

# The Government's Perspective

Ways companies can effectively respond to an investigation, and the interplay of FDA and the USAO in conducting investigations

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Opinions expressed during this presentation are solely those of the speakers, and do not represent the views of the FDA nor the Department of Justice.

# Overview

- Relationship between agency counsel and the USAO
- Before investigations – don't break the law
- During investigations – what cooperation impresses prosecutors
- Resolving investigations – clean-up

# Relationship between FDA and USAOs

- FDA needs USAO to prosecute violations of the FDCA
- FDA supports USAO

# Before Investigations

- Compliance Programs
- Communications with customers and regulators
- Education

# During Investigations

- Cooperate and act credibly
- Produce documents and witnesses
- Privilege waivers
- How US learns about what everyone in the company says and does

# During Investigations

- Tell us what happened
  - Assess what happened
  - Present US with support for position
    - White Papers
    - Presentations
  - Recognize that the government is not looking to impose criminal liability for mistakes, but that this is a highly regulated industry, so the stakes are higher

# Resolving Investigations

- Convince US that conduct will not happen again
- McNulty Memorandum
- Resolution
  - release
  - criminal vs. civil
  - individual vs. corporate liability

# Collateral Consequences

- False Claims Act
- Exclusion
- Civil money penalties
- Loss of accreditation
- Short-term lending rates
- Impact on mergers and other deals
- Product liability suits
- Shareholder derivative suits

Questions?

If not, BREAK