

**How the Recent Landmark \$311 Million Device
Settlements Will Change Industry Practices**
Practical Considerations for Cooperating in an Investigation

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Practical Considerations for Cooperating in an Investigation

- Role of In-House Counsel in a Large Governmental Investigation
 - DO NOT completely turn over the reins to your outside counsel – need to effectively partner to maximize the value of any cooperation
 - You know your business and how it operates better than either the prosecutors/investigators or your outside counsel

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- What Do You Need to Focus On?
 - Understanding the specifics of the allegations being investigated, to the extent possible – is it a kickback case, improper marketing, pricing/billing irregularities?
 - Line up the right people to become involved, participate in formulation of any document hold instructions to avoid documents/areas of inquiry being missed or mistakes being made.

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- What Do You Need to Focus On?
 - Understand not only what the case is about from your perspective, but also from the government's perspective.
 - Is the case about possible harm to patients?
 - Are there allegations of fraud on the FDA or other regulators?
 - Does it appear that the main harm was damage to federal or state benefit programs?
 - Any political considerations? Congressional Hearings?
 - Possible Qui-Tam/Internal relator?
 - Are criminal charges being discussed?

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- Know Your Counsel; Know Your District
 - Different offices and even different prosecutors in the same office can have very different relationships, style and perspectives
 - e.g., - deferred prosecution agreements – widely used in some districts, never used in others
 - Be aware of the involvement and role of criminal AUSAs, State AGs offices, Department of Justice in the particular matter – the “government” is not a monolith.

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- Don't be afraid to seek the input of counsel based on their effectiveness/relationship with a particular US Attorney's Office or their comfort level with a particular type of case.
- Conversely, don't be afraid to bring alternate counsel in if the negotiations are sidetracked or seem to be bogged down in personal animosity.

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- Additional Considerations:
 - **Damages** – do not leave this until the end. Work with counsel and outside experts on damage models and calculations as the case is progressing.
 - This area is evolving – a proactive, thoughtful, empirical approach can be invaluable as the case progresses.
 - **CIA Provisions** – make sure you have a good handle on what is negotiable and what is not, so that you can prepare your Company for what is to come.

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- Additional Considerations:
 - **“Covered Conduct”**
 - Is it in your client’s best interest to have this be broad or narrow?
 - What else is out there?

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- Cooperation

- Just about everyone (Companies and Individuals) say they want to “cooperate” with the government for purposes of Federal Sentencing Guidelines.
- Is there any value to a less-litigious approach to a large-scale investigation
 - i.e., affirmative disclosures by the Company vs. asking the government to explain its case
 - Considered (vs. shotgun) approach to attorney-client privileged documents
 - Frequent communications with government counsel on substantive (not production) issues.

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- Additional Considerations:
 - Is a lengthy vs. short investigation in your client's best interests?
 - Pros and Cons – financially and operationally

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- Conclusion:
 - For corporate counsel –
 - Be involved, every step of the way, with outside counsel and learn as much as is possible about the Government's theories, approach and concerns.
 - Educate government counsel and outside counsel about your company, its operations and culture.
 - Educate your company internally about the reality of the investigation, what it means now, and what it may mean in the future.