Regulatory Due Diligence for FDA Regulated Companies

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Agenda

Why Is Regulatory Due Diligence Important?

Elements of Regulatory Due Diligence

Post Due Diligence

Post Transaction



Importance



Contractual



Regulatory

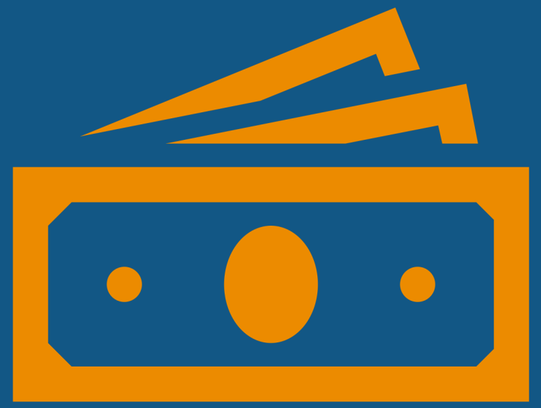


Administrative



Legal

Contractual



Financial Damage

compensatory,
Punitive



Specific Performance

Regulatory



Wont Approve Product(s)



Corrections



Untitled Letters



Warning Letters



Recalls

Penalties

Administrative

Temporary Exclusions

Permanent Exclusions

Legal

CIA

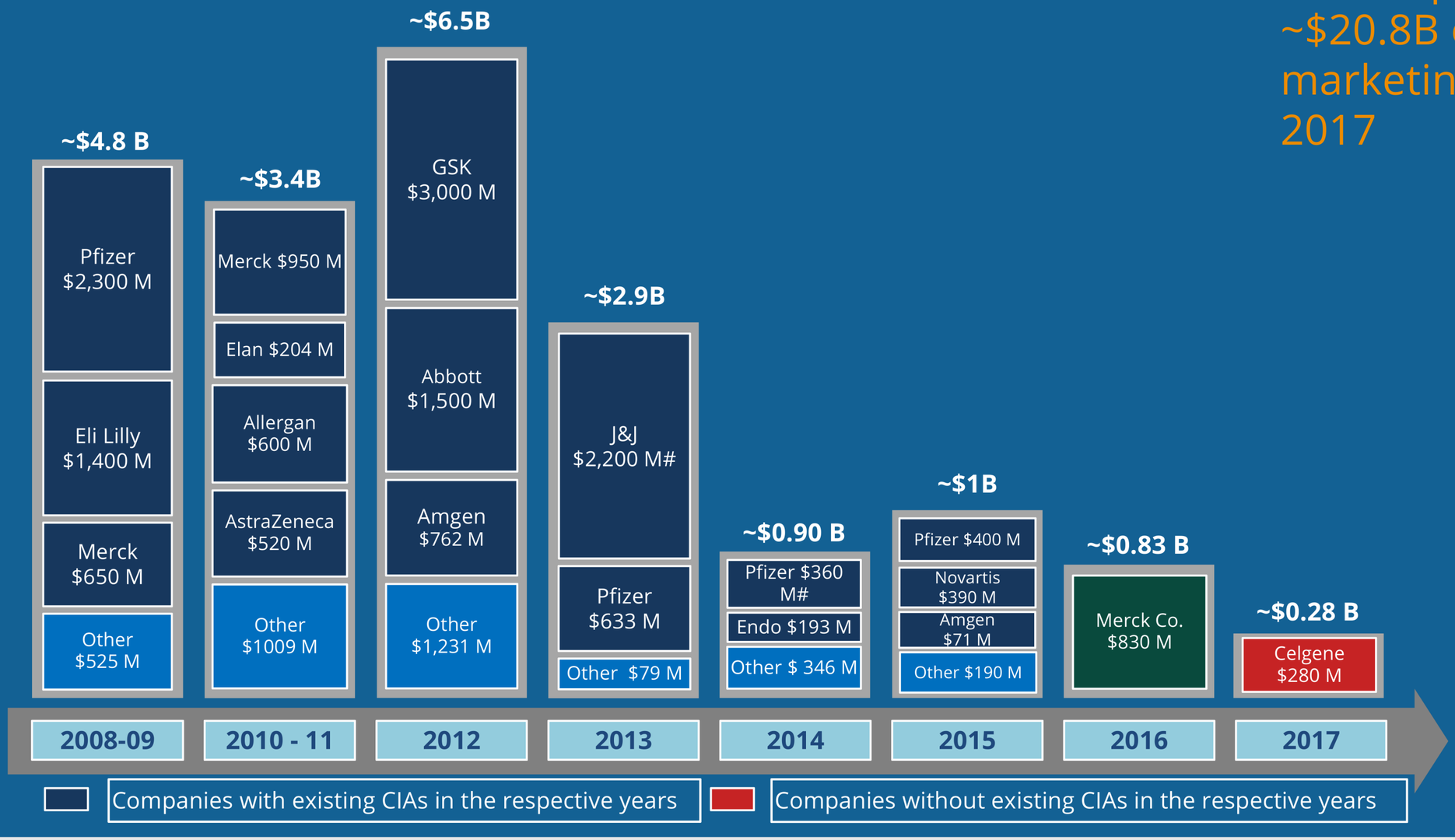
FCA

AKL

Stark

Park Doctrine

Conservative ZS estimates put US companies paying out ~$20.8B on fines for improper marketing between 2008 to 2017



Penalties

*2008 – July 2017; # Cumulative fine across multiple cases

Scope



Corporate Compliance



FDA

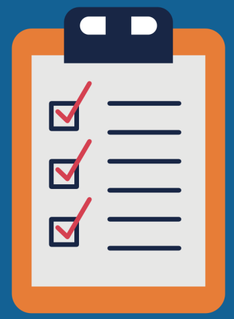


Privacy

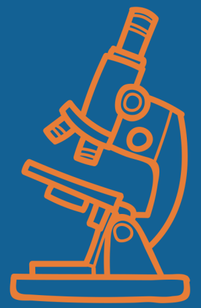
Elements of Regulatory Due Diligence



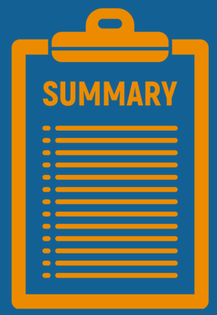
Determine Scope



Due Diligence List



Review Documents



Create a Summary

Corporate Compliance

Corporate Compliance - OIG

- Effective lines of communication.
- Internal monitoring and auditing.
- Effective training and education.
- Designated compliance officer and compliance committee.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Written policies and procedures.

Corporate Compliance



Corporate Compliance Program



Compensation Claw back



Voluntary Self Disclosure

Corporate Compliance Program



Is the corporation’s compliance program well designed?



Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?



Does the corporation’s compliance program work in practice?

See JM 9-28.800

Voluntary Self Disclosure



Company’s disclosure must be “timely, voluntary self-disclosure”



Go after employees



Advantages

Compensation Clawback

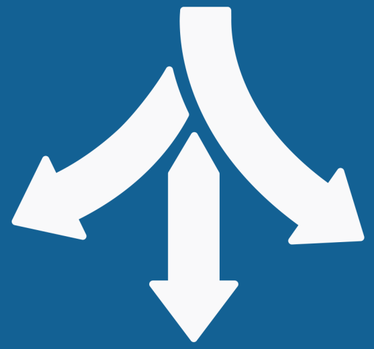


Requirements



Target

FDA Regulatory Compliance



Drug



Device



Cosmetics



Food



Pharmacy



Quality Program



Manufacturing:

6 System Review

quality,

production,

facilities and equipment,

laboratory controls,

materials, and

packaging and labeling

Clinical Research

Common Sponsor Findings

Marketing

- FDA Considerations
- OIG Considerations
- CMS Considerations

Privacy, Compliance – Scope

US v. Ex US

Federal v. State laws

Medical:

Non Medical Data

Data Privacy

Data Ownership

Cybersecurity

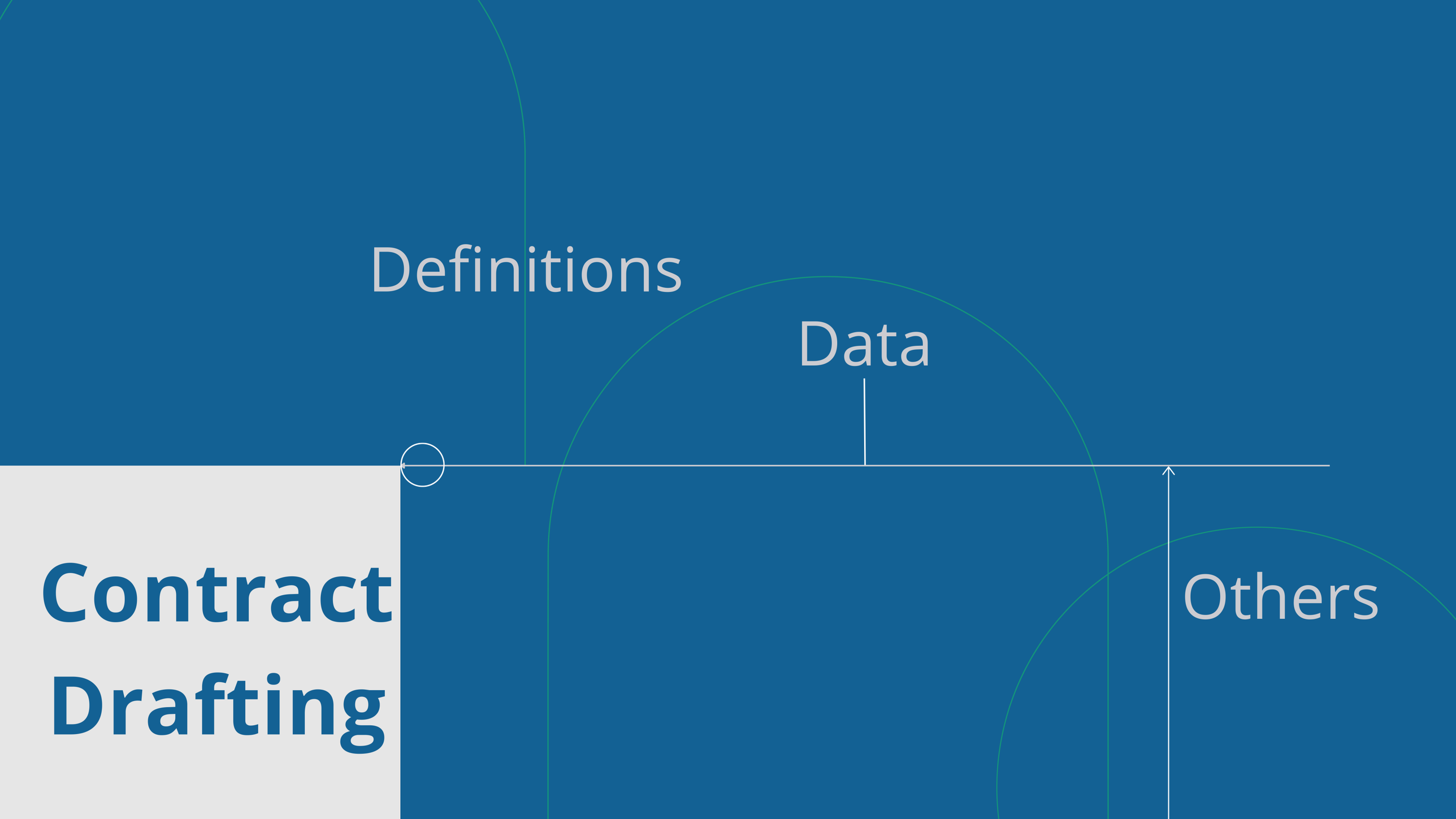
Summary of Findings

- Scope
- Out of Scope
- Summary of Findings
- Documents reviewed

Post Due Diligence

Contract Drafting

Post M&A Integration



Contract Drafting

Post M&A Integration

Development of an overall compliance program

Bring appropriate stakeholders to the table

Create risk based plan of action

Plan for reporting updates for key stakeholders

Plan to demonstrate compliance e.g. audit

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Thank you!


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