CRISIS AVERTED: PREPARING YOUR HEALTHCARE COMPANY TO HANDLE A GOVERNMENT SUBPOENA

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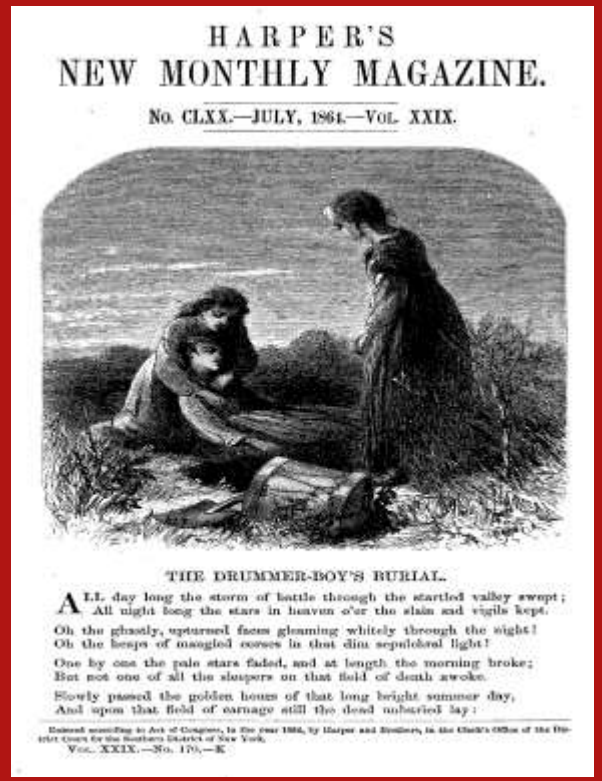
Agenda

- False Claims Act Overview
- Recent FCA Decision Trend
- COVID-19 Fraud Enforcement
- Recent Enforcement Cases
- Government's Investigative Tools/Practices
- What to Expect in 2022 and Beyond



HARPER'S
NEW MONTHLY MAGAZINE.

No. CLXX.—JULY, 1864.—Vol. XXIX.

THE DRUMMER-BOY'S BURIAL.

ALL day long the storm of battle through the startled valley swept;
All night long the stars in heaven o'er the slain and vigils kept.

Oh the ghastly, upturned faces gleaming whitely through the night!
Oh the heaps of mangled corses in that dim sepulchral light!

One by one the pale stars faded, and at length the morning broke;
But not one of all the sleepers on that field of death awoke.

Slowly passed the golden hours of that long bright summer day,
And upon that field of carnage still the dead unburied lay:

Entered according to Act of Congress, in the year 1864, by Harper and Brothers, in the Clerk's Office of the District Court for the Southern District of New York.

Vol. XXIX.—No. 170.—K

Civil War profiteering led to the enactment of the False Claims Act, "Lincoln Law," in 1863.

"For sugar [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols the experimental failures of sanguine inventors, or the refuse of shops and foreign armories."

- R. Tomes, *The Fortunes of War,* Harper's New Monthly Magazine 228 (July 1864).

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False Claims Act

- 31 U.S.C. §§ 3729-3733
- Targets fraud in federal contracts & programs
- Prohibits "knowingly" submitting or causing the submission of "material" falsehoods to federal health programs
- Implied false certification theory is increasingly common:
  - Liability based on alleged non-compliance with a "material" regulatory or contractual term despite any express statement of compliance

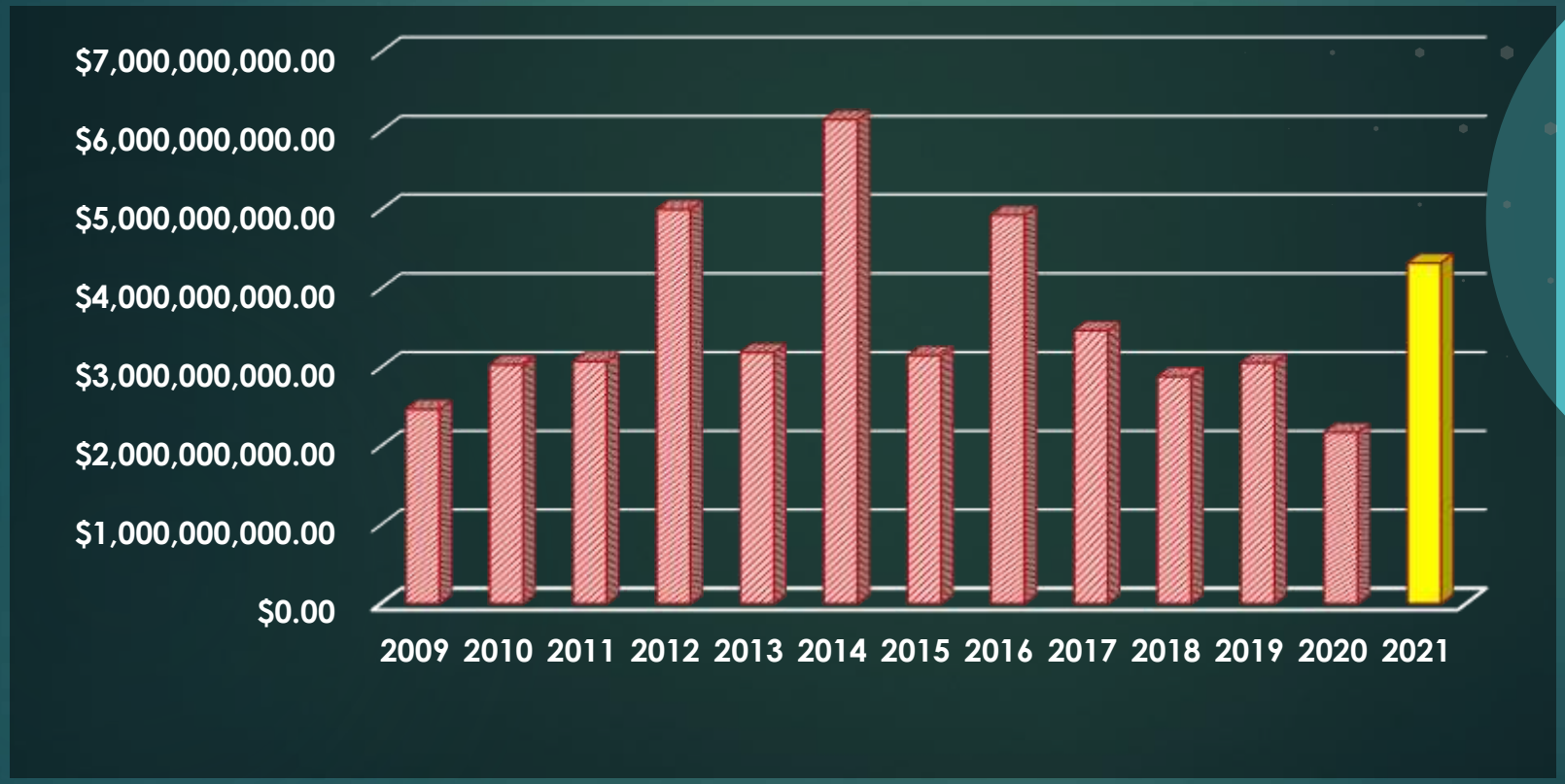
FCA

- Allows suits by private "*qui tam* relators"
  - Increasing trend of "corporate" relators, including for-profit ventures
- Significant financial incentives for relators and DOJ – and significant settlement incentives for defendants
  - DOJ recoveries (judgments + settlements) average: $3 billion annually since FY2009
  - DOJ can seek 3x damages *and/or* up to $23,607 penalty for EACH false claim
  - Relators can get 15% to 30% of DOJ's recovery, plus attorney's fees
- Many state analogues – often joined in federal suits, but also filed in state court and pursued as State AG investigations

Qui Tam Process

1. Relator files a sealed "*qui tam*" complaint and gives DOJ a copy, plus other material evidence
2. Under seal at least 60 days – often longer
3. DOJ investigates, consults affected agency (*e.g.*, CMS, DOD-IG, etc.), can reach out to defendant and issue subpoenas for documents and depositions
4. DOJ then decides whether to:
   - intervene in the suit (whether to litigate or to settle) - § 3730(b)(4)(A)
   - let the relator handle it (for now) - § 3730(b)(4)(B)
   - move to dismiss the suit altogether - § 3730(c)(2)(A)

Expect More False Claims Act Enforcement & Recoveries



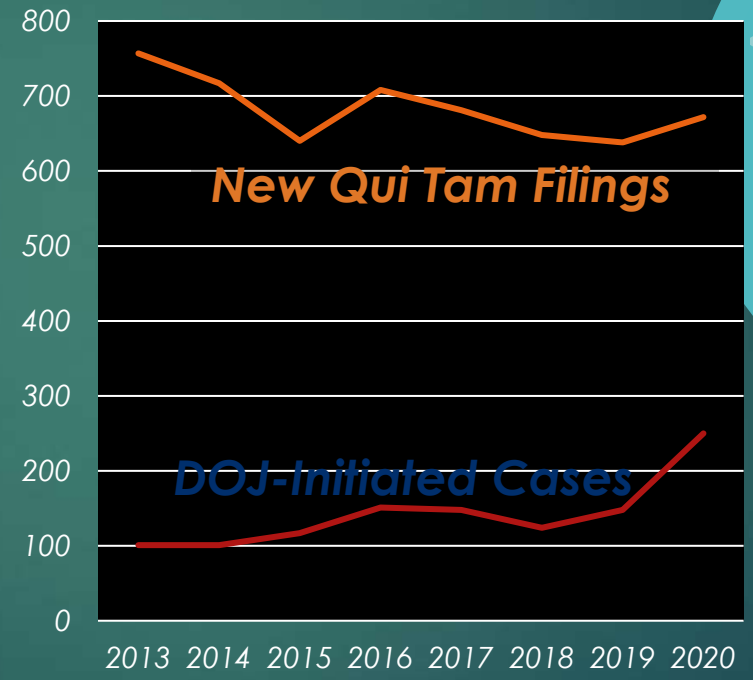
DOJ-Initiated Cases On The Rise

After 1986 amendments, *Qui Tams* skyrocketed & DOJ filings dropped:

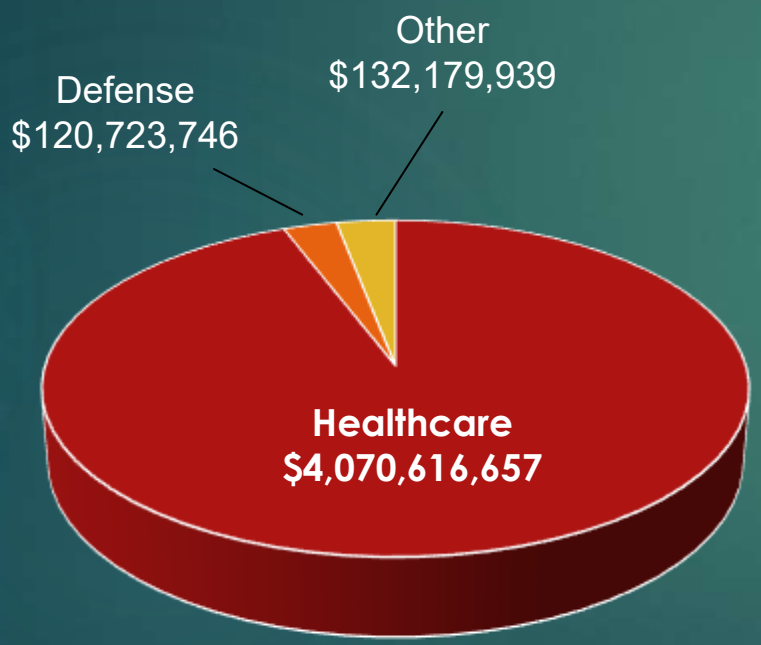
- *1986:* 30 QTs vs. 341 US actions
- *2020:* 672 QTs vs. 250 US actions

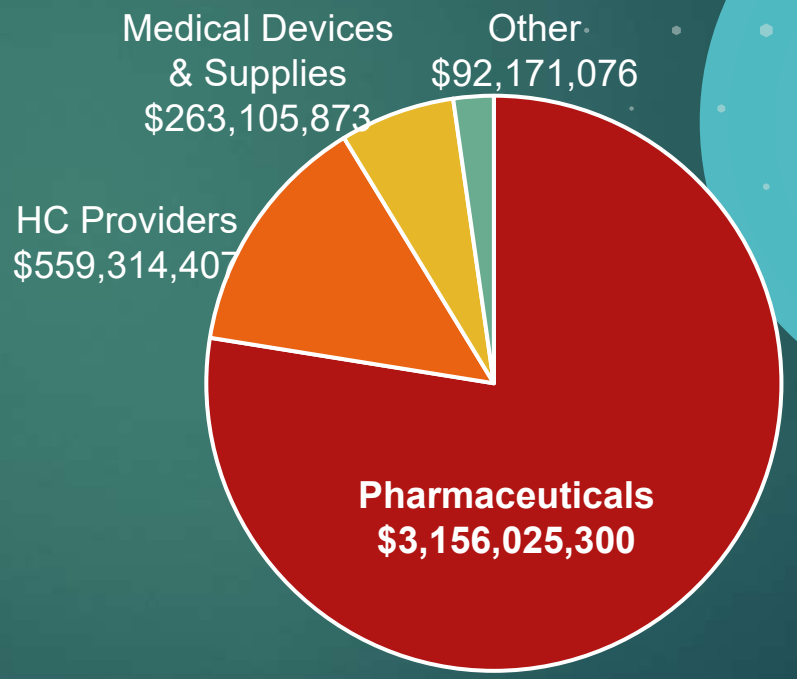
Since 2013, DOJ filings have regained steam:

- *2013:* 757 QTs vs. 101 US actions
- 2020: 672 QTs vs. 250 US actions



Most FCA Defendants Are Healthcare Companies/Providers





FCA Reaches Every Type of Healthcare Provider

- Kickbacks
- Part D
- Services Not Rendered
- Stark Law / Self-Referrals
- Up-Coding
- Unbundling
- False Certification (e.g. lack of medical necessity, risk adjustment factors)

Recent Major Settlements Involved:

- Ambulance & Transportation Services (4)
- Clinics (12)
- Dental (4)
- Device Companies (5)
- Diagnostic Services (1)
- Drug Companies (7)
- Drug Distributor (1)
- DME (3)
- Electronic Health Records (1)
- Home Health Providers (7)
- Hospice Care (2)
- Hospitals & Health Systems (6)
- Identity Theft (2)
- Laboratories (4)
- Managed Care / Medicare Advantage (2)
- Medical Devices (1)
- Nursing Homes & Facilities (4)
- Pharmacies (9)
- Physical Therapy (2)
- Physician & Other Practitioners (6)
- Prescription Drugs & Opioids (8)
- Private Health Insurance Fraud (1)
- Psychiatric & Psychological Testing & Services (3)

-HHS/DOJ Health Care Fraud and Abuse Control Program June 2020 Report
https://oig.hhs.gov/publications/docs/hcfac/FY2019-hcfac.pdf

Use of Guidance

- Memorandum issued July 1, 2021 by Attorney General Garland. Available at https://www.justice.gov/opa/page/file/1408606/download
  - "guidance documents do not bind the public and are not treated as binding by the courts"
  - "interpretive guidance can advise the public of how the agency understands, and is likely to apply, its binding statutes and legislative rules"
  - "guidance may also help explain an agency's programs and policies or communicate other important information to regulated entities and the public"
- Rescinds previous policy issued and to be reflected in updates to the Justice Manual.

U.S. ex rel. Schutte, et al., v. SuperValu Inc., et. al. (7th Cir.)

Objective Scienter Standard

- Relators alleged that from 2006 to 2016 SuperValu "knowingly" submitted to Medicare false reports of its pharmacies' "usual and customary" drug prices.
- 7th Circuit joined two other circuits to cabin FCA liability by holding that the Act requires an "objective scienter standard."
- The holding dictates that a defendant who acted under an incorrect interpretation of the relevant law did not act with the requisite knowledge under the FCA if (1) the interpretation was objectively reasonable and (2) no authoritative guidance warned the defendant away from that interpretation.
- Court held that a person's subjective intent has no bearing on this analysis, and that a relator's failure to meet *Safeco's* objective scienter standard doomed their claim under the FCA's three knowledge components—actual knowledge, deliberate indifference, or reckless disregard.

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COVID-19 Enforcement

- COVID-19 presents an opportunity for criminals to take advantage of beneficiaries, providers, and governmental assistance programs
  - Calls offering Covid19 testing in exchange for ID
  - PPP misuse
- On April 20, 2022, DOJ announced the nationwide coordinated law enforcement action to combat health-care-related COVID-19 fraud. Specifically, the DOJ revealed criminal charges against 21 defendants in multi-districts courts. These cases assert allegations resulting in nearly $150 million in COVID-19-related false billings.

How Do You Learn You're Being Investigated?

- Voluntary/informal contact
  - A. Request for information
  - B. Call or knock on the door from AUSA or agent
  - C. Letter, including target letter
  - D. Grapevine (employee interviews, investigations of business contacts)
- Site visit or request for records from CMS, state, or OIG
- Subpoena
  - A. Federal Grand Jury
  - B. HIPAA/AID subpoena
  - C. IG subpoena
  - D. Civil Investigative Demand (CID)
  - E. OIG administrative subpoena (42 USC 1320a-7a(j))
  - F. State AG/MFCU criminal or civil
- Search warrant

Frequently Investigated Conduct

- 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

Handling an Investigation

- Who to tell?
  - General counsel/in-house lawyers/outside counsel
  - Corporate officers/managers
- Handle Civil Investigative Demand (CID)

Expect Biden Administration To Expand Data Analytics

- "Sophisticated analyses of Medicare data to uncover potential fraud schemes" that relators don't identify
- Analyzing data on service and prescription patterns
  - Identify "highest risk physicians" via trends and outliers
  - Identify HCPs by state and federal district
  - Identify HCP costs to Medicare program
- Public data available to relators and defendants alike:
  - Medicare provider claims data (Parts B and D)
  - Physician Payments Sunshine Act (Pharma/device payments to doctors)

Civil Investigative Demands

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Best Practices: Responding to Civil Investigative Demands

The U.S. Department of Justice ("DOJ") uses Civil Investigative Demands ("CIDs")[1] to gather evidence in False Claims Act ("FCA") investigations.[2] Experienced counsel can help you create a *response strategy* so that your organization can effectively defend itself. Dealing with a federal investigation can be costly, and mistakes made in the initial days may inadvertently expand the investigation or waive certain rights and privileges.[3] In most cases, CIDs are served on companies that are defendants in sealed *qui tams* suits – meaning a whistleblower has filed a non-public complaint against the company. Courts give DOJ wide latitude to enforce CIDs where the requests are relevant[4] and DOJ abides by the procedural requirements.[5] The following roadmap can be used as a guide, but every investigation is unique and there are no easy solutions to end an investigation. Recommended steps:

(1) ***Retain counsel*** to deal directly with DOJ. Be mindful that when in-house counsel or employees of a company speak with DOJ, their statements are memorialized. Making a false statement to law enforcement is a crime.

(2) ***Maintain a close-hold*** on the fact that a CID has been received. Speculation and supposition about federal investigations spreads quickly and may lead to unintended consequences if individuals involved in alleged misconduct are alerted. Also note that the whistleblower who is responsible for filing the FCA *qui tam* suit may be a current employee who will relay information about the CID and internal response to their attorney. For publicly traded companies, consult with SEC counsel regarding disclosure obligations.

(3) ***Notify the head of information technology*** in your organization to assure that a complete backup copy of your network system is retained. This is the first step of the *document preservation process.*

(4) ***Create a response strategy*** with counsel. In many cases, experienced counsel can tell from the CID: (a) what types of allegations have been made, (b) where the *qui tam* suit is pending, (c) the nature of potential damages, (d) whether HHS-OIG is likely to require a corporate integrity agreement ("CIA"), and (e) whether criminal allegations might have been lodged.

(5) ***Counsel should contact DOJ*** to discuss the nature of the investigation, timing and scope of the response. While DOJ is authorized to demand a response *within 20 days* of service, DOJ likely will agree to a schedule that allows document production on a "rolling basis" such that the company will have time for responsiveness and privilege review. Counsel also will be able to *negotiate the scope of the requests* by suggesting "search terms" be applied across the collected materials to identify responsive document and by suggesting the names of relevant custodians to search. Limiting custodians and well-crafted search terms can reduce the cost of CID response significantly.

(6) ***Issue a formal legal hold memorandum*** to employees who may have responsive materials. After speaking with DOJ, counsel can develop a list of all individuals who may have responsive materials and prepared the hold memorandum. The hold memorandum should put individuals on notice that they are required to keep and not destroy relevant materials. The hold should be specific to assure compliance, but not so detailed that it causes confusion.

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(7) ***Collect responsive materials.*** DOJ is usually amenable to starting the production with basic items like organization charts or key contracts. For more involved requests such as those that call for e-mails and text messages, negotiating with DOJ to limit the number of custodians and search terms as far in advance as possible may save substantial costs. Depending on the nature of the requests and documents collected, counsel will want to conduct a responsiveness and privilege review prior to production. While a claw-back agreement with DOJ should be in place in case of the inadvertent production of documents, care should be taken during production to avoid providing non-responsive or privileged materials.

(8) ***Conduct an appropriate internal investigation.*** As part of the response strategy, you could prepare an *internal investigation plan* that allows you to understand the facts as quickly as possible. This will include document review and witness interviews. The tone and tenor of the discussions with DOJ will guide how your organization conducts its investigation. An employee's documents should be reviewed prior to any interview.

(9) ***Remedy compliance related issues.*** In most instances, if a compliance issue or gap is discovered during an internal investigation (whether the problem is the subject of the CID or not) the organization should develop an action plan to remedy the issue or close the gap.

(10) ***Present the facts and law to DOJ.*** In many cases, after the internal investigation and document review, your counsel may suggest a meeting with DOJ to explain why the allegations against your organization are incorrect and do not merit intervention. On occasion, your counsel may want to submit a "white-paper" to DOJ under *Rule* 408 that lays out your legal defenses and factual positions. In over two-thirds of *qui tams*, DOJ declines to intervene. A *qui tam* is more likely to be dismissed by the court after declination.

If you have questions about a CID please contact **Kirk Ogrosky** at (o) 202-346-4379 (c) 202-360-8899 or **Annie Railton** at (o) 212-459-7434 (c) 646-279-3798. Mr. Ogrosky and Ms. Railton co-lead the Firm's Healthcare Government Enforcement & False Claims Act Defense Practice Group.

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[1] CIDs may require (a) the production of documents, (b) responses to written interrogatories, and (c) oral testimony of employees, executives, or board members, and material received by DOJ may be shared with federal agents, agencies, and whistleblowers. *See* 31 U.S.C. § 3733.

[2] CIDs are DOJ's compulsory process of choice for healthcare and life science companies. In 2009, Congress expanded the use of CIDs when it passed the Fraud Enforcement and Recovery Act of 2009 ("FERA"), P.L.111-21. FERA allowed designees of the Attorney General, and the 93 U.S. Attorneys, to issue CIDs, and it permitted DOJ civil trial attorneys to share information obtained under a CID with "any person." *See* 31 U.S.C. § 3733(a)(1).

[3] Only federal rights and privileges (such as the right against self-incrimination, attorney-client privilege, and work-product privilege) apply to CIDs. 31 U.S.C. § 3733(b)(1); *See Cleveland Clinic Found. v. U.S.*, No. 1:11MC14, 2011 WL 862027, at *1-3 (N.D. Ohio Mar. 9, 2011) (concluding that state physician-patient privilege was not applicable in CID context); *see also U.S. v. Advanced Pain Mgmt.*, No. 2:17-CV-272, 2018 WL 4381192, at *3-4, 7-12 (M.D. Fla. June 28, 2018) (concluding that federal attorney-client privilege did apply).

[4] *U.S. v. Piccetti*, 2019 WL 1895057, at *2 (Prior to an intervention decision or the filing of a FCA case, DOJ may serve a CID if "it has 'reason to believe' a person 'may be in possession, custody, or control' of any documents or information relevant" to DOJ's FCA investigation) (citing 31 U.S.C. § 3733(a)); *See also U.S. v. Markwood*, 48 F.3d 969, 975-76 (6th Cir. 1995); *U.S. v. ASG Solutions Corp.*, Case No. 17-cv-1224, 2018 WL 1418023 (S.D. Cal. March 22, 2018) (*R&R adopted in full*), 2018 WL 3471405 (S.D. Cal. July 18, 2018)).

[5] *See U.S. v. Kernan Hospital*, 2012 WL 5879133 (D. Md. Nov. 20, 2012) (One of the rare occasions when a CID can be quashed is when DOJ has already filed or intervened in a FCA case).

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Questions

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