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DIA Drug Information Association

FDA

Preventive Drug Development
complexities and challenges

April 12-13, 2007 | DoubleTree Hotel and Executive Meeting Center, Bethesda, MD, USA

PROGRAM COMMITTEE

SANDRA BENTON
Project Manager, Office of Medical Policy, CDER, FDA

RACHEL E. BEHRMAN, MD, MPH
Director, Office of Critical Path Programs, Office of the Commissioner, FDA

JAMES A. CROWELL, PhD
Chief, Chemopreventive Agent Development Research Group, Division of Cancer Prevention, , NCI, NIH

ANN T. FARRELL, MD
Acting Deputy Division Director, Office of Oncology Drug Products, Office of New Drugs, CDER, FDA

LESLIE G. FORD, MD
Associate Director for Clinical Research, Division of Cancer Prevention, NCI, NIH

MARY A. FOULKES, PhD
Director, Office of Biostatistics and Epidemiology, CBER, FDA

SUSAN L. HONIG, MD
Medical Reviewer, Guidance and Policy Team, Office of New Drugs Immediate Office, CDER, FDA

GARY J. KELLOFF, MD
Special Advisor, Division of Cancer Treatment and Diagnosis, CIP, NCI, NIH

COLLEEN LOCICERO, BS
Associate Director for Regulatory Affairs, Office of Drug Evaluation I, CDER, FDA

DIANE MALONEY, JD
Associate Director for Policy, CBER, FDA

COLLEEN MOCKBEE, RPh
Associate Director, Regulatory Affairs, Eli Lilly and Company

MAX ROBINOWITZ, MD
Medical Officer, Office of In Vitro Diagnostics Device Evaluation and Safety, CDRH, FDA

ANNE RYAN
Program Specialist, Office of the Director, Division of Cancer Prevention, NCI, NIH

NANCY STANISIC
Office of Critical Path Programs, Office of the Commissioner, FDA

EVA SZABO, MD
Chief, Lung and Upper Aerodigestive Cancer Research Group, Division of Cancer Prevention, NCI, NIH

ROBERT J. TEMPLE, MD
Associate Director for Medical Policy, FDA

JANET WOODCOCK, MD
Deputy Commissioner and Chief Medical Officer, FDA

FEATURED SPEAKERS

Design Issues Unique to Prevention Trials: An Overview

JANET WOODCOCK, MD
Deputy Commissioner and Chief Medical Officer, FDA

Developing Risk Reduction and Prevention Therapies

ROBERT J. TEMPLE, MD
Associate Director for Medical Policy, FDA

OVERVIEW

The high cost of disease treatment and the impact that diseases have on the U.S. economy (e.g., loss of productivity) have reached staggering proportions. This will continue as life expectancy increases. Thus, the prevention of illness is essential to controlling healthcare costs. Examples of effective preventative therapies include: the aggressive treatment of hypertension to reduce the risk of stroke, statins to lower cholesterol, the use of low-dose aspirin and beta blockers to prevent death in patients after a myocardial infarction, tamoxifen to reduce the risk of breast cancer, aggressive control of blood glucose to reduce the long-term consequences of diabetes, and most recently, the vaccine against the human papillomavirus, which causes cervical cancer.

This workshop will discuss and explore ways to design disease prevention programs and the complexities and challenges associated with such programs.

WHO SHOULD ATTEND

This program will benefit professionals in government, academia, and industry involved in the areas of:

- Research & development
- Regulatory affairs
- Third-party payment
- Health economics and outcomes research
- Public health
- Statistics
- Patient advocacy

LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

- Discuss public health goals and health economic models
- Identify technical and commercial barriers to the development of prevention indications
- Explain design issues unique to prevention trials
- Discuss the importance of using disease surrogates as part of a prevention program
- Explain how to maintain subject safety during the clinical trial

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See page 1 for learning objectives.

WEDNESDAY • APRIL 11

6:00-8:00 PM REGISTRATION

THURSDAY • APRIL 12

8:00-9:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

9:00-10:00 AM WELCOME AND OPENING REMARKS
Janet Woodcock, MD
Deputy Commissioner and
Chief Medical Officer, FDA

KEYNOTE ADDRESS

DEVELOPING RISK REDUCTION AND PREVENTION THERAPIES
Robert J. Temple, MD
Associate Director for Medical Policy,
FDA

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:30 PM SESSION 1

ILLUSTRATIVE EXPERIENCES IN PREVENTION

CHAIRPERSONS

Colleen Mockbee
Associate Director, Regulatory Affairs, Eli Lilly and Company

Eva Szabo, MD
Chief, Lung and Upper Aerodigestive Cancer Research Group, Division of Cancer Prevention, National Cancer Institute, National Institutes of Health

DEVELOPING DRUGS FOR DISEASE PREVENTION: POPULATION BENEFIT VERSUS INDIVIDUAL RISK
Alastair Wood
Managing Director
Symphony Capital, LLC

CHOLESTEROL AND CARDIOVASCULAR PRESENTATION
DAVID GORDON, MD, PHD
Special Assistant for Clinical Studies, Division of Heart & Vascular Diseases, NHLBI

WHAT'S PREVENTING US FROM PREVENTING BREAST CANCER? OVERCOMING BARRIERS TO CHEMOPREVENTION
Victor G. Vogel, MD, MHS, FACP
Professor of Medicine and Epidemiology, University of Pittsburgh Cancer Institute/Magee-Women's Hospital

DEVELOPMENT OF A DRUG FOR A PREVENTION INDICATION -- RALOXIFENE HCL FOR THE PREVENTION OF OSTEOPOROSIS
Mike Draper, MD, PhD
Medical Fellow, Lilly Research Laboratories
Assistant Professor, Indiana University School of Medicine

12:30-1:45 PM LUNCHEON

VACCINES PRESENTATION
NANCY MILLER, MD
Office of Vaccines, FDA

SESSION 1 QUESTION & ANSWER PERIOD

1:45-5:00 PM SESSION 2

TECHNICAL AND COMMERCIAL BARRIERS TO DEVELOPMENT OF PREVENTION INDICATIONS

CHAIRPERSONS

Gary J. Kelloff, MD
Special Advisor, Division of Cancer Treatment and Diagnosis, CIP, National Cancer Institute, National Institutes of Health

Neil Gibson, PhD
Chief Scientific Officer, OSI Pharmaceuticals

Challenges to Chemoprevention Agent Development in the New Era of Molecular Targeting
Neil Gibson, PhD
Chief Scientific Officer, OSI Pharmaceuticals

Assessment of Precancer, Intraepithelial Neoplasia, and Opportunities for Cancer Prevention Drug Development
Gary J. Kelloff, MD
Special Advisor, Division of Cancer Treatment and Diagnosis, CIP, National Cancer Institute, National Institutes of Health

Unexpected Outcomes of the PCPT
Howard Parnes, MD
Chief, Prostate and Urologic Cancer Research Group, Division of Cancer Prevention, National Institutes of Health

2:55-3:20 PM **REFRESHMENT BREAK**

A Phase III Trial to Prevent Prostate Cancer in a High-grade PIN (Prostatic Intraepithelial Neoplasia) Cohort
Mitch Steiner
CEO, GTx

Designing Colorectal Cancer Chemoprevention Trials
Monica Bertagnolli, MD
Associate Professor of Surgery, Harvard Medical School, Dana Farber Cancer Institute, Brigham and Women's Hospital

Novel Prevention Opportunities: Possible Prototypes
Jen Stotka
Vice President, US Regulatory Affairs, Eli Lilly and Company

Session 2 Question & Answer Period

5:00 PM **DAY 1 CONCLUDES**

FRIDAY • APRIL 13

8:00-9:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

9:00-11:30 AM **SESSION 3**

Designing a Prevention Development Program

CHAIRPERSONS

Janet Woodcock, MD
Deputy Commissioner and Chief Medical Officer, FDA

Robert J. Temple, MD
Associate Director for Medical Policy, FDA

Design Issues Unique to Prevention Trials: An Overview
Janet Woodcock, MD
Deputy Commissioner and Chief Medical Officer, FDA

Monitoring Safety in Prevention Trials
Janet Wittes, PhD
President, Statistics Collaborative Inc.

10:30-10:50 AM **REFRESHMENT BREAK**

Labeling Presentation
Russell Katz, MD
Director, Division of Neuropharmacologic Drug Products, FDA

Prevention Claims in Labeling
Janet Norden, MSN, RN
Associate Director, Regulatory Affairs, Office of Medical Policy, CDER, FDA

Session 3 Question & Answer Period

11:30 AM-12:45 PM **LUNCHEON**

12:45-3:00 PM **SESSION 4**

Lessons Learned and Defining Next Steps

Seeing the Trees for the Forest: The Challenge of Individualizing Risk for a Global Burden of Disease
Clifton Leaf
Senior Editor-at-Large, *Fortune Magazine*

Panel Discussion

Leslie G. Ford, MD
Associate Director for Clinical Research, Division of Cancer Prevention, National Cancer Institute, National Institutes of Health

Neil Gibson, PhD
Chief Scientific Officer, OSI Pharmaceuticals

Gary Gordon
Global Project Head, Abbott Laboratories

Gary J. Kelloff, MD
Special Advisor, Division of Cancer Treatment and Diagnosis, CIP, National Cancer Institute, National Institutes of Health

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Robert J. Temple, MD
Associate Director for Medical Policy, FDA

Janet Woodcock, MD
Deputy Commissioner and Chief Medical Officer, FDA

3:00 PM WORKSHOP ADJOURNED

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Register online or fax this page to +1-215-442-6199

CONTACT INFORMATION

Event information: Contact Kathleen Donner at the DIA office by telephone +1-215-293-5810, fax +1-215-442-6199 or email Kathleen.Donner@diahome.org.

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