

CBI's Premiere Forum on Bio/Pharmaceutical and Medical Device

CORPORATE INTEGRITY AGREEMENTS (CIAs)

Improve Compliance Practices and Processes through the Analysis of Recent CIA and DPA Experiences

JUNE 17-18, 2009 • THE WESTIN ARLINGTON GATEWAY • ARLINGTON, VA

Conference Co-Chairs:



Thomas Gregory,
Partner, Fraud Investigation
& Dispute Services,
Ernst & Young



Eileen Erdos, Principal,
Fraud Investigation &
Dispute Services,
Ernst & Young

Key Take-Aways:

- Create and maintain arrangements databases
- Implement specific recommendations for a practical Fair Market Value (FMV) solution
- Employ effective training programs to ensure appropriate business unit activities
- Hear case examples of strategies to effectively manage field-based personnel

First-Hand CIA and DPA Experiences from Industry and Independent Review Organizations (IROs):

- Biomet Trauma and Spine
- Crowell & Moring LLP
- FTI Consulting
- King Pharmaceuticals
- Polaris Management Partners
- Bristol-Myers Squibb
- Daylight Forensic & Advisory LLC
- Huron Consulting Group
- Medicis
- Purdue Pharma L.P.



Plus! Don't Miss the Prosecutor's Panel Discussion:

"Understand the Collaboration between State and Federal Authorities for Integrity Obligations — Consent Decrees, NPAs, DPAs and CIAs"

Choose from Two Pre-Conference Workshops — Wednesday, June 17, 2009:

A. Apply a CIA Implementation Plan to Enhance Compliance Programs

B. Ensure Compliant Engagements with HCPs and Identify Methods to Determine Fair Market Value

Organized By:



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8:30

A. Apply A CIA Implementation Plan to Enhance Compliance Programs

Workshop Objective:

This workshop provides attendees with ways to leverage technology for compliance initiatives by addressing all seven elements of a compliance program. Workshop leaders guide attendees through best practices by walking through the implementation of a CIA which requires companies to ramp up their compliance programs under tight deadlines. At the end of this workshop, attendees are able to enhance the efficiency and effectiveness of their compliance programs and, should the need arise, be prepared to implement CIA requirements within required deadlines. This workshop also provides a foundation for the main program by giving attendees a concrete outline of compliance initiatives to reference throughout the conference.

Key Questions to Be Addressed Include:

- What does a CIA implementation plan look like and how can that plan be applied to an everyday compliance program?
- What types of resources are required?
- Which employees, contractors and vendors are typically covered under a CIA and how can I be especially sure I am reaching those groups?
- How do I keep track of what requirements have been completed?
- How do I track reportable investigations, like the ones that are typically required under a CIA, and how do I report appropriately if I were under a CIA?
- What ongoing monitoring programs need to be in place to sustain compliance, and if I were under a CIA, how do I ensure the longevity of these programs after the initial dates are met?

Workshop Outline:

- I. Identify the Key Pieces to a CIA Implementation Plan**
 - Understand the scope of a project plan
 - Develop an appropriate resource plan
 - Discuss a technology plan that leverages compliance initiatives
- II. Understand Available Technology Options to Make Compliance Initiatives More Efficient and Effective**
 - Discuss CIA management solutions
 - * what pieces of compliance do they help streamline?
 - Understand uses for content providers
 - Determine how to use exclusion search vendors
 - Integrate new technology with existing systems
- III. Key Implementation Strategies**
 - Identify and target covered employees, contractors and vendors
 - Distribute policies, procedures and online training
 - Perform exclusion searches
 - Centralize CIA evidence
 - Manage investigations and disclosures
 - Ensure proper auditing and monitoring
 - Track progress, escalating exceptions and reporting

Interactive Activity:

Companies under CIAs provide best practices on their implementation. Learn how technology helped enable the implementation and reporting process. Companies not under CIAs discuss what preventive programs they may have in place. Examine other lessons learned and next steps to take after the CIA.

12:00 *Close of Workshop A*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

About Your Workshop Leaders:

Christopher J. Santarcangelo is Assistant Director of Corporate Compliance at **Purdue Pharma L.P.** Mr. Santarcangelo currently manages the Auditing and Monitoring Programs in Purdue's Corporate Compliance Department. He assisted in the negotiation and implementation of Purdue's CIA and manages the engagement of Purdue's Independent Review Organization (IRO). He is responsible for Purdue's implementation of AXENTIS Enterprise for GRC Compliance. Mr. Santarcangelo has spent fifteen years in multiple areas of Quality Assurance, Quality Control and Corporate Compliance in Pharmaceuticals and Neutraceuticals. He holds a BS in Chemistry from Rensselaer Polytechnic Institute and an MS in Management from Albertus Magnus College. He is a senior member of the American Society for Quality (ASQ) and is an ASQ Certified Quality Auditor. He has been implementing and leading audit programs for more than ten years.

Gary M. Fingerhut is Senior Vice President at AXENTIS. He was instrumental in the creation of AXENTIS and served as Senior Vice President and Chief Technology Officer from the company's inception through July 2005. Currently, Mr. Fingerhut is responsible for the AXENTIS sales organization. Prior to joining AXENTIS, he was a senior executive at **Compliant** (the original parent company of AXENTIS) and CEO of **Business Technologies Incorporated**, a software-development and technology-consulting firm that provided web application development services. Mr. Fingerhut is also the founder and president of the non-profit organization GSD Type IV Foundation. He is a seasoned executive with more than twenty-five years of technical and management leadership in the software industry.

Leila A. Daiuto is the Sales Director for Life Sciences and Healthcare at AXENTIS. During her seven year tenure, she has also served as Director of Client Services and Director of Pre-Sales. In her current role, Ms. Daiuto is responsible for the sales and account management of AXENTIS' Life Science and Healthcare customers. Prior to joining AXENTIS, Ms. Daiuto spent several years as a management consultant for **PricewaterhouseCoopers** and **Ernst & Young**.

8:30 **B. Ensure Compliant Engagements with HCPs and Identify Methods to Determine Fair Market Value**

Workshop Objective:

In 2007, five medical device companies came under scrutiny and ultimately ended up with CIAs or DPAs regarding their consulting agreements with physicians. In this workshop, examine the requirements that the government expects you to meet in regards to working with physicians, from identifying and engaging the appropriate consultants to creating appropriate arrangements with them — including proof of a method to determine FMV — to managing these relationships through a structured arrangements database.

Key Questions to Be Addressed Include:

- What procedures can be put in place to ensure consultants are:
 - * appropriately identified — by whom within your company and how?
 - * contracted in accordance with regulatory requirements and healthcare compliance principles?
 - * monitored and audited to ensure they meet performance objectives?
 - * managed through a structured database?
- What methods and processes does your company have for assessing FMV?

Workshop Outline:

- I. Overview of Recent CIAs and DPAs Relating to Interaction with HCPs**
 - Discuss specific areas of alleged misconduct
 - Examine trends across recent settlements
- II. Examine Lessons Learned from Investigations and Prosecutions**
 - Evaluate what can be gleaned from current investigations
 - Hear an overview of the PhRMA guidelines on interactions with HCPs
- III. Engaging a Consultant**
 - What are appropriate and inappropriate practices?
 - What issues may raise red flags to prosecutors?
- IV. Government Guidance on Fair Market Value (FMV)**
 - Examine regulations and advisory opinions
 - Review case law in this area
 - Discuss DPAs and CIAs
- V. Determining FMV**
 - What methodologies are available?
 - How should companies document these processes?

Interactive Activity:

Companies under CIAs and/or investigation discuss the industry best practices that they have identified to assist in limiting compliance risk. Companies that are not under CIAs or investigation provide insight on internal processes designed to detect and prevent such activities or at a minimum, limit risk. An interactive discussion on good and bad experiences relating to engaging consultants, as well as assessing the FMV of those arrangements (using both internal or external resources), takes place.

12:00 *Close of Workshop B*

There will be a 30-minute networking and refreshment break at 10:00 a.m.

About Your Workshop Leaders:

Timothy J. Nugent, CPA is Managing Director of Forensic and Litigation Consulting at **FTI Consulting**. He has more than twenty years of experience providing advisory and audit services to the pharmaceutical and healthcare industries. He specializes in assisting pharmaceutical manufacturers in all aspects of regulatory compliance and operational improvements. He regularly works closely with CEOs, CFOs, internal counsel, corporate compliance officers, senior operation professionals and the outside legal counsel who support these professionals. Prior to joining FTI, Mr. Nugent spent eight years at **PricewaterhouseCoopers LLP** as a director in the firm's Life Sciences practice. He was also a leader of the firm's national Government and Commercial Contracting Services practice. Previously, he held various roles in assisting clients as a trusted advisor in all areas of operation and finance for the healthcare industry. His ability to provide hands-on industry experience to all levels of executives from senior management to operations brings a distinct client experience.

David A. Hile, MHA, CMPE, AVA is Senior Managing Director of Forensic and Litigation Consulting at **FTI Consulting**. He has specialized his practice within the healthcare industry providing valuation, regulatory, forensic, litigation, operational, strategic and financial advisory consulting services specifically within the sector. Mr. Hile has more than eighteen years of combined healthcare experience from within the industry as a consultant. Prior to joining FTI, he led the healthcare forensic and dispute consulting practice for **Deloitte and Touche's** Mid-America region. Before joining Deloitte, he ran several large multi-specialty physician practices and a management services organization. He has worked extensively with external and internal counsel, as well as management on financial, forensic, regulatory and operational matters as they relate to facts and the determination of values in litigation and regulatory matters, as well as assisting clients with DOJ, OIG, IRS and qui tam investigations.

M. Timothy Renjilian, CPA is Senior Managing Director of Forensic and Litigation Consulting at **FTI Consulting**. He has been providing audit, accounting and advisory services to attorneys and corporate clients for more than twenty-one years. In the early part of his career, his work consisted primarily of audit and advisory engagements for private and publicly traded companies involved with government contracting. This work included assignments related to cost accounting and compliance matters and to contract claims and disputes. Drawing on this background, he shifted focus to concentrate full time on addressing compliance, dispute and investigative projects across a wide range of industries. In recent years, he has concentrated largely on the healthcare sector where he has helped clients in addressing qui tam lawsuits, administrative inquiries, criminal false claims allegations, compliance investigations and other matters.

MAIN CONFERENCE

Day One — Wednesday, June 17, 2009

12:00 *Main Conference Registration*

1:15 *Co-Chair's Welcome and Opening Remarks*



Thomas Gregory, Partner, Fraud Investigation & Dispute Services,

Ernst & Young

Mr. Gregory focuses his practice on applying finance and accounting methodologies to complex commercial litigation problems. He has performed detailed analysis and led significant investigations involving financial modeling, forecasting, valuation, market studies, audits and other complex financial analysis. Mr. Gregory has conducted such analyses for organizations in a wide variety of industries with a particular focus on the healthcare and pharmaceutical industries. His experience includes all phases of the dispute resolution process from compliance and risk management, through development of case strategy, damage calculations and trial and testimony support in both a civil and criminal setting. Mr. Gregory is a certified public accountant and a chartered financial analyst. He holds a bachelor's degree in finance from the University of Tennessee and an MBA from the University of Georgia.



Eileen Erdos, Principal, Fraud Investigation & Dispute Services,

Ernst & Young

Ms. Erdos is a leader in the health sciences team with the Fraud Investigation & Dispute Services practice of Ernst & Young. She specializes in assisting health science companies, including pharmaceutical, biotechnology and medical technology companies, identify and mitigate risks. Ms. Erdos is relied upon by client management teams to assist in identifying enforcement risks, determining vulnerabilities and recommending improvements from both a business and operations perspective. Having led engagements with more than twenty pharmaceutical, biotechnology and medical technology companies in more than sixty countries, Ms. Erdos has a wide range of experience assisting clients in the management of regulatory risks associated with interactions with healthcare professionals and government officials, product communications, pricing and contracting practices and use of third-party vendors. Ms. Erdos also regularly serves as a technical advisor to health science clients and their legal counsel in fraud investigations, compliance inquiries and litigation strategy. As a registered pharmacist and active participant in the industry for more than twenty years, Ms. Erdos has provided operational, clinical, managerial, consulting and litigation services to various segments of the healthcare industry. She is a frequent speaker and author on the management of domestic and international regulatory risks associated with promotion, education and clinical activities in the pharmaceutical and medical technology industries and served as a primary contributor to the compliance guidance for pharmaceutical sales and marketing activities developed by the Open Compliance and Ethics Group. She holds a bachelor's degree in pharmacy from The Ohio State University.

Examine the Integrity Obligations within the Current Enforcement Landscape

1:30 **The Evolution of CIAs — How Did We Get to Where We Are Today?**

Understand how CIAs have evolved over the last decade and the challenges they present for pharmaceutical and device companies. Address how these trends have changed the burdens and risks associated with doing business under a CIA.

- What are the key components of a CIA?
- How do pharmaceutical and device industry CIAs differ from those in the provider industry?
- How have they changed over the last five to ten years?

Keith M. Korenchuk, Partner, Arnold & Porter LLP

INDUSTRY PANEL DISCUSSION

2:00 **Compliance Takeaways from Recent Settlements**

Hear from drug and device companies with a deep understanding of the challenges of CIA compliance based on recent experiences. This panel discusses the major challenges and lessons learned from the implementation of CIA provisions. In an interactive discussion, these panel members address:

- New requirements that they face and what they predict may be on the horizon for future CIAs
- Challenges in identifying the right IRO and negotiating the IRO agreement
- Keys to obtaining management support and needed resources
- Unexpected problems confronted and how they can be avoided
- What they would have done differently in the negotiation and/or implementation process knowing what they know now

Moderator:

Keith M. Korenchuk, Partner, Arnold & Porter LLP

Panelists:

Seth Rodner, Senior Vice President and Chief Compliance Officer, Medicis

Michael R. Clarke, Vice President, Compliance,

Biomet Trauma and Spine

3:00 *Networking and Refreshment Break*

PROSECUTORS' PANEL DISCUSSION

3:30 **Understand the Collaboration between State and Federal Authorities for Integrity Obligations — Consent Decrees, NPAs, DPAs and CIAs**

When a company is faced with alleged misconduct, a variety of government agencies begin investigations. In this panel discussion, hear insight into the investigatory process directly from prosecutors who have been involved in recent settlements with large pharmaceutical and medical device companies.

- Understand the difference between a Consent Decree, Non-Prosecution Agreement, Deferred Prosecution Agreement and Corporate Integrity Agreement
- Learn how the U.S. Attorneys, Attorneys General and the OIG work together when investigating and prosecuting a case
- Discuss similar and differing requirements companies face under a DPA and CIA
 - * how do they come together?
- Use case examples to illustrate current integrity obligations

Moderator:

*Lynn Shapiro Snyder, Senior Member,
Epstein Becker and Green P.C.*

Panelists:

*Kevin O'Dowd, Assistant U.S. Attorney,
U.S. Attorney's Office of New Jersey*
*Ryan Tyrrell Lipinski, Assistant Attorney General,
Attorney General's Office of Illinois*

- Develop effective working relationships with the OIG and an IRO that achieve consistent clarity, agreement and alignment
- Use metrics, benchmarking and trend analysis to demonstrate measurable progress, meeting CIA requirements and compliance program effectiveness
- Align your organization from the Board and C-suite to managers and employees on how to implement the CIA and identify opportunities for constructive outcomes that add business value
- Position your organization for successful implementation and possible early termination of a CIA

*L. Stephan Vincze, J.D., LL.M., MBA,
National Managing Director, Life Sciences/Forensic & Dispute Services,
Deloitte Financial Advisory Services, LLP;
Former Chief Ethics & Compliance Officer/Privacy Officer,
TAP Pharmaceuticals*

4:30 **Understand the Role and Relationship of an Independent Review Organization (IRO)**

CIA's frequently require an organization settling False Claims Act and overpayment allegations with the government to engage an IRO to review compliance with the CIA and the terms of the settlement agreement. The IRO reviews the organization's compliance with federal and state laws and regulations, the company's arrangements database, documentation, claims, processes, systems and unallowable costs. At the conclusion of each reporting period under the CIA, the IRO writes a report which is delivered to the organization and included in the annual report to the OIG. In this session, attendees learn about HHS-OIG Guidance concerning the IRO process and examine the relationship between IROs and manufacturers, distributors or other healthcare providers. Among other areas, the session examines:

- What does it mean that the IRO is "Independent" during the review stage?
- How best to cooperate with the IRO
- Communication between the IRO and the organization
- How to keep IRO costs down
- What happens after the first reporting period?
- The nature of unallowable costs
- The narrow scope of review
- Hear feedback from organizations under IROs

*Virginia B. Evans, Managing Director,
Daylight Forensic & Advisory LLC*

5:15 **Turn a CIA Lemon into Operational Lemonade — Preparing for Success Before You Are Hit**

Negotiating and implementing a CIA with the OIG is a daunting and ominous event, often fraught with fear, uncertainty and negativity. But, there are specific steps organizations can take both in preparation and during implementation to turn this "lemon into lemonade." In this session, discuss key factors to transform a CIA from bad news into good news with associated positive results and outcomes.

6:00 *Close of Day One*



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Day Two — Thursday, June 18, 2009

7:30 *Continental Breakfast*

- 8:00 *Co-Chair's Welcome and Review of Day One*
*Thomas Gregory, Partner, Fraud Investigation & Dispute Services,
Ernst & Young*
*Eileen Erdos, Principal, Fraud Investigation & Dispute Services,
Ernst & Young*

Use Industry CIA Experiences to Enhance Compliance Practices

8:15 **Develop and Maintain an Arrangements Database — Analyze Your Company's Readiness**

Many recent CIAs require life science companies to create and maintain an arrangements database and develop procedures that help ensure the arrangements do not violate company processes or legal requirements. This can be a large scale initiative that may cut across a number of corporate functions including Ethics & Compliance, Legal and Information Technology as well as other various business units.

- Identify and address key requirements and considerations before beginning the process of data and document collection
- Create optimal business processes and streamline technical architecture for database creation

- Understand the need for collaboration between Business, IT and Compliance teams to ensure a system is in place to accurately track arrangements
- Develop procedures to test the accuracy and completeness of the database (before the IRO does or to test the effectiveness of the database)

Tracy Mastro, Director, Life Sciences Advisory Services,

Huron Consulting Group

Manny Tzavlakis, Director, Life Sciences Advisory Services,

Huron Consulting Group

9:00 **Determine Fair Market Value (FMV) — A Practical Guide**

Long a requirement of the Anti-Kickback Stature (AKS) safe harbor, FMV is getting increasing attention from regulators and life science companies. Disclosure requirements initially associated with the DPAs of the orthopedic companies are now appearing as a common element in settlement agreements. Developing compliance strategies for FMV remains challenging as standard definitions do not provide actionable guidance. In this session, examine:

- Basic requirements of a defensible FMV methodology
- Varying methods used to determine FMV for physician/HCP services
- Specific recommendations for a practical FMV solution
- Additional requirements of the AKS safe harbor
- Challenges in implementing FMV successfully

Fred Eaton, Partner, Polaris Management Partners

9:45 *Networking and Refreshment Break*

EXTENDED SESSION

10:15 **Refine Policies and Procedures and Implement through Effective and Efficient Training Programs**

As part of a CIA implementation, companies must be sure to train the appropriate groups of employees on a variety of enhanced or new policies and procedures that reflect an updated look at practices taking place within their company that the government found an issue with. In this extended session, hear pharma and device compliance perspectives as well as a legal perspective on their experiences on updating policies and procedures to ensure government expectations were met. Discuss who needs to be trained and how to best do it to ensure an effective and efficient training program that acts as a preventive measure to make sure that appropriate, compliant activities are being pushed out to the business from the start. Attendees have the opportunity to participate in an interactive dialogue to discuss best practices to refine policies and procedures and implement them through effective training.

I. Enhance Policies and Procedures

- Are these a matter of perspective?
 - * satisfying the OIG's expectations
 - * the business has to keep running — what adjustments should be made to enhance practices while working within current business operations?
 - * can you satisfy the IRO?
 - * how do you identify the highest risk areas?

- CIA policies vs. non-CIA policies
 - * should there be a difference?
- Can you have new CIA policies in periods after the implementation report?
- How do you address the importance of keeping proper documentation and records of interactions with HCPs?

II. Implement Effective and Efficient Training Programs

- How do you address new employee training
 - * blitz at their start?
- Compare internal training of employees to training of vendors or suppliers
- Design training to be preventative
- Employ effective training models
 - * role playing
- Identify covered persons as compared to relevant covered persons
 - * how do you organize and track this?
- Prioritize a training timeline
 - * what is considered Day 1 Training vs. Day 120 Training vs. Day 360 Training?
 - * address challenges in annual compliance training
- Determine what training can be done in-house as compared to outsourced
- Discuss challenges of annual CIA training
 - * components are driven by the CIA
- Should a company go above and beyond training requirements?
 - * tests and certification
 - * training records

Michael R. Clarke, Vice President, Compliance,

Biomet Trauma and Spine

John Knighton, Senior Manager, Corporate Compliance,

King Pharmaceuticals Inc.

Karen A. Gibbs, Partner, Crowell & Moring LLP;

Former Senior Corporate Counsel, Applied Medical

11:45 *Luncheon*

EXTENDED SESSION

1:00 **Field Monitoring Strategies and Approaches to Implementation**

Many investigations that lead to CIAs stem from some alleged misconduct of field teams in regards to their interactions with physicians. These activities must be monitored and closely audited to ensure appropriate and compliant interactions exist. Preventative and corrective action plans, as well as policies for any disciplinary actions, must also be in place. The government has shown leniency against companies who make an effort at self-reporting and transparency after uncovering inappropriate actions within their company. In this extended session, hear new and improved procedures for monitoring and auditing field-based personnel following CIA requirements. Attendees again have the opportunity to participate in an interactive dialogue to share best practices.

I. Case Examples of Effective Auditing and Monitoring Strategies

- Field Force monitoring including call note analysis and direct observations
- Analyze requests from HCP for medical information submitted by sales reps — Formalizing the process
- Transactional reviews of product and promotional activity such as consultancy arrangements, speaker and other informational programs
- Using verbatims from detailing sessions — Process, stakeholders and reporting
- From CIA to implementation

II. Preventative and Corrective Action Plans

- Determine root cause
- Means to correct actions
- Consistent disciplinary/remedial actions
- Communication of corrective/disciplinary actions

Monica Jonhart, Director, Compliance and Auditing,

Bristol-Myers Squibb

Christopher J. Santarcangelo, Assistant Director, Corporate Compliance, Purdue Pharma L.P.

2:30 Key Takeaways from CIA Experiences

Participate in an interactive Question & Answer period with the conference co-chairs. They identify the key issues discussed throughout the forum and suggest takeaways that attendees can implement to improve their compliance programs based on CIA experiences.

Thomas Gregory, Partner, Fraud Investigation & Dispute Services,

Ernst & Young

Eileen Erdos, Principal, Fraud Investigation & Dispute Services,

Ernst & Young

2:45 *Close of Conference*

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Who Should Attend:

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CBI's Premiere Forum on Bio/Pharmaceutical and Medical Device

CORPORATE INTEGRITY AGREEMENTS (CIAs)

Improve Compliance Practices and Processes through the
Analysis of Recent CIA and DPA Experiences

JUNE 17-18, 2009
THE WESTIN ARLINGTON GATEWAY • ARLINGTON, VA

Real-World Compliance Program Enhancements

Refine Policies and Procedures and Implement
through Effective and Efficient Training Programs

Presented by: **King Pharmaceuticals,**
Biomet Trauma and Spine, Crowell & Moring LLP

Field Monitoring Strategies and Approaches
to Implementation

Presented by: **Bristol-Myers Squibb, Purdue Pharma L.P.**

Choose from Two Pre-Conference Workshops on
Wednesday, June 17, 2009:

**A: Apply a CIA
Implementation
Plan to Enhance
Compliance Programs**

**B: Ensure Compliant
Engagements with HCPs
and Identify Methods to
Determine Fair Market Value**

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In order to receive CBI's special discounted hotel rate, you must call Travel Concepts at 800-640-8082 (508-879-8600 outside the U.S.) or email reservations@travelconcept.com by May 17, 2009. Travel Concepts can also negotiate low group airfares and car rentals. Mention that you are attending **CBI's Premiere Forum on Bio/Pharmaceutical and Medical Device Corporate Integrity Agreements (CIAs)** to qualify for hotel and travel discounts. All travel arrangements subject to availability.

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