

Medical Device Congress: What to do When the Subpoena Arrives

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Overview

- Parallel Matters
- Assembling and Managing the Team
- Document Retention and Collection
- Employee Interviews

Parallel Matters

- Government investigations spawn parallel litigation
 - The opposite also is true
- Litigation/investigations go 0-60 in record speed
- Critical to quickly identify broadest possible scope
 - Drives team
 - Drives strategy
 - Avoids subsequent surprises
- Requires rapid understanding of the facts

Parallel Matters

- Likely parallel matters
 - Product liability
 - State consumer fraud actions
 - Public and private third party payer actions
 - Securities fraud actions
 - Derivative actions
 - HR disputes, including *qui tam*
 - Insurance coverage litigation (p/l, D&O)
 - Congress
- None of these will wait while you resolve matters with USAO

Parallel Matters

- Each additional parallel matter makes any resolution more difficult. So important to resolve what you can.
- What matters can you control? Influence?
- Model for “global resolution” seems still be with DOJ/FDA at the “hub”

Assembling and Managing the Team

- External Team
 - White collar
 - E-discovery
 - Product liability
 - Securities/Derivative
 - Insurance
- Structure: how many firms?
- Counsel for board?

Assembling and Managing the Team

- Internal Team
 - Single point of contact (“Field Marshall”)
 - Substantive in house experts (securities, e-discovery, product liability)
 - Document retention/collection group
 - Secondary Team
 - Compliance
 - Audit
 - IR
 - Corporate communication

Document Collection and Retention

- Need to be ready in advance
- Processes for Collection—Important
 - Speed
 - Efficiency
 - Reliability
- Processes for Retention—Critical
 - Spoliation
 - Obstruction
 - Poor retention becomes an independent crisis

Document Collection and Retention

- Retain at first sign of trouble
 - Don't wait for subpoena
 - Don't take comfort in clever legal arguments that failure to retain is defensible
 - Retain broadly, then add specificity and narrow when possible
 - Document, document, document
 - Communicate retention methodology to USAO in transparent way

Document Collection and Retention

- Collection
 - Begin early
 - Needed for investigation
 - Better for lawyers to have control of key documents
 - Target key people first
 - Don't rely on file owners alone to produce documents
 - Document, document, document
 - Communicate collection methodology to USAO in transparent way
- Production

Employee Interviews

- Trap for the unwary—take legal advice before beginning interviews. Standardize protocol and script.
- Led by outside counsel
- Who do you represent? If you represent company and the witness, what happens if a conflict occurs?
- Is this privileged? Who owns the privilege?
- Criticality of honesty. Explain consequences of dishonesty including termination and potential obstruction charges.
- Issues related to separate counsel for employees