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# Legal Strategies for FDA Consent Decrees

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## Slide 1

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## Four Themes

1. Anticipating a Decree
2. Negotiating a Decree
3. Implementing a Decree
4. Preventing a Decree

## 1. Anticipating a Decree

## FDA Action Is Often a Surprise

- Companies tend to view history in positive light
- They assume meetings with FDA will convince Agency of their *bona fides*
- They believe “progress” toward “substantial” compliance should satisfy FDA
  - Tracking and reporting on commitments to FDA are infrequent, however
- Senior management may not be aware of issues

## 1. Anticipating a Decree

## Signals of Potential Problems

- **483 “Metrics”**
  - Numbers of inspections, observations, and observations per inspection day
- **Patterns in 483 observations**
  - Repeated occurrences (failure to correct effectively)
  - Similar occurrences at other sites
  - Indications of systemic weaknesses
- **Seriousness of individual observations**

## 1. Anticipating a Decree

**Look at the words**

**“Corporate senior management has reported to the agency that deficiencies noted during previous inspections have been corrected. Not all of these corrections have actually been implemented. Those corrections that were implemented were not always effective.”**

1. Anticipating a Decree

## More Signals of Problems

- Early termination of inspection
- Prior history of site/company
- Prior Warning Letters or “voluntary agreement”
- Refusals of FDA to meet
- FDA collection of inventory information, evidentiary samples, affidavits
- FDA holds on pending applications, export documents, government contracts

## 2. Negotiating a Decree

## How the Process Begins

- The “call” or letter from FDA or Office of Consumer Litigation (OCL) in DoJ
- Draft decree offered by OCL/DoJ
- Demand for early commitments
  - FDA wants early signal on key issues
  - Threat to stop talks and go to court
  - A challenge to a surprised Company
- FDA & DoJ may refuse to meet without draft decree language back from Company



## 2. Negotiating a Decree

## Serious Psychological Effects

- Internal reactions at Company follow pattern
  - Initially: Anger, denial, grief, search for relief
  - Ultimately: Business calculation
- Morale and cooperation are affected
  - Individuals will be named
  - Heads will generally roll
  - Finger-pointing vs. problem-solving dynamic

## 2. Negotiating a Decree

## Key Substantive Issues

- “Shut down” or “Going forward” decree?
- Scope of facilities and products covered
  - Medically necessary products
  - R&D, IND, export-only materials
- Timetables and milestones for remediation actions
- Naming of individuals as defendants
- Conflict resolution procedures

2. Negotiating a Decree

## Other Substantive Issues

- Liquidated damages for missing milestones
- Disgorgement (prospective, retrospective profits)
- FDA powers over Company under Decree
- Post-remediation 3rd party audits
- Duration and termination of Decree

## 2. Negotiating a Decree

## The Negotiation Process

- Timetable – Usually 6-8 weeks
- Early face-to-face meetings
- Separate counsel for individuals?
- **There is no “standard” text for a consent decree**
- FDA may refuse to let Company meet with senior FDA management to resolve key issues

## 2. Negotiating a Decree

## Managing the Negotiations

- **Numerous teams required**
  - Face-to-face negotiations
  - Senior management policymaking
  - Technical GMP expertise
  - Financial analyses
  - Implementation of decree
  - Third-party consultants and auditors
  - Communications to investors, employees, media, customers
  - Collateral litigation
- **Overall coordination and management is special challenge**

## 3. Implementing a Decree

**Company Goals**

- **Achieve complete, effective, and timely fulfillment of decree commitments**
  - Remediation is not the only option
    - Rationalization of product line, manufacturing chain
  - Options, priorities may change after decree is entered
- **Apply learning to activities, facilities beyond scope of decree**
- **Convince FDA that the Company “gets it”**
  - Problem that led to decree will not recur
  - Company culture reformed

## 3. Implementing a Decree

## Strategic Challenges

- **Management leadership**
  - Regular, effective management briefings
  - Tough choices about competing priorities, personnel, and culture choices
- **Morale and cooperation of employees**
  - Anxiety, anger within organization
  - Ownership and accountability for execution
- **Endurance and persistence of effort**
  - Three tasks — making products, doing remediation, managing decree
  - Adequate resources throughout life of decree
- **Coordination and communication**
  - Within Company
  - To constituencies outside Company

## 3. Implementing a Decree

## Operational Challenges

- **Managing the 3rd party audit process**
  - Auditors also consultants for remediation?
  - Planning remediation in limited time frame
- **Tracking process and response against commitments and deadlines**
  - Complex program management effort
  - Anticipating bottlenecks; responding to surprises
- **Managing communications with FDA**
  - Numerous written submissions
  - Unexpected developments and delays



3. Implementing a Decree

## More Operational Challenges

- Verification of completion of actions
- Assessment of effectiveness of actions
- Documentation of actions
  - Quality and transparency of documents
  - Completeness (including ancillary proof of implementation) of records

## 3. Implementing a Decree

## Managing FDA's Expectations

- **Don't let FDA be adversely surprised**
  - If there is bad news, be the source
  - Keep in mind FDA's other constituencies
- **Don't waste FDA's time with unnecessary meetings**
  - FDA is not interested in good faith
  - FDA wants actions and compliance

## 4. Preventing a Decree

**Assure QA Infrastructure**

- **Best protection from a Consent Decree**
- **Provide adequate resources**
  - **FDA benchmarking staff ratios of QA to production**
- **Assure QA has meaningful respect and influence**
  - **Commitment of QA staff**
  - **Commitment of others to QA (priorities)**
  - **Commitment of management to quality**

#### 4. Preventing a Decree

## Respond Effectively to Every 483

- See materials on “How to Respond to FDA 483s and Warning Letters” based on my September 2002 PDA speech

## Summary

- **You do not want an FDA Consent Decree**
- **You should always consider your Company at risk**
  - **Suspend disbelief and assume it possible**
  - **Act accordingly**
- **Aggressive self-assessment and self-correction are the best means of prevention**
- **If you face a Decree, prepare for acute and long term management challenges**

# Questions and Discussion

**The floor is open**

**If you have additional questions, feel free to contact me at:**

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