

**SHOOTING THE MESSENGER:
“OFF-LABEL MARKETING” ATTACKS
AGAINST PHARMACEUTICAL COMPANIES
BY STATE ATTORNEYS GENERAL**

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1. Introduction

Increasingly, state attorneys general are suing pharmaceutical companies over alleged off-label marketing of prescription drugs. Typically, such lawsuits are filed on behalf of the state and contend that, as a result of off-label marketing by the pharmaceutical company, the state Medicaid program or other state medical assistance program paid for drugs prescribed to patients for off-label uses that are not reimbursable under state law.

In reality, the claims for reimbursement submitted to the state Medicaid/medical assistance program were made by a pharmacist after filling a prescription ordered by a physician who exercised his or her independent medical judgment about which drug would work best for a given patient who exhibited a given condition. Nevertheless, the attorney general usually asserts that the pharmaceutical company engaged in off-label marketing to promote such “false” claims, and that the pharmaceutical company therefore should be held liable for the money the state paid for all off-label prescriptions (even if those prescriptions successfully treated the patients’ conditions). State attorneys general sometimes also assert claims of fraud that seek reimbursement and civil penalties under state unfair trade practices statutes or other fraud-based causes of action based on allegations that the defendant pharmaceutical company fraudulently marketed its drugs for off-label uses.

State attorneys general have a long history of prosecuting purported Medicaid fraud by bringing actions against healthcare providers who allegedly submit false claims to state Medicaid programs. The usual (and often deserving) targets of such actions are healthcare providers (*e.g.*, doctors, pharmacies, medical device sellers) who submit claims for inflated amounts, or pertaining to nonexistent or unnecessary prescriptions. Lawsuits by state attorney generals over off-label marketing by pharmaceutical manufacturers who never submit *any* claims to the state are a relatively new, and legally

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suspect, phenomenon that began in the mid-1990s.

Although off-label marketing of prescription drugs to physicians has long been prohibited,² it has historically been an area of regulation within the domain of the U.S. Food and Drug Administration (“FDA”). The FDA has primary responsibility for the regulation of the truth or falsity of prescription drug labeling; it exercises primary jurisdiction over all matters regarding the labeling of prescription drugs.³ But since the mid-1990s, state attorneys general, often encouraged or backed by private contingency-fee-financed lawyers, have encroached upon the FDA’s jurisdiction over this issue, seeking to become *de facto* regulators who advance their own policy objectives regarding prescription drug policy. Since 1999, pharmaceutical companies have paid more than **\$2 billion** to settle off-label marketing claims, including substantial payments to state attorneys general.⁴

The enthusiasm and vigor with which many state attorneys general have pursued these claims may be welcomed by those who believe that the FDA has failed to enforce the “no-off-label-marketing” laws with sufficient energy or resources. But it threatens the unified national prescription drug policy crafted by the FDA. It also may limit treatment options for physicians and their patients and damage the modern practice of medicine.

The assumption underlying state attorney general lawsuits attacking purported off-label marketing of drugs is that prescribing a drug for a patient or condition as to which the FDA has not approved the drug is presumptively a bad thing because (a) the drug will not effectively treat the condition, and/or (b) the patient will incur an excess risk of adverse side-effects. This assumption is contrary to reality. In fact, doctors are allowed by standards of professional ethics to, and do, prescribe drugs for off-label purposes every day for the simple reason that doing so promotes the health interests of their patients. No statute, regulation, court decision, or medical standard prohibits doctors from prescribing a particular drug to a particular patient to treat a particular condition on the basis that the FDA has not approved that drug for use in those circumstances. That the FDA has formally endorsed the use of a particular drug for treatment of specified conditions in specified patient populations in no way precludes doctors from deciding, based on the exercise of their independent medical judgment, that the drug would also help a different patient combat a particular condition, or help an FDA-designated patient combat a different problem. FDA-approved uses of a drug are, and are known to be, inherently conservative, and they leave doctors free to prescribe drugs for patients and

² 21 U.S.C. § 331(d).

³ See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18539 (Sept. 16, 1971).

⁴ Off-label marketing claims have been settled for the following prescription drugs, among others: Protropin (\$50 million), Neurontin (\$430 million), Evista (\$36 million), Serostim (\$704 million), Temodar and Intron A (\$435 million), Actimmune (\$36 million), OxyContin (\$19.5 million), Zyprexa (\$15 million), Loprox (\$9.8 million), and Actiq (\$425 million).

conditions different than those for which the FDA has formally approved a drug. The federal courts have accepted this reality of medical practice.⁵ Indeed, the U.S. Supreme Court has recognized off-label use of prescription drugs as “an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.”⁶

Although doctors are free to prescribe FDA-approved drugs for non-approved uses,⁷ pharmaceutical companies are prohibited from marketing those drugs to doctors and patients for conditions and patient populations other than those for which the FDA has approved the drug.⁸ Although pharmaceutical companies are permitted, under certain conditions, to convey to doctors independent studies examining the utility of a drug for treatment of patients or conditions for which the drug is not-FDA approved,⁹ they may not actively “market” a drug for FDA-unapproved uses.¹⁰

These rules create some uncertainties in the law—inviting speculation about whether particular “off-label” prescriptions by doctors were caused by unlawful drug marketing campaigns by manufacturers. State attorneys general often seek to use evidence of off-label prescriptions by physicians as proof of an illegal off-label marketing conspiracy by pharmaceutical companies, second-guessing the physician’s decision that the off-label prescription was necessary and appropriate for a particular patient. State attorneys general who bring such suits do not care what the prescribing doctor thought about the efficacy of the drug—they simply want to further discourage a practice that is already illegal at the federal level, while obtaining a large settlement or judgment for their state. While off-label marketing lawsuits may increase the amount of money sent to a given state’s treasury, they ultimately do a disservice to the citizens state attorneys general purport to protect.

This article examines why state attorneys general have led the charge to litigate off-label marketing claims, and explains the consequences of that phenomenon. The article also addresses some of the challenges and opportunities that pharmaceutical

⁵ *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (“the prescription of drugs for unapproved uses is commonplace in modern medical practice and ubiquitous in certain specialties”).

⁶ *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (“‘off-label’ usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.”).

⁷ See 21 U.S.C. § 396 (1994 ed. Supp. IV) (“nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”).

⁸ 21 U.S.C. § 331(d).

⁹ 21 U.S.C. § 360aaa.

¹⁰ 21 U.S.C. § 331(a).

companies face in off-label marketing litigation waged by state attorneys general.¹¹

2. Coherent Regulation Of Prescription Drugs Is Being Imperiled By An Alliance Of State Attorneys General And Contingency-Fee Lawyers.

Many lawsuits filed by state attorneys general accusing pharmaceutical companies of illegally marketing prescription drugs for off-label uses are the progeny of an evolving relationship between public officials and private attorneys. This relationship reached maturity in the mid-1990s, when state attorneys general began partnering with private contingency-fee lawyers to recover money their states paid to treat alleged tobacco-related illnesses. Entrepreneurial plaintiff's attorneys, perceiving that lawsuits against tobacco companies for reimbursement of third party medical expenses had the potential to yield extraordinary fees, marketed themselves to state attorneys general as public advocates who would pursue the states' interests in exchange for a share of any monetary recovery. As explained by legal scholar Robert Levy, "[i]n effect, members of the private bar were hired as government subcontractors—their remuneration tied to the magnitude of their conquest. Thus, the sword of the state was brandished by outside counsel whose overriding duty, as public servants filling a quasi-prosecutorial role, was to seek justice."¹² The fact that "justice" was not outside counsel's only—or even primary—concern is not surprising. These private contingency-fee lawyers stood to gain millions or billions of dollars by partnering with multiple state attorneys general and claiming for themselves a share of whatever recovery the state might obtain. And profit they did. In just one state, the contingency-fee lawyers received \$625 million in legal fees—or \$13,000 for every hour they worked on the tobacco case.¹³

Many private contingency fee lawyers are hoping that off-labeling marketing claims against pharmaceutical companies will provide similar pay-offs. As with the tobacco actions, off-label marketing lawsuits often are conceived by private contingency-fee lawyers who hope to convince state attorneys general to let them prosecute a case on the state's behalf in exchange for a financial interest in its outcome. The tantalizing prospect of earning millions of dollars in contingency fees in cases that seek multiples of that amount in damages or penalties has led private contingency-fee lawyers to aggressively lobby state attorneys general to hire them to represent the state in off-label marketing lawsuits. The right to represent the states in high-value off-label marketing litigation, like political favors, is being doled out by some state attorneys general to friendly members of the plaintiffs' bar—sometimes the same people who contributed

¹¹ While the Department of Justice has increasingly pursued criminal enforcement of off-label marketing allegations, criminal liability for off-label marketing activities is outside the scope of this article.

¹² Robert A. Levy, *States Share Blame for Tobacco Lawyers' Greed*, *Insight Magazine* (May 10, 1999).

¹³ Judge Questions Legal Fees in New York Tobacco Case, *New York Times* (March 17, 2003).

money to their political campaigns.¹⁴ From the state attorney general’s perspective, appointing a private lawyer as a “special assistant attorney general” expands the attorney general’s resources without impacting his budget. Economic factors and state budget decisions have reduced the amount of money state attorney generals have available to pursue high-cost cases; hiring talented private counsel to represent the state on a contingency fee basis allows the attorney general to expand his reach off-budget. Moreover, for the state attorney general, a settlement from a politically disfavored defendant—such as a pharmaceutical company—translates into political capital. Since the attorney general often deputizes the private lawyer as a public official for the limited purpose of litigating the off-label marketing case, the attorney general’s office is able to claim the credit for any litigation result (whether litigation or settlement-induced) that appears to benefit the state.

Partnerships with state attorneys general to assert Medicaid reimbursement claims based on off-label marketing or other fraud-based allegations is the Holy Grail for many contingency-fee plaintiffs’ lawyers. Representing the state gives the lawyers instant credibility and provides them with extraordinary leverage that helps them extract large monetary settlements or awards from targeted defendants. Partnering together, state attorneys general and private plaintiffs’ lawyers can pursue lawsuits that otherwise would not be worth pursuing. More pointedly, state attorneys general can bring cases that normally would not be brought because they likely do not yield enough social utility to justify the devotion of limited public resources.

Given these incentives, the partnership between private contingency-fee lawyers and state attorneys general may lead to litigation strategies and policy decisions that maximize contingency fees for private plaintiff attorneys, rather than the welfare of state citizens. Absent intervention by state legislatures or the federal government, state attorneys general are increasingly likely to retain private counsel to litigate off-label marketing claims.

3. An Example of Typical Off-Label Marketing Litigation

Off-label marketing claims have been brought under a number of legal theories, but the common denominator is usually an alleged misrepresentation or fraud by the pharmaceutical company about the risks or benefits of the drug’s off-label uses. Typically, the state attorney general seeks a reimbursement from the pharmaceutical company for prescription drugs that a state medical assistance program, such as Medicaid, paid to provide to third party patients. For example, the state attorney general may seek a refund of all payments a state Medicaid program made to pharmacists for

¹⁴ Rob Luke, *Houston Firm Lands AG Contracts After Dem. Donations*, LegalNewsline.com, Feb. 21, 2008, <http://www.legalnewsline.com/news/208241-houston-firm-lands-ag-contracts-after-dem.-donations>; James Nash, *‘Pay to Play’ limits have a weakness: middlemen*, The Columbus Dispatch, Oct. 28, 2007, at 1A.

filling prescriptions for a given drug that were written by doctors to treat conditions for which the FDA did not approve the drug. If the state attorney general contends that the pharmaceutical company misled physicians about the risks or side-effects of the prescription drug when used for unapproved conditions or patients, the attorney general may seek compensation for money paid by the state to treat persons allegedly injured by the drug.

Although initially commenced by a private litigant, the litigation concerning alleged off-label marketing of the prescription drug Neurontin highlights many of the issues that arise in a typical attorney general off-label marketing case. Neurontin is the brand name for gabapentin, a prescription drug approved by the FDA to treat epilepsy. In addition to its approved use, Neurontin was prescribed by many physicians for a variety of off-label purposes, including pain control, as a mono-therapy for epilepsy, for control of bipolar disease, and as a treatment for attention deficit disorder. Off-label use of Neurontin was not limited to the United States. Sixty countries permit Neurontin to be prescribed for treatment of pain—a use not approved by the FDA.¹⁵ By some accounts, doctor-prescribed off-label use of Neurontin was extensive, with one study of its use in a state Medicaid plan showing that off-label use accounted for 95% of all Neurontin prescriptions.¹⁶ This widespread use of the drug was arguably due to its lack of serious side effects, few drug interactions, its comparatively better tolerance by patients, and its ease of use.¹⁷

Neurontin is an expensive drug. In 2004, a 30-day supply of Neurontin at a common dose cost approximately \$200 per month.¹⁸ With approximately 12 million people using Neurontin between 1994 and 2004, the amount of money state medical assistance programs spent on Neurontin was extraordinary. For some states, reimbursements for Neurontin prescriptions ranked near the top of all prescription drug expenditures.¹⁹

In 1996, allegations of off-label marketing of Neurontin by Parke-Davis, then a division of Warner-Lambert Company, began to surface.²⁰ Dr. David Franklin, a former employee of Parke-Davis, sued Parke-Davis in the United States District Court for the District of Massachusetts under the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729-33, for allegedly engaging in off-label marketing of Neurontin. Dr.

¹⁵ Julie Schmit, *Drugmaker admitted fraud, but sales flourish*, USA Today, Aug. 17, 2004, at 1A.

¹⁶ Alicia Mack, *Examination of the Evidence for Off-Label Use of Gabapentin*, 9 J. Managed Care Pharm. 559, 559 (2003).

¹⁷ John Barbuto, M.D., *Gabapentin and indications of appropriate use*, 8 J. Managed Care Pharm. 293 (2002).

¹⁸ Press Release, William H. Sorrell, Attorney General of the State of Vermont, Attorney General William H. Sorrell Announces Historic Settlement With Pfizer Division Over Improper Off-Label Drug Marketing (May 13, 2004), <http://www.atg.state.vt.us/display.php?pubsec=4&curdoc=685>

¹⁹ Julie Schmit, *Drugmaker admitted fraud, but sales flourish*, USA Today, Aug. 16, 2004, at 1A.

²⁰ In 2000, while the litigation was ongoing, Warner-Lambert Company merged with Pfizer Inc.

Franklin was a “medical liaison” for Parke-Davis for a five-month period in 1996. He claimed that Parke-Davis engaged “in an extensive and far-reaching campaign to use false statements to promote increased prescriptions of Neurontin and Accupril for off-label uses which caused the filing of false claims for reimbursement by the federal government.”²¹ Dr. Franklin alleged that Parke-Davis instructed him and other “medical liaisons” to make false or exaggerated claims about the safety and effectiveness of Neurontin for off-label uses. Dr. Franklin also claimed that doctors received kickbacks for prescribing large quantities of Parke-Davis drugs.

The theory of recovery in the case was that Parke-Davis profited at the expense of the state Medicaid program. In many states, Neurontin was ineligible for reimbursement from Medicaid when prescribed for an off-label use because it was not included in the one of several state-approved compendia. The plaintiff contended that Parke-Davis knew that claims for reimbursement for off-label use of Neurontin would be submitted to state Medicaid programs, but nevertheless continued to recommend the drug for off-label use. Although the case was initiated by a private party, state attorneys general later became involved and, eventually, all fifty states and the District of Columbia—led by Vermont Attorney General William H. Sorrell—asserted off-label marketing claims against Parke-Davis.

The case was heard before Judge Patti B. Saris. At the motion to dismiss stage, Parke-Davis did not, for reasons that are unknown, deny that an off-label prescription submitted for reimbursement by Medicaid would constitute a false claim.²² Instead, Parke-Davis argued that (1) the claims were an end-run around the enforcement provisions of the FDCA; (2) impermissible off-label marketing does not necessarily include a false statement or fraudulent conduct; (3) the independent actions of the physicians who wrote the off-label prescriptions, and the pharmacies that accepted and filled the prescriptions, broke the chain of causation stemming from any alleged misconduct by Parke-Davis marketing personnel; and (4) the plaintiff failed to allege that the allegedly false statements made to doctors were material to the government’s decision to pay for off-label prescriptions of Neurontin.²³ While noting that this area of law was “not well charted by the decisional law,” the court rejected each of these arguments.

First, Judge Saris rejected Parke-Davis’s argument that the claims were an end-run around the enforcement provisions of the FDCA. The court ruled that “the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit.”²⁴ The court reasoned that “the failure of Congress to provide a cause action [sic] for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude on [sic]

²¹ 147 F. Supp.2d at 45.

²² 147 F. Supp. 2d at 51.

²³ 147 F. Supp. 2d at 51-53.

²⁴ 147 F. Supp. 2d at 51.

FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government” in violation of the FCA.²⁵

The court then turned to Parke-Davis’s argument that off-label promotions do not necessarily involve a false statement and therefore cannot constitute false claims. The court construed the plaintiff’s complaint differently, interpreting it to allege that Parke-Davis made false statements that, in turn, caused false claims to be submitted to state Medicaid programs. The court stated that “[a] much closer question would be presented if the allegations involved only the unlawful—yet truthful—promotion of off-label uses to physicians who provide services to patients who are covered by Medicaid, as well as patients who are not, without any fraudulent representations by the manufacturer.”²⁶

The court also rejected Parke-Davis’s arguments regarding lack of causation, holding that “when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.”²⁷ Furthermore, the court found it immaterial that Parke-Davis never made any statements or claims directly to the federal government. According to the court, “the government would not have paid the claims if it had known of the use for which they were being submitted.”²⁸

Later, at the summary judgment stage, Parke-Davis changed tack. Instead of conceding that off-label prescriptions submitted for reimbursement by Medicaid are false claims, it argued that states have discretion under the Medicaid statute to provide reimbursement for off-label prescriptions.²⁹ Hence, Parke-Davis argued, there can be no false claim if the state permits reimbursement for off-label use. The court left this question open, and sought amicus briefing from federal officials that would provide the federal government’s position on the extent to which the Medicaid statute empowers states to provide coverage for off-label, non-compendium prescriptions.³⁰ This issue was never resolved. The case settled on May 13, 2004, with the defendants agreeing to pay \$430 million, with \$38 million going directly to the states.³¹

The Parke-Davis case presented novel theories that are now the starting point for most off-label marketing litigation. Some of these theories—which were developed by

²⁵ *Id.* at 52.

²⁶ *Id.*

²⁷ *Id.* at 52-53.

²⁸ *Id.* at 53.

²⁹ *United States ex rel. Franklin v. Parke Davis*, Civ. A. No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 at *7 (D. Mass. Aug. 22, 2003).

³⁰ 2003 U.S. Dist. LEXIS 15754 at *8-9.

³¹ \$240 million was paid to resolve criminal fines, \$83.6 million was paid to the federal government, and \$38 million to the states. Dr. Franklin, the individual who filed the initial *qui tam* lawsuit, was paid \$24.6 million.

financially interested parties pursuing novel theories of recovery—required novel interpretations of existing law. For instance, the plaintiff contended that pharmaceutical companies could be held liable for false claims made by physicians and pharmacists to state Medicaid programs—claims that the pharmaceutical company was likely unaware of both before and after the fact—simply because the prescription decision may have been based, in part, on information supplied by the pharmaceutical company. Such a theory requires expansive notions of causation and may in many instances raise constitutional concerns.³² Because the court decisions that arose from the Neurontin litigation comprise the first reported cases addressing civil liability to state and federal medical assistance programs for off-label marketing claims, they will prove central to any future off-label marketing battles.

4. Risk Factors for Off-Label Marketing Lawsuits

Following the financially remunerative settlement of the Neurontin case, state attorneys general filed more off-label marketing lawsuits against a number of pharmaceutical companies pertaining to a wide variety of prescription drugs. The typical off-label marketing lawsuit targets a manufacturer of a prescription drug that is approved by the FDA for narrow uses, but which in practice is widely prescribed by doctors for off-label purposes. However, there are additional risk factors that may be used to evaluate the threat of off-label marketing litigation:

Issuance of an FDA Warning Letter. The most significant risk factor for an off-label marketing lawsuit is the issuance of an FDA warning letter raising off-label marketing concerns. FDA warning letters are typically the immediate precursor to off-label marketing litigation. An FDA warning letter is an informal advisory statement issued by the FDA to the manufacturer of a prescription drug that communicates the agency’s position on the matter, but it does not commit the FDA to take any enforcement action.³³ FDA warning letters do not constitute final agency action; rather, warning

³² Attacks by state attorney general seeking penalties or damages for truthful off-label communications raise substantial First Amendment concerns that have not yet been sufficiently addressed. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998); *Washington Legal Foundation*, 56 F. Supp. 2d 81 (D.D.C. 1999); *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000). Indeed, the problem of policing truthful off-label communications is compounded by the fact that “[w]hat is on-label in Europe may be off-label in the U.S.” and “[m]odern information technology makes it almost impossible to restrict communications by geography, training, or position.” Ralph F. Hall, “*Off-Label*” *Speech: Uncertainty Reigns for Device and Drug Makers*, Legal Backgrounder, Washington Legal Foundation (Dec. 2, 2005).

³³ FOOD AND DRUG ADMINISTRATION, REGULATORY PROCEDURES MANUAL 4-2 (March 2007); see also *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (Nev. Ct. App. 1983) (“The letters do contain conclusions by subordinate officials of the FDA that products . . . are in violation of federal law and also indicate a readiness on the part of the FDA to initiate enforcement procedures if corrective measures are not taken. As the Secretary points out, however, such letters do not commit the FDA to enforcement action.”).

letters are intended to establish a dialogue with the pharmaceutical company.³⁴ Warning letters concerning off-label marketing may, for example, set forth the agency's view that statements made by the pharmaceutical company are in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations because the company makes representations about the drug that are false or misleading. Unlike notions of fraud and deception common to judges and lawyers, "[i]n the FDA world, labeling can be misleading even if technically or literally true."³⁵ Even though FDA warning letters are not formal adjudications, they provide potential plaintiffs with a roadmap for constructing an off-label marketing complaint. FDA warning letters may also become powerful evidence in the trial of off-label marketing claims, although there is no general rule regarding their admissibility.³⁶

High ratio of off-label to on-label use. The most compelling targets for state attorneys general are drugs with off-label prescription volumes that dwarf on-label use. Although, as discussed above, off-label prescriptions are entirely legitimate, enterprising attorneys general may point to frequent prescriptions of a drug for off-label use as a basis for alleging that the pharmaceutical company's marketing practices must be the reason why this has occurred.

Relative expense of the drug vis-à-vis other reimbursed prescription drugs. High-priced drugs are a third warning flag for potential off-label marketing lawsuits. Reimbursement of the cost of relatively high-priced prescription drugs is an attractive proposition for state attorneys general seeking to recover costly Medicaid expenses, or contingency-fee lawyers seeking to maximize a damage award and attorney fees. Recent litigation has highlighted how important this factor may be. Certain kinds of prescription drugs, such as newly developed antipsychotics, have received particularly close scrutiny from state attorneys general because they are much more expensive than their less-effective counterparts. When high-priced pharmaceuticals are used more often for off-label than on-label use, and the FDA has sent a warning letter expressing concerns about off-label marketing, lawsuits by state attorneys general seeking compensation or penalties will not be far away.

5. What Role Should State Attorneys Generals Play in Policing Off-Label Marketing?

³⁴ See *Prof'ls and Patients for Customize Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. 1994) ("Warning letters merely establish a dialogue between the FDA and the pharmacist and do not necessarily lead to further sanctions.")

³⁵ Ralph F. Hall, "*Off-Label*" *Speech: Uncertainty Reigns for Device and Drug Makers*, Legal Backgrounder 20:59.

³⁶ "It has been held that FDA letters are irrelevant to liability because of their lack of legal finality, or because their meaning is open to interpretation. However, such warnings have been admitted as relevant to the issue of punitive liability, or as probative of knowledge or scienter, where relevant." Drug and Medical Device Product Liability Deskbook § 11.01[1][a].

It may seem quite natural for state attorneys general to vigorously pursue off-label marketing claims since most such claims assert a fraud on the state medical assistance program. But with so much money up for grabs in these cases, the potential long-term consequences of the novel theories sometimes being advocated is often an afterthought. In fact, litigation of off-label marketing claims by state attorneys general is not helpful to achieving a rational and uniform national prescription drug policy. In the rush for quick settlements to replenish state treasuries (and sometimes fill the pockets of private contingency fee lawyers), consideration of the long-term consequences of this fractured approach to pharmaceutical regulation is taking a back seat.

The chief negative effect of off-label marketing litigation by state attorneys general is the destabilization that occurs when fifty state attorneys general, plus the federal government, engage in uncoordinated attacks against pharmaceutical companies about statements made to healthcare providers that may not be false or misleading. The FDA is the federal entity charged with the authority to regulate off-label marketing of prescription drugs to healthcare providers.³⁷ Involvement by state attorneys general may undercut the FDA and effectively establish myriad regulatory regimes with different standards depending on how the law has developed in each jurisdiction. Because state attorneys general—unlike the FDA—have little incentive to constrain their behavior to satisfy broader social objectives, their effort to regulate off-label marketing via litigation may be counter-productive.

Furthermore, the increasing propensity of some state attorneys general to appoint private counsel as “special assistant state attorneys general” to litigate off-label marketing claims results in prescription drug policy being driven by profit, instead of by the public interest. Unlike true public officials who are paid fixed salaries out of the public treasury, state attorneys general are increasingly entrusting the power of the executive branch to contingency-fee lawyers who have personal financial interests in the outcome of the case. Since these hired guns obtain their compensation only if they are successful, and the size of their compensation is directly proportional to the amount of money recovered for the state, it stands to reason that off-label marketing claims will be asserted based on a cost-benefit function that does not sufficiently account for broader societal objectives. But if the central focus of an attorney general action is simply to maximize recovery, divorced of policy objectives, society suffers. In fact, the state attorney general has an ethical obligation to protect larger public interests. The state attorney general “is expected to exercise prosecutorial discretion that takes into account what social goods might be sacrificed by initiating a lawsuit.”³⁸ Cloaking private contingency fee lawyers with the mantle of state authority may lead to the pursuit of novel theories of recovery or the taking of positions that conflict with social welfare writ large.

³⁷ See Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18539 (Sept. 16, 1971).

³⁸ Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. Mich. J.L. Reform 281, 297 (2007).

Absent a private contingency-fee lawyer who is effectively insuring the state against a loss, state attorneys general would more carefully weigh the likelihood of success and the societal benefit to be achieved if the lawsuit is successful against the negative effects of bringing suit. Although success may bring political rewards to the attorney general, personal financial gain is never a part of the calculus. The state attorney general must consider whether, subject to the budget constraints imposed by the state legislature, the benefits to be gained by the state outweigh the cost of expending limited resources. By employing private contingency-fee lawyers to pursue off-label marketing claims, state attorneys general can behave opportunistically and litigate cases they would otherwise not assert.³⁹ As a result, state attorneys general may “exercise[] suboptimal caution in selecting legal theories, which arguments to make, and which strategies to employ.”⁴⁰

Opportunistic attacks on pharmaceutical companies by fifty state attorneys general may also result in greater legal uncertainty. While some commentators have praised crusading attorneys general as “policy entrepreneurs” for their efforts to fill what some see as a void in FDA enforcement of off-label marketing, actions by state attorney generals have not clarified the potential for liability for communications concerning the off-label use of prescription drugs.

Perhaps most importantly, it is not clear how off-label marketing lawsuits have achieved greater social utility. With hindsight, cases such as the Neurontin litigation appear to be little more than an expensive means of transferring wealth from pharmaceutical companies to state treasuries. Many of the states that sued Parke-Davis to recover payments made for off-label prescriptions continue to pay for those off-label prescriptions without question. Indeed, four years after the case was settled, only 4 of 50 state Medicaid programs now require pre-approval of Neurontin prescriptions to ensure that it is being used for FDA-approved purposes.⁴¹ By all accounts, Neurontin remains just as popular among physicians as before. In the quarter immediately following the settlement over off-label marketing of the drug, sales of Neurontin actually *increased* 32% from the year prior, and there is no reason to believe this increase resulted from either off-label marketing or explosive growth in on-label use.⁴² It cannot be doubted that states are aware that they are paying for off-label use of Neurontin. Nor can it be doubted that states have it within their power to avoid payment for off-label use of Neurontin if they really believe it improper, but they refrain from doing so. The state attorneys general had their victory, but evidence is now showing that the victory was undeserved, and consumers are paying the price.

³⁹ See *id.* at 300-301.

⁴⁰ *Id.* at 301.

⁴¹ Julie Schmit, *Drugmaker admitted fraud, but sales flourish*, USA Today, Aug. 16, 2004, at 1A.

⁴² *Id.*

6. Strategies for Defending Against Off-Label Marketing Claims by State Attorney Generals

Off-label marketing actions by state attorneys general pose great challenges for defendants. State attorneys general have instant credibility before courts. They also have access to vast quantities of data about prescriptions made in the state that are unavailable to defendants at the time the case is filed. The attorney general will typically seek to use this information to construct a statistical model ostensibly proving that off-label marketing influenced prescription decisions. In combating these claims, the defendant in an off-label marketing lawsuit must independently evaluate the appropriate strategy based on the unique facts in each case. Nevertheless, the following are some strategies that should be considered:

Investigate private counsel's appointment. If the off-label marketing claim is being litigated by a private attorney who has either been retained or appointed by the state attorney general to be a “special assistant attorney general,” the defendant’s first step should be to determine whether the appointment conforms to state law. Despite the widespread practice of appointing “special assistant attorneys general” to operate on a contingency fee basis, some states prohibit the practice or otherwise establish substantive and procedural rules for contracting out litigation work. There may also be state ethical rules that regulate the retention, especially if the private lawyers have contributed to state officials or have financial relationships with the state government.

If the state has rules that must be followed, the defendant’s next step should be to determine whether the attorney general complied with the rules. To help make this determination, defendants should make requests for information under state-level freedom of information acts seeking the retention agreement between the attorney general and private counsel. Sometimes, state attorneys general try to evade laws prohibiting contingency fee agreements between the state and private lawyers by creatively hiding the manner in which the private attorneys are to be paid. If the evidence supports it, the defendant should consider a motion to strike the pleadings or seek to have the private attorney disqualified from representing the state.

Seek Broad Discovery. The discovery device gives defendants a significant advantage in off-label marketing actions by state attorneys general that is not usually present when the plaintiff is a private party, such as in a *qui tam* action filed by a private litigant. Discovery of state Medicaid databases will yield large amounts of information about how and why the drug was prescribed. Furthermore, the state may have access to medical records which may yield evidence about the number of actual off-label prescriptions. The state may also have evidence in its possess about interactions the defendant had with state agencies, including discussions state officials had regarding the efficacy or side-effects of the drug.

Depositions of state-employed pharmacists or physicians may further undercut the

state's claim that the drug is dangerous or ineffective. Indeed, discovery may also show conflict within the state. Since the state attorneys general typically do not consult with state public health officials prior to bringing the off-label marketing lawsuit, discovery may highlight disagreement between the state attorney general and state public health officials regarding the propriety of off-label use. Furthermore, evidence may also exist that the state continues to allow a drug to be used for a purpose the state claims to be ineffective or harmful. Since the attorney general is suing on behalf of the state, this information is available to the defendant in discovery.

The threat of vigorous discovery, once it is recognized by the attorney general, will also help the state understand the costs involved with continued litigation. In this sense, discovery of the state creates a beneficial side-effect in cases litigated by private attorneys acting as "special assistant attorneys general" insofar as it forces states to reevaluate the cost-benefit function of continued litigation by considering more fully the amount of investment that must be made.

Avoid the Statistical Case. In the typical off-label marketing case, the state attorney general seeks a refund of money spent on a prescriptions the attorney general contends were the result of improper off-label marketing by the defendant. To establish these claims, the attorney general will usually attempt to prove, via statistical evidence, that the increase in state expenditures for a drug is tied to the defendant's off-label marketing of the drug. However, defendants can break the chain of causation if they can show that the purported off-label marketing did not, in fact, influence prescribing physicians. It is therefore crucial to distinguish sales of prescription drugs that result from physicians' science-based decisions about how to treat an individual patient from sales of prescription drugs that result from a pharmaceutical company's marketing efforts. This will require that the defendant obtain individualized evidence such as depositions of treating physicians who actually prescribed the drug. While the state will usually fight such discovery efforts, claiming that individualized evidence is unwieldy and inappropriate, the defendant is under no obligation to conform its defense to the contours of the plaintiff's case-in-chief.

Litigate the Science. State attorneys general often take the position in off-label marketing litigation that the prescription drug at issue is not as safe or effective as the pharmaceutical company claimed it to be. This position may, in fact, mirror claims asserted in an FDA Warning Letter previously sent to the pharmaceutical company raising allegations of off-label marketing. The veracity of the alleged off-label marketing claims will therefore be squarely at issue. In addition to seeking expert testimony to rebut the claims, defendants can often look to the state's own conduct for evidence disproving these claims. For example, even though the state attorney general may contend that a drug is dangerous or ineffective, pharmacists or physicians employed by the state department of health may have a different view. The experienced physicians who work with real patients and have everyday experiences with the risks and benefits of

the drug will often provide proof of efficacy in the absence of random, double-blind studies. Defendants should use such evidence of the state's post-filing conduct to their own advantage.

7. Conclusion

While the FDA acts conservatively in approving prescription drugs for the treatment of specified conditions in specified patients, doctors are free to prescribe those drugs for "off-label" purposes if they believe, based on all sources of information available to them, it would help their patients contend with the medical conditions they suffer. While federal law prohibits manufacturers of those drugs from affirmatively marketing them for off-label purposes, they are allowed to provide doctors with independent information about the possibly effective uses of their drugs to treat conditions or patients for which FDA approval has not been obtained. Although the line between lawful and unlawful conduct in this area is sometimes blurry, the public interest ultimately is well-served by doctors making independent patient-specific decisions about what course of treatment is best for a given patient facing a given condition, even if that course of treatment involves using a drug in a way that the FDA has not approved.

While state attorneys general clearly have the right and obligation to prosecute unlawful commercial practices in their state that adversely affect state citizens, the pecuniary and political benefits of pursuing lawsuits against pharmaceutical companies accusing them of legal culpability for all off-label prescriptions that occur in their state has led some attorneys general to file (via private lawyers working on a contingency basis primarily for profit-motivations) lawsuits that arguably do not advance the public interest.

If the principles of doctor freedom to make independent prescribing decisions, and of drug manufacturer freedom to disseminate information about the uses of its drugs are to be respected, companies targeted by "off-label marketing" attorney general actions that lack merit should vigorously defend themselves against such actions. Although the attorneys general enjoy various institutional advantages, it is by no means impossible for a defendant to successfully defend itself against such a case, provided that it has both the courage and the ability to challenge the propriety of the case brought against it.