SPECIAL EARLY/EARLY BIRD RATES EXPIRE AUGUST 7, 2009

THE FOURTH NATIONAL FDA REGULATORY SYMPOSIUM

Addressing FDA's Regulatory Agenda for 2010 and Beyond

A Hybrid Conference & Internet Event

See pg. 2

September 30 – October 2, 2009 • Renaissance Washington DC Hotel

KEYNOTE ADDRESS BY:

Margaret A. Hamburg, MD, Commissioner of Food and Drugs, FDA; Former Commissioner, Department of Health and Mental Hygiene, New York City

FDA LEADERS:

Thomas W. Abrams, RPh, MBA, Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research (CDER), FDA

Jonathan Sackner Bernstein, MD, Associate Center Director, Post Market Operations, Center for Devices and Radiological Health (CDRH), FDA

Sarah Goldkind, MD, Senior Bioethicist, FDA

Sanjay J. Koyani, Director, FDA Web Communications, Office of Public Affairs, FDA

Robert Temple, MD, Associate Director for Medical Policy, Center for Drug Evaluation and Research, FDA

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), FDA

LEADING LEGAL AND REGULATORY PROFESSIONALS:

Ed Berg, Esq., Deputy General Counsel, Sanofi-Aventis

Marc L. Berger, MD, Vice President, Global Health Outcomes, Eli Lilly and Company

Cathryn M. Clary, MD, MBA, Vice President, US External Medical Affairs, Pfizer

John Ferguson, MD, PhD, Vice President and Global Head, Pharmacovigilance, Vaccines and Diagnostics, Novartis Pharmaceuticals

Rekha Garg, MD, Executive Director, Global Regulatory Affairs and Safety, Amgen

Elisabeth M. George, Vice-President , Quality, Regulatory, Sustainability & Product Security, Philips Medical Systems, Inc.

Kay Holcombe, Senior Policy Advisor, Genzyme Corporation

Elizabeth V. Jobes, Esq., Chief Compliance Officer, Adolor Corporation

Geoffrey Levitt, Esq., Vice President and Chief Regulatory Counsel, Wyeth Pharmaceuticals

John Moriarty, Esq., Senior Vice President, Legal/Commercial Operations, Elan; Former Executive Director & Associate General Counsel, Amgen; Former Special Assistant United States Attorney

Michael Morton, Senior Director Global Regulatory Affairs, Medtronic Corporation

Marc Wilenzick, Esq., Assistant General Counsel, Pfizer

FORMER FDA CHIEF COUNSEL:

Sheldon Bradshaw, Esq., Partner and Co-chair, Food and Drug Practice Group, Hunton & Williams LLP; Former Chief Counsel 2005 – 2007, Office of the General Counsel, FDA

Nancy L. Buc, Esq., Partner, Buc & Beardsley, LLC, Former Chief Counsel 1980 – 1981, Office of the General Counsel, FDA

Richard Cooper, Esq., Partner, Williams & Connolly, LLP; Former Chief Counsel 1977 – 1979, Office of the General Counsel, FDA

Peter Barton Hutt, Esq., Senior Counsel, Covington & Burling; Former Chief Counsel 1972 – 1975, Office of the General Counsel, FDA

Gerald F. Masoudi, Esq., Partner, Covington & Burling; Former Chief Counsel 2007 – 2009, Office of the General Counsel, FDA, Deputy Assistant Attorney General, International, Policy and Appellate Matters, Antitrust Division, US Department of Justice

SPECIAL PRECONFERENCE SESSION ON CLINICAL TRIALS

SPECIAL PRECONFERENCE SESSION ON DANGEROUS DOCUMENTS:

Nancy Singer, Esq., President, Compliance-Alliance, LLC; Former Special Counsel, AdvaMed; Founder, AdvaMed Medical Technology Learning Institute

Silver Grantor: SIDLEY AUSTIN LLP SIDLEY

A GREEN EVENT Details on Website

Bronze Grantors: Davis Wright Tremaine LLP DEFINING SUCCESS TOGETHER; Huron CONSULTING GROUP; KING & SPALDING

Sponsored by: HEALTH AFFAIRS; HARVARD health policy REVIEW; RX COMPLIANCE REPORT

THE FOURTH NATIONAL FDA REGULATORY SYMPOSIUM

Addressing FDA's Regulatory Agenda for 2010 and Beyond

Conference Overview

Rarely has the life science industry been met with so many major changes and uncertainties with such far-reaching consequences to drug development, manufacturing, monitoring and marketing. And rarely has there been a greater need to bring leaders from the FDA and Congress together with thought leaders from industry and outside experts to share strategies for regaining consumer confidence in today's medicines.

Who Should Attend

Senior executives and managers of pharmaceutical companies, especially those responsible for the oversight of:

- Regulatory affairs
- Pharmacovigilance
- Drug manufacturing
- Quality management systems
- Medical affairs
- Clinical research
- Risk management
- Labeling
- Legal affairs
- Sales and marketing

Learning Objectives

- To examine the latest changes at the FDA—including new people, policies and priorities—and prepare for more changes to come
- To hear directly from FDA's top leaders the agency's priorities and programs for drug safety, REMS, Safe Use, comparative effectiveness, health outcomes, and other key initiatives
- To formulate ideas and discuss specific successful strategies for reducing risks throughout the life cycle of a product—from development to delivery
- To understand the impact of new guidance, new enforcement trends, and recent changes in federal preemption
- To hear directly from Congressional leaders, key staff, and outside experts how healthcare reform is likely to impact the FDA and industry

Symposium Media Partners

The Harvard Health Policy Review is dedicated to broadening awareness of health policy issues and aims to educate people about healthcare policy and to stimulate thinking about the pressing healthcare questions facing the nation and the world. The *HHPR* is published by Exploring Policy in Health Care at Harvard and is supported by the University-wide Interfaculty Initiative in Health Policy. *www.HHPR.org*

Health Affairs is the leading journal of health policy thought and research. The journal was founded in 1981 under the aegis of Project HOPE, a nonprofit international health education organization. *Health Affairs* explores health policy issues of current concern in both domestic and international spheres. *www.HealthAffairs.org*

Rx Compliance Report is the only news source devoted exclusively to the government's crackdown on pharmaceutical sales and marketing practices. This 12-page bi-weekly newsletter uncovers emerging investigations and offers practical firsthand advice on implementing effective compliance programs. *Rx Compliance Report* focuses on the state and federal agencies leading these fraud and abuse investigations including the U.S. Dept. of Justice, the HHS OIG, state Attorneys General, state Medicaid Fraud Control Units, and other federal agencies. *www.RxComplianceReport.com*

The Time is Now for New, Efficient and Cost-Effective Alternatives to Traditional Learning Approaches!

MANY DIFFERENT FORCES—the nation's economic crisis, costly and difficult air travel, the mandate for cost efficiency in healthcare, the proliferation of greater Internet bandwidth, the emergence of the popularity of online video via You Tube, and the explosion of online training in the health sector—have come together to create both a dramatic need and an extraordinary opportunity for innovative approaches to sharing new ideas and best practices. This Symposium offers not only traditional conference attendance, but also the opportunity to attend the event live and archived online.

How can we be expected to reform the nation's health system if we cannot reform the way we do our own business?

Participation Options

Traditional Onsite Attendance

Simply register, travel to the conference city and attend in person.

PROS: subject matter immersion; professional networking opportunities; faculty interaction.

Onsite

Live and Archived Internet Attendance

Watch the conference in live streaming video over the Internet and at your convenience at any time 24/7 for the six months following the event.

At your office . . .

The archived conference includes speaker videos and coordinated PowerPoint presentations.

PROS: Live digital feed and 24/7 Internet access for next six months; accessible in office, at home or anywhere worldwide with Internet access; avoid travel expense and hassle; no time away from the office.

. . . or home

Wednesday, September 30, 2009 • Preconference Agenda (Optional; Choose one)

PRECONFERENCE I: CLINICAL TRIALS

7:00 AM — REGISTRATION

8:00 AM — WELCOME AND INTRODUCTIONS

Mark DeWyngaert, PhD, Managing Director, Huron Consulting Group, LLC, New York, NY (Chair)

8:15 AM — NEW TRENDS IN CLINICAL RESEARCH: INCREASED OVERSIGHT AND TRANSPARENCY

Elizabeth V. Jobes, Esq., Chief Compliance Officer, Adolor Corporation; Former Senior Director, Global Compliance Officer, Cephalon, Inc.; Former Assistant District Attorney, Philadelphia District Attorney's Office, Exton, PA

Nikki Reeves, JD, MPA, Partner, FDA & Life Sciences Practice Group, King & Spalding, Washington, DC

9:00 AM — MITIGATING THE GROWING RISK POSED BY THE FCPA AND GLOBAL ANTI-BRIBERY REGULATIONS

Peter S. Spivack, Esq., Partner, Hogan & Hartson, Former Assistant United States Attorney, Central District of California, Washington, DC

9:30 AM — UNDERSTANDING THE NEW COMPLEXITIES OF CLINICAL TRIALS FROM RESULTS REPORTING AND FMV TO OFF-LABEL PROMOTION AND AGGREGATE SPEND

Debjit Ghosh, Managing Director, National Life Sciences Practice, Huron Consulting Group, New York, NY

Mark DeWyngaert, PhD, Managing Director, Huron Consulting Group, LLC, New York, NY

10:15 AM — BREAK

10:45 AM — REGULATORY ISSUES ASSOCIATED WITH MULTI-REGIONAL TRIALS

Sarah Goldkind, MD, Senior Bioethicist, Food and Drug Administration, Silver Spring, MD

Karen J. Maschke, PhD, Editor, *IRB: Ethics and Human Research,* The Hastings Institute, New York, NY

Kevin Shulman, MD, Associate Director, Duke Clinical Research Institute; Professor of Medicine, Director, Center for Clinical and Genetic Economics; Vice-chair for Business Affairs, Department of Medicine, School of Medicine, Duke University; Director, Health Sector Management Program, Fuqua School of Business, Durham, NC

Marc Wilenzick, Esq., Assistant General Counsel, Pfizer; Former Assistant Chief Counsel, Food and Drug Administration, New York, NY

NOON — PRECONFERENCE ADJOURNMENT; LUNCH ON YOUR OWN

PRECONFERENCE II: DANGEROUS DOCUMENTS: FINDING LAND MINES IN YOUR FDA REPORTS AND EMAILS

During this interactive session, attendees will learn how prosecutors and plaintiffs' lawyers can take sentences from memos and emails out of context and have them imply inappropriate conduct.

Specifically this session will cover:

- Who can be held criminally liable under the law
- What FDA investigators look for when reviewing documents
- The risks of leaving blanks and using white-out in required records
- How to distinguish between fact and opinion
- The dangers in not monitoring employees emails
- Types of information never to include in documents
- Words that will attract the attention of prosecutors or plaintiffs' lawyers
- Why it is crucial to follow a document retention program
- How to build a program to avoid dangerous documents

8:00 AM — WELCOME AND INTRODUCTION

Nancy Singer, Esq., President, Compliance-Alliance, LLC; Former Special Counsel, AdvaMed; Founder, AdvaMed Medical Technology Learning Institute, Arlington, VA

NOON — PRECONFERENCE ADJOURNMENT; LUNCH ON YOUR OWN

Wednesday, September 30, 2009 • Day I Opening Plenary Session

1:00 PM **Welcome, Introductions And Opening Comments on FDA's Regulatory Agenda**

Peter J. Pitts, President, Center for Medicine in the Public Interest; Director of Global Healthcare, Porter Novelli; Former Associate Commissioner for External Relations, Food and Drug Administration, New York, NY (Co chair)

1:15 PM **Keynote Address: The FDA's Regulatory Agenda for 2010 and Beyond**

Margaret A. Hamburg, MD, Commissioner of Food and Drugs; Food and Drug Administration; Former Commissioner, Department of Health and Mental Hygiene, New York City, Silver Spring, MD

2:00 PM **FDA's Drug Approvals and Safe Use Initiative: A New Paradigm for Drug Safety**

Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD

THE PERSPECTIVE OF FORMER CHIEF COUNSEL

2:45 PM **Off-Label Promotion: Will FDA's Draft Off-Label Guidance Survive?**

Gerald Masoudi, Esq., Partner, Covington & Burling; Former Chief Counsel, Office of the General Counsel, Food and Drug Administration, Washington, DC

3:15 PM **Law-shaped Incentives and Criminal Enforcement**

Richard Cooper, Esq., Partner, Williams & Connolly, LLP; Former Chief Counsel, Office of the General Counsel, Food and Drug Administration, Washington, DC

3:45 PM **Break**

4:15 PM **New Directions in Federal Preemption**

Sheldon Bradshaw, Esq., Partner and Co-chair, Food and Drug Practice Group, Hunton & Williams LLP; Former Chief Counsel, Office of the General Counsel, Food and Drug Administration, Washington, DC

4:45 PM **FDA What Lies Ahead?**

Nancy L. Buc, Esq., Partner, Buc & Beardsley, LLC, Former Chief Counsel, Office of the General Counsel, Food and Drug Administration, Washington, DC

PERSPECTIVE ON THE FUTURE OF THE FDA

5:15 PM **Perspective on the Future of the FDA**

Scott Gottlieb, MD, Resident Fellow, American Enterprise Institute; Former Commissioner for Medical and Scientific Affairs, Food and Drug Administration; Former Senior Adviser to the Administrator, Centers for Medicare & Medicaid Services, Washington, DC

5:45 PM **Closing Keynote Address: The Role of the FDA in Health Reform**

Mark McClellan, MD (Invited), Director, Engelberg Center for Health Care Reform; Senior Fellow in Economic Studies and Leonard D. Schaeffer Director's Chair in Health Policy Studies; Brookings Institution; Former Commissioner, Food and Drug Administration; Former Administrator, Centers for Medicare and Medicaid Services, Washington, DC

6:30 PM **Adjournment and Opening Networking Reception**

Thursday, October 1, 2009 • Day II

7:00 AM **Registration**

8:00 AM **Welcome and Introductions: Reflections on Future Regulatory Challenges of the FDA**

Scott Bass, Esq., Partner and Chair, Global Life Sciences Team, Sidley Austin LLP, Washington, DC (Co chair)

8:15 AM **FDA's Device Approval and Safety Initiatives**

Jonathan Sackner Bernstein, MD, Associate Center Director, Post Market Operations, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, Silver Spring, MD

DRUG SAFETY AND RISK MANAGEMENT

8:45 AM **The Future of Drug Safety: An Insider's View of Key Initiatives**

John Ferguson, MD, PhD, Vice President and Global Head, Pharmacovigilance, Vaccines and Diagnostics, Novartis Pharmaceuticals, Florham Park, NJ

9:15 AM **The Evolution of Risk Evaluation Mitigation Strategies (REMS)**

Rekha Garg, MD, Executive Director, Global Regulatory Affairs and Safety, Amgen, Thousand Oaks, CA

Meredith Manning, Esq., Partner, Hogan & Hartson, Former Assistant US Attorney, Civil Division, US Attorney's Office; Former Associate Chief Counsel, Food and Drug Administration, Washington, DC

10:00 AM **Break**

10:30 AM **New Directions in Life Cycle Risk Management**

Elisabeth M. George, Vice President, Quality, Regulatory, Sustainability & Product Security, Philips Medical Systems, Inc., Andover, MA

Michael Morton, Senior Director Global Regulatory Affairs, Medtronic Corporation, Minneapolis, MN

Mary Ellen Turner, MD, MPH (Invited), Vice President, Global Safety, Surveillance & Epidemiology, Wyeth Pharmaceuticals, Collegeville, PA

Axel K. Olsen, PhD, Executive Director, Pharmacovigilance and Risk Management, Quintiles; Former Vice President of Global Medical Operations, Wyeth (Moderator)

11:15 AM **Perfect Storm: Recent Developments in Risk Management, Preemption and Product Liability**

Howard L. Dorfman, Esq., Counsel, Ropes & Gray, Former Chief Legal Officer, Pharmaceutical Division, Bayer Healthcare LLC; Former Counsel, US Medicines Group, Bristol-Myers Squibb, New York, NY

Geoffrey Levitt, Esq., Associate General Counsel and Chief Regulatory Counsel, Wyeth Pharmaceuticals, Collegeville, PA

12:00 PM **Confronting China's New Drug Safety Paradigm**

Scott Bass, Esq., Partner and Chair, Global Life Sciences Team, Sidley Austin LLP, Washington, DC

12:30 PM **Networking Luncheon**

1:30 PM **Introduction to Afternoon Session**

Jennifer Lynn Bragg, Esq., Partner, FDA & Life Sciences Practice Group, King & Spalding; Former Associate Chief Counsel for Enforcement, Food and Drug Administration, Washington, DC (Co chair)

COMPARATIVE EFFECTIVENESS AND HEALTH OUTCOMES

1:45 PM **The Impact of Comparative Effectiveness on the FDA**

Robert Temple, MD, Associate Director for Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, DC

2:15 PM **Comparative Effectiveness and Health Outcomes: Beyond the FDA**

Ed Berg, Esq., Deputy General Counsel, Sanofi-Aventis, Bridgewater, NJ

Marc L. Berger, MD, Vice President, Global Health Outcomes, Eli Lilly and Company, Indianapolis, IN

Coleen Klasmeier, Esq., Partner, and Chair, FDA Regulatory Practice Group, Sidley Austin LLP; Former Staff Attorney and Special Assistant to the Chief Counsel, Food and Drug Administration, Washington, DC

Robert Temple, MD, Associate Director for Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, Washington, DC

DRUG AND DEVICE ADVERTISING REGULATION

3:00 PM **An Update on FDA Drug Enforcement and New Guidance**

Thomas W. Abrams, RPh, MBA, Director, Division of Drug Marketing, Advertising, and Communications, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD

3:30 PM **Break**

4:00 PM **An Update on FDA Device Enforcement and New Guidance**

Timothy Ulatowski, Esq. (Invited), Director, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, Silver Spring, MD

4:30 PM **New Trends in Social Media and New Media**

Jennifer Lynn Bragg, Esq., Partner, FDA & Life Sciences Practice Group, King & Spalding; Former Associate Chief Counsel for Enforcement, Food and Drug Administration, Washington, DC

Sanjay J. Koyani, MPH, Director, FDA Web Communications, Office of Public Affairs, Food and Drug Administration, Rockville, MD

John Moriarty, Esq., Senior Vice President, Legal/Commercial Operations, Elan; Former Executive Director & Associate General Counsel, Amgen; Former Special Assistant United States Attorney, South San Francisco, CA

Robin Strongin, President and Chief Executive Officer, Amplify Public Affairs, Washington DC (Moderator)

5:30 PM **Adjournment**

HOTEL INFORMATION/RESERVATIONS

A special rate of $289 single/double per night (plus tax) has been arranged for Symposium Attendees. Please make your hotel reservations online via the FDA dedicated booking website: **https://resweb.passkey.com/go/FDARegandCompSymposium2009** or by calling the FDA reservation phone line directly at: 800-266-9432 and mention the FDA Symposium to receive the special, group rate. Reservations will be accepted until 4 PM Eastern, Wednesday, September 16, 2009. After this cutoff date, reservations will be accepted on a space-available basis at the prevailing rate.

RENAISSANCE WASHINGTON DC HOTEL
999 9th Street, NW • Washington DC 20001

Direct: 800-468-3571 • 202-898-9000
Reservations: 800-266-9432 or
https://resweb.passkey.com/go/FDARegandCompSymposium2009

Friday, October 2, 2009
Day III Closing Plenary Session

7:00 AM REGISTRATION

8:00 AM WELCOME AND INTRODUCTIONS

Peter Barton Hutt, Esq., Senior Counsel, Covington & Burling; Chief Counsel 1972 - 1975, Office of the General Counsel, Food and Drug Administration, Washington, DC (Co chair)

8:15 AM KEYNOTE ADDRESS:

Senator Charles Grassley (R-IA) (Invited), Ranking Member, Senate Finance Committee, United States Senate, Washington, DC

8:45 AM KEYNOTE ADDRESS:

Congressman Henry A. Waxman (D-CA) (Invited), Chairman, Committee on Oversight and Government Reform, and Member, Committee on Energy and Commerce, United Sates House of Representatives, Washington, DC

9:15 AM FDA'S GLOBAL REACH

Claudio Pincus, President, The Quantic Group, Ltd., Livingston, NJ

R. Owen Richards, President, Quantic Regulatory Services, LLC, Livingston, NJ

9:45 AM PANEL: FDA/DRUG MARKETING LEGISLATION

Kay Holcombe, Senior Policy Advisor, Genzyme Corporation; Former Deputy Associate Commissioner for Legislative Affairs, Food and Drug Administration; Former Senior Health Policy Advisor, Committee on Energy and Commerce, US House of Representatives; Former legislative Staff, Committee on Labor and Human Resources, US Senate, Cambridge, MA

Steven E. Irizarry, Esq., Senior Vice President, Capitol Hill Consulting Group; Former Senior Health Counsel, Special Committee on Aging, United Sates Senate, Washington, DC

Amanda Makki, Legislative Assistant, Health Care - Office of Senator Lisa Murkowski (R-AK), United States Senate, Washington, DC

Jack Mitchell, Chief of Oversight and Investigations, Special Committee on Aging, United Sates Senate; Former CNN Reporter, Washington, DC

John F. Kamp, JD, PhD, Executive Director, Coalition for Healthcare Communication; Of Counsel, Wiley Rein, Washington, DC (Moderator)

10:45 AM BREAK

11:00 AM STRIKING THE RIGHT BALANCE: HOW TO MANAGE CONFLICTS OF INTEREST IN THE WAKE OF THE IOM REPORT AND CONGRESSIONAL REFORM PROPOSALS

Eric G. Campbell, PhD, Associate Professor, Harvard University, Institute for Health Policy; Committee, Member, Conflict of Interest in Medical Research, Education and Practice, Institute of Medicine, Boston, MA

Cathryn M. Clary, MD, MBA, Vice President, US External Medical Affairs, Pfizer, New York, NY

Peter J. Pitts, President, Center for Medicine in the Public Interest; Former Associate Commissioner for External Relations, Food and Drug Administration, New York, NY

Wayne L. Pines, President, Regulatory Services and Healthcare, APCO Worldwide, Former Associate Commissioner for Public Affairs, Food and Drug Administration, Washington, DC (Moderator)

NOON CLOSING COMMENTS

Peter Barton Hutt, Esq., Senior Counsel, Covington & Burling; Chief Counsel 1972 - 1975, Office of the General Counsel, Food and Drug Administration, Washington, DC (Co chair)

12:30 PM ADJOURNMENT

THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY

REGARDING INTERNET REGISTRATIONS

1. Individuals or groups may register for Internet access. Organizations may register for group access without presenting specific registrant names. In such instances the registering organization will be presented a series of user names and passwords to distribute to participants.

2. Each registrant will receive a user name and password for access.

3. Internet registrants will enjoy six (6) months access from date of issuance of user name and password.

4. Only one user (per user name and password) may access archived conference. It is not permissible to share user name and password with third parties. Should Internet registrants choose to access post conference content via alternative media (Video iPOD™, CD-ROM and Flash Drive), this individual use limitation applies. It is not permissible to share alternative media with third parties.

5. User name and password use will be monitored to assure compliance.

6. Each Internet registration is subject to a "bandwidth" or capacity use cap of 5 gb per user per month. When this capacity use cap is hit, the registration lapses. Said registration will be again made available at start of next month so long as registration period has not lapsed and subject to same capacity cap.

REGARDING ONSITE REGISTRATION, CANCELLATIONS AND SUBSTITUTIONS

1. For onsite group registrations, full registration and credit card information required for each registrant. List all members of groups registering concurrently on fax or scanned cover sheet.

2. For onsite registrants there will be no refunds for "no-shows" or for cancellations. You may send a substitute; please call the Conference Office at 1-800-684-4549 for further information.

METHOD OF PAYMENT FOR TUITION

Make payment to Health Care Conference Administrators LLC by check, MasterCard, Visa or American Express. Credit card charges will be listed on your statement as payment to Health Care Conference Administrators LLC. Checks or money orders should be made payable to Health Care Conference Administrators LLC. A $20 fee will be charged on any returned checks.

PAYMENT OPTIONS

Registration may be made online or via mail, fax or scan.

You may register online at www.FDASymposium.com.

Alternatively, you may use our printed registration form, enclose payment and return it to the Symposium registrar at 3291 West Wilson Road, Pahrump, NV 89048, or fax the completed form to 760-418-8084 or scan the completed form to registration@hcconferences.com. Checks or money orders should be made payable to Health Care Conference Administrators LLC.

The following credit cards are accepted: American Express, Visa or MasterCard. Credit card charges will be listed on your statement as payment to Health Care Conference Administrators LLC.

For registrants awaiting company check or money order, a credit card number must be given to hold registration. If payment is not received by seven days prior to the Symposium, credit card payment will be processed.

TAX DEDUCTIBILITY

Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor.
Federal Tax ID: 91-1892021.

CONTINUING EDUCATION UNITS (CEUs)

The Symposium does not offer CEUs; however, on-site attendees may request a Certificate of Attendance which they can present to their specific continuing education provider.

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THE FDA SYMPOSIUM

REGISTRATION FORM

HOW TO REGISTER: Fully complete the following (one form per registrant, photocopies acceptable). Payment must accompany each registration (U.S. funds, payable to Health Care Conference Administrators, LLC).

ONLINE: Secure online registration at www.FDASymposium.com.

FAX: 760-418-8084 (include credit card information with registration)

MAIL: Conference Office, 3291 West Wilson Road, Pahrump, NV 89048

FOR REGISTRATION QUESTIONS:

PHONE: 800-684-4549 (Continental US, Alaska and Hawaii only)
Monday-Friday, 9 AM - 5 PM PST

E-MAIL: registration@hcconferences.com

(Registration is not available by phone or e-mail.)

COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:

NAME

SIGNATURE OF REGISTRANT - REQUIRED

JOB TITLE

ORGANIZATION

DEPARTMENT

ADDRESS

CITY/STATE/ZIP

TELEPHONE

FAX - Please include fax number if you wish to receive a confirmation letter.

E-MAIL

❑ Special Needs (Dietary or Physical)

ONSITE CONFERENCE ATTENDANCE

Onsite conference registration includes onsite attendance, professional networking, and live interaction with the faculty, plus a conference materials Data-DVD.

PRECONFERENCE REGISTRATION:

9/30 Morning Preconferences

❑ Preconference I - Clinical Trials $ 495

❑ Preconference II - Dangerous Documents: Finding Land Mines in Your FDA Reports and Emails $ 495

CONFERENCE REGISTRATION:

(Does not include Preconference):

❑ Through Friday, August 7, 2009 $1,395

❑ Through Friday, September 4, 2009 $1,595

❑ After Friday, September 4, 2009 $1,795

GROUP REGISTRATION DISCOUNT:

Three or more registrations submitted from the same organization at the same time receive the following discounted rates for conference registration only. To qualify, all registrations must be submitted simultaneously:

Conference:

❑ Through Friday, August 7, 2009 $ 995

❑ Through Friday, September 4, 2009 $1,195

❑ After Friday, September 4, 2009 $1,395

ONLINE CONFERENCE ATTENDANCE

All online registrants are registered for the preconferences and conference.

Online conference registration includes live Internet feed from the Symposium, plus six months of continued archived Internet access, available 24/7.

As an alternative to post-conference archived internet access, online conference registrants may choose to access post-conference content in one of the following media: 8GB Video iPOD™ Nano (for additional $150 charge), CD-ROM and Flash Drive.

INDIVIDUAL REGISTRATION:

Includes preconferences and conference:

❑ Through Friday, August 7, 2009 $ 995

❑ Through Friday, September 4, 2009 $1,195

❑ After Friday, September 4, 2009 $1,395

GROUP REGISTRATION:

Group Registration offers the substantial volume discounts set forth below. All group registrants are enrolled in the preconferences and conference.

Group registration offers the possibility of implementing an FDA Regulatory online training program. Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track conference participation by employees.

Conference Access:

❑ 5 or more $595 each ❑ 20 or more $395 each

❑ 10 or more $495 each ❑ 40 or more $295 each

See INTELLECTUAL PROPERTY POLICY policy below.

Terms and Conditions, continued

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Unauthorized sharing of Symposium content via Internet access through the sharing of user names and passwords or via alternative media (30GB Video iPOD™, CD-ROM and Flash Drive) through the sharing of said media is restricted by law and may subject the copyright infringer to substantial civil damages. The Symposium aggressively pursues copyright infringers.

If a registrant needs the ability to share Symposium content within his or her organization, multiple Symposium registrations are available at discounted rates.

The Symposium will pay a reward for information regarding unauthorized sharing of Symposium content. The reward will be one half of any recovery resulting from a copyright infringement (less legal fees and other expenses related to the recovery) up to a maximum reward payment of $25,000. The payment will be made to the individual or individuals who in the opinion of our legal counsel first provided the factual information, which was necessary for the recovery.

If you have knowledge regarding the unauthorized Symposium content sharing, contact the Symposium registration office.

GENERAL TERMS AND CONDITIONS

The Symposium program is subject to change. An executed registration form constitutes binding agreement between the parties.

FOR FURTHER INFORMATION

Call 1-800-684-4549, send e-mail to registration@hcconferences.com, or visit our website at www.FDASymposium.com.

PAYMENT

DISCOUNT CODE

TOTAL FOR ALL OPTIONS, ONSITE OR ONLINE:

Please enclose payment with your registration and return it to the Registrar at The FDA Symposium, 3291 West Wilson Road, Pahrump, NV 89048, or fax your credit card payment to 760-418-8084.
You may also register online at www.FDASymposium.com.

❑ Check/money order enclosed (payable to Health Care Conference Administrators LLC)

❑ Payment by credit card: ❑ American Express ❑ Visa ❑ Mastercard

If a credit card number is being given to hold registration only until such time as a check is received it must be so noted. If payment is not received by seven days prior to the Symposium, the credit card payment will be processed. Credit card charges will be listed on your statement as payment to Health Care Conference Administrators LLC.

TOTAL $

ACCOUNT #

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NAME OF CARDHOLDER

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