

The Basics of Government Investigations

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Basics of Government Investigations

- Initial Demand for Documents
 - Grand Jury Subpoena
 - HIPAA Subpoena
 - CID for documents -- State or federal
 - Letter Request
- First steps
 - Issuance of Hold Notice
 - Consideration of Disclosure Obligations
 - Hiring of Counsel
 - Which USAO and prosecutors

Basics of Government Investigations

- Initial Considerations
 - Prior related enforcement actions
 - Existence of a qui tam
 - Scope and burden of document demand
 - Sophistication of government IT demands
 - Time period
 - Volume of potentially responsive materials
 - Government interviews of employees

Basics of Government Investigations

- Contact with Prosecutor
 - Initial response is critical
 - Discussion of scope of document requests
 - Offering alternatives re: time periods/segregation of certain business units (e.g. clinical research)
 - Obtain priorities for document collection
- Organization of Document Collection and Review
 - Collection within organization
 - Counsel review of documents for privilege and responsiveness

Basics of Government Investigations

- Trends in Government Investigations
 - Evolving theories of off-label promotion
 - Comparative claims
 - Dosing
 - Treatment Regimens
 - Clinical Research Misconduct
 - Use of CME Vendors and Publication Strategy
 - Development of Treatment Guidelines/Compendia Coverage