Due Diligence Decoded

M&A Success in FDA-Regulated Industries

Gardner Law

Friday, September 20th, 2024

Program Introduction

- Program is being recording and the recording will be available post-event.
- Slides are available during the presentation virtually via the handout window on the control panel.
- Remote participants: Please submit questions via the question function on the control panel.
- CLE credits: 2.75 credits are pending approval by the Minnesota Board of Continuing Legal Education. CLE approval code will be sent out in a program follow up email. Please request a CLE certificate to self report in other states from office@gardner.law.

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Agenda

10:00 – 10:05 AM	**Program Introduction**
10:05 – 10:30 AM	**Smart Due Diligence: Navigating FDA Regulations with Confidence** Speaker: *Nate Downing, Senior Attorney*
10:30 – 11:00 AM	**Is Honesty the Best Policy? Exploring the M&A Safe Harbor** Speaker: *Amanda Johnston, Partner*
11:00 – 11:30 AM	**Revealing Risk: Cybersecurity Due Diligence** Speaker: *Paul Rothermel, Senior Attorney*
11:30 – 11:45 AM	**BREAK**
11:45 – 12:15 PM	**Exploring the *Loper* Decision: Impacts on FDA-regulated Transactions** Speaker: *David Graham, Senior Counsel*
12:15 – 1:00 PM	**Panel Discussion** Moderator: *Mark Gardner, Managing Partner* Panelists: Alan Carlton, Division General Counsel, FUJIFILM Holdings America Corporation Irana Ridley, Chief Legal Officer, Aerin Medical

Smart Due Diligence: Navigating FDA Regulations with Confidence

Nathan Downing

Friday, September 20th, 2024

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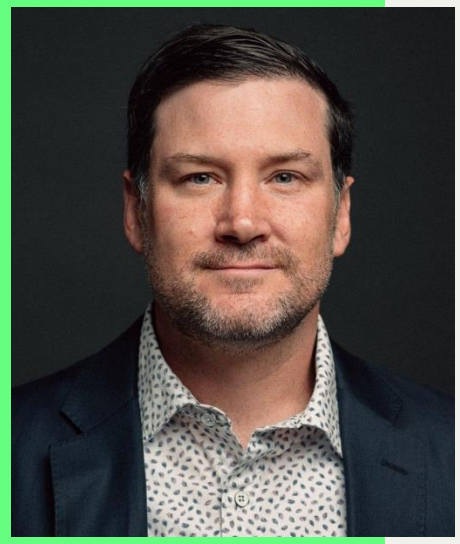
Presenter Introduction



Nathan focuses his practice on FDA-regulated clients. His industry experience allows him to provide actionable legal advice on a variety of health law matters.

Nathan regularly advises FDA-regulated clients on regulatory and compliance matters. He advises clients on their advertising and promotion programs, represents clients in front of the FDA on a variety of matters, and assesses industry initiatives for compliance concerns. Nathan's extensive regulatory experience allows him to advise clients regarding a variety of medical products, including pharmaceuticals, medical devices, medical foods, and nutritional supplements.

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Objectives

- Overview of Regulatory Strategy
- Product Classification
- Quality System Readiness
- Pre-Market Communications
- Promotional Labeling
- Burning Down Risk
- Key Takeaways for Acquirers
- Key Takeaways for Targets

Overview of Regulatory Strategy

- Understand what is most important
- Determine what can be changed and what cannot be changed
- Focus on any FDA interaction
- Challenge assumptions

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Product Classification

- Pre-Market
  - FDA review
  - Classification match intended use/claims
  - Predicate devices or other precedent
  - Global considerations

Product Classification

- Post-Market
  - FDA clearance/approval
  - Claims consistent with labeling
  - Change control

Indications

- General v. Specific
- Phased approach
- Product capability

Quality System Readiness

- 21 CFR 820
  - Design History File
  - Risk Documentation
  - Supporting Evidence
- Global Considerations

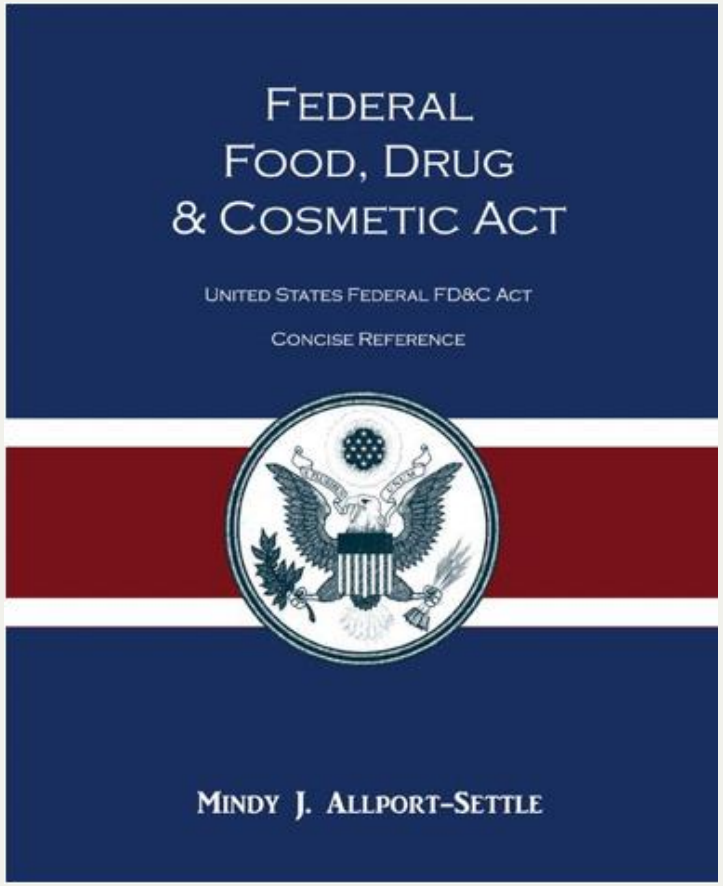
Quality System Diligence

- Good Documentation Practices
- Corrective and Preventative Actions
- Audit Ready

Pre-Market Communications

- Safety and efficacy
- Investor
- Advisory Boards

What Is “Labeling”?



“Label”

“a display of written, printed, or graphic matter upon the immediate container of any article”

FFDCA § 201(k)

“Labeling”

“all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article”

FFDCA § 201(m)

When Does Advertising Become Drug or Device *Labeling*?

"Most, if not all advertising, is labeling. The term 'labeling' is defined in the [Federal Food, Drug, and Cosmetics Act] as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."

United States v. Research Laboratories, 126 F.2d 42 (9th Cir. 1942)

Promotional Labeling

- Review everything
- Claims matrix
- Understand risk tolerance disparities
- Scrutinize substantiation

Burning Down Risk

- Proper issue spotting
  - Misclassification
  - Misbranding/adulterated
  - Quality system deficiencies

Poll the Audience

- Most Difficult Issues to Spot
  - Quality System
  - Device Classification
  - Marketing Communications
  - Other (feel free to comment in chat)

POLL

Burning Down Risk

- Be proactive
- Understand timing and effort to make changes
- Address all issues, no matter how small

Key Takeaways for Acquirers

- Ensure adequate time for a full review
- Understand business goals
- Address all issues

Key Takeaways for Targets

- Do not neglect your quality system
- Regulatory assessments
- Avoid limiting future potential

Questions

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Is Honesty the Best Policy? Exploring the M&A Safe Harbor

Amanda Johnston

Friday, September 20th, 2024

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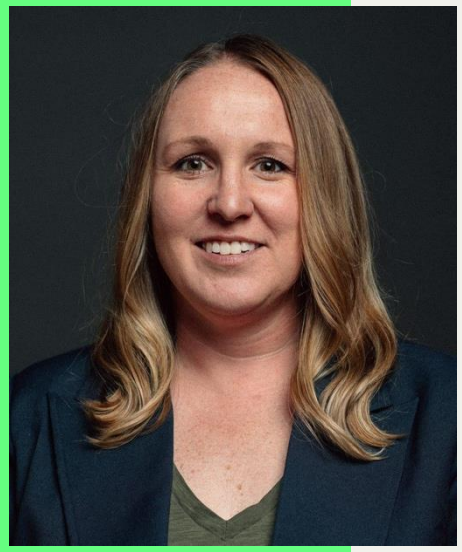
Presenter Introductions



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Amanda Johnston is a distinguished FDA attorney with expertise in counseling medical device and pharmaceutical companies on FDA law, regulatory submissions, healthcare compliance programs, and healthcare fraud and abuse laws. With an impressive background spanning several in-house legal, regulatory, and compliance roles within the medical device industry, Amanda brings an exceptional understanding of business and industry dynamics to her practice. Her extensive experience includes serving as interim compliance officer at a global medical device company, overseeing 130+ FDA submissions, compliance program implementation, and helping commercial teams navigate healthcare fraud and abuse laws.

Objectives

- Overview of M&A Safe Harbor Policy
- Benefits of the Safe Harbor Policy
- Risks
- 10 Factors to Consider when Deciding Whether to Self-Disclose
- Potential Effects on M&A Activity
- Key Takeaways for Acquirers
- Key Takeaways for Targets

Overview of the DOJ's M&A Safe Harbor Policy

- Announced by Deputy Attorney Lisa Monaco on October 4, 2023
- DOJ-wide policy to encourage transparency without penalizing acquiring companies that uncover misconduct during due diligence or post-acquisition.
- Safe Harbor Policy Basics:
  - Misconduct disclosed within 6 months of acquisition, regardless of whether it was discovered before or after the acquisition.
  - Full remediation completed within 12 months
  - Presumption of declination
- Impact of "Aggravating Factors"

Benefits of the Policy

- Presumption of declination
- Potentially more favorable outcomes (lower fines, penalties)
- Predictable timelines for disclosure and remediation
- Safeguard against reputational damage by demonstrating corporate responsibility
- Serves as further justification for company to invest in compliance

Risks

- Risks of Disclosing:
  - DOJ could expand into other areas
  - Can’t go back
  - No guarantee
  - Risk of uncovering additional issues

- Risks of Not Disclosing:
  - Enforcement agencies discovering misconduct
  - Whistleblower risk
  - Penalties may be more severe

Is Honesty the Best Policy?

Top 10 Factors for Acquiring Companies to Consider When Deciding to Self-Disclose

Hypothetical M&A Scenario

Sterling Medical Solutions Targets Precision HealthTech

Factors to Consider

1. Nature and severity of the misconduct
    - Is the misconduct related to severe violations?
    - How widespread? Aggravating factors?
    - Harm to customers or patients?
2. Legal and Regulatory Obligations
    - Are there mandatory disclosure requirements (e.g., securities violations, contract obligations)?
3. Timing and Disclosure Requirements
    - Can the misconduct be disclosed within the six-month window?

Factors to Consider

4. Remediation Feasibility
    - Can the company realistically complete full remediation within the 12-month window?
    - What will it cost, and are resources available to manage the process?
5. Legal and Financial Penalties
    - Potential fines, penalties, or successor liabilities
    - What are the risks if enforcement agencies discover the issue on their own?
    - How severe are the aggravating factors (e.g., high-level management involvement)?
    - Non-disclosure may lead to full successor liability for the acquiring company

Factors to Consider

6. Reputational Risks
    - Consider the long-term reputational impacts of both disclosing and not disclosing.
    - Self-disclosure can demonstrate responsibility, while non-disclosure may cause lasting reputational damage.
7. Impact on Future Business
    - Evaluate how self-disclosure will affect current and future relationships with customers, stakeholders, and investors

Factors to Consider

8. Risk of Discovery
    - If misconduct is likely to be discovered by regulators or whistleblowers
    - Potential severe penalties if discovered without voluntary disclosure
9. Risk Management
    - De-risk potential penalties
    - Maintain control over the narrative
10. Alternative Strategies
    - In cases of minor misconduct, companies may opt to remediate without disclosure quietly.

Potential Effects on M&A Activity

Increased Due Diligence and Scrutiny

- Disproportionate impact on smaller companies; less attractive targets

Financial and Operational Impacts

- Valuation adjustments
- Higher costs

Impact on Deal Strategy

- Narrower acquisition focus
- Compliance as a deal-breaker

Effect on Deal Timelines

- Prolonged deal and due diligence timelines

Innovation and Market Dynamics

- Innovation stifled by risk aversion

Post-Acquisition Compliance Requirements

- Quick, focused post-acquisition remediation plans

Key Takeaways

- Invest early in compliance
- Weigh M&A Safe Harbor pros and cons *before* due diligence
- Involve compliance from the start
- Compliance must be integral to M&A discussions
- Proactive compliance boosts valuation and attractiveness
- Compliance can make or break a deal

Poll Question

- What would you recommend if you were on the Deal Team at Sterling Medical Solutions?
  - Proceed with the deal and disclose to the DOJ
  - Proceed with the deal, but do not disclose to the DOJ
  - Walk away from the deal

POLL

Questions

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Revealing Risk: Cybersecurity Due Diligence

Paul Rothermel

Friday, September 20th, 2024

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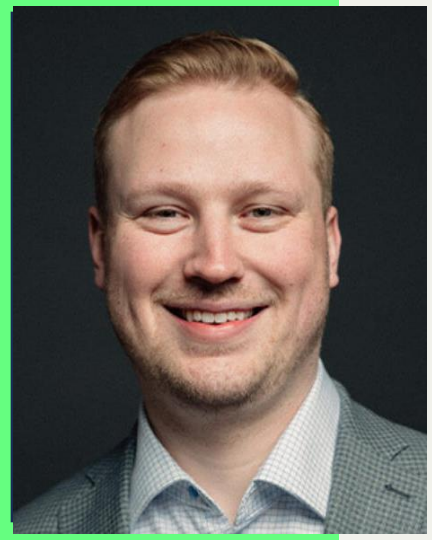
Presenter Introduction



Paul Rothermel specializes in privacy and cybersecurity. Paul's practice includes HIPAA, GDPR, and other state, federal, and international privacy laws as well as health care compliance matters. Before practicing at Gardner Law, Paul worked for a large medical device manufacturer advising on these topics applied t o innovative health care technologies, clinical research, and vendor risk management. Prior to that, Paul counseled a state government agency on health and human services program laws, including HIPAA implementation. Paul is a licensed attorney in Minnesota and is credentialed as a certified information privacy manager through the International Association of Privacy Professionals.

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Objectives

- Understand Cybersecurity Landscape
- Gain Insight Into M&A Impact of Cybersecurity
- Learn How To Avoid M&A Pitfalls
- Review Examples of Requests and Responses
- Questions

Cybersecurity Trends

- **Data breaches**
  - Zoll Medical data breach affects 1 million[1]
    - March 2023 e-mail phishing attack resulted in e-mail compromise
    - Ongoing litigation
  - LivaNova breach affects 130,000[2]
    - Hackers infiltrated system October 2023, discovered November 2023
    - Breach of patient information not confirmed until April 2024
    - Incurred costs of over $2.6m in Q4 2023 alone
  - Henry Schein breach affects 29,000[3]
    - September 2023 ransomware attack with significant business interruption and data leak
    - Lowered sales expectations and business interruption
    - Finance analysts indicated "$500 million headwind" tied to cyber attack

1

2

[3]https://www.medtechdive.com/news/henry-schein-cyberattack-19k-affected/702004/

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Cybersecurity Trends

- **Device safety and efficacy**
  - Medtronic[1]
    - June 2023, disclosed cybersecurity vulnerability in Paceart Optima cardiac device and notified health care providers
    - No report of unauthorized access or patient harm
  - Becton Dickinson[2]
    - July 2023, disclosed cybersecurity vulnerabilities in Alaris System and implemented remediation and deployment plan
    - No report of unauthorized access or patient harm

[1]https://www.aha.org/news/headline/2023-07-06-cisa-warns-high-risk-cyber-vulnerability-medtronic-cardiac-device-data-management-system
[2]https://www.bd.com/en-us/about-bd/cybersecurity/bulletin/bd-alaris-system-with-guardrails-suite-mx

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M&A Impact

- Cybersecurity issues will be present – the question is how significant are they, and do you know about them
- Average cost of breach in 2024*:
  - $9.8 million (health care)
  - Approx. $180 per record (not industry-specific)
  - Note: Does not include business impact – these are direct costs
- Increased scrutiny of cybersecurity is trending in M&A transactions

**per IBM "Cost of a Data Breach Report 2024"*

M&A Impact

- Breaches and other cybersecurity issues identified during or after diligence can directly affect
  - valuation
  - remediation
  - integration costs
- Note: Threat of cyber incident may increase after deal announced

Poll the audience

- Has your company received a request (as a target) or asked for (as an acquirer) cybersecurity evidence during a diligence request?

POLL

(Avoiding) M&A Diligence Pitfalls

- Take cybersecurity seriously
  - High costs: Business interruption, reputational damage, litigation risk, class actions, cost of remediation and breach response, harm to patients/other stakeholders
  - Many regulators: Federal Trade Commission, state attorneys general, HHS Office of Inspector General, Department of Justice, Securities Exchange Commission
- Understand target: use risk-based approach (industry, key products and/or programs, etc.)
- Assume vulnerabilities identified in diligence may be exploited

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(Avoiding) M&A Diligence Pitfalls

- No Breach = No Risk?
  - Target may be unaware of an ongoing breach or be vulnerable to attack
- Consider alternative methods to vet target (e.g., dark web search)
- Use multi-disciplinary approach
  - Legal
  - CISO
  - IT
  - Data/system architecture
  - Engineering

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Example Requests

- Provide documentation of the Company's information security program including policies and procedures.
- Provide an organization chart and relevant job description(s) for information security program roles.
- Provide data mapping and inventory demonstrating Company system and data flow.
- Provide sample information security clauses and/or agreements executed by Company with its service providers.
- Provide the latest security assessment completed by Company.
- Provide a copy of Company's current cyber liability insurance certificate.
- Provide documentation of the last penetration test(s) completed by Company.
- Provide copies of security awareness training plans and training records for prior 12 months.
- Provide evidence of security control audit and testing performed over the past 12 months.
- Provide details regarding Company incident response plan and how it has been tested over prior three years.
- Provide evidence of cybersecurity risk assessment for products/medical devices.
- Provide documentation showing total product life cycle (TPLC) approach to cybersecurity.

Example Requests

- When was the last data security audit conducted by the Company and what were the findings?
- Discuss the audits, risk assessments, penetration tests and other analyses performed by the Company in the last three years.
- Discuss the Company's personal information (PI) data flows and processing activities, including any processing of sensitive PI (e.g., health information, precise geolocation data, biometric information).
- Discuss the extent to which device level data is segmented and/or deidentified from user data and the point at which such information can be re-identified, and by whom.
- Discuss any complaints, investigations, litigation (pending, threatened, or ongoing), and/or inquiries, including from regulators, received by the Company regarding its privacy or cybersecurity practices.
- Discuss any data breaches experienced by the Company in the last three (3) years.
- Discuss the Company's cyber-liability insurance coverage.
- Discuss how cybersecurity incidents are detected and addressed.
- Discuss Company's software development security training and processes.

Conclusion

1. Cybersecurity continues to offer significant risk and require investment, both in data protection and product safety
2. Data breaches are the tip of the iceberg: look for vulnerabilities and anticipate exploitation
3. Take a risk-based approach and deploy the right experts
4. Anticipate increased threat-level after transaction is announced: vulnerabilities may be exacerbated during transition

Questions

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Exploring the Loper Decision: Impacts on FDA Regulated Transactions

David P. Graham

Friday, September 20th, 2024

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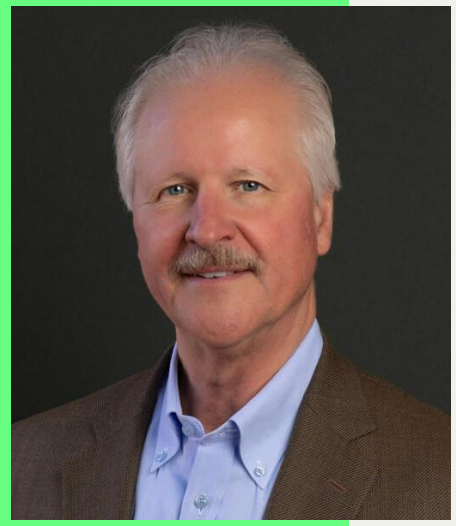
Presenter Introductions



David Graham focuses on product liability, health law and food law litigation and counseling. He also works with clients in the food, cannabis, and psychedelics industries with regulatory matters, labeling and advertising, recalls, and food borne illness investigations and defense. David's focus in the health care area is defending entities in false claims act cases and other allegations of fraud. David teaches food law at Mitchell Hamline School of Law, the University of Minnesota School of Law, and is the chair of the Mitchell Hamline Food Law Center.

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Objectives

- Understanding the Loper Decision
- Loper Impact on MedTech and Transactions
- Due Diligence for Medtech Transactions
- Questions

Loper Bright Decision

- Loper Bright Enterprises v. Raimondo and Relentless v. Department of Commerce

- Overturning of the Chevron Deference Doctrine
  - Deference to agencies' interpretations of ambiguous statutes
  - Agencies have knowledge and experience
  - Agencies will do better than judges

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Loper Bright Decision Highlights

- Judge’s job to interpret statutes and they should do so
- Past cases decided based on Chevron not overturned
- Agency's interpretations still important "to the extent it rests on factual premises within the agency's expertise”
- Evidence supporting FDA interpretations important

Loper Decision and FDA

- Impact on FDA
  - Likely will not impact normal approval process
  - Likely will not have major impact on CFSAN or CVM
  - Will receive more challenges to its interpretations
  - May slow down decisions and rule making

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Technologies Possibly Impacted

Types of technology which might be impacted more than others:

- Combination Products
- Device v. Drug determinations
- Laboratory Developed Tests
- Market Exclusivity Under Hatch-Waxman
- Novel drugs or biologics approvals

Other Impacted Subject Matter Areas

- FTC-Antitrust and Unfair methods of competition
- FTC-Privacy and Consumer Protection
- SEC
  - Increased Protection of Investors
  - Rules around personal information
  - Use of AI and algorithms in pricing

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What Parts of the Regulatory Landscape Affect the Transaction?

- Is there an FDA or other agency decision that could be or is being challenged?
- How might the law change based on what you know about the agency's position and whether they are vulnerable to challenge?
- How might the analysis change your view of the value of the target or feasibility of the transaction?

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Due Diligence Focus Areas

- Is there an FDA decision that can be challenged and is there evidence to make it?
  - Representations and Warranties
  - Government-Compliance with Laws
  - Communications with FDA or other agencies
  - Inquiries, Reports, Notices, or other correspondence regarding statutory interpretations
  - Pending or threatened actions and identified liabilities
  - Regulatory Compliance Reports and Policies, e.g. studies and data related to compliance efforts
  - Business and competitive intelligence
  - Marketing documents

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Questions

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Panel Session

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Thank you!

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