W. Bush Administration, several states brought lawsuits against the Environmental Protection Agency, eventually winning several key cases concerning climate change and acid rain policy.<sup>6</sup>

Much state litigation, as with the tobacco litigation, has targeted private industry. In conjunction with federal prosecutors, for example, states have recently negotiated a giant \$26 billion settlement with the nation's largest banks concerning the banks' role in the foreclosure crisis.<sup>7</sup> In addition to the money involved, this settlement requires banks to change the way they service home loans and grants greater state oversight of federally regulated banks. Through litigation, the states have also targeted practices of Internet firms, major beverage manufacturers, the financial sector, and many other firms, wresting settlements imposing new regulatory requirements not required by federal regulators. Most importantly for the purposes of this paper, states have brought dozens of lawsuits against drug companies seeking not only monetary recoveries but important regulatory changes throughout the pharmaceutical industry.

Whether targeting the federal government or private corporations, the effect and often the explicit intent of this state-driven litigation is to change public policy. State litigation against the federal government aims to nullify congressional enactments such as the PPACA or force federal agencies such as the Environmental Protection Agency to change their regulatory posture. State litigation against large private corporations aims at reaching major settlements containing a mix of monetary and regulatory provisions. These settlements have succeeded in creating new *de facto* national

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<sup>5</sup> Martha Derthick, *Up in Smoke: From Legislation to Litigation in Tobacco Politics* (Washington D.C.: CQ Press, 2005).

<sup>6</sup> *Massachusetts v. EPA*, 549 U.S. 497 (2007).

<sup>7</sup> Nelson D. Schwartz and Shaila Dewan, "States Negotiate \$26 Billion Agreement for Homeowners," *New York Times*, February 8, 2012.

standards covering a variety of industries – frequently going beyond and even against express congressional action.

I focus on pharmaceutical litigation in this paper for a number of reasons. First, the developments I describe in this paper have been vitally important in the overall picture of health care policy – a policy area touching upon a significant percentage of the American economy. Through litigation conducted both independently and in conjunction with federal prosecutors and private litigators, states have subtly transformed the regulatory landscape for pharmaceutical products. This has been particularly true in the area of drug pricing and marketing.

Second, the state-driven pharmaceutical litigation described in this paper is part of a larger dynamic in which states have increasingly turned to litigation to achieve their policy goals. As the examples briefly noted previously indicate, states have engaged in regulatory litigation in a variety of policy areas including environmental protection, consumer protection, and antitrust enforcement. They have sought (and achieved) stricter oversight of industries ranging from mortgage lenders to Internet firms. In many of these areas, the states have claimed that they were acting to fill "regulatory gaps" left open by congressional or administrative inaction on the federal level.

Further, the emergence of state litigation in this area is a reminder of how policymaking in the fragmented American political system requires attention to the many interactions between different political institutions and different levels of government. Litigation, including state litigation, is best analyzed not in isolation but as part of the larger system of public policy in which developments on one level affect developments on another.<sup>8</sup> Understanding how and why states have increasingly turned to litigation as a powerful regulatory tool requires examining the actions of other political actors in the political system, including Congress and federal administrative agencies. For scholars interested in the dynamics of contemporary policymaking and regulation, this development is a reminder to be mindful of the many

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<sup>8</sup> For other studies emphasizing the important of inter-branch relationships, see Thomas Burke, *Lawyers, Lawsuits, and Legal Rights* (Berkeley, CA: U. of California Press, 2002); Jeb Barnes, *Overruled? Legislative Overrides, Pluralism, and Contemporary Court-Congress Relations* (Stanford, CA: Stanford U. Press, 2004); Sean Farhang, *The Litigation State: Public Regulation and Private Lawsuits in the U.S.* (Princeton, N.J.: Princeton University Press, 2010),,,

important and consequential complexities of the American political system.

## **Lawyers, Drugs, and Money: Litigating Pharmaceutical Prices**

The health care sector represents one of the largest and fastest-growing shares of the American economy, with total health care spending representing more than 17% of the United States' entire gross domestic product.<sup>9</sup> A significant portion of this spending is associated with spending for pharmaceutical products, which reached \$307 billion in 2010.<sup>10</sup> This rapid rise in health care costs has led to health care policy emerging as one of the most hotly contested items on the political agenda in recent years.

Because of the role prescription drugs have played as a driver of health care costs, pharmaceutical companies have increasingly come under the spotlight. The high cost of prescription drugs is of interest to state governments as well as the federal government because the Medicaid program, which provides medical care to those unable to pay for it, is jointly funded by both levels of government. Several members of Congress have suggested that the high costs of pharmaceuticals are the result of unscrupulous business practices, and several states have enacted legislation aimed at reducing the costs of prescription drugs for their residents.<sup>11</sup> Perhaps the most consequential development, however, has been state efforts to regulate drug prices through litigation.

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<sup>9</sup> "Health Care's Share of U.S. Economy Rose at Record Rate," *New York Times*, February 4, 2010.

<sup>10</sup> Gary Gatyas, "IMS Institute Reports U.S. Spending on Medicines Grew 2.3 Percent in 2010, to \$307.4 Billion," <http://www.imshealth.com/portal/site/ims/menuitem.d248e29c86589c9c30e81c033208c22a/?vgnnextoid=24b2f14cddc40310VgnVCM10000071812ca2RCRD&vgnnextfmt=default>.

<sup>11</sup> For a good overview of these state legislative efforts, see John Bentivoglio, Rosemary Maxwell, and Marc Stanislawczyk, "State Controls on Drug Costs: An Out-of-Control Experiment in Federalism?" *Pharmaceutical Law & Industry Report*, October 11, 2001. Also see Jill Wechler, "'War On Drugs' Attacks High Prices," *Pharmaceutical Technology*, June 2000, 14.

## *Prescription Drug Reimbursement in the Medicaid Program*

Before discussing these litigation efforts, it is important to understand the structure of Medicaid and how the program pays for prescription drugs. Unlike the federally funded and administered Medicare program, the health insurance program for the elderly, Medicaid places much of the responsibility for program operations on the states. Every state must create an agency to implement the Medicaid program, which is in turn overseen by the Centers for Medicare and Medicaid Services within the Department of Health and Human Services ("HHS"). These state agencies are tasked with carrying out various details of program administration.

As a joint federal/state venture, the funding for Medicaid services is also a shared responsibility between the two levels of government. The amount of the federal share for Medicaid payments varies from 50% to 76% of the total program costs, depending on the state. As of 2009, the total program costs for Medicaid totaled \$373.9 billion.<sup>12</sup> These costs have risen rapidly over the course of Medicaid's existence, driven in large part by the rapid increase in expenditures for pharmaceuticals. Unlike Medicare, which provided only a limited number of prescription drugs under the Part B health insurance program prior to the adoption of the Medicare Part D prescription drug benefit in 2005, Medicaid pays for a variety of prescription drugs for eligible individuals. Between 1997 and 2000, expenditures under Medicaid's drug benefit grew at an average annual rate of 18.1%, more than two times the 7.7% annual growth in total Medicaid spending.<sup>13</sup>

Pharmaceutical companies are not reimbursed directly under Medicaid. Instead, health care providers (such as pharmacies) pay drug companies for the drugs and are then reimbursed by the government according to a pricing benchmark for each drug. In both the Medicaid and Medicare programs, this pricing benchmark has long been the "Average Wholesale Price" (AWP) of the drug. In theory, the

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<sup>12</sup> Center for Medicaid Services, "National Health Expenditures 2009 Highlights," accessed March 9, 2012, <http://www.cms.gov/NationalHealthExpendData/downloads/highlights.pdf>.

<sup>13</sup> Dawn M. Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?" *National Health Policy Forum*, June 7, 2002.

AWP is meant to reflect the average price at which wholesalers sell prescription drugs to physicians, pharmacies, and other customers. The AWP, however, has no statutory definition, and the states have relied upon commercial publishers of drug pricing data, the most prominent being First DataBank, for the AWP of drugs covered by Medicaid. These commercial publishers in turn receive the AWP pricing information "based on data obtained from manufacturers, distributors, and other suppliers."<sup>14</sup> In other words, the AWP for any given drug have no set benchmark but instead originate from information provided by the manufacturers of that drug. Because of this manufacturer-reported pricing system, the AWP is akin to a "sticker price" or "list price" similar to those used in automobile sales.

Because the term "AWP" is not defined in law or regulation, the manufacturer may set the AWP at any level, regardless of the actual price paid by purchasers. A major consequence of this pricing system is that it gives health care providers – whom the government reimburses for their drug purchases based upon the AWP benchmark – an incentive to prescribe drugs where the greatest difference exists between the listed AWP and the actual price they pay for the drug. This difference is often referred to as the "spread," which the providers can then use to bolster their own revenues. This, in turn, gives drug manufacturers an incentive to increase the spread by increasing the AWP benchmark they report to commercial drug price publishers such as First DataBank. By doing so, drug companies can encourage the utilization of their drugs by providing larger spreads to health care providers.

### *The Clinton Administration Tries to Change the AWP Benchmark*

The government has long been aware of the potential that these incentives would drive up drug costs. As early as 1968, the Task Force on Prescription Drugs of the Department of Health Education and Welfare noted that the AWP could be used as an "umbrella" beneath which the [pharmaceutical] company can maneuver against competing products." In 1977, the Health Care Financing Administration (the predecessor to the Centers for Medicare and Medicaid Services within

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<sup>14</sup> Ibid.; Medical Economics Staff, eds., *Red Book, 106th ed.* (Montvale, N.J.: Thomson Medical Economics, (2002), 169.



HHS) unsuccessfully tried to get states to move away from AWP. As concern about rising health care costs reached even higher levels in the 1990s, President Clinton noted the potential for higher costs to the government because of the flawed, but legal, AWP system. In a 1997 address calling for additional efforts to reduce health care costs, Clinton explained the AWP system as an example of a type of "waste and abuse" that "aren't even illegal [because] they're just embedded in the practices of the system."<sup>15</sup> For years, the difference between AWP and the actual market prices for drugs led pharmaceutical industry observers to refer to AWP as "Ain't What's Paid."<sup>16</sup>

Despite these concerns, neither Congress nor the states replaced the use of the manufacturer-reported AWP benchmark. The reason had largely to do with the testimony of physicians, particularly oncologists, who argued that there would be no way for them to stay in business and serve Medicare and Medicaid recipients without benefiting from the "spread" created by the AWP.<sup>17</sup> While the AWP indeed exceeded the providers' costs for drugs, the spread helped to make up for inadequate government payments related to other professional services provided under Medicare and Medicaid.

Congress was generally swayed by these arguments, particularly the prospect that AWP cuts would lead to more limited access to services available to Medicare and Medicaid enrollees. This was true even when the Clinton Administration made a significant push in the 1990s to alter the AWP system for the purposes Medicare drug reimbursements. In his 1998 budget proposal, Clinton proposed eliminating AWP and replacing it with a formula directly related to actual acquisition costs paid by providers. Congress rejected this proposal, instead making much less drastic changes to the drug reimbursement formula.<sup>18</sup> The Administration subsequently fought for

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<sup>15</sup> James M. Spears and Jeff Pullman, "Using Litigation to Regulate Drug Prices: The Assault," *Medical Marketing and Media*, June 2002, 72.

<sup>16</sup> Paul E. Kalb, I. Scott Bass, and Robert Fabrikant, "The Average Wholesale Price: It 'Ain't What the Government Wants to Pay,'" *Health Care Fraud Report*, February 21, 2001, 182.

<sup>17</sup> Terry Carter, "Drug Wars," *ABA Journal*, December 2002, 44.

<sup>18</sup> Public Law No. 105-33 §4556(a), 11 Stat. 251 (1997). Also see "Plan Targets Medicare Waste to Save Billions," *Washington Post*, December 7, 1998, A2; Joan H. Krause, "A Conceptual Model of Health Care Fraud Enforcement," *Journal of Law and Policy*, 127 (2004).

larger tweaks to the AWP payment system in both 1999 and 2000, but neither of these proposals gained traction in Congress.

### *The Fight Moves from Congress to the Courts*

Amidst these failed attempts at statutory changes of the AWP formula in Congress, the Clinton Administration DOJ, along with several states, began shifting to a litigation strategy by investigating the use of AWP by certain pharmaceutical companies. The investigation, which focused on the activities of more than a dozen large pharmaceutical firms, examined the way in which drug companies "marketed the spread" between AWP and actual costs to provide incentives to providers to prescribe their products and apply for reimbursements under Medicare and Medicaid. According to the government prosecutors, this practice represented actionable fraud. One letter from New York Attorney General Eliot Spitzer to Medicaid pharmacy directors across the country announced that this investigation "has revealed a pattern of misrepresentation by some drug manufacturers" resulting in Medicare and Medicaid "substantially" overpaying for certain drugs.<sup>19</sup> This "misrepresentation" was the use of allegedly inflated AWP information reported by manufacturers to the commercial publishers of drug pricing data.

The governments' first step was to pressure First DataBank, the largest of these commercial publishers, to alter the way it reported prices for several dozen prominent drugs. In the face of the growing federal/state investigation, the company agreed in 2000 to list prices that the state prosecutors determined were closer to what providers actually paid for the drugs. Following this informal agreement, Spitzer noted that this pricing change would likely result in "initial complaints or objections about lowered Medicaid payments" by providers,<sup>20</sup> which is precisely what occurred when the Health Care Financing Administration announced plans to use these new rates reported by First DataBank to compensate providers.

Following the predicted outrage from health care providers, particularly oncologists worried about reimbursement rates under Medicare, Congress enacted the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000. This act, among

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<sup>19</sup> Julie Appleby, "Drug Pricing Probed," *USA Today*, April 6, 2000, 1A.

<sup>20</sup> *Ibid.*

other things, precluded the HHS Secretary from "directly or indirectly decreas[ing] the rates or reimbursement...under the current reimbursement methodology" until the General Accounting Office released a study on the matter of AWP and it was reviewed by HHS.<sup>21</sup>

With Congress clearly hesitant to proceed with any significant changes to the AWP system, state and federal prosecutors pressed ahead with their investigation. The government coalition reported that it had uncovered a variety of "fraudulent" behavior by the pharmaceutical companies that had ultimately cost the federal and state governments billions of dollars. Some of the activity was the sort of garden-variety fraud the states had been prosecuting for years. Central to the investigation, however, was the notion that marketing the "spread" between the drug's listed AWP and the actual cost of that drug represented illegal fraud.<sup>22</sup>

The government coalition made clear that it was willing to turn to active litigation if necessary to recover government funds expended because of this alleged AWP fraud. The governments' legal hook relied upon an innovative use of the False Claims Act ("FCA"), a Civil War-era statute that originally aimed to crack down on "rampant fraud" among defense contractors doing business with the Union army.<sup>23</sup> The prospect of FCA liability was particularly disturbing for pharmaceutical firms, since every filled Medicare or Medicaid prescription might be considered a "false claim" subject to treble damages and the maximum penalty under the statute. These penalties could quickly add up to create potential exposure to these firms running into the hundreds of millions of dollars. Additionally, if a company was found guilty of any criminal violations involved in a potential suit, the company could be excluded from Medicare and other federal health programs, a penalty some have described as a corporate "death sentence."<sup>24</sup> Under these conditions, drug companies quickly realized

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<sup>21</sup> §429(c) of the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000* (P.L. 106-554).

<sup>22</sup> Julie Appleby, "Drugmakers Accused of 'Unethical' Pricing," *USA Today*, September 27, 2000, 3B.

<sup>23</sup> Joan H. Krause, "A Conceptual Model of Health Care Fraud Enforcement," *Journal of Law and Policy* 12 (2004): 65.

<sup>24</sup> Christopher D. Zalesky, "Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests, Moving Beyond Regulation-Through-Litigation," *Journal of Health Law* 39(2): 235-264 (2006).

that litigating any government claims all the way to a jury verdict would be very risky and potentially fatal to the corporations.

### *The Precedent for "AWP as Fraud" – the Bayer and TAP Pharmaceuticals Settlements*

State and federal prosecutors understood the potential leverage they maintained over potential drug company defendants because of their FCA claims, and made no secret of the fact that they sought to force a settlement with a major manufacturer in the hope that it would set a precedent for other companies to move towards a more accurate pricing system.<sup>25</sup> In January of 2001, the government coalition achieved its first major victory. Since May of the previous year, the group had been in talks with Bayer Pharmaceuticals over the pricing of several its drugs used to treat hemophilia and AIDS. The government prosecutors alleged that Bayer was "marketing the spread" to physicians and other health care providers and that the company had inflated the cost of drugs under Medicaid.

Essentially, the governments argued that the way that Bayer calculated the AWP for these drugs represented fraudulent actions leading to liability under the FCA. Bayer, along with the rest of the industry, argued that setting prices for AWP was in no way "fraudulent" given that the government had known for years that marketing the spread was an accepted industry practice and nevertheless kept AWP as part of the government reimbursement system. Nevertheless, under pressure from threatened litigation, Bayer decided to settle the governments' allegations. In separate but closely related settlements, the DOJ and the states reached an agreement with Bayer containing a small monetary payment of \$14 million to be divided up between the federal government and the 45 states involved in the suit. Reflecting the ambitions of the governments to use the settlement to send a message to the pharmaceutical about the legality of AWP, however, the importance of the regulatory requirements in the settlement overshadowed the relatively minor monetary payments.

The key provision of the settlement required Bayer to report the "average sale price" (ASP) for all of the drugs reimbursed by Medicaid

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<sup>25</sup> David S. Cloud and Laurie McGinley, "U.S., States, Bayer Start Settlement Talks," *Wall Street Journal*, May 10, 2000, A3.

rather than the AWP for each of these drugs.<sup>26</sup> In contrast to AWP, this new pricing benchmark was defined in the settlement as the weighted average of all non-Federal sales of drugs to wholesalers, including all discounts, rebates, and other benefits tied to the purchase of the drug. Because the ASP, unlike the AWP, was a defined term and set by the market rather than by the manufacturer, this was intended to reduce the sort of price "manipulation" by the pharmaceutical industry involved in these cases. Because companies could not create a spread between the AWP and market prices, the aim was to reduce costs of drugs reimbursed under government health care programs. State Medicaid officials would be able to use the ASP data to set "fair" reimbursement rates for prescription drugs.

The government prosecutors viewed the Bayer settlement as a watershed agreement that could be used to replace the existing AWP system with the "more accurate" ASP system. New York Attorney General Eliot Spitzer characterized the settlement as "a significant victory...[that] sends a strong message to other pharmaceutical manufacturers and health care providers that we will not allow them to enrich themselves at the expense of taxpayers and those most in need."<sup>27</sup> This "strong message" resonated across the industry, as Bayer was but the first domino to fall in the government prosecutors' strategy to attack the AWP reimbursement system.

The next domino was an even more significant agreement later in 2001 involving TAP Pharmaceuticals and their cancer drug, Lupron. In this case, the governments alleged that TAP engaged in a wide range of illegal conduct, some of which appeared to be clear fraud under existing federal statutes. This included allegations that TAP had offered kickbacks to doctors to encourage them to prescribe TAP's products, in violation of federal law.

However, as with the Bayer case, the allegations also included as evidence of "fraud" TAP's marketing the spread between its published AWP for Lupron and the actual purchase price. As with

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<sup>26</sup> *Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Bayer Corporation* (January 23, 2001), 11-12, accessed March 17, 2012, <http://www.oig.hhs.gov/fraud/cia/agreements/BayerCorporation120301.PDF>.

<sup>27</sup> Robert Pear, "Bayer to Pay \$14 Million to Settle Charges of Causing Inflated Medicaid Claims," *New York Times*, January 24, 2001, A16.

Bayer, the TAP allegations aimed to introduce the notion that the AWP payment system was inherently fraudulent. This was despite the fact, as TAP argued, that "marketing the spread" and similar practices concerning AWP had been legal for years – and that Congress had even considered the spread an acceptable way to ensure that physicians and other providers remain in the Medicare and Medicaid programs.

However, the government prosecutors saw in the TAP case an opportunity to make the statement that they had begun with Bayer. Despite the legally questionable nature of these AWP claims in the case, none of which had previously been tested in court, the accusations of other illegal kickbacks and other violations of federal law were on firmer legal ground. Because these charges could lead to criminal as well as civil liability if proven in court, TAP faced the prospect of exclusion from Medicare and other federal health programs.

The threat of this "death sentence" gave the federal and state prosecutors additional leverage to force a significant settlement related to not only the kickback claims, but the alleged AWP fraud as well. In October of 2001, the strategy came to fruition in the form of a massive \$875 million settlement between TAP and the government prosecutors, the largest health care fraud settlement in history to that time.<sup>28</sup> As part of the settlement, TAP also entered into an agreement requiring strict oversight of TAP's marketing and sales practices for seven years, the first ever settlement to require this sort of strict scrutiny. Perhaps most importantly of all, the settlement required TAP to report the ASP for each of its drugs on a quarterly basis, similar to the provision the prosecutors had won in the Bayer settlement. The settlement also permitted the Center for Medicare and Medicaid Services (CMS) to rely upon this ASP data in setting reimbursement rates for TAP's products under Medicare as well as by state Medicaid programs in setting their own reimbursements rates.<sup>29</sup> This settlement provision therefore allowed the CMS to go beyond its explicit authority established by

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<sup>28</sup> Department of Justice, "TAP Pharmaceutical Products Inc. and Seven Others Charged With Health Care Crimes."

<sup>29</sup> Settlement Agreement Between the United States and TAP Pharmaceutical Products, Inc. (September 28, 2001), at §III.D.2.d.



Congress, which had specifically set Medicare reimbursement rates using AWP as the pricing formula.

### *The Floodgates Open and the States Rush In*

These two settlements were viewed as watershed cases and a "wake-up call" throughout the industry. As one health care fraud attorney stated at the time, "[t]he TAP settlement sent a huge chill through the pharmaceutical industry."<sup>30</sup> Not only did the size of the TAP settlement raise eyebrows throughout the pharmaceutical industry, but both the Bayer and TAP settlements introduced the notion that the AWP pricing mechanism, which had long been seen as standard company practice, was inherently fraudulent.

State prosecutors fully understood that the Bayer and TAP precedents opened up additional opportunities for state litigation. As former Maine AG Andrew Ketterer stated at the time, "the area [of AWP] is fertile for attorneys general to look into. Pharmaceutical companies spend a fair amount of money on research and development for wells that don't have oil and they have to recover from those losses in some way. [A lawsuit] is not out of the range of possibilities that would come on to the radar screen. It's an area that is of great interest to a lot of people."<sup>31</sup>

Attorney General Ketterer's words proved prescient, because states began litigating AWP suits independently of the federal government during and especially shortly after the Bayer and TAP settlements were announced. Republican Texas AG John Cornyn, in the midst of the Bayer and TAP investigations, filed the first state AWP lawsuit in the fall of 2000. Similar to the allegations in the Bayer and TAP cases, this state lawsuit alleged that three pharmaceutical firms had inflated the AWP for asthma inhalants and marketed the spread to pharmacists.<sup>32</sup>

The suit had a near-immediate effect on how Texas reimbursed drugs under its Medicaid program. Shortly after Cornyn filed the case, the head of Texas's Medicaid program ordered an audit of its drug

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<sup>30</sup> Pamela M. Prah, "Fraud Cops Target Drug Makers, Clinical Trials," *Kiplinger Business Forecasts*, April 9, 2002 (quoting David E. Matyas, a lawyer specializing in health care fraud in the law firm of Epstein Becker & Green).

<sup>31</sup> Guiden, "States Mull Suit."

<sup>32</sup> *Ibid.*

reimbursements, and soon after cut the reimbursement rates for the drugs involved in the suit. Eventually, all three defendants named in Texas's AWP lawsuit reached settlements with the Attorney General's office. These settlements included combined monetary recoveries of over \$55 million, representing nearly twice the damages allegedly caused by the defendant's "inflating" their drug prices. The settlements also required the defendants to enter into pricing agreements with the state Medicaid division to ensure "accurate" pricing in the future.<sup>33</sup>

A number of other attorneys general across the country piggybacked on Texas's pioneering efforts by bringing expansive AWP lawsuits of their own. In January of 2002, Nevada AG Frankie Sue Del Papa filed a suit in Nevada state court accusing seventeen pharmaceutical companies of inflating the AWP's and thus driving up the costs of Nevada's Medicaid program. Del Papa's lawsuit went well beyond that of Cornyn's in Texas. Not only did the state name a broader range of defendants, but the complaint listed a variety of Medicaid fraud, antitrust, and consumer protection claims in the lawsuit.<sup>34</sup> In addition to allegedly employing "deceptive practices" constituting consumer fraud that harmed Nevada residents and the state budget, Nevada alleged that the companies' behavior also constituted a "racketeering enterprise" aimed at deriving profits from states across the nation by inflating AWP's.<sup>35</sup> "We're trying to assert every possible claim of relief," stated Tim Terry, the chief of the Nevada Medicaid fraud unit.<sup>36</sup> The complaint also repeatedly referred to the pharmaceutical companies' behavior as part of an "AWP Scheme," a seeming attempt to coin a negative label for pricing behavior that had for decades been part of the government's reimbursement practice.

Del Papa explained her rationale for filing the lawsuit by noting that "[t]his country and our state have struggled to provide cost-effective health care while the elderly are often forced to choose expensive medicines over food and housing." In Howard Beale-esqe

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<sup>33</sup> See, for example, Settlement Agreement and Release, *State of Texas v. Roxane Laboratories*, No. GV3-03079 (District Court of Travis County, Texas), III(3).

<sup>34</sup> *Complaint For Injunctive Relief (State of Nevada v. Abbott Laboratories)*, Counts I-VII.

<sup>35</sup> *Ibid.*, Count IV.

<sup>36</sup> Caffrey, "States Go To Court."



terms, she remarked, "[t]oday, we have fired the first salvo sending a message on behalf of our state and our citizens that we aren't going to take it anymore."<sup>37</sup> In addition to requesting damages of "three times the amount unlawfully obtained" and at least \$5,000 for each allegedly false claim – monetary recoveries that could easily reach at least into the tens of millions – the complaint also asked for a redefinition of AWP. Rather than continuing with the long-settled notion that AWP represented the manufacturer-defined "sticker price" for prescription drugs, the complaint requested "the Court enjoin defendants and order that any and all future disseminations of AWP...accurately reflect the average wholesale prices paid by physicians and pharmacies." Del Papa noted that the breadth of the complaint meant that her litigation "has nationwide applications because of its similarities to the historic tobacco litigation in which the states eventually recovered billions of dollars."<sup>38</sup>

A month after Nevada's lawsuit, Montana AG Mike McGrath filed similar litigation. This state court lawsuit alleged very similar charges against eighteen defendants, most of whom Nevada's suit also targeted. Like Nevada's complaint, Montana's alleged the AWP's reported by the pharmaceutical manufacturers bore little or no relationship to prices actually paid by physicians or pharmacies in the state.<sup>39</sup> The complaint also contained a variety of causes of action, seeking civil penalties of \$2,000 per false claim, double damages, and legal costs and fees.<sup>40</sup> As with the Nevada lawsuit, the Montana complaint also asked the court to "enjoin Defendants and order that any and all future disseminations of AWP...accurately reflect the average wholesale prices paid by physicians and pharmacies."

### *Subsequent Lawsuits and Litigation Successes*

Building upon this earliest multistate AWP litigation, which also included West Virginia, the quantity of litigation expanded, both in terms of the number of states involved in bringing lawsuits as well as

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<sup>37</sup> Dana A. Elfin, "Nevada Sues Drug Companies to Recover Millions of Dollars in Alleged Overpayments," *Pharmaceutical Law & Industry Report*, January 24, 2002.

<sup>38</sup> Elfin, "Nevada Sues Drug Companies."

<sup>39</sup> *Ibid.*

<sup>40</sup> *Complaint For Injunctive Relief, Damages, Restitution, Disgorgement, Penalties and Other Relief and Demand for Jury Trial, State of Montana v. Abbott Laboratories, et al (First Judicial District Court, Lewis and Clark County), Count V.*

the number of defendants involved in the lawsuits. Table 1 indicates the progression of these lawsuits over time.

**TABLE 1: AWP-RELATED STATE MEDICAID FRAUD LAWSUITS (THROUGH 2010)**

<u>State</u>	<u>Date Filed</u>	<u>Defendants</u>
Texas	September 2000	Dey Laboratories, Schering-Plough, and Roxane
West Virginia	October 2001	Schering-Plough and Abbott Labs
Nevada	January 2002	17 defendants
Montana	January 2002	18 defendants
Minnesota	June 2002	Pharmacia
California	January 2003	Abbott Labs (expanded to 39 defendants in September 2005)
New York	February 2003	Pharmacia and GlaxoSmithKline
Connecticut	March 2003	7 defendants
Florida	July 2003	3 defendants (amended to include three others in April 2005)
Kentucky	September 2003	5 defendants
Massachusetts	October 2003	13 defendants
Arkansas	January 2004	4 defendants
Ohio	March 2004	5 defendants
Pennsylvania	March 2004	13 (later expanded to 38)
Wisconsin	June 2004	20 defendants
Kentucky	November 2004	41 defendants
Alabama	January 2005	72 defendants
Illinois	February 2005	48 defendants
Missouri	May 2005	Dey and Warrick (expanded to 4 others in December 2005)
Mississippi	October 2005	86 defendants
Arizona	December 2005	42 defendants
Hawaii	April 2006	44 defendants
Alaska	October 2006	44 defendants
Idaho	January 2007	18 defendants
Utah	September 2007	10 defendants
Iowa	October 2007	78 defendants
Kansas	November 2008	17 defendants
Louisiana	November 2010	18 defendants

While states brought most of these suits in individual state courts under state law, they collaborated closely on these cases. The

key organizational mechanism was the Pharmaceutical Task Force established in 2002 under the auspices of the National Association of Attorneys General (NAAG). The goal of this Task Force was to encourage communication and collaboration among the states and accelerate and coordinate investigation and litigation efforts with other states, federal enforcement agencies, and the private bar.<sup>41</sup> The coordination achieved with this NAAG Task Force helps explain the similarity of the various state lawsuits brought against pharmaceutical companies.

In addition to these state lawsuits, a wave of private party lawsuits also emerged at the same time. This litigation involved a number of patients, private insurers, labor unions, health care advocates, and others. Many of these groups coordinated their litigation under the direction of the "Prescription Access Project," a coalition of over one hundred organizations founded in 2001 "working to end illegal pharmaceutical industry practices and fighting for more affordable drug prices."<sup>42</sup> This private litigation attacked the same general AWP practices as the state lawsuits.

Faced with a growing plethora of similar state and private party lawsuits, the defendants sought to consolidate the claims in federal court. Many of the states' lawsuits, including those of Nevada, Montana, and several others, were consolidated along with many of the private claims in a massive lawsuit in federal district court in Massachusetts, in a case known as *In Re Pharmaceutical Industry Average Wholesale Price Litigation*.<sup>43</sup> This litigation continued for years, with the state plaintiffs winning several key motions. Perhaps most importantly of all, in November of 2006 Judge Patti Saris adopted the definition of AWP the states had urged. For the purposes of the upcoming trial in the case, the pharmaceutical defendants had wanted AWP to be defined as a term of art – as the "sticker price" that the industry had long assumed AWP meant under federal drug reimbursement practice. Instead, the court held that "[d]etermining

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<sup>41</sup> Meredyth Smith Andrus, Robert L. Hubbard, and Paul Novak, "State Attorneys General: Efforts to Address the High Costs of Prescription Drugs," ABA Section of Antitrust Law, accessed March 18, 2012, <http://apps.americanbar.org/antitrust/at-committees/at-state/pdf/publications/other-pubs/highcostofdrugs.pdf>.

<sup>42</sup> Prescription Access Litigation, "PAL Coalition," accessed March 11, 2012, <http://www.prescriptionaccess.org/about?id=0003>.

<sup>43</sup> *Pharmaceutical Average Wholesale Price Litigation*, Docket No. 01-CV-12257-PBS, MDL No. 1456.

the plain language meaning of the regulatory and statutory term 'average wholesale price' is a straightforward exercise that begins with the dictionary."<sup>44</sup> Using the "plain meaning" of the term meant that AWP should be defined as the average price at which wholesalers sell drugs to their customers – precisely the definition that the state plaintiffs sought.<sup>45</sup> This key decision undercut the companies' contention that AWP was in fact "Ain't What's Paid."

The states also secured a number of multistate and individual-state settlements with many industry defendants as the *In Re Pharmaceutical Industry* litigation continued. GlaxoSmithKline (GSK) was the first defendant to resolve the claims it faced in the *In Re Pharmaceutical Industry* litigation, entering into settlements with five states and a number of private litigants concerning allegedly inflated AWP's for two of the company's cancer medications, Zofran and Kytril. In addition to a \$70 million monetary payment split between the various plaintiffs, the company was also required to report the ASPs for the two drugs to the states' Medicaid programs. Gaining this information was critical to the states, since these prices, which were not previously available, could form a new baseline for Medicaid reimbursements in these states. Combined with an earlier settlement with GSK, these settlements were viewed by one of the private plaintiffs as "a nail in the coffin of AWP and a move toward a more transparent system that will prevent drug companies from charging inflated prices that have no relation to the actual cost of a drug."<sup>46</sup> Eliot Spitzer described the lawsuit as helping "stop a longstanding practice that inflated the cost of drugs for people suffering from cancer and cheated the Medicaid system."<sup>47</sup>

Shortly after GSK settled, other defendants involved in the federal district court case followed suit. This included AstraZeneca in May of 2007 regarding Zolodex, and eleven other companies in March of 2008. Many of these settlements were precipitated by a victory on the merits by several of the private plaintiffs in one part of the *In Re*

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<sup>44</sup> "As Drug Pricing Trial Begins, Judge Says Meaning of 'Average Wholesale Price' Plain," *Pharmaceutical Law & Industry Report*, November 10, 2006, 1167.

<sup>45</sup> Finding of Fact and Conclusions of Law, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, M.D.L. No. 1456 (D. Mass, June 21, 2007), 144.

<sup>46</sup> Martha Kessler, "GSK Pays \$70 Million to Settle Lawsuit Alleging Artificial Inflation of Drug Prices," *Pharmaceutical Law & Industry Report*, August 18, 2006, 909.

<sup>47</sup> Office of the New York Attorney General, "Leading Pharmaceutical Company Settles."

*Pharmaceutical Industry* consolidated federal case. In a ruling handed down in July 2007, Judge Saris held that the industry defendants "unfairly and deceptively caused to be published false AWP...knowing that [third party payers] and the government did not understand the extent of the mega-spreads between published prices and true average provider acquisition costs." Saris adopted the characterization of the companies' activities as an "AWP Scheme," finding that the companies' "[u]nscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup was unethical and oppressive...[causing] real injuries to the insurers and the patients who were paying grossly inflated prices for critically important, often life-sustaining, drugs."<sup>48</sup> Following this order, several of the states' cases consolidated in the lawsuit settled out-of-court.<sup>49</sup>

AWP litigation continues to this day, with states reaching individual and multistate settlements with pharmaceutical company defendants. While the days of the AWP benchmark may be numbered largely because of these lawsuits, AWP litigation will likely continue, especially since the government has stated that drug prices are still inflated.<sup>50</sup> Indeed, the states have worked closely together to settle several multi-million dollar multistate lawsuits throughout the past few years.

### *AWP Litigation as Political Strategy*

Throughout the AWP litigation campaign conducted by the states and other parties over the past decade, the states made no secret that they were attempting to alter practices in the pharmaceutical industry on a national scale. As Ohio Attorney General Betty Montgomery stated in reference to the states' pharmaceutical litigation, "[o]ur major task is to change behavior. Money is incidental." Another observer noted that in this AWP litigation, state prosecutors were "filing cases where they know full well it's not clear that they can win if

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<sup>48</sup> Finding of Fact and Conclusions of Law, *In Re Pharmaceutical Industry*, 144. Also see "Court Says Rx Companies Engaged in Unfair Pricing Practices by Inflating Average Prices," *Pharmaceutical Law & Industry Report*, June 29, 2007, 667.

<sup>49</sup> See, for example, Richard Vanderford, "Teva to Pay \$315M to Settle Price Inflation Suits," *Law 360*, February 5, 2010 (noting that "Teva joins several drug companies that have already settled the AWP legislation").

<sup>50</sup> James Swann, "Medicaid Payments Still Inflated for Many Drugs, OIG Report Finds," *Pharmaceutical Law & Industry Report*, January 22, 2010, 96.

they go to trial...they're not seeking damages in many of these situations – they're seeking structured settlements."<sup>51</sup>

Through these lawsuits and settlements, the states sought to change the long-standing industry practice of using AWP as an incentive for health care providers to prescribe their prescription drug products – a practice Congress repeatedly countenanced as a way to compensate providers for losses incurred by their provision of other services under Medicare and Medicaid. For all of the flaws in the system, the industry relied upon and accepted this practice. "Three or four years ago, if you surveyed manufacturers and asked if AWPs were kickbacks," stated one attorney for the industry following the TAP settlement, "they'd have looked at you like you were from another planet."<sup>52</sup> Yet through this explosion of litigation and settlements, the states (in conjunction with federal prosecutors and private litigants in several cases) have transformed the meaning of "health care fraud" to mean something completely different from what Congress and the industry alike understood it to mean for decades.

This litigation campaign occurred as policy advocates for stricter price controls on prescription drugs attempted to alter the way government provided reimbursement prescription drugs both on the national level and in the states. A Maine statute enacted in 2000 placed price controls on drugs sold in the state, making it "illegal profiteering" for a drug manufacturer to charge a price that is "unconscionable" or produces an "unjust or unreasonable profit." Other states, including Indiana, attempted to cut Medicaid reimbursement rates paid to pharmacies unilaterally. These state legislative and administrative strategies, however, faced the problem that their impact was limited to individual states, as well as the fact that these policy developments were frequently challenged in court. Courts granted injunctions to stop states from unilateral cuts in reimbursement rates, for example, and the Maine price control law and similar statutes were challenged in court by the pharmaceutical

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<sup>51</sup> "New Cops on the Beat," *Institutional Investor Magazine*, July 24, 2002; Reed Abelson and Jonathan D. Glater, "New York Will Sue 2 Big Drug Makers on Doctor Discount," *New York Times*, February 13, 2003, A1.

<sup>52</sup> Carter, "Drug Wars," at 44.



industry's peak association, PhRMA.<sup>53</sup> Meanwhile, industry critics in Congress were losing their battle to end AWP on a national level, winning only modest reductions in prescription drug reimbursement rates.

The campaign to redefine AWP by means of litigation solved both problems by sidestepping Congress to force drug pricing changes throughout the entire industry. In many of these cases, the states teamed up with both private class action attorneys and public interest groups to attack AWP as fraudulent and attempt to change the pricing benchmark from the previously long-standing practice. The litigation was also an attempt to obtain more information about drug prices, which could be used both in future litigation as well as to alter the states' payments for drugs. Texas's AWP litigation provides an example of this, with the state Medicaid agency relying upon the "accurate transaction prices" obtained by the Texas AG through settlements to set the new reimbursement benchmark for state Medicaid payments.<sup>54</sup>

Further, these lawsuits continued to exert more pressure on Congress to address alleged "regulatory lapses" in the area of drug pricing. As noted earlier, Congress had declined to change the AWP system for years. However, as government prosecutors reached significant settlements with Bayer and TAP, and AWP litigation proliferated in courtrooms all around the country, Congress finally acted. In the Medicare Prescription Drug, Improvement and Modernization Act, signed into law in December of 2003, Congress addressed the issue of prescription drug reimbursement under Medicare. The provisions intended to reduce Medicare's reimbursement rates for physician-administered prescription drugs while at the same time increasing reimbursement rates for the services associated with administering those drugs.<sup>55</sup>

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<sup>53</sup> For a good overview, see John Bentivoglio, Rosemary Maxwell, and Marc Stanislawczyk, "State Controls on Drug Costs: An Out-of-Control Experiment in Federalism?" *Pharmaceutical Law & Industry Report*, October 11, 2001.

<sup>54</sup> Sugerman-Brozan and Woolman, "Drug Spending and the Average Wholesale Price" ("States stick with AWP because they do not have access to more accurate information and they do not have the capacity to collect it themselves").

<sup>55</sup> Covington & Burling, "Average Wholesale Price Reform Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," December 11, 2003, accessed March 11, 2012, <http://www.cov.com/files/Publication/2533fcae-e193-44a9->

Most importantly, Congress changed the pricing benchmark from AWP to the "Average Sales Price" – precisely the benchmark state and federal prosecutors had devised in the Bayer and TAP settlements and that various states cited in their own individual lawsuits and settlements. Under the Medicare Modernization Act, Congress set the new prescription drug reimbursement for Medicare at 106% of ASP. The Act defined ASP in the same way as did the Bayer and TAP settlements – as an average of the final sales prices to all U.S. purchasers, net of rebates and other discounts. Congress also required companies participating in the Medicare program to report the ASPs for their drugs to CMS on a quarterly basis, similar to the provisions previously achieved in the Bayer and TAP settlements.<sup>56</sup> These congressional changes came only after the concerted litigation campaign by government prosecutors and a series of settlements provided a model for later statutory changes.

In short, the states' AWP litigation, along with the federal and private lawsuits, had several effects on the industry. For one, it was part of a concerted campaign to redefine the existing AWP system as industry "fraud," despite neither Congress nor state Medicaid agencies electing to change the system. Second, through a series of settlements, states were able to achieve regulatory settlements creating an alternative pricing benchmark and placing additional pricing disclosure requirements on drug firms. Third, following these successful settlements, Congress reacted not by preempting the litigation for encroaching upon its legislative jurisdiction and threatening previously agreed-upon congressional policies. Instead, Congress ratified several of the elements previously contained in these settlements. The result has been the gradual decline of AWP as a pricing benchmark, a policy change with implications reverberating throughout the health care industry.

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<sup>56</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Public Law 108-173, *U.S. Statutes at Large 117 (2003)*: 2067, codified at 42 U.S.C. 1395w(3)(a).

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## **Standing in for the FDA: Litigating Pharmaceutical Advertising**

In addition to seeking dramatic changes in government drug reimbursements, states have also sought to regulate the advertising and marketing of pharmaceutical products through litigation strategies. Like the drug pricing litigation, this litigation effort is premised on the notion that certain actions by pharmaceutical firms have driven up the cost of prescription drugs. Also like the pricing litigation, state litigation has employed a sue-and-settlement strategy that has achieved numerous regulatory changes that have resonated throughout the industry and in Congress, ultimately resulting in stricter regulation of pharmaceutical advertising. Much of this activity has occurred even as both Congress and the Food and Drug Administration, which retains the primary responsibility of regulating prescription drug advertisements, have loosened restrictions on pharmaceutical advertising to doctors and consumers.

### *Loosening Federal Restrictions on Direct-to-Consumer Advertising and Off-Label Marketing*

State litigation concerning pharmaceutical marketing has focused on two key forms of pharmaceutical marketing: direct-to-consumer (or "DTC") advertising and off-label marketing. DTC advertising strategies, as the name suggests, focus on marketing pharmaceuticals to consumers through broadcast and print media as opposed to solely focusing marketing efforts on doctors and other health care providers. DTC advertising became much more prominent in the United States beginning in the 1980s. This was due in part to the decision of the Reagan Administration's FDA to adopt a relatively "hands-off" approach to DTC advertisement regulation, after some initial consumer-related concerns, because of the agency's conclusion that restrictions would violate the First Amendment and because the agency believed that existing federal law provided adequate consumer protections.

Most DTC advertisements throughout the 1980s and 1990s remained in print due to a FDA requirement that all advertisements aimed at consumers include all warnings, precautions, and adverse side effects of the drug. These requirements made short broadcast advertisements all but impossible. In the mid-1990s, the FDA began to reevaluate this policy, and in 1997 the FDA released new guidelines to

the pharmaceutical industry entitled "Guidance for Industry: Consumer-Directed Broadcast Advertisements."<sup>57</sup> This guidance clarified existing regulations concerning broadcast advertising of prescription drugs, making clear that pharmaceutical firms were no longer required to state every warning and side effect associated with the drug. Instead, the advertisements need only grant consumers "reasonably convenient access to the advertised product's approved labeling" through a telephone number, website, or referral to a healthcare professional.<sup>58</sup>

This FDA Guidance made it much easier for pharmaceutical firms to advertise their products in the broadcast media and helped lead to a sharp increase in DTC ads overall. For example, one study found that DTC advertising increased by 330% between 1996 and 2005.<sup>59</sup> Another study in 2008 found that pharmaceutical manufacturers spent approximately \$4.8 billion on direct-to-consumer television, radio, magazine, and newspaper advertising.<sup>60</sup> This burgeoning DTC advertising in America contrasts with nearly every other nation, as DTC advertising is highly restricted or illegal in every other country with the exception of New Zealand.

In addition to paving the way for greater DTC advertising, the federal government has also loosened restrictions on so-called "off-label" marketing. Prior to the FDA's approval of a drug, the company must prove that the drug is "safe and effective for its intended use(s)."<sup>61</sup> When a drug is approved for a particular intended use, the drug's labeling must reflect only this use. Promotion of a drug for uses beyond those specified on the labeling is generally prohibited. This restriction on promoting drugs for off-label use helps ensure that all drugs pass through the proper procedures to be deemed appropriate for "safe and effective" use.

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<sup>57</sup> FDA, "Guidance for Industry: Consumer-Directed Broadcast Advertisements," April 18, 2002, accessed March 17, 2011,

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125039.htm>.

<sup>58</sup> Ibid. See also Steven A. Sheller, "Direct-to-Consumer Advertising: The Case for Regulation," *Pharmaceutical Law & Industry Report*, April 9, 2004, 407.

<sup>59</sup> "Spending on Direct-to-Consumer Drug Ads Increased in Spite of Criticism, Study Finds," *Pharmaceutical Law & Industry Report*, August 24, 2007, 888.

<sup>60</sup> Natasha Singer, "Citing Risks, Lawmakers Seek to Curb Drug Commercials," *New York Times*, July 27, 2009, 1.

<sup>61</sup> *Food, Drug, and Cosmetic Act*, 21 U.S.C. § 355(a) (2006).

Despite this general prohibition on promoting the off-label utilization of prescription drugs, however, the underlying federal statutory scheme recognizes the considerable medical benefits that can flow from the off-label use of drugs. For that reason, doctors and other health care professionals can legally prescribe drugs for off-label purposes. Indeed, for a number of drugs, this off-label prescribing is very common. One 2006 study found that more than 20% of prescriptions written for the most commonly used prescription drugs in the United States were prescribed for off-label use.<sup>62</sup> The National Comprehensive Cancer Network estimates that between 50% and 75% of all uses of cancer drugs were off-label.<sup>63</sup>

The public health benefits of off-label uses spurred lawmakers to reconsider the extent of the restrictions on the off-label promotion of prescription drugs. In the same year that the FDA issued its Guidance concerning DTC advertising, Congress enacted the FDA Modernization Act of 1997. This statute abolished the long-standing prohibition on drug manufacturers disseminating information related to "off-label" uses of their products to healthcare providers.<sup>64</sup> While maintaining the general prohibition on off-label promotion, this statute allowed firms to provide doctors with information about how their drugs might be used to treat conditions for which the FDA had not approved. For example, the statute allows firms to disseminate peer-reviewed journal articles regarding off-label uses for their products. Doctors, as they had before, were still free to prescribe drugs for off-label uses.

### *Balancing Priorities in Advertising*

Much like the debates about the proper pricing mechanism for prescription drugs under Medicaid, the conversation about pharmaceutical advertising was about how to best balance competing concerns. On the one hand, critics of loosening restrictions of prescription drug advertising have focused on the potentially negative effects such advertisements might have on consumers. Such critics have claimed that DTC advertisements are at best unnecessary and at

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<sup>62</sup> David C. Radley, Stan N. Finkelstein, and Randall S. Stafford, "Off-Label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine* 166:1021-1026 (2006).

<sup>63</sup> Vicki W. Girard, "Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx," *Journal of Health Care Law & Policy*, 12:131 (2009).

<sup>64</sup> *Food and Drug Administration Modernization Act of 1997* (P.L. 105-115), 111 Stat. 2330.

worst completely misleading to consumers.<sup>65</sup> In addition, by heavily promoting the use of brand-name drugs rather than generic equivalents, critics argued that DTC advertising may be partially responsible for driving up health care costs. For example, one 2000 study examining drug inflation found that the fifty drugs most frequently advertised to consumers in 2000 were responsible for 47.8% of the rise in retail spending on prescription drugs from 1999 to 2000.<sup>66</sup> Critics have also suggested that allowing companies to suggest the benefits of off-label use of their drugs to healthcare professionals risks subverting the entire system of FDA regulation. Because the FDA has not evaluated off-label uses of drugs, the increased use of off-label utilization may lead to the very sort of public health risks that necessitated stronger FDA regulation in the first place.

On the other hand, others have noted the public health benefits associated with DTC advertising and off-label drug utilization. DTC advertising, for example, may help patients realize that their condition is treatable and may spur medically helpful conversations with his or her doctor. Pharmaceutical firms have also been quick to point out evidence that DTC ads may improve health care by increasing patient compliance with their therapies.<sup>67</sup> Further, allowing greater dissemination of information regarding off-label use can give doctors and their patients more options in their health care treatments.

The federal government has balanced these competing concerns by retaining certain restrictions on prescription drug advertising while also moving away from wholesale advertising prohibitions. The FDA Modernization Act of 1997 recognized a balance between the need to regulate new drug utilizations as well as the potential health benefits of off-label use, a balance generally shared by the FDA. Officials at the FDA have also noted that there is "no evidence that DTC promotion is harming the public health" by, for example, encouraging doctors to prescribe inappropriate medications.<sup>68</sup> The FDA has thus taken a more

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<sup>65</sup> Amanda Gardner, "Direct-to-Consumer Ads Booming Despite Criticisms," *Healthday Reporter*, August 15, 2007.

<sup>66</sup> "Study Says Direct Consumer Ads Play Big Part in Increased Drug Spending," *Pharmaceutical Law & Industry Report*, November 29, 2001.

<sup>67</sup> "DTC Ads: Promoting Compliance a Win-Win Prospect," *Pharmaceutical Executive* (December 1999).

<sup>68</sup> Dana A. Elfin, "Drug Ads Don't Cause Improper Prescribing, Top FDA Official Tells Senate Subcommittee," *Pharmaceutical Law & Industry Report*, July 26, 2001.

hands-off approach to DTC advertising, believing that the benefits of this advertising outweigh any of the potential negatives.

This hands-off approach has generated plenty of criticism in Congress and elsewhere. Testimony in one congressional panel in 2001, for example, noted a more than 50% drop-off in overall FDA enforcement actions from 1997 to 2001.<sup>69</sup> Another recent study also cited the decreasing FDA enforcement during the George W. Bush Administration, noting that the FDA had issued 142 warning letters in 1997, but only 21 in 2006.<sup>70</sup> Members of Congress also began criticizing the FDA's alleged lack of strong enforcement. Representative Henry Waxman (D-CA), a frequent critic of the pharmaceutical industry, issued a report in 2004 claiming that the FDA was guilty of "weak enforcement" of rules regarding "false and misleading" drug advertisements.<sup>71</sup> Waxman's report demanded that the FDA Commissioner, Mark McClellan, explain why the FDA was not taking more aggressive enforcement actions. The Government Accountability Office released a report in 2006 raising similar concerns criticizing the FDA's effectiveness in overseeing DTC advertising and in reducing consumers' exposure to false and misleading advertising.<sup>72</sup> One theme running through these criticisms of the FDA was that the agency's alleged lack of oversight of DTC advertising and off-label uses had the effect of driving up the costs of health care by unnecessarily encouraging greater utilization of brand-name pharmaceuticals.<sup>73</sup>

### *Multistate Litigation Concerning Pharmaceutical Advertising*

It was in this political context that state prosecutors became considerably more active in using litigation to challenge the way pharmaceutical companies market their products. As the examples below illustrate, this litigation has resulted in greater limits on drug marketing and has created new regulatory requirements for the settling firms to follow. Additionally, settlements between states and

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<sup>69</sup> Elfin, "Drug Ads Don't Cause."

<sup>70</sup> "Spending on Direct-to-Consumer Drug Ads Increased."

<sup>71</sup> "Waxman Report Says FDA Enforcement Of Misleading Advertising Rules Ineffective," *Pharmaceutical Law & Industry Report*, February 6, 2004, 147.

<sup>72</sup> Bronwyn Davis, "Restrictions on DTC Drug Ads Needed To Protect Consumers, House Democrats Say," *Pharmaceutical Law & Industry Report*, May 16, 2008, 576.

<sup>73</sup> Ziad F. Gellad, Kenneth W. Lyles, "Direct-to-Consumer Advertising of Pharmaceuticals," *American Journal of Medicine* 120: 475-480 (2007), 478.

drug firms have had the effect of expanding state regulatory oversight of the pharmaceutical industry. By adopting the arguments of drug advertising's critics and transforming them into a form of national regulation, state litigation has effectively altered the balance between competing concerns reached by federal regulators.

### *Limiting DTC Advertising*

One of the states' first significant lawsuits concerning DTC advertising involved Pfizer's blockbuster antibiotic drug, Zithromax. Zithromax was (and is) approved by the FDA as a safe and effective treatment for childhood ear infections, and Pfizer marketed the drug for this purpose. In 2001, a coalition of nineteen states began investigating Pfizer's advertising of Zithromax out of concerns that some of the company's advertisements contained "false and deceptive" claims under state consumer protection statutes.

The states claimed that while Pfizer's DTC advertising contained information regarding how many doses and how often Zithromax should be administered, it failed to disclose information about antibiotic resistance and other factors that physicians must consider before prescribing antibiotic treatment for ear infections. The states also claimed that Pfizer had misrepresented the efficacy of Zithromax in treating ear infections in comparison to other antibiotics on the market. In the words of Connecticut AG (now Senator) Richard Blumenthal, the states initiated this investigation because "[d]rug ads like Pfizer's must put health before hype...[p]arents deserve to know that the antibiotic won't work against viral infections, such as colds or the flu, and that excess or unnecessary medication leads to antibiotic resistant infections."<sup>74</sup>

Pfizer, however, noted that it was marketing Zithromax consistently with all applicable federal laws as well as the FDA-approved labeling for the product. In fact, Pfizer had voluntarily submitted the exact DTC advertisements challenged by the states to the FDA for review before Pfizer ran the ads, and the FDA had approved them. Once the DTC advertising was on the air, consistent

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<sup>74</sup> Assurance of Voluntary Compliance, *In the Matter of Pfizer Inc.* (December 27, 2002), ¶13; Connecticut Attorney General's Office, Press Release, "State Reaches Agreement With Pfizer On Advertisement Of Antibiotics," January 6, 2003, accessed March 17, 2012, <http://www.ct.gov/ag/cwp/view.asp?A=1778&Q=283978>.



with the agency's approval of the ads, the FDA had taken no enforcement actions against Pfizer for its marketing of Zithromax.

Nevertheless, the states' legal theories rested on *state* consumer protection law, not federal labeling laws. The states claimed that under the laws of the nineteen states involved in the investigation, Pfizer's failure to disclose certain information and claims about the efficacy of the drug represented fraudulent misrepresentation and deceptive trade practices. Pfizer publically denied the states' claims, but faced with the prospect of a protracted and public litigation battle with a significant coalition of state prosecutors, Pfizer agreed to enter into a settlement with the states in December of 2002.

The amount of monetary recovery involved in the settlement was a relatively small \$6 million. Of this amount, Pfizer agreed to pay \$4 million to the states to cover all investigatory costs and attorneys' fees. The remaining \$2 million was to fund a public service announcement campaign over the next three years to educate parents about "the proper use of antibiotics" to treat childhood ear infections. The settlement also prohibited Pfizer from mentioning Zithromax specifically in any of these PSAs. To help enforce the provision, the states required Pfizer to submit a "written affirmation setting forth Pfizer's compliance" with these provisions to the nineteen signatory attorney general offices.

Most importantly, the settlement also placed various restrictions on Pfizer's DTC advertising of Zithromax in the future. First, the settlement required Pfizer to cease the DTC ads that were the subjects of the investigation. Additionally, the settlement required Pfizer to make specific statements about Zithromax in all of its future advertisements for the product. For example, the settlement required Pfizer to including the following specific phrase in their marketing: "Remember that antibiotics don't work for viral infections, such as a cold or flu, so don't insist on a prescription for an antibiotic. Only your doctor can decide what type of infection your child has and the best way to treat it." Finally, the settlement stated that if consumer ads for Zithromax refer to data in a scientific study related to dosing convenience, frequency of use or effectiveness, Pfizer must disclose whether the study was published, peer-reviewed, or funded by Pfizer. The company also must make available to consumers the full study or

a summary of the study, and must post the study or a summary on its Internet site. Federal law or the FDA required none of these various disclosures and advertising changes. By requiring them in this settlement, however, the states wanted to send a "strong message" not only to Pfizer but also to the pharmaceutical industry generally that (in the words of New York AG Eliot Spitzer) "advertisements that mislead or fail to provide complete information about pharmaceutical products will meet with tough enforcement actions."<sup>75</sup>

The states followed up this watershed settlement with Pfizer with numerous additional multistate settlements with other major drug manufacturers. Several of these settlements have served as a vehicle to regulate pharmaceutical company behavior reaching beyond a single blockbuster drug. One such settlement involved Bayer Corporation and its cholesterol reduction drug Baycol. The FDA approved Baycol in 1997, but following its post-marketing studies Bayer learned that Baycol might lead to elevated instances of a rare but severe muscle disorder. After notifying the FDA about this possibility, Bayer voluntarily removed the product from the market four years later. Following the voluntary recall, thirty states began investigating Bayer in 2004. They claimed that while Bayer voluntarily notified the FDA about possible problems with Baycol and subsequently removed the FDA-approved product from the market, the company violated state consumer protection laws by failing to adequately warn prescribers and consumers about these problems with Baycol.

The states saw in this case a way to reform the way in which pharmaceutical firms disclosed the results of internal clinical studies of drugs – an issue that was the contemporaneous subject of considerable debate in Congress.<sup>76</sup> To that point, neither Congress nor the FDA placed requirements on companies to disclose the results of both positive *and* negative clinical drug studies, as federal law required

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<sup>75</sup> Office of the Attorney General of New York, Press Release, "Ads for Leading Antibiotic Found to Be Misleading," January 6, 2003, accessed March 17, 2012, [http://www.ag.ny.gov/media\\_center/2003/jan/jan06a\\_03.html](http://www.ag.ny.gov/media_center/2003/jan/jan06a_03.html).

<sup>76</sup> For example, Senators Ted Kennedy and Michael Enzi introduced the Enhancing Drug Safety and Innovation Act in 2006 that would have required the establishment of a publically available clinical trials database containing information about clinical trial results. Enhancing Drug Safety and Innovation Act of 2006 (S.3807, 109th Congress).



only limited clinical trial disclosures.<sup>77</sup> The main reason for this inaction was because of concerns that releasing broader clinical trial data was both unnecessary and could stifle innovation by revealing sensitive business information.

Through a settlement reached by several states and Bayer in January of 2007, however, states were able to achieve broader clinical trial requirements that industry critics in Congress had been unable to achieve. In addition to a payment of \$8 million to the states to cover litigation expenses, the settlement required Bayer to register clinical trials of most of its prescription products, and post *all* results, not just those with positive outcomes.<sup>78</sup> The states intended this settlement to serve as a stepping-stone for similar regulation of other large drug firms. "By agreeing to publicly disclose information on both positive and negative studies about the safety and efficacy of its drugs," Michigan AG Mike Cox stated, "Bayer has provided an important new direction for the entire pharmaceutical industry to follow."<sup>79</sup> In addition to this important clinical trial provision, the settlement also required Bayer to comply fully with state laws regulating marketing, sale, and promotion of its pharmaceutical and biological products and from making "false and misleading" claims relating to any of its product sold in the United States.<sup>80</sup>

### *Limiting the Dissemination of Off-Label Drug Information*

In addition to focusing on DTC advertising and alleged failures to warn consumers about potential prescription drug side effects, states have brought litigation against pharmaceutical companies concerning the off-label use of drugs. Much as in the pricing litigation, some of these cases have featured federal-state collaboration in enforcement to achieve significant regulatory settlements. In other

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<sup>77</sup> For example, policy advocates had achieved limited clinical trial disclosures in the Food and Drug Administration Modernization Act of 1997 (P.L. 105-115, § 113, 111 Stat. 2296), which mandated the creation of a website (clinicaltrials.gov) providing the public with limited access to information regarding clinical trials for drugs developed to treat serious or life-threatening illnesses.

<sup>78</sup> See, for example, Final Judgment and Agreed Permanent Injunction, *State of Texas v. Bayer Corporation* (District Court of Dallas County, Texas, 2007), ¶15-¶23.

<sup>79</sup> Drew Douglas, "Bayer Agrees to Pay \$8 Million, Post Results Of Study to Resolve States' Probe of Baycol," *Pharmaceutical Law & Industry Report*, January 26, 2007, 83.

<sup>80</sup> Final Judgment and Agreed Permanent Injunction, *State of Texas v. Bayer*, ¶15.

cases, states have worked independently of federal enforcers to reach key settlements.

An early example of federal-state collaboration in this area involved the governments' investigation into pharmaceutical giant Warner-Lambert's marketing of Neurontin, which ended in a major settlement in 2004. Neurontin was approved by the FDA specifically to treat epilepsy, though the drug proved highly effective in treating general pain, attention deficit disorder, and bipolar disease. These alternative uses, as well as the drug's use of use and relative lack of serious side effects, led to approximately 90% to 95% of Neurontin prescriptions used for off-label purposes. In 1996, however, a former employee of the company brought a whistleblower suit under the False Claims Act, alleging that the division of Warner-Lambert tasked with advertising the drug was marketing it for some of its many off-label uses. Federal and state prosecutors subsequently intervened in the case, alleging that Warner-Lambert had made false statements to government health programs and offered illegal kickbacks to prescribers, in the form of trips and falsely labeled consulting fees, to promote off-label uses of Neurontin. The governments also claimed that Warner-Lambert disseminated information to doctors about the off-label uses of the drug in such a way that it constituted illegal off-label marketing. These off-label marketing violations, the governments claimed, led to the increased utilization of Neurontin under the Medicaid program, helping to drive up costs for the federal and state governments.

The federal DOJ concentrated on the criminal allegations in the case and collaborated with the states concerning the civil Medicaid fraud aspects of the case, while the states activated not only their fraud enforcement personnel for this case but their consumer protection divisions as well. The states' consumer protection investigation focused on alleged violations of state consumer protection laws occurring when Warner-Lambert promoted the drug for off-label uses. These consumer protection claims rested upon innovative interpretations of existing law, raising questions both about the theories of causation employed in the case as well as constitutional concerns. For one, the government enforcers suggested that pharmaceutical companies could and should be held liable for false claims made to health care programs by providers because the

provider's prescription decisions were based upon information provided to them by the drug company, despite the fact that the company was likely unaware that any of these claims were made by the physicians.<sup>81</sup> Further, because the alleged communications by Warner-Lambert about off-label uses were in fact truthful, the claims also raised constitutional free speech issues.

Warner-Lambert initially fought these claims in federal district court, but after losing a couple of key rulings at the motion to dismiss and summary judgment stages, the company opted to settle. The government prosecutors announced a \$430 million settlement in May 2004, representing the largest health care fraud recovery since the previously mentioned TAP Pharmaceuticals case in 2001. The bulk of the monetary recovery consisted of criminal fines paid to the federal government, though the settlement directed Warner-Lambert to pay federal and state Medicaid programs \$190 million for losses allegedly incurred by the company's off-label marketing of Neurontin.

On the same day as this broader settlement, forty-six states also entered into a separate but closely related settlement resolving their consumer protection claims. In addition to injunctive provisions aimed at barring Warner-Lambert from continuing its alleged off-label marketing, the multistate settlement established a new "Neurontin Multistate Executive Committee" headed by the attorneys general of California and North Carolina.<sup>82</sup> This new committee would administer the new "Attorney General Consumer and Prescriber Education Grant Program" funded by a \$21 million payment by Warner-Lambert, the purpose of which would be to fund programs around the country designed to educate physicians and patients about prescription drug marketing and other related issues. Governmental entities, academic institutions, and not-for-profit groups would be eligible to apply for grants from this program, which attorneys general on this committee would administer. An additional \$6 million of the states' settlement was allocated to a "corrective advertisement campaign" regarding Neurontin to be run by Warner-Lambert, and \$10 million went directly

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<sup>81</sup> Anderson and Stamp, "Shooting the Messenger," at 9.

<sup>82</sup> Order Governing the Administration of the Multistate Grant and Advertising Program, *In the Matter of Warner-Lambert Company, LLC* (Circuit Court, County of Marion, Oregon, 2004), ¶2.2 and ¶2.3.

to the participating attorney general offices to compensate them for investigation and litigation expenses.

This early Warner-Lambert settlement served as a beachhead for numerous subsequent investigations of pharmaceutical companies' off-label marketing strategies. This included a prominent state litigation campaign concerning Purdue Pharma's powerful pain reliever OxyContin. After numerous criticisms from state officials that the FDA had "turned its back on its serious responsibility with regard to OxyContin" by allegedly ignoring how the company was persuading providers to prescribe more frequent doses of the drug than that approved by the FDA, state attorneys general took matters into their own hands. A lengthy investigation by twenty-six states resulted in a 2007 settlement in which Purdue Pharma agreed to pay \$19.5 million to the states as well as significantly reform its marketing practices.

A recent multistate settlement concerning Eli Lilly's Zyprexa further illustrates the extent of regulatory provisions contained in these off-label marketing settlements. In 2007, several states sued Eli Lilly claiming that the company launched an "aggressive" marketing campaign in 2001 called "Viva Zyprexa!" in which the company illegally marketed the drug for a number of off-label uses beyond its FDA-approved use to treat schizophrenia and bipolar disorder.<sup>83</sup> According to the lawsuits, which were based upon state consumer law, Eli Lilly knew Zyprexa increased greatly the risk of diabetes, heart attacks, and other health problems, but nevertheless actively marketed it to doctors for use with patients who were not diagnosed with mental illness. The company then failed to warn consumers of the risks associated with the drug.<sup>84</sup>

As have a number of companies facing similar off-label marketing lawsuits, Eli Lilly viewed the state lawsuits as a disservice to patients who had been successfully treated by the drug after receiving advice from their doctors. Eli Lilly also noted that all information they provided to health care professionals was truthful, not "false and misleading." Nevertheless, facing a growing number of state lawsuits concerning the drug, the company entered into an agreement with

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<sup>83</sup> Andrew Ballard, "Eli Lilly to Pay States \$62 Million Under Zyprexa Marketing Settlement," *Pharmaceutical Law & Industry Report*, October 10, 2008, 1153.

<sup>84</sup> Sherry Jones, "Montana AG Joins Others in Suing Eli Lilly Over Marketing of Zyprexa," *Pharmaceutical Law & Industry Report*, March 16, 2007, 264.

thirty-two states to resolve the investigation in 2008. The \$62 million settlement, then a record monetary recovery for a multistate consumer protection case, placed a variety of regulatory restrictions on the company. Among other requirements, the settlement barred Eli Lilly from giving product samples of Zyprexa to health care providers whose specialties are not consistent with Zyprexa's label or from using any grant funds to promote the drug.<sup>85</sup> The settlement also required Eli Lilly's medical staff, rather than its marketing staff, to have the ultimate responsibility for the medical content of medical letters and references regarding Zyprexa. In addition to these regulatory provisions governing internal company operations, the agreement also required a significant amount of new disclosures, including information about grants received, lists of "promotional speakers and consultants who were paid more than \$100 for promotional speaking and/or consulting," and the results of the company's clinical trials. Echoing a number of his colleagues, Florida AG Bill McCollum described agreement as a "landmark settlement [that] sends the message that pharmaceutical companies will be held responsible for their actions, including any inappropriate marketing practices which may promote off-label uses that have not been approved."<sup>86</sup>

### *Establishing Greater Government Oversight of Advertising*

In addition to establishing stricter marketing practices and disclosures on companies than federal law requires, several of recent multistate settlements has used state consumer protection law as a legal hook to create greater government oversight of a broad range of pharmaceutical advertising in the future. In one settlement involving Merck's blockbuster arthritis drug Vioxx, the states essentially provided themselves to power to enforce provisions of the Food, Drug, and Cosmetic Act – a power that is nowhere in the statute itself.

Merck voluntarily recalled Vioxx from the market in 2004 after a study the company sponsored found that the drug nearly doubled the

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<sup>85</sup> Oregon Department of Justice, "AG Reaches \$62 Million Settlement with Eli Lilly Pharmaceutical," October 7, 2008, accessed March 21, 2011, <http://www.doj.state.or.us/releases/2008/rel100708.shtml>.

<sup>86</sup> Ballard, "Eli Lilly to Pay States."

risk of a heart attack and stroke.<sup>87</sup> Shortly after the Vioxx recall, several states began investigating Merck's marketing of the drug, claiming that since 1999 the company waged an aggressive direct-to-consumer advertising campaign that misrepresented the safety of Vioxx and concealed increased risks associated with the product's use. These claims, again based upon state consumer protection law, were resolved in what was then the largest consumer protection case against a pharmaceutical company (prior to the Eli Lilly case settlement noted above).

The settlement included a substantial \$58 million monetary payment to twenty-nine states, but as with many other consumer protection settlements, the most important part of the settlement was its regulatory provisions. As with the Eli Lilly Zyprexa settlement, the states required Merck to adhere to a number of new procedures relating to the disclosure of clinical trials and potential conflicts of interest.<sup>88</sup> The settlement also included a number of provisions requiring anyone named on a Merck-sponsored study to adhere to a variety of authorship conditions before their names can appear on the study. This provision was meant to address controversies over so-called "ghostwriting" in the industry, in which companies would allegedly pay authors to put their names on independent research that was instead actually conducted by the pharmaceutical company. Certain guidelines regarding these practices had been suggested by the International Committee of Medical Journal Editors,<sup>89</sup> but before this settlement had not been required by any law or regulation in the United States. This settlement provision, however, essentially adopted the guidelines promulgated by this International Committee and turned them into an affirmative requirement that Merck had to follow.

In addition to these regulatory requirements, the settlement also contained provisions increasing the authority of the FDA to oversee Merck's advertising. According to the settlement, Merck must submit its television commercials to the FDA for approval before any

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<sup>87</sup> Drew Douglas, "Merck Will Pay \$58 Million to Settle States' Probe Into Marketing of Vioxx," *Pharmaceutical Law & Industry Report*, May 23, 2008, 611.

<sup>88</sup> Stipulated General Judgment, *State of Oregon v. Merck & Co.* (Circuit Court for the County of Marion, Oregon, 2008).

<sup>89</sup> International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication," accessed March 11, 2012, [http://www.icmje.org/2008\\_urm.pdf](http://www.icmje.org/2008_urm.pdf).



DTC advertisements are broadcast, further requiring the company to comply with any FDA recommendation to delay advertising for new pain medications. In a subsequent settlement with Merck over another of its drugs, Vytarin, states extended this pre-clearance provision to cover *all* of Merck's products, not just the drugs involved in the investigations.<sup>90</sup> These provisions mirrored several of the unsuccessful attempts of congressional supporters to require FDA pre-approval of DTC advertisements.<sup>91</sup>

In addition to increasing FDA oversight of Merck's DTC advertising, the Vioxx settlement also essentially granted the power to states to enforce federal law. In the settlement, Merck agreed to refrain from making "false, misleading or deceptive" promotional claims as defined under state law, as well as to comply with the Food, Drug, and Cosmetic Act and FDA regulations in connection with advertising and promotion. Merck was already under an affirmative obligation to adhere to federal law and regulations or face potential penalties from federal enforcers, but this provision allowed the *state attorneys general* to oversee Merck's compliance with federal law as well. Particularly since so many states had criticized the FDA's performance in regulating pharmaceutical firms, this provided them with additional leverage to forge ahead with the enforcement of federal law even where the FDA has "failed" to do so.

One problem with the Vioxx settlement from the states' perspective was that despite granting themselves additional ability to enforce existing federal law, states still relied on the FDA to "properly" review the DTC advertising the settlement required Merck to submit before running the advertisements. The states solved this problem in a subsequent settlement with Pfizer in October 2008 supplementing their capacity to pre-clear DTC advertisements. This settlement resolved thirty-three states' investigation of Pfizer's alleged off-label marketing of a pair of Pfizer's drugs, Celebrex and Bextra.<sup>92</sup> The \$60 million settlement included many of the same disclosure and conflicts of

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<sup>90</sup> Susanne Pagano, "Merck, Schering-Plough Settle With States Over Vytarin Study Release," *Pharmaceutical Law & Industry Report*, July 17, 2009, 821.

<sup>91</sup> See, for example, Enhancing Drug Safety and Innovation Act of 2007 (S.484, 110th Congress); Food and Drug Administration Safety Act of 2007 (S.468, 110th Congress).

<sup>92</sup> Final Consent Judgment, *State of New Jersey v. Pfizer Inc.* (Superior Court of New Jersey, No. MER-C-134-08). As with a number of these cases, the FDA chose not to investigate Pfizer's alleged off-label marketing of these drugs.

interest requirements that several previous settlements had, and became the second multistate settlement to include a requirement that a company receive pre-clearance of all of its DTC advertisements before broadcasting them. Unlike the Merck settlement, however, the Pfizer settlement required the company to report to the participating state attorneys general if the FDA did not act within a certain amount of time. The settlement also required Pfizer to provide the states with all of the DTC advertising information that the company provided to the FDA. Essentially, then, this provision created a two-layered enforcement regime that simultaneously expanded the FDA's authority while granting the states additional information with which to enforce their new pre-clearance regulation if the FDA for whatever reason did not act to enforce it.

### *Litigation as Drug Advertising Regulation*

The increase in the number of investigations brought by states targeting the marketing activities of pharmaceutical in recent years is matched by the growing extensiveness of the regulations contained within the settlements resolving the investigations. Table 2 summarizes several of the states' major multistate consumer protection advertising cases brought against pharmaceutical firms in recent years.<sup>93</sup>

**TABLE 2: MULTISTATE CONSUMER PROTECTION LITIGATION AGAINST PHARMACEUTICAL FIRMS (THROUGH 2009)**

<b>States</b>	<b>Defendant</b>	<b>Product</b>	<b>Year Settled</b>	<b>Significant Settlement Terms</b>
19 states	Pfizer	Zithromax	2003	\$6 million; specific alterations to advertisements
46 states	Warner-Lambert	Neurontin	2004	\$38 million; corrective advertisements
30 states	Bayer	Baycol	2007	\$8 million; disclosure of clinical trial results
26 states	Purdue Pharma	OxyContin	2007	\$19.5 million; various marketing restrictions and disclosure requirements

<sup>93</sup> Note that Table 2 includes only multistate cases, and not industry settlements reached by individual states.



33 states	Pfizer	Celebrex; Bextra	2008	\$60 million; pre-clearance provisions, clinical trial disclosures
32 states	Eli Lilly	Zyprexa	2008	\$62 million; various disclosures and marketing requirements
29 states	Merck	Vioxx; Zocor; Pepcid	2008	\$58 million; pre-clearance provisions, bans on "ghostwriting"
35 states	Merck	Vytorin	2009	\$5.4 million; pre-clearance provisions, disclosure of clinical trial results, various conflict-of-interest regulations
27 states	Bayer	Yaz	2009	\$20 million; pre-clearance provision, corrective advertisement campaign

By achieving settlement after settlement with some of the nation's largest pharmaceutical firms, states have managed to step into the role of Congress and the FDA by establishing stricter marketing restrictions on industry than anything required by federal statutes or regulations. In a few short years, states have managed to implement strict rules concerning disclosure of clinical trial results, new conflict of interest regulations, specific requirements companies must follow when advertising their products, and requirements that companies receive pre-clearance before running any DTC advertisements.

While these provisions technically only apply to the companies party to a particular settlement, they provide a new regulatory baseline the entire industry must follow to be certain that they will not be subject to potentially expensive multistate investigations that could harm their public image. This is why the states' frequent talk about these settlements "sending a message" to the entire pharmaceutical industry is not mere bluster. Indeed, the impact of the settlements even beyond the significant consequences for the individual companies involved in the agreements is apparent when the pharmaceutical industry peak association adopted new voluntary guidelines aiming to help avoid liability for its members. These guidelines were mirrored after recent multistate settlements.<sup>94</sup>

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<sup>94</sup> For example, see "PhRMA Issues Drug Advertising Guidelines, But Some Want Moratorium, Firmer Oversight," *Pharmaceutical Law & Industry Report*, August 5,

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Through their investigations and settlements, state prosecutors have built themselves up as a sort of miniature FDA on the state level. Even as Congress and the FDA generally viewed DTC and off-label marketing generally in a positive light, adopting policies loosening advertising restrictions on drug firms, the states have pursued precisely the opposite policy agenda through a series of regulatory settlements. Relying heavily on state consumer protection law, states have been able to redefine the responsibilities of the pharmaceutical industry nationwide in relation to the marketing of their products. Despite facing no such requirements in federal statutes or regulations, several companies must now abide by the provisions of multistate settlements, including new disclosure requirements and preclearance provisions. Further, the states have used these settlements to extend government regulatory oversight over drug company advertisements into the future and build up their own enforcement capacity. The new requirements that the FDA pre-clear DTC advertisements granted the FDA powers the agency did not even seek out for itself. While helping to build up the FDA's regulatory power, the states also built up their own. The Vioxx and Vytorin settlements, for example, gave the states the ability to enforce federal laws and regulations against Merck. The Celebrex and Bextra settlements contained provisions giving states more tools to monitor industry compliance with their new regulations.

This action by states allowed another avenue for critics of the drug industry to press their claims. After failing to recalibrate the balance of concerns established by Congress and the FDA in these areas, state prosecutions served as an opportunity point to achieve these regulatory changes in a different venue. What is more, this method of policymaking has been able to not only sidestep the broader national debate about drug regulation, but it has also been able to sidestep some important constitutional issues as well. Attempts in Congress to require drug companies to pre-clear their advertisements with the FDA before broadcast have generally failed, largely because of

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2005, 823; "International Pharma Trade Group Adopts New Code Barring Some Marketing Activities," *Pharmaceutical Law & Industry Report*, January 5, 2007, 16; "Rx Industry Group Issues New Guidelines For Companies on Direct-to-Consumer Ads," *Pharmaceutical Law & Industry Report*, December 12, 2008, 1382.

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concerns that any such legislation or agency regulations would be unconstitutional restraints on speech.<sup>95</sup>

The preclearance provisions established by the states get around this constitutional constraint by placing the preclearance requirement in an out-of-court settlement. Because the states' preclearance provision is the result of an "agreement" between the states and the involved companies, it is not vulnerable to the same sort of constitutional challenges that a congressional enactment or agency regulation would be. After all, if the company agreed to abide by this provision, how could it then turn around and claim that it is unconstitutional? As indicated throughout this dissertation, however, companies often do not agree with the legal theories employed by the states but nevertheless feel compelled to sign settlements to reduce their own risk and uncertainty. Merck, for example, objected to preclearance provisions as unconstitutional prior restraints before ultimately acceding to them in order to resolve all of the government litigation surrounding the drug. Essentially, the states have discovered a way to leverage state judicial power to force settlements, but simultaneously shield the regulations contained therein from constitutional challenge by placing them in an out-of-court "agreement."

## **Conclusion**

The recent rise of state pharmaceutical litigation is important for several reasons. For one, underlying this litigation is a new style of policymaking that has not received the attention it deserves. While state prosecutors typically characterize their lawsuits and investigations as "law enforcement," the reality is that these litigation campaigns go beyond merely "enforcing" the law and instead give prosecutors the opportunity to redefine corporate responsibilities. In conjunction with the federal DOJ and private litigants, state litigation redefined the "AWP" pricing mechanism used in government health care programs as "fraudulent" despite the industry relying upon this pricing structure for years. State litigation also cracked down on two of the chief ways in which pharmaceutical firms promote their products

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<sup>95</sup> Natasha Singer, "Citing Risks, Lawmakers Seek to Curb Drug Commercials," *New York Times*, July 27, 2009, B1. For example, see Representative Jerrold Nadler's (D-NY) comments in *ibid.* ("On First Amendment grounds, I am not going to say we will ban" drug advertising).

by litigating a host of DTC and off-label advertising cases, using this litigation as a vehicle for regulatory requirements not required under federal law.

The goal of these lawsuits was generally not to win in court, but rather to achieve large settlements with key members of the drug industry. In addition to large monetary payouts, these settlements have contained a variety of provisions adding additional regulatory requirements on the industry going beyond that required by congressional enactments and agency policy. By resolving these disputes by means less formal than active litigation in court, this settlement process amounts to "bargaining in the shadow of the law."<sup>96</sup> Particularly interesting, however, is that "the law" casting a shadow over the process is typically *state* law, including state False Claims Acts as well as state antitrust and consumer protection statutes. While state law casts the shadow in this bargaining process, the result is new policy dictating new regulatory requirements that apply nationwide, settlement by settlement, to one of the United States' largest industries.

In some ways, achieving policy results through settlements is even more powerful than those reached by the typical lawmaking or regulatory process, because they are immune from judicial review. This is a particularly important benefit to regulation reached through out-of-court settlements, given the shaky legal ground of many of these lawsuits. The contention that AWP was "fraudulent" faced a number of legal problems, including the fact that *doctors*, not pharmaceutical firms, actually benefited from the AWP spread, as well as the fact that governments knew for years that AWP really meant "Ain't What's Paid." Attempts to regulate drug advertising – either by requiring pre-clearance of DTC advertising or by restricting companies' ability to distribute truthful information about their drugs to physicians – raises important free speech issues arising under the First Amendment. By lodging their regulation of the pharmaceutical industry in out-of-court settlements, states have sidestepped potential legal challenges to these provisions. Ironically, then, states have simultaneously leveraged the judicial power to force new regulations

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<sup>96</sup> Robert H. Mnookin and Lewis Kornhauser, "Bargaining in the Shadow of the Law: The Case of Divorce," *Yale Law Journal*, Apr. 1979.

through settlements, but then insulated these regulations from future review by courts.

Further, this litigation illustrates how it is important to tie in legal actions to the broader political climate. Using litigation and settlements to achieve stricter regulatory oversight of pharmaceutical firm activities occurred only after advocates of policy change failed to make these changes in Congress. This failure moved the action to different venues in the America separation of powers system – both horizontally towards courts and litigation and vertically to the states. As litigators on the state level, state prosecutors are perfectly positioned as an alternative policy venue to take advantage of the demand for policy change.

The state prosecutors frequently claim to be acting only because of alleged congressional and federal agency "inaction," but it is worth noting that this "inaction" on the federal level was actually a conscious decision to balance the regulatory regime in a manner different than what the litigators sought. Congress, for example, did not alter the AWP payment system because of concerns that lower payments to health care providers would serve to stop providing Medicaid services. Congress and the FDA alike maintained a looser regulatory approach to DTC advertising and off-label marketing because of the belief that these marketing efforts could have positive health benefits. By achieving settlements that, piece by piece, served to place stricter regulations on the industry, states effectively recalibrated the balance of concerns previously achieved by federal institutions.

It should also be noted that in addition to altering the regulatory landscape, state litigation and settlements helped to alter the political landscape as well. After years of refusing to substantially change the AWP formula for drug reimbursements, Congress did an about-face following the success of the Bayer and TAP settlements and the wave of state litigation that followed. Building upon the existing federal and state investigations, an increasing number of members of Congress decided to respond with their own investigations.<sup>97</sup> Indeed, key congressional committees sought and incorporated information from

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<sup>97</sup> "House Committee Questions Drugmakers In Expanded Medicaid Fraud Investigation," *Pharmaceutical Law & Industry Report*, July 4, 2003, 711.

these lawsuits as part of their own congressional investigations.<sup>98</sup> After decades of acknowledging the AWP payment system as accepted practice, Congress held at least two hearings on the problem of pricing "fraud" following the federal and multistate Bayer and TAP settlements and subsequent individual state litigation.<sup>99</sup>

Ultimately, Congress increasingly accepted the view of AWP-as-fraud and ratified the settlements achieved by federal and state prosecutors. Congress codified the new ASP benchmark – created and defined in the Bayer and TAP settlements and subsequent state complaints – in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In essence, this was acquiescing to the national changes in pharmaceutical pricing that the states were already achieving, settlement by settlement, through their litigation.

Congress made several policy changes following the states' other multistate pharmaceutical litigation campaigns as well. Congress's subsequent ratification of a number of the regulatory disclosure requirements resulting from the states' consumer protection settlements, such as regarding the results of internal clinical trials, applied these provisions to the entire industry.<sup>100</sup> Further, state litigation has forced the industry peak association to reevaluate its own guidelines for its members, providing vindication for attorneys general who wished for their settlements with individual industry leaders to "send a message" to the broader industry.

Understanding policymaking in a fragmented political system like the United States involves a great number of subtleties and complexities, as the state litigation campaigns against pharmaceutical companies indicate. However, this complexity should not deter close examinations of the interactions between different political actors in the making of public policy. Policy failures at one venue may spur a transformation of the means of policy creation at another. This is

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<sup>98</sup> "Grassley Asks DOJ for Confidential Information From Medicaid Investigations," *Pharmaceutical Law & Industry Report*, May 28, 2004, 604.

<sup>99</sup> *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, Joint Hearing Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, September 21, 2001 (No. 107-65); *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*, Joint Hearing Before the Subcommittee on Oversight and Investigations, December 7, 2004 (No. 108-126).

<sup>100</sup> Food and Drug Administration Amendments Act of 2007, 42 U.S.C. § 282(j)(3)(D) (expanding required clinical trial disclosures by pharmaceutical firms).

precisely what has happened with the growth of state litigation in recent years, in pharmaceutical litigation and beyond. State litigation is particularly a rich area for exploration because it involves both the horizontal aspects of fragmentation (interactions of the courts, Congress, and administrative agencies) as well as the vertical interactions (states and the federal government). As state litigators continue to make headlines and aggressively target the federal government and private corporations alike in their lawsuits and investigations, it is all the more important for scholars to continue exploring the implications of this emerging activity for the broader American political system.