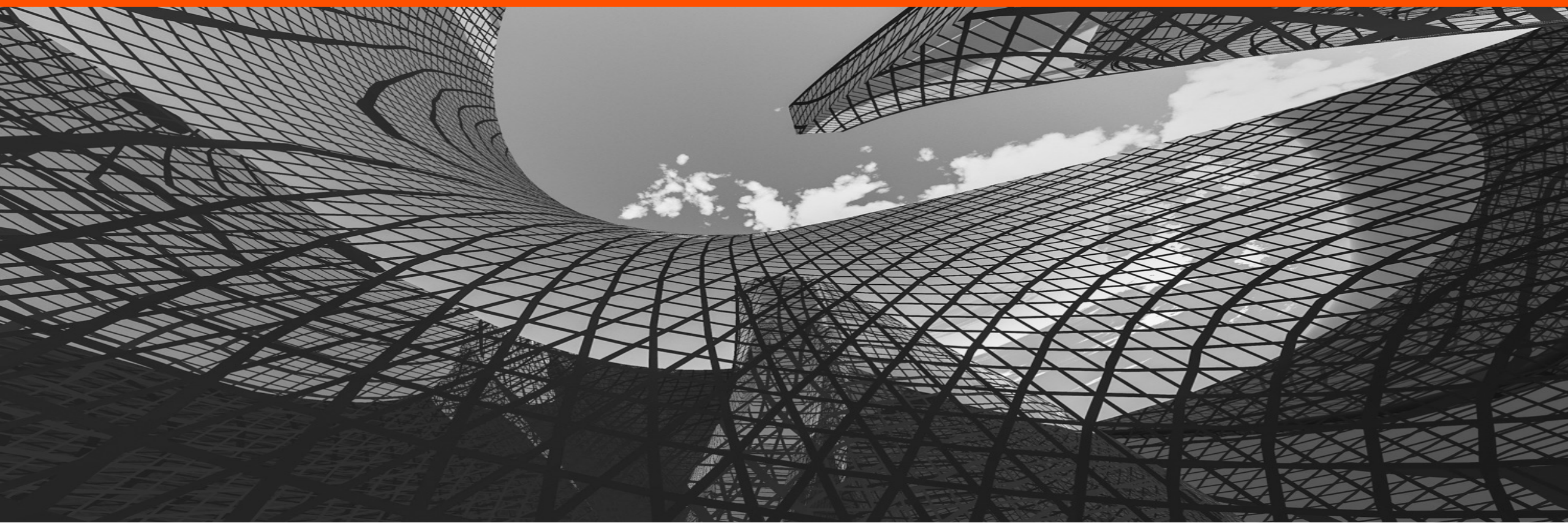


# **ACC NCR FALL CONFERENCE**

## **In-House Primer**

# **Enforcement Priorities and Responsive Strategies in a (Post?) Pandemic World**

**Buchanan**  
Ingersoll • Rooney



# Enforcement Priorities and Responsive Strategies in a (Post?) Pandemic World

**Buchanan**  
Ingersoll • Rooney

**ACC** Association of  
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— NATIONAL CAPITAL REGION —

# Introductions



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# Agenda

- What We Are Seeing Today
- Agency Enforcement Priorities
- Best Practices for Government Investigations

# What We Are Seeing Today

# What We Are Seeing Today

- Zoom is here to stay but many processes have returned to “normal”
- New Administration with new priorities
  - Significant focus on protection of consumer and employee rights
  - Emphasis on antitrust and consumer protection – tech, healthcare, pharma
  - Post-COVID emphasis on fraud / False Claims Act for entities that received COVID funds
- Increasingly assertive state-level enforcers
- Greater cooperation between agencies on shared enforcement priorities
- Use of government investigations / litigation to drive public policy outcomes

# Agency Enforcement Priorities



# Federal Trade Commission – Bureau of Competition

**Priorities driven in part by Pres. Biden's Executive Order on Promoting Competition in the American Economy by aggressive use of antitrust laws**

- Focus on labor, healthcare, pharma, and large companies (e.g., Big Tech, Private Equity)
- Antitrust laws address primarily:
  - Conduct between competitors
  - Conduct by monopolists
  - Mergers and acquisitions
- FTC and DOJ are the two federal agencies tasked with enforcing antitrust laws



# Federal Trade Commission – Bureau of Competition

## Labor and the Competition for Talent

- Overlapping priority with DOJ – DOJ tackling criminal conduct
- Information sharing agreement with NLRB
- Exploring new rule prohibiting or limiting non-compete agreements
- Increased inquiry on merger effects on employees and labor markets
  - Alleging labor market in hospital merger
- Requiring removal/reduction of non-compete clauses as a condition to close transactions
  - 7-Eleven
  - DaVita
  - ARKO

# Federal Trade Commission – Bureau of Competition

## Healthcare continues to be a priority in the face of constantly rising costs

- Hospital mergers remain in cross-hairs
  - 4 victories in the last fiscal year – parties to hospital mergers abandoned the transactions
- Advocacy
  - Recently issued paper on anticompetitive effect of Certificates of Public Advantage - Retrospective analysis of health system mergers that states permitted through a COPA showed higher prices, reduced quality of care, and reduced wages
  - Current study into effect of physician acquisitions by health systems
- Other healthcare related products and services, e.g., medical devices, also targeted
  - Required divestiture to approve a medical device company merger
  - [PBM study]

# Federal Trade Commission – Bureau of Competition

## **Pharmaceutical industry also facing political pressures to battle rising drug costs**

- FTC still using its “traditional” analysis for pharma mergers – drug by drug overlap
- But looking at new/different ways to analyze these mergers, e.g.,
  - Overall influence on PBMs by virtue of blockbuster or must-have
  - Move away from drug-specific divestiture remedies
  - Presumption of an anticompetitive effect of the merger of any two of the top 10 pharma companies
  - Heighted scrutiny if merger of two mid-sized firms, or the merger involves a blockbuster drug
  - Prior bad acts
  - “Killer” acquisitions of small companies

# Federal Trade Commission – Bureau of Competition

## Large companies, e.g., “Big Tech” and Private Equity

- General concern with acquisition of next generation technologies, maintaining neutrality of technology that enables downstream providers, and, access to competitively sensitive information of third party competitors
- FTC taking a “holistic approach” to identifying anticompetitive effects of mergers – including looking at effects on innovation and stifling nascent competitors
  - Facebook – challenged acquisition of Within Unlimited; FTC viewing as stifling a nascent competitor and dampening innovation
  - Nvidia – challenged acquisition of Arm Ltd.; FTC viewed as a means to stifle innovation
- Sweeping prior approval/notice in PE settlement agreement
  - Seeing more questions during pre-merger notification period regarding PE Fund holdings and relationships

# Federal Trade Commission – Bureau of Consumer Protection

**Trying to go after industries and companies that are affecting the most consumers or the most vulnerable consumers**

- Data Privacy and Security
- Fair Lending/anti-discrimination in lending and financing

**Efforts are complementary to CFPB and SEC efforts on data privacy, security and anti-discrimination**

# Federal Trade Commission – Bureau of Consumer Protection

- Data Privacy and Security
  - Preparing to crack down on “Commercial Surveillance” (the business of collecting, analyzing, and profiting from information about people)
  - Health Breach notification rule expanded to apps and similar technologies
  - *De Facto* breach notification requirement under Section 5?
    - Blog post: “Regardless of whether a breach notification law applies, a breached entity that fails to disclose information to help parties mitigate reasonably foreseeable harm may violate Section 5 of the FTC Act.”
  - Updated Safeguards Rule implementing Section 501(b) of GLBA
    - limit who can access customer information, require the use of encryption to secure such information, and require the designation of a single qualified individual to oversee an institution’s information security program and report at least annually to the institution’s board of directors or equivalent governing body

# Federal Trade Commission – Bureau of Consumer Protection

- Fair Lending/anti-discrimination in lending and financing
  - Enforcement under traditional fair lending statutes (e.g., Truth in Lending Act, Equal Credit Opportunity Act)
  - Commissioners also believe it is a violation of Section 5, prohibiting unfair or deceptive practices
  - Interagency Task Force on Fair Lending – includes CFPB, DOJ, the Department of Housing and Urban Development (HUD), and the federal banking agencies



# U.S. Department of Justice

- While DOJ generally operates with independence from political actors, Department priorities generally track those of the current Administration
- In July 2022, AG Garland announced DOJ's 2022-2026 strategic plan outlining five broad areas of focus:
  - Upholding the rule of law
  - Keeping the country safe – address threats posed by criminals, terrorist groups, and cyber threats
  - Protecting civil rights – reinvigorate civil rights enforcement, defend voting rights, address violations of environmental laws
  - **Ensuring economic opportunity and fairness – strengthen antitrust and consumer protection enforcement, investigate and prosecute of fraud and corporate crime**
  - Administering just court and correctional systems

# U.S. Department of Justice – Antitrust

**Like FTC, Antitrust Division priorities driven in part by Pres. Biden's Executive Order on Promoting Competition in the American Economy, especially with effects on labor markets**

- Almost more active than FTC
- Information sharing agreement with DOL
- Criminal, civil, and merger enforcement relating to labor markets
  - Two criminal trials – DOJ lost but has promised continued enforcement
  - Currently securing a criminal plea deal for no-poach agreements
  - Civil settlement with poultry companies and their consultant for exchange wage and benefit data
  - Penguin/Random House merger challenge alleging anticompetitive effects on authors

# U.S. Department of Justice - False Claims Act

- False Claims Act is the primary statutory tool for addressing alleged fraud on the government
  - False claims: liability for knowingly presenting, or causing to be presented, a false or fraudulent claim for payment (31 U.S.C. 3729(a)(1)(A))
  - False statements: liability for knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim (31 U.S.C. 3729(a)(1)(B))
- Vast majority of actions related to alleged fraud in federal healthcare programs; other actions concern alleged procurement fraud by defense and other government contractors
- Primary characteristics:
  - Significant exposure – mandatory treble damages + mandatory civil penalties (up to \$25,076 per violation)
  - Role of whistleblowers + strong whistleblower incentives – up to 30 percent of the government's recovery
  - Permissive knowledge requirement – includes reckless disregard and deliberate ignorance

# U.S. Department of Justice – False Claims Act

- False Claims Act procedure:
  - Both DOJ and private parties are authorized to bring a civil action under the FCA
  - If filed by a private party, the complaint remains under seal while DOJ investigates
    - CIDs are DOJ's primary investigative tool – document requests, interrogatories, depositions
    - Use of CIDs increased significantly after 2009 due to FCA amendments delegating CID authority to designees of the Attorney General – typically more than 1,000 issued each year
  - DOJ may or may not intervene and take over the case – complaint is then unsealed and litigation goes forward
    - Intervention has a significant impact on the outcome – only about 5 percent of FCA recoveries are from cases in which DOJ declined intervention
    - Effective engagement during the CID process is key

# U.S. Department of Justice – False Claims Act

- Recent developments
  - Congressional efforts to weaken “demanding” materiality requirement
    - In *Escobar* (2016), the Supreme Court reaffirmed that the FCA includes a “demanding” materiality requirement – that is, the FCA is addressed to fraud and not a “vehicle for punishing garden-variety breaches of contract or regulatory violations”
    - Plaintiff must show that the alleged FCA violation would affect the “likely or actual behavior” of the government in paying the relevant claims
    - *Escobar* provides defendants with a powerful tool to defeat FCA claims where the government was aware of the conduct at issue but continued to pay claims
    - Legislation introduced by Sen. Grassley would convert materiality into an affirmative defense – defendant would bear the burden of showing by clear and convincing evidence that alleged conduct was immaterial

# U.S. Department of Justice – False Claims Act

- Recent developments
  - Granston Memo and standard for DOJ dismissal of qui tam cases
    - Historically, when declining intervention, DOJ rarely seeks dismissal of qui tam cases
    - In Jan. 2018, DOJ published a memo outlining factors the government should consider when determining whether to exercise its statutory authority to dismiss qui tam cases
    - Various Circuits have adopted different standards for evaluating DOJ's authority to dismiss:
      - 1<sup>st</sup> and DC: DOJ has “unfettered” authority to dismiss
      - 3<sup>rd</sup> and 7<sup>th</sup>: DOJ must satisfy FRCP 41(a)'s standard for voluntary dismissals
      - 9<sup>th</sup> and 10<sup>th</sup>: DOJ must identify a “valid government purpose” and a “rational relation between dismissal and accomplishment of that purpose”
    - In June, the Supreme Court granted certiorari to resolve a Circuit split on the standard for evaluating DOJ's authority to dismiss a qui tam suit over the relator's objection
      - Case to be briefed during the October term with decision sometime in or before June 2023

# U.S. Department of Justice – False Claims Act

- Trends

- Continued / significant case activity
  - 801 cases unsealed in FY 2021 – about average for the last 10 years
  - \$5.6 billion in recoveries in FY 2021 versus \$2.2 billion in FY 2020
    - Due in part to opioid litigation – e.g., \$2.8 billion settlement with Purdue Pharma
- Continued “vigorous pursuit” of alleged healthcare fraud
  - More than 90 percent of FY 2021 recoveries relate to alleged healthcare fraud
  - Recent announced recoveries involving insurers, healthcare systems, pharmaceutical companies, home health agencies, and clinical labs
  - Current issues include Medicare Advantage and patient assistance programs (Anti-Kickback Statute)
- Multi-year focus on alleged fraud related to COVID-era programs (e.g., PPP)



# Consumer Financial Protection Bureau

Trying to keep up with technological advancements and post-COVID volatility that could put consumers at risk

## Data Privacy

- Position statement (April): Entities can violate the prohibition on unfair acts or practices in the Consumer Financial Protection Act (CFPA) when they have insufficient data protection or information security
  - E.g., Inadequate authentication, password management, or software update policies or practices
- Legal Interpretation of Fair Credit Reporting Act (July) emphasizes data privacy as a consideration in permissible use
  - Will help to hold responsible any company, or user of credit reports, that violates the permissible purpose provisions of the FCRA, e.g., due to insufficient matching procedures that results in the report being provided to a company that does not have a permissible purpose; using “possible matches” when a specific match is required
  - Emphasized that covered entities can face criminal liability for obtaining a background report on an individual under false pretenses or by providing a background report to an unauthorized individual

# Consumer Financial Protection Bureau

## Cryptocurrency – multi-agency enforcement approach

- Overlap with SEC and FTC
- Executive Order on Ensuring Responsible Development of Digital Assets
  - Encourages FTC and CFPB to consider what, if any, effects the growth of digital assets could have on competition policy
  - How the agency can use privacy or consumer protection rules enforced by CFPB to protect consumers
- Position statement: likely violate the CFPA's prohibition on deception if you misuse the name or logo of the FDIC or engage in false advertising or make misrepresentations to consumers about deposit insurance
  - Came just before FDIC's advisory that crypto-assets are not FDIC insured and should not advertise as such
  - Followed up with cease and desist letters to 5 crypto asset companies for making false and misleading statements about FDIC insurance

# Consumer Financial Protection Bureau

- Unfair discrimination in consumer finance
  - Final rule pending on requiring financial institutions to report information concerning credit applications made by women-owned, minority-owned, and small businesses in order to enforce the Equal Credit Opportunity Act.
  - Overdraft fees, particularly for those struggling financially due to COVID

# Securities and Exchange Commission

- Challenged by evolving markets, business models, and technology
- “Robust enforcement, robust compliance, robust remedies”
  - 434 enforcement actions filed in FY 2021; 7 percent increase over FY 2020
  - Approximately 2,000 pending litigations and 1,500 open investigations
  - Increased pace of activity is expected to continue; Enforcement Division is seeking a substantial increase in its budget to enable expansion including additional staff

# Securities and Exchange Commission

- Current priorities:
  - Cybersecurity
    - In March 2022, SEC proposed amendments to its rules to enhance and standardize disclosures regarding cybersecurity
    - Proposed amendments would require reporting of material cybersecurity incidents, periodic reporting about previous incidents, periodic reporting about policies and procedures, and other matters
    - Paired with Examinations focus on reviewing business continuity and disaster recovery plans
  - Insider trading and the protection of material, non-public information
    - All companies must create and maintain controls reasonably designed to prevent the misuse of material, non-public information

# Securities and Exchange Commission

- Current priorities:
  - ESG
    - In May 2022, SEC proposed amendments to its rules and reporting forms to promote consistent and comparable information for investors concerning funds' and investment advisors' incorporation of environmental, social, and governance factors
    - Proposed amendments would require more specific disclosures in prospectuses and other documents – driven by concerns about “greenwashing”
    - In general, disclosures would require a description of the specific impact sought and a summary of progress in achieving that impact – e.g., disclosure of greenhouse gas emissions for a fund focused on consideration of environmental factors

# Securities and Exchange Commission

- Current priorities:
  - Digital assets
    - Focus on digital asset offerings (e.g., initial coin offerings) and adjacent activity – potential securities laws violations related to exchanges, broker-dealers, lending and staking products, decentralized finance platforms, non-fungible tokens, and stablecoins
      - Partnership with DOJ Criminal Division related to investigations of cryptocurrency exchanges
    - Ongoing issue regarding status of cryptocurrency – security versus commodity
      - Coinbase – three former employees charged with securities fraud based on alleged insider trading
      - CFTC: “a striking example of regulation by enforcement”
    - Focus on ensuring funds and others engaging in digital asset transactions have an initial and ongoing understanding of the products



# FDA

- Also facing political and consumer-facing pressures
- Current priorities reflect these realities
  - Drug shortage issues
  - Nitrosamine
  - Public health issues (COVID, monkeypox)

# State Attorneys General

- Significant uptick in SAG activity during the Trump Administration based on perceived lax enforcement by federal authorities
- Current priorities generally track federal agency priorities
  - Antitrust (healthcare, pharma, tech, employee rights)
  - Consumer protection (e.g., price-gouging)
  - False Claims Act / fraud

# Best Practices for Government Investigations

# Overview

- Primary types of government inquiries:
  - Search warrants
  - Grand Jury subpoenas
  - Civil subpoenas and Civil Investigative Demands (CIDs)
  - Informal requests for information
- Numerous potential origins:
  - Whistleblower complaint
  - Referral from another agency
  - Industry-wide review
- **What you are seeing may only be the tip of the iceberg**

# Preparation

- Every company should have a robust corporate compliance program and a written policy governing appropriate responses to government investigations
- Written policy has three goals:
  - Set the tone
  - Establish a process
  - Advise employees of their rights

# Preparation

- **Set the tone**

- The Company will cooperate with authorized government investigations
- Employees may not alter, conceal, or destroy documents related to a government investigation
- Employees may not intentionally mislead government investigators

- **Establish process**

- Designate a point person (e.g., general counsel or compliance officer) to be notified in the event of a government investigation and to lead / manage the Company's response

- **Advise employees of their rights**

- Employees may decide to speak – or not speak – with government investigators
- Employees may have counsel present when speaking with government investigators
- Employees may condition speaking with government investigators on doing so at a convenient time / place

# Document Preservation

- Every company should have a written policy governing retention and destruction of documents and data
- Effective and timely preservation is critical
  - Failing to preserve information could result in an expanded government investigation addressing the reasons information was lost
    - Targets or subjects of an expanded investigation could include in-house counsel or company executives with potential exposure for obstruction of justice
- Send a timely and thorough preservation notice
  - Identify which employees (custodians) may have relevant information
  - Identify custodial and non-custodial data sources where relevant information may be located
    - In addition to hard copy electronic documents, include non-traditional sources such as voicemail and personal devices



# Document Preservation

- Coordinate with IT personnel to ensure preservation of enterprise and archived data
  - Suspend or modify automatic deletion protocols
  - Suspend regular deletion of archived data and backup tapes
  - Suspend employee ability to delete email prior to backup
  - If appropriate, begin the process of capturing / imaging mailboxes or hard drives (and conducting custodian interviews)
- Inform third parties (e.g., vendors, contractors) of their obligation to preserve documents and data
- Be mindful of laws impacting collection and transfer of personnel data (particularly non-U.S. laws, if applicable)

# Document Collection, Review, and Production

- Engage a qualified e-discovery firm for any substantial collection
- Track documents and data collected – custodial and non-custodial sources, date ranges, and search terms
- Ensure effective procedures for review
  - Code for / protect confidentiality and privilege
  - Train and supervise review team
  - Impose ongoing quality control
- **Bottom line #1: Be able to defend your process**
- **Bottom line #2: Know what is in the production before it goes out the door**

# Communication with Government Investigators

- Credibility is key – choose outside counsel wisely
- In many instances, early engagement is the best way to reduce the burden of compliance
  - It is appropriate to defer substantive engagement until outside counsel is retained
  - First impressions matter and can have a significant impact on the long-term relationship
    - If strategically appropriate, establish the Company's intent to cooperate – you can learn a lot at the outset by seeming nice
    - Communicate clearly and in a timely way about burden, scope, or timing issues impacting the Company's response
      - Likelihood of success is greater if you are specific and can show your work
      - Slow document production at the outset can get the relationship off to a rocky start
      - Often government investigators will accept a small initial production (e.g., organizational charts) and view this as a sign of good faith
      - Be aware of agency-specific processes (e.g., FTC process on deadline extensions)

# Communication with Government Investigators

- General cooperation (particularly at the outset) can be independent of the decision whether to engage to resolution or contest
  - Pushback may be appropriate but should be reasonable and communicated effectively
- Be prepared for ongoing requests – more documents, employee interviews
- Pressing for information is appropriate – even advisable
  - Differentiate between witness / subject / target
  - Ongoing information exchange – you need to give to get

# Notifications and Disclosures

- Numerous interested stakeholders – both aligned with the Company's interests and not
  - Internal – Board, senior management, employees
  - External – other government agencies, insurers, auditors, lenders and business partners
  - Public – SEC filing if the Company has registered securities
- There is no set formula for disclosure – depends on many factors:
  - Materiality
  - Who or what is at issue
  - Applicable contracts or policies

# Internal Investigations

- Numerous benefits to the Company
  - Information gathering; potential remediation of policies / procedures; potential self-reporting
  - **Above all: understand the broader context for a government investigation and the Company's potential exposure**
- Key issues:
  - Privilege / work product
  - Legal representation
  - Employee interviews – Upjohn warnings
  - Investigation reports

# Resolution

- Decision to cooperate to resolution versus challenge is premised on assessment of business and legal considerations – every case is unique
- Resolution mechanisms:
  - Deferred Prosecution Agreements: filed with a charging document and subject to judicial review
  - Non-Prosecution Agreements: letter agreements between a government agency and the entity subject to the agreement
  - Corporate Integrity Agreements: agreement outlining the obligations that the entity makes with a government agency as a part of a civil settlement

# Special Case: Search Warrants

- Search warrants are unique because of the exigency and the lack of notice
- Lawful and effective response is premised on the following steps:
  1. Remain calm; be polite to the authorities but be prepared to assert the Company's rights
  2. Do not interfere with or impede the authorities executing a search warrant
  3. Contact the general counsel or other Company point person immediately; that person should take the lead in communicating with the authorities and coordinating the Company's response; call outside counsel if engaged
  4. Request a copy of the search warrant; review it to understand the scope of the search; ask what crime or conduct is being investigated
  5. Direct all employees not to discard, alter, or destroy any documents or data that may be within the scope of the warrant; confirm this instruction in writing



# Special Case: Search Warrants

- Lawful and effective response is premised on the following steps:
  6. Consider sending non-essential employees how; remind employees of their rights and responsibilities related to government interview requests
  7. Designate a point person in each area to be search to keep a record of locations search, documents or devices seized, and comments made by the authorities during the search
  8. Request on-site copying of business essential documents and data being seized by the authorities
  9. Politely notify the authorities if they search in areas not covered by the warrant or if they review or seize potentially privileged material; do not consent to a search of areas not covered by the warrant without first consulting counsel
  10. Do not engage with the media or other third parties without first consulting counsel

# Takeaways

# Takeaways

- Federal and State agencies are aggressive – and very public about their wins
- Some priorities are industry specific, some cross-industries – all aimed at protecting consumers
- All companies should have a robust compliance program and ensure it is aligned with current government priorities
- All companies should have a government investigation response plan

# Questions?

# Thank you!

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