

Health Care 2010: Managing Risks in the New Compliance and Enforcement Environment

New York City, April 26, 2010

Atlanta and New Brunswick Groupcast Locations,
April 26, 2010

Live Webcast, April 26, 2010 — www.pli.edu

Why You Should Attend

The time couldn't be better to get up-to-date on all of the recent changes in health care law. And with the recently passed health care reform bill you may well be wondering – what now? Get prepared for these changes (and more) by attending PLI's brand new program, **Health Care 2010: Managing Risks in the New Compliance and Enforcement Environment**. Join our expert faculty, including speakers from the FDA, FTC, DOJ, OMIG, an IRB (Harvard), and in-house and outside counsel, as we examine the new reform bill, as well as recent enforcement initiatives, including the focus on FCPA violations by pharmaceuticals, the creation of HEAT, and prosecutions of executives under the FDCA.

This program will cover the broad range of issues confronting you and your clients today: structuring compliant relationships with health care providers and clinical investigators; scientific discourse and promotional guidelines affecting FDA-regulated products; federal and state compliance and investigation issues, including issues arising under disclosure, false claims, anti-kickback, and Stark laws; ethical issues in advising clients in the health care industry; and, of course, health care reform developments affecting your client.

What You Will Learn

- Scientific discussion vs. Off-label promotion
- Pharma Marketing: Internet and new social media
- False claims, anti-kickback, and Stark laws
- State and federal financial disclosure requirements (pending Physician Payments Sunshine Act of 2009 and new state laws)
- Clinical Investigator disclosure and compliance requirements
- Structuring and organizing a compliance program: who, where and when
- Health Care Reform: compliance and enforcement initiatives

Who Should Attend

This program is designed for health care attorneys (newly admitted and experienced) and allied professionals.

FACULTY



Co-Chairs:

Susan W. Berson

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Program Attorney: Grace O'Hanlon

PROGRAM SCHEDULE

Please plan to arrive with enough time to register before the conference begins. A networking breakfast will be available upon your arrival.

Morning Session: 9:00 a.m. – 1:00 p.m.

9:00

Opening Remarks and Introduction

Susan W. Berson, Ellen J. Flannery

9:15

Promotion, Advertising and Marketing

- Scientific discussion vs. Off-label promotion
- Internet and new social media
- Reimbursement interplay issues
- Enforcement activities

*Scott D. Danzis, Leonard L. Gordon, Karen S. Lovitch,
Kathleen M. Sanzo*

10:30 *Networking Break*

10:45

Structuring Compliant Provider Relationships

- False claims, anti-kickback, and Stark laws
- State and federal financial disclosure requirements (pending Physician Payments Sunshine Act of 2009 and new state laws)
- Codes of conduct and other guidance
- Case Studies

*Laurence J. Freedman, Robert A. Hussar, Margaret Hutchinson,
Paul Kaufman*

12:00

Legal and Ethical Issues in Clinical Studies

- Clinical Investigator disclosure and compliance requirements
- Disclosure of Financial Relationships in scientific publications and other venues
- Comparative effectiveness

*Kate Cook, Christina M. Markus, Michele K. Russell-Einhorn,
Sally Strauss*

1:00 *Lunch*

Afternoon Session: 2:00 p.m. – 5:00 p.m.

2:00

Health Care Reform: Impact on Compliance and Enforcement Initiatives

- Expanded authority and initiatives
- Funding under health reform
- Enhanced enforcement tools
- Agency operational changes

*Clifford E. Barnes, Kathleen K. Hogan, David W. Ogden,
Andrew J. Strenio, Jr.*

3:30 *Networking Break*

3:45

Compliance Function: Protecting Your Business

- Structuring and organizing a compliance program: who, where and when
- Internal auditing
- Self-disclosure
- Running an investigation

*Keith M. Korenchuk, Michael D. Quinlan, Jeff Rosenbaum,
Michael C. Theis*

5:00 *Adjourn*

Reserve your place today, call (800) 260-4PLI or visit www.pli.edu.

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