

# Emerging Trends in Healthcare Fraud Enforcement

Ellen H. Persons, Shareholder, Polsinelli

Austin Hall, Assistant United States Attorney for the Northern District of Georgia

Katie Fink, Senior Counsel at HHS/OIG

Charles Hackney, Assistant Special Agent in Charge at HHS/OIG

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## Government Fraud Enforcement Partners

- Department of Justice/USAOs
- HHS Office of Inspector General
- Federal Bureau of Investigations
- State Attorney General's Office/Medicaid Fraud Control Units
- CMS and contractors (e.g., UPICs, MEDIC)
- State Boards of Medicine, Nursing etc.

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## Sources of Case Referrals

- *Qui tam* (whistleblower) complaints
- OIG Hotline- competitor/patient/family complaints
- Information developed during OIG audits, evaluations, and reviews
- Data mining
- Partner agency (e.g., UPICs, MEDIC) referrals
- Self-disclosures

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## Criminal, Civil & Administrative Proceedings

<i>Factor</i>	<b>Criminal</b>	<b>Civil</b>	<b>Administrative</b>
<i>Standard of Proof</i>	"Beyond a reasonable doubt"	"By a preponderance of the evidence"	"By a preponderance of the evidence"
<i>Case Initiation</i>	Indictment or Information	Complaint	Complaint or formal notice/demand letter
<i>Dispute Resolution</i>	Federal Judicial Proceedings	Federal Judicial Proceedings	Administrative Law Judge/Departmental Appeals Board
<i>Prosecution Authority</i>	Department of Justice	Department of Justice	Agency Head (HHS Secretary)
<i>Purpose</i>	To punish and deter	To remedy past and/or prevent future injuries	To remedy past and/or prevent future injuries
<i>Remedies</i>	Imprisonment, Supervision, Fines, Restitution, and Special Assessments	Civil Penalties, Damages, Injunctions, and Restraining Orders	Civil Penalties, Damages, Exclusions, Suspensions, Debarments, and other Adverse Actions

## Self-Disclosure Option

- HHS-OIG Self Disclosure Protocol
  - Good faith disclosure indicative of a robust and effective compliance program
  - Presumption against requiring an integrity agreement
  - Potential for a lower multiplier
- Disclosure Directly to the U.S. Attorney's Office

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## DOJ Policy Changes

- Sept. 2015 - Memorandum Re: Individual Accountability for Corporate Wrongdoing ("Yates Memo") is released
  - Announced formal policy of combating corporate crime by targeting and seeking accountability from the individuals involved in the wrongdoing
  - Required corporations to identify "all individuals involved in or responsible for the misconduct" in order to receive cooperation credit
  - Reiterated and formalized mandatory coordination among civil and criminal divisions in cases of corporate malfeasance
  - Applies to both Criminal and Civil investigations
  - Outlined 6 "key steps" for federal prosecutors to follow in order "to most effectively pursue the individuals responsible for corporate wrongs"

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## DOJ Policy Changes

- Nov. 2018 - Rod Rosenstein remarks on cooperation credit during International Conference on the FCPA announced a clarification of the Yates Memo's requirements
  - Still a focus on pursuing individuals involved in corporate fraud
  - "Investigations should not be delayed merely to collect information about individuals whose involvement was not substantial, and who are not likely to be prosecuted"
  - To qualify for cooperation credit in criminal cases companies now need to identify individuals who were *substantially involved* in the wrongdoing

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## DOJ Policy Changes

- May 2019 – DOJ Civil Division issued guidance on False Claims Act Matters and updates to the Justice Manual
- Cooperation credit in False Claims Act cases may be earned by:
  - Voluntarily disclosing misconduct unknown to the Government
  - Cooperating in an ongoing investigation
    - Sharing of information gleaned from an internal investigation
    - Identifying individuals involved in the misconduct or who have knowledge of the misconduct
    - Preserving/producing documents, information and metadata beyond what is legally required
  - Undertaking remedial measures in response to a FCA violation
- The amount of credit that the DOJ will provide remains highly discretionary

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## False Claims Act Enforcement Activity

- More than \$3 billion in FCA recoveries in Fiscal Year 2019
- Approximately \$2.6 billion relates to matters that involved the health care industry
- Insys Therapeutics: \$195 million to settle civil allegations that company paid kickbacks to induce physicians and nurse practitioners to prescribe Subsys – sham speaker events, lavish meals and entertainment, etc.
- Reckitt Benckiser: \$1.4 billion to resolve criminal and civil liability related to the marketing of opioid addiction treatment drug Suboxone
- Avanir Pharmaceuticals: \$95 million to resolve kickback allegations and false and misleading marketing to induce providers to improperly prescribe Neudexta

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## United States v. AseraCare

- FCA case where *qui tam* relator alleges that AseraCare knowingly and falsely certified that certain Medicare recipients were terminally ill in order to receive Medicare reimbursements.
  - Bifurcated trial between falsity and other FCA elements.
- After a partial verdict in favor of the government on falsity, the district court judge reversed, noting:
  - Falsity requires proof of an objective falsehood, difference of opinion between physicians is not enough.

\*176 F. Supp. 3d 1282 (N.D. Ala. 2016)

\*938 F. 3d 1278 (2019)

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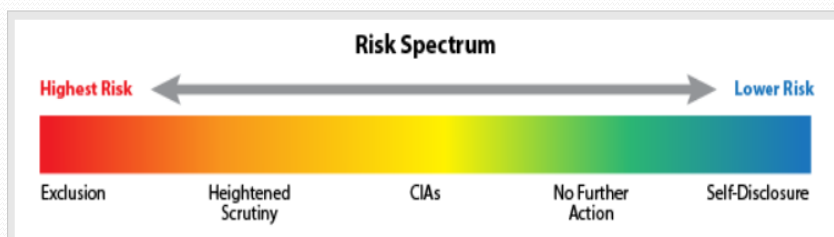
## Application of *AseraCare*

- *United States ex rel. Dildine v. Pandya*, Case No. 13-0336 (N.D. Ga. July 9, 2019): FCA case involving allegations that ophthalmologist performed medically unnecessary cataract surgeries.
  - “The conflicting hospice care eligibility expert testimony involves a subjective difference of medical opinion.”
  - “However, the Complaint here alleges objective falsity—for example, that Dr. Pandya falsely diagnosed cataracts and then performed unnecessary cataract surgeries on those patients.”

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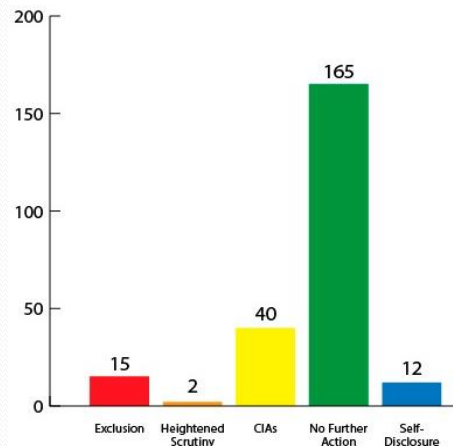
## Exclusion Risk Spectrum

- OIG assessment of future risk posed by persons who have allegedly engaged in civil health care fraud
- Makes **public** all health care providers that refuse to agree to enter into a CIA in connection with an FCA settlement



<https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp> <sup>12</sup>

## FCA Settlements on the OIG Risk Spectrum FY 2019 Q1-Q4



<https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp>

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## Enforcement Focus: Opioids

- High government spending on opioids
  - Medicare prescription drug program spent more than \$4 billion on opioids in 2016
- Mechanisms for DOJ enforcement?
  - Anti-Kickback Statute;
  - False Claims Act;
  - Controlled Substances Act-
    - Distribution and ordering,
    - Prescribing,
    - Corresponding responsibility,
    - Theft and loss reporting
- OIG Work Plan: Steady addition of opioid-related items

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## Enforcement Focus: Opioids

- In 2018, DOJ announced its vigorous attack on the opioid crisis
- Opioid focus in largest-ever enforcement action (June 2018)
  - Of 601 defendants, 162 (76 physicians) charged related to opioids and other narcotics
  - Of 2,700 individuals excluded from federal health care programs from July 2017 through June 2018, 587 providers were excluded related to opioid diversion and abuse
- Strike Forces
  - April 2019 – Appalachian Regional Prescription Opioid Strike Force charged 60 individuals, including 53 medical professionals, across 11 federal districts, for their alleged participation in illegally prescribing and distributing opioids in a health care fraud scheme.
  - DEA/DOJ: New Opioid Fraud and Abuse Detection Unit, \$20M plus 12 DOJ attorneys to focus only on opioid-related fraud; focus districts.
  - FBI/DOJ: Joint Criminal Opioid Darknet Enforcement (J-CODE) team.

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## Enforcement Focus: Genetic Testing Fraud

### Genetic Testing **SCAM**

Scammers are offering Medicare beneficiaries "free" genetic testing or cheek swabs in order to obtain beneficiaries' personal information for fraudulent purposes.



#### Recruiter

The recruiter (who may also be called a marketer or telemarketer), targets the beneficiary to take a genetic test in person or by mail.



#### Doctor

The doctor orders a test for the beneficiary even if it's not medically necessary. The doctor gets a kickback from the recruiter for ordering the test.



#### Lab

The lab runs the test and receives the reimbursement payment from Medicare. The lab shares the proceeds of that payment with the recruiter.

The alleged scheme is current as of September 2019.

Source: <https://oig.hhs.gov>

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## Enforcement Focus: Genetic Testing Fraud

- CGx (cancer DNA test) – collected by buccal swab, this test determines an individual's predisposition to developing certain types of cancers based on an analysis of genetic markers
- PGx (pharmacogenomic DNA test) – collected by buccal swab, this genetic test can predict an individual's likelihood to experience an adverse event or not respond to a given drug based on how he or she metabolizes and responds to medications
- CGx and PGx billing can be in excess of \$13k per beneficiary
- CGx and PGx reimbursement is approximately \$6k to \$9k per beneficiary

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## Enforcement Focus: Genetic Testing Fraud

- Genetic testing fraud focus in nationwide takedown (September 2019)
- Charged 35 individual for their participation in genetic testing schemes that caused \$2.1 billion in losses
- Includes 9 charged physicians

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## Enforcement Focus: Telemedicine

- April 2019 Telehealth Takedown - 24 telemedicine and durable medical equipment (“DME”) company executives and physicians charged for their alleged participation in a \$1.2 billion healthcare fraud scheme.
- General Telehealth Fraud Allegations
  - Physicians never talked to or treated patients
  - Patients did not need or even want prescriptions, DME, genetic testing, etc.
  - Prescriptions, DME, genetic testing was routed directly to specific pharmacies, DME distributors, or laboratories
  - Kickbacks/fee-splitting between pharmacies, DME companies, or laboratories and telemedicine companies

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## Predictions for 2020?

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