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QUI TAM CONFERENCE

FEBRUARY 23-25, 2022

The Modern Relator

The evolution of *qui tam* cases from the traditional individual whistleblower to the corporate relator

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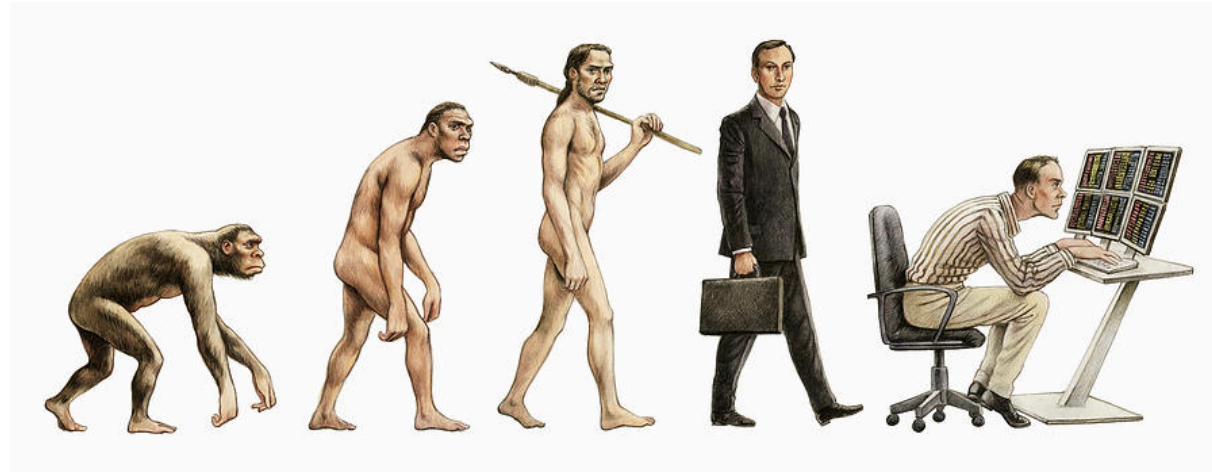


Classic Relators

- The Do-Gooder
 - Employees or witnesses wanting to do the right thing
- The Co-Conspirator
 - “[T]he qui tam provisions are based upon the idea of setting a rogue to catch a rogue.” *Mortgages, Inc.*, 934 F.2d 209, 213 (9th Cir. 1991).
- The Double-Agent
 - E.g., the doctors being offered the kickbacks
- The Victim
 - E.g., Medicare beneficiaries, Section 8 housing tenants

Modern Relators

- The Competitor
- The Corporation
- The Data Miner



Who can and cannot be a relator?

- 3730(b)(1) “Any person...”
 - Individuals
 - Corporations
 - Associations, Partnerships, Etc.
 - But not certain government employees.

Typical Scenarios

- An individual, typically an insider, has direct knowledge of the issue
- An individual, not an insider, pieces together the story from available information.
- Several people come forward as a group and form a legal entity to act as one relator. Why?
- A company, typically a competitor, brings an action because of its unique vantage point about facts on the ground.

An example

- U.S. ex rel. Sanofi v. Mylan Labs. (D. Mass.)
- \$465 million Epi-Pen settlement
- Involved allegations that Mylan violated the federal and state False Claims Acts by knowingly misclassifying EpiPen[®], a branded epinephrine auto-injector drug, as a generic drug, to avoid paying rebates owed to Medicaid.
- Why might a competitor think of this as another tool in the toolbox?

Successful Litigation of Declined Cases Trending

- The percentage of favorable settlements or judgments in which the Government declined over the total number of successful FCA cases is on a steep rise over the last decade.
- Prior to 2000, the number of successful declined *qui tam* cases out of the total number of successful FCA cases was negligible.
- From 2000 to 2010, the percentage became measurable but remained relatively low (around 1.7%).

Source: DOJ "Fraud Statistics – Overview" (Jan. 14, 2021)

Declined *Qui Tams* are Beginning to Account for a Higher Percentage of Recovery Outcomes

- From 2010 to 2020, the percentage more than quadrupled (7.5%)
- During the 4 years between 2016 and 2020 the number jumped to over 10%
- Nearly 1/5 of all successful FCA cases in 2017 were declined qui tams

Source: DOJ "Fraud Statistics – Overview" (Jan. 14, 2021)

What Does This Mean?

- The Government is declining meritorious cases for a variety of reasons.
- Experienced litigation counsel are getting into the business of declined *qui tam* cases.
- Coalitions of lawyers and plaintiff-relators are becoming both more necessary and more prevalent, upending the old model and calling into question whether the proper policies are served by the statutory bar provisions.

A Special Problem With the Corporate Relator

How

U.S. ex. rel Elite Emergency Services, LLC v. Vaughn Regional Medical Center

became

U.S. ex. Rel Samuel Clemmons v. Vaughn Regional Medical Center, Lifepoint Hospitals, Inc., and Integrity Emergency Care, Inc.

A Special Problem with the Corporate Relator

Case 2:14-cv-00416-TFM-C Document 8 Filed 05/14/15 Page 1 of 4 PageID #: 34

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
NORTHERN DIVISION

UNITED STATES OF AMERICA)	
<u>ex. rel.</u> ELITE EMERGENCY SERVICES,)	
LLC and ELITE EMERGENCY)	
SERVICES OF ALABAMA, LLC)	Civil Action No. 14-416
Plaintiffs,)	JURY TRIAL DEMANDED
vs.)	
)	FILED IN CAMERA
VAUGHAN REGIONAL MEDICAL)	AND UNDER SEAL
CENTER, LLC,)	
Defendant.)	

MOTION TO SUBSTITUTE SAMUEL C. CLEMMONS AS RELATOR

COME NOW relators Elite Emergency Services, LLC (“Elite”) and Elite Emergency Services of Alabama, LLC (“Elite Alabama”), on behalf of the United States of America, as relators, and on behalf of themselves, and pursuant to Rule 17(a) of the Federal Rules of Civil Procedure, move this Court to substitute Samuel C. Clemmons (“Clemmons”) as relator, based upon the following:

1. On April 30, 2015, Elite and Elite Alabama (along with certain affiliated companies) sold certain of their respective assets to a third party purchaser.
2. As part of this transaction, on April 30, 2015, all of Elite’s and Elite Alabama’s respective claims and causes of action asserted in active litigation,

including those claims asserted in this cause of action, were assigned and became the property of Clemmons.

3. Clemmons, either individually or by entities wholly owned by him, owns Elite and Elite Alabama. Accordingly, each of the allegations asserted in the Complaint (Doc. 1) are based upon Clemmons’ knowledge as the original source in this action.

4. Pursuant to FRCP Rule 17(a), Clemmons is the real party in interest with exclusive standing to assert the qui tam claim as relator, and this motion has been made within a reasonable period of time and relates back to the filing of the Complaint.

5. No party will be prejudiced by the requested substitution.

WHEREFORE, based on the foregoing, relators Elite Emergency Services, LLC and Elite Emergency Services of Alabama, LLC move this Court to substitute Samuel C. Clemmons as relator in this action.

Respectfully submitted,


Brandy M. Lee


Brice M. Johnston

Counsel for Relators

Case 2:14-cv-00416-TFM-C Document 9 Filed 05/19/15 Page 1 of 1 PageID #: 38

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA
NORTHERN DIVISION

UNITED STATE OF AMERICA)	
<u>ex rel.</u> ELITE EMERGENCY)	
SERVICES, LLC, and ELITE)	
EMERGENCY SERVICES OF)	
ALABAMA, LLC,)	
Plaintiffs,)	
vs.)	CIVIL ACTION NO. 14-0416-CG-C
VAUGHAN REGIONAL MEDICAL)	UNDER SEAL
CENTER, LLC,)	
Defendant.)	

ORDER

This cause is before the court on the relators’ Motion to Substitute Samuel C. Clemmons as Relator (Doc. 8).

Upon due consideration of the grounds cited and pursuant to the provision of Rule 17(a) of the Federal Rules of Civil Procedure, the motion is hereby **GRANTED in part**. Samuel C. Clemmons is hereby substituted as the relator in this action.

The relator is **ORDERED** to file an amended complaint with the correct style, and that appropriately references Samuel C. Clemmons as the relator throughout the body of the amended complaint no later than **May 26, 2015**. Relator is further **ORDERED** to serve a copy of his amended complaint on the United States, and provide proof of said service by the aforementioned date.

DONE and ORDERED this 19th day of May, 2015.

/s/ Callie V. S. Granade
UNITED STATES DISTRICT JUDGE



Case Study: Alexander Volkhoff, LLC

- *United States ex rel. Alexander Volkhoff, LLC v. Janssen Pharmaceutica N.V.*, 945 F.3d 1237, 1240 (9th Cir. 2020)
- *Qui tam* filed by Alexander Volkhoff, LLC shortly after its incorporation
- Defendant moved to dismiss for lack of standing
- Relator filed FAC replacing Volkhoff with Jane Doe
- Jane Doe barred by first-to-file rule, because she and Volkhoff were distinct legal persons
- Volkhoff could not appeal because nonparty
- *But see In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig. (No. II)*, 974 F.3d 228 (3d Cir. 2020) (permitting new relators to enter a qui tam suit).

Case Study: CKD Project, LLC

- Can a Corporation Be An Original Source?
- *United States ex rel. CKD Project, LLC v. Fresenius Med. Care Holdings, Inc.*, 2021 WL 3240280, at *4 (E.D.N.Y. July 30, 2021).
- “Relator admits that it is an entity formed for the sole purpose of this litigation and that it acquired its information from a third party. Under the pre-2010 FCA, as an entity that has never been involved with Fresenius prior to the filing of this action, and whose information is wholly derived from an anonymous third party... and public disclosures, Relator, by definition, cannot have either direct or independent knowledge of the alleged fraud...”

Publicly Available Data

- <https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service>
 - Information on use, payments, and submitted charges organized by National Provider Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code, and place of service.
- <https://projects.propublica.org/coronavirus/bailouts/>
- <https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/>

Data Miner Issues – Public Disclosure Bar



“Under the post-March 23, 2010 public disclosure bar, a relator is an original source if he ‘has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.’ 31 U.S.C. § 3730(e)(4)(B). A relator cannot ‘merely mirror allegations that were already publicly disclosed.’ Rather, the relator must materially add to the allegations by ‘contribut[ing] information – distinct from what was publicly disclosed – that adds in a significant way to the essential factual background: the who, what, when, where and how of the events at issue.’”

United States ex rel. Sirls v. Kindred Healthcare, Inc., 2021 WL 1721864, at *5 (E.D. Pa. Apr. 29, 2021).



Data Miner Issues – Public Disclosure Bar

- *United States ex rel. Yannacopolous v. Gen. Dynamics*, 315 F. Supp. 2d 939, 954 (N.D. Ill. 2004) (publicly disclosed material “discovered and synthesized” during an independent investigation makes relator an original source).
- “Relator’s action is based upon an alleged fraud that was first discerned through Relator’s synthesis and analysis of otherwise apparently innocuous, garden-variety real estate/financial information.” *United States ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 U.S. Dist. LEXIS 96434, at *12 (S.D. Fla. July 12, 2012).
- “Relator also contended the FCA’s public-disclosure bar did not apply, as (1) certain documents were not publicly available and (2) data published by CMS does not constitute a public disclosure as it would not have put the Government on notice of Dr. Odom’s fraud, as Relator ‘applied his medical knowledge and experience to what the data revealed and to what it did not reveal.’ ” *United States ex rel. Eastlick v. Odom*, 2021 WL 5014116, at *7 (D.S.C. Oct. 28, 2021).

Case Study: St. Jude Medical

- *United States ex rel. Burke v. St. Jude Medical, Inc.*, 2021 WL 6135202 (D. Md. Dec. 29, 2021)
- Relator received faulty, previously-recalled implant; Government intervened and settled qui tam
- Government argues that public disclosures lay out the entire scheme: recall, continued distribution of device, and payment for devices
- Court rejects application of Public Disclosure Bar at this stage but applies reduced relator's share provision (0%-10%), awards .5% "finder's fee"

Data Miner Issues – Annoyed Government

- Intent of the Statute – disinterested AUSA or investigators
- Stymied Investigation due to lack of insider information (facts, witnesses, defenses)
- “Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation.” 31 U.S.C. § 3730(d)(1).

Case Study: Venari Partners

- *See, e.g., United States ex rel. Cimznhca, LLC v. UCB, Inc., 970 F.3d 835, 838 (7th Cir. 2020)*
- Relator that had been created as investment vehicles for financial speculators brought kickback case
- VP had four corporate members, with six total investors, and formed eleven daughter companies for the purpose of prosecuting separate *qui tams* alleging identical violations by dozens of defendants
- Government exercised dismissal authority



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