PAUL HASTINGS

A Fireside Chat on Whistleblowers

Twenty-Fourth Annual Pharmaceutical and Medical Device Ethics and Compliance Congress

October 25, 2023

Panel Members

Kirsten Mayer, ACLU of Massachusetts

Interim Legal Director (Former Head of US Compliance and VP of Legal at argenx; Former partner at Ropes & Gray)

- As a former law firm partner and in-house head of compliance, advised healthcare and life sciences companies in enforcement matters, related civil litigation, compliance assessments, remediation, and CIA implementation
- Currently serving the ACLU of Massachusetts before turning to new work in 2024

Gregg Shapiro, Gregg Shaprio Law

Founder (Former US Attorney's Office, District of Massachusetts, US DOJ, Boston, MA)

- Led Department of Justice False Claims Act investigations and cases that resulted in over $3 billion in recoveries from companies and individuals that allegedly defrauded the government
- Represents whistleblowers in False Claims Act *qui tam* cases, SEC whistleblower filings, and other whistleblower proceedings

Gary Giampetruzzi, Paul Hastings

Global Chair of Life Sciences (Former Head of Government Investigations at Pfizer)

- Designs and enhances global compliance programs for life sciences companies, including proactive diagnostics / compliance reviews
- Defends companies in healthcare cases before U.S. Attorney's Offices, and FCPA cases before the DOJ and SEC

Discussion Agenda

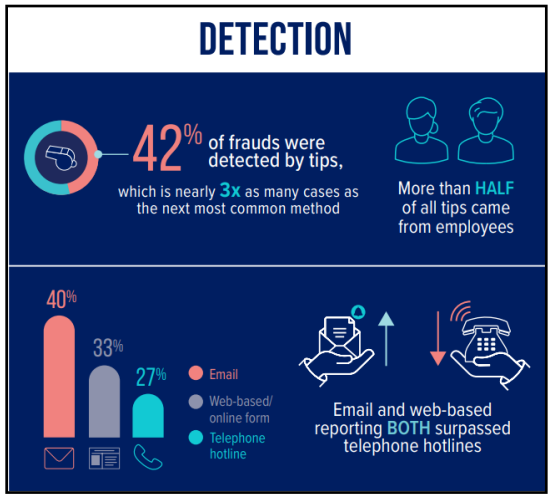
I. **Whistleblowers in Life Sciences and Beyond**
   - A. **What Are We Seeing?**
   - B. **How Does Compliance / Speak Up Culture Fit In?**
   - C. **Relevant, Recent Guidance From The DOJ**

II. **How Do Whistleblower Profiles Impact Cases?**
   - A. **Compliance Officers as Whistleblowers**
   - B. **The Information / Case Brought Forward**
   - C. **How Does Each Side Handle Potential Theft of Trade Secrets?**

III. **Recent Supreme Court Decisions: *SuperValu* and *Polansky***
   - A. **What Is The Significance Of These Cases?**
   - B. **Do These Affect The Work / Approaches of Compliance?**

IV. **Q&A**

Whistleblower Profiles – Overview

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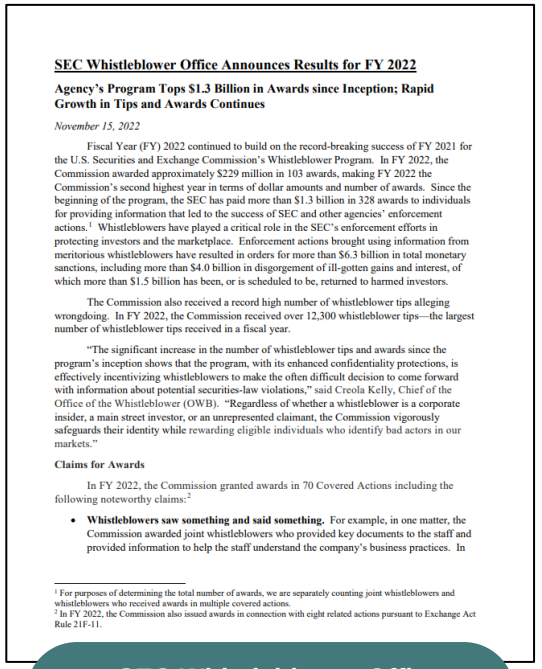
Recent Whistleblower Activity Increases Pressure on Internal Reporting and Investigation Mechanisms

By Gary Giampetruzzi, Corinne A. Lammers, Josh Christensen, Jessica R. Montes, & Marlyse Vieira

- According to a 2022 report on Occupational Fraud by the Association of Certified Fraud Examiners, **42% of frauds were detected by a tip, over half of them were reported by employees,** and **email and web-based reporting** were the most common forms


SEC Whistleblower Office Announces Results for FY 2022

Agency's Program Tops $1.3 Billion in Awards since Inception; Rapid Growth in Tips and Awards Continues

November 15, 2022

Fiscal Year (FY) 2022 continued to build on the record-breaking success of FY 2021 for the U.S. Securities and Exchange Commission's Whistleblower Program. In FY 2022, the Commission awarded approximately $229 million in 103 awards, making FY 2022 the Commission's second highest year in terms of dollar amounts and number of awards. Since the beginning of the program, the SEC has paid more than $1.3 billion in 328 awards to individuals for providing information that led to the success of SEC and other agencies' enforcement actions.[1] Whistleblowers have played a critical role in the SEC's enforcement efforts in protecting investors and the marketplace. Enforcement actions brought using information from meritorious whistleblowers have resulted in orders for more than $6.3 billion in total monetary sanctions, including more than $4.0 billion in disgorgement of ill-gotten gains and interest, of which more than $1.5 billion has been, or is scheduled to be, returned to harmed investors.

The Commission also received a record high number of whistleblower tips alleging wrongdoing. In FY 2022, the Commission received over 12,300 whistleblower tips—the largest number of whistleblower tips received in a fiscal year.

"The significant increase in the number of whistleblower tips and awards since the program's inception shows that the program, with its enhanced confidentiality protections, is effectively incentivizing whistleblowers to make the often difficult decision to come forward with information about potential securities-law violations," said Creola Kelly, Chief of the Office of the Whistleblower (OWB). "Regardless of whether a whistleblower is a corporate insider, a main street investor, or an unrepresented claimant, the Commission vigorously safeguards their identity while rewarding eligible individuals who identify bad actors in our markets."

Claims for Awards

In FY 2022, the Commission granted awards in 70 Covered Actions including the following noteworthy claims:[2]

- **Whistleblowers saw something and said something.** For example, in one matter, the Commission awarded joint whistleblowers who provided key documents to the staff and provided information to help the staff understand the company's business practices. In

[1] For purposes of determining the total number of awards, we are separately counting joint whistleblowers and whistleblowers who received awards in multiple covered actions.
[2] In FY 2022, the Commission also issued awards in connection with eight related actions pursuant to Exchange Act Rule 21F-11.

- In FY 2022, the SEC received over 12,300 whistleblower tips—the largest number of whistleblower tips received in a fiscal year

DOJ View on Importance of Compliance Culture

– As everyone here knows, ***it all comes back to corporate culture***. . . . [W]e identified encouraging trends and new ways in which compliance departments are being strengthened and sharpened. But **resourcing a compliance department is not enough; it must also be backed by, and integrated into, a corporate culture that rejects wrongdoing for the sake of profit**. And companies can foster that culture through their leadership and the choices they make.

Excerpts from **Lisa O. Monaco, Deputy Attorney General (September 2022)** *delivering remarks on corporate criminal enforcement at NYU.*

Statistical Value of Company "Speak Up" Culture

Studies suggest that an open, speak up culture that welcomes compliance issues and addresses them without retaliation in a circle of continuous improvement will reduce the numbers of lawsuits and regulatory fines

Forbes

- Forbes reported that a recent study, based on proprietary data from the world's largest provider of internal whistleblower systems (NAVEX), found that, with employee hotlines, **a greater number of internal reports are linked to fewer external problems like lawsuits and regulatory fines (analyzed nearly two million whistleblower reports for over 1,000 public companies)**
  - Only 29% of reports are filed anonymously
- "Most importantly, **more reports are a sign of an open feedback culture where companies are actively soliciting employees to provide insight** . . . Companies getting fewer whistleblower reports don't have fewer problems, management is just less aware of the problems."

Harvard Business Review

- Harvard Business Review studied this data and found that **companies that have more complaints from hotlines actually have fewer lawsuits, smaller bills from legal settlements, and fewer fines**
- It was also concluded that **companies with more internal whistleblower reports have more positive attributes** (**e.g. they are more profitable** and have better governance practices)
- Secondhand reports were, on average, more likely to be substantiated by management than firsthand reports
- Of the 71.5% of reporters who disclosed their identity, "**it is the eventual follow up and conversation that engenders trust, improves communication lines, and provides actionable information to prevent minor issues from becoming larger, more costly problems.**"

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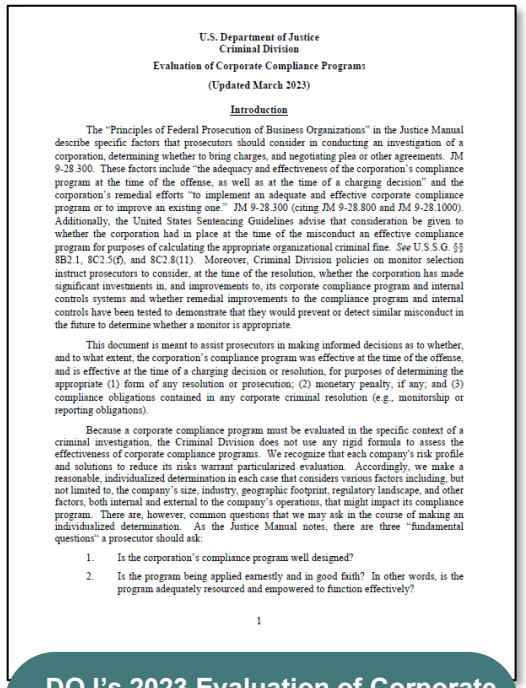
DOJ View on Compliance Incentives

"Companies should ensure that executives and employees are personally invested in promoting compliance. And nothing grabs attention or demands personal investment like having skin in the game, through direct and tangible financial incentives."

- Deputy AG Lisa Monaco
ABA's National Institute on White Collar Crime
(March 3, 2023)



U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

(Updated March 2023)

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. *See* U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, Criminal Division policies on monitor selection instruct prosecutors to consider, at the time of the resolution, whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems and whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future to determine whether a monitor is appropriate.

This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three "fundamental questions" a prosecutor should ask:

1. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?

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DOJ's 2023 Evaluation of Corporate Compliance Programs Guidance

- The 2023 Evaluation Guidance's most significant changes are in the section titled "**Compensation Structures and Consequence Management**," which underscores that corporations should develop and maintain a positive compliance culture by establishing incentives for compliance and disincentives for compliance failures.

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Whistleblower Profiles – Compliance & Audit

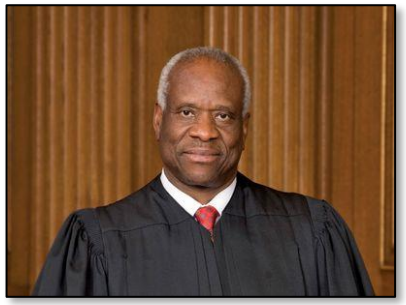
- Unknown company (2022) – SEC letter announced a $450k award to a compliance professional who waited over 120 days to contact the SEC after reporting internally
- Unknown company (2020) – SEC awarded $300k to an employee who identified potential securities law violations in connection with audit-related responsibilities because the whistleblower had a reasonable basis to believe the entity engaging in misconduct would impede the agency's investigation
- Incyte (2021) – DOJ announced that Justin Dillon, a former compliance executive, would receive approximately $3.59 million
- Merit Medical Systems (2020) – DOJ announced that Charles J. Wolf, the former CCO, would receive $2.65 million
- Olympus (2016) – DOJ announced that John Slowik, the former compliance officer, would receive $51 million
- Halifax Health (2014) – DOJ announced that Elin Baklid-Kunz, a former compliance officer, would receive $20.8 million

Whistleblowers and Potential Theft of Trade Secrets

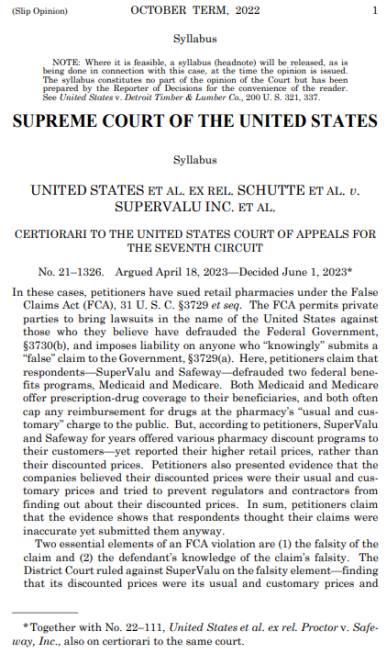
Considerations when an employee who has taken valuable confidential business information claims to be a whistleblower

- Continuing access to data
- Whether any trade secrets were already disclosed
- NDA or other agreements with restrictive language
- Defend Trade Secrets Act and other relevant whistleblower laws
- Optics of filing suit and the likelihood of success
- Public policy to allow relators to use corporate documents from the defendant in the prosecution of False Claims Act claims

United States ex rel. Schutte v. SuperValu



"Based on the FCA's statutory text and its common-law roots, the answer to the question presented is straightforward: ***The FCA's scienter element refers to respondents' knowledge and subjective beliefs***—not to what an objectively reasonable person may have known or believed."



(Slip Opinion) OCTOBER TERM, 2022 1

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

UNITED STATES ET AL. EX REL. SCHUTTE ET AL. *v.* SUPERVALU INC. ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

No. 21–1326. Argued April 18, 2023—Decided June 1, 2023*

In these cases, petitioners have sued retail pharmacies under the False Claims Act (FCA), 31 U. S. C. §3729 *et seq.* The FCA permits private parties to bring lawsuits in the name of the United States against those who they believe have defrauded the Federal Government, §3730(b), and imposes liability on anyone who "knowingly" submits a "false" claim to the Government, §3729(a). Here, petitioners claim that respondents—SuperValu and Safeway—defrauded two federal benefits programs, Medicaid and Medicare. Both Medicaid and Medicare offer prescription-drug coverage to their beneficiaries, and both often cap any reimbursement for drugs at the pharmacy's "usual and customary" charge to the public. But, according to petitioners, SuperValu and Safeway for years offered various pharmacy discount programs to their customers—yet reported their higher retail prices, rather than their discounted prices. Petitioners also presented evidence that the companies believed their discounted prices were their usual and customary prices and tried to prevent regulators and contractors from finding out about their discounted prices. In sum, petitioners claim that the evidence shows that respondents thought their claims were inaccurate yet submitted them anyway.

Two essential elements of an FCA violation are (1) the falsity of the claim and (2) the defendant's knowledge of the claim's falsity. The District Court ruled against SuperValu on the falsity element—finding that its discounted prices were its usual and customary prices and

*Together with No. 22–111, *United States et al. ex rel. Proctor* v. *Safeway, Inc.*, also on certiorari to the same court.

Justice Thomas delivering the opinion of the Court in *U.S. ex rel. Schutte v. SuperValu Inc.*

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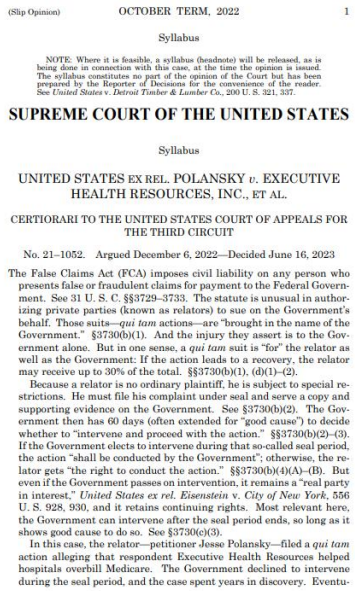
U.S. ex rel. Polansky v. Executive Health Resources

"Today, we hold that the ***Government may seek dismissal of an FCA action over a relator's objection so long as it intervened sometime in the litigation***, whether at the outset or afterward. We also hold that in handling such a motion, district courts should apply the rule generally governing voluntary dismissal of suits: Federal Rule of Civil Procedure 41(a)."



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SUPREME COURT OF THE UNITED STATES

Syllabus

UNITED STATES EX REL. POLANSKY *v.* EXECUTIVE HEALTH RESOURCES, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 21–1052. Argued December 6, 2022—Decided June 16, 2023

The False Claims Act (FCA) imposes civil liability on any person who presents false or fraudulent claims for payment to the Federal Government. See 31 U. S. C. §§3729–3733. The statute is unusual in authorizing private parties (known as relators) to sue on the Government's behalf. Those suits—*qui tam* actions—are "brought in the name of the Government." §3730(b)(1). And the injury they assert is to the Government alone. But in one sense, a *qui tam* suit is "for" the relator as well as the Government: If the action leads to a recovery, the relator may receive up to 30% of the total. §§3730(b)(1), (d)(1)–(2).

Because a relator is no ordinary plaintiff, he is subject to special restrictions. He must file his complaint under seal and serve a copy and supporting evidence on the Government. See §3730(b)(2). The Government then has 60 days (often extended for "good cause") to decide whether to "intervene and proceed with the action." §§3730(b)(2)–(3). If the Government elects to intervene during that so-called seal period, the action "shall be conducted by the Government"; otherwise, the relator gets "the right to conduct the action." §§3730(b)(4)(A)–(B). But even if the Government passes on intervention, it remains a "real party in interest," *United States ex rel. Eisenstein* v. *City of New York*, 556 U. S. 928, 930, and it retains continuing rights. Most relevant here, the Government can intervene after the seal period ends, so long as it shows good cause to do so. See §3730(c)(3).

In this case, the relator—petitioner Jesse Polansky—filed a *qui tam* action alleging that respondent Executive Health Resources helped hospitals overbill Medicare. The Government declined to intervene during the seal period, and the case spent years in discovery. Eventu-

Justice Kagan delivering the majority opinion of the Court in *United States, ex rel. Polansky v. Executive Health Resources, Inc.*

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Questions

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