



## State False Claims Acts and “Off-Label” Promotion

Off-Label Uses of Approved Drugs: Medicine, Law, and Policy  
AEI Legal Center for the Public Interest

Kyle Sampson  
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### Introduction

- Last year, federal legislation encouraging states to enact false claims acts became effective.
  - State FCAs at least as effective as the federal FCA qualify the state for an increased portion of any Medicaid fraud recovery.
  - State legislatures are stirring.
- In recent years, state and federal prosecutors have increasingly investigated pharmaceutical companies for allegedly engaging in off-label promotion.
  - Expansive theories of liability.
  - Including off-label promotion = false claims to Medicaid.

### Introduction (cont'd)

- ➔ What will be impact of multiple state FCAs, combined with enforcement officials' continued focus on off-label promotion?



### The Deficit Reduction Act

- As part of the DRA, Congress passed legislation to provide incentive for states to enact their own state FCAs modeled on the federal FCA.
  - The incentive was an increase in the share of any amounts recovered from a Medicaid fraud lawsuit brought under a qualifying state FCA.
    - Medicaid is joint state-federal program.
    - Federal match can be anywhere from 50% to 83%.
  - Under the federal FCA, any recovery in Medicaid fraud cases are apportioned according to the FMAP.

### The Deficit Reduction Act

- Under the DRA, in a Medicaid fraud case brought under a qualifying state FCA, the FMAP is decreased by 10 percentage points, thereby increasing the state share by 10 percentage points.
- Example:
  - In 2008, Texas has qualifying state FCA and FMAP of 60.53%.
  - In a Medicaid fraud case brought under Texas' state FCA, recovery would be apportioned as follows:
    - 50.53% to federal government.
    - 49.47% to Texas.
      - In same case under federal FCA, the federal government would get 60.53% of the recovery, and Texas would get 39.47%.

### The Deficit Reduction Act

- To qualify for the financial incentive, state FCAs must meet the DRA’s statutory requirements as determined by the Inspector General of HHS (in consultation with DOJ).
- To meet DRA’s requirements, state FCAs must:
  - Establish liability to the state for a false or fraudulent claim made to Medicaid.
  - Have *qui tam* provisions that are as strong as the federal FCA’s.
  - Provide for the filing of an action under seal for 60 days with review by the state Attorney General.
  - Contain a civil penalty that is not less than the civil penalty in the federal FCA.

### Office of Inspector General Guidelines

- After the DRA was enacted, OIG issued guidelines on how it would evaluate state FCAs.
- OIG painstakingly reviewed the federal FCA's liability, *qui tam*, and civil penalty provisions and outlined corresponding requirements for any state FCA.
- The DRA requires state FCAs essentially to mirror or be “less restrictive” (i.e., more favorable to whistleblowers) than the federal FCA.
  - Query: what if federal FCA is amended?
  - Sen. Grassley has introduced legislation that would expand the federal FCA's liability and *qui tam* provisions.

### OIG’s Review of State FCAs

- Since the DRA was enacted, OIG has reviewed 13 state FCAs.
- Of those 13, OIG has determined that eight meet the requirements of the DRA:
  - Hawaii
  - Illinois
  - Massachusetts
  - Nevada
  - New York
  - Tennessee
  - Texas
  - Virginia

### OIG’s Review of State FCAs (cont’d)

- OIG has strictly interpreted the DRA requirements.
- It has rejected five state FCAs for various reasons:
  - California: no minimum civil penalties
  - Florida: (1) no liability for “fraudulent claims” and (2) shorter limitations period
  - Indiana: definition of “knowing” and “knowingly”
  - Louisiana: (1) no state intervention later upon a showing of good cause, (2) minimum floor for relator shares to low, and (3) no minimum civil penalties
  - Michigan: no liability for “reverse” false claims

### OIG’s Review of State FCAs (cont’d)

- OIG’s work likely to continue
  - Last year, nearly 30 states introduced legislation to enact or amend an existing state FCA
  - Already this year, New Jersey enacted a state FCA
    - Not yet reviewed by OIG
    - Appears to comply with federal FCA



### Investigations and Litigation Under State FCAs

- State AGs have a long history of investigating and prosecuting HCPs who present false claims to Medicaid.
- Recent years have seen increased investigation and litigation directed at pharmaceutical companies for alleged false claims.
  - Allegation is that off-label marketing of prescription drugs by pharmaceutical companies has resulted in false claims being presented to Medicaid.
  - Examples:
    - State settlements with Medicis for off-label marketing of Loprox.
    - Ongoing New Jersey and Connecticut investigations of Amgen’s marketing of Enbrel.

### Investigations and Litigation Under State FCAs (cont’d)

- Thus far, most cases brought by states against pharmaceutical companies have been “global” Medicaid fraud cases.
  - Allegations of nationwide fraud, investigations by the federal government and multiple states, resolution of all issues at one time.
  - Most state FCA actions “piggy-back” on federal investigative efforts and join in global settlements.
- Because of DRA, more state FCA actions are likely:
  - States will want to get their 10 percent increase.
  - Relators will want to get a share of the state recovery.

### Investigations and Litigation Under State FCAs (cont'd)

- Query: Will this likely increase in state FCAs result in an increase in the total amount of Medicaid recoveries?
  - Will the increase in state FCA actions only be a matter of pleading practice (i.e., will any increase only come from piggy-backing)?
  - Will new, meritorious actions that would not otherwise be brought as federal FCA actions be brought under state FCAs?
  - Will relators and/or states bring state FCA actions in state court and then work to prevent them from being removed to federal court?

### The Impact of Multiple State FCAs on Off-Label Promotion

- Three main consequences
  - Further fragmentation in the regulation of pharmaceutical marketing
  - No increased resources for state or federal enforcement
  - Increased burden on both regulators and industry



### Atomization in the Regulation of Pharmaceutical Marketing

- Regulation of off-label promotion is a matter of federal law.
- FDA has national scope and experience and expertise to balance competing interests.
  - At a minimum, it is better-positioned that 50 state courts evaluating hundreds of state FCA actions alleging unlawful off-label promotion.
- In enacting state FCAs, states will not be “laboratories of democracy” because:
  - DRA only permits one-way innovation
  - OIG strictly interprets the DRA
    - E.g., Texas Medicaid Prevention Act.

### Atomization in the Regulation of Pharmaceutical Marketing (cont'd)

- States may engage in "race to the bottom":
  - The risk is that states (legislatures and judges) compete to "outbid" other states to make their state more attractive to relators and relators' counsel.
  - Relators in state FCA actions will push fraud theories that DOJ is uncomfortable or unwilling to pursue.
- Result
  - Irrational and fractured regulatory regime
  - Much legal uncertainty
  - Adoption of inefficient compliance systems to account for lowest common denominator state

### Illusory Benefits to State and Federal Enforcement

- Some have argued that more state FCAs will help build up investigative and prosecutorial resources
- Increase in investigative and prosecutorial resources = increase in state FCA actions
- Increase in state FCA actions = good for law-abiding pharmaceutical companies
- But . . .
  - More state FCAs does not necessarily mean more resources and increased enforcement
    - Only portion of recovery, if any, goes to state enforcement budgets
    - Relator share in state FCA actions largely consumes the increase in the state’s share

### Increase Burden on Regulators and Industry

→ Regulators

- More people = more coordination needed
- Less control for federal regulators/prosecutors
  - Increased difficulties for criminal prosecutions

→ Industry

- Increased complexity
- Unfairness and increased risk in criminal context
- Resolution more difficult when more parties



### Conclusion

- Trend of more state FCAs + trend of more off-label promotion investigations and litigation =
  - Fragmented regulatory regime
  - No real benefit to the states
    - Big benefit to relators and relators' counsel
  - More legal uncertainty and risk for the pharmaceutical industry

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WILLIAMS

Thank you.

Kyle Sampson  
(202) 955-1587  
ksampson@hunton.com