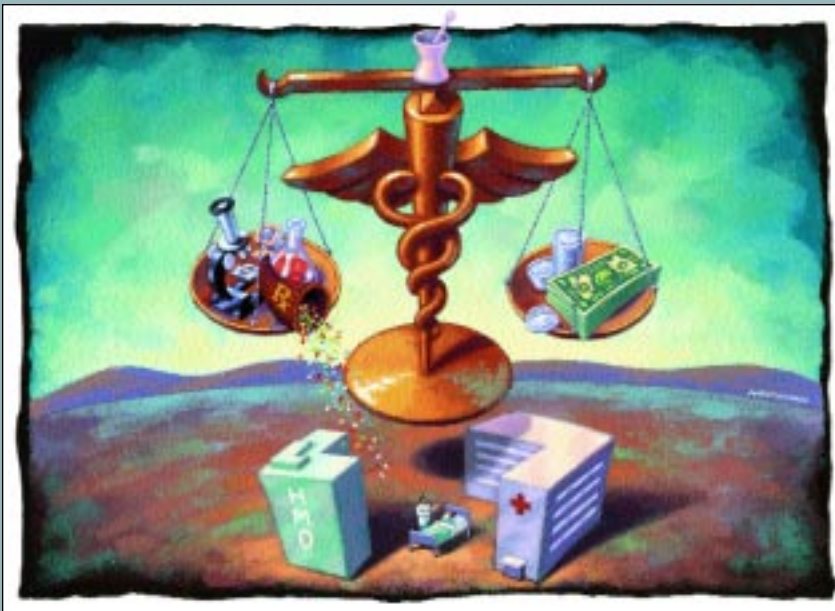


The First Annual Pharmaceutical Industry Regulatory & Compliance Summit



Featured Speakers:

John Bentivoglio, Esq., Partner, Arnold & Porter and Former Associate Deputy Attorney General and Special Counsel for Health Care Fraud, Department of Justice

William McCongha, Esq., Associate Chief Counsel, US Food and Drug Administration, Office of the Chief Counsel

Carolyn J. McElroy, Director, Maryland Medicaid Fraud Control Unit

Lewis Morris, Assistant Inspector General for Legal Affairs, Office of the Inspector General in the US Department of Health and Human Services

Arvin P. Schroff, Ph.D., Arvin Schroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration

James Sheehan, Esq., Assistant US Attorney and Chief of the Civil Division, US Attorney's Office for the Eastern District of Pennsylvania

Loretta Stipa, Resident Agent-in-Charge, FDA's Office of Criminal Investigations

Participating Pharmaceutical Companies Include:

Aventis
Express Scripts
Merck
Pharmacia
Smithkline Beecham
Warner-Lambert

*Wednesday October 18, 2000
Grand Hyatt Hotel, Washington, DC*

*Co-Sponsored by:
Health Care Compliance Association*



*in association with the
Food and Drug Law Institute*



*and  Medical Education Collaborative
A Nonprofit Education Organization*

THE FIRST ANNUAL PHARMACEUTICAL INDUSTRY

The Issue

Over the past few years, the pharmaceutical industry has come under increased scrutiny from the federal government. The US Government and the FDA have begun to more rigorously enforce the rules and regulations that apply to the pharmaceutical industry. Until recently, the majority of the government's enforcement efforts have focused on health care providers. Now pharmaceutical companies are finding themselves under the gun. Pharmaceutical companies are being forced to update their knowledge of existing laws and incorporate them into their business plans as well as create future business plans that comply with the often ambiguous and confusing federal regulations. Critical issues such as drug pricing, sales and marketing practice, conducting clinical trials and a proposed Medicare prescription drug benefit are many topics that will be discussed at this important summit.

The Summit

The First Annual Pharmaceutical Industry Regulatory and Compliance Summit has been established as a direct result of the heightened need for corporate compliance programs, increased government scrutiny and new regulations being imposed upon the pharmaceutical industry. It will bring together the nation's leaders in the pharmaceutical industry. This one-day conference, sponsored by the Health Care Compliance Association in association with the Food and Drug Law Institute will be held October 18, 2000, at the Grand Hyatt Hotel, Washington, DC.

Pharmaceutical professionals looking for a comprehensive understanding of the current and future compliance laws and regulations and enforcement initiatives affecting the pharmaceutical industry should plan to attend.

Sponsoring Organizations

The First Annual Pharmaceutical Industry Regulatory & Compliance Summit is sponsored by:

The Health Care Compliance Association (HCCA), the 501(c)(6) association representing approximately 2000 of the nation's healthcare chief compliance officers. HCCA offers a number of programs. For more information on HCCA, call 1-800-580-8373 or go to the HCCA website at www.hcca-info.org.

In Association with the:

Food and Drug Law Institute (FDLI) is a non-profit institute dedicated to advancing the public health by providing a neutral forum for critical examinations of the laws, regulations, and policies related to drugs, medical devices, other healthcare technologies, and food. For more information call (800) 956-6293 or visit www.fdpi.org.

Extensive Written Materials

The Faculty of the Summit will prepare written materials to accompany their presentations, including copies of presentation overheads, slides and related materials that will be included with the summit materials.

Who Should Attend:

Health Care Executives and Board Members
Health Plan, Health System and Physician Organization Medical Directors
Physicians
Pharmacists
Registered Nurses
Purchasers, including Private Employers and Public Purchasers
Pharmaceutical Manufacturers
Generic Pharmaceutical Manufacturers
Site Management Organizations
Clinical Research Organizations
Pharmacy Benefit Management Companies
Health Plans and Health Insurers
Wholesale, Retail, Mail Order and Internet Pharmacies
Health Care Attorneys and In-house Counsel
Compliance Officers
Privacy Officers
Ethics Officers
Pharmaceutical Consultants
Investment Bankers
Venture Capitalists
Health Care Regulators and Policy Makers
Health Services Researchers and Academics

Summit Goals and Objectives

At the conclusion of the Summit, attendees should be able to:

- Discuss the regulators' enforcement initiatives pertaining to the pharmaceutical industry.
- Explain how clinical trials should be conducted and build controls to mitigate potential risk.
- Relate to case studies that demonstrate how multinational corporations expanded their compliance programs to international operations.
- Take appropriate steps if a government investigation is initiated.
- Discuss the legal and ethical issues raised by advances in Genomics.
- Apply practical tips about implementing compliance programs in Pharmaceutical Companies.
- Understand the FDA labeling and advertising requirements and build compliance programs around those requirements.
- Appreciate the field of BioEthics and its relation to the pharmaceutical industry.
- Understand legal obstacles associated with promoting drugs on the internet and develop strategies to deal with them.
- Learn drug sample regulations and develop strategies for dealing with them.
- Gain appreciation for applicability of HIPAA statute to the pharmaceutical industry and learn compliance strategies.
- Learn the do's and don'ts of government pricing and develop necessary controls to bill Medicaid.

Prerequisites: None

SAVE THE DATE: NOVEMBER 15 – 17, 2000

*The National Congress on the Future of Genomics,
Biotechnology & Pharmaceuticals in Medical Care*

Hyatt Regency Hotel, Crystal City, VA

www.PharmaCongress.com • 888-294-3504

REGULATORY & COMPLIANCE SUMMIT

Wednesday, October 18th

- 8:00 am Welcome
- 8:00 – 8:30 am The OIG's Enforcement Initiatives in the Pharmaceutical Industry
Lewis Morris, *Assistant Inspector General for Legal Affairs, Office of the Inspector General in the US Department of Health and Human Services*
- 8:30 – 9:00 am State Enforcement Initiatives in the Pharmaceutical Industry
Carolyn J. McElroy, *Director, Maryland Medicaid Fraud Control Unit*
- 9:00 – 9:30 am A Federal Prosecutor's Perspective on the Pharmaceutical Industry
James Sheehan, Esq., *Assistant US Attorney and Chief of the Civil Division, US Attorney's Office for the Eastern District of Pennsylvania*
- 9:30 – 10:00 am Insights into the Department of Justice's Enforcement Initiatives
John Bentivoglio, Esq., *Partner, Arnold & Porter and Former Associate Deputy Attorney General and Special Counsel for Health Care Fraud, Department of Justice*
- 10:00 – 10:30 am FDA Enforcement Initiatives
Arvin P. Schroff, Ph.D., *Arvin Schroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration*
- 10:30 – 11:00 am Regulator Q & A
Questions and answers with the morning presenters.
- 11:00 – 11:30 am Break
- 11:30 am – 12:30 pm
- CONCURRENT SESSIONS I**
- A. The Practical Implications of the Anti-Kickback Laws to Pharmaceutical Sales and Marketing
Joseph Metro, Esq., *Partner, Reed Smith Shaw & McClay*
Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company*
- B. Clinical Trials: Compliance Implications and Solutions
Larry McDade, Esq., *Office of Consumer Litigation, Department of Justice*
Loretta Stipa, *Resident Agent-in-Charge, FDA's Office of Criminal Investigations*
Claudia Baldassano, MD, *University of Pennsylvania*
- C. Compliance on a Global Scale: How to Shape a Compliance Program for a Multinational Pharmaceutical Company
Bert Weinstein, Esq., *Vice President and Assistant General Counsel, Merck & Co., Inc.*
Caroline West, Esq., *Vice President, Global Litigation and Compliance, Aventis Pharmaceuticals*
- D. "Houston We Have a Problem" What to Do When the Feds Come Knocking
Mike Kendall, Esq. (Moderator), *Partner, McDermott, Will & Emery*
Rick Robinson, Esq., *Partner, Fulbright & Jaworski*
Patricia Meador, Esq., *Partner, Womble, Carlyle Sandridge & Rice*
- 12:30 – 2:30 pm Luncheon and Presentations
- 1:00 – 1:30 pm The Legal and Ethical Issues Raised by Advances in Genomics
Barbara P. Fuller, JD, RHIA, *Senior Policy Advisor, National Human Genome Research Institute, National Institutes of Health*
- 1:30 – 2:30 pm Compliance Roundtable
Eric Siegel, Esq., *Counsel, SmithKline Beecham*
Valli Baldassano, Esq., *Director, Global Compliance, Pharmacia Corporation*
Janice Forsyth, Esq., *Chief Compliance Officer, Express Scripts, Inc.*
Douglas M. Lankler, Esq., *Counsel, Worldwide Corporate Compliance, Warner-Lambert Company*
Brent L. Saunders, JD, MBA (Moderator), *Director, PricewaterhouseCoopers*
- 2:30 – 2:45 pm Break
- 2:45 – 3:45 pm
- CONCURRENT SESSIONS II**
- A. Compliance with FDA Labeling and Advertising Requirements
Louis Morris, Ph.D., *Senior Vice President, SCP Communications*
Robert B. Nicholas, Esq., *Partner, McDermott, Will & Emery*

CONCURRENT
SESSIONS II
Continued

- B. **BioEthics and the Pharmaceutical Industry**
Art Kaplan, Ph.D., *Center for Bio-Ethics, University of Pennsylvania*
- C. **Internet Drug Promotions: Legal and Compliance Issues**
Douglas Snyder, Esq., *Senior Counsel, SmithKline Beecham*
William McCongha, Esq., *Associate Chief Counsel, US Food and Drug Administration, Office of the Chief Counsel*
Stephen J. Haynes, Esq., *Vice President, Integrity Resource Group, Inc.*
- D. **PDMA Compliance & Drug Samples**
Raymond A. Bonner, Esq., *Partner, Sidley & Austin*
Donald O. Beers, Esq., *Partner, Arnold & Porter; Former Associate Chief Counsel, FDA*

3:45 – 4:00 pm

Break

4:00 – 5:00 pm

CONCURRENT
SESSIONS III

- A. **Applicability of HIPAA to the Pharmaceutical Enterprise and Potential Compliance Strategies**
Aidan Collins, *Partner, Deloitte & Touche LLP*
Paul T. Smith, Esq., *Partner, Davis Wright Tremaine*
Elizabeth E. Friberg RN, MSN, PAHM, *PricewaterhouseCoopers*
- B. **Using Technology to Build a Cooperative Relationship with FDA**
Janice McFarland, *Executive Vice President, EduNeering, Inc.*
- C. **Hot Topics: Recent Investigations and Probes**
Paul Kalb, MD, JD (Moderator), *Partner, Sidley & Austin*
Paul Silver, *Ernst & Young*
Joseph F. Savage, Jr., Esq., *Testa, Hurwitz & Thibault*
W. McKay Henderson, *Partner, PricewaterhouseCoopers LLP*
- D. **Medicaid Pricing Compliance**
Donna Boswell, Esq., *Partner, Hogan & Hartson*
Lynn Shapiro Snyder, Esq., *Partner, Epstein Becker & Green*
Anthony L. Farino, *Partner, PricewaterhouseCoopers*
Laurie Radler, *Partner, Deloitte & Touche LLP*

Continuing Education Credits



This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Collaborative and Health Care Conference Administrators, LLC. Medical Education Collaborative (MEC), a non-profit education organization, is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of this CME activity.

Medical Education Collaborative designates this educational activity for a maximum of 7.5 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.



Medical Education Collaborative, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Medical Education Collaborative, Inc. has assigned 7.5 contact hours/.75 CEUs of continuing pharmaceutical education credit. ACPE provider number: 815-999-00-067-L04

Participants will be required to sign in daily and complete an evaluation form for credit. Registration fee includes certificate, which will be mailed within six weeks after the meeting.

CNA (Nursing Credit) - This educational activity for 9 contact hours is provided by Medical Education Collaborative. Medical Education Collaborative is approved as a provider of continuing education in nursing by the Colorado Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

California BRN Provider Number: CEP-12990
Florida BN Provider Number: FBN-2773

ACHE - Medical Education Collaborative is authorized to award 7.5 hours of pre-approved Category II (non-ACHE) continuing education credit for this program toward advancement or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward Category II credit should list their attendance when applying for advancement or re-certification in ACHE.

ABA MCLE - Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 7.5 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of \$1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at (303) 278-1900 ext. 151 starting two to three weeks prior to the program date.

NASBA - Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN, 37219-2417. Telephone: 615-880-4200.

A maximum of 9 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

ACMPE - This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

HCCB - This program has been approved for 9 HCCB continuing education credits for compliance certification.

HOTEL ACCOMMODATIONS

Special rates of \$213 (plus tax) per single per night, and \$238 (plus tax) per double per night, have been arranged for The First Annual Pharmaceutical Industry Regulatory & Compliance Summit. **There are a limited number of rooms available at the special rate.** Please make your reservations directly with the Grand Hyatt Hotel and mention the First Annual Pharmaceutical Industry Regulatory & Compliance Summit to receive the reduced rate. Reservations will be accepted until Sept. 22, 2000. After that cut-off date, reservations will be accepted on a space-available basis only. Grand Hyatt Hotel, 1000 H Street, NW, Washington, DC 20001
Reservations: 202-582-1234

AIRLINE TRAVEL

Get there for less! HCCA has selected Stellar Access, Inc. (SAI; formerly Conventions in America) as the official travel agency for this meeting. Call 1-800-929-4242 and ask for Group #551 to receive the following discounts or the lowest available fares on any other carrier:

American Airlines and US Airways: Save 5-10% on the lowest applicable fares. Ask about applicable zone fares and discounts. All rules and restrictions apply. Travel between October 13 – 23, 2000.

Call SAI: 1-800-929-4242, ask for Group #551
Website: www.stellaraccess.com

NOTE: First time users must register and refer to Group # 551

- Lowest available fares on any airline
- Free flight insurance of \$100,000
- Save 50% on transaction fees – only \$10

Outside US & Canada, call 619-232-4298/fax 619-232-6497
Reservation Hours: M-F 6:30am – 5:00pm Pacific Time

If you call direct or use your own agency, refer to these codes:
American Airlines 1-800-433-1790 File# 75HOAS
US Airways 1-877-874-7687 GF#43651608

FAX OR MAIL REGISTRATION

Fax: 215-545-8107

Email: conference.office@hcca-info.org

No registrations will be accepted by phone.

Make payment by check (to Health Care Conference Administrators, LLC), MasterCard, Visa or American Express. A \$20 fee will be charged on any returned checks. Purchase orders must be paid by the conference date or payments will be required by the individual on site.

Groups: Have registration and credit card information for each person. List all group members on FAX cover sheet.

CANCELLATIONS/SUBSTITUTIONS

Cancellations must be received in writing *no later than September 18, 2000*. Registration fees, less a \$100 administrative fee, will be refunded following the program. No refunds will be given for “no-shows” or for cancellations made after September 18, 2000. You may send a substitute; please contact the Conference Office at 1-800-546-3750.

FOR FURTHER INFORMATION

Call 1-800-546-3750, Monday-Friday, 9AM – 5PM Eastern Time

REGISTRATION FORM

Before Oct. 1 \$649

After Oct. 1 \$749

TOTAL PAYMENT

Please type or print

Group discount available when two or more register from same organization. Save \$50 on second and all other registrations.

First Name

Last Name

Degrees

Title

ACHE Credentials:

CHE

FACHE

Place of Employment

Work Address or Home Address
(List only preferred mailing address)

Address

City

State

Zip

Daytime Phone ()

Fax ()

Years in Compliance

Position

Areas of Most Interest/Compliance Focus

Special Disability Needs

First name as it will appear on your badge

REGISTER TODAY!

Fax: 215-545-8107

Or mail this form with correct tuition fee (U.S. funds) to:
Conference Office, 1211 Locust Street, Philadelphia, PA 19107

PAYMENT TERMS

Please enclose payment with your registration and return it to the conference registrar at the above address, or fax your credit card payment to 215-545-8107. No registrations will be accepted by phone.

Check/money order enclosed

(checks payable to Health Care Conference Administrators, LLC)

American Express

Visa

MasterCard

Account No.

Name of Cardholder

Signature

Exp. Date

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.