October 25, 2023

Government Enforcement Actions Piggy-Backing on Product Liability Litigation

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SIDLEY

Agenda

- Background on Relevant Federal and State Laws
- Federal Enforcement Actions Piggybacking on Product Liability Litigation
- State Enforcement Actions Piggybacking on Product Liability Litigation

Background on Relevant Federal and State Laws

The FCA Prohibitions

False Claims:

It is unlawful to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval.

31 U.S.C. 3729(a)(1)(A)

False Statements:

It is unlawful to knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. 3729(a)(1)(B)

“Reverse” False Claims:

It is unlawful to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government. 31 U.S.C. 3729(a)(1)(G)

What’s a claim?

Any request for payment submitted directly to the government (federal health care programs) or to third-parties for monies that are provided in whole or in part by the Government

The Elements

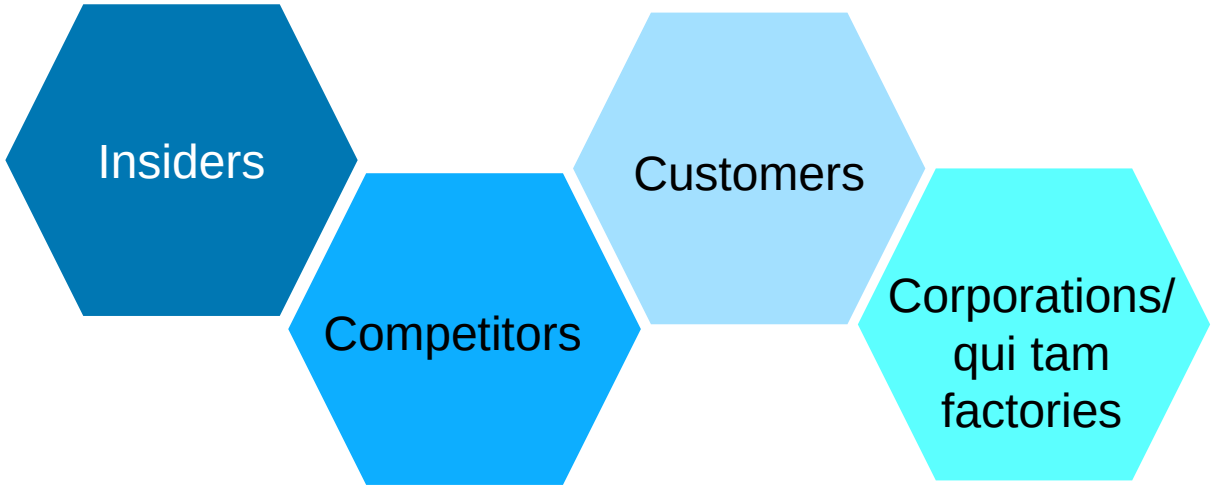
1. Knowledge
   – Including deliberate ignorance and reckless disregard
2. False or Fraudulent
   – Factually False
   – False Express Certification
   – False Implied Certification
3. Claimed submitted to the government
4. Materiality
   – "Having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."
   – SCOTUS' 2016 *Escobar* determined that the key analysis here is whether "the defendant knowingly violated a requirement that defendant knows is material to the Government's payment decision"

The Penalties

- Civil Penalties
  - $13,508–$27,018 per violation (penalty amount updated annually for inflation) ***plus***
  - Up to 3X the government's damages
    - The "aggregate dollar amount of fraudulent bills" submitted to a government health care program "shall constitute prima facie evidence" of the government's loss
- Exclusion from participating in federal healthcare programs
- The FCA has a long statute of limitations – six years, which can be extended to ten years in certain circumstances – that can increase the potential liability

Qui Tam Relators

- Private whistleblowers who bring suits on behalf of the federal government under the FCA. They can be:



- Relators receive between 15% and 30% of the amount recovered by the U.S. government.

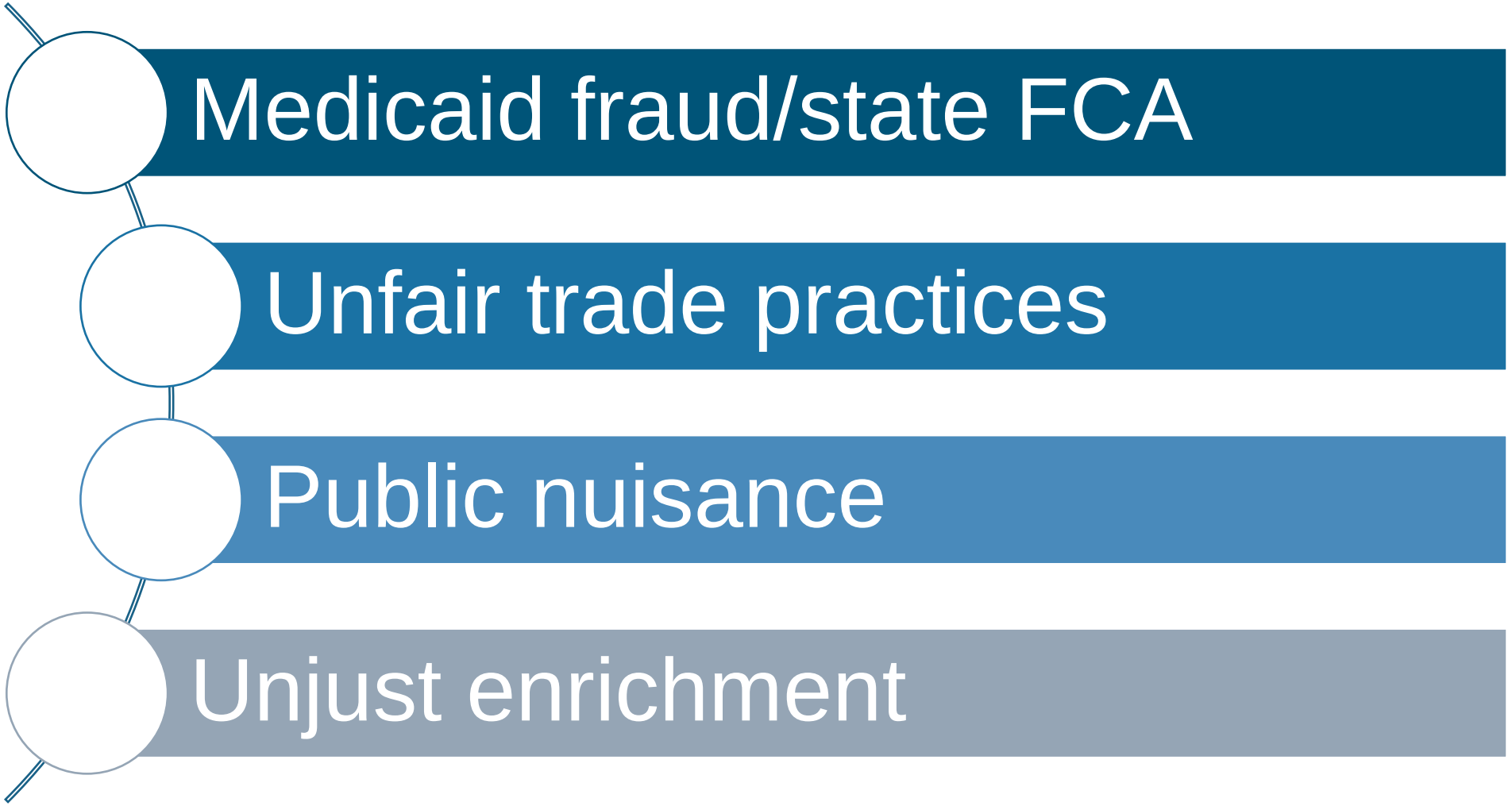
Government Investigations—Key Players and Legal Theories

Agency	CMS Centers for Medicare & Medicaid Services; HHS; FDA; HHS Office of Inspector General			DOJ
Key Statutes/ Regulations Enforced	Social Security Act, e.g., Medicaid Drug Rebate Program	Food, Drug and Cosmetic, Act	Anti-Kickback Statute ("AKS"), Beneficiary Inducement Statute ("BIS")	False Claims Act ("FCA")
Enforcement Theory	• Civil monetary penalties ("CMPs") for false reporting	• Promoting a drug for an unapproved use renders the drug "misbranded" • FDA can look to a range of conduct to determine a new "intended use" • FDA may pursue criminal or administrative resolutions	• AKS: Prohibits knowingly offering or receiving anything of value, in return for purchasing or recommending products; violated if even "one purpose" is improper • BIS: Prohibits remuneration to patients to induce choice of items from a particular provider • Enforced with CMPs or criminal liability for the AKS	• Prohibits knowingly submitting or causing others to submit material false claims to the government • Falsity interpreted very broadly and violations of the other statutes or regulations on this slide can create "false" claims

Across agencies, context drives enforcement decisions:

✓ Potential to interfere with clinical decision-making, encourage over-utilization, harm patients, or increase costs to the federal government?

Relevant State Law Causes of Action



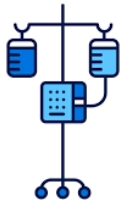
Federal Enforcement Actions Piggy-Backing on Product Liability Litigation

Traditional FCA Theory of Liability for Pharmaceutical Companies

The FCA prohibits anyone from knowingly causing a false claim to be submitted to a federal healthcare program

Alleged misconduct, e.g., kickbacks

Pharmaceutical company manufactures prescription drug

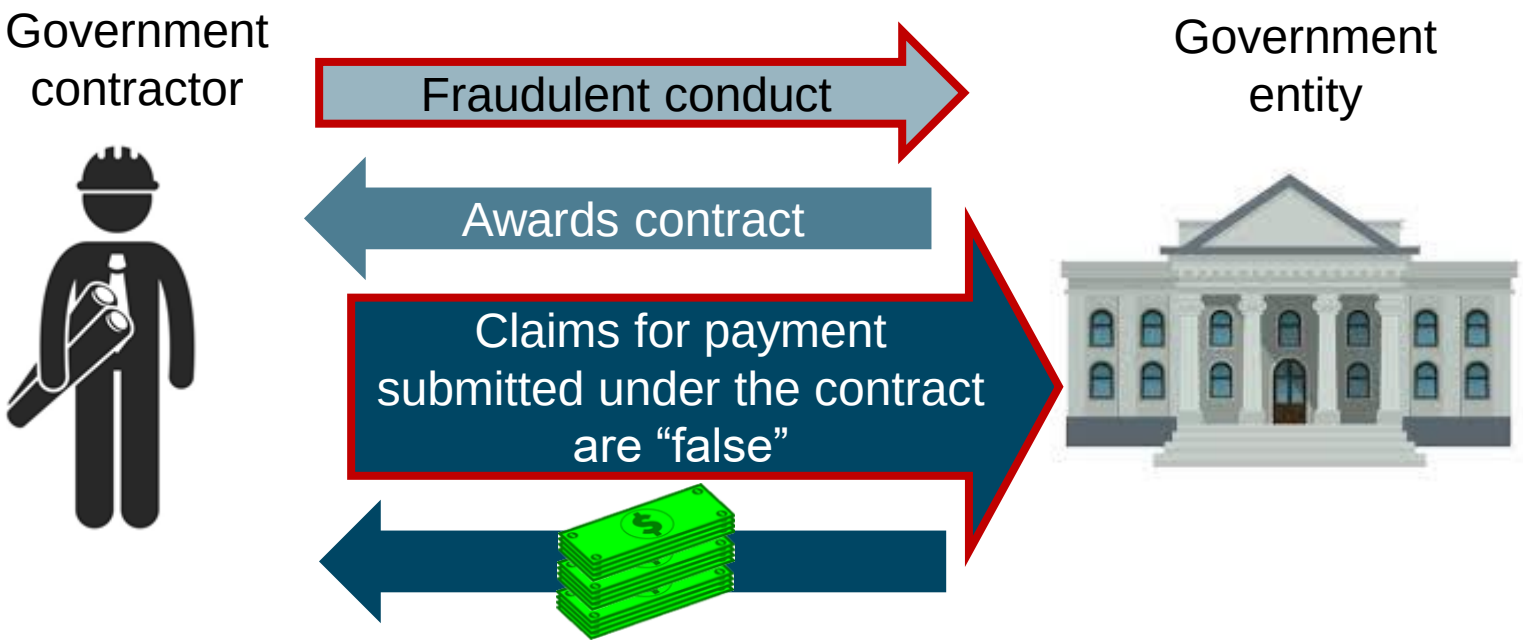


Healthcare provider prescribes the drug to a patient

Cause submission of claim for payment for drug

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Fraudulent Inducement Theory of FCA Liability



"This fraud did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the [government]…. The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal – payment of government money to persons who had caused it to be defrauded."
-*United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544 (1943)

“Fraud-on-the-FDA” Theory of FCA Liability

Fraudulent conduct

Approves drug, or does not withdraw

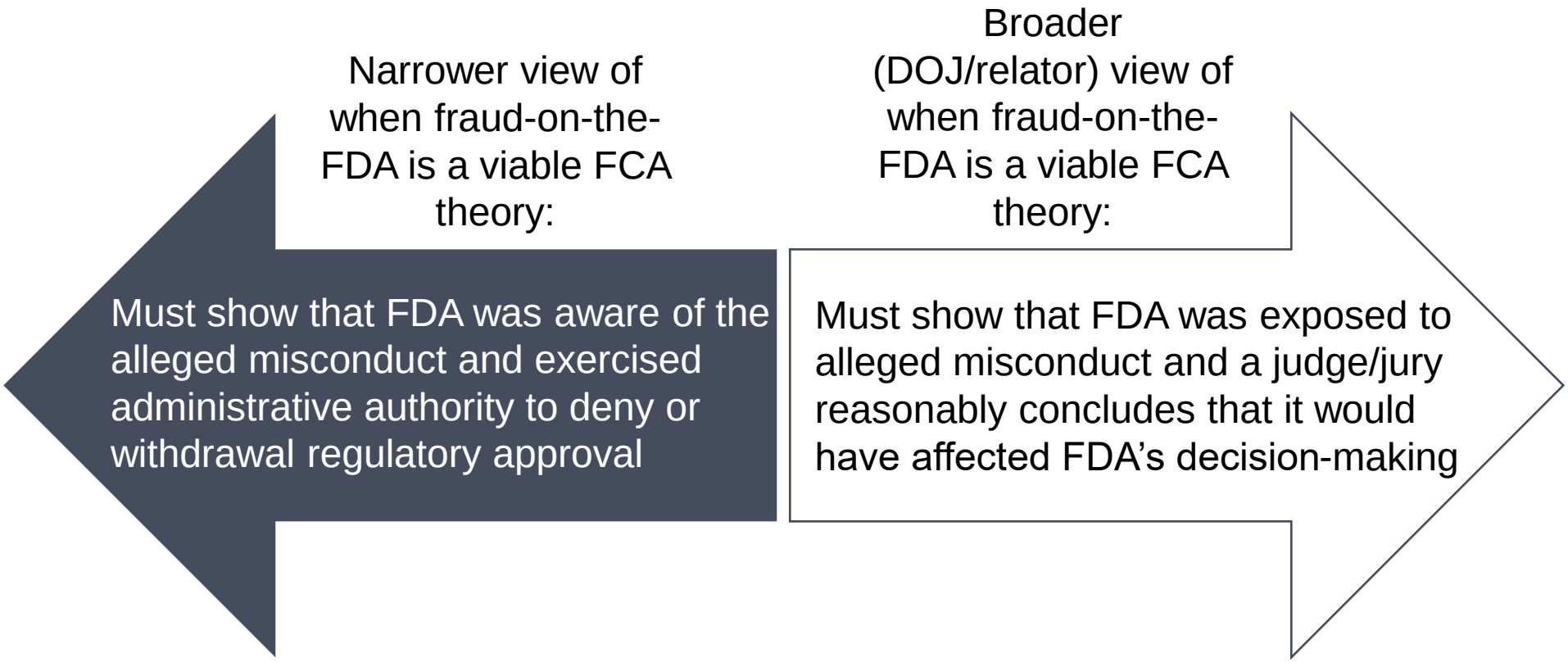
FDA

Purchases drug

Claim for payment for drug

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

What Do Relators Need to Show to Establish that Alleged Fraudulent Conduct Directed at FDA Caused False Claims?

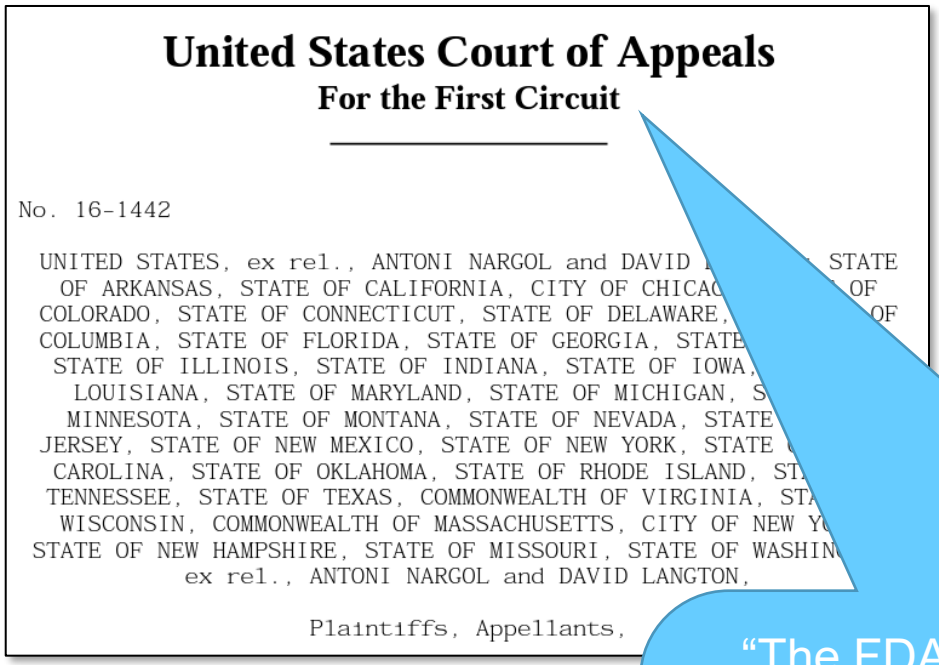


DOJ Statements of Interest Addressing the Fraud-on-the-FDA Theory

"When a manufacturer's fraud allows a medical device to either gain FDA approval or to avoid a recall and federal healthcare programs then pay for the medical device, that fraud can be 'integral to a causal chain leading to payment' and can be actionable under the FCA.… Fraud on the FDA that was material to the agency's determination about whether a medical device could be sold may, therefore, bear a sufficient nexus to the government's payment decision for that device to give rise to liability under the FCA."

"[Where] the defendant's false statements or material omissions masked problems that, for example, would have prompted the FDA to institute or require a product recall, subsequent claims relating to the affected devices could be rendered "false or fraudulent" because the government would not have paid the claims for those affected devices but for the defendant's conduct."

Some Courts Have Been Skeptical of This Theory of Liability



United States Court of Appeals
For the First Circuit

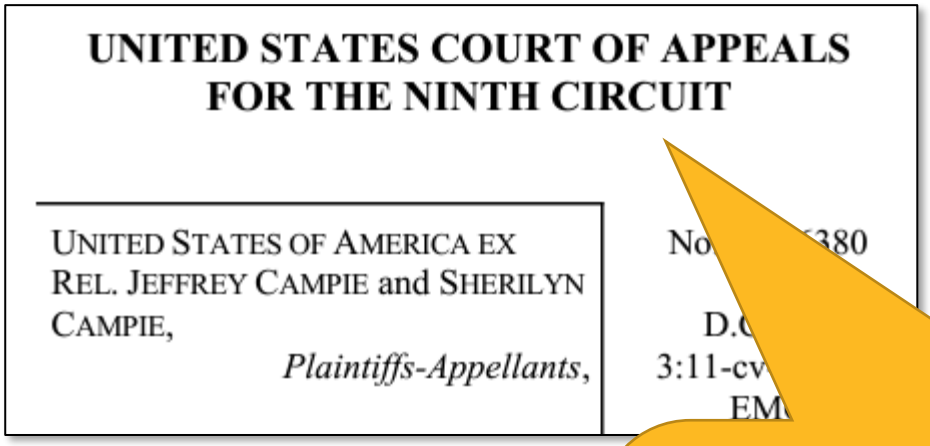
No. 16-1442

UNITED STATES, ex rel., ANTONI NARGOL and DAVID [illegible] STATE OF ARKANSAS, STATE OF CALIFORNIA, CITY OF CHICAC[illegible] OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, [illegible] OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE [illegible] STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, [illegible] LOUISIANA, STATE OF MARYLAND, STATE OF MICHIGAN, S[illegible] MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE [illegible] JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE [illegible] CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, ST[illegible] TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STA[illegible] WISCONSIN, COMMONWEALTH OF MASSACHUSETTS, CITY OF NEW Y[illegible] STATE OF NEW HAMPSHIRE, STATE OF MISSOURI, STATE OF WASHIN[illegible] ex rel., ANTONI NARGOL and DAVID LANGTON,

Plaintiffs, Appellants,

"The FDA, in turn, possesses a full array of tools for "detecting, deterring, and punishing false statements made during . . . approval processes." *Id.* at 349. Its decision not to employ these tools in the wake of Relators' allegations so as to withdraw or even suspend its approval of the…device leaves Relators with a break in the causal chain between the alleged misstatements and the payment of any false claim. "

Other Courts Have Been More Receptive



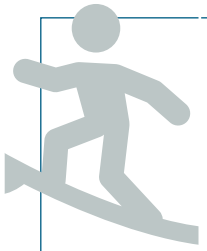
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA EX REL. JEFFREY CAMPIE and SHERILYN CAMPIE,
Plaintiffs-Appellants,

No. 380
D.C.
3:11-cv
EM

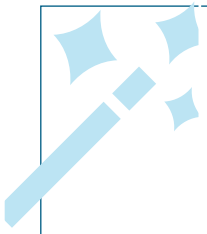
"Finally, relators have adequately satisfied the falsity requirement under a theory of promissory fraud. Because [defendant] committed either factually false or impliedly false certification through its representations to the FDA and labeling of its products, see supra, each claim was fraudulent even if false representations were not made therein."

Challenges to Responding to Fraud-on-the-FDA FCA Cases

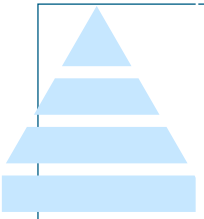


Caselaw significantly in flux

Company must fight a hypothetical – what would FDA have done – often without the benefit of direct engagement with FDA



Particularly where there was a product recall, DOJ will maintain falsity and materiality are automatically satisfied



Damages can accrue quickly under a theory that the entire product line is at issue

State Enforcement Actions Piggy-Backing on Product Liability Litigation

State AGs Leverage Broad State Laws to Pursue Settlements and Judgments

California Department of Justice Announces $188.6 Million Multistate Settlement with Medical Device Manufacturer Boston Scientific Corporation

Tuesday, March 23, 2021

Contact: (916) 210-6000, agpressoffice@doj.ca.gov

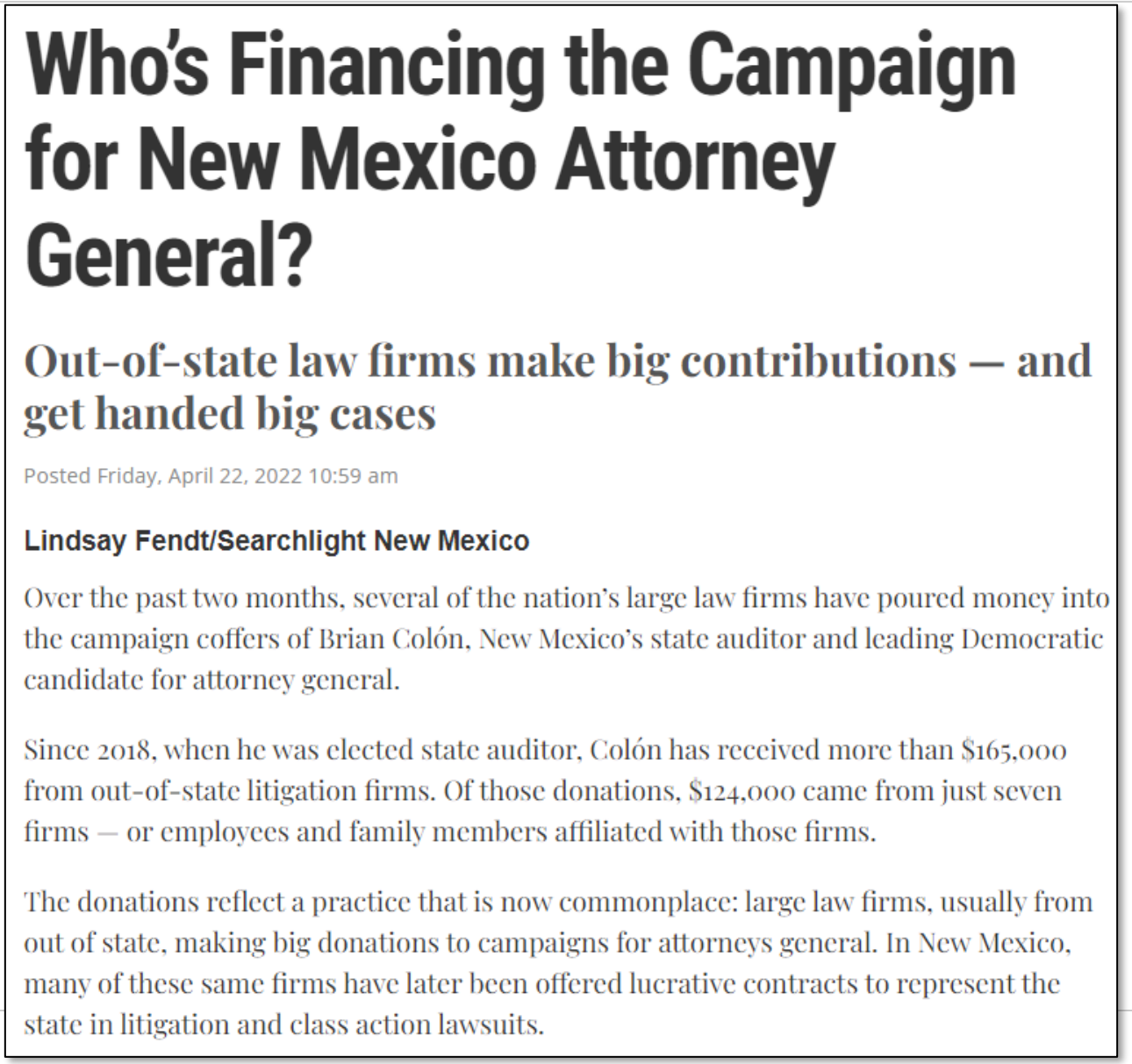
SACRAMENTO – The California Department of Justice and Washington Attorney General Bob Ferguson today announced a multistate settlement with Boston Scientific Corporation (Boston) to resolve allegations of deceptive marketing of its surgical mesh products for women. The settlement requires Boston to pay $188.6 million to 47 states and the District of Columbia to resolve allegations that it deceptively marketed transvaginal surgical mesh devices to patients. California's share of the settlement is $19.3 million.

For Immediate Release
February 15, 2021

News Release 2021-13

$834 Million Order Entered in Hawai'i State Court Against Bristol-Myers Squibb and Sanofi For Failing to Investigate and Disclose Ineffectiveness of Plavix®

State AGs Often Work Through Private Counsel Operating on a Contingency Basis



Who's Financing the Campaign for New Mexico Attorney General?

Out-of-state law firms make big contributions — and get handed big cases

Posted Friday, April 22, 2022 10:59 am

Lindsay Fendt/Searchlight New Mexico

Over the past two months, several of the nation's large law firms have poured money into the campaign coffers of Brian Colón, New Mexico's state auditor and leading Democratic candidate for attorney general.

Since 2018, when he was elected state auditor, Colón has received more than $165,000 from out-of-state litigation firms. Of those donations, $124,000 came from just seven firms — or employees and family members affiliated with those firms.

The donations reflect a practice that is now commonplace: large law firms, usually from out of state, making big donations to campaigns for attorneys general. In New Mexico, many of these same firms have later been offered lucrative contracts to represent the state in litigation and class action lawsuits.

State AGs Often Work Through Private Counsel Operating on a Contingency Basis

New Mexico pays its opioid lawyers $150 million, almost triple national rate

Jun 19, 2023

SANTA FE, N.M. (Legal Newsline) - New Mexico Attorney General Raúl Torrez is paying outside lawyers more than $150 million out of a $453 million opioid settlement with Walgreens, nearly triple the rate other states paid their lawyers to negotiate agreements with major pharmacy chains.

The $148 million contingency fee charged by law firms Baron & Budd, Robles Rael Anaya and Levin Papantonio represent a rate of 33% before allocating $11.2 million to a national "common benefit fund" that Baron & Budd and Levin Papantonio also are expected to participate in. New Mexico for unexplained reasons pulled out of a $4.7 billion national settlement with other states under which the contingency fee rate is 12%.

States Are Even Starting to Push Back on Abusive Contingency Fee Arrangements

Published
March 23, 2023

State AGs Cut Ties with Contingency-Fee Lawyers

According to an editorial in the ***Wall Street Journal***, "Mr. Kobach ... fired Morgan & Morgan because its "performance was not up to what we expected," including delays and the firm's use of subcontractors. Ms. Bird notes that her job is to make sure contingency-fee agreements are right for the taxpayer. "Sometimes they might be, but other times they might primarily benefit out-of-state trial lawyers. That was the case here," she says."

Oklahoma's attorney general Gentner Drummond also terminated a contract with the firm Whitten Burrage on February 14, **stating in a letter**, "While your efforts under the Contract have certainly succeeded in enriching yourselves far beyond what you deserve, those efforts have fallen far short of delivering the results that Oklahomans are entitled to receive." According to the letter the firm will receive $34 million in fees related to the opioid settlement.

Such Contingency Fee Arrangements Have Attracted Criticism But Courts Have Upheld Them

CITY AND COUNTY OF SAN FRANCISCO, et al., Plaintiffs,
v.
PHILIP MORRIS, INC., et al., Defendants.

No. C-96-2090 DLJ.

United States District Court, N.D. California.

February 26, 1997.

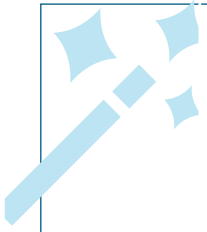
"[T]he Court finds that this case is sufficiently distinguishable from *Clancy* to allow for the government's retention of private counsel. First, as plaintiffs explain, Lieff, Cabraser is acting here as co-counsel, with plaintiffs' respective government attorneys retaining full control over the course of the litigation. Because plaintiffs' public counsel are actually directing this litigation, the Court finds that the concerns expressed in *Clancy* regarding overzealousness on the part of private counsel have been adequately addressed by the arrangement between Lieff, Cabraser and the plaintiffs.

The Court also finds that the civil tort nature of this action meaningfully distinguishes it from *Clancy*. This lawsuit, which is basically a fraud action, does not raise concerns analogous to those in the public nuisance or eminent domain contexts discussed in *Clancy*. Plaintiffs' role in this suit is that of a tort victim, rather than a sovereign seeking to vindicate the rights of its residents or exercising governmental powers."

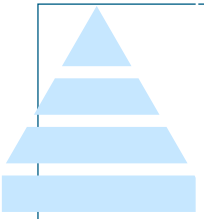
Challenges to Responding to State AG Actions

State acts with the power of a sovereign but often private contingency-fee counsel drive the case

Broad statutes often with undefined elements open to interpretation



Some important defenses often unavailable, such as statute of limitations



Damages can accrue quickly because they are generally not limited to state purchases

Questions?

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BRENNA E. JENNY leverages her experience in senior roles both within the U.S. Department of Health and Human Services (HHS) and the Department of Justice (DOJ) Civil Division to represent clients in the healthcare industry in government enforcement actions, internal investigations, and compliance reviews.

Brenna previously served as the Principal Deputy General Counsel at HHS and the Chief Legal Officer for the Centers for Medicare & Medicaid Services (CMS). In that role, Brenna supervised an unprecedented wave of regulatory flexibilities during the COVID-19 pandemic and served as the principal legal adviser to the $178 billion CARES Act Provider Relief Fund. Brenna led HHS's coordination with DOJ and the HHS Office of Inspector General (HHS-OIG) on civil and criminal enforcement of fraud relating to the Provider Relief Fund. Brenna was also deeply involved in HHS's regulatory reform efforts, including the changes finalized in 2020 to the Stark Law and the Anti-Kickback Statute regulations, the development and implementation of the HHS Good Guidance Practices regulation and the Transparency and Fairness in Civil Administrative Enforcement Actions regulation, and the Department's work to come into compliance with notice-and-comment obligations under the Social Security Act, as interpreted by the Supreme Court in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

Brenna routinely advised CMS on a variety of regulatory matters, including major payment rules, and she supervised HHS attorneys who defended the Department in Administrative Procedure Act challenges to HHS regulatory actions. Through her leadership at HHS, Brenna is familiar with the most pressing issues facing both healthcare providers and life sciences companies. Brenna counsels clients on a range of fraud and abuse risk areas, including remediation through self-disclosures to HHS.

Brenna was a co-founder of the HHS False Claims Act Working Group and regularly consulted with law enforcement at DOJ and HHS-OIG on fraud and abuse matters relating to HHS programs. Prior to joining HHS, Brenna served as Council to the Assistant Attorney General of the Civil Division of DOJ. In this capacity, Brenna supervised False Claims Act matters and opioid-related investigations, in addition to advising on litigation strategy for healthcare-related lawsuits.