

STATE FALSE CLAIMS ACTS AND
“OFF-LABEL” PROMOTION

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I. Introduction

Last year, federal legislation encouraging states to enact false claims acts became effective.¹ Under the legislation, any state that enacts its own false claims act (state FCA) with liability, *qui tam*, and penalty provisions that are at least as effective as those of the federal False Claims Act (federal FCA) becomes eligible for a 10 percent increase in its share of any Medicaid fraud recovery.² The legislation has prompted states that did not previously have false claims statutes to enact them and caused states wishing to qualify for the additional funds to amend their existing state FCAs.

In recent years, state and federal prosecutors have increasingly investigated pharmaceutical companies and pressed civil and criminal actions alleging illegal “off-label” marketing of drugs.³ Such cases have embraced expansive theories of liability that have implicated state equities. In false claims act cases, for example, both private litigants (called “relators”) and state and federal officials have alleged that pharmaceutical manufacturers, by promoting their products for uses not approved by the Food and Drug Administration (FDA), have caused the submission of false or fraudulent claims to state Medicaid programs.⁴

The enactment of multiple state FCAs, and the increase in investigations and litigation alleging illegal off-label marketing of drugs by pharmaceutical manufacturers, raise important questions: What impact will passage of multiple state FCAs have on investigations of off-label promotion in an already complex regulatory world? Will multiple state FCAs result in a coherent regulatory regime for

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¹ See Deficit Reduction Act of 2005, Pub. L. No. 109-171, tit. VI, § 6031, 120 Stat. 4, 72-73 (2006) (adding new § 1909 to title XIX of the Social Security Act), codified at 42 U.S.C. § 1396h (effective Jan. 1, 2007).

² See 42 U.S.C. § 1396h(a); see also Michael A. Sullivan, A “False Claims Act” Is Finally Enacted in Georgia: What Georgia Lawyers Should Know About the “State False Medicaid Claims Act”, Ga. Bar J. (Oct. 2007), at 13.

³ See Michael K. Loucks, Pros and Cons of Off-Label Promotion Investigations and Prosecutions, 61 Food & Drug L.J. 577, 583 (2006) (“Off-label investigations and prosecutions will not go away.”); Joan McPhee, The survival dilemma, Nat’l L.J. (Jan. 21, 2008), at 22 (lamenting the “government’s recent aggressive campaign to prosecute and punish the dissemination of truthful, nonmisleading off-label information by pharmaceutical manufacturers”).

⁴ See Allegations of Waste, Fraud and Abuse in Pharmaceutical Pricing: Financial Impacts on Federal Health Programs and the Federal Taxpayer: Hearing Before the House Comm. on Oversight and Gov’t Reform, 110th Cong. (Feb. 9, 2007) (statement of Lewis Morris, Chief Counsel to the Inspector General, Dep’t of Health and Human Services).

pharmaceutical marketing? Will states actually benefit? How will regulatory officials and pharmaceutical companies be affected? What about the public health?

This article analyzes the federal legislation encouraging state legislatures to enact their own false claims statutes and the manner in which the Inspector General of the Department of Health and Human Services (HHS) evaluates state FCAs to determine whether they comply with the requirements of the federal law. The article then discusses briefly the Inspector General's determinations regarding the state FCAs it has evaluated, as well as the manner in which investigations and litigation typically are conducted under state FCAs. Finally, the article considers the impact of multiple state FCAs on the investigation and prosecution of off-label promotion of drugs. Ultimately, the article concludes that multiple state FCAs likely will result in an incoherent regulatory regime that provides little benefit to the states while greatly complicating the operations of government regulatory and enforcement officials and pharmaceutical manufacturers.

II. Encouraging the Enactment of State False Claims Acts

A. The Deficit Reduction Act

In 2006, as part of the Deficit Reduction Act (DRA), Congress enacted legislation to provide incentive for states to enact state FCAs modeled after the federal FCA.⁵ The DRA gave incentive to the states to enact legislation that would make persons who submit false claims to Medicaid liable to the state. The incentive provided by the DRA to states that enact such legislation is an increase in the share of any amounts recovered from a lawsuit brought under a qualifying state FCA.⁶

Medicaid is a joint federal and state program that provides health benefits to low-income beneficiaries. States administer Medicaid within broad federal guidelines and receive matching funds from the federal government. The federal contribution (called the "federal medical assistance percentage") varies from state to state, depending on each state's poverty level. The wealthiest states receive a federal contribution of 50 percent, while poorer states receive a larger contribution.⁷

Individuals and firms who present false claims to Medicaid may be held civilly liable under the federal FCA.⁸ Under the federal FCA, any person who knowingly submits a false or fraudulent claim to Medicaid is liable to the federal government for three times the amount of the fraud, plus money penalties for each false or fraudulent claim.⁹ In a federal FCA lawsuit involving Medicaid, the federal government shares any damages it recovers with a state in the same proportion as the state's share of

⁵ See 42 U.S.C. § 1396h.

⁶ See *id.* at § 1396h(a).

⁷ See generally Notice, Federal Financial Participation in State Assistance Expenditures, FY 2008, 71 Fed. Reg. 69209 (Nov. 30, 2006).

⁸ See generally 31 U.S.C. §§ 3729-3733.

⁹ See *id.* at § 3729(a).

the costs of the Medicaid program.¹⁰ If, for example, a state's federal medical assistance percentage is 60 percent, then that state receives 40 percent of any recovery in a federal FCA case involving false claims submitted to Medicaid. Conversely, if a state obtains a recovery as the result of a state FCA action involving false claims submitted to Medicaid, then it shares the damages recovered with the federal government in the same proportion as the federal government's share in the cost of the state Medicaid program.¹¹

Under the DRA, however, the apportionment of the recovery is altered if a state enacts a state FCA that meets certain requirements listed in the DRA. If the state enacts a qualifying state FCA, then the federal medical assistance percentage will be decreased by 10 percentage points for purposes of apportioning any amounts recovered in a state FCA action.¹² As a result, the state's share will be increased by 10 percentage points. For example, Texas has a qualifying state FCA and the federal medical assistance percentage for Texas is approximately 60 percent.¹³ Under the DRA, instead of receiving approximately 40 percent of the proceeds of a Medicaid recovery in a state FCA case, Texas' federal medical assistance percentage would be decreased by 10 percent, resulting in Texas receiving approximately 50 percent of such proceeds.

For a state to qualify for the 10 percentage point increase to its share of the recovery obtained in a state FCA action, however, the Inspector General of HHS, in consultation with the Attorney General, must determine that the state FCA meets the following statutory requirements:

(1) The law establishes liability to the State for false or fraudulent claims described in [the federal FCA¹⁴] with respect to any expenditure described in [the Medicaid statute¹⁵].

(2) The law contains provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in [the federal FCA].

(3) The law contains a requirement for filing an action under seal for 60 days with review by the State Attorney General.

(4) The law contains a civil penalty that is not less than the amount of the civil penalty authorized under [the federal FCA].¹⁶

¹⁰ See Notice, Publication of OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48552, 48552 (Aug. 21, 2006). The relator in such a federal FCA case is entitled to between 15 and 30 percent of the federal share of damages and penalties, depending on whether the federal government intervened and whether the relator's contribution to the prosecution of the case was substantial. See 31 U.S.C. § 3730(d).

¹¹ See OIG Guidelines, 71 Fed. Reg. at 48552.

¹² 42 U.S.C. § 1396h(a).

¹³ See Notice, Federal Financial Participation in State Assistance Expenditures, FY 2008, 71 Fed. Reg. 69209-11 (Nov. 30, 2006) (establishing the FY 2008 federal medical assistance percentage for Texas as 60.53 percent).

¹⁴ See 31 U.S.C. §§ 3729-3733.

¹⁵ See 42 U.S.C. § 1396b(d).

¹⁶ Id. at § 1396h(b).

After the DRA was enacted, Senator Charles Grassley -- the legislation's sponsor and champion -- emphasized the importance of the requirement that state FCAs have a *qui tam* provision that encourages private plaintiffs to file suit on behalf of the state. "In drafting the second requirement for state FCAs to qualify for the 10% recovery increase," he stated, "it was envisioned that a state FCA would contain *qui tam* provisions and that the state FCA would be at least as effective as the provisions contained in the federal FCA."¹⁷ At a minimum, he said, state FCAs "must (1) contain a *qui tam* mechanism for relators, (2) facilitate a system for relators to file suit on behalf of the government, and (3) reward a *qui tam* relator with a portion of the recoveries. The importance of meeting each element of the *qui tam* requirement cannot be understated; the FCA works to detect and prevent fraud and abuse because of the *qui tam* provisions."¹⁸ Finally, Senator Grassley expressed concern that state law "modifications and deviations" to the federal FCA provisions might "undermine the ability of whistleblowers to file *qui tam* complaints on behalf of the government."¹⁹

B. The OIG Guidelines

After the DRA was enacted, HHS' Office of the Inspector General (OIG) published guidelines on how it would evaluate state FCAs to determine whether they meet the requirements of the DRA.²⁰ The OIG guidelines specifically analyzed and explained OIG's understanding of the statutory requirements -- primarily relating to liability, *qui tam* lawsuits, and civil penalties -- that a state FCA must meet if the state is to qualify for the 10 percentage point increase in any state Medicaid fraud recovery brought under a state FCA.

First, when evaluating a state FCA to determine whether it "establishes liability to the State for false or fraudulent claims described in" the federal FCA, OIG considers whether the state FCA provides for liability for:

- knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the Medicaid program;
- knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Medicaid program;
- conspiring to defraud the Medicaid program by getting a false or fraudulent claim allowed or paid; or
- knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medicaid program.²¹

¹⁷ Letter from Sen. Charles E. Grassley, to Daniel R. Levinson, Inspector General of HHS, and Alberto R. Gonzales, United States Attorney General (Mar. 17, 2006), available at <http://www.senate.gov/~finance/press/Gpress/2005/prg032106.pdf>.

¹⁸ Id.

¹⁹ Id.

²⁰ See generally OIG's Guidelines, 71 Fed. Reg. at 48552.

²¹ See id. at 48553. As such, OIG only considers whether the state FCA contains four of the seven bases for liability available under the federal FCA. Cf. 31 U.S.C. § 3729(a)(1)-(7).

The OIG guidelines require that state FCAs define the terms “knowing” and “knowingly” like the federal FCA does, to encompass “actual knowledge,” “deliberate ignorance of the truth or falsity of the information,” and “reckless disregard of the truth.”²²

Second, when evaluating a state FCA to determine whether it contains *qui tam* provisions “at least as effective” as the federal FCA’s *qui tam* provisions, OIG considers whether the state FCA provides for:

- a relator to bring a civil lawsuit for a violation of the state FCA on behalf of the relator and the state, with the lawsuit being brought in the name of the state;
- a copy of the complaint and written disclosure of material evidence to be served on the state Attorney General;
- a “first to file” provision where no person (other than the state) is permitted to intervene in a pending *qui tam* action;
- the state to have primary responsibility for lawsuits in which it intervenes (with the relator to continue as a party) or, in lawsuits where the state does not intervene, the relator to conduct the action (with the state retaining a right to intervene later upon a showing of good cause);
- the relator to be rewarded at least 15 percent of the proceeds of the lawsuit if the state intervenes, at least 25 percent of the proceeds if the state does not intervene, and, in either case, reasonable expenses, including attorneys’ fees and costs;
- a statute of limitations period not shorter than six years after the date of the violation, or three years after the date when material facts reasonably should have been known to the responsible state official, whichever is later;
- a burden of proof no greater than a preponderance of the evidence; and
- a cause of action for relators who suffer retribution from employers for whistleblower activities.²³

If the *qui tam* provisions of the state FCA are more restrictive than the provisions in the federal FCA, then OIG will determine that the state FCA is not as effective as the FCA in rewarding or facilitating *qui tam* actions. In such cases, states will not be eligible for the 10 percentage point increase in any state Medicaid fraud recovery. OIG determines whether state FCAs are in compliance with the DRA’s requirements on a case-by-case basis in consultation with the Department of Justice.²⁴

Finally, when evaluating whether a state FCA contains a civil penalty that “is not less than the amount of the civil penalty authorized” under the federal FCA, OIG assesses whether the state FCA provides for “at least treble damages (or double damages in instances of timely self-disclosure and full cooperation) and civil penalties at amounts of at least \$5,000 to \$10,000 per false claim.”²⁵ Although the Department of Justice is authorized to adjust for inflation the federal FCA’s civil penalties, and has

²² Compare OIG Guidelines, 71 Fed. Reg. at 48553, with 31 U.S.C. § 3729(b).

²³ Compare OIG Guidelines, 71 Fed. Reg. at 48553-54, with 31 U.S.C. §§ 3730(b)-(d) & 3731(b)-(c).

²⁴ See OIG Guidelines, 71 Fed. Reg. at 48554.

²⁵ Id. at 48554.

done so,²⁶ OIG evaluates state FCAs based on the text of the federal FCA statute, which establishes the range of civil penalties as \$5,000 to \$10,000.²⁷

Recently, Senator Grassley introduced legislation that would amend the federal FCA. The proposed legislation, entitled the “False Claims Act Correction Act of 2008,” would expand the liability and *qui tam* provisions of the federal FCA in significant ways. The legislation would remove the federal FCA’s requirement that false claims be presented directly to government employees and instead extend liability to any false claim regarding government money or property.²⁸ It also was designed to limit the public disclosure bar and thereby increase the amount of fraud against the government for which a relator may seek recovery.²⁹ If enacted, these changes to the federal FCA presumably would have to be incorporated into state FCAs for those state FCAs to continue to meet the requirements of the DRA. By its terms, the DRA requires that state FCAs, in order for states to qualify for the 10 percentage point increase in Medicaid fraud recoveries, contain provisions that essentially mirror, are “as least as effective,” or are “not less than” the federal FCA’s liability, *qui tam*, and penalty provisions.³⁰ For its part, OIG appears to have contemplated that, as laws are amended (be they state or federal FCAs), state FCAs may fall into or out of compliance with the DRA requirements.³¹

C. OIG Determinations Regarding State FCAs

Since the DRA’s enactment, 13 state FCAs have been evaluated by OIG (in consultation with the Department of Justice) to determine whether they meet the requirements of the DRA. Of those 13, OIG

²⁶ Civil penalties under the federal FCA currently range from \$5,500 to \$11,000. See 28 U.S.C. § 2461; see also 28 C.F.R. § 85.3(9) (increasing the amount of penalties under the federal FCA).

²⁷ See 31 U.S.C. §§ 3729(a). OIG also considers whether the state FCA requires a complaint to be filed in camera and under seal for 60 days and whether the “seal provisions operate in a way that conflict[s] with the Federal seal in a pendant FCA case.” Compare OIG Guidelines, 71 Fed. Reg. at 48554, with 31 U.S.C. § 3730(b)(2).

²⁸ See False Claims Act Correction Act of 2008, S. 2041, 110th Cong. (2008); see also 153 Cong. Rec. S11506 (daily ed. Sep. 12, 2007) (statement of Sen. Grassley). As such, this proposed legislation amending the federal FCA would effectively overturn United States ex rel. Totten v. Bombardier Corp., 380 F.3d 488 (2004) (holding that false claims to government grantees were not “presented” to a government employee and therefore not cognizable under federal FCA). See also Lisa A. Estrada, Congress to Consider Dramatic Expansion of False Claims Act, J. Health Care Compl. (Mar.-Apr. 2008), at 5 (concluding that “this strengthening of the False Claims Act -- which undoubtedly will heavily favor whistleblowers -- is sure to energize the *qui tam* bar and generate a next wave of False Claims Act litigation activity”).

²⁹ See 153 Cong. Rec. at S11506-07 (statement of Sen. Grassley) (noting provision in proposed legislation designed to effectively overturn Rockwell Int’l Corp. v. United States, 127 S. Ct. 1397 (2007), which held that the federal FCA’s public disclosure bar requires a *qui tam* relator to be an original source for all claims that are ultimately settled or upon which a verdict is rendered).

³⁰ 42 U.S.C. § 1396h(b)(1)-(2), (4).

³¹ See, e.g., Letter from Daniel R. Levinson, HHS Inspector General, to Mark J. Bennett, Hawaii Attorney General (Mar. 13, 2007) (stating that state FCA will be deemed in compliance with the DRA only “for so long as” it continues to meet the DRA requirements, which incorporate by reference the standards of the federal FCA).

determined that the state FCAs of eight states meet the requirements of the DRA. The qualifying states are: Hawaii, Illinois, Massachusetts, Nevada, New York, Tennessee, Texas, and Virginia.³²

For various reasons, OIG determined that five of the state FCAs it evaluated do not meet the requirements of the DRA. OIG determined that the California False Claims Act does not meet the requirements of the DRA because “it provides for civil penalties of up to \$10,000 for each false claim, but [unlike the federal FCA] does not set a floor for civil penalties.”³³ Similarly, OIG determined that the Florida False Claims Act does not meet the requirements of the DRA because (1) although it extends liability to the state for knowingly presenting *false claims*, it “does not appear” to extend liability for knowingly presenting *fraudulent claims* like the federal FCA does and (2) it provides for a shorter limitations period than the federal FCA.³⁴ OIG determined that the Indiana False Claims Act is deficient because it does not define “knowing” and “knowingly” to include the intent standards found in the federal FCA.³⁵ OIG also determined that Louisiana’s Medical Assistance Programs Integrity Law does not meet the DRA requirements because (1) it “does not appear to contain a . . . provision permitting the State of Louisiana to intervene in an action at a later date upon a showing of good cause,” (2) in intervened cases, it sets the floor for the relator share at 10 percent (as compared to the federal FCA’s 15 percent), and, in non-intervened cases, it does not set a floor for the relator share at all (as compared to the federal FCA’s 25 percent floor), and (3) it “does not set a floor for civil penalties.”³⁶ Finally, OIG determined that the Michigan Medicaid False Claims Act does not meet the requirements of the DRA because it does not extend liability for “reverse false claims”³⁷ and does not permit the state to recover a penalty for each false claim.³⁸

³² See HHS Office of Inspector General, State False Claims Act Reviews, available at www.oig.hhs.gov/fraud/falseclaimsact.html; see also Taxpayers Against Fraud Education Fund, The False Claims Act Legal Center: State False Claims Acts, available at www.taf.org/statefca.htm (listing statutes).

³³ Letter from Daniel R. Levinson, HHS Inspector General, to Bill Lockyer, California Attorney General (Dec. 21, 2006) (reviewing Cal Gov’t Code §§ 12650-12656), available at <http://www.oig.hhs.gov/fraud/docs/falseclaimsact/California.pdf>.

³⁴ See Letter from Daniel R. Levinson, HHS Inspector General, to L. Clayton Roberts, Florida Deputy Attorney General (Dec. 21, 2006) (reviewing Fla. Stat. §§ 68.081-68.09), available at <http://www.oig.hhs.gov/fraud/docs/falseclaimsact/Florida.pdf>.

³⁵ See Letter from Daniel R. Levinson, HHS Inspector General, to Allen K. Pope, Director of Indiana Medicaid Fraud Control Unit (Mar. 13, 2007) (reviewing Ind. Code §§ 5-11-5.5-1 through 5-11-5.5-18), available at <http://www.oig.hhs.gov/fraud/docs/falseclaimsact/Indiana.pdf>.

³⁶ Letter from Daniel R. Levinson, HHS Inspector General, to Jennifer S. Martinez, Louisiana Assistant Attorney General (Dec. 21, 2006) (reviewing La. Rev. Stat. Ann. §§ 46:437.1-440.3), available at <http://www.oig.hhs.gov/fraud/docs/falseclaimsact/Louisiana.pdf>.

³⁷ Cf. 31 U.S.C. § 3729(a)(7).

³⁸ See Letters from Daniel R. Levinson, HHS Inspector General, to Wallace T. Hart, Director of Michigan Medicaid Fraud Control Unit, and Brett Visner, Legislative Director for Michigan Rep. David Law (Dec. 21, 2006) (reviewing Mich. Comp. Laws § 400.601-400.613), available at <http://www.oig.hhs.gov/fraud/docs/falseclaimsact/Michigan.pdf>.

Last year, nearly 30 states introduced legislation to enact a state FCA (or amend an existing state FCA).³⁹ Already this year, New Jersey has enacted a false claims statute that, although not yet reviewed by OIG, appears to meet the requirements of the DRA.⁴⁰ Because of the DRA's inflexible terms, and OIG's strict and literal review of state FCAs, the New Jersey statute does not vary significantly from the federal FCA.

III. Investigations and Litigation Under State FCAs

Many of the investigations and litigation conducted under state FCAs, both before and after the DRA, have involved allegations of health care fraud.⁴¹ Indeed, state attorneys general have a long history of investigating and prosecuting health care providers who submit false claims to state Medicaid programs. In most cases, the defendants in such actions are line-level healthcare providers -- doctors, pharmacies, medical device sellers -- who submit false or fraudulent claims directly to Medicaid for reimbursement.⁴²

In recent years, however, joint state and federal investigations have targeted pharmaceutical manufacturers in false claims investigations and litigation and, in doing so, have recovered hundreds of millions of dollars for state Medicaid programs.⁴³ The focus on pharmaceutical companies has led state attorneys general, like their federal counterparts, to allege that off-label marketing of prescription drugs by pharmaceutical companies has resulted in false claims being submitted to Medicaid.⁴⁴ In such cases,

³⁹ Jonathan L. Diefenhaus, The Proliferation of State *Qui Tam* Statutes and the Increasing Complexity of Multi-State Program Fraud Investigations 5 (Oct. 2007) (unpublished manuscript, on file with author).

⁴⁰ See New Jersey False Claims Act, S. 360, 213th Legislature (2008) (signed by Gov. Corzine on Jan. 14, 2008); see also False Claims Act With Whistleblower Provisions Moves to Governor's Desk, BNA Health Care Fraud Report (Jan. 16, 2008), at 81.

⁴¹ See James F. Barger, Jr., et al., States, Statutes, and Fraud: An Empirical Study of Emerging State False Claims Acts, 80 Tulane L. Rev. 465, 483 (2006).

⁴² See Brian C. Anderson & Michael E. Stamp, Shooting the Messenger: "Off-Label Marketing" Attacks Against Pharmaceutical Companies by State Attorneys General 1 (May 2008) (unpublished manuscript, on file with author).

⁴³ See, e.g., Linda Loyd, Cephalon to settle U.S. state probes: It will pay \$425 million after investigations into marketing practices, Phil. Inquirer (Nov. 9, 2007) (reporting agreement of Cephalon, Inc. "to settle federal and related state Medicaid investigations into its marketing practices"); see also Diefenhaus, supra note 39, at 15 n. 16 (discussing settlements between "Medicaid Participating States" and Serono Laboratories, Inc., Glaxo Wellcome, Inc., Parke-Davis, and Bayer Corp.).

⁴⁴ See Anderson & Samp, supra note 42, at 1, 3, 18; see also State Medicaid Fraud Office Recovers \$20 Million in 2007 From Rx Settlements, BNA Health Care Fraud Report (Jan. 2, 2008), at 29 (listing North Carolina's Medicaid fraud recoveries in 2007 against pharmaceutical companies, including its portion of a "national settlement with Medicis Pharmaceutical Corp. over allegations that the company encouraged physicians to use its drug Loprox for diaper-rash treatment despite lacking approval by the federal Food and Drug Administration"); Brenda Sandburg, New Jersey Launches Investigation of Amgen's Enbrel Marketing Practices, The Pink Sheet (Jan. 21, 2008), at 22 ("New Jersey Attorney General Anne Milgram announced . . . that the state had issued a subpoena to Amgen 'concerning allegations that, in an effort to increase the sale of its injectable drug Enbrel, the company . . . marketed the drug for uses for which it was not approved.'").

“the attorney general usually asserts that the pharmaceutical company engaged in off-label marketing to promote . . . ‘false’ claims, and . . . therefore should be held liable for the money the state [Medicaid program] paid for all off-label prescriptions.”⁴⁵

Thus far, most of the cases brought by the states against pharmaceutical manufacturers have been “global” Medicaid fraud cases.⁴⁶ “Global” Medicaid fraud cases “are those that identify a nationwide fraud, usually investigated by multiple federal and state offices, and resolve the criminal, civil, and administrative liability defendants face in multiple jurisdictions all at one time.”⁴⁷ To date, most relators filing Medicaid fraud cases alleging violations of state FCAs “appear to have done so in federal court.”⁴⁸ As a result, most of the settlements of cases brought against pharmaceutical companies alleging violations of state FCAs, including cases alleging unlawful off-label marketing, “have come from ‘piggy backing’ on federal law enforcement efforts and from joining in global settlements.”⁴⁹

In the typical case, a relator files a complaint in federal court alleging violations of state and federal FCAs. State and federal investigators and prosecutors then work together to “share evidence as necessary . . . in investigating each federal Medicaid *qui tam* case filed.”⁵⁰ State Medicaid officials, Medicaid Fraud Control Units, and state prosecutors work with federal officials “to facilitate a coordinated investigation and either negotiation of a ‘global’ resolution, if settlement is achievable, or coordinated litigation, if it is not. As these cases settle (very few cases are litigated), the federal government recovers its damages and penalties by compromising claims under the federal FCA and the state or states recover their damages by compromising common law or” state FCA claims.⁵¹

Historically, in multi-state Medicaid fraud cases, states have not bothered to file parallel state FCA actions in state court. Due to Medicaid’s joint federal and state nature and the manner in which fraud recoveries are allocated as between the state and the federal government (providing for apportionment of recoveries to states according to the federal medical assistance percentage), doing so has not been necessary. This has been so because, in cases filed under the federal FCA alleging Medicaid fraud, “even states without *qui tam* or FCA statutes recover damages.”⁵² In cases where states have not filed parallel actions in state court (but merely participated in settlement negotiations or otherwise aided federal litigation), the “relator’s share of the ‘proceeds’ . . . has been measured as a

⁴⁵ Anderson & Samp, supra note 42, at 1, 3, 18.

⁴⁶ Sullivan, supra note 2, at 21.

⁴⁷ Barger, supra note 41, at 483.

⁴⁸ Diesenhaus, supra note 39, at 5.

⁴⁹ Sullivan, supra note 2, at 21.

⁵⁰ Diesenhaus, supra note 39, at 3-4.

⁵¹ Id. at 4.

⁵² Id. at 3.

percentage of, and paid from, the federal recovery.”⁵³ No portion of the state recovery in federal FCA cases is allocated to the relator.⁵⁴

The DRA provision encouraging states to enact false claims acts was intended to (1) increase the total number of state FCA actions alleging Medicaid fraud and (2) increase the total amount of recoveries. “By involving more states and more lawyers, supporters [of the DRA] hope to increase recovery amounts across the board.”⁵⁵ It seems likely that that the volume of state FCA actions will increase. At a minimum, parallel state FCA actions “piggy-backing” on federal FCA actions will increase.⁵⁶ First, relators will file such actions so as to obtain a relator’s share of any state recovery.⁵⁷ Indeed, relators already have increasingly “begun to file separate state claims in state court.”⁵⁸ Second, state attorneys general in states with qualifying FCAs will file such actions so as to obtain the 10 percentage point increase in recovery share vis-à-vis the federal government. Whether the increase in state FCA actions results in an increase in the total amount of recoveries, however, will depend on whether new, meritorious cases that would not otherwise have been brought as federal FCA actions are brought under state FCAs. Commentators disagree on this point.⁵⁹

IV. The Impact of Multiple State FCAs on “Off-Label” Promotion

The enactment of multiple state FCAs, with the concomitant increase in state FCA actions filed in state court (even if only “piggy-backing” on federal FCA actions), likely will only make more complex the regulatory and enforcement regime governing off-label promotion of approved drugs. Moreover, multiple state FCAs likely will provide little benefit to the states while complicating the operations of both government and industry.

⁵³ Id.; see also id. (“Because the federal government bears at least 50% of the cost of most Medicaid claims, whistleblowers are entitled to a share of that ‘federal share’ under the federal FCA.”).

⁵⁴ See OIG Guidelines, 71 Fed. Reg. at 48553-54 (stating that because the federal FCA “applies only to false claims against the Federal Government, the relator is not entitled to a share of the State portion of a Medicaid recovery under the [federal] FCA”).

⁵⁵ John Gibeaut, Seeking the Cure: With Health Care Fraud Rampant, States Are Urged to Pass Their Own False Claims Acts, but Foes Warn of Windfalls for Plaintiffs Lawyers ABA J. (Oct. 2006), at 46.

⁵⁶ See id. at 49 (multiple state FCAs “hold the possibility of parallel proceedings across numerous jurisdictions”).

⁵⁷ See Deisenhaus, supra note 39, at 5 (arguing that relators will “seek to maximize their own recovery under *qui tam* statutes by invoking the federal FCA, to obtain a share of the federal Medicaid recovery, and all available state FCAs, to obtain a share of each state’s Medicaid recoveries”). Relators’ counsel will strongly encourage them to do so: “Because of the large recoveries available to private plaintiffs under the federal FCA through statutorily mandated percentages of large, fixed penalties, private plaintiffs’ counsel can receive significant fees. Their fees are often a combination of court-awarded attorneys’ fees and a percentage of the recovery they negotiated pre-trial with their clients.” Barger, supra note 41, at 476 & n. 72.

⁵⁸ Diesenhau, supra note 39, at 5 & n. 28.

⁵⁹ Compare id. at 3 (arguing that “states will recover few if any additional dollars”), with Gibeaut, supra note 55, at 52 (arguing that “total damages are expected to increase”).

A. Atomization in the Regulation of Pharmaceutical Marketing

Multiple state FCAs likely will cause a lack of “uniformity and consistency of action” when it comes to the regulation of pharmaceutical marketing.⁶⁰ The regulation of off-label promotion is a matter of federal law,⁶¹ the contours of which are established by the FDA.⁶² The FDA is the federal entity charged with regulating the marketing of prescription drugs to health care providers. It has “primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising,” as well as “all matters regulating the labeling of foods, drugs, devices, and cosmetics.”⁶³ As in other areas within its mission, it is the entity with national scope and with the experience and expertise to balance, as best it can, the competing commercial and public health interests related to off-label marketing of approved drugs. Although the FDA has been subjected to criticism for the balance it has struck,⁶⁴ it certainly is better-positioned to strike the balance than 50 state courts evaluating hundreds of state FCA lawsuits alleging illegal off-label promotion of drugs.⁶⁵

⁶⁰ Cf. Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18539 (1971).

⁶¹ The Federal Food, Drug, and Cosmetic Act (“Federal FD&C Act”) prohibits the introduction of a misbranded drug into interstate commerce. See 21 U.S.C. § 331(a). A drug is misbranded if its labeling is “false or misleading,” *id.* at § 352(a), or if its labeling does not contain “adequate directions for use,” *id.* at § 352(f)(1). Off-label promotion, it is argued, introduces a drug label that is “misleading” or fails to provide adequate directions for the off-label use. The Federal FD&C Act also prohibits the introduction of an unapproved new drug into interstate commerce. See *id.* at §§ 331(d) & 355(a). Government prosecutors have charged that off-label drug promotion causes the introduction of an “unapproved new drug,” i.e., a drug marketed for an unapproved new use.

⁶² See, e.g., Warning Letter from James R. Rogers, Regulatory Review Officer of Division of Drug Marketing, Advertising, and Communications (DDMAC), FDA, to Paul M. Kirsch, Senior Director for Regulatory Affairs, Cephalon Inc. (Jan. 3, 2002) (asserting that Cephalon’s promotional materials for its drug Provigil amount to “promotion for unapproved uses”); Warning Letter from Thomas W. Abrams, Director of DDMAC, FDA, to Peter R. Dolan, Chairman & CEO, Bristol-Myers Squibb Co. (Aug. 7, 2003) (stating that Bristol-Myers Squibb’s promotional materials for its drug Pravachol “are false or misleading in that they claim that Pravachol has been approved by the . . . [FDA] for conditions and patients for which it has not been approved”).

⁶³ Memorandum of Understanding Between Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18539 (1971); see also Federal FD&C Act, 21 U.S.C. §§ 301-99.

⁶⁴ Compare Scott Gottlieb, Stop the War on Drugs, Wall St. J. (Dec. 17, 2007), at A21 (“Efforts to confine patients and doctors to FDA-approved uses have their own health consequences, raising the question: Just who is in the best position to make these hard choices?”), with Becky Jungbauer, FDA’s Off-Label Dissemination Guidance Opens “Loophole” -- Rep. Waxman, The Pink Sheet (Dec. 3, 2007), at 7 (reporting that Rep. Henry Waxman, in “another move in his fight against off-label drug promotion,” warned that FDA’s draft guidance on good reprint practices “would open the door to abusive marketing practices . . . [and] undercut the basic prohibition against marketing drugs and devices for unapproved uses”).

⁶⁵ The FDA similarly is the entity with national scope and with the experience and expertise to establish regulatory standards governing drug labeling changes, not state judges applying state tort law. See Kyle Sampson, Labeling Changes and FDA’s Oversight of Drug Safety, HealthLaw360 (May 14, 2008), at 5 & n. 28 (citing preemption cases).

The enactment of more state FCAs likely will induce relators and state attorneys general to commence more investigations and bring more actions in state court.⁶⁶ One commentator has argued that a multitude of state FCAs is beneficial because “states provide mini-laboratories to study statutory variations.”⁶⁷ Under this “laboratories of democracy” theory,⁶⁸ states will utilize their legislative authority to develop innovative and creative solutions to the common problem of Medicaid fraud which then can be adopted by other states. Unfortunately for this theory, however, the DRA’s strict requirements (and OIG’s strict application of them), prevent states from experimenting in ways that might be beneficial. State FCAs that strike a balance favoring more circumscribed theories of liability, or greater control of cases by the government over the relator, for example, are deemed to be deficient under the DRA.

The Texas Medicaid Prevention Act, for example, which existed before the DRA, did not permit whistleblowers to continue to litigate cases when the state investigated the case and declined to intervene -- a provision often discussed as a possible amendment to the federal FCA.⁶⁹ After OIG determined that the Texas statute did not meet the requirements of the DRA, Texas amended the law so that it hewed more closely to the federal FCA, and it was approved.⁷⁰ Thus, in important respects, the DRA operates to stifle innovation that might otherwise take place in the state legislatures.

To be sure, states may enact state FCAs that are less restrictive than the federal FCA -- with, for example, broader theories of liability, more generous *qui tam* provisions, and stiffer penalties -- and still qualify under the DRA. This one-way “innovation” ratchet in the enactment of state FCAs has been described as “increased competition . . . between the states and the federal government [that] will inure to the benefit of taxpayers.”⁷¹ The more apt characterization, however, and possible consequence of the DRA, is a “race to the bottom,”⁷² where state legislators (enacting state FCAs) and elected state judges (presiding over state FCA actions) compete to “outbid” other states to make their state more

⁶⁶ Some state FCA actions may be removed to federal court, but, depending on the facts, some may not. See, e.g., Wisconsin v. Amgen, Inc., 516 F.3d 530, 531-32 (7th Cir. 2008) (affirming federal district court’s remand of state FCA case “charging fraudulent pricing of pharmaceutical drugs” to state court).

⁶⁷ Barger, supra note 41, at 487.

⁶⁸ See New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”); see also Michael S. Greve, Laboratories of Democracy: Anatomy of a Metaphor, Federalist Outlook: AEI Online (Apr. 1, 2001) (calling “Brandeis’s dictum” of the states as “laboratories” for policy experiments “the most familiar and clichéd image of federalism” and analyzing the “half-hearted nature of Brandeis’s federalist commitment”).

⁶⁹ See Barger, supra note 41, at 487. The Texas statute also provided for lower percentages paid to whistleblowers and lower penalties than the federal FCA. See Sullivan, supra note 2, at 23 & n. 69.

⁷⁰ See id. at 23 & n. 69.

⁷¹ Barger, supra note 41, at 487.

⁷² See Louis K. Liggett Co. v. Lee, 288 U.S. 517, 558-59 (1933) (Brandeis, J., dissenting) (discussing state legislatures’ “race to the bottom” to enact “least restrictive” incorporation laws and describing “race” as “one not of diligence but of laxity”).

attractive to relators and relators' counsel. In such a regime, "[q]ui tam relators could" -- and will -- "push fraud theories that the DOJ felt uncomfortable or unable to pursue."⁷³

In sum, the investigation and litigation of off-label marketing claims by relators and state attorneys general under multiple state FCAs likely will not result in a rational and uniform regulatory regime. To the contrary, the likely result of such a fractured approach is a multitude of regulatory regimes with different standards and much legal uncertainty for pharmaceutical manufacturers (as well as investors). Under this scenario, as the law develops in numerous jurisdictions, manufacturers will be required to ascertain the jurisdiction with the most onerous rules and either conform its marketing conduct to that jurisdiction's rules⁷⁴ or exit that market.

B. Illusory Benefits to State and Federal Enforcement

State FCAs offer the promise of "an unprecedented opportunity for states with depleted treasuries to build up their investigative and prosecutorial resources and return needed funds to beleaguered state programs."⁷⁵ New Jersey's new false claims statute, for example, provides that in cases brought under the state FCA, "10 percent of the amount recovered [will] be deposited in a newly-created fund to cover the attorney general's costs to investigate and prosecute false claims."⁷⁶ With an increase of investigative and prosecutorial resources, states will be able to commence even more off-label promotion investigations and related civil *qui tam* actions.

An increase in off-label promotion investigations and related civil *qui tam* actions may, in particular instances, benefit pharmaceutical companies as against their competitors. A prominent federal prosecutor has argued just that: that pharmaceutical companies should welcome an increase in off-label marketing actions as a sort of barrier-to-entry against competitors.⁷⁷ He even has urged companies to consider filing, in the appropriate case, FCA actions alleging off-label promotion against their competitors, arguing that doing so may be "in their self interest."⁷⁸ Under this theory, state FCAs are good because they will provide law enforcement more resources and generate more off-label cases, which will benefit law-abiding pharmaceutical companies.

Even if true, the proliferation of state FCAs adds few, if any, investigative and prosecutorial resources to state and federal law enforcement coffers. In a successful state action brought pursuant to

⁷³ Barger, supra note 41, at 487.

⁷⁴ Cf. Sarina D. Rivera, State Marketing Disclosure Laws: The Unintended Consequences, FDLI Update (May/June 2007), at 30 (discussing the proliferation of state marketing disclosure laws and stating that "companies must continue to monitor state laws and be prepared to adjust their marketing practices for the unexpected").

⁷⁵ Barger, supra note 41, at 487.

⁷⁶ False Claims Act With Whistleblower Provisions Moves to Governor's Desk, BNA Health Care Fraud Report (Jan. 16, 2008), at 81.

⁷⁷ See Loucks, supra note 3, at 582 ("Industry and its counsel should view the off-label regulatory barrier to entry with the same vigor as it views the patent barrier to entry.").

⁷⁸ Id. at 583.

a qualifying state FCA, the federal portion of the recovery is reduced by 10 percent and the state recovery is increased by 10 percent -- but then the state recovery is reduced by 15 to 30 percent, the amount awarded to the relator.⁷⁹ Thus, the federal recovery is reduced and most, if not all, of the corresponding increase to the state recovery is diverted to the relator. Only if new, meritorious cases that would not otherwise have been brought as federal FCA actions are brought as state FCA actions will gains (including additional investigative and prosecutorial resources) be realized. Whether this will occur is unclear.⁸⁰

C. Burden on Regulators and Industry

Finally, multiple state FCAs are sure to impact both government regulators and enforcement officials, as well as industry. For investigators and prosecutors, multiple state FCAs bring “more people into the mix, which requires more efforts at coordination.”⁸¹ They also mean less control for federal prosecutors and more control for relators and their lawyers.⁸² One possible consequence is a reduced ability for federal prosecutors to conduct criminal investigations. “[C]riminal enforcement may become a major victim of stepped-up state civil litigation in multiple forums . . . [due to] . . . the possibility of a rogue state unsealing a civil complaint on its own or allowing discovery and tipping off defendants who may be under criminal investigation elsewhere, where complaints remain sealed.”⁸³

The increased difficulties for prosecutors conducting criminal investigations also raise challenges for industry already operating in a complex prosecutorial environment, especially in the netherworld of off-label marketing. “When there are multiple prosecuting entities, it is more difficult for a defendant to reach a global resolution of a nationwide regulatory problem.”⁸⁴ While difficulties for federal prosecutors conducting criminal investigations may seem a blessing, such difficulties may also work significant unfairness and increase risk to the subjects or targets of such investigations.⁸⁵

Even where criminal allegations have not been contemplated, multiple state FCAs impose greater legal uncertainty on industry and increase the “burden and complexity of multi-state *qui tam* investigations and litigation.”⁸⁶ In sum, multiple state FCAs pose problems for all players: companies

⁷⁹ See Diesenhaus, supra note 39, at 3-5.

⁸⁰ See supra note 59 and accompanying text.

⁸¹ See Gibeaut, supra note 55, at 53.

⁸² Id.

⁸³ Id.

⁸⁴ Barger, supra note 41, at 486.

⁸⁵ See Diesenhaus, supra note 39, at 5 (“Separate actions can also threaten the rights of individual defendants who may also be subject to parallel criminal investigation.”); see also id. at 7 (discussing fairness and due process issues).

⁸⁶ Id. at 4; see also Gibeaut, supra note 55, at 53.

“who, for business purposes, need to anticipate and resolve all liability they may face, and federal and state regulators who seek to coordinate their investigations.”⁸⁷

IV. Conclusion

The DRA, in an effort to address the challenge of Medicaid fraud, encourages states to enact their own false claims statutes. State and federal regulatory and enforcement officials increasingly are investigating allegations of unlawful off-label marketing by pharmaceutical companies, and bringing actions asserting novel theories of FCA liability. The combination of increased false claims actions and increased focus on off-label promotion likely will result in an incoherent regulatory regime that, ultimately, will provide little benefit to the states while significantly increasing legal uncertainty and risk for the pharmaceutical industry.

⁸⁷ Barger, supra note 41, at 486.