

Government Enforcement



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AMANDA P.M. STRACHAN
CHIEF, HEALTH CARE
FRAUD
U.S. ATTORNEY'S OFFICE
BOSTON, MA

MIRANDA HOOKER
PARTNER
PEPPER HAMILTON LLP
BOSTON, MA

BRANDON J. MOSS
PARTNER
WILEY
WASHINGTON, DC

KIRK OGROSKY
PARTNER
ARNOLD & PORTER
WASHINGTON, DC
MODERATOR

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Agenda

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- COVID-19 Fraud Scheme Enforcement
- Impact of COVID-19 on On-Going Matters
- Impact of COVID-19 on enforcement trends - 2020 and beyond
- The Government's Investigative Tools
- Best Practices for Handling a Government Investigation

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COVID-19: Current Impact

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- COVID-19 shelter in place orders across country
- Closed courts and businesses
- Focus of providers on combating disease
- Grand Jury operations and delays
- Statutes of Limitations
- Speedy Trial waivers

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COVID-19: DOJ Response

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- COVID-19 presents an opportunity for criminals to take advantage of beneficiaries, providers, and governmental assistance programs
- US DOJ has experience with opportunistic fraud (e.g., TARP, Katrina)
- Price Gouging Task Force
- Types of Schemes

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Frequently Investigated Conduct

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- Fraud/False Claims
- Kickbacks/Financial Relationships with Health Care Providers
- Insurance Reimbursement
- HIPAA/Patient Privacy Violations
- Opioid Distribution/Diversion
- Misbranding/Off-label Promotion
- Conspiracy/Racketeering Conspiracy
- False Statements
- Obstruction of Criminal Health Care Investigation
- Witness Tampering

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Health Care Fraud: One of DOJ's Favorite Targets

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- DOJ Health Care Fraud Unit
 - ✦ Charged 344 individuals in 2019 (alleged \$401B in fraud losses)
 - ✦ More than 75 prosecutors
 - ✦ Strike force model (includes FBI, HHS-OIG, CMS CPI, DEA, IRS, DCIS, USAO, and state/local law enforcement)
 - ✦ Major actions in 2019:
 - “Operation Brace Yourself” - \$1.2B nationwide health care fraud scheme involving telemedicine and DME
 - Appalachian Regional Prescription Opioid (ARPO) Strike Force Takedowns – 60 defendants charged
 - Coordinated takedown of nationwide \$2.1B fraudulent genetic testing scheme

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Health Care Fraud: One of DOJ's Favorite Targets

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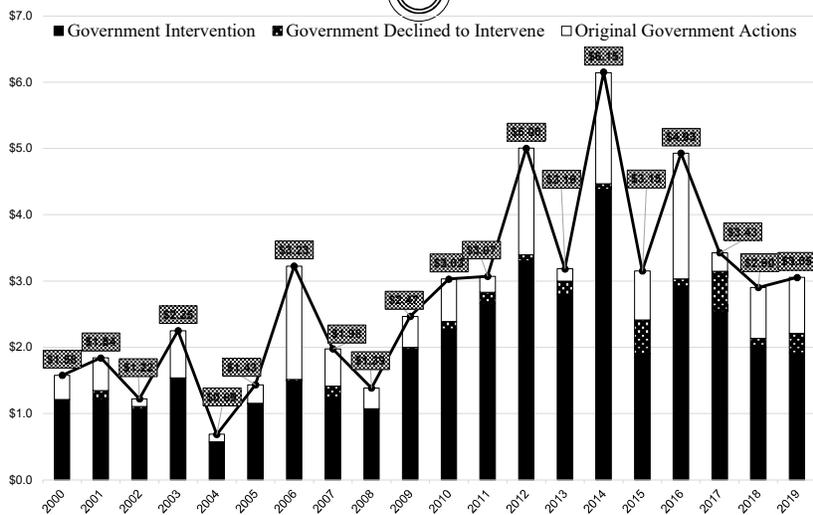
- FY 2019 FCA
 - \$3B in total recoveries
 - ✦ 2.6B from healthcare sector
 - 10th straight year of recoveries exceeding \$2B

FY	NEW MATTERS*		SETTLEMENTS AND JUDGMENTS*				RELATOR SHARE AWARDS*			
	NON QUI TAM	QUI TAM	NON QUI TAM TOTAL	QUI TAM		TOTAL QUI TAM AND NON QUI TAM	WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED	TOTAL	
				WHERE U.S. INTERVENED OR OTHERWISE PURSUED	WHERE U.S. DECLINED					
2015	26	426	160,758,915	1,492,103,005	476,633,065	1,968,736,070	2,129,494,985	272,916,832	133,135,640	406,052,471
2016	70	504	97,354,415	2,552,230,592	75,145,688	2,627,376,280	2,724,730,696	464,016,821	20,481,847	484,498,668
2017	55	495	32,627,357	1,667,051,294	445,241,304	2,112,292,597	2,144,919,954	292,996,150	123,462,284	416,458,434
2018	59	445	568,069,015	1,868,860,223	97,390,606	1,966,250,829	2,534,319,843	279,046,853	27,091,647	306,138,500
2019	56	449	695,579,721	1,837,769,878	272,135,976	1,909,905,854	2,605,485,575	176,017,786	68,188,692	244,206,479

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FCA Trends: Total Recoveries Deconstructed

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Common Origins of Healthcare Fraud Investigations

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- Qui Tam Complaints
- Agency Investigations
 - HHS-OIG
 - FBI, FDA, VA, IRS, etc.
 - Consumer/Public Complaints
- Data Analytics
- Public Events
 - e.g., COVID-19 Outbreak, Opioid Epidemic
- Actions against industry competitors
- News/Press

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Investigative Tools

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- Criminal Tools
 - Search warrants
 - Electronic surveillance
 - Subpoenas (grand jury/HIPAA)
 - Cooperating witnesses (i.e., relators)
- Civil Tools
 - Civil Investigative Demands
 - Administrative Subpoenas
 - Informal requests
- Covert vs. Overt Investigations:
 - Investigators seek to learn as much as possible before issuing a subpoena and making investigation overt
- Recipient is often playing catch up to the investigating agency

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You're Under Investigation: Now What?

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- **Who to tell?**
 - General counsel/other in-house lawyers
 - Corporate officers/managers
 - Depending on circumstances, outside lawyers
- **What to do?**
 - Have counsel issue litigation hold/document preservation notice
 - Identify persons likely to have relevant documents and knowledge
 - Collect relevant documents and data sources (e.g., emails, laptops, cell phones)
- **Communicate with investigators**
 - Identify subject matter of investigation
 - Narrow scope of document requests
- **Initiate parallel internal investigation**
 - Learn the facts to respond to government inquiries & demonstrate cooperation and commitment to compliance

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Benefits of Conducting Parallel Internal Investigation

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- **Gain understanding of relevant facts**
- **Assess potential exposure/liability**
 - Company versus individual exposure/liability
 - Ascertain whether certain employees/individuals need independent counsel
- **Take any appropriate remedial action**
 - Update corporate policies
 - Enhance compliance program and training
- **Engage the government early on substance**
 - Opportunity to address potential areas of concern & establish relationship and open dialogue
- **Analyze potential defenses**

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Factors Likely To Impact Criminal Enforcement Decisions

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- Nature and Circumstances of Conduct
 - Rogue or systemic within company?
 - Does target have history of similar conduct?
 - One-off event or scheme to defraud?
 - Government focus is on actual fraud, kickbacks
- Patient Harm
- Economic Harm
- Whether Defendant Occupies Position of Trust
 - e.g., Health Care Provider, etc.
- Timing/Resources
 - Government has limited resources and wants to make an impact

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Strategic Considerations: Cooperation/Self-Disclosure

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- Cooperation/Self-Disclosure:
 - Credit is available for companies that cooperate and disclose
 - Government cannot condition cooperation credit on waiver of privilege...
 - BUT, will want to know:
 - ✦ What the company knew about alleged misconduct
 - ✦ Who the bad actors were (especially senior managers/executives)
 - ✦ The results of the company's investigation
 - Facts/evidence not privileged

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Conclusion

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Questions?

Thank you and stay safe!

Amanda P.M. Strachan Chief, Health Care Fraud U.S. Attorney's Office Boston, MA	Miranda Hooker Partner Pepper Hamilton LLP Boston, MA	Brandon J. Moss Partner Wiley Washington, DC	Kirk Ogrosky Partner Arnold & Porter Washington, DC
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