

# Emerging Trends in Healthcare Fraud Enforcement

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1

## 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.

2

## 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

3

## 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

5

## 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"

6

## 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

7

## 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

8

## 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

9

## 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)

10

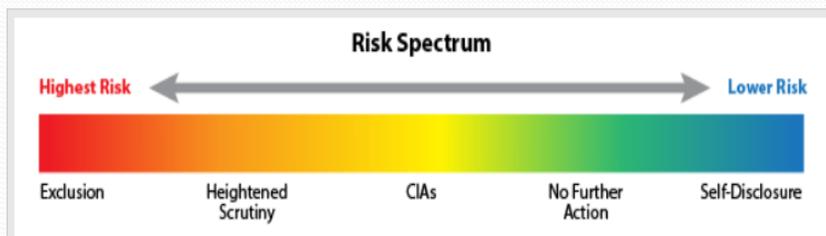
## Application of *AseraCare*

- *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.”

11

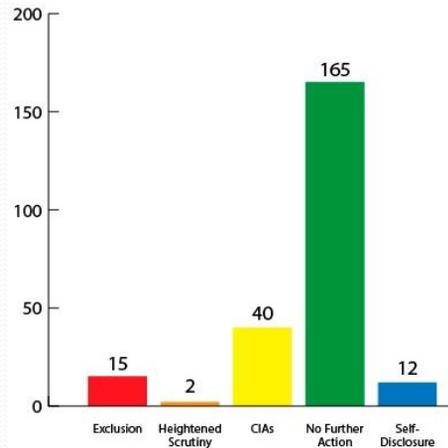
## Exclusion Risk Spectrum

- 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>

13

## 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

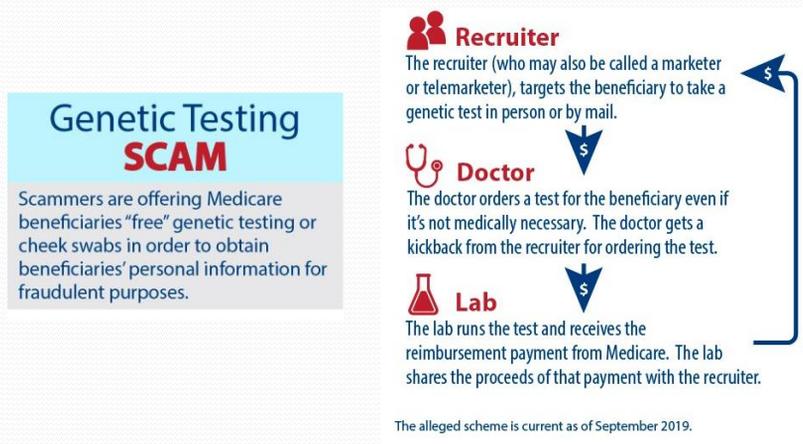
14

## 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.

15

## Enforcement Focus: Genetic Testing Fraud



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

16

## 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

17

## 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

18

## 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

19

## Predictions for 2020?

20