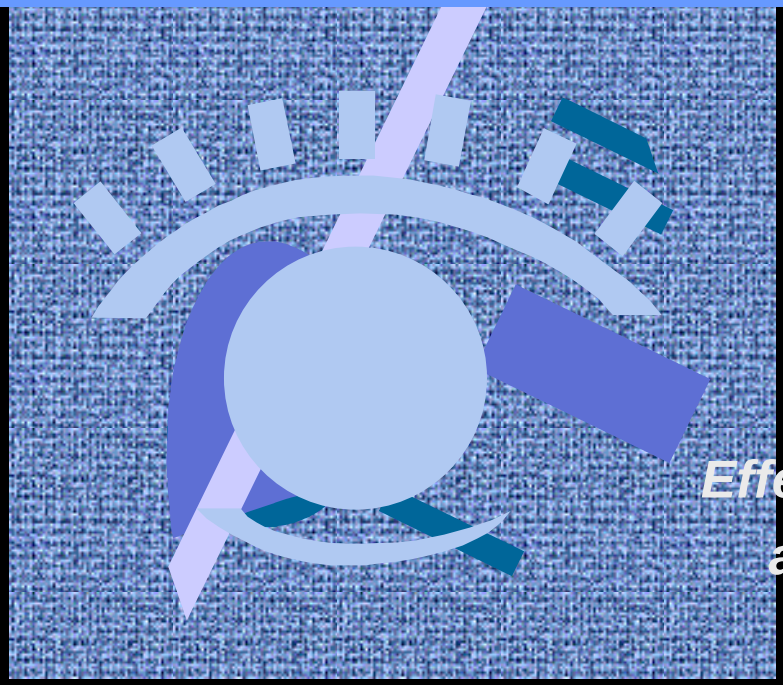
The Second Annual Pharmaceutical Industry Regulatory & Compliance Summit

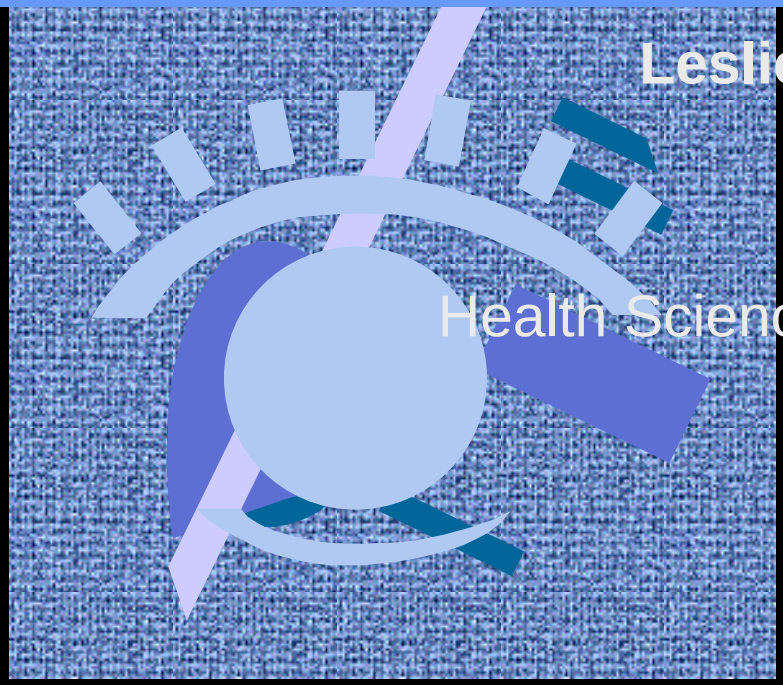


June 12, 2001

Arlington, Virginia

Effective Compliance Strategies for a New Era in Clinical Research

Presented by:



Leslie A. Platt, Principal and Leader
and Daniel Richter, Member

Health Sciences Research Compliance Group
Ernst & Young LLP

Effective Compliance Strategies for a New Era in Clinical Research

- **It's a New Era in Clinical Research:**
  - There Has Been an Expansion in Our Scientific Knowledge Base, With Associated Progress in Biomedical and Life Sciences Research and Applications
  - There Is Now a Greater Availability of Intellectual and Financial Capital Devoted to Biomedical and Life Sciences Research and Development
  - Intellectual Property Has Become a Primary Means Through Which Research Developments Are Recognized As Advances, Used in Further Research and Translated Into Downstream Applications

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- **It's a New Era in Clinical Research (Continued):**
  - Highly Publicized Research Compliance Compromises And Failures Have Threatened Public Trust In And Support For Clinical Research
  - Federal Officials Have Stepped Up Oversight And Enforcement, And Are Enacting New Research Requirements

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II. We Don't Want To Scare You But…

Fred Hutchison Cancer Research Center

- Seattle Times Series Entitled "Uninformed Consent" (03/11/03/15/01)
- Class Action Lawsuit Filed (03/26/2001)

University of Oklahoma Health Sciences Center – Tulsa

- Department of Health and Human Services (HHS) Suspends Research (06/29/00)
- USA Today Article Entitled "Research Suspended After Flaws Found" (07/10/00)
- Civil Lawsuit Filed (01/29/2001)
- Civil Lawsuit Filed (09/17/2000)

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II. We Don't Want To Scare You But…(Continued)

Thomas Jefferson University

- First Institutional Integrity Agreement (05/19/2000)
- $2.6 Million Settlement Agreement (05/19/2000)

University of Pennsylvania

- Washington Post Article Entitled "Teen Dies Undergoing Gene Therapy" (05/26/1999)
- FDA Halts Gene Therapy Research (01/21/2000)
- Civil Lawsuit Filed (09/17/2000)

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III. Keys to research success in this new environment

- Funding
- Publications
- Patents

IV. Levers

- Fear of Enforcement and its Consequences
- Potential Organization and Intellectual Property Value Enhancements

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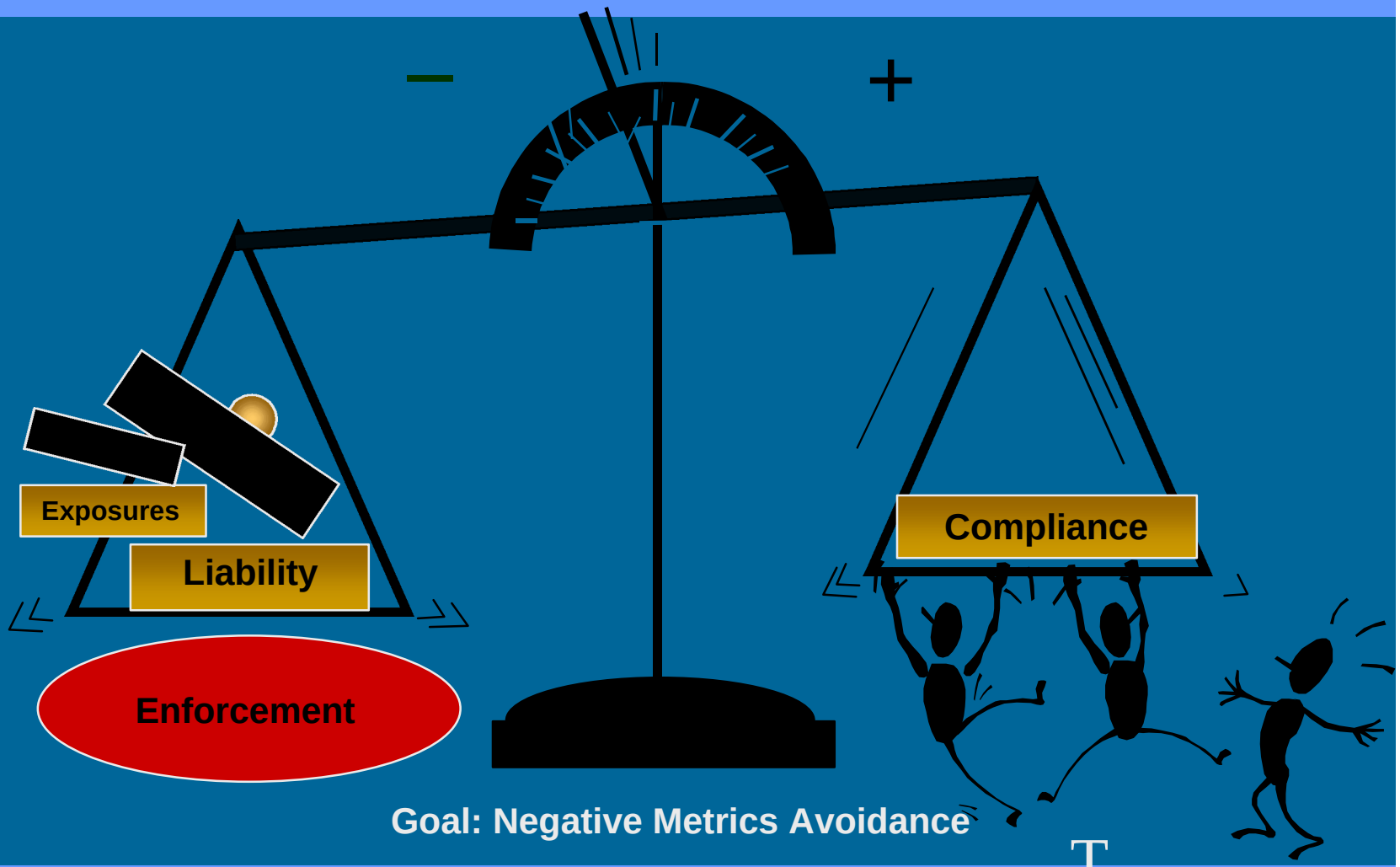
V. A New Era Requires a New Way of Thinking About Research Compliance:

- **Current State**: Primary Goal of Compliance Is Avoidance of Enforcement by Managing and Minimizing Compliance Compromises and Failures;

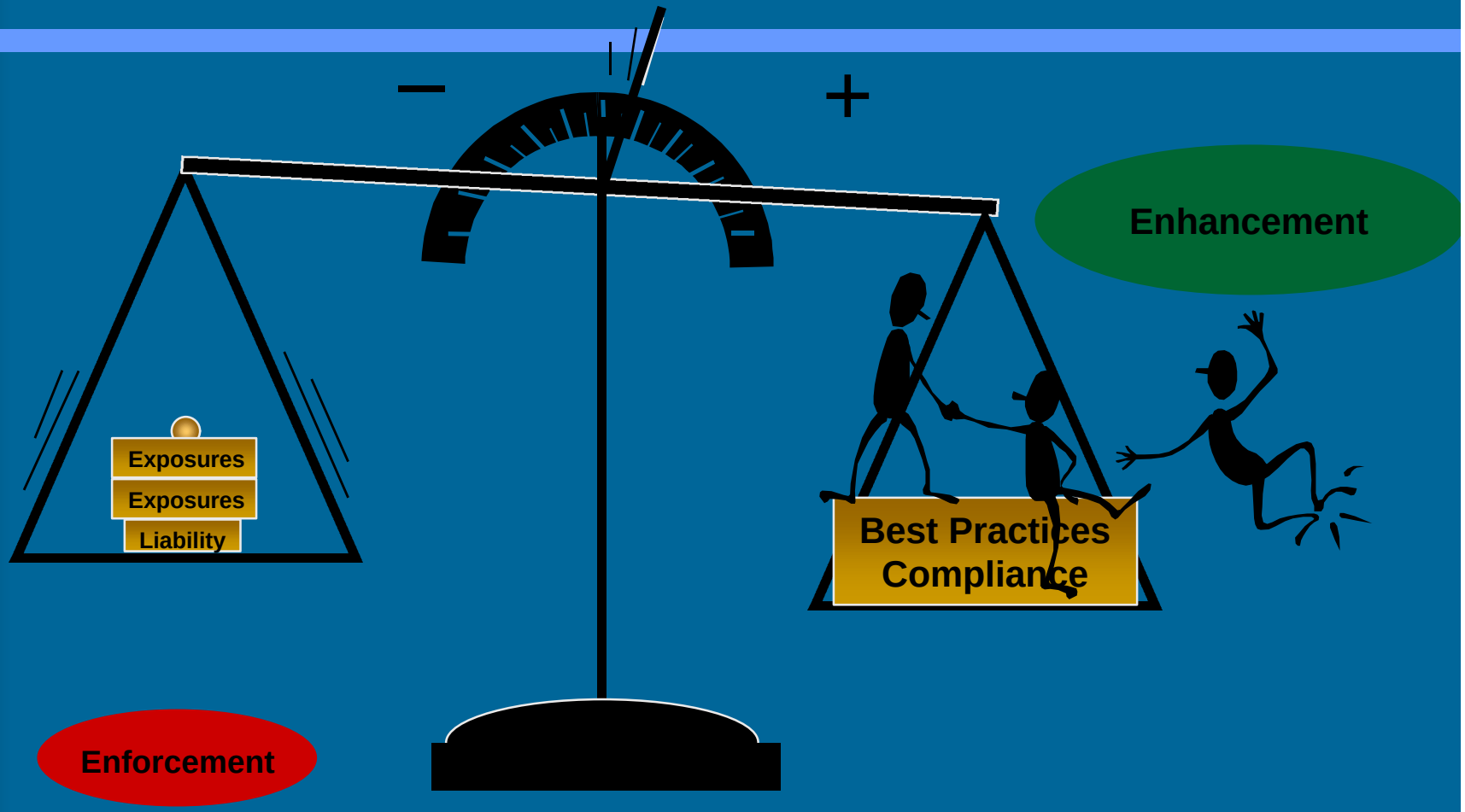
- **Better State**: Primary Goal of Compliance Becomes Organization Enhancement Through Compliance Linked to Best Practices, With Enforcement Avoidance As an Integral Result.

Compliance Strategies for a New Era in Clinical Research *(Current State)*



Goal: Negative Metrics Avoidance

Compliance Strategies for a New Era in Clinical Research *(Better State)*



Goal: Positive Metrics of Better Regulatory/IP Compliance and Higher IP Portfolio Value, Security and Transferability

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- **Traditional Compliance Elements**
- Organization Commitment
- Leadership
- Compliance Program

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Vii. A New Way of Thinking About Research Compliance

- Continuous Assessment of and Improvement to All of the Traditional Compliance Elements
- Continuous Commitment to Best Practices in All Compliance Actions, Where Compliance Is Benchmarked *Not* to Minimum Requirements but to Best Practices Including Recognized Optimal Performance Standards and Methods
- Integrated Compliance System Oriented to Best Practices

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VII. A New Way of Thinking about Research Compliance (continued)

- Rapid responses to all key compliance exposure areas
- Continuous compliance improvement based on measurement to Best Practice goals

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Viii. Benefits and Payoffs

- Higher and More Secure Organization Value
- Ability to Improve Organization Performance
- Ability to Document and Demonstrate Research and Development Compliance to Government Regulatory and Grant-making Agencies, the Investment Community and the General Public
- Proactive Self-protection Against the Expansion of Anti-fraud and Abuse Regulatory Initiatives Into Biomedical and Life Sciences Research and Development

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- **Benefits and Payoffs (Continued)**
  - Assurance That Scientific Insights and Discoveries of Enormous Potential and Market Value Are Identified Rather Than Missed or Lost During the Research Process
  - Ability of an Organization to Identify, Protect, Better Value and Leverage Intellectual Property in Leading Intellectual and Commercial Capital Marketplaces

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IX. Adverse Events Reporting Benefits the Public

- Adverse Events Occur With Both Pre-approved And Approved
- A Recent Examples
- Difference Between Clinical Setting and Real-World Setting
- Importance of Rapid, Complete, Accurate ADR Documentation in Clinical Trials
- Various ADR Reports for Drugs, Medical Devices and Biologics
- Various Realms of Federal Oversight

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- **Recent Developments**
- Modification of Declaration of Helsinki Highlights the Importance of Benefits Outweighing Risks in Clinical Trials (10/00)
- NIH Investigators To Submit Monitoring Plans for Phase I and Phase II Clinical Trials (10/00)
- Draft Guidance for Industry Post-marketing Safety Reporting for Conflict-of-interest (03/01)
- Draft Guidance for Acceptance of Foreign Clinical Studies (03/01)
- ICH seeks to Implement Common Technical Documents (CTDs) for Exchange of Information (05/01)

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XI. Summary and Questions and Answers