



In the Crosshairs of FDA Enforcement and Congressional Investigations: Lessons for Managing Responses

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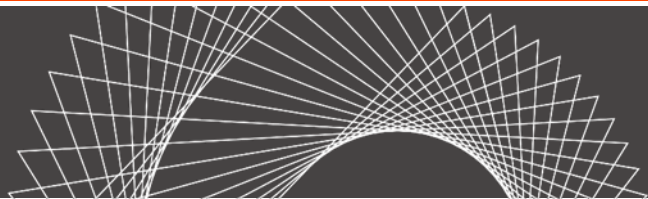
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Enforcement, Litigation, and Compliance Conference



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Why is Congress Conducting an Investigation?

Variety of potential motivations for a Congressional investigation:

- Intention to create new law or update an existing law
- Weigh-in on an issue under regulatory review or pressure Executive Branch agencies to take action
- Pressure private sector to take action
- A member may have a “pet” issue that is ripe for investigation
- Political, constituent and/or public relations/media considerations

Although an investigation may be politically driven, this can mean a variety of things

- Seeking to capitalize on investigating an unpopular or compromised target
- Targeting an individual or company seen as politically aligned with an opposing party or view
- “Collateral damage”: seeking information from a private party relevant to a broader investigation driven by political considerations

Why is Congress Conducting an Investigation?

2020 Election

- Both parties are focused here
- The Democrats have many candidates vying for the spotlight
- Investigations will likely play a major narrative role

President Trump

- Democrats remain focused on contractors and industries that intersect with the Administration

A Favorite Pattern

- **Last two “wave” midterm elections in 2006 and 2010 brought major changes in the composition and control of Congress**
 - Heightened focus on investigations in key congressional committees
 - Oversight of private industry as a proxy issue to attack White House
- **Democrats in 2007 took control of both houses of Congress**
 - Rep. Henry Waxman (D-CA) as chair of House Oversight Committee investigated U.S. defense contracting in Iraq and Afghanistan as a proxy against the war
- **Republicans in 2011 took back the House**
 - Investigated insurance companies and other health care companies as a proxy against the Affordable Care Act

How Does a Congressional Inquiry Begin?

A Congressional investigation may begin in a variety of ways

- Investigations often rapidly unfold
- Typical investigations follow a general process including an initial letter/subpoena requesting documents, document productions and a potential hearing and/or written committee report
- These investigations follow a process more akin to a typical government investigation, albeit with much different rules and on a very expedited schedule

Different Congressional committees are known to take differing general approaches

- For example, the Senate Permanent Subcommittee on Investigations is known to conduct lengthier, more in-depth investigations (often foregoing pursuit of media coverage until the culmination of a multi-month or multi-year inquiry), while other Committees will pursue the “rip and read” method

Lifecycle of a typical investigation:

- Request → Discovery (Documents/Narratives/Interviews/Depositions) → Final Hearing and/or Report

Does Congress have the Power to make this Request?

Congress has broad authority to investigate a wide range of subject matters

- Congress may investigate any issue on which it may legislate, including virtually any matter relating to interstate commerce (i.e., the private sector)
 - See, e.g., *McGrain v. Daugherty*, 273 U.S. 135 (1927)
- Congress is uniquely tasked with overseeing the Executive Branch, including its agencies and, by extension, their contractors

There are, however, limits on Congress's oversight authority

- Inquiries must relate to the “legislative function”
- Inquiries designed to expose the private affairs of individuals, without further legislative justification, have been ruled invalid
- Congress is not a law enforcement agency

Legislation need not follow a Congressional investigation

- In the contemporary political climate, this means “made-for-TV” investigations may be politically-driven and not necessarily intended to change the law

What Rules Govern this Process?

Inquiries are further limited by the rules of the Congress and its committees

- The rules largely depend on which committee is conducting the investigation
- The House and Senate each adopt their own general rules

Individual committees and subcommittees will then adopt rules governing their own affairs, including oversight activities such as the issuance of subpoenas and the conduct of hearings

- Think of these like “local rules”
- There are many similarities across various House and Senate committees, but the nuances are key

The House recently changed its rules to allow staff depositions to occur without any members present



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Executive Branch Overlap

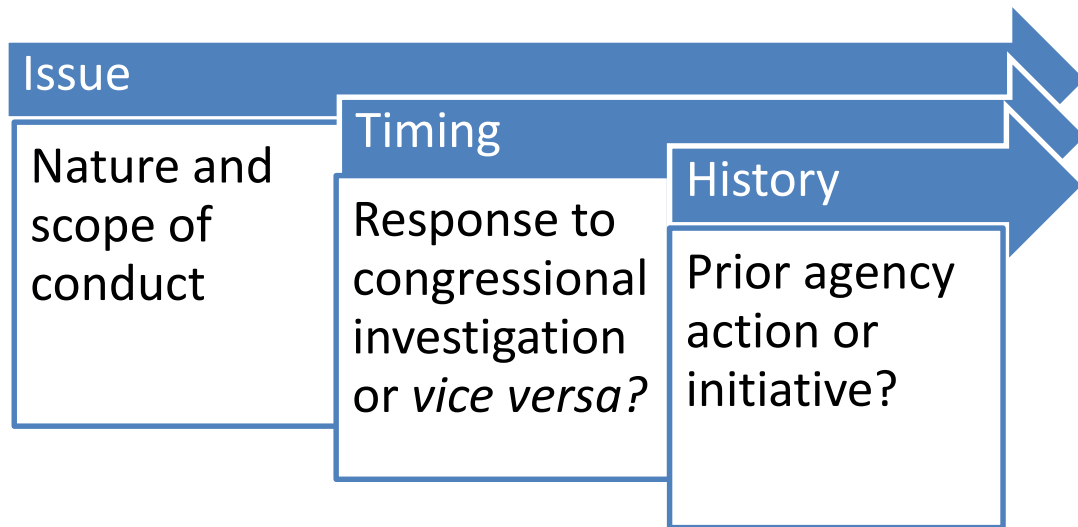
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Gus Eyler
Director
Consumer Protection Branch
U.S. Department of Justice

Mr. Eyler's views are his own and do not express official policy.

Executive Branch Involvement

Relevant Factors



Factors affect which agencies investigate and the course of an investigation

Investigative Coordination / Overlap

- Inter-Branch Coordination
- Investigative Overlap
 - Expect shared productions
 - Collect and review information accordingly
 - Write and speak thoughtfully
 - Consider multi-disciplinary teams
 - Know the different rules and authorities
 - Evidence gathering tools and standards
 - Recognition of privilege doctrines
 - Public relations practices



Cooperation and Compliance Considerations

Potentially competing interests:

- Delay or limited engagement may be the best response to a congressional inquiry, BUT the DOJ places great value on—and gives credit for—timely self-reporting and cooperation.
- Remediation encouraged by DOJ and agencies, BUT no adverse inference protection in Congress.

Unique DOJ Benefits of Self-Reporting

Executive Branch Enforcement of Congressional Investigations

Incomplete and false responses to Congress can give rise to criminal liability:

- 18 U.S.C. 1001, 1505, 1512, 1519
- Speech or Debate Clause implications
 - *United States v. Rainey*, 12-cr-291 (E.D. La.)
- 25 Cornell J. Law & Pub. Pol'y 453





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Dealing with Parallel Proceedings

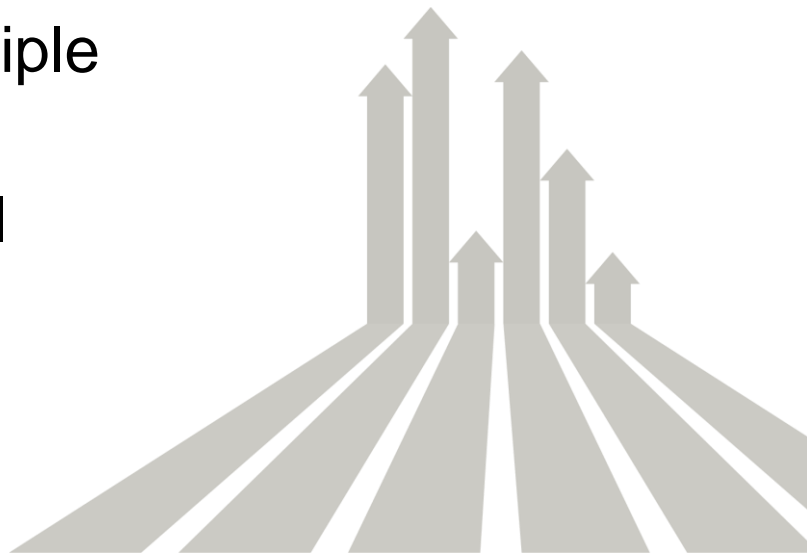
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Dealing with Parallel Proceedings

- What are the potential risks?
- How do you prioritize the multiple regulators?
- Immediate steps and practical considerations.



Potential Risks

- Inconsistent messaging and production of documents.
- Absence of any real, enforceable confidentiality protections.
- Congressional investigations can garner further scrutiny and/or expand the scope of other investigations.
- Strategic missteps can play out in the media.



Prioritizing Multiple Regulators

- There is no guarantees in terms of trying to control the agenda of any one regulator but sometimes you can strategically raise issues with a targeted regulator to assist you with another regulator.
- Are there benefits to allowing the other regulators to get out in front?
- Is one of the regulators at issue your daily regulator (e.g., the FDA) such that there could be a long term impact on day-to-day business operations?
- How significant is the issue?
 - A congressional committee likely will use its public relations savvy to try to secure media coverage.
 - A congressional investigation is conducted in a less controlled environment and often politically motivated.



Immediate Steps and Practical Considerations

- Public relations considerations.
- Coordination of outside counsel.
- Assessing your position vis-a-vie your competitors in connection with an industry-wide investigation.
- Do not underestimate the importance of establishing a transparent relationship with committee staff.
- Take prompt steps to preserve documents and get your arms around the subject matter at issue to identify sensitivities and likely pitfalls.





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