Assessing Benefits and Risks of Medicinal Products in Regulatory Decisions

Tutorial: November 3, 2009
Meeting: November 4-5, 2009
Hyatt Regency Bethesda, Bethesda, MD, USA

PROGRAM COMMITTEE

PAUL COPLAN, ScD, MBA
Senior Director, Risk Management, Global Safety Surveillance and Epidemiology,Wyeth; Adjunct Professor, University of Pennsylvania School of Medicine

JOYCE KORVICK, MD
Deputy Director for Safety Division of Gastroenterology Products, Office of Drug Evaluation III, Center for Drug Evaluation and Research (CDER), FDA

ERIC ABDIE, MD
Chairman of the Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMEA), European Union
Scientific Advisor to the General Director, AFSSAPS, The French Health Products Safety Agency, France

EVENING KEYNOTE ADDRESS

Wednesday, November 4, 5:30-6:30 pm
BARUCH FISCHHOFF, PhD
Howard Heinz University Professor,
Department of Social and Decision Sciences
Carnegie Mellon University
Chair, FDA Risk Communication Advisory Committee

PRE-MEETING TUTORIAL
November 3, 2009, 9:00 am–5:00 pm

¬ PART 1: Multicriteria Decision Analysis to Assist the Process of Making Decisions
LAWRENCE PHILLIPS, PhD
Consultant to the European Medicines Agency (EMEA), European Union; Visiting Professor of Operational Research, London School of Economics

¬ PART 2: Stated Choice Methods for Valuing Benefits and Risks
F. REED JOHNSON, PhD
Senior Fellow and Principal Economist, Research Triangle Institute

¬ PART 3: Incremental Net Benefit for Quantifying Benefit-Risk Tradeoffs
LARRY LYND, PhD
Associate Professor, MSFHR Scholar, CIHR New Investigator, University of British Columbia
LOU GARRISON, PhD
Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington

CONFEREE OVERVIEW

Join FDA, EMEA, Health Canada, PMDA, patient representatives, industry, academics, and practicing physicians to discuss progress of benefit-risk approaches, including how to:

• Develop a common understanding of evolving explorations of benefit-risk assessment by FDA, EMEA, Health Canada, PhRMA, BIO and academics,
• Assess how scientific approaches applied in other fields may be employed as an aid to structured and transparent decision analysis in the field of medicinal products,
• Discuss approaches and methods to enhance transparency and communication of benefit-risk decisions,
• Identify opportunities and challenges of implementing exploratory approaches to benefit-risk assessment in a regulatory framework through a series of case studies, and
• Identify and discuss processes and methods that may enhance regulatory decision making, with the ability to:
  – Engage multiple perspectives;
  – Quantify values;
  – Evaluate the impact of uncertainty;
  – Incorporate preference analysis and measurement;
  – Provide greater infrastructure and consistency;
  – Increase transparency.

Maria Willy
Director, Policy
European Medicines Agency

WHO SHOULD ATTEND

¬ Regulators facing complex benefit-risk decisions, as well as regulatory and drug development policy makers
¬ Industry scientists involved in the evaluation of the benefit-risk assessment of products in development or marketed products
¬ Patient representatives and advocates who wish to have greater representation of their needs and concerns in regulatory decision making

REGULATORY AGENCY PARTICIPANTS

FDA
DOUGLAS THROCKMORTON
JOHN JENKINS
JOYCE KORVICK
ROBERT T. O’NEILL
MARK O. WALDERHAUG
RICHARD A. FORSHEE
C. GEORGE ROCHESTER
MARY WILLY
ROBERT TEMPLE

EMEA
ERIC ABADIE
BRUNO FLAMION
HANS-GEORG EICHLER

HEALTH CANADA
ROBYN LIM

PMDA
KAORU MISAWA

AHRQ
ANNE TRONTELL

CANADIAN COMMON DRUG REVIEW
SANDY PAGOTTO

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• BASIL, SWITZERLAND • TOKYO, JAPAN • MUMBAI, INDIA • BEIJING, CHINA
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<td>8:00-9:00 AM</td>
<td>TUTORIAL REGISTRATION AND CONTINENTAL BREAKFAST</td>
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<td>9:00 AM-5:20 PM</td>
<td>TUTORIAL</td>
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<td>9:00-9:20 AM</td>
<td>INTRODUCTION AND OVERVIEW BY FACULTY</td>
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| 9:20-11:20 AM | PART 1: 9:20-11:20am (120 minutes) MULTICRITERIA DECISION ANALYSIS TO ASSIST THE PROCESS OF MAKING DECISIONS Lawrence Phillips, PhD Consultant to the European Medicines Agency (EMEA), European Union; Visiting Professor of Operational Research, London School of Economics, UK

This session provides an opportunity for participants to become acquainted with multicriteria decision analysis (MCDA) as a framework to help regulators explore and evaluate the benefits and risks of options, e.g., drug versus placebo or comparator. The interplay between data, values, and uncertainty will be explored, with clear distinctions made between activities that are best left to human judgment and those that can be better assigned to computers. Ultimately, it is regulators who decide, not computers, but MCDA models can assist in the journey of assessing the benefit-risk ratio.

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<tr>
<td>11:20-11:40 AM</td>
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**PART 2: 11:40am-2:20pm (120 minutes)**

**STATED CHOICE METHODS FOR VALUING BENEFITS AND RISKS**

F. Reed Johnson, PhD
Senior Fellow and Principal Economist, Health Preference Assessment Group, RTI Health Solutions, RTI International

This session will introduce participants to the use of stated-choice methods for eliciting benefit-risk trade-off preferences from key stakeholders and the use of these preferences to calculate risk tolerance. Participants will become familiar with the concepts of maximum acceptable risk (MAR) for a given level of therapeutic benefit and minimum acceptable benefit (MAB) for a given level of treatment-related risk. Both MAR and MAB will be presented as independent measures of the benefit-risk balance and as inputs into incremental net health benefits (INHB) models. The presenters will describe how these results can be used to assist decision makers in understanding the relative importance of benefits and risks to key stakeholders in the medical decision-making process.

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<td>12:35-1:20 PM</td>
<td>LUNCH BREAK BETWEEN SPEAKERS IN SESSION 2</td>
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**PART 3: 2:25-4:50pm (120 minutes)**

**INCREMENTAL NET BENEFIT FOR QUANTIFYING BENEFIT-RISK TRADEOFFS**

Larry Lynd, PhD
Associate Professor, MSFHR Scholar, CIHR New Investigator, University of British Columbia, Canada
Lou Garrison, PhD
Professor, Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington

This tutorial and program are designated for 21.5 contact hours or 2.15 continuing education units (CEUs). 286-000-09-032-L04-P.
This session will introduce participants to the use of incremental health benefits (INHB) as a framework for quantifying benefit-risk trade-offs for pharmaceuticals. This approach uses the modeling tools (e.g., Markov modeling and discrete event simulation) and preference weights common to pharmacoeconomics to project health outcomes – both health benefits and risks (harms). The aims are to estimate the expected net benefit of a new drug compared to standard treatment, generally in terms of quality-adjusted life years (QALYs) gained, and to characterize the uncertainty in both benefits and risk (harms). The framework is amenable to considering risk management strategies and the health opportunity cost of delays to gather more data as well as how net benefit varies by population subgroup. Both theoretical issues and case studies will be discussed.

3:30-3:50PM PM BREAK BETWEEN SPEAKERS IN SESSION 3
4:50-5:20PM Q&A DISCUSSION TO FOLLOW (30 MINUTES)
4:00-6:00 PM CONFERENCE PRE-REGISTRATION

WEDNESDAY • NOVEMBER 4
7:30-8:30 AM REGISTRATION AND CONTINENTAL BREAKFAST

DAY 1:
Current Status of Benefit-Risk among Key Stakeholders

8:30-8:45 AM SESSION 1
INTRODUCTIONS AND GOALS OF THE CONFERENCE
Session chairs
Eric Abadie, MD
Chairman of the Committee for Medicinal Products for Human Use (CHMP), European Medicines Agency (EMA), European Union; Scientific Advisor to the General Director, AFSSAPS, The French Health Products Safety Agency, France
Joyce Korvick, MD
Deputy Director for Safety Division of Gastroenterology Products, Office of Drug Evaluation III, CDER, FDA
Paul Coplan, ScD, MBA
Senior Director, Risk Management, Global Safety Surveillance and Epidemiology, Wyeth; Adjunct Professor, University of Pennsylvania School of Medicine

8:45-10:15 AM SESSION 2
FRAMING THE NEED FOR IMPROVING BENEFIT-RISK ASSESSMENT

EMEA PERSPECTIVE
Eric Abadie, MD (20 minutes)
European Medicines Agency (EMA), European Union; AFSSAPS, The French Health Products Safety Agency, France

FDA PERSPECTIVE
Douglas C. Throckmorton, MD (20 minutes)
Director, CDER, FDA

PMDA PERSPECTIVE
Kaoru Misawa (20 minutes)
Director, Office of Safety, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

PATIENT PERSPECTIVE
Durhane Wong-Rieger, PhD (20 minutes)
President and CEO of the Institute for Optimizing Health Outcomes; President, Canadian Organization for Rare Disorders and Head of Consumer Advocare Network

QUESTION AND ANSWER PERIOD (10 MINUTES)

10:15-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION 3
ONGOING INITIATIVES TO TEST STRUCTURED BENEFIT-RISK ASSESSMENTS
Session chairs
Joyce Korvick, MD
CDER, FDA
John Ferguson, MD
Vice President and Global Head, Pharmacovigilance and Medical Safety, Novartis Vaccines and Diagnostics

There has been ongoing interest in refining the approach to benefit-risk assessment. This session will provide the audience with information on the status of case studies, perspectives or experiences that have been explored to evaluate a structured benefit-risk analysis over the past several years.

- Have any case studies been conducted to evaluate a structured benefit-risk analysis?
- What lessons were learned?
- What value was there in conducting structured benefit-risk assessments?
- What conclusions were reached in how to develop benefit-risk assessment?

CDER: EXPLORING FRAMEWORKS IN BENEFIT-RISK DECISION MAKING
Joyce Korvick, MD (20 minutes)
Deputy Director for Safety Division of Gastroenterology Products, Office of Drug Evaluation III, Center for Drug Evaluation and Research (CDER), FDA

CBER: BENEFIT-RISK ACTIVITIES
Mark Walderhaug, PhD (20 minutes)
Associate Director for Risk Assessment, Office of Biostatistics and Epidemiology, CBER, FDA

EXPERIENCE WITH CHMP BENEFIT-RISK TEMPLATE
Bruno Flamion, MD, PhD (20 minutes)
Chair, Scientific Advice Working Party (CHMP); Professor, Clinical Pharmacology, University of Namur, Belgium

GOALS AND PROGRESS OF THE PHRMA BENEFIT-RISK ASSESSMENT TEAM IN DEVELOPING A STRUCTURED FRAMEWORK FOR BENEFIT-RISK ASSESSMENT
Rebecca Noel, DrPH, MSPH (20 minutes)
Research Scientist, Global Patient Safety, Eli Lilly and Company

PANEL DISCUSSION AND QUESTION & ANSWER PERIOD (10 MINUTES)
12:00-12:45 PM  NETWORKING LUNCHEON

12:45-1:30 PM  SESSION 4

METHODS FOR VALUING RISKS AND BENEFITS

Session chairs
F. Reed Johnson
RTI Health Solutions, RTI International
Lawrence Phillips, PhD
Consultant to the European Medicines Agency (EMEA),
European Union; Visiting Professor of Operational Research,
London School of Economics, UK

Stated Choices Derived from Conjoint Analysis
F. Reed Johnson (15 minutes)
RTI Health Solutions, RTI International

Quality Adjusted Life Years (QALYs)
Lou Garrison, PhD (15 minutes)
Professor, Pharmaceutical Outcomes Research and Policy
Program, Department of Pharmacy, University of Washington

Values Derived from Multicriteria Decision Analysis Methods
Lawrence Phillips, PhD (15 minutes)
Consultant to the European Medicines Agency (EMEA),
European Union and London School of Economics, UK

1:30-3:20 PM  SESSION 5

CASE STUDIES OF BENEFIT-RISK ASSESSMENT

Session chairs
Rebecca Noel, DrPH, MSPH
Eli Lilly and Company
Paul Coplan, ScD, MBA
Wyeth; University of Pennsylvania School of Medicine

Applying Multicriteria Decision Analysis Methods in a Regulatory Body
Lawrence Phillips, PhD (15 minutes)
Consultant to the European Medicines Agency (EMEA),
European Union and London School of Economics, UK

Patient Preferences Using Natalizumab and Other Examples
F. Reed Johnson (15 minutes)
RTI Health Solutions, RTI International

Net Clinical Benefit Assessment Using Rivaroxaban
Bennett Levitan, MD, PhD (15 minutes)
Director, Quantitative Safety Research, Johnson & Johnson
Pharmaceutical Research & Development

Application of PhRMA BRAT (Benefit-Risk Action Team)
Framework to Three Examples
Bennett Levitan, MD, PhD
Director, Quantitative Safety Research, Johnson & Johnson
Pharmaceutical Research & Development
Elizabeth B. Andrews, PhD, MPH
Vice President, Pharmacoepidemiology and Risk Management,
RTI Health Solutions (20 minutes)

Incremental Net Benefit Case Studies
Larry Lynd, PhD (15 minutes)
Associate Professor, MSFHR Scholar, CIHR New Investigator,
University of British Columbia, Canada

3:20-3:35 PM  REFRESHMENT BREAK

3:35-4:05 PM  SESSION 6

THE PLACE OF MODELS FOR BENEFIT-RISK ASSESSMENT

Session chairs
Lou Garrison, PhD
University of Washington
Mark Walderhaug, PhD
Associate Director for Risk Assessment, Office of Biostatistics and
Epidemiology, CBER, FDA

Regulatory benefit-risk assessments require the consideration of
complex factors and data. Mathematical models provide a frame-
work to integrate this information into a consistent and transparent
format that is more explicit than expert or personal judgment. This
session will discuss the value, strengths, and weaknesses of models
as applied in the case studies of the benefit-risk assessments pre-
sented in the previous session and in other scientific disciplines.

Reinforcing Lessons Learned from Case Studies –
The Surprise Factor
Mark Walderhaug, PhD (15 minutes)
CBER, FDA

The Place of Models for Health Technology Assessment and Lessons for Benefit-Risk Assessment
Lou Garrison, PhD (15 minutes)
University of Washington

4:05-5:00 PM  SESSION 7

PANEL DISCUSSION

Session chairs
Bruno Flamion, MD, PhD
Chair, Scientific Advice Working Party (CHMP); Professor,
Clinical Pharmacology, University of Namur, Belgium
Filip Mussen, PhD
Vice President, Psychiatry and EU RED Regulatory Affairs,
Johnson & Johnson Pharmaceutical Research & Development

Regulators
John Jenkins, MD
Director, Office of New Drugs, CDER, FDA
Bruno Flamion, MD, PhD
Chair, Scientific Advice Working Party (CHMP); Professor,
Clinical Pharmacology, University of Namur, Belgium
Robyn Lim, PhD
Science Advisor, Progressive Licensing Project, Therapeutic
Products Directorate, Health Products and Food Branch, Health
Canada

Industry and Academia
Baruch Fischhoff, PhD
Howard Heinz University Professor, Department of Social
and Decision Sciences, Carnegie Mellon University;
Chair, FDA Risk Communication Advisory Committee
Societal acceptance of benefits and risks of a medical intervention is particularly important for preventative public health measures, such as routine childhood vaccinations as well as immunization as a strategy for pre-pandemic influenza preparedness. Individual therapeutic interventions also are subject to group decisions on what should be maximally tolerated risks and minimally accepted benefits.

Principles on public health trade-offs, the deliberative process, group-decision making, and how to balance individual and group health interests will be presented.

Deliberative Discourse Supplemented by Modeling
Lawrence Phillips, PhD (20 minutes)
Consultant to the European Medicines Agency (EMEA), European Union and London School of Economics, UK

Principles of Group Decision Making and Lessons Learned at Lilly
James Felli, PhD (20 minutes)
Research Fellow, Eli Lilly and Company

What is the Role of Ethics in Group Decisions on Benefit-Risk Assessments?
Margaret Somerville, AM, FRSC, DCL (20 minutes)
Founding Director, McGill Centre for Medicine, Ethics and Law and Samuel Gale Professor of Law, McGill University, Canada

Question & Answer Period (15 minutes)
UNCERTAINTY IN WEIGHT OF EVIDENCE ASSESSMENTS OF RISKS AND BENEFITS
Douglas L. Weed, MD, MPH, PhD (25 minutes)
Managing Member, DLW Consulting Services, LLC; Past Chief, Office of Preventive Oncology, National Cancer Institute, National Institutes of Health

VISUAL DISPLAY OF UNCERTAINTY
Richard A. Forshee, PhD, Robyn Lim, PhD, and Mark Walderhaugh (15 minutes)

Question and Answer Period (15 minutes)

10:55-11:15 AM
EMEA PROJECTS IN BENEFIT-RISK ASSESSMENT
Hans-Georg Eichler, MD, MSc
Senior Medical Officer, European Medicines Agency

11:15AM-12:05PM SESSION 11
INTERFACING BENEFIT-RISK ASSESSMENT WITH HEALTH TECHNOLOGY ASSESSMENT AND COMPARATIVE EFFECTIVENESS FOR THE PAYER’S PERSPECTIVE
SESSION CHAIR
Paul Coplan, ScD, MBA
Wyeth; University of Pennsylvania School of Medicine

This session will assess the interface between benefit-risk assessment and health technology assessment. Speakers will describe how payers use benefit-risk assessments produced by regulators and sponsors for regulatory decisions when payers conduct health technology assessments. The comparative effectiveness initiative sponsored by the US government will be described and the potential for synergy between benefit-risk assessment and the comparative effectiveness initiative will be discussed.

INTERFACE BETWEEN COMPARATIVE EFFECTIVENESS RESEARCH AND BENEFIT-RISK ASSESSMENT
Anne Trontell, MD, MPH (20 minutes)
Program Director, Centers for Education and Research on Therapeutics; Senior Advisor, Pharmaceutical Outcomes and Risk Management Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ)

HOW BENEFIT-RISK ASSESSMENT CAN BE USEFUL FOR HEALTH TECHNOLOGY ASSESSMENT IN CANADA
Sandy Pagotto (20 minutes)
Director, The Common Drug Review Program
The Canadian Agency for Drugs and Technologies in Health

Question and Answer Period (10 minutes)

2:15-3:15 PM SESSION 13
COMMUNICATING BENEFIT-RISK TO THE END USER – PATIENTS
SESSION CHAIRS
Wanju Dai, MD, DrPH, FISPE
Vice President and Head of Epidemiology
Global Pharmacovigilance
Louis Morris, PhD
President, Louis Morris and Associates; Former Director of DDMAC, FDA

Communicating risks to the patient requires knowledge of the audiences’ ability to understand, integrate, remember, make decisions, and follow through with behaviors to use a drug safely. It also requires a clear understanding of the purpose of the risk/benefit communication (eg, decision making, risk perception, recall of risk factors, behavioral compliance). This session will discuss new research into how to communicate benefits and risk to improve drug
safety. It will focus on: 1) new methods used to communicate benefit and risk and 2) neurocognitive insights into how the risk decision makers decode, integrate, remember and use the risk information to make informed decisions.

MODELS AND IMPLICATIONS OF PHARMACEUTICAL RISK COMMUNICATION: RESEARCH PERSPECTIVE
Louis Morris, PhD (20 minutes)
Louis Morris and Associates; Formerly DDMAC, FDA

EVALUATION OF PATIENT UNDERSTANDING OF RISKS AS COMMUNICATED IN MED GUIDES AND OTHER TOOLS
Mary Willy, PhD (15 minutes)
Senior Risk Management Analyst, Team Leader, Division of Risk Management, Office of Surveillance and Epidemiology, CDER, FDA

DISCUSSION OF BENEFIT-RISK COMMUNICATION FROM THE CONSUMER’S PERSPECTIVE
Art Levin, MPH (10 minutes)
Director, Center for Medical Consumers

QUESTION & ANSWER PERIOD (10 minutes)

3:15-3:30 PM REFRESHMENT BREAK

3:30-4:00 PM SESSION 14
OPEN FORUM FOR AUDIENCE COMMENTS AND INPUT
Session chairs
Joyce Korvick, MD
Paul Coplan, ScD, MBA

i. How to incorporate stakeholder values into benefit-risk assessments and group processes for explicit value-based decision making
ii. Approaches to integrating benefit-risk into the lifecycle of medicinal products
iii. How to improve the understanding and communication of benefit-risk balance

4:00-5:00 PM SESSION 15
PANEL DISCUSSION:
NEXT STEPS AND PRIORITIES GOING FORWARD
Session chairs
Joyce Korvick, MD
CDER, FDA
Paul Coplan, ScD, MBA
Wyeth; University of Pennsylvania School of Medicine

Panelists
Margaret Somerville, AM, FRSC, DCL
McGill University, Canada

Bruno Flamion, MD, PhD
CHMP; University of Namur, Belgium

Louis Morris, PhD
Louis Morris and Associates; Formerly DDMAC, FDA

Robert T. O’Neill, PhD
CDER, FDA

Robert Temple, MD
CDER, Office of Medical Policy, FDA

Frank W. Rockhold, PhD
GlaxoSmithKline; University of Pennsylvania and Penn State College of Medicine Department of Public Health Sciences

Lawrence Phillips, PhD
Consultant to the European Medicines Agency (EMEA), European Union and London School of Economics, UK

Robyn Lim, PhD
Scientific Advisor, Office of Legislative Regulatory Modernization, Health Products and Food Branch, Health Canada

5:00 PM CONFERENCE ADJOURNED

TRAVEL AND HOTEL
The most convenient airport is Reagan National Airport and attendees should make airline reservations as early as possible to ensure availability. The Hyatt Regency Bethesda is holding a block of rooms at the reduced rate below until October 12, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

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Assessing Benefits and Risks of Medicinal Products in Regulatory Decisions

Hyatt Regency Bethesda, Bethesda, MD, USA
November 3-5, 2009  Event ID #09027

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

CONTACT INFORMATION
Event information:
Contact Benjamin Zaitz at the DIA office by telephone +1-215-293-5803, fax +1-215-293-5937 or email Benjamin.Zaitz@diahome.org.

Travel and Hotel information:
See page 7 for complete details.

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US $1275

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TUTORIAL, NOVEMBER 3
9 am-5:00 pm
US $ 710

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Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

I cannot attend but please keep me informed of DIA’s future events. (requires completion of name, postal address and email address on this form)