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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. invitation	re: phone number (partial) (1 page)	04/21/1999	P6/b(6)
002a. letter	Patricia C. Donnelly to Christopher Jennings re: Medical System Reform Proposal (partial) (1 page)	03/14/1999	P6/b(6)
002b. report	Proposal for Medical system Reform re: phone number (partial) (2 pages)	01/27/1999	P6/b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Chris Jennings (Meetings, Trips, Events)
OA/Box Number: 17045

FOLDER TITLE:
Speaking Engagements (April, May, June 1999) [6]

2011-0747-S
rc424

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

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NOVARTIS HONORS MIKE AILSWORTH

PLEASE JOIN NOVARTIS CORPORATION
AND THE WASHINGTON OFFICE FOR A CELEBRATION
HONORING

MIKE AILSWORTH

FOR HIS 36 YEARS OF SERVICE TO THE COMPANY

Regrets, but pl send my best
~~best~~ wishes

YOU ARE CORDIALLY INVITED TO ATTEND
A FAREWELL RECEPTION FOR
MIKE AILSWORTH

APRIL 21, 1999
5 - 7 PM
B. SMITH'S AT UNION STATION

RSVP TO ERIN HALLSTROM
P6/(b)(6) [001]

NOVARTIS

HEALTHCARE EXECUTIVES' CLUB

2897 Saw Mill Road, Wantagh, New York 11793 Tel:(516)221-5277

March 30, 1999

Regrets

Chris Jennings
Deputy Assistant to the President, for Health Policy

via facsimile - (202) 456-5557

Dear Mr. Jennings:

As discussed with your secretary, Therese Jones, I had been referred to you by Howard Bedlin with regard to your availability to serve as our keynote speaker at our annual Stern Memorial Lecture, to be held the evening of Tuesday, April 20, 1999.

The event is co-sponsored by The Joint Industry Board of the Electrical Industry, (Local 3 IBEW), and will be held at their headquarters building on Parsons Boulevard and harry Van Arsdale Avenue, in Flushing.

The Healthcare Executives' Club is an affiliate organization of the American College of Healthcare Executives, and our membership includes management and administrative personnel in public and voluntary organizations in the New York City area, in hospitals, nursing homes, education, etc.

The Stern Lecture is attended by some 120 people, and is named in memory of our first president. The evening event begins with an informal cocktail party at 6 PM, a gourmet buffet at 6:45, and program at 7:30. We would ask that you speak for some half hour on the subject of the "Administration's Healthcare Initiatives for the Next Two Years", or such other topic as you would deem appropriate.

Thank you for your involvement, and we look forward to hearing from you. I may be contacted by phone at (516) 221-KARP (5277); by fax (516) 221-5279; or by e-mail at KARPEONCAL@AOL.COM, or I will call you early next week.

Sincerely,

Henry R. Karpe, M.S., FACHE
Chair, Stern Memorial Lecture

HRK:an

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#704

March 14, 1999

Mr. Christopher Jennings
Special Assistant to the President
for Healthcare
The White House
1600 Pennsylvania Avenue
Washington, D. C. 20500

Dear Mr. Jennings:

Re: **Medical System Reform Proposal**
Harrison Edward Donnelly
June 30, 1992 - February 7, 1997

On February 16th and 17th I met with fifty-seven legislative aids of Congress in Washington. Our purpose is to protect the patient while in their care of their physician and hospital: National standards for physicians and access to The National Practitioners' Data Bank so that consumers can make informed decisions about their doctor and hospital work history.

I will be in Washington again on Thursday, March 18th at the Capitol, the House and the Senate and will call your office and hope to have the opportunity to speak with you briefly.

Any day at your convenience I would appreciate meeting with you Mr. Jennings to discuss the issues of Medical Reform In August, 1998, I sent President Clinton the package for Medical Industry Reform.

Regards - Ark
Sarah if she can

Respectfully yours,

Patricia C. Donnelly

Patricia C. Donnelly

THE HARRY DONNELLY FOUNDATION

Post Office Box 42, Howard Beach, New York 11414

P6/(b)(6)

C002a3

PROPOSAL FOR MEDICAL SYSTEM REFORM

OUTLINE

FEDERAL ISSUES:

Correct weak **Monitoring** and **Accountability** by the Federal Health Regulatory Agencies. Limited/restricted access to consumers' need for health care information results in over 100,000 deaths annually in the United States.

1. **The National Practitioner's Data Bank: Repeal Article 28 of The Freedom of Information Act**

   Consumers have the right to evaluate their healthcare providers performance history.

   The consumers' ability to make informed decisions in selecting physician/hospital providers would reduce the healthcare budget for our government. Physician and hospital mistakes cost money. We, the taxpayers, pay for the right of access to the National Practitioners Data Bank.

2. **Federal Inquiry/Investigation into the Joint Commission on the Accreditation of Healthcare Organizations**

   The Joint Commission to be required to conduct inspections of hospital facilities unannounced. Many hospitals prepare for the Commission's inspections by increased staffing prior to the arrival of the inspectors. (See N.Y. Public Advocate Report, January 1998.)

   Monitoring and accountability of JCAHO's rating reports are weak. In a data base of 1,528 hospitals used for comparative analysis, only one percent received the Commission's lowest ranking. JCAHO's power is great - they inspect over 5,843 hospitals and over 10,000 healthcare facilities. Reduce Medicare and Medicaid funding by scrutinizing the findings of the JCAHO. They are treated as royalty when they set foot on the premises of the hospital they are about to inspect. Root out negligence and incompetence in hospitals - it cost us taxpayers money and the patient suffering or death. The JCAHO is a private organization loosely accountable to the Federal Government.

3. **Video Taping of Surgical Procedures**

   Reduce insurance and litigation costs. Provide improved services due to monitoring and accountability; e.g. reduce the needless injuries and deaths nationwide. Video taping is in-expensive and very effective and in line with other lesser forms of monitoring in the operating room. PROTECT THE PATIENT

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4. **Pharmaceutical Industry**

See The New York Times, Monday, January 25, 1999: "Steep Increases Seen In Charges for Drugs" - some increases run as high as 300% or more. This industry is the most lucrative within the United States and weakly regulated. Cost versus product research of all pharmaceutical agents is long overdue. Intense marketing of both prescription and over-the-counter drugs unduly influence physician and consumer alike. Thirty-five percent (35%) of all hospital admissions of senior citizens are directly attributable to adverse reactions from prescription and over-the-counter drugs.

The physician must be mandated to report adverse drug reactions to **MedWatch** at the Food and Drug Administration (1-800-FDA-1088) - less than 10% of physicians report their patients adverse events from prescription or over-the counter drugs. Please refer to "Bitter Pills: Inside the Hazardous World of Legal Drugs," by Stephen Fried and "Prescription for Disaster," by Thomas Moore, "Worst Pills, Best Pills," by Public Advocate, Sidney Wolfe.

According to the Office of the Inspector General of the Dept. of Health and Human Services and auditors of the Health Care Financing Administration and the General Accounting Office report, the Medicare system is rife with corporate fraud and ripoffs. Let our representatives in Congress scrutinize the compensation, bonus and 'perks' of the administrators of the HMOs and hospital hierarchy while they instruct their analysts to reduce or deny benefits to the citizens of our great country.

"The Federal government must demand full public disclosure from all managed care plans in plain English about the nature of the care they give and the complaints that each plan accrues each year. State authorities and insurance departments should be able to perform audits on demand to check on quality of care and costs." "Due Consideration" by A. Caplan (1998)

The key to correcting the multifarious deficiencies within the healthcare industry is scrutiny: Monitoring and Accountability. Every member of the United States Senate and United States House of Representatives must join together to correct the glaring deficiencies within the healthcare industry. Examine the issues of FRAUD, NEGLECT, INCOMPETENCE AND EXCESSIVE GREED FOR THE ASTRONOMICAL RISE IN HEALTH CARE

Patricia Donnelly
Post Office Box 42, Howard Beach, New York 11414
P6/(b)(6)
(00263)
1-27-99.

PROPOSAL FOR MEDICAL SYSTEM REFORM

OUTLINE

STATE ISSUES:

1. **Mandatory Continuing Education for Physicians/Physician Assistants and Nurses**
   The rapid technological advances within the medical industry demand knowledge and skills of new procedures. Continuing education of these healthcare providers would result in less costly mistakes. Skilled and knowledgeable healthcare practitioners = fewer errors. Please see the Pew Commissions study, November 16, 1998.

2. **Hospital Care**
   Inspection of hospital facilities should be placed back in the hands of State Department of Health. The Joint Commission on the Accreditation of Healthcare Organizations is a private agency. The State Department of Health is the regulatory agency and they alone should oversee hospital inspections. In a database of 1,528 hospitals used for comparative analysis, only one percent of the hospitals received the Commissions's lowest ranking. The vast majority, 85% received the highest possible score.

3. **Video Taping of Surgical Procedures**
   Reduce insurance and litigation costs. Provide improved services by hospitals, physicians due to monitoring and accountability, e. g. reduce the needless injuries and deaths. It is inexpensive and very effective - in line with other lesser forms of monitoring.

   It is estimated that 2,380 surveillance cameras are trained on public spaces in New York City. (The New York Times Metro Sunday, December 13, 1998.) There is no patient advocate in the operating room while the patient is in an utterly helpless state.

4. **Restructure Physician Licensing Board**
   Currently two physicians and a lay person are chosen from a pool of 200 appointed to the Board. Multi-healthcare professionals must be included to better and more fairly evaluate alleged physician negligence and/or incompetence. We strongly recommend the inclusion on the Board of: Physician Assistant, Nurse, Nurse Practitioner, Pharmacologist, PATIENT ADVOCATE and a CONSUMER. Please see the Pew Commission study, Nov. 16, 1998

   "If airline pilots were as poorly regulated as physicians, we would have one plane crashing every day killing 200 people," said Dr. Wolfe of Public Citizen Health Research Group. Medical Boards are predominantly staffed by doctors who appear disinclined to judge their colleagues sufficiently incompetent to lose the right to practice. Board members are generally less sympathetic toward immoral behavior such as drug use or sexual exploitation of patients.

STATE Proposal For Medical System Reform Outline

5. **Protect Our Children**
The State Department of Health must create a drug interaction data base whereby it would be mandatory for the anesthesiologist to review the drug interaction chart before writing up the anesthesia plan. The surgeon also would be required to sign off on the review of the drug interaction data base - AND learn what drug to be used to counteract an adverse reaction.

6. **The Pharmaceutical Industry**
Thirty-five percent of all hospital admissions of senior citizens are directly attributable to adverse reactions from prescription and over-the-counter drugs. It is indeed a hazardous world of legal drugs as minimal tracking of drug interactions are recorded in a nationwide data base and drug adverse reactions.

BEFORE the physician writes a prescription - informed consent should apply. The patient must be informed of the benefits, risks and alternative to taking the drug. The number of children across the country taking Ritalin, estimated at well over three million, more than doubled the 1990 figure. (See The New York Times article of January 28, 1999.)

The physician must be mandated to report adverse drug reactions to **MedWatch**, at the Food & Drug Administration (1-800-FDA-1088) - less than 10% of physicians report their patients adverse events from prescription or over-the-counter drugs. Please refer to "Bitter Pills: Inside the Hazardous World of Legal Drugs" by Stephen Fried, "Prescription for Disaster" by Thomas Moore and "Worst Pills, Best Pills" by Public Advocate Sidney Wolfe.

Beginning with the Governor of the State of New York and every member of the New York State Senate and Assembly - ALL - must join together to correct the glaring deficiencies within the Health Care Industry ***and Prevent the tragic, unnecessary deaths of over 200,000 men, women and children each year in our country.***

It is the obligation of the State to protect the public.

Patricia Donnelly
Post Office Box 42, Howard Beach, New York 11414
P6/(b)(6)
1-27-99

FACCT
Foundation for Accountability

Date: April 08, 1999

To:
Christopher Jennings
Phone:
Fax: 202-456-5557

From: Foundation for Accountability
Fay Reynolds
Phone: 503-223-2228
Fax: 503-223-4336

Pages: ___3___

Subject:FACCT Leadership network - e-mail update

Unfortunately we do not have your e-mail address so we had to fax this instead. Could you please call us with an e-mail address so in the future you will receive this communication via e-mail. Also, we do not have a telephone number for you in our database - only your fax number. Please call us with your telephone number as well. THANKS!

520 SW Sixth Ave., Suite 700, Portland, OR 97204 (503)223-2228, Fax:(503)223-4336

The Board of Supervisors of the County of Los Angeles

Cordially Invites You
To A Reception

Wednesday, May 5, 1999
5:30 p.m. - 7:00 p.m.
B340 Rayburn House Office Building

RSVPs: 202-393-2404

faxed 4/15/99

The American College of Obstetricians and Gynecologists
and Representatives Sue Kelly (R-NY), Carolyn Maloney (D-NY),
Kay Granger (R-TX), and Juanita Millender-McDonald (D-CA)

invite you to

A Toast to Women's Health

Celebrating the Bipartisan Efforts of Members of Congress to
Promote Women's Health

Monday, April 19, 1999

6:30 - 8:00 pm

Eisenhower Lounge
The Capitol Hill Club
300 First Street, S.E.
Washington, D.C.

Name CHRISTOPHER JENNINGS

Title Deputy Assistant to the President For Health Policy

Office White House

✓ YES, I will attend ACOG's A Toast to Women's Health.

NO, I regret I am unable to attend.

_____ of my staff will attend in my place.

Please fax response to (202) 488-3985 by April 15, 1999

****
*** TX REPORT ***
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Washington, D.C.

Name CHRISTOPHER JENNINGS

PROGRESSIVE POLICY INSTITUTE

Regulating Medical Necessity: Is It Necessary?

Memorandum

To: **Health Care L.A.'s**

From: **Will Marshall, PPI President**

Subject: **Upcoming Event**

Date: **April 12, 1999**

In the debate over a patients' bill of rights, the issue of medical necessity is critical for both clinical and economic reasons. Managed care plans have restrained costs by denying coverage for services that are not medically necessary. As a result, health care costs are lower, but doctors and patients question whether managed care plans have gone too far in controlling medical care.

The legislative options before Congress range from regulating how health plans determine medical necessity to doing nothing. A third option is to require each health plan to disclose how they determine medical necessity and to use competition to punish plans that are overly restrictive.

To debate these options and others, the Progressive Policy Institute holding a briefing, ***Regulating Medical Necessity: Is it Necessary?*** It will feature David Eddy, Senior Advisor to Kaiser Permanente, Southern California, Sara Rosenbaum, Professor of Health Law and Policy at the George Washington University Medical Center, and David Kendall, Senior Analyst for Health Policy at the PPI.

Date: Tuesday, April 13, 1999
Time: 8:30 a..m. to 9:30am
Place: Room SC-4 in the Capitol.

We hope you will join us for this timely and informative event. Breakfast will be served. To RSVP, contact Kerrry Dobbins at PPI at (202) 547-0001.

PUBLIC HEALTH POLICY ADVISORY BOARD

Cancelled

April 12, 1999

Mr. Chris Jennings
Deputy Assistant to the President for Health Policy Development
Office of the President
216 Old Executive Office Building
Washington, DC 20502

Attention: Teresa Jones, Via Facsimile (202) 456-5557

Dear Mr. Jennings:

I am writing to request a brief meeting with you on April 16 for Dr. Maria New, a Distinguished Fellow of the Public Health Policy Advisory Board (PHPAB), to provide you with a preview of our upcoming report on children's health.

As you may know, the PHPAB is an independent, nonpartisan 501 (c)(3) organization founded by Louis W. Sullivan, M.D. to advance sound, science-based policy making in public health. The PHPAB's mission is to identify emerging public health issues, evaluate the relevant science available on these topics, stimulate public discussion, and recommend appropriate public policy priorities. Attached please find more information about our organization and a bio of Dr. New, Chairman of the Department of Pediatrics of Cornell University Medical College.

The PHPAB is currently preparing to release our first report, which will focus on children's health. This report will provide a comprehensive review of the leading causes of mortality in children and is designed to foster a dialogue about creating a national strategy for addressing children's health needs.

Given President Clinton's great interest in children's health issues, Dr. New would like the opportunity to provide you with the highlights of our work prior to the report's public release. Kathleen Siedlecki will be calling to follow up on this request, or you may call her directly at (202) 828-8871.

Thank you for your consideration.

Sincerely,

Marybeth Rossomando

Marybeth Rossomando, M.E.
Executive Director

Attachment

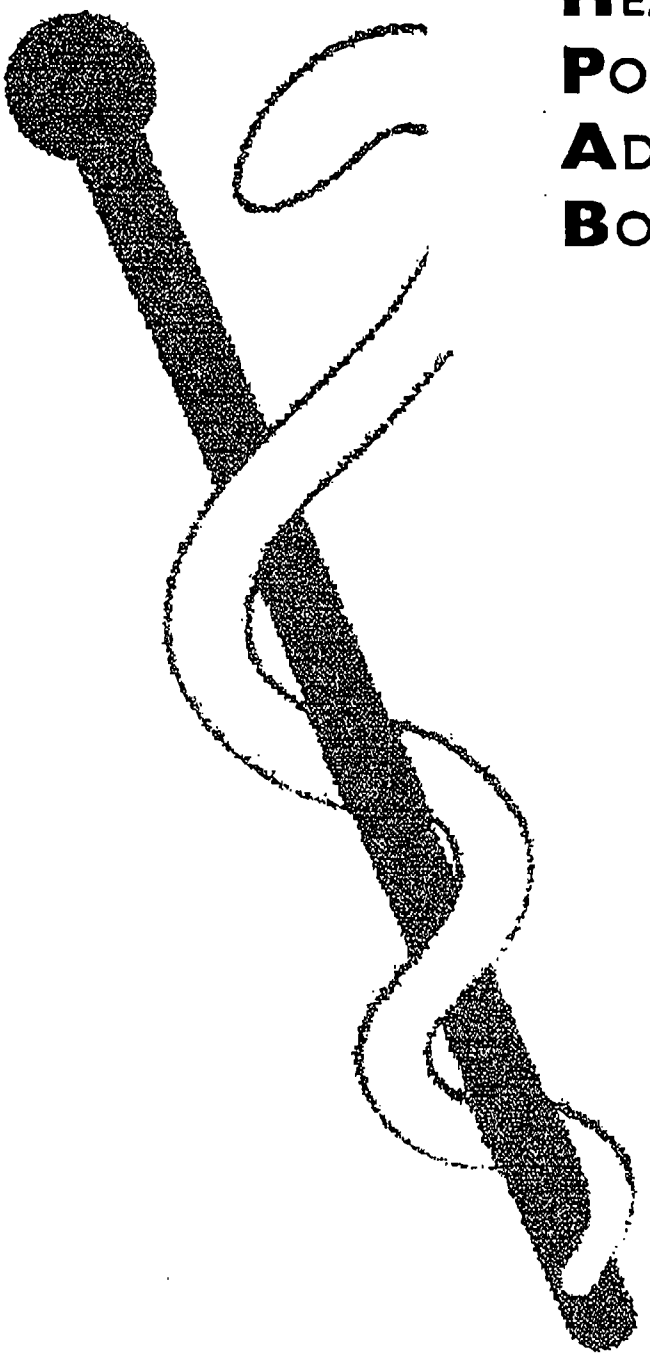
1350 EYE STREET, NW
SECOND FLOOR
WASHINGTON, DC 20005
202-312-8238 FAX: 202-842-2676
E-MAIL: PHPAB@EROLS.COM

Maria I. New, M.D.
Chairman,
Department of Pediatrics,
Cornell University Medical College

Dr. Maria New is the beneficiary of a long and distinguished career as a physician, teacher, and author. Since completing her M.D. at the University of Pennsylvania School of Medicine in 1954, Dr. New has earned the reputation as one of the nation's leading pediatric endocrinologists. She is now Chairman of the Department of Pediatrics at the Cornell University Medical College in New York as well as the division head of Pediatric Endocrinology and Pediatrician-in-Chief.

Dr. New serves on numerous boards and committees including Past President of the Endocrine Society; Panel Member of the Board of Appeals/Pediatric Endocrinology; organizing Chairperson, Kroc Foundation for "Estrogen Treatment of the Young"; member of the Food and Drug Administration's Endocrine Metabolic Drug Advisory Committee; board member of the Lawrentian Hormone Conference; various committees of the International Endocrine Society; and former Chairman of the Committee on Estrogen and Cancer, The Lawson Wilkins Pediatric Endocrine Society. She has not only maintained several editorial positions, but continues to serve on the Editorial Board of the Journal of Women's Health and is Corresponding Editor for the Journal of Steroid Biochemistry. In addition, Dr. New has nearly 500 published articles and papers.

Her professional and humanitarian efforts have been recognized with dozens of awards and honors including Elected Fellow, The American Academy of Arts and Sciences, 1992; Outstanding Woman Scientist, Metropolitan New York Chapter of American Women in Science (AWIS) 1986; the Due Case Award, International Partnership Program, Office of the Governor of New York State, 1990; Elected Member of the National Academy of Sciences, 1996; and the Basic Science Award for the Social Advancement of Women's Health Research, 1996.



PUBLIC HEALTH POLICY ADVISORY BOARD

1350 Eye Street, NW Washington, DC 20005

Mission: The Public Health Policy Advisory Board (PHPAB) is a private, independent, and nonprofit 501(c)(3) advisory body created and chaired by Louis W. Sullivan, M.D., the former Secretary of Health and Human Services and current President of Morehouse School of Medicine. The Distinguished Fellows of the PHPAB represent a broad range of expertise, including clinical medicine, epidemiology, risk analysis, and public policy. The PHPAB identifies emerging public health issues, evaluates the relevant science available on these topics, stimulates public discussion, and recommends appropriate public policy and priorities.

The PHPAB is designed to identify and prioritize critical health issues of highest concern, evaluate research findings and formulate policy recommendations based on its clinical, analytical, and policy experience. Drawing on the input of a wide range of experts and discussions at public forums, the Board's recommendations will be grounded in the best available science and reflect the most pressing public health priorities. The PHPAB will contribute its insights to policymakers, government officials, non-profit organizations, and industry as these groups develop public health policies and construct research agendas. The PHPAB will also serve as a credible and independent source of information on these issues for the media and the general public.

Structure:

The intellectual core of the PHPAB is its group of Distinguished Fellows: Dr. Patricia Buffler, Dean Emerita and Professor of Epidemiology at the University of California-Berkeley, School of Public Health; Dr. John Graham, Director of the Harvard Center for Risk Analysis; Dr. J. Donald Millar, former Director of the National Institute for Occupational Safety and Health; and Dr. Maria New, Chairman of the Department of Pediatrics at the New York Hospital-Cornell Medical Center. Former Surgeon General Antonia Novello also serves in a non-voting capacity. This group, known as the Executive Policy Committee, is responsible for policy and strategic management of the organization. The PHPAB is governed by a Board of Trustees, which is responsible for the organization's financial health and overall governance.

Financial Support:

Funding for the PHPAB comes from unrestricted grants from private industry and government, corporate, and non-profit organization conference grants. The PHPAB is actively seeking funding from diverse sources, including government, foundations, individuals and other groups. The PHPAB will act independently of all contributors and the Board's decisions on topic selection, policy, and research recommendations will not be subject to any endorsement or approval.

Operations:

The PHPAB will conduct periodic public forums on key diseases, risk factors, prevention, or policy issues. During these discussions recognized scientific experts and public health spokespersons will present medical, clinical, scientific, and policy

information. The PHPAB will consider these viewpoints and will issue its recommendations for public health policies and research.

The format for these open forums will vary depending on the topic, and will likely include panel discussions, town hall meetings, invited symposia, workshops, etc. After each meeting, the Board will issue a manuscript for publication in a scientific journal and/or an article in the general media outlining the Board's thinking on the public policy implications and priorities.

To ensure the highest quality discussions, the PHPAB will rely on representatives from well respected, internationally recognized academic institutions to participate and/or assist in the conduct of the meetings.

Based on the input from the various meetings and workshops, the PHPAB will:

- Evaluate the relative importance and impact of the emerging public health issue.
- Summarize the knowledge base that exists for the particular public health issue, based on the best available science. This would include the overall profile of the illness in the U.S. population, relative priority of risk factors, and preventive measures.
- Recommend a clear policy direction or objectives for the future, based on the current state of knowledge. The PHPAB will also evaluate the adequacy or appropriateness of current policies and related resource allocation.
- Recommend priorities for research to fill critical knowledge gaps that would substantially improve or inform policymaking. Research recommendations will consider the degree of scientific uncertainty surrounding the issue, particular risk factor, or preventive measure. The PHPAB will consider current research priorities and resource allocation in both the public and private sectors.

Issues:

Annually, the PHPAB will consider a list of possible candidate topics. The PHPAB will identify questions of critical importance by reviewing the findings and on-going discussions of key scientific and policy groups as well as monitoring issues of concern to the public and public interest groups, government, and industry.

To help select specific topics that are most in need of an independent examination, the PHPAB will place priority on issues where:

- the PHPAB has a unique contribution to make, which is not being made by other groups or institutions or which cannot be made by those groups;
- there is a window of opportunity to participate in the development of future public policy, research priorities, and resource allocation;
- the PHPAB can bring to consensus, or narrow the range of controversy, an issue where there is a wide spectrum of opinions, thereby enabling the advance of research or public policy;

- the PHPAB can place an issue in the larger public health context, to assess and advise policymakers on the relative allocation of resources and policy focus;
- the PHPAB can raise or address policy issues not currently being addressed or addressed adequately;
- the PHPAB can educate the lay public about complex scientific and policy questions, creating an environment where responsible balanced policy can be implemented.

The PHPAB may focus on specific health issues or broader, generic policy questions. In examining specific health issues, one of the unique perspectives that the PHPAB intends to bring is a consideration of a variety of risk factors that influence health status, such as genetic makeup, personal lifestyle, urban pollution, and economic circumstances. The PHPAB will consider information from animal toxicity studies, human epidemiology, public perception of risk, and other factors.

FOR IMMEDIATE RELEASE
December 10, 1998

CONTACT: Rica Guarnieri
202/828-9732

PUBLIC HEALTH POLICY ADVISORY BOARD STUDIES CHILDREN'S HEALTH PRIORITIES

New Organization Formed by Former HHS Secretary Sullivan Holds Workshop to Discuss Major Health Threats to Children Under 19

(WASHINGTON, DC) Pediatricians, researchers and public health policy professionals gather at the first Public Health Policy Advisory Board (PHPAB) workshop to discuss the current state of children's health in the United States. The workshop, **Children's Health Priorities: *Setting the Best Course for our Nation's Children***, is the first in a series of forums created to examine current and emerging health issues and to make policy recommendations to answer changing needs.

Issues to be examined at the workshop include causes of childhood death such as adolescent violence, child abuse, unintentional injury, drug and alcohol abuse and risk factors for disease that stem from both physical and social environments such as poverty, homelife breakdown and behavioral disorders.

In addition to the Public Health Policy Advisory Board's Distinguished Fellows (listed below), speakers featured at the workshop included Surgeon General David Satcher, M.D.; Mark Rosenberg, M.D., of the Centers for Disease Control and Prevention; and Martha Linet, M.D. of the National Cancer Institute. Public Health administrators presenting at the workshop are Commissioner Nick Scopetta of the State of New York Administration for Children's Services, Dr. James Ware, Ph.D., of the Harvard School of Public Health, and Dr. Thomas Boyce, M.D. of the University of California, Berkeley, School of Public Health.

Dr. Maria New, Chairman of the Department of Pediatrics at Cornell University Medical College, said of the workshop, "We are looking at a broad picture of threats to children's health and asking what things should be done and by whom, whether by government, schools or other outlets that reach children."

Discussion and information presented at the workshop, in addition to other data available and the expertise of a multi-disciplinary group of public health and medical leaders, will be used for a Report to the Nation on Children's Health Priorities scheduled to be issued during the first quarter of 1999 by PHPAB.

-more-

The PHPAB was created in 1997 by Dr. Louis Sullivan, M.D., Former Secretary of the Department of Health and Human Services under President Bush and President of Morehouse Medical School.

"I brought the members of PHPAB together because I saw a need for an objective voice in the public health policy arena. Frequently, when I was Secretary of HHS, I would see cases where there was little science but a lot of passion on both sides of an issue," said Dr. Sullivan, chairman of PHPAB.

The PHPAB was established as an independent, non-partisan, 501(c)(3) organization designed to advance sound, science-based policy making in public health. The organization will examine emerging and overlooked public health issues, evaluate the relevant science available, stimulate public discussion and make recommendations for appropriate public health policy and priorities.

PHPAB's Distinguished Fellows are:

- Louis Sullivan, M.D., *Chairman and CEO* of PHPAB; *President* Morehouse School of Medicine; *Former Secretary*, Department of Health and Human Services
- J. Donald Millar, M.D., D.T.P.H. (London), *Vice-Chairman* of PHPAB; *President*, Don Millar and Associates; *Former Director*, National Institute for Occupational Safety and Health; National Center for Environmental Health
- Patricia A. Buffler, Ph.D., M.P.H., *Dean Emerita* and *Professor of Epidemiology*, School of Public Health, University of California Berkeley
- John D. Graham, Ph.D., *Founding Director*, Center for Risk Analysis, Harvard School of Public Health
- Maria I. New, M.D., *Chairman*, Department of Pediatrics, Cornell University Medical Center
- Antonia C. Novello, M.D., M.P.H., *14th Surgeon General*, U.S.P.H.S.; *Visiting Professor*, Department of Health Policy and Management; *Special Director*, Community Health Policy, The Johns Hopkins University School of Hygiene and Public Health (non-voting member)

PROGRESSIVE POLICY INSTITUTE

Regulating Medical Necessity: Is It Necessary?

Memorandum

To: **Health Care L.A.'s**

From: **Will Marshall, PPI President**

Subject: **Upcoming Event**

Date: **April 5, 1999**

In the debate over a patients' bill of rights, the issue of medical necessity is critical for both clinical and economic reasons. Managed care plans have restrained costs by denying coverage for services that are not medically necessary. As a result, health care costs are lower, but doctors and patients question whether managed care plans have gone too far in controlling medical care.

The legislative options before Congress range from regulating how health plans determine medical necessity to doing nothing. A third option is to require each health plan to disclose how they determine medical necessity and to use competition to punish plans that are overly restrictive.

To debate these options and others, the Progressive Policy Institute holding a briefing, ***Regulating Medical Necessity: Is it Necessary?*** It will feature David Eddy, Senior Advisor to Kaiser Permanente, Southern California, Sara Rosenbaum, Professor of Health Law and Policy at the George Washington University Medical Center, and David Kendall, Senior Analyst for Health Policy at the PPI.

Date: Tuesday, April 13, 1999
Time: 8:30 a..m. to 9:30am
Place: Room SC-4 in the Capitol.

We hope you will join us for this timely and informative event. Breakfast will be served. To RSVP, contact Kerrry Dobbins at PPI at (202) 547-0001.

American Enterprise Institute for Public Policy Research

AEI

Invitation

HEALTH POLICY DISCUSSION

The 1999 Medicare Trustees' Reports: How Much Time for Reform?

Tuesday, April 6, 1999
9:15–11:30 a.m.
Wohlstetter Conference Center
Twelfth Floor, AEI

The 1999 Medicare Trustees' Reports released on March 30 present the Board of Trustees' first findings following a full year of operation under the changes included in the Balanced Budget Act of 1997. Many experts are predicting substantial changes from last year in the projections of future revenues and expenditures. Are the changes since last year permanent, leaving Medicare in better financial health? Or have the trustees been misled by temporary changes and bad data? What are the implications of the new reports on the future of Medicare and on the intense political debates surrounding it?

These and related issues will be discussed by a distinguished and knowledgeable panel consisting of Rick Foster, chief Medicare actuary; Dan Crippen, the new director of the Congressional Budget Office; Marilyn Moon, one of the two public trustees; Norman Ornstein, AEI; Robert Reischauer, the Brookings Institution; and Gail Wilensky, cochair of the Medicare Payment Advisory Commission. Discussion and questions from the audience will be encouraged.

8:45 a.m. Registration and Continental Breakfast

9:15 *Presentation:* RICHARD FOSTER, Health Care Financing Administration

Panelists: DAN CRIPPEN, Congressional Budget Office
MARILYN MOON, Urban Institute
NORMAN ORNSTEIN, AEI
ROBERT REISCHAUER, Brookings Institution
GAIL WILENSKY, Medicare Payment Advisory Commission

Moderator: ROBERT B. HELMS, AEI

11:30 Adjournment

1150 Seventeenth Street, N.W., Washington, D.C. 20036 202.862.5800 Fax 202.862.7178 http://www.aei.org

American Enterprise Institute for Public Policy Research

Registration Form

HEALTH POLICY DISCUSSION

The 1999 Medicare Trustees' Reports: How Much Time for Reform?

Tuesday, April 6, 1999
9:15–11:30 a.m.
Wohlstetter Conference Center, Twelfth Floor, AEI

Name _____

Title _____

Affiliation _____

Address _____

City/State/Zip _____

Telephone _____ FAX _____

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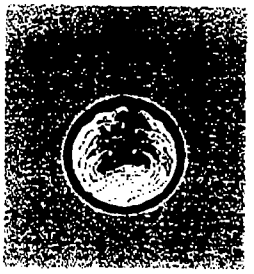
Send this form to : Seminars and Conferences
American Enterprise Institute
1150 17th Street, N.W.
Washington, D.C. 20036

Or FAX to Seminars and Conferences at 202.862.7171.

Contact Sharon Utz with any questions at 202.862.5865.



ASIAN HEALTH SERVICES

March 22, 1999

The Honorable Christopher Jennings
Deputy Assistant to the President for Health Policy
The White House
Washington D.C.

Tell them that the schedule precludes me from doing. See if Deborah would like to host. Will some folks from HHS. Thanks.

VIA FACSIMILE

Dear Mr. Jennings:

We met a while ago during health care reform discussions in Washington D.C. I appreciated your understanding and concern related to language access issues.

I respectfully request a meeting April 15 or 16 to discuss insuring the uninsured populations. Along with representatives from the Asian and Latino health community, including U.S. Civil Rights Commissioner Yvonne Lee, I would like to discuss innovative approaches to resolving this health dilemma. Additionally, we are interested in hearing more about the President's initiative to improve health care access for uninsured workers and how we can be of assistance to the Administration's efforts to insuring the uninsured population.

We have private and public funding to develop creative strategies to insure uninsured working immigrants. As you may be aware, that the majority of California's 7 million uninsured population are Latino and Asian. We would like to share our plans with you. We are addressing these issues through a Blue Ribbon Committee comprised of Congresswoman Barbara Lee, former Congressman Norman Mineta, California Health and Human Services Secretary Grantland Johnson, San Francisco Foundation CEO Dr. Sandra Hernandez, McKesson Legal Counsel Art Chong and George Washington University Professor Dr. Sara Rosenbaum.

We will also meet with Ms. Irene Bueno regarding immigration issues on April 16. I hope your schedule will permit us to meet. Please call Jeanette Dong, Community Voices Project Director at (510) 986-6898 if you have comments or questions.

Sincerely,

Sherry M. Hirota

Sherry M. Hirota
Executive Director

Sylvia Park
6830

cc: U.S. Civil Rights Commissioner Yvonne Lee

[redacted]
Main Office
818 Webster Street
Oakland, CA 94607-4220
Phone 510.986.6830
FAX 510.986.6890

[redacted]
Asian Medical Center Clinic
818 Webster Street
Oakland, CA 94607-4220
Phone 510.986.6800
FAX 510.986.6896

[redacted]
Adult Medical Services
at Hotel Oakland
275 Fourteenth Street
Oakland, CA 94612
Phone 510.986.8688

Mark Your Calendars!

The National Association of Area Agencies on Aging
24th Annual Conference & Exhibition

July 17-21 1999

DoubleTree Lloyd Center, Portland, Oregon

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Come explore the unique treasures the city has to offer as we discuss new ideas and innovations to prepare for the graying boomers in the 21st Century.

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We're looking forward to seeing you, so make a trail to Oregon, July 17-21, 1999.

For more information:
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(800) RPA-7525
(301) 468-3511
e-mail rpa@renalmd.org

March 22, 1999

Mr. Christopher Jennings
216 Old Executive Building
Washington, DC 20502

Dear Mr. Jennings:

A recent report from the National Health and Nutrition Examination Survey suggests that up to 12 million people in the United States have chronic renal disease (CRD). Presently the Health Care Financing Administration spends $14 billion annually to care for patients with end-stage renal disease (ESRD) and expenditures are expected to increase due to the projected 8% annual growth of this patient population. Individuals with ESRD comprise only a small percentage of the total population and related costs of people with CRD.

Early detection and treatment of individuals with CRD offers the promise of more effective intervention and prevention of ESRD and the other complications of CRD while challenging the traditional models of health care delivery. A more comprehensive strategy for the prevention, detection, evaluation and treatment of CRD is urgently needed to more appropriately address the needs of this growing population. This population presents challenges and opportunities for all sectors of the health care system.

The Renal Physicians Association, American Society of Nephrology, and National Kidney Foundation have joined together to plan a pivotal meeting to present opportunities for improving patient outcomes in the growing population of individuals who have chronic renal disease.

We invite you to join us on Monday, May 24, at the Westin Grand Hotel, 2350 M Street, NW, in Washington, DC, to learn more about the scope of chronic renal disease along with the renal community's proposed initiatives to reduce the impact of the disease and delay its progression to kidney failure.

(over)

Your participation in this meeting and support for one or more of our proposals is critical to the future of the nation's health care policies related to chronic renal disease. A preliminary agenda is enclosed for your information. Please return the enclosed registration form to confirm your participation in this meeting. If you have any questions, please contact Rob Blaser, RPA's Director of Federal Affairs, at 202-261-4551. Thank you in advance for your support!

Sincerely,
The Chronic Renal Disease Summit Planning Committee:

Joan Blondin, MD, and Ray Hakim, MD (Renal Physicians Association)

Andrew Levey, MD, and Roland Blantz, MD (American Society of Nephrology)

R. Michael Culpepper, MD (National Kidney Foundation)

Enclosures

CHRONIC RENAL DISEASE IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES

Sponsored by the Renal Physicians Association, American Society of Nephrology, and the National Kidney Foundation

May 24, 1999
The Westin Grand Hotel
2350 M Street, NW
Washington, DC

9:00 am	The Current Status of Chronic Renal Disease in the US and Challenges for the Future: The Nephrologist's Perspective	Dr. William Bennett
9:30 am	End-stage Renal Disease in the US: Outcomes and Opportunities for Prevention *Lessons Learned from the USRDS*	Dr. Raymond Hakim
10:10 am	Chronic Renal Insufficiency in the US: The Silent Disease *How Large is the Problem?*	Dr. Andrew Levey
10:45 am	Chronic Renal Insufficiency in Children in North America	Dr. Sandra Watkins
11:15 am	Opportunities for Early Intervention in Chronic Renal Insufficiency	Dr. Allen Nissenson
11:50 am	Working Together: Where Do We Begin?	Dr. Chaim Charytan
12:30 pm	Lunch Forum for Idea Exchange	Selected invitees
2:00 pm	Adjourn	

CHRONIC RENAL DISEASE IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES

Sponsored by
The Renal Physicians Association, American Society of Nephrology, and
The National Kidney Foundation

May 24, 1999 ◊ The Westin Washington, DC Hotel ◊ 2350 M Street, NW

REGISTRATION FORM

PRINT the information below as you would like it to appear on your badge:

NAME: Degree:

(First name or nickname)

(Last name)

CITY/STATE:

Mailing Address

FULL NAME: _____ Degree: _____

ORGANIZATION: _____

STREET ADDRESS: _____

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WORK PHONE: ( ) _____ FAX: ( ) _____

EMAIL: _____

Please return this form to the RPA office by May 10, 1999
4701 Randolph Road, Suite 102 • Rockville, MD 20852 • Phone: 301-468-3515 • Fax: 301-468-3511

RSVP *for*:
Capital Area Rural Health Roundtable Forum
Rural Health Workforce Programs:
Separating Myths from Realities

•April 15, 1999 • 3:00 PM – 5:00 PM (Reception to follow) •
RUSSELL SENATE OFFICE BUILDING, ROOM 236
When you arrive, please register and pick up your badge and packet.

Since the nation's first attempt to redress major shortages in health care with a supply-side boost in the numbers of graduating health professionals, public policy has come a long way in promoting health care in underserved communities. The National Health Service Corps, Community Health Centers, Rural Health Clinics, enhanced Medicare reimbursements, recognition of mid-level practitioners, interdisciplinary rural training programs, and research grants have constituted an almost 30 year effort to redirect some of the nation's health care resources to the poor and underserved. However, the legacy of that first supply-side strategy was to increase the national dilemma with a surfeit of providers, particularly specialists, concentrated in wealthier metropolitan areas. Today's "shortage amid surplus" puts rural constituents and policymakers under pressure to assure that programs of support are well targeted and effective. This Roundtable will examine the reach, the efficiency, and the synergy (or lack of it) of such programs. The impending reauthorization of the National Health Service Corps, and recent attention on the J-1 visa program from the Medicare Payment Commission and the Bipartisan Commission on Medicare makes this a timely opportunity.

1. ___YES, I will attend.
___NO, I will not attend.
___No, I cannot attend. _____ from my organization will be attending in my place.

2. Name: _____
Organization: _____
Phone number: _____
Fax number: _____

3. **Ask Us Your Questions:** We would like this session to be as informative to you as possible by giving you an opportunity to pose questions you have now before the session. Please indicate your question(s) below and the speaker to whom you would like it directed. We will share it with the presenter(s) and make sure it is addressed in the Q&A session at the forum:

_____

_____

_____

4. ***Please fax this response to: 703-993-1555, or if busy, to: 703-993-1953. Our phone number is: 703-993-1907. E-mail responses can be sent to:*** *carhr@gmu.edu*
*website:*www.*gmu.edu/departments/chp/rhr*

George Mason University, Center for Health Policy & Ethics

Rural Health Workforce Programs: Separating Myths from Realities

Date: April 15, 1999
Time: 3:00 pm to 5:00 pm (reception to follow)
Place: Russell Senate Office Building, Room 236

Since the nation's first attempt to redress major shortages in health care with a supply-side boost in the numbers of graduating health professionals, public policy has come a long way in promoting health care in underserved communities. The National Health Service Corps, Community Health Centers, Rural Health Clinics, enhanced Medicare reimbursements, recognition of mid-level practitioners, interdisciplinary rural training programs, and research grants have constituted an almost 30 year effort to redirect some of the nation's health care resources to the poor and underserved. However, the legacy of that first supply-side strategy was to increase the national dilemma with a surfeit of providers, particularly specialists, concentrated in wealthier metropolitan areas. Today's "shortage amid surplus" puts rural constituents and policymakers under pressure to assure that programs of support are well targeted and effective. This Roundtable will examine the reach, the efficiency, and the synergy (or lack of it) of such programs. The impending reauthorization of the National Health Service Corps, and recent attention on the J-1 visa program from the Medicare Payment Commission and the Bipartisan Commission on Medicare makes this a timely opportunity.

- **One Size Doesn't Always Fit All**
  Senator Kent Conrad (D-ND)

- **Workforce Education and Supply Issues**
  Vincent C. Rogers, DDS, MPH, Associate Administrator for Health Professions, Bureau of Health Professions, Health Resources and Services Administration

- **What We Know (and Don't) About Provider Need and Supply**
  Tom Ricketts, PhD, Director of the North Carolina Rural Health Research Center, Chapel Hill, North Carolina

- **The Route to More Collaboration**
  Fred Moskol, Director of the Rural Recruitment & Retention Network and Director of the Wisconsin State Office of Rural Health

- **The National Health Service Corps in the 21st Century**
  Don Weaver, MD, Director of the National Health Service Corps

Capital Area Rural Health Roundtable
George Mason University, Center for Health Policy & Ethics
www.gmu.edu/departments/chp/rhr

FACSIMILE COVER PAGE

To :	**Christopher Jennings**	**From :**	gmu
Sent :	3/18/99 at 3:15:26 PM	**Pages :**	3 (including Cover)
Subject :			

ıed is an Invitation to the Capital Area Rural Health Roundtable for April 15, 1999. For questions and to RSVP, please call Mary Mooney at 703-993-1907.

CAPITOL HILL HEALTH POLICY ROUNDTABLE

— R. S. V. P. —

New Models for Training Health Care Professionals: Exploring Public Policy Options

•April 28, 1999 • 3:00 PM – 5:00 PM (Reception to follow) •
Dirksen Senate Office Building Room 106
When you arrive, please register and pick up your badge and packet.

Changes in the way health professionals are educated are beginning to take place with the re-configuration of the health care delivery system. Decreased hospital-inpatient care and increased emphasis on providing care in non-acute settings has created a new environment for educating nurses and physicians. Some innovative state and privately-funded initiatives already afford a glimpse of new training models for graduate medical and nursing education (GMNE). These are interdisciplinary, community-based training programs that take the health care provider out to the community where the patients are. Such new models complement and enhance the tradition of hospital training. This forum will explore policy options to finance and implement such interdisciplinary, community-based programs. Panelists will offer specific policy recommendations for spurring federal support.

1. ☐ YES, I will attend.
   ☐ NO, I will not attend.
   ☐ NO, I cannot attend. _____ from my organization will be attending in my place.

2. Name: _____
   Organization: _____
   Phone number: _____
   Fax number: _____

3. **Ask Us Your Questions:** We would like this session to be as informative as possible by giving you an opportunity to pose questions now before the session. Please indicate your question(s) below and the speaker to whom you would like it directed. We will share it with the presenter(s) and make sure it is addressed in the Q&A session at the forum:

_____

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4. **Please fax this response to: 703-993-1555, or if busy, to: 703-993-1953. Our phone number is: 703-993-1907. E-mail responses can be sent to: carhr@gmu.edu** website:www.gmu.edu/departments/chp

George Mason University, Center for Health Policy & Ethics

CAPITOL HILL HEALTH POLICY ROUNDTABLE

The W.K. Kellogg Foundation and George Mason University
Center for Health Policy and Ethics
Invite you to

New Models for Training Health Care Professionals: Exploring Public Policy Options

• *Date*: **April 28, 1999** • *Time*: **3:00 PM to 5:00 PM (Reception to follow)** •
Place: **Dirksen Senate Office Building Room 106**

Changes in the way health professionals are educated are beginning to take place with the re-configuration of the health care delivery system. Decreased hospital-inpatient care and increased emphasis on providing care in non-acute settings has created a new environment for educating nurses and physicians. Some innovative state and privately-funded initiatives already afford a glimpse of new training models for graduate medical and nursing education (GMNE). These are interdisciplinary, community-based training programs that take the health care provider out to the community where the patients are. Such new models complement and enhance the tradition of hospital training. This forum will explore policy options to finance and implement such interdisciplinary, community-based programs. Panelists will offer specific policy recommendations for spurring federal support for these programs.

- **Opening Remarks**

  Henrie Treadwell, PhD, Program Director, W.K. Kellogg Foundation

- **Importance of Federal Support for Graduate Medical and Nursing Education**

  Congressman Bill Thomas (R-CA) (invited)

- **Current Policy Work on Graduate Medical and Nursing Education**

  David Fleischer, Office of Senator Bill Frist (R-TN)

  Craig Lisk, staff to the Medicare Payment Advisory Commission

- **Panel Discussion: Designing Federal Policy to Support Community Graduate Medical and Nursing Education**

  Doreen C. Harper, PhD, National Coordinator, Community Partnerships-Graduate Nursing and Medical Education Initiative, W.K. Kellogg Foundation

  Tzvi Hefter, Director, Division of Acute Care, Health Care Financing Administration

  Richard Knapp, PhD, Executive Vice President, Association of American Medical Colleges

  Polly Bednash, PhD, Executive Director, American Association of Colleges of Nursing

  Barbara Tomar, Senior Associate Director in Policy Development, American Hospital Association

  Janet Coffman, Assistant Director, GME Policy, Pew Health Professions Commission

  Moderator: Tim Henderson, National Conference of State Legislatures

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To :	**Christopher Jennings**	**From :**	gmu
Sent :	3/16/99 at 2:08:00 PM	**Pages :**	3 (including Cover)
Subject :			

'tation to a Capitol Hill Health Policy Roundtable forum: New Models for Training Health Care Professionals: loring Public Policy Options

For questions, please call Jan Bull at (703) 993-1907.

#412

CC: Mike Hash

THE AMERICAN DIETETIC ASSOCIATION
216 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60606-6995
312/899-0040

DIVISION OF GOVERNMENT AFFAIRS
1225 EYE STREET, NW #1250
WASHINGTON, DC 20005
202/371-0500

March 23, 1999

Chris Jennings
Deputy Assistant to the President
For Health Policy Development
Domestic Policy Council
216 Old Executive Office Building
17 St. & Pennsylvania Ave., NW
Washington, D.C. 20502

Dear Chris:

I am writing to request a meeting to discuss coverage for medical nutrition therapy (MNT) services under Medicare Part B. The ADA is interested in the prospects for including an MNT provision in the Medicare reform proposal said to be under development at the White House. Tricia Hollis, ADA's Director of Government Affairs would join me at this meeting.

When we met with you in December you indicated the administration was withholding any specific recommendations on benefit enhancements in deference to the work of the Medicare Commission. As the Commission has not produced a reform plan, we are hopeful that our proposal will now receive a full vetting and favorable consideration as part of any Medicare reforms drafted by the administration.

Legislation to cover MNT obtained 225 House and 23 Senate cosponsors in the 105th Congress. An updated version of the bill was reintroduced last week with 121 original cosponsors in the House and 12 in the Senate. We believe this extraordinary level of bipartisan support warrants that this proposal receive serious consideration within the Administration.

We understand your schedule is very busy, so we want to provide a range of possible meeting dates. Our schedules can accommodate meeting on April 1st or 2nd, or any day the week of April 5th. We look forward to hearing from you and discussing this important matter.

Sincerely,

Paul T. Kelly
Senior Federal Lobbyist

Cc: Tricia Hollis, Director of Government Affairs

— forward (fax) to Mike Hash 4/1/99

THE AMERICAN DIETETIC ASSOCIATION
216 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60606-6995
312/899-0040

DIVISION OF GOVERNMENT AFFAIRS
1225 EYE STREET, NW #1250
WASHINGTON, DC 20005
202/371-0500

THE AMERICAN DIETETIC ASSOCIATION
GOVERNMENT AND LEGAL AFFAIRS GROUP

FAX COVER SHEET

DATE: 3-24-99

TO: TERESA JONES, POLICY ASSISTANT

PHONE#:

FAX#: 456-5557

FROM: Paul T. Kelly

PHONE#: 202/371-0500 OR 1-800/877-0877

FAX#: 202/371-0840

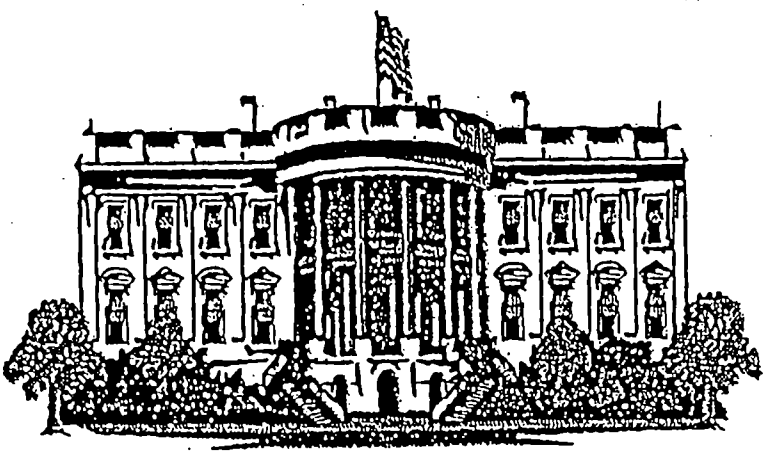
NUMBER OF PAGES INCLUDING COVER SHEET: 2

REMARKS: Meeting Request

Thanks for your help.

Paul

THE WHITE HOUSE



Christopher C. Jennings
Deputy Assistant to the President for Health Policy
216 Old Executive Office Building
Washington, DC 20502
phone: (202) 456-5560
fax: (202) 456-5557

Facsimile Transmission Cover Sheet

To: MARY HOMANA (MIKE HASH)

Fax Number: (410) 786-8060

Telephone Number: (410) 786-3151

Pages (Including Cover): 2

Comments: per conversation (thanks)

FROM: Teresa Jones

TELEPHONE NUMBER: (202) 456-5594 FAX NUMBER: (202) 456-5557

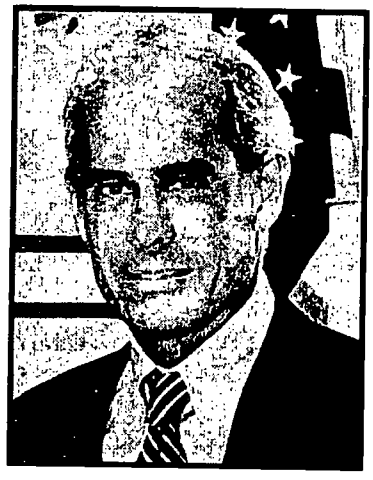
NATIONAL HEALTH COUNCIL

BREAKFAST BRIEFING

Nope

The Future of the NIH Budget-Doubling Effort

A Breakfast Briefing with Representative John Porter (R-IL)



The Washington Court Hotel
Ballroom 2
525 New Jersey Avenue, NW
Washington, DC 20001

Wednesday, April 14, 1999
8:30 AM to 9:30 AM

Last year NIH received a historic 15% increase in funding – the first step in doubling the NIH budget by 2003. Will the Congress provide NIH with a second 15% increase for FY 2000? Can the NIH budget be doubled without sacrificing other important programs?

For answers to these important questions, please join us to hear from Rep. John Porter (R-IL), Chair, House Labor, Health and Human Services and Education Appropriations Subcommittee.

Registrations and cancellations must be received by **noon, Monday, April 12, 1999**. Registrants canceling after the deadline will not receive refunds and will be responsible for any unpaid fees. Checks should be made payable to the National Health Council.

Sponsored by an educational grant from Juvenile Diabetes Foundation International.

RETURN TO: **National Health Council**; 1730 M Street, NW, Suite 500; Washington, DC 20036
FAX: (202) 785-5923

PORTER BREAKFAST BRIEFING

Name _____ Title _____
(as you wish it to appear on your badge)

Organization _____

Address _____

City, State, Zip _____

Phone (____) _____ Fax (____) _____

__MEMBER ($20-one free registration per member organization) __NON-MEMBER ($30 enclosed)

❑ Please send me membership information

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(202) 785-3910 • FAX (202) 785-5923
E-MAIL: info@nhcouncil.org

NATIONAL HEALTH COUNCIL
1730 M Street, NW • Suite 500 • Washington, DC 20036-4505

Chris Jennings
Special Assistant to the President
The White House
1600 Pennsylvania Avenue
Washington DC 20036

HEALTHCARE EXECUTIVES' CLUB

2897 Saw Mill Road, Wantagh, New York 11793 Tel:(516)221-5277

March 30, 1999

Thanks but Regrets. Coincides w/ other Inst Medicare re scheduling conflicts. Perhaps next year?

Chris Jennings
Deputy Assistant to the President, for Health Policy

via facsimile - (202) 456-5557

Dear Mr. Jennings:

As discussed with your secretary, Therese Jones, I had been referred to you by Howard Bedlin with regard to your availability to serve as our keynote speaker at our annual Stern Memorial Lecture, to be held the evening of Tuesday, April 20, 1999.

The event is co-sponsored by The Joint Industry Board of the Electrical Industry, (Local 3 IBEW), and will be held at their headquarters building on Parsons Boulevard and harry Van Arsdale Avenue, in Flushing.

The Healthcare Executives' Club is an affiliate organization of the American College of Healthcare Executives, and our membership includes management and administrative personnel in public and voluntary organizations in the New York City area, in hospitals, nursing homes, education, etc.

The Stern Lecture is attended by some 120 people, and is named in memory of our first president. The evening event begins with an informal cocktail party at 6 PM, a gourmet buffet at 6:45, and program at 7:30. We would ask that you speak for some half hour on the subject of the "Administration's Healthcare Initiatives for the Next Two Years", or such other topic as you would deem appropriate.

Thank you for your involvement, and we look forward to hearing from you. I may be contacted by phone at (516) 221-KARP (5277); by fax (516) 221-5279; or by e-mail at KARPEONCAL@AOL.COM, or I will call you early next week.

Sincerely,

Henry R. Karpe, M.S., FACHE
Chair, Stern Memorial Lecture

HRK:sn

"Administrators On Call," Inc.

FACSIMILE TRANSMITTAL SHEET

DATE 3/30/99

FAX # (202) 456-5557

ATTENTION: Chris Jennings

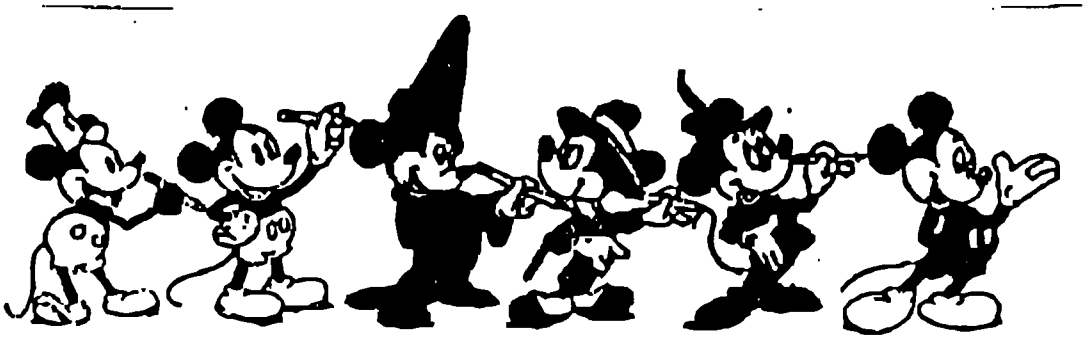
DEPARTMENT: Health Policy

FROM: Tony Karp

PAGES SENT: INCLUDING COVER SHEET 2

REPLY REQUESTED: (YES) ____ NO ____

COMMENTS: Re: Healthcare Executives' Club-



FAX #

2897 Saw Mill Road, Wantagh, New York 11793 • (516) 221- KARP • (516) 221- 5279

Council on the Economic Impact of Health System Change

Stuart H. Altman, Ph.D.
Brandeis University
Chair

David Shactman, MPA, MBA
Project Director

4/5/99
per Chris's call

March 29, 1999

Christopher Jennings
Domestic Policy Council
1700 Pennsylvania Avenue
Washington, DC 20502

Regrets. But ask Jeanne Lambrew if she'd like to go CIT she has not already been invited. Show the real report. CJ

Dear Chris:

I would like to extend an invitation to you to attend the sixth Princeton Conference, to be held from the evening of April 29th through May 1st on the campus of Princeton University. The conference is co-hosted by the Council on the Economic Impact of Health System Change and Dr. Uwe Reinhardt and is sponsored by the Robert Wood Johnson Foundation. The title of this year's conference is:

FINANCING LONG-TERM CARE: POLICY OPTIONS AND THEIR ECONOMIC IMPACT

A number of factors, including the aging of the U.S. population, changes in medical capabilities and practice patterns, and evolving social norms, are placing increased pressure on our long-term care financing infrastructure. Although policy makers have recognized the need for wider access to long-term care, it has rarely reached the top of the public policy agenda.

At the conference, we will conduct a non-partisan dialogue among all participants to explore new models for long-term care financing. The conference is structured to maximize discussion and debate among speakers and invited guests. A wide range of perspectives will be presented by policy analysts, economists, academics, consumer advocates, and representatives of government and industry.

This is an invitational conference and, as such, there are no conference fees. We will reimburse you for all travel, food, and lodging expenses that you incur. In accordance with the rules regarding financial disclosure of gifts, government employees must obtain the required written authorization as specified under current law. You will find a preliminary agenda and reply card enclosed. Please respond at your earliest convenience, even if you cannot attend, as we will use your reply to maintain our invitation list. If you plan to attend, please secure your lodging reservations from the limited number of rooms we have blocked off at the Hyatt Regency Princeton (see enclosed agenda). Further information will be forthcoming upon our receipt of a positive reply.

The President's recent long-term care initiative has focused attention on this important issue. I am pleased that we have been able to put together a comprehensive program that should be well timed to contribute to the impending national dialogue. I hope you will be able to participate.

Sincerely,

Stuart H. Altman

The Council is supported by a grant from The Robert Wood Johnson Foundation and is administered by The Institute for Health Policy,
The Heller School, Brandeis University, MS-035, Waltham, Massachusetts 02454-9110 ◆ Tel: (781) 736-3807 ◆ Fax: (781) 736-3905 ◆ http://ihp.brandeis.edu/council

AMERICAN SOCIETY OF
PLASTIC AND RECONSTRUCTIVE
SURGEONS

March 12, 1999

The Honorable Christopher Jennings
Deputy Assistant to the President for
Health Policy Development
Office of Policy Development
Executive Office of the President
1600 Pennsylvania Ave., NW
Washington, D.C. 20500

Dear Mr. Jennings:

As President of the American Society of Plastic and Reconstructive Surgeons (ASPRS), I am pleased to invite you to be our keynote luncheon speaker at the ASPRS annual Washington Legislative Conference on Monday, April 19, 1999.

As you know, ASPRS represents nearly 5,000 (97%) of the board certified plastic surgeons in the United States. The Washington Legislative Conference brings together both local and national ASPRS leaders from across the country. We expect 30 to 50 attendees at this year's Conference.

Our members are most interested in and concerned about a number of issues currently being discussed in Washington, including managed care and patient protections, mandated coverage proposals, and the expansion and solvency of the Medicare program. As a key advisor to the President, you are in an ideal position to discuss the Administration's agenda for the future of health care.

The Conference will be held here in Washington, D.C., on Monday, April 19, 1999 at the Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW . Our program presently calls for you to speak beginning at 12:30 p.m., concluding with a question and answer session no later than 1:30 p.m. Your remarks will be preceded by lunch at 12:00 noon. If your schedule allows, we would be delighted to have you also join us for lunch.

I hope you will be able to accept our invitation to join us for lunch and to be our keynote speaker. Please contact Mark Cribben in our Washington office (202/223-6222) if you have any questions or need additional information.

Sincerely,

Paul L Schnur, MD

Paul L. Schnur, M. D.
President

#405

Panelists

Julia T. Alvarez
Ambassador & Alternate Representative
of the Dominican Republic to the UN

Robert N. Butler, MD
President & Founder
International Longevity Center

Marta Larraechea de Frei
First Lady of Chile

John Feather, PhD
Director, AARP Andrus Foundation

Jeannette Takamura, PhD
Assistant Secretary for Aging
US Department of Health and Human Services

Terri Wetle, PhD
Deputy Director, National Institute on Aging

The American Association for World Health

in conjunction with the

Pan American Health Organization
U.S. Department of Health & Human Services
Centers for Disease Control and Prevention
The Robert Wood Johnson Foundation
and the 1999 World Health Day Advisory Committee

Cordially invites you to attend
the launching of our 1999 initiative

"Healthy Aging, Healthy Living—START NOW!"
in observance of World Health Day 1999

Wednesday, April 7, 1999 ~ 9:00 a.m. to 12:00 p.m.

with keynote speaker
David Satcher, MD, PhD
United States Surgeon General & Assistant Secretary for Health

Followed by a discussion with leading experts
in the field of aging

The program will be held at the
Pan American Health Organization

525 23rd Street, NW • Washington, DC 20037
Please R.S.V.P. by Friday, April 2, 1999 to 202-466-5883

The 1999 World Health Day Advisory Committee

American Association for Geriatric Psychiatry
American Association for World Health
American Association of Homes & Services for the Aging
American Association of Retired Persons
American Diabetes Association
American Nurses Association
American Occupational Therapy Association
American Physical Therapy Association
American Society on Aging
Association of Schools of Public Health
Catholic Health Association
Centers for Disease Control and Prevention
The Gerontological Society of America
Harvard School of Public Health
Health Care Financing Administration
Health Resources & Services Administration
Howard University
International Association of Homes & Services for the Aging
Institute of Medicine
International Longevity Center
Jewish Council for the Aging
Meals on Wheels Association of America
National Association of Area Agencies on Aging
National Association of Hispanic Elderly
National Association of Local Boards of Health
National Association of Meal Programs
National Association of Social Workers
National Association of State Units on Aging
National Caucus & Center on Black Aged
National Coalition of Hispanic Health & Human Services Organizations
National Committee to Preserve Social Security and Medicare
National Council of Senior Citizens
National Council on Aging
National Council on Churches
National Hispanic Council on Aging
National Institute on Aging, National Institutes for Health
National Osteoporosis Foundation
National Rural Health Association
National Senior Games-Senior Olympics
Older Women's League
Pan American Health Organization
President's Council on Physical Fitness and Sports
Retirement Research Foundation
Society for Public Health Education
US Administration on Aging
US. Conference of Mayors
US Department of Health & Human Services
US Department of Labor
US Department of Veterans Affairs
World Health Organization

World Health Day – April 7, 1999

You are cordially invited . . .

#410

COUNCIL OF JEWISH FEDERATIONS
WASHINGTON ACTION OFFICE

1700 K St., N.W. • Suite 1150 • Washington, DC 20006

Diana Aviv, Senior Associate Executive Vice President, Public Policy
Director, Washington Action Office

Conrad L. Giles, MD, President
Jay Yoskowitz, Executive Vice President

March 12, 1999

Mr. Christopher C. Jennings
Deputy Assistant to the President
Domestic Policy Council
216 OEOB
Washington, DC 20500

Dear Mr. Jennings :

On behalf of the Jewish Federation system, I am writing to invite you to address the 1999 UJA Federations of North America Washington Leadership Summit on Tuesday, April 13, 1999, between 4:00 and 6:00 pm at the Grand Hyatt Hotel. Vice President Gore has agreed to keynote this session. My hope is that you will also be joined in this session by Kevin Thurm, Deputy Secretary of the Department of Health and Human Services, Michael Deich, Associate Director for General Government and Finance at OMB, and Dr. Eric Schwartz, Senior Director for Democracy, Human Rights & Humanitarian Affairs at the NSC.

The Summit will be a historic event. The merger between the Council of Jewish Federations, United Jewish Appeal and United Israel Appeal will be ratified shortly so this will be the first Washington Leadership Summit of our new combined national entity.

As you may know, UJA Federations of North America (the partnership between the Council of Jewish Federations, United Jewish Appeal, and United Israel Appeal) is a national organization representing 189 local Jewish Federations that raises and distributes substantial funds to support its health and welfare programs. It serves as the central planning and coordinating organization for Jewish health and social services in approximately 800 municipalities throughout the United States and Canada. This network embraces more than 6.1 million Jews and provides vital assistance to the Jewish community as well as to many individuals in the general community. The leadership of our Federations includes virtually all the major Jewish figures in the United States.

This Administration has fought to make health care more affordable and accessible for consumers, while at the same time allowing providers who participate in public programs a fair reimbursement. We believe that this mission will provide a prime opportunity to discuss the Administration's agenda in this regard, including its recent proposals in the area of Medicare home health care. It would permit some of the most prominent members of the American Jewish community to hear your thoughts regarding the Administration's proposal to provide some relief for family members and others who care for elderly people living in the community. We are also

(202) 785-5900 • Fax: (202) 785-4937 • www.cjfny.org/dc

interested in your thoughts about reauthorization of the Older Americans Act and the Administration's Patient's Bill of Rights.

We will contact your office in the near future to follow-up on this request. If you have any questions, please do hesitate to have your staff contact our national Legislative Director, Jeff Lande, at (202) 736-5864.

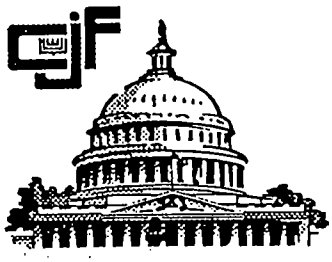
Thank you.

Sincerely,

Diana Aviv
Senior Associate Executive Vice President for Public Policy

cc: Lynn Lyss, Washington Leadership Summit Chair, St. Louis
Ted Benard-Cutler, Washington Leadership Summit Vice Chair, Boston

#4110



COUNCIL OF JEWISH FEDERATIONS
WASHINGTON ACTION OFFICE

1700 K St., N.W. • Suite 1150 • Washington, DC 20006

Diana Aviv, Senior Associate Executive Vice President, Public Policy
Director, Washington Action Office

Conrad L. Giles, MD, President
Jay Yoskowitz, Executive Vice President

March 10, 1999

Mr. Chris Jennings
Deputy Assistant to the President for Health Policy Development
Office of Policy Development
Executive Office of the President
1600 Pennsylvania Avenue, NW, 216 OEOB
Washington, DC 20500

Dear Mr. Jennings:

On behalf of UJA Federations of North America, it is my pleasure to invite you to join us at the opening reception of our 1999 Washington Leadership Summit. The reception will be held on Tuesday, April 13, from 6:45 - 8:00 p.m. in room 902 SHOB. You will be introduced upon your arrival and have the opportunity to make a few brief remarks if you would like.

The Summit will be a historic event. The merger between the Council of Jewish Federations, United Jewish Appeal and United Israel Appeal will be ratified shortly so this will be the first Washington Leadership Summit of our new combined national entity. Your address would be a highlight of the Summit and would provide our lay community with an understanding of the Washington political environment. The Summit will be attended by several hundred of the most prominent leaders of the United Jewish Appeal (UJA), Council of Jewish Federations (CJF) and United Israel Appeal (UIA).

As you may know, UJA Federations of North America (the partnership between the Council of Jewish Federations, United Jewish Appeal, and United Israel Appeal) is the national organization representing the 189 local Jewish Federations nationwide that serves as the central planning and coordinating organization in approximately 800 municipalities throughout the United States and Canada. This network embraces more than 6.1 million Jews and provides assistance to the members of the Jewish community in the United States, Israel and aborad as well as to many individuals in the general community. The leadership of our system includes virtually all the major Jewish figures in the United States.

We will contact your scheduler in the near future to follow-up on this request. If you have any questions, please do hesitate to have your staff contact Jeff Lande, Legislative Director for UJA Federations of North America, at (202) 736-5864.

Thank you.

Diana Aviv
Senior Associate Executive Vice President for Public Policy

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Timothy A. Boggs

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Mike McKay, *AIDS Outreach Center*
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The Xchange Point

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Peters D. Willson
Christopher Wolf & James Beller

Chris
We would be pleased to see you there as our guest.
Daniel

The Board of Directors of **AIDS Action Foundation**

Timothy A. Boggs, *Event Chair*

and

Daniel Zingale, *Executive Director*

cordially invite you to honor the 1999 National Leadership Award recipients

AIDS ACTION FOUNDATION 1999 NATIONAL LEADERSHIP AWARDS

ROSIE PEREZ
Public Service

THE CONGRESSIONAL BLACK CAUCUS
Public Policy

THE HONORABLE JAMES M. JEFFORDS (R-VT)
Public Policy

STARBUCKS COFFEE COMPANY
Community Service

JEANNE WHITE
Pedro Zamora Memorial Award for Youth Advocacy

Monday, April 5, 1999

The Lansburgh Theatre
450 Seventh Street NW
Washington, DC

6:30pm **Reception**
7:30pm **Awards Ceremony**
8:30pm **Buffet Dinner**

Business attire. In-building parking available.

until it's over
AIDSACTION

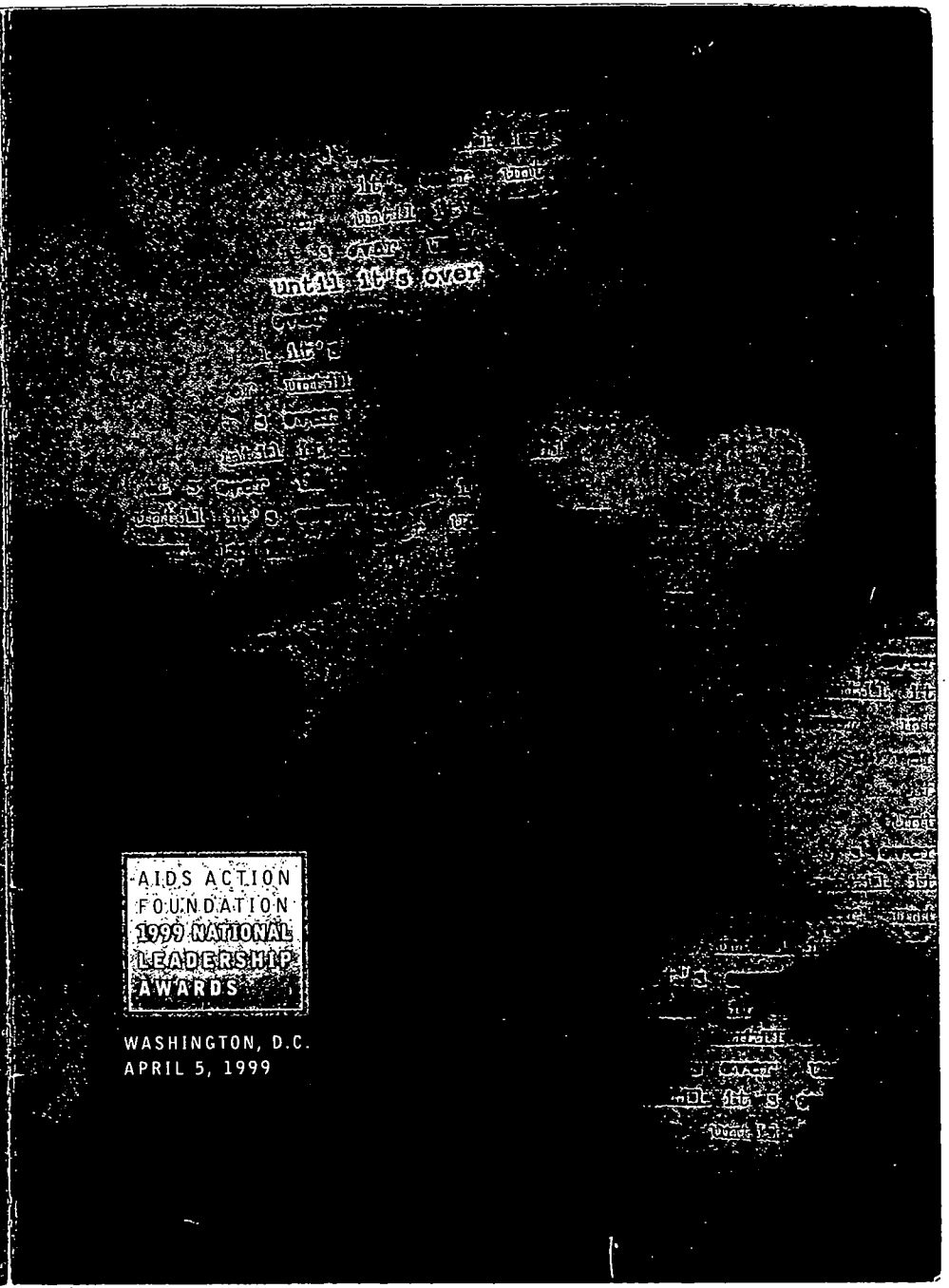
AIDS Action Foundation is a 501(c)(3) organization fighting the AIDS epidemic by working for public policy that prevents new HIV infections, provides care for people living with HIV and AIDS, defends their rights and searches aggressively for a cure. AIDS Action Foundation works in partnership with AIDS Action Council as the national voice for all Americans affected by HIV/AIDS and 3,200 community-based organizations that serve them.

To learn more about the work of AIDS Action, please contact Dana Myers, Development Office, at 202.986.1300 x3060.

Thank you for your support of AIDS Action.

AIDS Action Foundation 1875 Connecticut Ave. NW Suite 700 Washington, DC 20009 www.aidsaction.org

Daniel Zingale, Executive Director



AIDS ACTION
FOUNDATION
1999 NATIONAL
LEADERSHIP
AWARDS

WASHINGTON, D.C.
APRIL 5, 1999

AIDS ACTION FOUNDATION 1999 NATIONAL LEADERSHIP AWARDS

I would like to reserve tickets in the following category:

- ○ **Executive Host Committee** (2 tickets at $250 each
- ○ **Host Committee** 2 tickets at $150 each
- ○ **Individual Tickets** ___ tickets at $150 each

○ I cannot attend but would like to contribute $_____ to support the work of AIDS Action.

Check enclosed for $_____.

Please make checks payable to AIDS Action Foundation.

Please charge $_____. ○ Mastercard ○ Visa

_____
card number

_____
expiration date

_____
signature

COMPLIMENTARY

Name: _____

Address: _____

City/State/Zip: _____

Phone: _____

For more information please call Dana Myers at 202.986.1300 x3060.

AIDS Action estimates the fair market value of the event to be $50. All contributions above this amount are tax deductible to the extent allowed by law.

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John H. Chafee
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Henry A. Waxman

AIDS ACTION FOUNDATION
1875 Connecticut Ave. NW
Suite 700
Washington, DC 20009

#409

AHCA
American Health Care Association

1201 L Street, NW
shington, DC 20005-4014
202 842-4444
FAX: 202 842-3860

WWW.AHCA.ORG

AHCA SINCE 1949 50 Celebrating Service

Writer's Telephone: 202-898-2858
Writer's E-mail: byarwood@ahca.org

March 8, 1999

Chris Jennings
Deputy Assistant to the President for Health Policy
Old Executive Office Building #216
1700 Pennsylvania Avenue, NW
Washington, DC 20502

Ask me on Monday
CJ

Dear Mr. Jennings: Chris

On behalf of the American Health Care Association (AHCA) Board of Directors, I would like to invite you to speak at our Board Meeting on the morning of Wednesday, April 7, 1999 at the Hyatt Regency in Crystal City,VA. As you may know, AHCA is a federation of 50 affiliated state associations representing 12,000 non-profit and for-profit nursing facilities, assisted living facilities and subacute providers nationwide.

During the meeting, we will discuss critical issues impacting the long term care industry in Fiscal Year 2000. As Health Policy Advisor to President Clinton, we believe your remarks will provide unique insights into long term care provisions in the President's Budget as well as the future of health policy in Washington. In addition, you will have the opportunity to meet 150 health care providers from across the nation.

We hope that your schedule will permit you to speak. As always, we will be flexible in accommodating your needs. We are happy to provide you with any additional information you may need. Please feel free to contact me at the above number.

Sincerely,

Bruce Yarwood
Legislative Counsel

C=Kim
(202) 898-2802

INTERNATIONAL ASSOCIATION OF HOMES AND SERVICES FOR THE AGEING

in collaboration with

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www.aahsa.org/iahsa

- ❑ Please send a copy of the conference brochure.
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Make any necessary changes to the address label and mail or fax this postcard to IAHSA.

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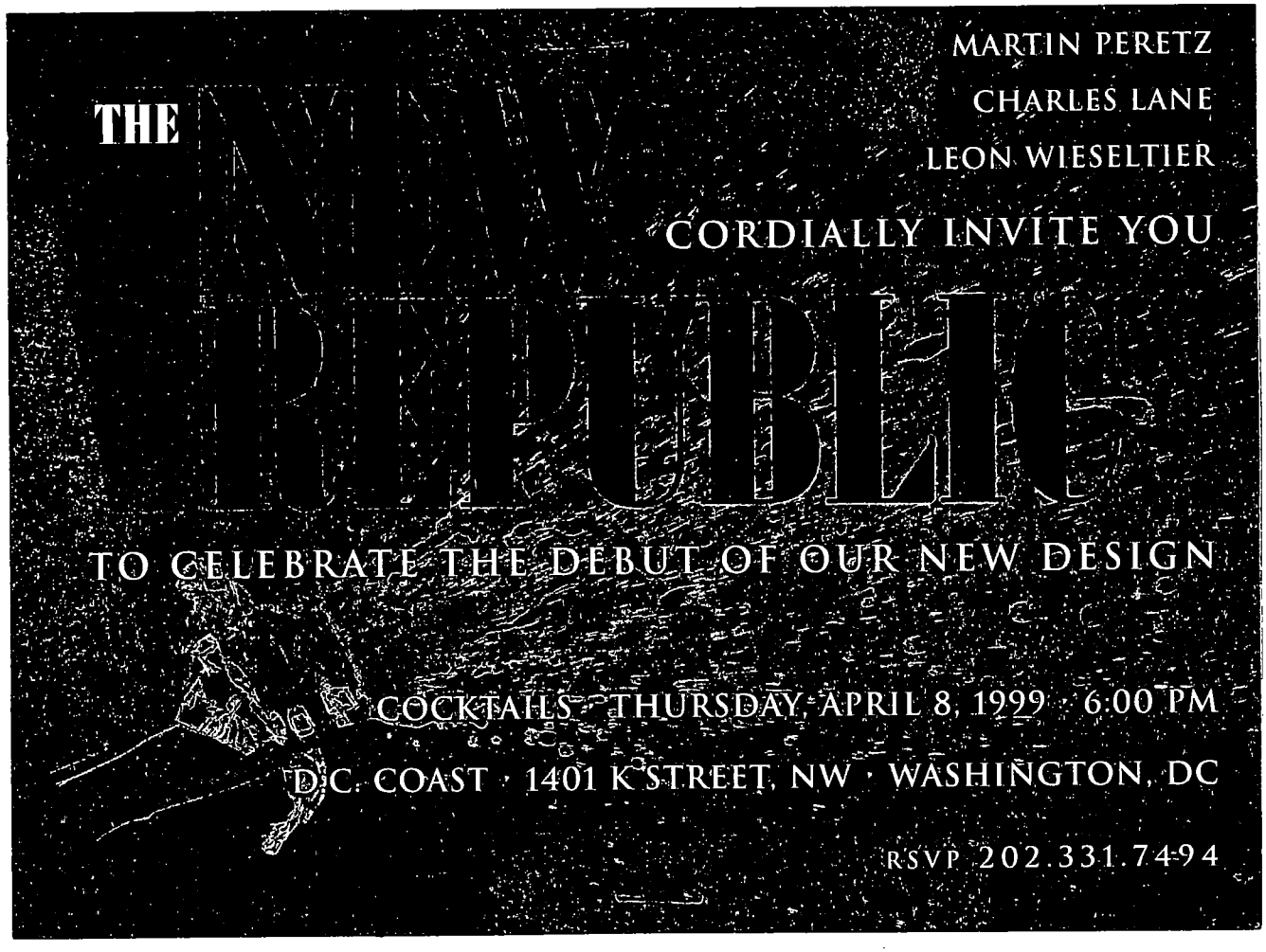
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RSVP 202.331.7494

The American Psychiatric Association

The Honorable Pete V. Domenici and the Honorable Paul Wellstone
Leaders of the Senate Working Group on Mental Health

and

The Honorable Marge Roukema,
The Honorable Robert E. Wise and the Honorable Peter A. DeFazio
Leaders of the House Working Group on Mental Illness and Health Issues

Cordially invite you to attend a reception welcoming

The APA's Federal Legislative Representatives
and the Academic Consortium
From your District and State

On Tuesday, April 13, 1999
5:30 - 7:30 p.m.

RSVP 202/682-6060

Foyer, Rayburn House Office Building

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MAY 19 – 21, 1999
THE FAIRMONT HOTEL
DALLAS, TEXAS

A special invitation to the
Alumni of the Integrated Healthcare Symposium, the National Congress Health Care Conference Series, and the subscribers of the Integrated Healthcare Report.

The next century is both intimidating and inspiring for today's healthcare leaders. It's a challenging time. It's an exciting time. At the dawn of the new year, the vast majority of physician groups and healthcare systems are engaged in reinventing patient care. We've graduated from "form" to "content." But, those who have failed to graduate, have suffered the consequences.

In the beginning of the movement to develop integrated healthcare systems, the concept was simple. Traditionally, patients have been shuttled among providers with duplicative costs, little or no coordination, continuity, or attention to quality of care. The lack of a system promoted loss of quality and increased costs. Simply put, the integrated healthcare strategy had a goal of fixing what was wrong with healthcare.

We are now past the point of agreeing to the vision and are deeply involved with strategies to make it work. How do you align the incentives of physicians and hospitals? How do you stem the losses of your PHO or MSO? How do you deal with capitation? What course corrections do you need to make to get back into synch with the vision of integrated healthcare?

This conference will be the summit meeting of the year for healthcare systems throughout the country. There has never been more uncertainty and volatility in our industry. But, there are solutions and we are pleased to extend an invitation to you and your team to attend a conference that has only one goal—to present solutions.

Featuring

Daniel M. Cain, Principal/CEO, Cain Brothers & Company LLC ~ ***Russell C. Coile, Jr.,*** Senior Vice President, Superior Consultant ~ ***Patrick G. Hays,*** President/CEO, Blue Cross and Blue Shield Association ~ ***Lawrence B. Leisure,*** Partner, Andersen Consulting ~ ***Camille D. Miller,*** President/CEO, Texas Institute for Health Policy Research ~ ***C. David Morehead, M.D.,*** President, Scott and White Health Plan ~ ***Ian Morrison, Ph.D.,*** Senior Fellow, Institute for the Future and Chairman, Health Futures Forum, Andersen Consulting ~ ***Patricia E. Powers,*** Executive Director, Pacific Business Group on Health ~ ***James C. Robinson, Ph.D.,*** Professor of Economics, School of Public Health, University of California, Berkeley ~ ***Uwe E. Reinhardt, Ph.D.,*** James Madison Professor of Political Economy, Princeton University ~ ***Jacque J. Sokolov, M.D.,*** President/CEO, JJS, Inc./PSO Development Corp. ~ ***Steve Wetzell,*** Executive Director, Policy and Public Affairs, Buyers Health Care Action Group ~ ***Walter A. Zelman, Ph.D.,*** President/CEO, California Association of Health Plans

And the Following Special Events

Preconference Program

Wednesday, May 19, 1999, 1:00 to 4:30 p.m.

Six special workshops focusing on prevalent health care issues.

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- Understand why Latin America has gone from a high risk market to a **high profit market** through health care reforms and economic growth
- Learn how regional harmonization can benefit the pharmaceutical market — Including the most current information on the **Mercosur** and **Andean trade pacts**
- Maximize the opportunities in this growing center for **clinical trials** by following regional protocol, setting clear expectations and standards, obtaining accurate data and developing a standardized reporting system
- Safeguard your **intellectual property** and technology transfer through a clear understanding of regulations and strategies to protect your product in any stage of drug development
- Speed the filing process and get your product to market first by implementing a **streamlined product registration**

Plus Panel of 5 Pharmaceutical Regulatory Directors Share Their Perspectives and Experiences of Working within Latin American Regulations

FULL DAY

An In-Depth Pre-Conference Workshop
Wednesday, March 24, 1999

Supply Chain Management

Moving Pharmaceuticals, Samples, Clinical Supplies and Chemicals through Multiple Markets in Latin America

(See inside for details)

Organized By:

The CENTER for BUSINESS INTELLIGENCE

CBI's Pharmaceutical Series

Full Day Pre-Conference Workshop — Wednesday, March 24, 1999

Supply Chain Management

Moving Pharmaceuticals, Samples, Clinical Supplies and Chemicals through Multiple Markets in Latin America

"Logistics firms provide...service to their international clients by helping them establish alliances, partnerships, venture and relationships with the "players" in the foreign country."

— *Bio/Pharmaceutical Outsourcing Report,* November 1998, Volume 3, Number 11, "Strategic Sourcing"

In this one day intensive workshop, experts give you the information you need to move your materials and finished products into, and around, Latin America. Hear in-depth strategies on distribution, transportation, contracting, building a base of operations, choosing a third party logistics provider and partnering.

8:30 *Workshop Registration*

9:15 *Workshop Leader's Welcoming Remarks*
Robert Diaz, COO-Latin America, **Circle International**

9:30 **Starting Up in a Latin American Country — A Logistical Case Study in Chile**

- Should you outsource?
  - * focus on your core competencies — free up resources
  - * 3PLs have the local and logistical experience
- Should your logistics company have a local partner?
- What areas should you look at as a pharmaceutical or biotech company when choosing a logistics partner in Latin America
  - * location * experience * integration capabilities
  - * labor relations * value for money
  - * systems capabilities * understanding your goals
  - * can they implement in single and multiple locations
- Should you risk it alone or find a partner
  - * reward vs. risk * success vs. failure
- Facilities and equipment available
- Permitting, licensing and registration

Robert S. Simcoe, Vice President/General Manager, Business Development/Latin America, **GATX Logistics**

Continued on reverse side of flap

Clinical Trials Conduct and Contracting

10:45 **Develop Clinical Trials in Latin America that Provide the Most Accurate Data and the Highest Return on Investment** — Pharmaceutical Perspective

Latin America has become a hot spot to conduct clinical trials, however it offers unique challenges that pharmaceutical companies don't have to face in more traditional markets.

- How do you investigate a site?
  - * experience * past results * setting standards
- Regional protocol • Transporting samples
- Importing clinical trial material • Communication

Vikki Brandi, Associate Director, Clinical Development, **Dura Pharmaceuticals**

11:30 **Strategies to Develop Strong and Flexible Clinical Trial Contracts** — Pharmaceutical Perspective

Contracts are a critical piece of the clinical trial process, and are more so when you are dealing with an international clinical trial. How do you develop a contract that meets your needs and allows for the specific legal requirements of the region.

- Flexibility • Risk sharing
- Contract development • Should you outsource
- Putting in place systems that allow for incentives and "punishments" if deadlines are not met

Mary Lou Furstnau, Latin America, Clinical Research Leader, **Eli Lilly**

12:15 *Luncheon*

1:45 **Conducting Clinical Trials in Latin America — A Sponsor/CRO Perspective** — PANEL PRESENTATION

As the need for conducting clinical trials on a global basis increases, we find that some of these studies are being performed in some unlikely places. Five years ago conducting clinical trials in Latin America was unheard of. Today it's becoming as common place as the US or Western Europe. Searle has been working in Latin America for several years with its affiliates and CROs. The combined panel of Searle and Quintiles discuss the unique issues that we faced in conducting large multi-center trials in **Brazil, Chile, Argentina, Mexico** and **Venezuela.**
The panel examines monitoring and data management issues as well as central laboratory transportation, specimen handling and processing. It also looks at the changing environment in Latin America and the impact of these changes.

Moderator: Richard K. Musselman, Senior Director, Contract Management and Procurement, **G.D. Searle Pharmaceutical Company**

Panelists: Craig Amburgey, Senior Clinical Research Associate, Cardiovascular Clinical Research, Research and Development, **G.D. Searle Pharmaceutical Company**

Margarita Eiletz, Director, Operations, **Quintiles Latina**

Maria H. Martinez, Clinical Research Associate II, Cardiovascular Clinical Research, Research and Development, **G.D. Searle Pharmaceutical Company**

Jay Vigotor, Vice President, Latin America, **Quintiles Latina**

3:00 *Networking and Refreshment Break*

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This 26 Billion Dollar E

MARCH 24-26, 1999 • HYA

— Learn from 12 Top Bio/P

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- Safeguard your **intellectual property** and technology transfer through a clear understanding of regulations and strategies to protect your product in any stage of drug development
- Speed the filing process and get your product to market first by implementing a **streamlined product registration**

Supply Chain Management

(Continued from reverse side)

11:00 **Reduce Costs through Clinical Trial Supply Chain Management in Latin America**
- Sourcing
- Reduce clinical trial supply chain costs
  * clinical drug supply chain system
- Regulatory issues with moving clinical trial material
- Create a supply chain strategy that meets these regulations and reduces costs
- Information technology that can save you time/money

Matthew Sers, Senior Associate, **Pricewaterhouse**

12:00 *Luncheon hosted by* **Circle International®** One World. One Team.

Keynote Speaker

David I. Beatson, President and CEO, **Circle International**

1:30 **Cost Effective Logistics Programs for Latin America**
- Case study- Brazil
- Developing a lean logistics program
- Reducing transportation costs
- Improving cycle times
- Lowering costs of inventory

Kim Wertheimer, Executive Vice President- Logistics, **Circle International**

2:30 **Outsourcing Opportunities for the Pharmaceutical Industry**
- Transportation management • Procurement assistance
- Warehousing and inventory control
- "Pick and Pack" and other value-added services

Randy Clark, COO - North America, **Circle International**

3:20 *Networking and Refreshment Break*

3:40 **Managing Latin American Customs Issues for Streamlined Materials Movement**
- Documentation and compliance
- Taking advantage of deferred duty programs
- Free trade zones • Bonded warehousing

Moises Najmann, Director of Customs Brokerage Operations - Brazil, **Circle International**

4:30 **Total Supply Chain Services Review**

Robert Diaz, COO - Latin America, **Circle International**

5:00 *Close of Workshop*

— About Your Workshop Leader —

Robert Diaz, COO-Latin America, **Circle International**

Prior to his appointment in April of 1997, Mr. Diaz served as the company's Senior Vice President and Chief Financial Officer from December, 1994 to April, 1998. Mr. Diaz joined Circle International in 1994, after serving in senior financial and operational management capacities at other multinational companies such as Coors Brewing Company, the Clorox Company and ITT. A native of Argentina, Mr. Diaz was educated in the United States and is fluent in English, Spanish and Portuguese. Joined by:

Matthew Sers, Senior Associate, **Pricewaterhouse;**

Robert S. Simcoe, Vice President/General Manager, **GATX Logistics;**

Kim Wertheimer, Executive Vice President – Logistics, **Circle International;**

Randy Clark, COO – North America, **Circle International;**

Moises Najmann, Director of Customs Brokerage Operations – Brazil, **Circle International**

MAIN CONFERENCE

Day One — Thursday, March 25, 1999

8:00 *Main Conference Registration*

8:30 *Chairperson's Opening Remarks*
Jenny Peters, Senior Regulatory Manager, **Pharmacia & Upjohn**

8:45 **Develop Intelligence Networks for Market Entry in Hot Latin America Markets**

Although the Latin American pharmaceutical market is booming, some markets are hotter than others and some markets provide higher profits and fewer risks. Which markets should your company focus on and how do you identify which markets are strongest for your products?

- Identify opinion leaders
- Develop relationships as a potential new entrant to the market
- Extend the contact network beyond medical opinion leaders
- Gain input into operational, clinical, regulatory and marketing strategies
- Government policies that impact the distribution and sales of non-domestic made pharmaceutical products
- Do regional trade pacts — Mercosur, The Andean Group, NAFTA — impact potential markets?

Suzanne Beverage, Business Development Manager, Latin America, **Amgen**

9:30 **The WTO Agreement on Intellectual Property Rights — Actuality and Implementation in Latin America**

The transition period in the WTO's TRIPS Agreement for developing countries ends on January 1, 2000. As a result, companies need to consider what can be done to help Latin American countries conform their intellectual property laws to the TRIPS Agreement, evaluate what changes Latin American countries have made or are contemplating, and what actions may be taken against those countries that fail to meet the WTO deadline.

- What are the Latin American's intellectual property laws?
- How do they impact the bio/pharma industry and technology transfer?
- Evaluate the changes that have been or can expected to be made by Latin American countries
- How should your company be prepared to protect itself against intellectual property theft?

Charles S. Levy, Partner, **Wilmer, Cutler & Pickering**

10:15 *Networking and Refreshment Break*

Clinical Trials Conduct and Contracting

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Maria H. Martinez, Clinical Research Associate II, Cardiovascular Clinical Research, Research and Development, **G.D. Searle Pharmaceutical Company**

Jay Vigotor, Vice President, Latin America, **Quintiles Latina**

3:00 *Networking and Refreshment Break*

3:45 **Conducting Pediatric AIDS Trials in Latin America — Agouron Pharmaceutical Case Study**

Pharmaceutical Perspective

The development of this research program is presented, giving the perspective of a smaller sized pharmaceutical company.

- Recognizing the right investigative sites
- Points to consider in selection of CROs and clinical laboratories
- Proactive management of the regulatory process
- Pitfalls to avoid when importing investigational drugs
- Is routine monitoring really routine?
- Strategies for effective communication — The key to success

Annkatrin Petersen, M.D., M.A., Director Head International Clinical Research, **Agouron Pharmaceuticals, Inc.**

5:15 *Close of Day One*

5:15—6:15 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Friday, March 26, 1999

8:00 *Continental Breakfast*

8:30 *Chairperson's Review of Day One*
Jenny Peters, Senior Regulatory Manager, **Pharmacia & Upjohn**

Who Should Attend

From Bio/Pharmaceutical Companies

Vice Presidents, Directors, Medical Director and Regional Product Directors of Latin America

Vice Presidents, Directors International Regulatory Affairs

Vice Presidents, Directors, Managers, Clinical Development and Clinical Operations

From CROs, Outsourcers and Logistics Providers

Vice Presidents, Directors Latin American Operations

Vice Presidents, Directors, New Business Development

Vice Presidents, Directors, International Operations

Upcoming CBI Pharmaceutical Events

Computer & Software Validation
January 21-22 • Washington, DC

Drug Delivery Systems
January 25-26 • San Diego, CA

DTC Prescription Advertising
January 27-29 • Washington, DC

Outsourcing BIO/Pharmaceutical R&D & Manufacturing
January 28-29 • Washington, DC

Dietary Supplements
February 24-26 • Washington, DC

Global Pharmacovigilance
March 22-23 • Washington, DC

Navigate Latin American Regulatory Mazes

8:45 **Preparing the Latin American Dossier — Case Studies from Leading Pharmaceutical Companies**

PHARMACEUTICAL PANEL PRESENTATION

Preparing regulatory submissions to meet Latin American requirement can be a complicated and daunting task. Learn how to systematically meet Latin American regulations and prepare the paperwork and information necessary to have your products accepted by Latin American regulatory bodies.

- Overview of the local regulations for the preparation of Latin American dossier
- Filing requirements
- Does one set of paper work fit all?
- How can you be sure your meeting all the requirements?
- Keeping up with changing regulations — There is no set system
- What kind of technology is available to make regulatory submissions easier?
- Electronic submissions • Internet access
- Special sessions from Parke-Davis
  * operations on the ground in Lima to consult with on regulations for each new product
  * survey system for each new product — letters, forms, certificates etc.

Moderator: Silvia Perez, Regulatory Specialist, Latin America, **3M Pharmaceuticals**

Panelists: John Kirk, Director, International Regulatory Affairs, **Parke-Davis**
Jenny Peters, Senior Regulatory Manager, **Pharmacia & Upjohn**
Max Talbot, International Regulatory Director, **Rhone-Poulenc Rorer**
Vivian de Trespaciaciacios, Associate Director, Regulatory Affairs, Latin America, **Pfizer**

10:15 *Networking and Refreshment Break*

10:45 **Latin American Packaging and Labeling Requirements**

Pharmaceutical Perspective

- Identify the packaging and labeling requirements in each country
- How has harmonization, in particular Mercosur, impacted packaging and labeling requirements
- Meet regional standards
- Content and warning translation
- Is it possible to create standard packaging?

Nanci Bergamo, Senior Advisor, Corporate Regulatory Compliance, **Hoechst Marion Roussel**

11:30 **Marketing and Advertising Regulations and How They Impact Your Latin American Strategy**

Pharmaceutical Perspective

- Target audiences and key messages
- Medical promotion in the past
- Current sophistication in advertising
- DTCA, Internet and public relations techniques
- Ethical standards and control of advertising and medical promotion

Adrian Cruz, Regional Director, Latin America, **SmithKline Beecham**

12:15 *Close of Main Conference*

LATIN AMERICAN BIO/PHARMACEUTICALS

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- Full Day Pre-Conference Workshop – March 24th
  Supply Chain Management
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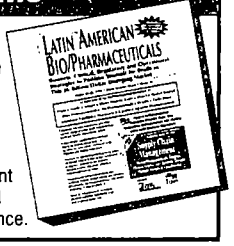
Fortunately — if you **can't attend** — you can still be informed of the latest developments in **Latin American Bio/Pharmaceuticals** by purchasing the Conference Compendium. Simply check the appropriate box on the registration form and send it with your payment of just $298. Your copy of the proceedings will be mailed immediately following the conference.



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■ **Substitution & Cancellation:**
Your registration may be **transferred** to a member of your organization up to 24 hours in advance of the conference. **Cancellations** received in writing on or before March 10, 1999 will be refunded, less a $195 administrative charge. No refunds will be made after this date; however, the registration fee less the $195 administrative charge can be credited to another CBI conference if you register within 6 months from the date of this conference. In case of **conference cancellation**, CBI's liability is limited to refund of the conference registration fee only. CBI reserves the right to alter this program without prior notice.

■ **Satisfaction Guaranteed:**
CBI stands behind the quality of its conferences. If you are not satisfied with the quality of the conference, a credit will be awarded towards a comparable CBI conference of your choice.

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Society for Neuroscience
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e-mail: nasrsvp@sfn.org

THE SOCIETY FOR NEUROSCIENCE
cordially invites you to

NEUROSCIENCE 2000:
a new era of discovery

a special event to mark
the achievements of the
"DECADE OF THE BRAIN"
and usher in a new millennium
of neuroscience discovery

April 12 – 13, 1999
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D.C.

Monday, April 12

Scientific Symposium Part I (8:00 a.m. - 5:00 p.m.)

Leading names in contemporary neuroscience will discuss the major research advances of the decade and offer projections on what's ahead in the field of brain research for the 21st century: from genetics and brain development, through neurological disease and trauma, to hearing and vision.

Evening Program and Reception (6:45 p.m. - 9:00 p.m.)

Join the biomedical research community, funding agencies, advocacy representatives, congressional leaders, and well-known proponents of brain research to mark the culmination of the congressionally designated "Decade of the Brain." Presentation of a special achievement award to actor-advocate Christopher Reeve and recognition of the 1999 Decade of the Brain Award recipient and past honorees.

Tuesday, April 13

Scientific Symposium Part II (8:00 a.m. - 12:00 p.m.)

Leading neuroscience researchers offer insight on the state of the art and future of clinical and fundamental neuroscience including brain imaging and models of the nervous system, higher brain functions and their disorders, and new findings on stress and mood disorders.

Roundtable Discussion (1:00 p.m. - 3:00 p.m.)

"Neuroscience to Neurological Recovery: The New Alliance" Hosted by Dr. Ira Black with guest participants Dr. Albert Aguayo, Christopher Reeve, and Senator Ted Kennedy, on forging alliances among advocacy groups, policy makers, and scientists to translate discoveries into new treatments for neurological illness and injury in the 21st century.

Please RSVP by March 15, 1999
(see enclosed response card)

For complete program information
visit our Web site at www.sfn.org

Casey Journalism Center for Children and Families FACT SHEET

The Casey Journalism Center for Children and Families is a national resource for journalists who cover children and family issues. Its mission is to enhance reporting about the issues and institutions affecting disadvantaged children and their families and to increase public awareness about the concerns facing at-risk children. The Center is funded by The Annie E. Casey Foundation of Baltimore, Md., the nation's largest philanthropy dedicated to improving the futures of disadvantaged children. The Center is part of the University of Maryland College of Journalism.

National Conferences: Annual fellowships for print and broadcast journalists to attend an intensive week-long conference on children's issues cover instruction, lodging, meals, reading material and a travel subsidy of up to $300. Previous conferences on welfare reform, child protection, children's health, violence and the young, and other social welfare issues have attracted a strong field of applicants. Conferences are held in June, with application deadlines in March. The next is scheduled for June 13-18, 1999. Participants join leading authorities from government, universities, research groups and the private sector for discussions on policy issues as well as practical reporting techniques and new models of children and family reporting from around the country. Previous speakers include First Lady Hillary Rodham Clinton, Department of Health and Human Services Secretary Donna E. Shalala, Attorney General Janet Reno, Children's Defense Fund President Marian Wright Edelman, Baltimore Mayor Kurt Schmoke, former *Philadelphia Inquirer* Editor Eugene Roberts and other key decision-makers and journalists. Previous recipients have said: "Among the most useful conferences I've ever attended."—Barbara Vobejda, *The Washington Post*. "If you cover children, this is one-stop shopping."--Vicky Que, *National Public Radio*.

Regional Conferences: These two-day mini-conferences target journalists in a three-to-four state area and focus on regional issues. In recent years, conferences on covering welfare reform's impact on families have been held in partnership with the Graduate School of Journalism at the University of California at Berkeley, Boston University's School of Communication, the University of South Carolina's College of Journalism and Mass Communications, and the Medill School of Journalism at Northwestern University. Fellowships cover instruction, lodging, meals, and reading materials.

Awards: The Casey Medals for Meritorious Journalism honor distinguished coverage of disadvantaged and at-risk children and their families, and the institutions and agencies charged with serving them. First-place winners in ten categories receive $1,000 awards and are eligible for $2,000 study/travel grants. Categories include newspapers, magazines, television, radio and photojournalism. Applications for the 1999 awards are due August 2, 1998. Work published or broadcast between June 1998 and June 1999 is eligible.

Resources: Information about programs and trends affecting children and families are provided to journalists in a variety of ways:

- **Database:** The Center's database of more than 3,000 experts on children and family issues is available to journalists working on daily stories or projects.
- **Kidbeat:** An e-mail discussion group is also available for journalists to exchange ideas about stories, sources and coverage problems. Journalists wishing to subscribe should send the message **subscribe kidbeat journalist's name** to listserv@umdd.umd.edu, leaving the subject line blank.
- **Web Site:** Much information is available on the Center's web site at http://casey.umd.edu. Details on everything the Center offers, past newsletters and summaries of the conferences are found here.
- ***The Children's Beat:*** Quality journalism on children and family topics is highlighted in the Casey Center's quarterly newsletter, *The Children's Beat*.

The Casey Center is a non-partisan, independent group with a national advisory board of journalists and experts on children's issues.

For more information, contact:
Casey Journalism Center; 8701-B Adelphi Road; Adelphi, Md. 20783-1716.
Phone: 301-445-4971. Fax: 301-445-9659. E-mail address: jmoore@casey.umd.edu

Casey Journalism Center for Children and Families

Cathy Trost
Director

...1-B Adelphi Road • Adelphi, Md. 20783-1716 • (301) 445-4971 • Fax: (301) 445-9659 • http://casey.umd.edu

...enter is operated by the
...niversity of Maryland,
College of Journalism.

Cathy Trost
Director

Dear Colleague:

The Casey Journalism Center for Children and Families is a national resource center for journalists who cover issues and institutions affecting disadvantaged children and their families. The center is funded by the Annie E. Casey Foundation and located at the University of Maryland College of Journalism.

We are continuously updating our database of sources and experts on a variety of issues related to children and families. Many journalists use our database to obtain the names of experts in a variety of fields. *Please take a moment to fill out the information requested below.* We would also appreciate it if you would check off your main areas of interest, types of publications available, and organizational type. As news reporters attempt to bring balance to their stories, it's helpful for them to know an organization's philosophical orientation. If you feel it is appropriate, please also check the category of organizational label that you believe best describes your organization.

Please attach a brief description of your organization and fax it to (301)445-9659 or fold this form into thirds, staple it and send it back to us.

Thank you for your assistance.

Name: **Phone:**
Title: **Fax:**
Organization: **E-mail:**
Address: **Web URL:**

MAIN AREAS OF INTEREST (please check all that apply)

- ❑Welfare
- ❑Teen & Out-Of-Wedlock Childbearing
- ❑Poverty
- ❑Child Health /Development
- ❑Adolescence
- ❑Juvenile Justice
- ❑Community Renewal
- ❑Child Abuse & Neglect
- ❑Child Welfare/Foster Care
- ❑Statistical Data
- ❑National/State Advocacy
- ❑Parenting/Family Supports
- ❑Child Care
- ❑Early Education
- ❑Education
- ❑Impact of Violence on Children
- ❑Juvenile Crime
- ❑Children & New Technologies
- ❑Media Violence
- ❑Work and Family
- ❑Model Programs
- ❑Divorce/Custody/child Support
- ❑Immigration
- ❑Resiliency
- ❑Economic Issues
- ❑Homelessness
- ❑Other (pls specify)

Organizational Type
- ❑Advocacy
- ❑Foundation
- ❑Academic
- ❑Research
- ❑Education
- ❑Corporation
- ❑Federal/State Government
- ❑Program
- ❑Other (pls specify)

Organizational Label
- ❑Liberal
- ❑Conservative
- ❑Moderate
- ❑N/A
- ❑Other (pls specify)

Publications
- ❑Newsletter
- ❑Survey & Data Analysis
- ❑Annual Report
- ❑Other (pls specify)

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- Find out when and why to **outsource** parts of your distribution process
- Two Pharmaceutical/Vendor success stories —
  - **Merck's vendor selection** and successful integration across it's European supply chain
  - **Zeneca's vendor partnership** and the resulting cost reduction through a shared distribution network
- Design **logistics networks** that serve several channels simultaneously
- The **SCOR model** — Cross enterprise/cross functional application for improving the bottom-line
- Overcome **customs, regulatory** and **cross border licensing** obstacles
- Understand the limitations imposed on **patent, trade secret, data protection** and **trademark systems** by various global IP systems
- Maintain a **zero defect** environment

Panel

Plus A Panel on U.S. Export Administration Featuring:
- U.S. Drug Enforcement Agency
- U.S. Customs Outbound Process
- Bureau of Export Administration

CHOOSE FROM TWO COMPREHENSIVE PRE-CONFERENCE WORKSHOPS — JUNE 24, 1999

I. Manage the "Cold-Chain"
Temperature Controlled Shipping

II. E-Commerce and On-line Pharmacies
How Big a Role They'll Play in Future Distribution Models

Distinguished Faculty

Phillip Abbate, Global Account Director, Pharmaceuticals, **Circle International, Inc.**

Jim Adams, Vice President, Customer Service, **Oncology Therapeutics Network (A Bristol-Myers Subsidiary)**

Mark Capofari, Director, Global Logistics and Planning, **Merck & Co., Inc.**

Herbert W. Davis, Chairman, **Herbert W. Davis and Company**

James E. Kulda, Manager, Order Fulfillment, **Zeneca Pharmaceuticals**

George Kulovic, Regional General Manager, **Circle International**

Jeffrey Kushan, Special Counsel, **Powell Goldstein, Frazer & Murphy, LLP**

Peter H. Powell Sr., CEO, **C.H. Powell Company**

Tom Pigott, CEO, **Soma Corporation**

Tom Pringle, President, **Insulated Shipping Containers, Inc.**

David Rogers, General Manager, **National Wholesale Druggist's Association Service Corporation**

Eugene Rostov, Senior Partner, International Trade, **Baker & McKenzie**

Tom Schafer, Vice President, Productivity and Technology, **National Wholesale Druggist's Association**

Scott Stephens, Chief Technology Officer **Supply Chain Council**

Michael A. Swanson, Vice President, Business Development, **Caliber Logistics Healthcare (An FDX Company)**

Jeanne Taborsky, Former FDA Scientist; Consultant, **Scientific & Regulatory Affairs Consulting**

John Thurow, Director of Industry and Solution Marketing, **Sterling Commerce**

Robert Ulery, Solution Development Manager, Consumer Sector, **Exel Logistics Americas**

Linda Walker, Department Head, Package Testing, **Wyeth Ayerst**

Cline York, Manager, Integrated Solutions Group, **Fed-Ex Global Sales**

Organized By:

The Center for Business Intelligence

CBI's Pharmaceutical Series

MAIN CONFERENCE

Day One — Thursday, June 24, 1999

12:30 *Main Conference Registration*

1:15 *Chairperson's Welcome and Opening Remarks*
Tom Pringle, President,
Insulated Shipping Containers, Inc

1:30 **Pharmaceutical Distribution Costs and Trends — Hard Core Techniques for Cost Reduction**
Benchmark studies have been conducted in this area for the past twenty five years. What is the average amount spent by a pharmaceutical company both at the manufacturing end of the business and at the wholesale and distribution end? Hear from both sides of the spectrum and find out what strategies to use in order to significantly reduce these costs.
- Cost and service data outlined and defined
- Manufacturers and wholesalers
- Discussion of trends in cost and service
- Implications for pharmaceutical logistics
- How this differs from other related industries
- Distribution strategies now being pursued

Herbert W. Davis, Chairman,
Herbert W. Davis and Company
Tom Schafer, Vice President Productivity and Technology, **National Wholesale Druggist's Association**

2:15 **Vendor Selection and Integration into Third Party Logistics Program**
Pharmaceutical/ Vendor Success Story
Merck Pharmaceuticals selected Circle International, a third party logistics company, to oversee all aspects of management and coordination of both raw materials and commercial products across the European supply chain. This case study focuses on what went into the decision making process, what if anything could be changed to better the process and lessons learned from the process.
- The selection process — key element in the decision making process
- The transitional challenge — lessons learned
- The final scope
- The benefits derived

Phillip Abbate, Global Account Director, Pharmaceuticals, **Circle International, Inc.**
Mark Capofari, Director, Global Logistics and Planning, **Merck & Co., Inc.**

3:00 *Networking and Refreshment Break*

3:30 **Develop Logistics Channels and Strategies — Optimize Your Network, While Balancing Service Levels and Logistics Expenses**
As customers continue to demand greater service and higher quality levels, the need for flexible and economic logistics strategies has never been more acute. Logistics channel strategies can provide specific values to unique customer subsets while keeping total logistics expenses under control.
- Understand the specific values your customers demand
- Approaches to identifying channel opportunities
- Build a logistics strategy for each channel
- Design logistics networks that serve several channels simultaneously
- Examine how logistics partners or vendors can help

Robert Ulery, Solution Development Manager, Consumer Sector, **Exel Logistics Americas**

4:15 **Supply Chain Management — Cross-Enterprise/Cross-Functional Strategies for Improving the Bottom-Line**
Over 450 companies have combined forces to determine new strategies for improving all phases of the process of delivering their products to their customers. The Supply Chain Council's Supply Chain Operations Reference (SCOR) Model has been used by member companies to improve source, make and delivery performance — and measure their improvements in dollar value.
- Use benchmarking and metrics for supply chain strategy and competitive analysis
- Process, best practice and technology
- Align business performance, supply chain practice and systems
- Implement supply chain improvements

Scott Stephens, Chief Technology Officer,
Supply Chain Council

5:00 *Close of Day One*

5:00-6:00 ***Wine & Cheese Networking Reception***
Join colleagues and friends in a relaxed setting.

Day Two — Friday, June 25, 1999

8:00 *Continental Breakfast*

8:30 *Chairperson's Review of Day One*
Tom Pringle, President,
Insulated Shipping Containers, Inc.

8:45 **Cost Reduction Through a Shared Distribution Network**
Pharmaceutical/ Vendor Success Story
Zeneca Pharmaceuticals, along with another major pharmaceutical company, joined forces with Caliber Logistics Healthcare to create a healthcare only temperature controlled delivery system.

This case study focuses on how this relationship developed and lessons learned from it.

- Background information — Pharmaceutical distribution needs at one end and USP validation compliance at the other
- Benefits of economies of scale by consolidating shipments from two separate clients and optimizing space requirements
- Efficient management of the trucking fleet using an automated "Routing Optimization Software"
- Reaching a win-win situation, costs avoided by both parties by formalizing this mutually beneficial relationship

Michael A. Swanson, Vice President, Business Development, **Caliber Logistics Healthcare (An FDX Company)**

James E. Kulda, Manager, Order Fulfillment, **Zeneca Pharmaceuticals**

9:30 **Manage Licensing and Regulatory Issues — The Legalities Pertaining to Global Distribution**

When entering an international market there is an entirely new set of barriers to work through. This session shows you how to identify and overcome key licensing and regulatory hurdles.

- Work within the regulatory framework to protect your market position — Use it to your advantage
- Understand what the member countries are hoping to achieve or prevent with their regulations
- Tap into the right channels to influence regulatory decisions
- Cross border licensing issues affecting the distribution process

Eugene Rostov, Senior Partner, International Trade, **Baker & McKenzie**

10:15 *Networking and Refreshment Break*

10:45 **The Importance of Protecting Intellectual Property in the Global Market**

To effectively compete in the global market, companies must adopt intellectual property protection strategies that will ensure effective protection of rights on a worldwide basis. Developing such strategies requires an understanding of the pitfalls and limitations of the global environment for intellectual property protection.

- Appreciating the international environment defined by treaties and regional and national systems
- Unique features of patent systems and how to overcome problems caused by these differences through use of the PCT and direct application filing strategies
- Selecting key markets for protection to manage costs of procuring and enforcing rights
- Understanding the limitations imposed on patent, trade secret, data protection and trademark systems by various intellectual property systems

Jeffrey Kushan, Special Counsel, **Powell Goldstein Frazer & Murphy, LLP**

11:30 **Customs — Legally Navigate Business Relating to the Export Administration Regulations of the United States**

Panel

In order to export your commercial products legally and most cost effectively, it is imperative to comply with U.S. export regulations.

- Is your customer the true end user?
- Compliance and reporting requirements with US governmental agencies
- Protect your company's ability to export
- Avoid fines, penalties and possible criminal action

Moderator: *Peter H. Powell Sr., CEO,* **C.H. PowellCompany**

Panelists: **U.S. Drug Enforcement Agency**
U.S. Customs Outbound Process
Bureau of Export Administration

12:30 *Luncheon*

2:00 **Transportation and Distribution – Developing a Strong Outsourcing Strategy**

Outsourcing – a threat or an opportunity? This discussion provides tactics and strategies on how to take charge and lead your companies efforts in this area.

- When does it get imperative to consider outsourcing?
- Understanding the value of outsourcing
- What aspects of this area should get outsourced?
- How much control should be retained in-house?
- What are the stages of "letting go"?

Jim Adams, Vice President, Customer Service, **Oncology Therapeutics Network (A Bristol-Myers Company)**

2:45 **Incorporate a Zero Defect Warehousing Strategy into your Distribution Network**

The biggest challenge inherent in a standard pharmaceutical warehousing operation today, is the struggle towards maintaining a zero defect environment.

- Improve your tracking and distribution through automated material handling systems.
- Inventory control — rotation and tracking of inventory
- Facility management — ensure security, sanitation and safety

George Kulovic, Regional General Manager, **Circle International;** *former Regional Warehouse Manager,* **Bristol-Myers Squibb**

3:30 *Close of Main Conference*

Maximize Your Networking Opportunities

Don't miss the opportunity to network and showcase your products and services to senior-level decision makers. CBI's **Solutions for Global Pharmaceutical Distributions** conference offers you an excellent opportunity to maximize your 1999 marketing dollars through these showcase opportunities:

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If you are interested in sponsorship & exhibit opportunities, please call Chris Currie at 781-939-2503 or fax 781-939-2495.

PRE-CONFERENCE WORKSHOP I — THURSDAY, JUNE 24, 1999

Manage the "Cold-Chain"

Temperature Controlled Shipping

With the increasing number of temperature sensitive, heat labile pharmaceuticals and vaccines in the distribution environment, this workshop provides background on the regulatory pressures that are now affecting how manufacturers protect their products all the way to the end user. Learn the common practices in industry for development and test analysis of thermal packaging, including valuable information on how the distribution environment is measured to develop pre-shipment testing criteria. The latest information on the new USP chapter covering temperature-controlled packaging is also presented.

7:30 *Workshop Registration*

8:30 **Regulatory Trends Impacting the Production, Packaging, Storage and Distribution of Temperature Sensitive Pharmaceuticals**

Pharmaceutical and related products are required to be handled safely and efficaciously from concept into the hands of the consumer. Government agencies and the private sector are working towards providing standards for the shipment and storage of these materials.

- Regulatory agencies involved in the process
- Current agency regulations
- Scientific considerations
- Regulatory trends for the future of temperature sensitive materials

Jeanne Taborsky, Former **FDA** *Scientist; Consultant,* **Scientific & Regulatory Affairs Consulting**

9:30 **The Fundamentals of Thermal Packaging — Current Materials and Practices in the Industry**

This session introduces the theory of thermal package design and testing. Examples of commonly used methods for short and long-term in transit are provided.

- Background on temperature control theory and package design
- Old and new methods of maintaining the cold-chain
- Choosing the right package for each application – preventing over and under engineering
- Industry practices for package qualification testing

Tom Pringle, President, **Insulated Shipping Containers, Inc.**

10:30 *Networking and Refreshment Break*

11:00 **Environmental Recording Process and Study Presentations Inherent in the Distribution Environment**

This session focuses on measuring the distribution environment and using this information to develop pre-ship testing criteria. It also talks about methods used to better understand the envelope of environmental transportation conditions and the normal distribution of temperature ranges.

- Temperature measuring devices
- Collecting field data
- Some examples of field data
- Using field data to create a test protocol
- Latest developments pertaining to the USP Chapter and its implications on temperature controlled shipping

Linda Walker, Department Head, Package Testing, **Wyeth Ayerst**

12:00 *Close of Workshop*

— About Your Workshop Leaders —

Jeanne Taborsky who is now a consultant with **Scientific & Regulatory Affairs Consulting** was a Former **FDA** Scientist. She has over 30 years experience with pharmaceuticals and related products. She specializes in the packaging, storage, and distribution of sensitive articles and has conducted extensive research in this area. Her previous employers include the FDA and US Pharmacopia and industry.

Tom Pringle is president and CEO of **ISC, Inc.** based in Phoenix, Arizona. ISC is a pioneer in the development and test analysis of high performance thermal packaging for the pharmaceutical and blood industries. Prior to joining ISC, Tom was Director of International for a US healthcare division of Boehringer Mannheim, and Marketing Manager for a division of Beckman Instruments. Tom holds a degree in Biology from Willamette University, has presented at many seminars and written several publications on temperature controlled packaging.

Linda Walker is Department Head, Package Testing at **Wyeth Ayerst.** She has nearly 30 years of experience in packaging, and has spent the last 20 years in pharmaceuticals. She has worked in designing and testing thermal packaging for 20 years. She re-wrote D 3103 and participated in developing both the draft ISTA method and USP General Chapter on Packaging.

PRE-CONFERENCE WORKSHOP II — THURSDAY, JUNE 24, 1999

E-Commerce and On-line Pharmacies

How Big a Role They'll Play in Your Future Distribution Models

As more companies are beginning to take the plunge into e-commerce, the world wide web's list of pharmacy sites is growing at an amazing pace. Everything from prescription drugs, to over-the-counter remedies can now be ordered by consumers on-line to be delivered to their homes the next day. What impact is this going to have on today's model pharmaceutical distribution network? This workshop focuses on using the internet and e-commerce successfully as an innovative new tool to expedite the distribution process.

7:30 *Workshop Registration*

8:30 **Simplify and Expedite the Electronic Exchange of Business Transactions Among Multiple Trading Partners — Build, Manage and Service Your Local, Regional and Global Trading Communities**

Sterling Commerce, a leading worldwide provider of business-to-business electronic commerce software and services, has had significant success in the pharmaceutical arena. Hear first hand about how the alliance of Sterling Commerce and the National Wholesale Druggist's Association can help you optimize your distribution process,and what the added benefits of doing this are.

- What is e-commerce?
- What is EDI?
- How does the use of an Intranet/Extranet help build closer relationships with suppliers and customers?
- How can the HEALTHCOM Catalog, a centralized electronic repository of critical product data, improve your profitability?
- What are some of the advanced e-commerce applications?
- What effect will this have on your bottom line?

John Thurow, Director of Industry and Solution Marketing, **Sterling Commerce**

David Rogers, General Manager, **National Wholesale Druggist's Association Service Corporation**

9:30 **Drug Stores on the Internet – How On-Line Pharmacies Impact Pharmaceutical Distribution Networks Worldwide**

As more companies get set to take the plunge into e-commerce, the World Wide Web's list of pharmacy sites is growing at an amazing pace. What impact is this going to have on today's model pharmaceutical distribution network?

- What are on-line pharmacies?
- The role of an on-line retail pharmacy and how this differs from retail chain drug stores
- The challenges of integrating front end web site applications with efficient back end fulfillment processes
- Industry dynamics and partners
- Where do we go from here? How will this change today's model distribution network and a customer's future perception of drugstores?

Tom Pigott, CEO, **Soma Corporation**

10:30 *Networking and Refreshment Break*

11:00 **Back-End Logistical Support for E-Commerce and Cataloging**

So if E-Commerce takes to the runway and customers worldwide start placing prescription orders on the internet — Who is going to ensure that orders placed, get to the right customer, on time, safely and efficiently?

- Fedex.com – Portal to FedEx Information Systems
- E-commerce connectivity tools
- Time definite delivery services via FedEx air-ground networks
- Integrated solutions

Cline York, Manager, Integrated Solutions Group, **Fed-Ex; Global Sales**

12:00 *Close of Workshop*

— About Your Workshop Leaders —

John Thurow is Director, Industry and Solutions Marketing for the Commerce Services Group of **Sterling Commerce,** a leading worldwide provider of electronic commerce solutions. John and his staff work with Sterling's product management and development organization to define electronic commerce solutions that solve known and anticipated business problems. Thurow has been with Sterling Commerce for over nine years, and has over 30 years of experience in computer information services, decision support systems, and electronic commerce. His industry activities include participation on the National Wholesale Druggists' Association's HEALTHCOM Advisory Council and the board of directors of the Association for Electronic Health Care Transactions (AFEHCT).

David Rogers is President of **Rogers Health Care Consulting, LTD (RHCC).** From Evansville, IN and Yardley PA offices, the RHCC principals specialize in developing Information Management Systems from a business perspective for healthcare manufacturers and distributors. Additionally, Rogers has served as the General Manager of **National Wholesale Druggists Association Service Corporation** since September of 1994. In his role as General Manager, he is responsible for the activities of the for-profit subsidiary of the NWDA and directed the creation of the HEALTHCOM®/ Sterling Commerce Alliance. Prior to Rogers forming his own company in 1994, he was employed by Bristol-Myers Squibb for 25 years, retiring as Director, Administrative Services. Rogers holds a B.S. in Economics from the Wharton School of the University of Pennsylvania and an MBA from the University of Evansville.

Tom Pigott is the CEO and Founder of **Soma Corporation** Fulfilling an interest in international commerce, Tom spent several years overseas with postings in Japan, China and Brazil. He worked for both Nextel and Caterpillar helping develop high technology systems and infrastructures. While overseas, Tom used the Internet for worldwide communications and quickly recognized the potential of the World Wide Web for e-commerce applications. After returning to Seattle, Tom did extensive research and formed Soma Corporation; a privately funded company based in Seattle. Soma.com provides people with the highest quality prescription medications, OTC products, vitamins, herbal and alternative medicines using Internet technology and available overnight delivery. Tom graduated from Stanford University.

Cline York is manager for **FedEx** Integrated Solutions Group. Cline has over twenty years of experience in Logistics, E-Commerce and Express Transportation.

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Solutions for Global Pharmaceutical Distribution '99

Cut Costs and Exceed Customer Expectations Worldwide through Advanced Distribution Networks

5 Key Reasons To Attend

- **A choice between two concurrent workshops:**
  1. **Manage the Cold Chain — Temperature controlled shipping**
  2. **E-Commerce and On-line Pharmacies — How big a role they'll play in future distribution models**
- **A Pharmaceutical/Vendor success story — Merck Pharmaceuticals and Circle International**
- **Panel**
  - **U.S. Drug Enforcement Agency**
  - **U.S. Customs Outbound Process**
  - **Bureau of Export Administration**
- **Pharmaceutical companies participating include –**
  - **Bristol-Myers Squibb • Merck Pharmaceuticals**
  - **Wyeth Ayerst • Zeneca Pharmaceuticals**

Compendiums

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  Contact the hotel directly by June 2, 1999 to qualify for special reduced rates. CBI's official travel service, Travel Concepts, can negotiate low group air fares and car rentals. Call them at 800-640-8082 (508-879-8600 outside the U.S.) Mention that you are attending CBI's **Solutions for Global Pharmaceutical Distribution '99** conference to qualify for hotel and travel discounts.
- **Substitution & Cancellation:**
  Your registration may be **transferred** to a member of your organization up to 24 hours in advance of the conference. **Cancellations** received in writing on or before June 10, 1999 will be refunded, less a $195 administrative charge. No refunds will be made after this date; however, the registration fee less the $195 administrative charge can be credited to another CBI conference if you register within 6 months from the date of this conference. In case of **conference cancellation**, CBI's liability is limited to refund of the conference registration fee only. CBI reserves the right to alter this program without prior notice.
- **Satisfaction Guaranteed:**
  CBI stands behind the quality of its conferences. If you are not satisfied with the quality of the conference, a credit will be awarded towards a comparable CBI conference of your choice.

5 Easy Ways to Register

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Utilize SMO Value-Added Services to Reduce Cycle Times and Improve Data Quality

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- ClinCare
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- Guilford Pharmaceuticals, Inc
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- Heller Ehrman White & McAuliffe
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- Matthews Media Group
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- Pharmaceutical Development Center
- Phase Forward
- PPD Pharmaco
- Protocare
- Quintiles
- Rheumatology Research International
- SmithKline Beecham
- University of Rochester Medical Center
- Waife & Associates

PANEL Choose the **best SMO model** —
Owned sites, affiliated, network groups, hybrids — *which add value?*

- Identify **value added SMO benefits** — Rapid study start up time, patient recruitment, QA and SOPs, staff training and accreditation, IRB approvals, centralized contract and budget negotiations, site integration process *and more...*
- **Accelerated patient recruitment** — materials development, call centers and media coverage
- **Site selection** — A step-by-step approach
- **Performance-based contracts** — Understand why and how to link "payment" to "performance", including *incentives and penalties*
- **Pricing models and matrix** — Use a standard per patient cost for all investigators
- **Fixed Unit Pricing** — More flexibility and less conflict with contract modifications
- Special issues in contracting with SMOs and other **hypercomplex "web" entities**
- Gain consistency between SMO-client and **SMO-Affiliate site agreements**

— CHOOSE FROM 2 INTERACTIVE PRE-CONFERENCE WORKSHOPS JUNE 17, 1999 —

WORKSHOP I

Evaluate Academic Medical Centers as Alternative Study Conduct Models

Academic Medical Centers are Delivering Results — Hear how AMC's respond to Sponsor demands for efficient study conduct models

WORKSHOP II

Information Technology — Providing SMOs with a Competitive Advantage

Improve your 5 most critical management areas

- Account Management
- Operations Management
- Clinical Data Collection
- Patient Recruitment
- Financial Management

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CBI's Pharmaceutical Series

CHOOSE FROM 2 CONCURRENT PRE-CONFERENCE WORKSHOPS JUNE 17, 1999

— WORKSHOP I —

Evaluate Academic Medical Centers as Alternative Study Conduct Models

An interactive discussion of the issues and opportunities with respect to clinical trials strategies successfully being implemented at Academic Medical Centers. The constraints inherent in academia's non-profit, education status and its academic research mission are far outweighed by the advantages of working with the thought leaders in the investigational field and decrease drug development cycle time. The following 4 hour, interactive discussion shows you why and how to use AMCs efficiently.

7:30 *Workshop Registration*

8:00 *Workshop Leaders Opening Remarks*

I. AMC Models Competing for Study Opportunities

II. Explore the Advantages and Disadvantages of Using Academic Medical Centers

- Scientific expertise
- Large, diverse patient population
- Central clinical research office
- Sales platform
- Bureaucracy
- Standardization with IRB
- Database control
- High impact publications

III. Evaluate Methods for Decreasing Contract Cycle Times

- Efficient cycling yields non-stop process for contract completion
- Avoiding legal pitfalls — the key to win-win repeat business
- Standardize the approach for optimal end result

IV. How AMCs are Budgeting to Stay Competitive

There will be a 20 minute networking and refreshment break at 10:30

12:00 *Close of Workshop*

— About Your Workshop Leaders —

Denni Day, RN, MSPH, is the Director of the Community Research Network and CFO of the Clinical Research Institute at the **University of Rochester Medical Center**. Prior to this position, Ms. Day served as Director of the Clinical Trials Coordination Center at the University of Rochester and administered both the Parkinson Study Group and the Huntington Study Group, which are international consortia of academic movement disorder specialists. Ms. Day received her education at the University of North Carolina, (Chapel Hill), American University and Alfred University.

Elizabeth C. Pratt (Lisa), is the President and CEO of **Health Research Association**. HRA develops and manages all private industry sponsored research projects that are under the direction of the University of Southern California School of Medicine faculty. Ms. Pratt received an AB degree from Princeton University, 1980 and an MBA degree from Pepperdine University, 1984.

H. Gilbert Smith, Ph.D., is the Associate Director of **Duke University Office of Science and Technology**, with responsibility for review, negotiation and approval of all commercially sponsored research agreements, including clinical trials, and for patent and licensing activities relating to medical devices. Dr. Smith joined Duke in April 1994 with over twelve years of industrial management and R&D experience and has held positions as Director of Chemistry and Biochemistry. Dr. Smith received his Ph.D. from the University of Virginia, M.S. from Northwestern University. Dr Smith holds four patents and has authored numerous scientific publications.

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4:00 **Site Selection — How Sponsors/CROs/SMOs Choose High Performance SMO and Investigative Sites**

- A step-by-step approach to the selection process
- What Sponsors look for during site and SMO selection
- Sponsors expectations from investigative sites
- Performance metrics used
- Site strategies for getting selected for a study
- Defining roles of each partner

Moderator: *Terry Osborn, Ph.D., President and CEO,* **Pharmaceutical Development Center**

Panelists: *Mary Wester, R.N., B.S.N., O.C.N., Associate Director Investigator and Government Relations,* **Quintiles Oncology Therapeutics**

David Carpenter, R.Ph., M.S., Associate Director, CNS Clinical Research, Development and Medical Affairs, **SmithKline Beecham**

Phil Tegeler, Director of Operations Site Management Organizations, **MDS Harris**

4:45 **Develop an Accelerated Patient Recruitment Program**

- Planning accelerated patient recruitment
- Audience analysis
- Materials development and use
- Call centers
- Generating media coverage
- Events and intermediary groups

Molly Matthews, President, **Matthews Media Group**

5:30 *Close of Day One*

5:30—6:30 Wine & Cheese Networking Reception

Join colleagues and friends in a relaxed setting.

DAY TWO — Friday, June 18, 1999

3:00 *Continental Breakfast*

3:30 *Chairman's Review of Day One*
Gary D. Lightfoot, CEO,
Association of Clinical Research Professionals

3:45 **Enhance and Measure Performance of Investigative Sites When Working with Sponsor, CRO and SMO**

A case history is presented on how Sponsors and CROs can use metrics to measure performance of investigative sites.

- Time to final budget/contract
- IRB submission and regulatory document completion
- Time to complete patient enrollment
- Time to database closure

Steve Rauscher, CEO, **Affiliated Research Centers, Inc.**
John Potthoff, Director of Clinical Operations, **PPD Pharmaco**
Marilyn Long, Clinical Research Manager, **Bristol-Myers Squibb Pharmaceutical Company**

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CONTRACTING THAT WORKS

9:45 **Risk and Risk Sharing — Regulatory and other Liability Considerations**

- What are the risks for the vendor and client
- Consistency between SMO-Client and SMO-Affiliate site agreements
- Special issues in contracting with SMO and other hypercomplex "web" entities
  - ➢ verification of site specific issues
  - ➢ intellectual property issues
  - ➢ financial disclosure
  - ➢ audit independence
  - ➢ indemnification and other risk management issues

Gary E. Gamerman, MS., J.D., Attorney at Law,
Heller Ehrman White & McAuliffe

10:30 *Networking & Refreshment Break*

11:00 **Performance-based Contracts — Assuring Timeline Adherence with Financial Accountability**

SPONSOR PERSPECTIVE

- Demonstrate the utility of performance-based contracts
- Understand the why and how to link "payment" to "performance"
- Roles of subcontractors in performance-based contracts
- How to use incentives and penalty clauses to your benefit
- How well written contracts will assist your project management function
- Evaluate use of full project vs. single study contracts

Charles R. Bradley, Director of Clinical Operations,
Guilford Pharmaceuticals, Inc.

12:00 *Luncheon*

APPLYING PRICING AND INCENTIVES

1:15 **Deciding When and How to Use Incentives**

SPONSOR PERSPECTIVE

- Objectives and types of incentives
- Benefits and risks of using incentives
- Model use of incentives

Mark R. Lange, Counsel for Legal (Regulatory Affairs-LRL),
Eli Lilly and Company

2:00 **Pricing Models and Matrix — How SMO's and Sponsors Work Together to Contain Costs and Remain within Budget**

SPONSOR PERSPECTIVE

- Defining who is responsible for what costs
- Pricing structure — per patient cost
- Pricing matrix
- Streamlined contracting — single contract between SMO and sponsor
- Standard per patient cost for all investigators within the SMO
- Bonus payments

Uma Storm, MBA, Clinical Business Analyst, **Biogen, Inc.**

Daniel Freedman, Ph.D., Clinical Project Manager, **Biogen, Inc.**

— WORKSHOP II —

Information Technology —Providing SMOs with a Competitive Advantage

An SMO's competitive advantage is based on inventory (patients, physicians), process and infrastructure. Without these components, SMOs do not bring sufficient value to the clinical research process. Information technology is a critical aspect of an SMO's infrastructure; indeed it is a measure of the SMO's likely effectiveness. Learn how to streamline the clinical trial process and understand how a centralized, real-time database provides complete business process integration.

7:30 *Workshop Registration*

8:00 *Workshop Leaders' Opening Remarks*

I. Information Technology Serves the SMO in 5 Critical Ways

- Account Management
- Operations Management
- Clinical Data Collection
- Patient Recruitment
- Financial Management

II. Presenters Engage the Participants in a Discussion on Each Application, with Special Emphasis on the First Three

In each application, we will present on:

- Typical SMO Business Requirements
- Technology Architecture Alternatives
- Build vs. Buy
- Cost Considerations, Short and Long Term
- Internal Support Requirements
- Implementation Implications
- Integration Issues
- Coordination with Sponsors/CROs

Participants are encouraged to prepare examples from personal experience and problems or issues they are wrestling with, for sharing and group discussion.

There will be a 20 minute networking and refreshment break at 10:30.

12:00 *Close of Workshop*

— About Your Workshop Leaders —

Ronald S. Waife is President of **Waife & Associates**, Inc., which has served over sixty clients since 1993, providing technology, business and marketing consulting to clinical research sponsors, CROs, SMOs and investors. Mr. Waife has consulted to SMOs since 1995 on IT priorities and marketing tactics. Prior to starting his own firm, he served in executive positions in high-tech companies and an international health foundation. He holds undergraduate degrees from Johns Hopkins and a master's from Harvard.

Michael Vernia is Senior Vice President and CIO of **Protocare Inc.**, the parent company of Protocare Trials, a major national SMO based in Los Angeles. Prior to joining Protocare, Mr. Vernia served for over nine years as the senior technology executive at Value Health Sciences, ultimately becoming Sr. Vice President and Chief Information Officer. Mr. Vernia received his BSc and MSc degrees in Computer Science from the Technion, Israel Institute of Technology.

Paul Bleicher, M.D., is Chairman and Chief Scientific Officer of **Phase Forward Incorporated**, providers of Internet-based clinical data management products and services to pharmaceutical, biotechnology and medical devise companies. Dr. Bleicher founded and moderated the Internet-based Clinical Trials Mailing List, is the Information Technology Editor of www.clinmark.com, and serves on the editorial board of the Dermatology Online Journal. He is a member of the DIA Steering Committee of the Americas.

MAIN CONFERENCE

DAY ONE — Thursday, June 17, 1999

12:00 *Registration & Refreshments*

1:00 *Chairman's Welcome and Opening Remarks*
Gary D. Lightfoot, CEO,
Association of Clinical Research Professionals

SMO MODELS & VALUE ADDED SERVICES

1:15 **Differentiate and Re-Evaluate SMOs — Identify and Compare the Study Conduct Models**

PANEL

- Understand the different models
  - ➢ owned sites
  - ➢ affiliates
  - ➢ network groups
  - ➢ hybrids
- What makes them different?
- How do they add value?

Moderator: *Gary D. Lightfoot, CEO,* **Association of Clinical Research Professionals**

Panelists: *William H. Stigelman, Jr. Pharm.D., Vice President Affiliate Site Relations,* **Collaborative Clinical Research, Inc.**

Robert E. Conway, Executive Vice President and COO, **Hill Top Research**

Roy Fleischmann, M.D., Chief Scientific Officer & Chairman, **Rheumatology Research International**

Darren Black, CEO, **ClinCare**

2:15 **Identify Value Added Benefits to Attract and Maintain the Sponsor's Attention**

- Rapid study start-up time
- Patient recruitment
- Quality assurance and process standards (SOPs)
- Staff training and accreditation
- IRB approvals
- Centralized contract and budget negotiations
- Site integration processes

Paul G. Conway, Ph.D., Vice President, Project Management and Clinical Services, **Clinical Studies Ltd.**

3:00 *Networking & Refreshment Break*

3:15 **CRO/SMO Mergers — Full Service Providers for Clinical Trial Product Development**

- What is a hybrid?
- Efficiencies of one service provider
- Communication issues
- Combined field operations
- Is there a conflict of interest with a CRO/SMO acting as one?
- Advantages and disadvantages of the merger

Jeff Jensen, Vice President Operations, **INC Research**

4:00 **Site Selection — How Sponsors/CROs/SMOs Choose High Performance SMO and Investigative Sites**

PANEL

- A step-by-step approach to the selection process
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Charles R. Bradley, Director of Clinical Operations, **Guilford Pharmaceuticals, Inc.**

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Mark R. Lange, Counsel for Legal (Regulatory Affairs-LRL), **Eli Lilly and Company**

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- Bonus payments

Uma Storm, MBA, Clinical Business Analyst, **Biogen, Inc.**

Daniel Freedman, Ph.D., Clinical Project Manager, **Biogen, Inc.**

2:45 **Fixed Unit Pricing — A Measurable Management Tool**

- More flexibility and less conflict with contract modifications
- Fair pricing and compensation
- Improved site management — creating better management tools for the SMO
- Shortened contract negotiation

Mark Slama, Manager, Bids and Contracts, **MDS Harris**

3:30 *Networking & Refreshment Break*

STANDARDIZATION AND QUALITY

3:45 **Partnerships Between Sponsors, CROs and SMOs — Expectations and Opportunities**

Understand how Sponsor/CRO/SMO work together to succeed and what performance measures sponsors need to put in place to maximize ROI with CROs and SMOs.

- Selecting partners vs. vendors
- Resourcing operations and business needs
- Setting expectations
- Partnering smarter
- Measuring success

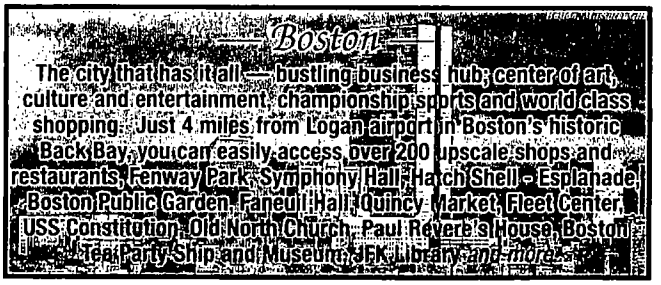
Bruce Maloff, Vice President Business Development, **Quintiles**

4:30 **Sponsor/CRO Usage Practices of SMOs — Impact on Quality, Speed and Costs**

- Overview of SMO market in the U.S. and Europe — Current and future market trends
- How are Sponsors and CROs using Site management organizations
- How do SMOs compare to independent sites? — A review of a new CenterWatch survey
- Market changes and implications on future SMO usage

Annick de Bruin, Research Analyst, **CenterWatch**

5:00 *Close of Main Conference*



SITE MANAGEMENT ORGANIZATIONS

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RAVE REVIEWS

Here Is What Previous CBI Attendees Had to Say:

"CBI ran one of the most professional and useful conferences I have attended in this area".
— Ron Cohen, President and CEO, **Acorda Therapeutics**

"A very useful meeting — several good presentations that discussed what CROs/SMOs can and can't do."
— Dan Levitt, Senior Vice President of Clinical and Regulatory Affairs, **Protein Design Labs, Inc.**

"Good networking."
— Richard Musselman, Senior Director, R&D, **Searle**

"Very good topics covering the spectrum of issues that everyone in the contract research industry experiences at one time or another."
— Edmond Plazkowgki, Senior Business Analyst, **R&D; Schwartz Pharma**

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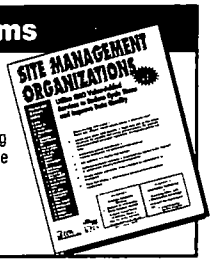
Fortunately — if you **can't attend** — you can still be informed of the latest developments in **Site Management Organizations** by purchasing the Conference Compendium. Simply check the appropriate box on the registration form and send it with your payment of just $298. Your copy of the proceedings will be mailed immediately following the conference.



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■ **Substitution & Cancellation:**
Your registration may be **transferred** to a member of your organization up to 24 hours in advance of the conference. **Cancellations** received in writing on or before June 3, 1999 will be refunded, less a $195 administrative charge. No refunds will be made after this date; however, the registration fee less the $195 administrative charge can be credited to another CBI conference if you register within 6 months from the date of this conference. In case of **conference cancellation**, CBI's liability is limited to refund of the conference registration fee only. CBI reserves the right to alter this program without prior notice.

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DESIGN AND MANAGEMENT OF PHARMACEUTICAL/BIOTECH R&D ALLIANCES

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Hear a Case Presentation on One of the Largest Biotech Deals in the Industry

The MILLENNIUM/BAYER ALLIANCE concept, negotiation and a review of collaboration management 6 months after the ink has dried!

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SIDDCO

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and more...

– FEATURED KEYNOTE ADDRESS –

HEWLETT-PACKARD, a grandmaster of alliance management, presents a special cross-industry keynote address. Find out what pharmaceutical and biotech companies can learn from the collaboration experiences of this high tech giant and the computer industry in general.

- Integrate R&D **alliance portfolios** with corporate business strategies
- Balance an external network in **discovery research, technology acquisition** or **product acquisition**
- Know the most hotly contested **terms and conditions** of bio/pharm alliance agreements
- Utilize advanced **financing models** to support your research collaboration — Equity investments, milestones, debt warrants, loan guaranties, co-promotions, non-cash assets *and more*
- Learn how **Wall Street** assesses pharma/biotech partnering deals
- Use **consortia** to provide small to midsize companies an R & D infrastructure comparable to big pharma
- Explore organizational models for **alliance management,** including multi-functional alliance management teams
- Manage competing interests in **multi-party relationships** — Decision structures and processes in project selection, rights allocation and conflict resolution
- Successfully **collaborate with universities** while protecting product-driven proprietary information
- **Alliance terminations** — The contractual 'pre-nup' as the basis for conflict avoidance in partnerships gone awry

Plus **A FOCUS ON SPECIFIC TECHNOLOGIES**

Combinatorial Chemistry and Gene Therapy Collaborations

A Special Post-Conference Workshop — Friday, April 30, 1999

Alliance Turnaround
Tools, Metrics & Management Techniques

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The CENTER for BUSINESS INTELLIGENCE

CBI's Pharmaceutical Series

"More than 40% of Pharmaceutical/Biotech Alliances

— Benefits of Attending —

The figures of geometric growth in pharmaceutical strategic alliances are widely known. What is not often broadcast, however, is that after the negotiating is over, ***more than 40% of the collaborations do not meet the partners' expectations and many fail outright.***

This conference addresses practical measures required for the successful design and management of pharmaceutical alliances, from laying the groundwork in negotiations to managing the day-to-day collaboration long after the deal-making is done. Presentations cover topics such as:

- **matching an alliance strategy to corporate goals;**
- **assessing the value of technologies for product development or acquisition;**
- **identifying and qualifying the right partner;**
- **financing the collaboration;**
- **negotiating deals with aligned objectives and clear expectations;**
- **building multifunctional teams for alliance management;**
- **handling conflict resolution;**
- **and contracting for equitable deal terminations**

This forum provides information critical to pharmaceutical and biotechnology business development teams, as well as financial, legal and R&D workgroups with an interest in managing successful R&D collaborations.

MAIN CONFERENCE

Day One — Thursday, April 29, 1999

7:15 *Registration and Continental Breakfast*

8:00 *Chairperson's Welcome and Opening Remarks*
Alan Crane, Vice President, Business Development,
Millennium Pharmaceuticals

— Cross-Industry Keynote Address —

8:15 **A High Tech Giant's Insights for Pharmaceutical/Biotech Collaborations**

In the fast paced business of computers, alliances are a recognized tool for fostering innovation and seizing market opportunities. By systematically documenting and codifying best practices in alliance management, Hewlett Packard has elevated itself to the level of grandmaster in technology collaborations. Meanwhile, the pace of innovation and complexity in drug discovery is increasing as well, yet pharmaceutical and biotech companies are still working their way up the learning curve in maximizing their collaborations. Find out what pharmaceutical and biotech companies can learn from the experiences of this high tech giant and the computer industry in general.

Mark Chandler, Director of Business Development,
Hewlett-Packard Corporation

9:00 **Integrating an Alliance Portfolio with Corporate Business Strategy**

Designing and developing an alliance portfolio of ideas, technology and products is essential for today's corporations. This presentation discusses the strategic considerations big pharma employs to develop successful external collaborations from a multitude of possibilities. Timely development and integration of the alliance network is necessary to support the corporation's competitive advantage.

- Assess the value of new technologies for product development
- Determine the relative need for either internal sourcing or acquisition of technology and products
- Balance an external network in discovery research, technology acquisition or product acquisition to support your competitive advantage

Ravi Kiron, Ph.D., Senior Alliance Analyst, **Pfizer Central Research**

9:45 *Networking and Refreshment Break*

10:15 **Identifying and Evaluating Prospective Partners**

Successful collaborations are built upon a melding of corporate culture, corporate objectives, management style and market timing. This panel discusses the tools needed to determine a candidate's collaborative potential through market research, on-site visits and assessment of initial interactions. Both large and small company perspectives on partner evaluations are presented.

- Narrow down the field of possible partners to manageable numbers
- Catch "warning signs" before committing to a deal
- Set the stage for faster deals and successful collaborations

PANEL DISCUSSION

Moderator: Mark A. King, President, **Kendall Strategies, Inc**

Panelists: Warren Lackstrom, Vice President, **Kendall Strategies Inc.;** *former Vice President, Business Development,* **Boehringer Ingelheim Pharmaceuticals, Inc.**
David S. Barlow, President Pharmaceuticals, **Sepracor, Inc.**

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o Not Meet Partners' Expectations." — PriceWaterhouseCoopers, May 1998

11:15 **Keys to Success in Negotiating Pharmaceutical R&D Alliances**

While much of the work in a collaboration occurs after the final deal-making, it is this first stage that lays down the framework for the partnership, both on paper and in the working relationship.

- Gathering facts about your own and your potential collaborator's interests, resources and commitments
- Navigate through the three phases of negotiation: investigation and evaluation, drafting and negotiating the term sheet and negotiation of the final Definitive Agreement
- Align interests — Creating strong links between business plans of both partners
- Establish clear and effective communication across the negotiation table
- Working and re-working the non-binding term sheet
- Avoid legal and procedural logjams on the way to the Definitive Agreement

Brian Cunningham, COO, **Rigel Pharmaceuticals;**
former Vice President and General Counsel, **Genentech**

12:00 *Luncheon*

1:15 **The Bayer/Millennium Alliance — Beyond Win/Win**

Alliances that have the potential to fundamentally transform companies can create extraordinary value. This presentation describes a mutually transforming alliance that:
1) will enable Bayer to alter its basic drug discovery process and significantly increase productivity and
2) will allow Millennium to realize its aggressive objectives for forward integration. Key elements of the presentation are:

CASE STUDY

- Development of a transforming alliance concept
- Design of an alliance structure that maximizes value creation and likelihood of success
- The negotiation — An inside look at closing the deal
- After the ink dries — Management of a complex relationship

Alan Crane, Vice President, Business Development,
Millennium Pharmaceuticals

2:00 **Key Terms and Provisions of Pharmaceutical Alliance Agreements**

This session focuses on the most hotly contested terms and conditions of pharmaceutical strategic alliance agreements. In particular, provisions relating to:

- Rights of first offer and first refusal
- Rights of reversion
- Limitations on the scope of license grants and similar provisions to be dealt with
- Numerous case examples are presented

Michael Lytton, Partner, **Palmer & Dodge**

2:45 **Financing Methods to Support Your Research Collaboration**

Biotech companies are seeking collaboration revenue as an alternative to dwindling venture and public capital financing, while large pharmaceutical companies look to make investments in new technology while minimizing their downside risk. This session provides an opportunity to explore the spectrum of possibilities in financially supporting collaborative research that will meet the objectives of both parties. Specific case studies will be analyzed in detail. Topics covered include:

- Equity investments
- Fund raising
- Non-cash assets
- Milestone terms, payments and timing
- Debt warrants
- Loan guaranties

Phil Sussman, Vice President, Business Development,
Cadus Pharmaceutical

3:30 *Networking and Refreshment Break*

4:00 **R&D Partnering as Viewed by Wall Street**

Wall Street often views the specific type of partnering decision as an irrevocable progression toward a certain business plan and corporate structure. With this in mind, framing the deal in a positive way is important since Wall Street's evaluation of a corporate partnership can have a lasting positive or negative effect on a small company's stock price. This session describes some of the key parameters that Wall Street (rightly or wrongly) uses to think about partnering deals.

- Upfront money versus downstream payments
- Strong versus weak partners
- Full integration versus the traditional royalty model
- Collaborations between biotech companies

Alex Zisson, Senior Research Analyst, **Hambrecht & Quist**

4:45 **The Consortium as a Financial and Business Model**

By pooling their resources in a consortium, small to midsize companies can create an R & D function infrastructure with capabilities comparable to that of a large pharmaceutical company. In a shared risk arrangement, each consortium

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partner gains access to the larger technology effort, while only contributing a fraction of the financing.

- Understand the need, aims and objectives of a consortium
- Sharing technology developments and know-how
- Financing operations entirely through collaboration contracts
- Integrating consortium activities into client drug discovery programs
- Determining ownership of technology

Colin Dalton, Ph.D., Executive Vice President, Business Development, **SIDDCO**

5:30 *Close of Day One*

5:30—6:30 ***Wine & Cheese Networking Reception***
Join colleagues and friends in a relaxed setting.

Day Two — Friday, April 30, 1999

7:30 *Continental Breakfast*

8:00 *Chairperson's Welcome and Opening Remarks*
Linda C. Hogan, Senior Director, Licensing and Alliances,
Hoescht Marion Roussel

8:10 **Multi-functional Alliance Management Teams**

CASE STUDY

- Rationale for alliance management
- Organizational models for alliance management
- Structuring a multi-functional alliance management team
- The HMR experience

Linda C. Hogan, Senior Director, Licensing and Alliances,
Hoechst Marion Roussel

8:50 **Managing Multi-party Relationships**

Multi-party collaborations provide a means of leveraging financial and technological resources across several parties. The challenge of achieving these benefits lies in balancing the competing interests of the collaborators to achieve a net positive output for all parties. Issues which can either impede or encourage success include project selection, conflict resolution and rights allocation. The presentation explores these issues in multi-party commercial/academic collaborations as well as in 2 ½ party collaborations wherein the third party is a quasi-autonomous subsidiary.

- Multi-party rights allocation
- Project selection and change management
- Multi-party decision structures and processes
- Use of success markers to encourage alignment

Keith Dionne, Ph.D., Director, Technology Development & Collaboration Management, **Millennium Pharmaceuticals**

9:30 *Networking and Refreshment Break*

— Special Focus on Technologies —

9:50 **Combinatorial Chemistry Alliances — Responding to a Changing Market**

CASE STUDY

The market for combinatorial chemistry has rapidly changed over the past three years as the demand and availability of compound libraries has increased. This presentation explores the evolution of Arqule's business model for establishing corporate alliances in a changing marketplace.

John M. Sorvillo, Ph.D., Vice President, Business Development, **Arqule**

10:30 **Examination of a Gene Therapy Collaboration between Schering-Plough and Transgene**

Technology platform alliances present unique challenges and opportunities that must be addressed to close a deal and successfully achieve the parties' mutual objectives. The partnership between Schering-Plough and Transgene in the field of adenoviral gene therapy is examined as a model technology platform alliance.

CASE STUDY

- What attracts two companies to one another
- Generating excitement throughout the organization
- Aligning objectives towards mutual value creation
- Establishing deal structure
- Valuation, management of risk and timing of financial returns
- Ensuring a successful working relationship and achievement of mutual objectives

Alfred Slanetz, Ph.D., Vice President, Business Development, **Transgene**

11:10 **Successfully Collaborating with Universities**

Collaborations with academic departments are on the rise, as universities scramble for new sources of funding, and industry seeks access to brain power. But the marriage of two distinct research environments, one based on product-driven proprietary information, the other based on academic freedom and open exchange of ideas, causes its own unique problems not encountered in other collaborations. This presentation explores effective methods for dealing with:

- Publication delay and review
- Sharing proprietary information in an open environment
- Corporate and academic governance of the collaborative project
- Minimizing academic conflicts of interest

Gregory Gardiner, Ph.D., Director, Office of Cooperative Research,
Yale University

12:00 **The Contractual "Pre-Nup" as the Basis for Conflict Avoidance in Collaborations Gone Awry**

Whether brought upon by a missed milestone, changes in technology or perhaps a reprioritization of a pharmaceutical company's research programs, even the best deals can go south. This discussion centers on contractual provisions that one should consider in establishing:

- The right to terminate: by which party; under what conditions; and who establishes that those conditions exist?
- Rights upon termination: who gets what, and under what terms, should "divorce" be upon us?

Mark Lee, Ph.D., Vice President, Worldwide Licensing,
Wyeth-Ayerst Laboratories/American Home Products Corp.

12:40 *Close of Main Conference*

POST-CONFERENCE WORKSHOP — FRIDAY, APRIL 30, 1999

Alliance Turnaround

Tools, Metrics & Management Techniques

A healthy alliance requires managers to accomplish two fundamental tasks. First, they must structure and negotiate a contract that benefits both sides. Second, they must develop a strong inter-firm relationship that allows the implementation team to accomplish the goals and objectives of the alliance.

Most companies have been successful at structuring and negotiating a fair contract. The use of experienced legal, corporate development, tax and accounting staff reduces much of the uncertainty in the alliance creation process.

The same cannot be said for the relationship development stage. Alliance managers cannot call upon staff personnel who understand the complexities of inter-firm cooperation, the dynamics of relationship building and the intricacies of coordinating resources across corporate boundaries. In fact, most companies have difficulty building strong inter-group relationships internally. Worse yet, managers responsible for implementing these alliances are called upon to develop inter-firm relationships during the early days of the alliance when workloads are heavy, time horizons short and company structure and culture differences hamper communications. Many alliances begin to fail simply because the partners were not able to develop strong inter-firm working relationships.

This workshop provides participants with the tools, metrics and management techniques needed to facilitate an alliance turnaround and get newly formed alliances off to a healthy start. You are invited to share any non-proprietary tools, metrics and training techniques that they have employed. Participants specifically learn:

1:45 *Workshop Leader's Welcome and Opening Remarks*

I. Tools For Following the Performance of the Relationship

II. How to Implement the Successful Integration of Resources and Talents of the Two Firms

III. How to Link Decision Making Structures of the Two Firms

IV. Strategies for Reporting the Value of the Alliance to the Senior Management of Both Parent Firms

V. How to Ensure that the Alliance Will Compete Effectively for Internal Resources in Each Parent Company

VI. The Anatomy of an Alliance and How that Anatomy Directs Turnaround Strategy

VII. Methods to Assess Cultural and Other Barriers to Success, and Leverage Points in an Alliance. Actions to Take Once Those Differences Are Understood

VIII. Conflict Resolution Strategies for Implementation Managers

IX. What Marriage Councilors Have to Teach Us About Alliance Management

5:00 *Close of Workshop*

There will be a 15-minute networking and refreshment break at 3:30 pm

— About Your Workshop Leader —

Gene Slowinsky is the Director of Strategic Alliance Studies at the Graduate School of Management, **Rutgers University** and a managing partner in the Alliance Management Group, a consulting firm devoted to the formation and management of strategic alliances. Prior to forming the Alliance Management Group, he held management positions at **Novartis** and **Bell Laboratories.** In addition to a Ph.D. in Management, Dr. Slowinsky holds an MBA and a Masters Degree in the sciences. For the last 17 years, Dr. Slowinsky has consulted and conducted research on the formation and management of strategic alliances. His clients include **GlaxoWellcome, Johnson & Johnson, Ethicon, Becton Dickinson, Searle, Cadus Pharmaceutical Company, Bayer, Chiron, NexStar Pharmaceuticals, Genaissance Pharmaceuticals, Protein Polymer Technologies, Pfizer, Merck** and many other firms.

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HEWLETT-PACKARD

— Alliance Case Studies —
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— Special Focus on Technologies —
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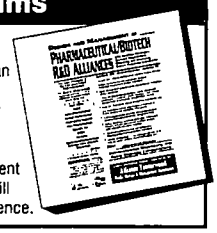

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2 INDUSTRY KEYNOTES

Robert R. Goodwin, PFIZER INC.

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PANEL PRESENTATION

THE INFORMATION IN THE PIPELINE NEEDED TO START CLINICAL TRIALS OVER THE INTERNET

PANELIST INCLUDE:

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- ➤ Understand Legal Liability Risks for Online Trials
- ➤ Application of IT, FDA and ICH Standards for Global Electronic Submissions
- ➤ Know FDA's Internal Process for Review of Electronic Submissions
- ➤ Security — Data Structures and Models including Digital Signatures and Systems Compliance

Choose from the 2 Concurrent Pre-Conference Workshops

Workshop A • Sunday, May 23, 1999

Patient Recruitment

Optimize the Internet to Attract, Screen, Motivate and Retain Participants in Multi-Center Clinical Trials

Workshop B • Sunday, May 23, 1999

Technology Strategies

Leverage Internet Technology to Speed Your Clinical Trials

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CBI's Pharmaceutical Series

A

Patient Recruitment

Optimize the Internet to Attract, Screen, Motivate and Retain Participants in Multi-Center Clinical Trials

Choose from Two Pre-Conference Workshops Sunday, May 23, 1999

This interactive workshop provides the direct marketing strategies required for success in centralized patient accrual, adherence initiatives and reinforcement techniques. More importantly, it demonstrates the increasing role the Internet plays as an integral part of the marketing mix.

8:00 *Workshop Registration*

8:30 *Workshop Leader's Welcome & Opening Remarks*

I. **Identify Qualified Study Participants for Multi-Center Clinical Trials is a Challenge; Keeping them in the Study Once Enrolled is Often a Greater Challenge, Yet Equally Critical to the Success of the Study**

II. **With Thousands of Communication Agencies, Telemarketing Call Centers and Internet Service Providers Available, How Do You Select a Vendor to Help You Who Not Only Understands Healthcare, the Challenges of Multi-Center Clinical Trial Recruiting, but also, the Integration with the Internet?**

III. **Utilize Market Research in the Recruitment and Retention Planning Process**

IV. **Multi-Center Clinical Trial Recruiting Strategies for Both Paid And Non-Paid Media, Even at the Individual Site Level**

V. **How Integrating these Strategies with the Internet Can Save Time and Money in Recruiting, Adherence and Retention**

VI. **Core Competencies and Internal Resources Required for Success or Selecting the Correct Vendor for Outsourcing**

VII. **Avoid Complications with Your IRB; Learn the "Big C's" — Coercion, Confidentiality and Compliance and How to Appropriately Deal with Them**

Workshop continued on the next page...

B

Technology Strategies

Strategies to Leverage Internet Technology for Clinical Trials

The Internet provides access to continuously expanding resources which is utilized by pharmaceutical research, development and business efforts. The Internet supports enabling technology and growth applications such as email and the Web. This session explores resources available to Internet connected companies.

8:00 *Workshop Registration*

8:30 *Workshop Leader's Welcome & Opening Remarks*

I. **Internet Technology Implementation**

II. **Internet Connectivity**

III. **"Flavors" of Internet Access**

IV. **Internet Software Tools**

V. **Issues and Concerns**

VI. **The Internet as a Platform for Client/Server Databases**

VII. **Utilizing Internet Technology for Clinical Trials**

- Massachusetts General Hospital Brain Tumor Center
- Case Studies

CASE STUDIES

12:00 *Close of Workshop*

There will be a 20 minute break at 10:30 during the workshop

— About Your Workshop Leader —

Brian K. Perry, President and Chief Technology Officer, Versal Technologies

Brian K. Perry is President and Chief Technology Officer at Versal Technologies of Cambridge, MA. He is responsible for the daily operation and direction of the company and for providing consulting services to Pharmaceutical/Biotech customers in the areas of: Systems Design/Development; Information Systems Strategies; and Vertical Applications which support Scientific Research, Clinical Research, and Business Development/Operations. Prior to starting the company in 1994, Perry was the Director of Information Systems at Vertex Pharmaceuticals Incorporated of Cambridge, MA. He was also a Systems Engineer with IBM Corporation. Mr. Perry holds a Bachelor of Science in Computer Science from Northeastern University.

Continued from previous page...

Pre-Conference Workshop A, Sunday, May 23, 1999

Patient Recruitment

Optimize the Internet to Attract, Screen, Motivate and Retain Participants in Multi-Center Clinical Trials

12:00 *Close of Workshop*

There will be a 20 minute break at 10:30 during the workshop

— About Your Workshop Leaders —

John Needham, President, Alliance Marketing Services Group, Inc.
John is co-founder of Alliance Marketing Services Group. The company was recently listed in Entrepreneur Magazine as #54 on their list of The Fastest Growing 100 Small Businesses in America. He has a strong background in marketing consumer products, clinical research and healthcare direct marketing.

Bonnie Brescia, Executive Vice President, BBK Patient Recruitment
Bonnie serves as executive vice president of BBK Patient Recruitment and directs a team of expert market researchers, strategic planners, media planners and account service personnel who create the blueprints for all patient recruitment campaigns developed by BBK.

Felix Khin-Maung-Gyi, Pharm D., M.B.A., President, Chesapeake Research Review, Inc.
Felix is Founder and President of Chesapeake Research Review, Inc., a professional services firm with an independent IRB, serving both biomedical research and healthcare industries. Dr. Gyi has served as a Clinical Scientist, Project Leader and Manager for a major pharmaceutical company and provided consultation services to research sponsors, CROs and sites.

Ken Jacobs, Manager, Internet Services, CenterWatch, Inc.
Ken Jacobs is the Manager of Internet Services for CenterWatch, Inc., a multi-media publishing and information-services company focusing exclusively on the clinical trials industry. Mr. Jacobs is responsible for the management and operations of the company's web site, CenterWatch.com.

Optimize Time to Market & Profitability Through Clinical Trials over the Internet

MAIN CONFERENCE

Day One — Sunday, May 23, 1999

1:00 *Main Conference Registration*

1:30 *Chairperson's Welcome and Opening Remarks*
George P. George, Deputy Topic Leader, ICH M2 EWG, **Booz Allen Hamilton**

— TWO INDUSTRY KEYNOTES —

Robert R. Goodwin, Senior Project Manager, Electronic Data Capture, **Pfizer Inc.**

1:45 **The Old Days of EDC — No Wonder We had Problems**
- Deployment of hardware — What is our business, drugs or hardware?
- Software updates — Are you sure they got it?
- Mid-Study changes
- Space requirements
- Not another laptop

John Orley, Clinical Trials Management System Administrator, US R&D Site Organization, **Pharmacia and Upjohn**

Unlocking the Potential of the Intra/Internet to the Clinical Community
- The nature of clinical trials
- The behavior of clinical trial personnel
- The business environment
- The consequences of not using the technology

2:30 **Use of the Internet for Operating in the Enterprise-wide Electronic Work Environment**
- Is it just a fad or will it become a fabric of the organization?
- Role of the Internet to facilitate transparent information exchange and knowledge management
- Importance of international standards for a common operating model
- The enterprise-wide electronic work environment
- Application of IT and ICH standards for global submissions

George P. George, Deputy Topic Leader, ICH M2 EWG, **Booz Allen Hamilton**

3:00 *Networking and Refreshment Break*

3:30 **Internet Clinical Trial Resources for CROs, Investigators and Sponsors**
- Internet based applications and communications and marketing
  - * Clinical-Trials Listserv? — consultative email discussion groups
- Benefit of incentive program such as the electronic phone card
- Promoting clinical trials on different websites
- Case study — CROs using the Internet

John Mack, Manager Professional Communities with Mediconsult.com Inc., and President, **VirSci Corporation**

4:00 **Computerized Clinical Trials Eliminate Lengthy Processes and Paperwork**
- The computer system allows pharmaceutical companies to expedite clinical trials
- It reduces the amount of time and money to retrieve results
- The elimination of hand-checking data
- Lengthy processes — even recruiting patients — are shortened

Mike Conlon, Chief Information Officer,
University of Florida Health Science Center

4:30 **Use the Internet for Collaboration in Knowledge Management**

- Discrepancy resolution and how it relates to RDE
- Incenting investigators to provide timely, accurate data
- Internet-based solutions for clinical trials development
- Data processing for a single study to the comprehensive design and management of large scale databases through the regulatory submission phase

Arien Malec, Data Management & Biostatistics, **PPD Informatics**

5:00 **How the Web Shifts Power in Clinical Trials**

- AIDS and HIV Information Resources on the Internet
- Adherence support and participant retention — adding value online
- Online postmarketing studies — Quality of life and the real world
- TheBody.com and HIV/AIDS patients

Jamie Marks, President, **Body Health Resources Corporation**

5:30 *Close of Day One*

5:30-6:30 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Monday, May 24, 1999

8:00 *Continental Breakfast*

8:15 *Chairperson's Welcome and Opening Remarks:*
Robert A. Bell, Former Director, Office of Management, CDER-US FDA Partner, **International Drug Registration, L.L.C.**

— Panel Discussion —

8:30 **Find Out the Information in the Pipeline Needed to Start Clinical Trials over the Internet**

PANEL

This panel discussion is a question and answer session for pharmaceutical companies who are thinking about implementing clinical trials on the Internet, including ongoing management.

Moderator — Robert A. Bell, Former Director, Office of Management, CDER-US FDA, **Partner, International Drug Registration, L.L.C.**

Panelists — Bob Kapitany, Division Chief, Knowledge Management Therapeutic Products, **Health Canada**

Brian Woodfork, Manager, Clinical Data Management, **Eli Lilly & Co.**

Dana Mangum, Senior Manager, Medical Telecommunications, **Glaxo Wellcome**

Robert R. Goodwin, Senior Project Manager, Electronic Data Capture, **Pfizer Inc.**

John Orley, Clinical Trials Management System Administrator, US R&D Site Organization, **Pharmacia & Upjohn**

Dave Evans, Senior Vice President and Chief Technical Officer, Clinical Data Management, **Premier Research Worldwide**

9:00 **Build a Clinical Trials Management System (CTMS) on the Intranet — Case Study from Pharmacia and Upjohn**

- Getting The right people involved
- Defining the requirements
- Testing the system
- Rolling out the system
- Maintaining the system
- Upgrading/enhancing the system

John Orley, Clinical Trials Management System Administrator, US R&D Site Organization, **Pharmacia & Upjohn**

9:30 **Understand the Internal Process of FDA Electronic Submissions Review and the Internet**

- Understand what happens in the FDA once an electronic submission is received
- How your company should prepare for meeting FDA guidelines for an electronic submission
- What are the drivers of the electronic submissions process
- Intent of the electronic submission process
- Archiving requirements
- Once it is submitted, there is discussion about compatibility with the FDA system — Is it resolved yet?
- Future direction of FDA

Robert A. Bell, Former Director, Office of Management, **CDER-US FDA Partner, International Drug Registration, L.L.C.**

10:00 *Networking and Refreshment Break*

10:30 **Understand Legal Implications of Online Trials**

- Patient recruitment using the Internet
- Legal liability risks for online trials
- Medical licensure in a connected world
- Understanding advertising and commercialization restrictions for investigational products online
- Overview of international regulatory issues

Mark Boulding, Partner, **Long Aldridge & Norman LLP**

11:30 *Luncheon*

1:30 **Security and Authentication Concerns over the Internet**

- Disclosure of information and privacy of intellectual property rights
  - * Investigators have privacy rights
  - * Pharmaceutical companies have privacy rights
- Data structures and models — digital signatures and systems compliance
- Key Infrastructure issues — technology solutions
- Who are the security providers?
- Firewalls
- Encryption coding
- How do authorities regulate validation and security?
- Canet3 of Canada is comparable to Internet 2 which was just signed in the United States

Bob Kapitany, Chief, Division Knowledge Management Therapeutic Products Program, **Health Canada**

1:30 **Validation of Automated Data Capture Systems Used in Clinical Research**

Any method of collecting data to be used in a clinical trial needs to be validated. This is extremely important in the application of automated data capture technology. This session discusses the processes used to validate both in-house developed systems and vendor-supplied systems, concentrating on the validation plans used for each system and their life-cycles. The benefits and weaknesses of each approach will be summarized and analyzed.

- Laboratory information system
- Centralized ECG processing system
- Fax-based CRF data capture system
- Web-based data capture system
- Comparison of In-house developed versus vendor supplied systems
- Comparison of various automated data capture technologies
- Insight into how validation processes are implemented by a CRO
- Comparison of different validation approaches

Dave Evans, Senior Vice President and Chief Technical Officer, Clinical Data Management, **Premier Research Worldwide**

2:00 **Clinical Data Warehousing and Management System in the Pharmaceutical Industry**

- What is warehousing and management all about?
- Webtrials and how data is extracted from warehouses
- Different kinds of algorithms to add value
- Data analysis to end users
- Delivery of complete end-to-end Clinical Research

Kumar Sagar, President, **The Sagar Group, Inc.**

2:30 *Networking and Refreshment Break*

2:45 **Practical Applications Approach to Overall Clinical Trial Management**

- Ease of use and cost-effectiveness
- Simplifies financial administration and payments
- Facilitates accelerated patient recruitment
- Better use of advertising dollars
- Real-time management reporting
- Applies to studies ranging from simple to complex/critical care
- Eases sites into future technologies
- Access to real-time patient recruitment/study management information is critical to achieving a successful, cost effective clinical trial.

Robert Sammis, President & CEO, **Clinicor, Inc.**

Susan Krivacic, Senior Vice President Marketing, **Clinicor, Inc.**

3:15 **PhaseForward — A Catalyst For Pharmaceutical Development and Testing for Clinical Trials on the Internet**

- Transform and industry — from paper-and-pencil to the Internet
- Propelling Pharmaceuticals to use the Internet
- Business re-engineering to substantially speed new drugs to market
- An Internet — or — Intranet-based network that enables data entry from any trial site in the world into a central database using a Web browser.
- Streamlining to making the process accurate and efficient

Shiv Tasker, Chief Executive Officer, **PhaseForward**

3:45 *Networking and Refreshment Break*

4:15 **Project Managing Clinical Trials in Real Time**

- How do clinical trials differ from other high-technology R&D?
- Criteria for successful multidisciplinary research teams
- Design concept — the Internet for building and managing on-line teams
- Asolepius — Total clinical trial management
- Communicating progress, problems and support
- Electronic data capture as the engine to drive project management
- CRA productivity tools
- Integrated document management
- User experience

Les Rose, Directing Manager, **Medical Scientific Services, Ltd., United Kingdom**

4:45 **Internet-enabled EDC Systems for Clinical Trials**

- Integration services and solutions for clinical trials
- Leveraging business processes to benefit Pharmaceutical companies performing clinical trials
  - * validation
  - * hardware
  - * software
  - * communications
  - * staffing and support
  - * contingency plans

Anne Zielinski, Director Product Division, **CB Technologies, Inc**

Sam Hume, Director Product Development, **CB Technologies, Inc.**

5:15 *Close of Conference*

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Computerized Clinical Trials

Apply Sophisticated INTERNET/INTRANET Technology for Data Collection and Trial Management

Sunday, May 23, 1999 • Pre-Conference Workshops

Workshop A
Patient Recruitment
Optimizing the Internet to Attract, Screen, Motivate and Retain Participants in Multi-Center Clinical Trials

Workshop B
Technology Strategies
Strategy to Leverage Internet Technology for Clinical Trials

Panel Discussion — Information in the Pipeline Needed to Start Clinical Trials over the Internet
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- *Use The Internet for Operating in the Enterprise — Electronic Work Environment*
- *Online Trials — Eliminate Lengthy Process and Paperwork*

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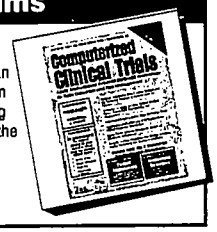

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Increase Sales Results through Effective Outsourcing and Improved CSO and Pharmaceutical Partnerships

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ENDO PHARMA AND SNYDER HEALTHCARE

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KNOLL PHARMACEUTICALS AND BLP GROUP COMPANIES

ALLERGAN AND PDI

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LAYTON BIOSCIENCE

— Featured Presenter —

Stephen Haynes, Special Agent in Charge, **FDA's Investigative Operations Division** presents key information on sample accountability

Plus the latest information on:

- How Biotech companies can benefit from using CSOs
- Performance measurement tools activity vs. ROI
- ROI activity based contracting vs. risk sharing
- Applications with RBU/CBU vs. centralized structures
- Protecting your company from liability issues

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The CENTER for BUSINESS INTELLIGENCE

CBI's Pharmaceutical Series

In 6 Months 6 of the Top 10 Pharmaceutical Companies have ad
Learn How to Join their Ranks and Take Advantage

MAIN CONFERENCE

Day One — Thursday, June 17, 1999

7:30 *Conference Registration and Continental Breakfast*

8:00 *Chairperson's Welcome and Opening Remarks*
Steven A. Tarnoff, Managing Partner,
The Franklin Group

8:15 **The ABC's — A to Z of the CSO Industry**
Today's healthcare market has been redefined by managed care, rapid changes in customer buying influences and shrinking margins. Whether your company has recently re-sized its sales force, introduced RBUs or CBUs, or maintained a centralized structure based on a product portfolio, a new set of critical success factors have been identified to achieve peak performance and profitability within this new environment.

To achieve these critical success factors, organizations have developed innovative and effective alternate sales channels. Without exception, the Contract Sales Organization has emerged as the fastest growing alternative sales channel. It has the potential for having both the most significant enhancement for earning while at the same time having the highest risk of not properly being developed and implemented. The conference provides a global overview of the contract sales force industry — A to Zs... they are not all the same.

This session includes assessment models and tools for pharmaceutical manufacturers in first determining their need for CSOs and subsequent models to identify and evaluate CSO competencies that are aligned to enhance organizational strategy and are require from a regulatory basis.

- Analysis and competencies defining and distinguishing first, second and third generation CSOs
- Customer and market segmentation — not all business is good business
- Performance measurement tools activity vs. ROI
- Contracting — activity based vs. risk sharing
- Sizing and deployment – managed care/pull through
- Applications with RBU/CBU vs. centralized structures

Steven A. Tarnoff, Managing Partner, **The Franklin Group**

10:15 *Networking and Refreshment Break*

10:45 **Evaluating CSO Proposals**
As a Biotech/Pharmaceutical Company, you want to be very selective when choosing your outsourcing partner particularly when it comes to outsourcing sales. Biotech companies have traditionally had a difficult time in selecting a CSO that can meet their company's needs and expectations. This presentation shows you how to evaluate and analyze CSO proposals as you prepare your outsourcing sales strategy.

- How do you solicit CSO proposals?
- Determine a CSO's specific strengths
- Move from vendor relationship to partnership

Robert J. Alonso, Vice President, Business Development & Marketing, **Layton Bioscience**

11:30 **Selecting Your CSO and Establishing a Long Term Relationship**
- What should you look for in a CSO?
- Can a CSO be all things to all Sponsors?
- Developing selection criteria

Kevin Skule, Director of Primary Care Marketing, **Allergan**
Steven Budd, COO, **PDI**

12:30 *Luncheon*

1:30 **Liability Issues Pertaining to CSOs**
When you outsource your sales – whether it's a portion or the entire process – you need to be aware of the liability issues that face your organization. What are the critical issues that your company could face and what are the best precautions to protect yourself?
- Criminal
- Civil
- Financial
- Sample accountability

Jack Rubin, Manager, Sales Administration, **Roche Labs Incorporated**
Stephen J. Haynes, Special Agent in Charge, Investigative Operations Division, **U.S. Food and Drug Administration**

2:30 **Troubleshooting CSO Relationships**
Transcend a mere contractual relationship and develop a true partnership with your CSO.
- Learn to share both expectations and goals in order to achieve maximum results
- What are the problem areas that most frequently arise?
- How can you develop strategies to preempt pitfalls?
- What kind of agreements can you put in place to make sure you and your SMO show the same interests?

Ray McDermott, Planning & Operations Leader, **Astra Pharmaceuticals**

3:15 *Networking and Refreshment Break*

3:45 **Syndication vs. Dedication – Rx to OTC**
One isn't better than the other, it's finding the one that works best for your organization given your specific circumstances. How do you optimize your application in the appropriate environment? This session helps you identify which application is best for your organizational needs.
William A. Jones, Sales & Marketing Manager, **Bristol-Myers Squibb Company**
Deborah J. Schnell, Vice President, **ProtoCall, Inc.**

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ed 2,250 Contract Sales Representatives to Their Sales Forces — f the Benefits that Outsourcing Your Sales Can Bring!

4:45 **CSO vs. CPO/CHO**

Pharmaceutical Vendor Perspective

- Definitions of the different models
- What are the success rates of each?
- What models could work best with your organizations needs?

John Grafington, National Sales Director, **Knoll Pharmaceutical Company**

William A. Connely, Vice President and General Manager, Outsource Sales Division, **BLP Group Companies**

5:45 *Close of Day One*

5:45 – 6:45 ***Casino Night Cocktail Party***
Don't miss the opportunity to network with colleagues and friends in this unique Atlantic City setting.

Day Two – Friday, June 18, 1999

8:00 *Continental Breakfast*

8:30 Chairperson's Review of Day One
Steven A. Tarnoff, Managing Partner, **The Franklin Group**

8:15 **Transforming the CSO into a CHO — A New Dimension in the Contract Organization**
The contract sales market sector has evolved rapidly in the dynamic pharmaceutical environment of the 1990s. As contracts have increased in size and scope, customer expectations have also increased. The commercial solutions provider of today is expected to deliver substantial, measurable value, especially with customers whose use of the commercial contract organization has evolved with a single relationship.

Announcing major industry breakthrough

The first generation, flex-time contract representative who was paid by the call, has evolved to a highly trained full-time representative whose compensation is based on product performance. In addition to field sales services, commercial organizations have added a full range of infrastructure capabilities such as training, sample accountability, human resources etc. These core capabilities move contract organizations into the third generation arena where the overall service of providing product-based commercial solutions is the business platform.

More recently, commercial solutions providers have expanded core competency to include information systems such as optimization and targeting, a full range of strategic marketing services such as commercial assessment and strategic planning, product marketing services such as pre-launch and launch strategic and tactical POAs, decision support analysis, reimbursement services and web-based knowledge transfer based communication vehicles. This enhanced service platform moves the contract model to the fourth generation CHO that moves the paradigm from a sales force supporting a product to a service company with core capabilities to take on total product responsibility.

David Stack, President, **Innovex Pharmaceutical Partner**

9:15 **A Case Study Example of How a Pharmaceutical Company and CSO can Work Together to Create Mutual Financial Success**

Pharmaceutical Vendor Perspective

Endo Pharma and Snyder-Health Sales have created a Pharma/CSO relationship that works. What strategies did they use, and do they continually employ, to ensure the long-term success of this partnership? What were the building blocks used to develop the relationship from contract to incentive planning and what are the tools they put in place to make sure that their relationship maintains its productivity from monitoring to communication.

Louis Vollmer, Executive Vice President, Sales & Marketing, **Endo Pharma**

Steve Cottrell, Vice President, Marketing, **Snyder Healthcare**

10:15 *Networking and Refreshment Break*

10:45 **CSO Automation — The Fine Line Between Disaster and Breakthrough Performance**
What you may never have even considered asking and what you really need to know. How can you really apply technology for breakthrough and to avoid audit disaster.

Brian J. Dillon, President, **Kelly Waldron**

11:15 **Co-Promotion vs. the CSO**
Case studies from the virtual, the biotech and established pharma perspectives on both sides of the fence give you the experienced information you need to make educated choices.

Terence S. Novak, Executive Vice President Sales & Marketing, **Algos Pharmaceutical Corporation**

12:00 *Close of Conference*

Maximize Your Networking Opportunities

Don't miss the opportunity to network and showcase your products and services to senior-level decision makers involved in Pharmaceutical sales. CBI's **CSO** conference offers you an excellent opportunity to maximize your 1999 marketing dollars through these showcase opportunities:

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International Stability Programs
May 20-21, 1999, Philadelphia, PA

Computerized Clinical Trials
May 23-24, 1999, Washington, DC

Electronic Adverse Event Reporting and Submissions
June 10-11, 1999, Washington, DC

Site Management Organizations
June 17-18, 1999, Boston, MA

Drug Discovery Project Management
June 17-18, 1999, Princeton, NJ

Medicaid Rebates
June 23-25, 1999, Atlantic City, NJ

Solutions for Global Pharmaceutical Distribution '99
June 24-25, 1999

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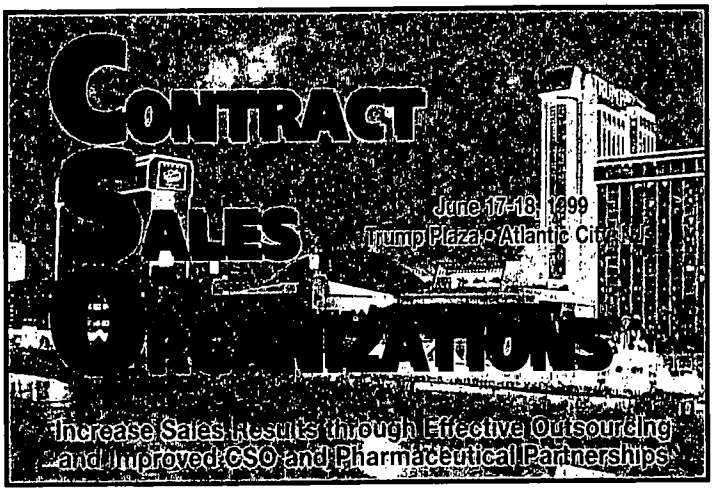

Four Key Reasons to Attend

- **5 Joint Presentations Between Pharmaceutical Companies and CSOs**
- **FDA Presentation on Sample Accountability**
- **New Information on How Biotech Companies Can Work with CSOs**
- **Casino Night Cocktail and Networking Reception**

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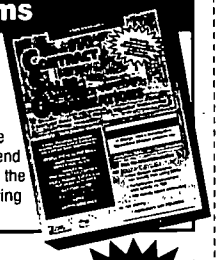

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CBI's Pharmaceutical Series

Special Presentation from the FDA Chemist Involved in the Barr Decision

Jean Blackstone Hill
Regulatory Pharmaceutical Chemist, **Food and Drug Administration**
discusses the FDA's approach to stability testing and regulatory compliance

Learn the Most Updated Information on:

- ICH testing and guidelines— how to make sure your drug passes the registration process on the first try
- SUPAC guidance and principals for post approval changes for solid and semi solid dosage forms
- Choice of humidity conditions and potential problems for global stability testing
- Time-line and implementation of the Common Technical Document
- Designing a cost-efficient stability testing program using matrixing and bracketing designs
- Key information on protocol design, statistical data analysis, sampling and consideration of specific dosage forms
- Conforming to monograph requirements under USP labile guidelines
- Design and validation of analytical methods to generate meaningful stability data

MAIN CONFERENCE

Day One — Thursday, May 20, 1999

7:30 *Main Conference Registration*

8:00 *Chairperson's Welcome and Opening Remarks*
Thomas Catalano, Ph.D., Associate Director,
Searle R&D Pharmaceutical and Analytical Sciences, Monsanto Life Sciences Co.

— KEYNOTE ADDRESS —

8:15 **FDA Approaches to Stability Testing and Regulations**
Hear top strategies and recent FDA decisions from the FDA chemist in the Barr Decision.
- Validation of stability indicating methods
- Stability analysis
- Barr Decision and agency guidelines for pharmaceutical chemistry inspections.

Jeanne Blackstone Hill Regulatory Pharmaceutical Chemist,
Food and Drug Administration

8:45 **Stability Programs from Development to Approval**
- Stability is the maintenance of safety and efficiency over time, temperature, light and humidity. The design and execution of stability protocols must reflect the regulatory stage of the drug process and the intended use of the product.
- Discussion of appropriate stability indicating assay specifications
- Designs of stability protocol using ICH guidelines
- Use of accelerated stability studies

Indu Isaacs, CEO, **Formatech**

9:15 **Stability Studies for Global Product Registration**
With the implementation of the ICH guidance documents, it has become possible, from the standpoint of the regulatory agencies involved, to conduct a single set of stability studies to support product registration in the US, the EU and Japan. The reality of a single set of stability studies has however often not been realized, for many reasons. The focus of this presentation is to identify key issues and discuss practical approached to resolving problem areas.
- When should a single set of stability studies be considered?
- The importance of company culture in proceeding with a global approach
- Specific requirements and approaches for the US, EU and Japan
- What to do about the countries not included in ICH
- The submission and post approval aspects.

Karen Malik, Director, Stability Operations,
Baxter Healthcare Corporation

9:45 **ICH Stability Guidelines and Draft FDA Guidance on Stability** Pharmaceutical Perspective
The ICH stability requirements are discussed as background to the draft FDA stability guidance document. The draft guidance is reviewed highlighting areas which are new and those which are updated from previous regulatory guidelines.
- ICH requirements — Drug substances
- ICH requirements — Drug product
- Draft stability guidance — What's new, what's updated
- Controversial issues

Frank J. Diana, Director, Analytical Technology,
DuPont Pharmaceutical Company

10:15 *Networking and Refreshment Break*

10:45 **Stability Regulations in the EU, Japan and Non-ICH Countries** Pharmaceutical Perspective
- Regulatory requirements of stability studies and data for:
  * filing for approval of a new drug product
  * making post-approval changes and variations
  * providing on going support for a marketed drug product
- Gain an overview of key regulations, expectations and trends
- What are the principle guidance documents and who writes them?
- Where do the differences and similarities lie in expectations of the different regulatory bodies?

David M. Wells, Jr., Team Leader, QA Stability,
Proctor & Gamble Pharmaceuticals

11:15 **Identify Where and When Time Savings Can Be Made in Stability Testing without Jeopardizing Regulatory Approval** Pharmaceutical Perspective
- Recognizing key product factors to consider
  * identifying bulk drug and formulated stability characteristics
  * formulation development and dose selection
  * understanding manufacturability on a large scale
- Pinpointing opportunities to apply protocol design as a way of reducing the number of batches required for testing
  * selecting conditions in which to apply bracketing and matrixing
  * identifying other unique protocol designs
- Clarifying areas to consider when contemplating out-sourcing
  * balancing the risks with potential time savings
  * deciding when to out-source and who to
- Considering key time saving opportunities during stability testing
  * automating data gathering to speed up analysis time

* designing efficient testing chambers and back up systems
* minimizing the risk of conditions lapsing
* recognizing the importance of communicating with regulators

Alex Robertson, Quality Manager, Stability,
Zeneca Pharmaceuticals, UK

12:00 *Luncheon*

1:15 **Pre-Approval Inspections and the Importance of Stability**

FDA inspectors uncover stability problems during pre-approval inspections (PAI). Receive guidance on how to help prevent adverse findings in a stability program.

- PAI background requirements
- Real life examples from PAIs
- Preparation for PAI audit of stability area

Richard A. Soltero, Ph.D., Vice President, Laboratory Operations,
Magellan Laboratories, Inc.

2:30 **Labile Preparations — Impact on Industry**

Pharmaceutical Perspective

As per USP requirements — individual preparations will be required to be run as per specified short-term stress studies. Failure of the preparation to conform to monograph requirements indicate that the preparation must be deemed Labile. The presentation outlines industry responsibilities for these labile preps.

- Definition of Labile preparation
- Specified short-term studies outlined in stability protocols
- USP general notices
- Time temperature indicators
- Industry response
- Labeling of product

Scott A. Goodberlet, Manager, Stability, **Medeva Pharmaceuticals**

3:15 *Networking and Refreshment Break*

3:45 **Photostability Studies within ICH Guidelines**

Learn ICH requirements for photostability as defined in the Tripartite Guideline for the Photostability Testing of New Drug Substance and Products, Q10B.

- ICH requirements
- Option 1 vs. Option 2
- Monitoring — Meters vs. Chemical Actinonmeters
- Chamber qualification
- Description of a photostability study using ICH Option 2
- The choices to be mad around lamp types
- Practical considerations of conducting testing
- Experience of the regulatory interpretation of photostability data

Jack B. Davis, Stability Manager, **Oread Inc.**

4:30 **Identify the Choice of Humidity Conditions and Potential Problems for Global Stability Testing**

Pharmaceutical Perspective

- Create global strategies for stability testing
- Identify climatic testing conditions and likely problems
- Compare the effects of different humidity conditions during stability testing
- Testing conditions for aqueous products in semi-permeable packs
- Regulatory interpretation of semi-permeable

Nick Turner, Project Team Leader, Facilities Team, QED,
Glaxo Wellcome, UK

5:00 **SUPAC Guidances — Stability Requirements**

Pharmaceutical Perspective

This session covers the stability requirements for those post-approval changes contained in the approved SUPAC guidances for solid oral dosage form (IR and MR), non-sterile semi-solid dosage forms (SS) and for post-approval changes to analytical testing laboratory sites (PAC-ATLS). Included will be the impact of the February 18, 1997 letter from Roger Williams clarifying the SUPAC-IR guidance. The draft of the manufacturing equipment addendum to SUPAC-IR and MR and the recently issued (17 November 1998) draft of the bulk active chemicals guidance (BACPAC I) will be explored for their impact on industry. The presentation concludes with considerations regarding the application of SUPAC principles to pre-approval changes.

- Understand the general principles and the template for the SUPAC guidances
- Understand the stability requirements for changes covered in the SUPAC guidances for solid oral dosages forms (IR and MR), non-sterile semi-solid dosage forms (SS) and analytical laboratory testing site changes (PAC-ATLS)
- Understand the impact of the draft manufacturing equipment addendum to the solid oral dosage form guidances (IR and MR)
- Understand the draft BACPAC I guidance and its impact on your stability program
- Understand the practical applications of the SUPAC guidances to changes contemplated during product development prior to approval
- Industry success stories

Gary R. Dukes, Ph.D., Specifications Development Manager,
Pharmacia & Upjohn
Larry Litle, Operation Stability Team Leader, **Hoechst Marion Roussel**

6:00 *Close of Day One*

6:00–7:00 ***Wine & Cheese Networking Reception***
Join colleagues and friends in a relaxed setting.

ccuracy of Your Stability Programs

Day Two — Friday, May 21, 1999

8:00 *Continental Breakfast*

8:30 *Chairperson's Review of Day One*
Thomas Catalano, Ph.D., Associate Director,
Searle R&D Pharmaceutical and Analytical Sciences, Monsanto Life Sciences Co.

8:45 **Bracketing and Matrixing**

International Pharmaceutical Perspective

- Definitions of Bracketing and Matrixing
- What factors can be included in B&M designs
- Reduction strategies
- Data evaluation
- Examples

Nick Turner, Project Team Leader, Facilities Team, QED,
Glaxo Wellcome, UK

9:30 **Pharmaceutical Stability Data Management**

Pharmaceutical Perspective

The use of custom and off the shelf software packages to manage and distribute stability data.

- Requirements for a data management system
- Commonly used packages – advantages/disadvantages
- Stability data management as a subset of a LIMs system
- Validation of data management systems
- Globalization of data management systems
- Return on investment

Dermot Mee, Stability Specialist,
Yamanouchi Shaklee Pharma

10:15 *Networking and Refreshment Break*

10:30 **Systematic Approach to the Development of Stability Indicating HPLC Methods and Stability Testing**

Pharmaceutical Perspective

This presentation demonstrates a systematic approach to the development of HPLC Stability Indicating methods, utilizing computer assisted method development software. Processes for the determination and reporting of degradation are also discussed.

- Efficient HPLC method development process
- Justification for the chromatographic conditions
- Development of a chromatographic data base for future method changes/optimization
- Consistent approach for determining and reporting degradation products in early development

Thomas Catalano, Ph.D., Associate Director,
Searle R&D Pharmaceutical and Analytical Sciences, Monsanto Life Sciences Co.

11:15 **In-House Qualification and Validation of Stability Storage Units — Eli Lilly and Co.**

Pharmaceutical Perspective

After a pharmaceutical company or other entity constructs and/or purchases environmental storage units (stability chambers, incubators, refrigerators and freezers), the units must be qualified and validated initially, as well as on a periodic basis following installation. The organization can contract this important work out an engineering firm, or it can rely on its own resources. This presentation describes one company's experience and the attendant benefits.

- Limits and tolerances for stability storage units (e.g. ICH, WHO, FDA)
- What in-house resources and expertise are essential?
- What needs to be done prior to qualification/validation (plans, protocols, etc)?
- The operation itself and post-testing documentation
- Periodic qualification and revalidation following maintenance or unit modification
- Short and long-term benefits gained by performing this work in-house

Daniel W. Bashore, R&D Stability Coordinator, **Eli Lilly & Co.**

12:00 *Luncheon*

1:30 **How to Carry Out and Document Stability Testing of Biologics in Compliance with ICH 95B**

International Pharmaceutical Perspective

How does the industry apply the ICH guidelines to biologics? How does your stability strategy need to differ from a pharmaceutical product?

- Impact of ICH 95B on testing requirements
- What tests should be undertaken and when?
  - * schedule
  - * bracketing
  - * number of batches
  - * accelerated tests
- Which characteristics should be tested and when?
- Which changes require additional stability testing?
  - * manufacturing process
  - * composition
  - * storage conditions
  - * storage conditions

Anne-Marie Georges, Associate Director Regulatory, Legal,
SmithKline Beecham, Biologicals, Belgium

Hear Strategies on Protocol Development, Matrixing, USP Labile Requirements and More from Over 14 Pharmaceutical Companies

2:15 **Stability Programs for Active Pharmaceutical Ingredients (API) — R&D to Marketed Product**

This presentation disscusses the unique nature and challenges of a stability program for APIs as products progress from R&D phase to registration phase and then to commercial phase. Stability requirements to support post approval changes to manufacturing process of APIs will also be discussed. The presentation concludes with a discussion of handling stabililty failure investigations.

- Three different phases — R&D, registration and commercial — of stability
- Stability requirements to suport post approval changes to manufacturing process of APIs
- How to investigate stability failures

Surendera Tyagi, Manager, Stability Services, **Abbott Laboratories**

3:00 *Networking and Refreshment Break*

3:30 **Applying Stability Guidelines to New Dosage Forms and OTC**

Pharmaceutical Perspective

- OTC requirements outside US
- Strategies for OTC NDA Products compared to NCE's
- OTC monograph regulations and requirements
- Internal requirements — The marketing factor

Abbie Gentry, Ph.D., Manager, Analytical Sciences,
Johnson & Johnson Merck Consumer Pharmaceutical Company

4:15 **Packaging and the Role of Stability Testing**

International Pharmaceutical Perspective

- Establishing adequate product protection and compatibility
- Pack product interaction and extractables
- ICH, FDA and CPMP guidelines
- Choosing the most appropriate pack
- Implications of the ICH Common Technical Document

David Pethick, Senior Principal Scientist, Pharmaceutical Division, Europe,
Glaxo Wellcome Research and Development, UK

5:00 *Close of Conference*

SEARLE

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4901 Searle Parkway
Skokie, Illinois 60077
Phone (847) 982-7000
Fax (847-982-4701

Dear Colleague,

These are exciting and challenging times for the pharmaceutical industry. The number of compounds in development are at all time highs and this trend is expected to continue in the upcoming years. In addition, the elderly portion of the pharmaceutical market is continually increasing and demanding that the pharmaceutical industry investigate new therapies aimed at treating diseases such as cancer, arthritis, alzheimers, cardiovascular conditions etc.

***Pharmaceutical stability** continues to be one of the most demanding areas within the industry. The official release and implementation of ICH stability guidelines and introduction of the FDA draft stability guideline have challenged stability professional to address changes in their current programs to be compliant with the various guidances. The Center for Business Intelligence has assembled a pharmaceutical stability seminar with the objective to provide information on the most pressing issues facing stability professionals.*

*Some of the major topics to be discussed included **statistical considerations, compliance with ICH and FDA guidelines, stability testing, photostability, stability regulations for EU and Japan, SUPAC guidelines, bracket** and **matrixing designs, stabilitly of biotech and biologics and much more.***

Attending this seminar will equip you with the most current information and thinking on current and future challenges you and your company may have to face. Individuals acquiring this information will be able to ensure that their stability programs are compliant and consistent with current best business practices. Whether an individual is an experienced stability professional or a novice this seminar will better equip you with the information and the tools needed to meet current and future stability challenges.

Tom Catalon Ph.D.
Associate Director Pharmaceutical and Analytical Sciences
Searle R&D
Monsanto Life Sciences Co.

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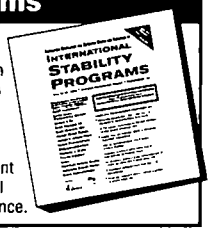

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A Must Attend Pre-Conference Workshop — June 17, 1999

Fostering Innovation and Efficiency through Knowledge Management

- **Improve communication and the transfer of knowledge among researchers**
- **Measure reduced lead discovery times and financial returns from a knowledge management program**

CASE STUDY PRESENTATIONS FROM MERCK & CO. AND MONSANTO

— Pre-Conference Workshop ○ Thursday, June 17, 1999 —

Fostering Innovation and Efficiency through KNOWLEDGE MANAGEMENT

7:30 *Registration and Continental Breakfast*

8:00 *Workshop Leader's Welcome and Opening Remarks*

8:15 **Designing and Implementing Knowledge Management Systems — More Innovative and Efficient Drug Discovery**

This session provides a framework for understanding the critical components of a world-class knowledge management system. We discuss case studies that illustrate the framework pieces and their interdependencies. For example, we examine workgroup communities and their impact on effectively managing different types of knowledge during drug discovery. We also discuss how community characteristics impact technology selection for knowledge management. In addition, this session presents a five step approach for starting a knowledge management project, presenting a case study from a leading pharmaceutical company which illustrates how the approach could be applied in drug discovery organizations.

Eric Darr, Ph.D., Senior Manager, Knowledge Based Business Solutoin Team, **Ernst & Young**

9:30 *Networking and Refreshment Break*

10:00 **IT Solutions to Transform the Way Scientists Collaborate on Research Projects — Merck's PartnerNet**

This session provides a summary of the components that comprise secure, end-end electronic information transfer. Points that are covered in this session include:

CASE STUDY

- The value and reality of accessing vast core repository of information with point-and-click ease
- Opening up secure lines of communication with business partners, laying the foundation for more productive research collaborations
- Enabling scientists to work from a common project database, regardless of location
- Implementing multilayered security to protect data and communications

Donald Amoruso, Research Information Services, **Merck & Co.**

10:45 **Measuring Return on Knowledge — Reducing Drug Discovery Cycle Times through Knowledge Management**

CASE STUDY

In a research-intense industry, intellectual capital becomes a basic economic resource and the principle means of creating value. Most would agree that the rapid transfer knowledge can significantly speed the process of identifying lead compounds in pharmaceutical or agricultural research programs. But with Knowledge Management still evolving or non-existent in most corporations, some assessment of its actual financial contribution can go a long way toward getting buy-in from senior management. Measuring the return-on-knowledge (ROK), both the "soft" financials (anecdotal) and "hard" numbers (bottom-line contributions), is co-evolving with the skills and understandings around Knowledge Management within Monsanto. This session presents a case study of financial returns and lead discovery advantages contributed by the knowledge management program at Monsanto.

- Measurement of financial returns and reduced lead discovery cycle time from a knowledge management program
- Promoting knowledge management in terms of bottom-line contributions
- Measuring the effectiveness of communication initiatives

Jane E. Rady, Vice President Knowledge Management-Prospecting
Monsanto Company

11:30 *Close of Workshop*

— About your Workshop Leaders —

Eric Darr is a Senior Manager in **Ernst & Young's** Knowledge Based Business Solution Team, and an Adjunct Professor of Organization and Strategy at the Anderson Graduate School of Management at UCLA. He specializes in organization design, social network analysis, and the design of processes and technology for knowledge acquisition, storage and sharing. He has over 12 years of experience designing and building knowledge management systems in a wide variety of industries, including; automotive, aerospace, energy, financial, insurance, pharmaceutical and retail. Eric has a Ph.D. in Organizational Design and an M.S. in Industrial Administration from Carnegie Mellon University. He also has an M.S. in Industrial Psychology.

Jane E. Rady is Vice President, Knowledge Management-Prospecting for **Monsanto Company**. Prior to joining the KM leadership team last year, Ms. Rady was President and General Manager of Lorex Pharmaceuticals, the US joint venture between Searle and Synthelabo. First joining Monsanto in 1984 as Director of Business Development and Venture Capital, Ms. Rady moved to Searle in 1986 holding positions of increasing responsibility including Vice President, Strategic Planning for the company and Vice President, Licensing and Business Development. Prior to that, she had been with Abbott in pharmaceutical research, business development, and operations management. She received MS in Microbiology from the University of Illinois, Urbana and her MBA from Northwestern University.

Donald Amoruso is Manager of **Merck Research Laboratories,** Computing Infrastructure Architecture group, Planning and Development since 1996. Previous to this, Mr. Amoruso was a member of the Senior Technical Staff at Lockheed-Martin Astro-Space Division, responsible for NASA's Spacecraft Guidance, Navigation and Communications programs. Mr. Amoruso is a graduate from Manhattan College with degrees in Electrical Engineering and Computer Science, currently enrolled at Harvard Business School Executive Education program and a member of the Delaware Valley Artificial Intelligence Association.

MAIN CONFERENCE

11:30 *Main Conference Registration*

12:30 *Chairperson's Welcome and Opening Remarks*
Douglas A. Livingston, Ph.D., Axys Pharmaceuticals, Vice President, **Combinatorial Chemistry**

12:40 **Opening Commentary — Rediscovering Discovery**

Many companies have reduced the duration of an average clinical development project by standardizing tasks and procedures, expanding information and data handling capabilities, and implementing resource management systems. Meanwhile, the front end of R&D, drug discovery, remains a major time consumer in the process. Recreating discovery to increase efficiency and quality of the product (the lead compound) is the necessary response. Improving research means quickly executing hypothesis, analysis, testing and revision to rapidly converge on ideas and leads, harvesting and mining expanding internal and external knowledge and increasing the effectiveness with which the entire process is managed.

Terri Cooper, Ph.D., Director, **PriceWaterhouseCoopers**

Operations Management for the New Pharmaceutical Research Technologies

1:00 **High Throughput Discovery Research — The Real Issues**

Many research organizations today are focused on increasing throughput of a discovery research "factory" by eliminating bottlenecks. Multi-million dollar investments are being made to put in the latest and fastest chemistry, robotics and screening automation. The end result, however, is not what you might expect. Often times it is not a modern "factory" operation delivering maximum quality and output, but a concatenation of expensive equipment exhibiting numerous process deficiencies. Rework, redundancy, sequential work activities, ineffectual policies and uncoordinated logistics undermine obtaining the expected results. Fundamentally, the real issue is how well engineered and executed is the overall process. This presentation highlights the key challenges of assembling a modern discovery factory independent of any one piece of equipment. Emphasis is given to strategies for streamlining the discovery process, using available technology, by paying particular attention to the logistics of how materials move around the system. There is significant payoff in costs savings to this approach, but more importantly the result is higher throughput and quality.

David A. Kniaz, Vice President, Research Informatics, **EMAX Solution Partners**

1:45 **Higher Throughput Target Discovery and Validation — Maximizing Productivity in Genomics**

CASE STUDY

As the recent wave of advanced genomics and drug discovery technology matures, attention must turn to the operational and procedural methods needed to maximize its productivity. Mere application of automated methods is not sufficient to ensure quality of research. This presentation examines case studies in the optimization of large scale genomics projects:

- Creating a culture aligned for speed
- Analysis of existing processes and benchmarking for best performance standards
- Realignment of groups, work processes and automation to increase efficiency
- Operations management for genomics research
- TQM/QC in gene target discovery

Geoffrey S. Ginsburg, M.D., Ph.D., Senior Program Director, **Millennium Pharmaceuticals**

2:30 *Networking and Refreshment Break*

3:00 **An Operations Approach to Combinatorial Chemistry and Assay Development — Organizational and Strategic Consequences**

CASE STUDY

During the successful buildup of a large combinatorial chemistry organization within our company, some very pragmatic considerations led us to redefine the manner in which we applied this capability to pharmaceutical research. In several ways, these considerations ran counter to our initial expectations. By dividing the organization strictly along functional lines, we found that resource requirements for chemistry development and validation are typically much greater than those required for library synthesis, despite the degree of automation. Thus, the cost of a project is often inherent in the synthesis protocols, rather than in the library itself. Consequences of this and other experiences on the chemistries developed, production technologies and lead optimization strategies are discussed.

Douglas A. Livingston, Ph.D., Vice President, Combinatorial Chemistry, **Axys Pharmaceuticals**

3:45 **'High Velocity Laboratory' Applying Manufacturing Process Techniques to Research**

The world's best manufacturing companies are typically paving the way for new process techniques, such as Just-in-Time. Reducing cycle time (from customer order to ship) is one of the key metrics that manufacturing companies must focus on to stay ahead of the competition. The pharmaceutical industry is now going through some of the same cycle time reduction challenges. Using basic concepts and case studies, the discussion follows on how to take proven manufacturing process systems and apply them to improve research processes at pharmaceutical companies. Improvements in cycle time, lead time, on time delivery, inventory levels and quality can be achieved through implemations of 'pull systems,' cellular manufacturing and process mapping.

Ed Thumith, Director of Operations, **Zymark Corporation**

— PANEL DISCUSSION —

4:30 **Uncovering the Real Bottlenecks**

Engage a panel of speakers in a discussion of the hidden (and not so hidden) rate-limiting steps in identifying leadcompounds; a look at the shifting environment in discovery research and how pharmaceutical corporations must adapt to changes in technology.

Moderator:

Douglas A. Livingston, Ph.D.,
Vice President, Combinatorial Chemistry,
Axys Pharmaceuticals

Panelists:

Terri Cooper, Ph.D.,
Director, **PriceWaterhouseCoopers**

Geoffrey S. Ginsburg, M.D., Ph.D.,
Senior Program Director,
Millennium Pharmaceuticals

David Kniaz,
Vice President, Research Informatics,
EMAX Solution Partners

Ed Thumith,
Director of Operations,
Zymark Corporation

5:00 *Close of Day One*

5:15-6:15 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting.

Day Two — Friday June 18, 1999

8:15 *Continental Breakfast*

8:45 *Chairperson's Opening Remarks*

Eucharia Meehan, Ph.D. CDipAF, Senior Project Manager,
Elan Pharmaceutical Technologies

Build Cultures of Creativity and Collaborations

9:00 **Building a Culture of Creativity and Innovation**

- Creators and Innovators — first you have to find them
- Keeping the innovators — create a sense of purpose
- The creativity uncertainty principle — how do you measure creativity without destroying it?
- Sitting around the campfire — The importance of stories in fostering a culture of innovation
- Is incrementalism the daughter of innovation or its nemesis?
- Selling innovation to "The Street"

Ian H. Williams, Senior Director, Strategic Management Group, **Pfizer Central Research**

9:45 **Collaborative Research — Managing Projects Across Corporate Boundaries**

- Before the ink has dried — evaluating potential partners, establishing rapport and relationship, setting expectations
- After the ink has dried — what are the first steps to successfully launch a collaborative research program
- Getting buy-in from researchers on both sides
- How to implement the successful integration of resources and talents of the two companies
- Establishing effective project communications between corporate partners
- Measuring and tracking the performance of collaborative research

Kathryn Smith, Head R&D Technology Office, **Pfizer**

10:30 *Networking and Refreshment Break*

IT Solutions for Research Productivity

10:45 **Integrated Information Systems for Global Collaborative Research**

CASE STUDY

- Global integration and consolidation of research information
- Standardizing data structures to for global access
- Extracting value and fostering innovation through intelligent data mining and visualization
- Integration of financial, environmental, chemical supply and scientific repositories of data to support the research process
- Application of basic supply chain philosophy to research productivity — an emphasis on speed, quality and decreased cost per unit of information
- Real-life case studies in research process improvement

Peter Loupos, Senior DirectorResearch Information Technology,
Rhone Poulenc Rorer Gencell, *Pharmaceutical Discovery*

11:30 **Improving Decision-Making in Pharmaceutical Research through Datamining and Visualization**

Delegates hear about integrated software solutions to manage data overload, simplifying multiple decision stages through datamining and visualization.

- Decision support systems that turn information into knowledge and decisions
- Turning information assets of genomics, combinatorial chemistry, proteomics and pharmacogenetics into decisions
- Mineset — an integrated tool for experts and non-experts

David M. Zirl, Ph.D., Chemistry Market Manager,
Silicon Graphics

12:15 *Luncheon*

Tools and Methods for Quality Decision-Making in Drug Discovery

1:45 **Assessing and Managing Risk in Discovery and Research**

- Identification and analysis of project risks in Drug Delivery research
- Addressing challenges from Drug Discovery
- Factoring in technical complexity and challenges
- Tools for projecting drug development costs and market potential
- Responding to project risks through a defined process
- Responding to changes in risk over the course of the project (e.g. the emergence of a competitor product, partner bails out)
- Balancing high risk, high potential R&D with lower risk R&D bringing incremental near term revenue

Eucharia Meehan, Ph.D. CDipAF, Senior Project Manager,
Elan Pharmaceutical Technologies

2:30 *Networking and Refreshment Break*

2:45 **Compound Selection and Intelligent Early Attrition**

- PK/PD Modelling
- Clinical trials simulation
- Surrogate markers/biomarkers
- Beyond Ki — toxicology and drug disposition as drivers of the clinical transition

Neil Bodick, M.D., Ph.D., Director of Clinical Operations, Global Clinical Research, **Lilly Research Laboratories**

3:30 **How to Create Value with Better Resource-Allocation Decision-Making**

SmithKline Beecham (SB) has completed a major initiative to improve its resource allocation decision-making. By addressing the soft issues — such as information quality, credibility and trust — SB improved its ability to address the hard ones: how much and where to invest. As a result, SB improved the value of its new product portfolio be more than 30 percent without increasing investment, and institutionalized an on-going capability to create additional value year after year. This session shows how it is possible to answer "yes" to all of the above questions, and how such results are realistically and practically accomplished. Essential ingredients include:

- Developing credible valuation metrics that align the organization toward higher value creation, while, at the same time, enhancing its creativity
- Recognizing and measuring added value creation potential from better resource allocation
- Achieving credibility in information and methodology from project teams through top management
- Achieving organizational buy-in and alignment to focusing resources on highest value activities, while pruning less valuable ones
- Designing and leading a process that inexorably ensures the above results

Thomas W. Keelin, Managing Director, Worldwide,
Strategic Decisions Group
Paul Sharpe, Former Vice President and Director of Project Management in Neuroscience,
SmithKline Beecham *(invited)*

4:15 *Close of Main Conference*

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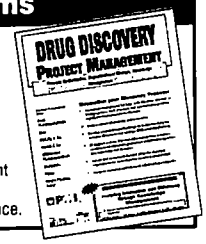

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— Keynote Speaker—

KATHRYN HUNTLEY
US member of MedDRA development team, MSSO Program Manager, TRW

Robert Bell
Partner, INTERNATIONAL DRUG REGISTRATION, L.L.C.
Former Director, Office of Management, CDER-US FDA

Mark Blake
Manager, Drug Safety and Epidemiology
ZENECA PHARMACEUTICALS

Mark E. Boulding
Partner
LONG ALDRIDGE & NORMAN

Anthony J. Calandra, Ph.D.
Manager, Regulatory Affairs
AMGEN, INC.

John Chidlow, Ph.D.
Executive Director of Regulatory Affairs Europe
QUINTILES, UK

Gary E. Gamerman, M.S., J.D.
Attorney
HELLER EHRMAN WHITE & MCAULIFFE

George P. George
Partner
BOOZ.ALLEN & HAMILTON INC

Rajesh Gosh
Global System Administrator
NOVARTIS

W. Gregory, Ph.D.
Director, Regulatory Affairs
PFIZER

Joanna Haas
Executive Director, Clinical Safety & Epidemiology
NOVARTIS

Stephen L. Klincewicz
Medical Director
ZENECA PHARMACEUTICALS

Vlasta Pinkston
Director, North American Product Surveillance
GLAXO WELLCOME

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- Hear current ICH recommendations to standardize adverse event reports and terminology worldwide
- Examine the Electronic Standards for the transfer of regulatory information (ESTRI) M2 + E2b and the effect on PSURS
- Know the future of AE submissions and the E2b standard for electronic submissions
- Evaluate legal and regulatory compliance background of electronic AE reporting to minimize risk
- Map your legacy data to MedDRA and your company dictionary
- Review outsourced ADR reporting errors to minimize risk
- Identify outsourced product liability issues with contractor SOPs, E2b Electronic Interface and MedDRA Coding Specifications
- Challenges of outsourced timelines for ADR reporting regulatory compliance
- How changing regulations affect your company's needs for effective epidemiology

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WORKSHOP A	WORKSHOP B
The US Electronic Record Rule and Its Application to Safety Data — Electronic Signatures	The ICH Common Technical Document — Develop the CTD for Global Registration Dossiers

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The US Electronic Record Rule and Its Application to Safety Data — Electronic Signatures

Choose from 2 Pre-conference Workshops June 10, 1999

This workshop looks at the regulation from both the FDA and industry perspective and provides a practical approach to complying with Part 11.

8:30 *Registration and Continental Breakfast*

8:45 *Welcome and Opening Remarks*

I. History of 23 CFR Part 11

II. Overview of the Final Rule

III. Scope and Definitions

IV. Closed Systems, Open Systems and Controls

V. Electronic Signatures

VI. Computer/Software Validation

VII. Change Control

VIII. System Documentation and SOP Alignment

IX. Considerations for Quality Assurance, Records to Submit, Records to Maintain

X. Approaches to Electronic Signature Certification and the Electronic Submissions Docket

XI. Where is the Agency Headed?

XII. Are there Global Implications for Industry?

12:00 *Close of Workshop*

There will be a 20 minute refreshment break at 10:00

— About Your Workshop Leaders —

Robert Bell, Partner, International Drug Registration, L.L.C., former Director, Office of Management, CDER-US FDA

Robert A. Bell is co-founder of International Drug Registration, L.L.C. an international consulting firm that provides services to the Pharmaceutical and related industry. He is a senior consultant to Electronic Submission Publishing Systems, Inc. Prior to establishing the consulting firm, Bob was Director, Office of Management, Center for Drug Evaluation and Research, FDA.

W. Gregory, Ph.D., Director, Regulatory Affairs, Pfizer

William Gregory is Director, Regulatory Affairs, at Pfizer Pharmaceuticals, where he has broad responsibility for regulatory affairs on a worldwide basis. He has more than 15 years of experience directing product candidate registration programs; he has been a clinical team leader for several anti-infective product development programs and has extensive experience in the evaluation and reporting of safety data. He also has experience in developing electronic data review aids for regulatory reviewers.

Elaine S. Price, President and CEO, Phoenix Systems Integration

Ms. Price has 18 years industry experience in the development, marketing, and implementation of "turn-key" solutions for global document management applications. She has personally managed the successful deployment of EDMS technology. Elaine has extensive international experience and an established track record for managing start-up companies from initial startup to sustained and profitable growth.

B

The ICH Common Technical Document — Develop the CTD for Global Registration Dossiers

The development of the Common Technical Document will enhance the way in which regulatory information is provided in the future, facilitating higher quality and more cost-effective management of regulatory dossiers. Global agreement on achievable technical requirements is needed and the current draft ICH guidelines on quality, safety and efficacy are providing the framework for working towards harmonization.

8:30 *Registration and Continental Breakfast*

8:45 *Welcome and Opening Remarks*

I. Overall Structure of ICH Draft Guidelines and Format Harmonization

II. Format of Reports and Documents for Use in Developing Company SOPs

III. Common Tabulated Summaries

IV. Construct Company Technical Manual

Real life — The new format facilitation of electronic submissions and the use of electronic document management systems still presents a challenge. Differences between USP, EP and JP are still an issue, but the implementation of common best practice is, as always, the pragmatic approach and the way forward towards global harmonization. A 'real life' presentation for users of CTD and the assessment of the challenges and "best practice" opportunities are discussed.

V. The Reality Harmonization within the Three Regions as Illustrated in Industry Models

VI. Regional Differences and the Use of Illustrative Examples

VII. ICH progress on the International Dossier for Registration — CTD-Safety and CTD-Efficacy

VIII. Scope of CDT-Quality, Restrictions for Biotechnology Products

IX. Best Practices

12:00 *Close of Workshop*

There will be a 20 minute refreshment break at 10:00

— About Your Workshop Leaders —

John Chidlow, Ph.D., Executive Director, Regulatory Affairs Europe, Quintiles, UK

Dr Chidlow has his B.Sc. in Chemistry and his Ph.D. in Microbiology and Immunology and has 30 years experience of Research and Development work, including 20 years in Regulatory Affairs. He began his pharmaceutical industry career in 1977 as a product development project manager in Unilever medical products division.

Anthony J. Calandra, Ph.D., Manager, Regulatory Affairs, Amgen Inc.

Anthony Calandra is a Manager of Regulatory Affairs at Amgen, Inc., Thousand Oaks, California where he manages a group of regulatory professionals focusing on the pre-clinical and clinical development of novel recombinant human proteins or new chemical entities indicated for neurodegenerative disorders, inflammation, and infectious diseases. Additionally, Tony is responsible for coordinating the department's strategic regulatory awareness activities. Dr. Calandra joined Amgen in 1992 as a Regulatory Specialist.

Meet Impending FDA Mandates on Ele

MAIN CONFERENCE

Day One — June 10, 1999

12:15 *Main Conference Registration*

1:00 *Chairperson's Welcome & Opening Remarks*
Robert Bell, Partner, **International Drug Registration, L.L.C.,** *former Director, Office of Management,* **CDER-US FDA**

FDA / ICH Regulatory Guidelines

— KEYNOTE SPEAKER —

1:15 **Implementation of MedDRA and the Maintenance and Support Services Organization (MSSO)**

This session defines the role of the MSSO regarding the ICH Medical Dictionary for Regulatory Activities (MedDRA) terminology. TRW was selected to develop support services for MedDRA. It was developed in response to ICH recommendations to standardize the reporting of clinical information including adverse events worldwide. Its role will be classification, retrieval, presentation and communication of medical information throughout the medical product regulatory cycle.

- What is MedDRA?
  - * contents of the new coding dictionary
  - * understand the 5 hierarchical levels of MedDRA
  - * define the role/use of MedDRA
- What will be the impact of MedDRA implementation?
  - * how MedDRA may impact reporting of adverse events both domestically and abroad?
  - * evolution of coding principals and reporting agreements
  - * choosing version of MedDRA and keeping up with the 1000 changes per month; recoding?
- The role of the MSSO
  - * Subscription services —
    - * what is the availability and pricing of MedDRA?
    - * what is the role of MSSO?
    - * change Management for terminology
    - * user groups in the three ICH regions
  - * Support services —
    - * tools for MedDRA use and enhanced services
    - * support and training

Kathryn Huntley, MedDRA / MSSO Program Manager, **TRW**

— About Our Keynote Speaker —

Kathryn Huntley, Director of Health Care Systems at TRW Systems & Information Technology Group, received her B.Sc. from Massachusetts College of Pharmacy and her MBA from Northeastern University. Over her career, Ms. Huntley has held positions in nuclear pharmacy, health physics consulting, academics, and management consulting before joining the FDA in 1991. While at the FDA she served as a clinical reviewer in the Center for Drug Evaluation and Research. In 1993 she accepted the position as Program Manager for the Agency,s Standardized Nomenclature Program. She also served as FDA's representative on the ICH expert-working group responsible for the development of the MedDRA terminology. She joined TRW in 1997.

2:15 **ICH Initiatives for Global Harmonization of Safety Data Reporting**

Pharmaceutical Perspective

Learn ICH initiatives that will impact the development and implementation of changes in adverse event reporting requirements and future expectations for electronic exchange of postmarketing safety data.

- Why ICH influences the regulatory process
- Relevant ICH topics and current status in the three ICH regions
  - * E2a — Definitions and Standards for Expedited Reporting
  - * E2b — Data Elements for Transmission of ADR Reports
  - * E2c — Periodic Safety Update Reports
  - * M1 — Medical Terminology (MedDRA)
  - * M2 — Electronic Standards for Transmission of Regulatory Information (ESTRI)
- The electronic vanguard
  - * US — Adverse Event Reporting System at the FDA
  - * PhRMA / FDA electronic reporting pilot and use of MedDRA
  - * Advanced Notice of Proposed Rulemaking—Electronic reporting of postmarketing adverse drug reactions
  - * Europe--EFPIA / EMEA electronic pilot in Europe

W. Gregory, Ph.D., Director, Regulatory Affairs, **Pfizer**

3:15 *Networking & Refreshement Break*

3:30 **ICH Standards for Electronic Submissions**

- ICH Standards for Electronic Submissions
- Recommend electronic standards for the transfer of regulatory information (ESTRI). M2 + E2b and the effect on PSURS
- Regulating standards for transmission of regulatory information
- Look at the future of AE submissions — E2b as an international standard. AERS has implemented the E2b format into its database and will require manufacturers to use the E2b standard for electronic submissions
- Review the ICH E2b document to gain insight into the use of the various items in the message
- Outline E2b structure and function
- Minimal requirements for an E2b data set, standard formats for including data in messages
- Overcome the pitfalls often encountered in early attempts to use the E2b format

George P. George, Deputy Topic Leader ICH, M2 & EWG, **Booz, Allen & Hamilton**

4:30 **Legal Issues in Electronic and Online Adverse Event Reporting**

As the technology for electronic AE reporting matures, new challenges are faced in dealing with regulatory compliance and legal liability. The popularity of the Internet also promises pure online reporting, but brings with it the burden of an increased volume of adverse event reports. This session provides useful perspectives on legal and regulatory compliance issues connected with electronic and online reporting and will offer constructive suggestions for minimizing risk• Legal and regulatory compliance background for electronic AE reporting

- Responsibilities subsidiaries and employees for reporting
- Application of regulations to electronic submissions
- Adverse events on the Internet — reporting requirements and opportunities
- Related FDA regulatory compliance and policies — digital signature, CANDAs

Mark Boulding, Partner, **Long Aldridge & Norman**

5:15 *Close of Day One*

5:15— 6:15 ***Wine & Cheese Networking Reception***

Join colleagues and friends in a relaxed setting.

Day Two — June 11, 1999

7:30 *Registration and Continental Breakfast*

8:00 *Chairman's Welcome and Opening Remarks*

Robert Bell, Partner, **International Drug Registration, L.L.C.,** *former Director, Office of Management,* **CDER-US FDA**

8:15 **AERS Pilot Participants — Regulatory Readiness on Electronic Submission of Individual Case Safety Reports to FDA**

Pharmaceutical Perspective

The FDA launched a new post marketing Adverse Event Reporting System (AERS) in November 1997. The system allows companies to submit adverse event reports electronically and several companies have been involved in a pilot project with the FDA. Electronic data interchange via ICH standards is an issue for the future for all companies and regulators. The pilot experiences of two companies are discussed in this session.

- Glossary of ICH terminology
- Understand E2b, M2, SGML file structure
- Electronic submission pilot objectives
- Electronic ADR Task Force – a collaborative effort
- Resources needed to get started and to keep going
- Implementation issues and lessons learned
- Next steps

Vlasta Pinkston, Director, North American Product Surveillance, **Glaxo Wellcome, Inc.**

Mark Blake, Manager, Drug Safety and Epidemiology, **Zeneca Pharmaceuticals**

9:30 **Changing Terminology Effect on Labeling Mapping and Data Storage**

Pharmaceutical Perspective

This session covers moving from legacy systems to new systems and exploiting the advantages of international accepted terminology to improve and standardize global processes.

- Strategies for mapping legacy data to MedDRA
- The potential impact of MedDRA on case expediting status?• The relationships between MedDRA terminology and product information?
- What effect will there be on domestic periodic reports and the PSUR?
- Identify issues with reassessed data

Joanna Haas, Executive Director, Safety & Epidemiology, **Novartis Pharmaceuticals**

10:15 *Networking & Refreshement Break*

How to Harmonize Your Safety Surveillance Process

10:30 **Convert Your Adverse Events Reporting Systems for Global Performance —- A Sponsor's Viewpoint**

Pharmaceutical Perspective

Globalization of post marketing surveillance implies managing evolving regulatory requirements: USA, EU, Japan and other national health authorities as well as ICH and CIOMS initiatives. This mandates creating and maintaining a global Pharmacovigilance system with electronic reporting facilities. What are the ensuing challenges and how can they can be met in a global environment? Success requires integrating business needs, regulatory demands and technology.

I. Evaluation -- What is to be Done?

- Overview of current global regulatory demands and future directions
  - * ICH and CIOMS initiatives
  - * FDA, European and Japanese requirements
  - * electronic data transfer (ICH E2b, electronic signature)
  - * coding (MedDRA, WHO-ART, CO-START)
- Understanding sponsor's needs
  - * organization, philosophy, size, available resources, external ties
- Globalization of business processes
  - * clear definition of responsibilities and processes
  - * meeting regulatory timelines
  - * coordination with internal and external customers

II. Execution — How to Do It?

- Business process reengineering: analysis and planning
- Structuring a model for global workflow and reporting
- Evaluation of available tools and technologies
- Configuring the system
- Implementation challenges
  - * legacy systems and data migration
  - * resources
  - * validation
- Maintenance and enhancements

Rajesh Ghosh, Global Systems Administrator Clinical Safety & Epidemiology, **Novartis**

Joanna Haas MD, Executive Director, Clinical Safety & Epidemiology, **Novartis**

11:15 **Epidemiology — Role in Safety Surveillance and Interpreting Signals**

Pharmaceutical Perspective

Pharmaceutical companies evaluate reports received for potential signals of a serious adverse event. Pharmaceutical companies will identify and act on these signals before a regulatory body requires them to do so.

- How changing regulations affect your company's needs for effective epidemiology
- Requirements for safety surveillance and reporting
- Evaluating data for potential signals of a significant event for reporting
- Creative approaches to signal detection that lead to hypothesis generation
- Tools and software applications available to detect signals
- Access to AERS/CDC LCDB FOI information, to obtain additional information

Stephen Klincewicz, Medical Director,
Zeneca Pharmaceuticals

12:00 *Luncheon*

1:15 **Compliance, Contractual and Liability Issues in Outsourced Adverse Event Reporting**

Increasing regulatory requirements and decreasing staff have resulted in the emerging need to outsource safety surveillance functions to external organizations. This session explores the potential legal, regulatory and contractual issues associated with outsourcing ADR reporting

- Chain of command, chain of reporting and timeline concerns
- ADR reporting errors-who is responsible?
- Product liability and confidentiality concerns in event classification?
- Address contractor SOPs, E2b electronic interface, MedDRA coding specifications and other contract issues in the outsourcing agreement
- Problems with partial and complete enterprise and global report outsourcing
- Four critical disciplines for all report outsourcing relationships
  - * selection discipline
  - * qualification discipline
  - * monitoring discipline
  - * action discipline

Gary Gamerman, M.S., J.D. Attorney,
Heller Ehrman White & McAuliffe

2:00 **Technology's Impact on Safety Surveillance Reporting Systems**

This presentation focuses on the technological aspects of ADR reporting. It addresses how modern technologies have impacted safety surveillance reporting systems and what's in store for the future of electronic reporting.

- Outline of the ADR data management process, with an emphasis on the areas where technology assists in improving the process
- Developments in the area of ADR reporting, which require new or extended IT functionality
- Developments in the area of information technology, which provide new opportunities to improve the ADR reporting process
- Emerging trends in ADR reporting

Janet Schorr, Clintrace Product Manager,
Domain Pharma Corporation

2:45 *Networking & Refreshment Break*

Multi-Regional Reporting Requirements

3:00 **Create and Manage an Adverse Event Reporting System in a Global Network**

Biotech Perspective

This session is a case study in creating and maintaining a global pharmacovigilance and safety reporting system. Amgen's experience in managing the variety of worldwide safety reporting requirements for drugs, biologics and devices is described.

- Plan and develop a global AE reporting system
- Monitor safety for pre and post-marketing
- Process a case worldwide
- Harmonize many distinct methodologies of AE reporting
- Cope with corporate and international cultural differences

Sandy Smith, Ph.D., Manager,
International Clinical Safety, **Amgen**

3:45 **Why Be Afraid of Electrronic Multiple Source AE Reporting?**

This session provides models and cover the various aspects of multi-source adverse event data capture and companies' experiences with decisions to multi-source and their outcomes.

- Identify company objectives with decisions to develop a multiple source AR system
- Eliminating the fear factor with responsible analysis and execution of a multi source plan
- Potential sources of AE information and data manipulation
- Interpreting potentially serious events
- Benefits of foresighted multi-source AE systems
- Consistency and quality of data
- Models from industry

Mark Boulding, Partner, **Long Aldridge & Norman**

4:30 *Close of Conference*

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- *Featured Presenter:* **Robert Bell, Partner, International Drug Registraton, L.L.C., Former Director, Office of Management, CDER-US FDA**
- **AERS Pilot Program Participants from Glaxo Wellcome and Zeneca Pharmaceuticals**
- **Hear from 6 Bio/Pharmaceutical Companies**

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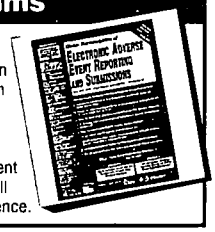

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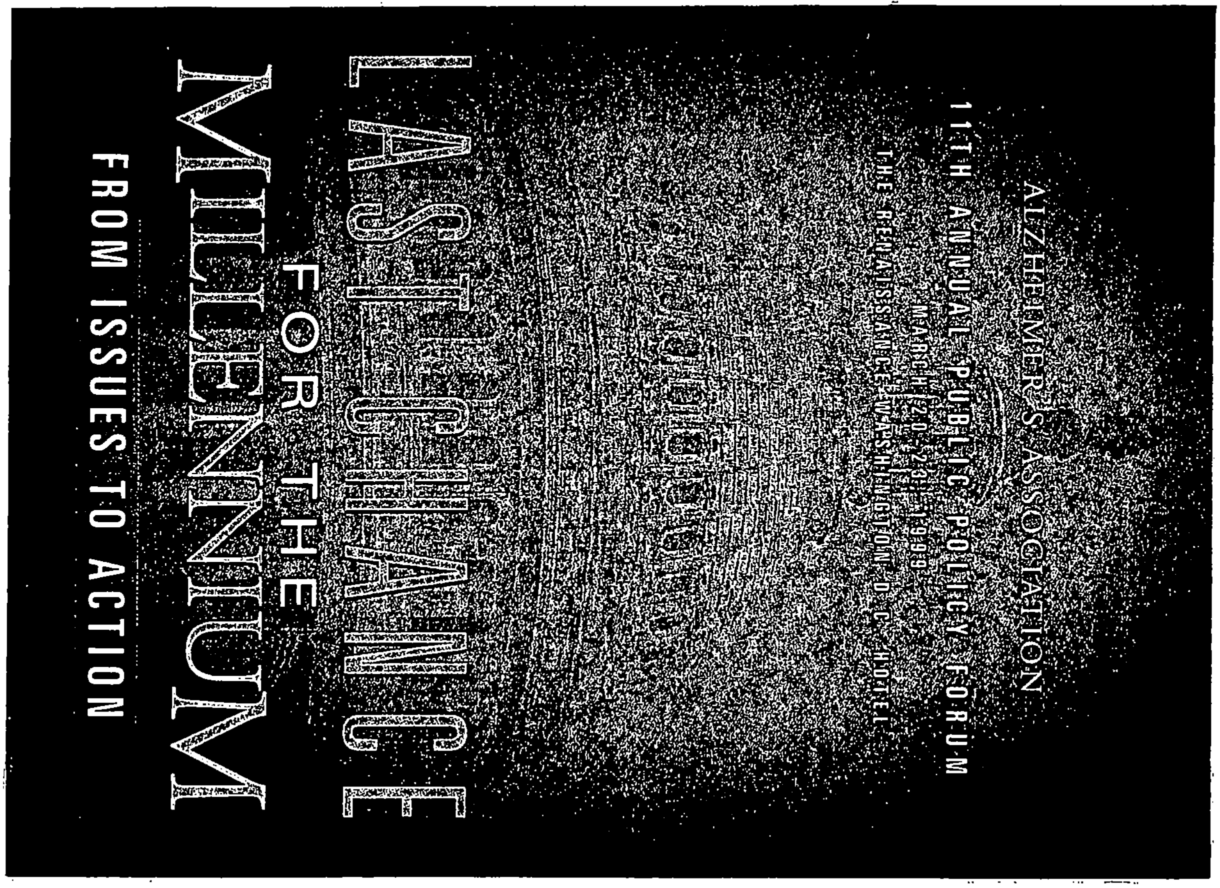

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- A Report from The Bipartisan Commission on the Future of Medicare
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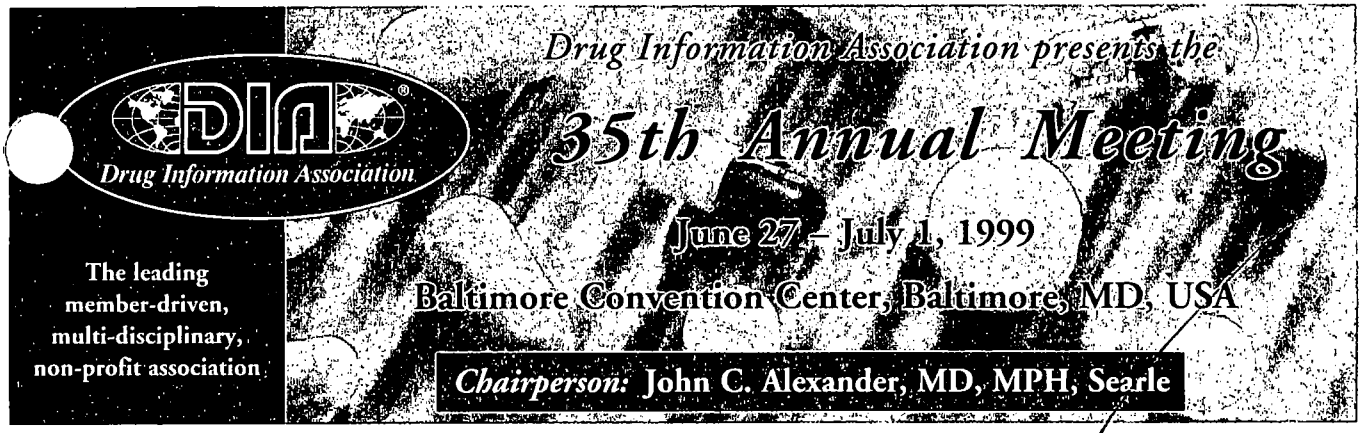

Plenary Session

Monday, June 28, 8:30-10:00 AM

The theme of the Plenary Session will be
Can Society Afford Innovative New Drug Therapies?

Keynote Speakers

William R. Brody, MD, PhD
President, Johns Hopkins University, MD, USA

Uwe Reinhardt, PhD
James Madison Professor of Political Economy
Princeton University, NJ, USA

Poster and Scientific / Academic Technology Session

An area has been set aside to provide certain attendees with an opportunity to exhibit scientific developments associated with the Pharmaceutical Development and Registration Process. In addition to the "Member Poster Session" scheduled for Tuesday, June 29, from 9:30 AM to 4:00 PM, there will be an additional "Student Poster Session" on Monday, June 28, from 10:00 AM to 4:00 PM. Both sessions will take place in the Exhibit Hall. The Poster Session Chairpersons are: **Francis B. Palumbo, PhD, JD**, University of Maryland; **Sheila R. Shulman, LLB, MPH**, State University of New York at Buffalo; and **Sheila R. Weiss, PhD**, University of Maryland.

If you are interested in presenting a poster at either session, please submit an abstract to:

Drug Information Association, 501 Office Center Drive
Suite 450, Fort Washington, PA 19034-3211 USA
Fax: +1 215 641 1229 email: braksator@diahome.org
Tel: +1 215 628 2288

The deadline for submission is April 1, 1999.

Please indicate if you are submitting an abstract for the *"Member Poster Session"* or the *"Student Poster Session."*

Tutorials

On Sunday, June 27, there will be a variety of tutorials offered for your interest and knowledge. Detailed information regarding these tutorials will be included in the preliminary program which will be mailed to the membership in early March, 1999. Below are some of the Tutorials being offered:

- Recruiting and Retaining Patients for Clinical Studies
- An Introduction to Electronic Document Management in the Pharmaceutical R&D Process
- Project Management Success Factors
- Multiple Imputation for Missing Data in Clinical Trials
- Clinical Statistics for Non-Statisticians
- Computer Validation Reality Check
- Winning Strategies for FDA Advisory Committee Meetings
- CRA (Clinical Research Associate) Challenges: An Interactive Problem Solving Session
- NDA Preparation – An Overview
- FDA Enforcement: What Every Clinical Director Should Know
- Practical Issues in Clinical Trials
- Pharmacoeconomics and Pharmacoepidemiology
- Outsource Contracting: Strategy and Tactics for Successful Negotiation, Drafting and Management
- An Overview of the New Electronic Records: Electronic Signatures Regulations and Their Impact on Pharmaceutical R&D Computer Systems
- Preparation of Integrated Statistical and Clinical Reports for Individual Studies
- Outcomes Research for Everyone Else: A Primer for the Non Outcomes Researcher
- Special Educational Seminar: European Regulatory Forum
- The Rules of Vocabulary Control in Safety Reporting
- Fourteen Steps from Research to Development
- Core Curriculum for Medical Communications Professionals Practicing in the Pharmaceutical Industry
- Individual Bioequivalence
- Working Across Cultures: Understanding Your International Colleagues' Frame of Reference

"SOME" of the topics that will be offered at the 1999 Annual Meeting are:

BIOTECHNOLOGY

The Manufacture of Biotherapeutics

The Jeopardy of Drug Development

Gene Therapy

Cell Therapies as an Alternative to Therapeutics

Pharmacoeconomics as a Tool for Biotechnology Firms

Drug Manufacturing in Biological Systems: Advances and Issues

Biotechnology in 1999: Where the Jobs Are

CLINICAL DEVELOPMENT

Revamping Clinical Drug Development at Rhône-Poulenc Rorer: A Global Initiative Encompassing All Therapeutic Groups

Defining the Role of Medical Affairs in Clinical Trials: Interfacing with Global Departments and the FDA Perspective

Pfizer's Strategic Initiatives Relative to Global Clinical Development and Its Impact on Metrics

Strategies for Fast Tracking Clinical Trials: Maximizing Speed and Minimizing Resources

Obstacles to Clinical Development and Regulation of Pharmaceuticals in Emerging Market Key Issues and Industry Strategies with a Focus on the Asia Pacific, Eastern Europe and Latin America

Challenges to Regulation in Japan: Impact of ICH Efficacy Guidelines and How to Overcome Current Difficulties

Financial Disclosure

Growing Size of Clinical Dossiers and Efforts to Reduce the Volume of Data

Outsourcing in Drug Development: New Findings from Worldwide Surveys and Their Implications

How to Improve Decision Making and Best Practices in Clinical Drug Development: Use of Benchmarking Data

Successful Planning in Clinical Development: Investment, Output, Attrition

Speeding Up the Regulatory Review Process in Seven Leading Companies

Accelerating Clinical Development: What Progress Has Been Made and What Gains Remain to Be Realized

Trends in New Drug Development Timelines

Correlation Between Study Design and Study Cost

Relationship Building Between Pharmaceutical Sponsors and Other Organizations in Facilitating Drug Development

Moving Beyond Patient Recruitment or Patient Retention

Changing Dynamics of Study Site Management and Impact on Clinical Research

Problems in Clinical Trial Design

Clinical Project Management in Facilitating the Clinical Research Process

Confidentiality and Disclosure in Clinical Trials

Communication of Clinical Research: What Is Good, What Is Not, What Needs to Change

IRB Reform: Government Intervention and What It Means for Industry

Patient Recruitment: the Good, the Bad, and the Ugly

Evolving Role of IRB in Working with Commercial Sponsors of Clinical Research

Accelerating Time to Peak Sales

Pharmaceutical Research in 2005: What Will It Look Like and How to Prepare for It

Role of Surrogate Markers in Clinical Studies

Presenting the Right Image (Radiologic) in Clinical Trials

Improving the Protocol Development Process

Minimizing Risks of Product Withdrawal After Launch: Lessons for Clinical Research Development

Web-Based Tools to Facilitate Integrated Clinical and Laboratory Data

Essential Elements of Site Training to Minimize Queries

The Impact of Emerging Integration Systems Technology on Clinical Research

Making Adverse Event Reporting Easy to Understand

Ensuring That Clinical Trial Investigators Are Appropriately Trained to Conduct Studies

Clinical Trials in Children

CNS Drugs

Oncology Drugs

Drugs for Heart Failure

Drugs for Pain

Hormone Replacement Therapy

Antibiotics

Osteoporosis

Diagnostic Drugs

Drugs for Diabetes

Pulmonary Drugs

Cholesterol-Lowering Drugs

Gender-Specific Medicine: A New Approach to Health Care and Drug Development

Difference in Managed Care Practice Patterns: Implications for Clinical Research

Strategic Approaches to Population Pharmacokinetics

Got Milk? Marketing Clinical Trials to Potential Participants

Is Outsourcing Paying Off in Expediting Clinical Development

Clinical Research in Japan: Comparison to Other Countries

Clinical Development in Japan: Bridging to ICH Guidelines

CLINICAL SAFETY/PHARMACOVIGILANCE

MedDRA and Pharmacovigilance: The Way Forward

Good Clinical Safety Case Management Practices

le of Poison Centers in Drug Safety

Different Viewpoints on Safety Labeling

Pediatrics and Safety

Managing and Marketing Safety as a Corporate Asset

Benefit-Risk Evaluations: CIOMS IV

Monitoring Safety in Biotechnology Products

Electronic Case Data Submission

Safety Aspects of Hormone Replacement in Women

Periodic Safety Update: Reporting into the Millennium

Randomized Clinical Trials: Safety Interpretation and Labeling Issues

What Computers Can Do for Pharmacovigilance

CLINICAL TRIAL MANAGEMENT FOR INVESTIGATORS

Future and Present Information and Communication Technology Impact and Implications on Biotechnology/ Pharmaceutical Organizations, Investigator Sites and Outsourcing

CONTRACT RESEARCH ORGANIZATION

Town Meeting – Part 1 and 2

CRO Consolidation and the Impact on Clinical Research: Is It Good? Is It Bad? Can the CRO Industry Sustain a 25% Growth Rate? Will the CRO Industry Crash with the Stock Market?

Matching Skill Sets Within the Company on a Global Basis to Select Compatible Vendors for Global Drug Development

Academic Research Organizations: What Are They, Where Do They Fit – Parts 1 and 2

Transitioning Clinical Studies Between CROs: Successful Partnerships

Measuring Clinical Trials Performance of Pharmaceutical Companies, CROs, SMOs and Sites

Utilizing New Technologies and the Impact on Biometrics

CROs in Japan – Parts 1 and 2

Listen to the Sponsor: Defining the Vision of Outsourcing in the New Millennium

Accelerating Clinical Development: Use of CROs and Consultants

EMERGING AND RE-EMERGING THERAPEUTICS

Sessions in this Interest Area are being developed.

GOOD CLINICAL PRACTICES

Evolution of GCP in Japan and the Impact on Clinical Development

GCP Training

QA Audits of Clinical Studies: Update on Trends in Clinical Research

GCP Compliance: Emerging Issues in Worldwide Clinical Trials

Sources of Agreement and Disagreement About Source Documents: Four Perspectives

Other GCP Arenas

Cultural Differences/Ethics in Clinical Trials

How to Optimize QA Resources: Joint Studies of Service Providers

Systems Audits

Implementation of ICH-GCP

Fraud

IMPACT

AHCPR Evidence-Based Practice Centers

Pharmacoeconomics for Drug/Device Combinations

Managed Medicare and Drug Policy for the Elderly

Planning Clinical Development for New Product Launch

Effectiveness Trial Recruitment: Statistical/Epidemiological/ Economics/Efficiency Issues

Issues in QoL Research: Picking the Right Instrument

Statistical Issues in Health Economics Including Bayesian Work

Patient Productivity: Methods of Measurement

Measuring the Severity of Disease

Recent Successful Launches: The Role of Pharmacoeconomics (Viagra/Lipitor)

Research in Managed Care

Outcomes Research in Long Term Care

Quality of Life and the FDA: Impact of Policy Change

Pharmacoeconomic Guidelines Update: Where Are We Now/ How Are They Used/Are They Used/Productivity

FDA Modernization Act and Health Economic Information Update on Guidelines

LEGAL

How State Laws and Regulations Affect Clinical Trials – A Potential Legal and Regulatory Nightmare

Clinical Trials on Trial – Civil, Criminal and Other Liability Issues in the Performance of a Clinical Trial

MARKETING/ADVERTISING

Heightened Scrutiny on the Part of FDA on Advertising Review and Complaints

MEDICAL COMMUNICATIONS

Crisis Management Role of a Medical Communications Department

Leveraging Technology to Expand Business Opportunities in Medical Communications – Parts 1 and 2

Managing Customer Expectations in Medical Communications – Parts 1 and 2

Drug Safety: Information Collection for Initial Adverse Experience Reporting

Global Medical Marketing

MEDICAL/TECHNICAL WRITING

Effective Working Relations

Parallel Writing, NDAs/EU Submissions

Training Writers

CROs

The Psychology of the Writing Task

Managing the Writing Task

Working Globally

Regulators and Regulations

Standardization

Related Writing

PEDIATRIC ISSUES

Making Trials Kid-Friendly: Practical and Ethical Issues to Consider

Update on US Regulations and Guidelines for Development of Drugs in Children

International Development of Pediatric Drugs

Existing and Potential Incentives for Stimulating the Development of Pediatric Drugs

Issues in Clinical Trial Design and Special Therapeutic Needs in Pediatrics

Conducting Trials in Children: Available Resources

Pharmacoeconomics of Vaccines and Pediatric Drugs

PROJECT MANAGEMENT

Virtual Drug Development

Managing Projects in China: Opportunities and Success Factors

Managing Projects in South Africa and India: Opportunities and Success Factors

Successful Clinical Project Management in Latin American Emerging Markets

Latin American Pharmaceutical Market and Its Influence on Clinical Trials

New Developments to Manage Clinical Trials in Central and Eastern Europe

Proof of Concept: Improved Planning for Improved Management

New Technologies to Support Project Management: Real Time Data Collection

Project Management: Risk Management

New Techniques to Support Project Management: Accelerated Patient Recruitment

New Success Factors in the Management of Cardiovascular Projects from Development to Marketing

Project Success Starts with Successful Team Interfaces Between Research and Development

Project Management Training – Parts 1 and 2

Specialty Area Project Management Within Drug Development

Project Budgeting

Portfolio Management

Performance Measures for Project Management

Project Management Roles in Regulatory Agencies

Project Management for Successful Reviews

Project Planning for Market Success

Joint Case Studies a la DIA Workshop with FDA and Industry on Project Management

Planning for Successful Manufacturing Technology Transfer

Project Management in Other Industries: Applications for Drug Development

Software Options for Project Management

Worldwide Co-Development with a Japanese Company Compared to a European Company

PUBLIC POLICY

FDAMA's Pediatric Labeling Initiative: A Solution to Worldwide Need?

Direct-to-Consumer Advertisements

Productivity Incorporating Patient Advocacy Groups in the Drug Development Process

From Market Authorization to Marketing: New Data and New Challenges

PERSONAL & PROFESSIONAL CAREER DEVELOPMENT

Meeting the Need for Tomorrow's Pharmaceutical Professionals

Business Etiquette

REGULATORY AFFAIRS

Centralized European Applications: Successful Case Studies

Obtaining Regulatory Advice in Europe During the Drug Development Process

When Regulatory Advice from Authorities Differs

EMEA Update: European Expertise Network

Mutual Recognition Procedures in the New Era

Centralized Procedures and Mutual Recognition:

Practical Difficulties

Regulation 2000

Orphan Drug Regulation in Europe

Strategic Considerations on the Choice of European Procedures

Preparing for FDA Advisory Committee Presentations: Views from Three Perspectives – Parts 1 and 2

Success Factors in Generic Applications

Is the FDA User Friendly?

Regional Harmonization of Regulatory Requirements for New Pharmaceutical Products – Asia Pacific

Regional Harmonization of Regulatory Requirements for New Pharmaceutical Products – Latin America

Regulatory Strategies for Early Introduction of New Pharmaceutical Products in Emerging Markets

NDAs/MAAs for Simultaneous Worldwide Submissions: Decentralized vs. Centralized

Influence of Advisory Committees and Advisors on the Regulatory Process

Report from South Africa

Global Registration Case Studies Towards the Common Technical Document

Registration Strategies and Pricing Strategies

Global Product Acquisitions: Regulatory Process and Issues

Need for Harmonized Pharmaceutical Specifications

Harmonization of Stability Guidelines

Building and Maintaining Productive Relationships in Global Electronic Regulatory Submissions

Knowledge Management in Pharmaceutical R&D: Leveraging the Intellectual Capital of Regulatory Submissions Team

Regulatory Assessment of Self Medication Products

Progressing from Accelerated Approval to Traditional Approval: Case Studies

Update on FDA Labeling Format Issues

Fast Track Drugs: The New Process

Implementation of SUPAC

Update from CDRH – Parts 1 and 2

Common Technical Documents: Quality

Common Technical Documents: Quality/Biotech

Common Technical Documents: Quality/Information Technology

Common Technical Documents: Efficacy

Common Technical Documents: Safety

Common Technical Documents: Active Pharmaceutical Ingredients

Update from CBER – Parts 1 and 2

Global Perspectives on Third Party Agreements for Regulatory Tasks

Pediatric Exclusivity Update

The Non-Review Division of FDA

FDAMA Implementation Update

Information Technology and Electronic Submission in Europe

Update from CDER – Parts 1 and 2

Update on Good Review Practices

Update from DDMAC – Parts 1 and 2

Recent Changes to the Japanese Regulatory Arena and Their Practical Application

Update on the New FDA Office of Post Market Drug Risk Assessment

STATISTICS

Use of the Propensity Score to Control Background Characteristics in Retrospective Studies

What Are We Doing About Benefit to Risk Assessment

The Use of Bayesian Decision Theory in Clinical Research

Adequacy for Evidence of Drug Approval

Some Common Statistical Methodology Issues in Medical Research

Statistical Methods to Monitor Quality of Clinical Trials

Missing Data and Multiple Imputation Methods

Recent Trends in PK/PD Modeling

Multiplicity of CNS Statistical Issues

SYSTEMS/DATA MANAGEMENT

Electronic Regulatory Affairs with Emphasis on Ensuring Data Integrity and Quality Electronically to Reduce FDA Need for QA of Regulatory Submissions

ICH – Parts 1 and 2

Document Management – Parts 1 and 2

FDA Information Management After FDAMA: Status Progress and Plans, FDA Perspective – Parts 1 and 2

Validation

1999 Annual Meeting Planning Group

Coordinating Committee
John C. Alexander, MD, MPH, G. D. Searle and Company, USA
Françoise de Crémiers, PharmD, MSc, ML
Wyeth-Ayerst Research, France
Kenneth I. Kaitin, PhD, Tufts University, USA

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Contract Research Organization Area
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Zeneca Pharmaceuticals, USA

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David R. Savello, PhD, Guilford Pharmaceuticals, USA
Dr. Manuel Zahn, Knoll AG, Germany

Statistics Area
Chair: Gary G. Koch, PhD, University of North Carolina, USA

Systems / Data Management Area
Chair: Stephen J. Kopko, MS, Wyeth-Ayerst Research, USA

FDA Issues
Lorrie Harrison, CBER, Food and Drug Administration, USA
Murray M. Lumpkin, MD, CDER
Food and Drug Administration, USA
Susan Alpert, MD, PhD, CDRH
Food and Drug Administration, USA

European Issues
Professor Jean-Michel Alexandre, MD, PhD, CPMP;
European Medicines Evaluation Agency, UK

International Issues
Mary Doug Tyson, MS, Food and Drug Administration, USA
Martijn ten Ham, PhD, World Health Organization, Switzerland

Council for Affordable Health Insurance

Regrets scheduling conflict

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Message

Attached is the agenda for our Annual Meeting April We would be honored if Chris Gunning could participate on the Tax County Panel which is on 4/22 from 9:00 am – 11:00 am.

Please let us know ASAP if he is able to participate.

Thanks!

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e-mail: mail@cahi.org

CAHI's Capitol Ideas for Health Care Reform

Draft Agenda Three (2/4/99)

Wednesday, April 21

1:00 p.m. Conference Registration Booth Open (closes at 5:30 p.m.)

2:00 p.m. Annual Meeting of the Members (visitors welcome)

2:30 p.m. Board of Directors Meeting (visitors welcome)

6:00 p.m. Congressional Reception, *Foyer of Rayburn House Office Building*

Thursday, April 22

8:00 a.m. Conference Registration

8:30 a.m. Breakfast with Member of Congress
Potential Speakers:
Dennis Hastert (Speaker of the House)
Rep. Dick Armey (R-TX)
Sen. Phil Gramm (R-TX)

9:00 a.m. **CAHI's Capitol Idea #1: Tax Equity**

Panel One: CAHI's Tax Credit Proposal

- Mark Litow, M&R – overview of CAHI's tax credit proposal, including a briefing on both issue briefs.

Panel Two: Private Sector Perspectives

- Janet Stokes Trautwein, NAHU – overview of need for tax equity and NAHU's tax credit proposal.
- Greg Scandlen, CATO – CATO's initiatives to provide tax equity.
- Grace-Marie Arnett, Galen Institute – discuss findings from Consensus Group.
- Dean Rosen, HIAA -- discuss HIAA's tax deductibility proposal.
- Brian McManus, Golden Rule – Fair Care overview.

Panel Three: Congressional and Presidential Perspectives

- Chris Jennings, Clinton Administration – discuss Clinton's health care tax credit proposal and/or LTC initiative.
- Dean Clancy, Dick Armey's office (R-TX)

- Rep. Jim McDermott (D-WA) (or someone from his office)
- Rep. Bill Thomas (R-TX) (or someone from his office)

11:30 a.m. **HCFA's Role in HIPAA Regulations**
- Bob Moffit, Heritage
- Randy DeRosa, GAO

12:00 p.m. Luncheon with Deborah Steelman, member of the Medicare Commission or Sen. John Breaux, co-chairs Medicare Commission, to discuss recommendations by the Commission (if any?!)

1:30 p.m. Hill Briefing Session and Hill Visits

7:00 p.m. Free Market Awards Dinner with Entertainment such as The Capitol Steps or a political comedian.

Friday, April 23

8:30 a.m. Continental Breakfast

9:00 a.m. **CAHI's Capitol Idea #2: *Expansion of MSAs***

Panel One: MSA Roundtable Discussion
- Dr. George Fisher or Jesse Hixson, AMA
- Recipient of an MSA
- Pharmacy Representative (Rep. from PHARMA)
- Hospital Administrator (Rep. from AHA)
- Agent Success Stories (John Fenton, Health Insurance Consultants of Iowa or Bill Summers)

Panel Two: Medicare MSAs – success or failure and why?
- Marainne Eterno, GTL –overview of Medicare MSAs
- Myra Tanamor, GAO – to discuss MSAs and HIPAA

Panel Three: Congressional Perspectives
- Mike Solon, Gramm's office
- Stacy Hughes, Nickles office

11:00 a.m. **CAHI's Capitol Idea #3: Why Free-Market Reforms Works**

Panel One: Overview federal legislation and the need for free market reform in lieu of more federal regulations.
- Amy McGee Polasky, AMS,
- Pat Gould, Chamber of Commerece

Panel Two: Overview state legislation and the need for free market reform in lieu of more state regulations.

- Bill Sterling, Fortis Health
- Duane Parde, ALEC

12:00 p.m. Closing Remarks by David Lack and Receipt of Box Lunch