

## Call to Order – Day 1

### JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

February 16-18, 2005, Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland.

DR. WOOD: Let's get started. For those of you who missed the memo, this is the committee to discuss the safety and efficacy of COX-2 inhibitors. It is worth perhaps just giving some thought to why we are here. We are here to evaluate the relative efficacy and risk of these drugs, and to decide whether the benefits from these drugs outweigh the risk, in contrast to whether the risks outweigh the benefits. It is probably also worth just saying what we are not here for. We are not here to delegate blame or revisit the past. We are here to look into the future and determine what we should do in the future. It is important I think for everybody to remember that as we move through the discussions. I guess the first thing to do is let people at this enormous table introduce themselves. Let's start down in this corner with John.

DR. JENKINS: Good morning. I am John Jenkins. I am Director of the Office of New Drugs in the Center for Drug Evaluation at FDA.

DR. O'NEILL: I am Bob O'Neill. I am the Director of the Office of Biostatistics in CDER.

DR. BULL: Good morning. I am Jonca Bull, the Director of the Office of Drug Evaluation V, in the Office of New Drugs.

DR. GALSON: I am Steven Galson, the Acting Director of CDER.

DR. TRONTELL: Anne Trontell, Deputy Director of the Office of Drug Safety.

DR. SHAFER: Steve Shafer. I am not the director of anything. I am a Professor of Anesthesia at Stanford and Biopharmaceutical Science at UCSF.

DR. HENNEKENS: Charlie Hennekens at the University of Miami School of Medicine and Florida Atlantic University.

DR. FRIEDMAN: Larry Friedman, from the National Heart, Lung and Blood Institute.

DR. PAGANINI: Emil Paganini, a nephrologist out of the Cleveland Clinic.

MS. SHAPIRO: Robyn Shapiro, I direct the Center for of Bioethics of the Medical College of Wisconsin. I am a Professor of Bioethics there and I chair the Health Law Practice Group at Michael, Best and Friedreich.

DR. CANNON: I am Richard Cannon. I am Clinical Director of the Division of Intramural Research, NHBLI, National Institutes of Health.

DR. MORRIS: Lou Morris, President, Lou Morris and Associates.

DR. D'AGOSTINO: Ralph D'Agostino, biostatistician from Boston University and the Framingham Study.

DR. ILOWITE: Norm Ilowite, Schneider Children's Hospital and Rheumatology at Albert Einstein College of Medicine.

MR. LEVIN: Arthur Levin, Director of the Center for Clinical Consumers and consumer representative on the Drug Safety Committee.

MS. MALONE: I am Leona Malone. I am a licensed clinical social worker and I am here as a patient representative for the Arthritis Committee, and I have struggled with rheumatoid arthritis and osteoarthritis for 35 years.

DR. BATHON: Joan Bathon, Johns Hopkins University, Department of Medicine, Division of Rheumatology.

DR. CUSH: I am Jack Cush. I am a rheumatologist from Presbyterian Hospital, Dallas.

DR. GIBOFSKY: Allan Gibofsky, Professor of Medicine and Public Health, Cornell University; Adjunct Professor of Law at Fordham University; and I am Chair of the Arthritis Advisory Committee.

MS. TOPPER: Kimberly Topper, with the FDA. I am the Executive Secretary for the Committee.

DR. GROSS: I am Peter Gross. I am Professor of Medicine and Community Health in New Jersey Medical School; Chair of Medicine, Hackensack

University Medical Center; and I chair the Drug Safety and Risk Management Advisory Committee.

DR. HOLMBOE: I am Eric Holmboe, Vice President for Evaluation Research at the American Board of Internal Medicine.

DR. FARRAR: I am John Farrar. I am a neurologist and epidemiologist at the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania.

DR. MANZI: I am Susan Manzi. I am a rheumatologist from the University of Pittsburgh Medical Center, and with an appointment in epidemiology at the Graduate School of Public Health.

DR. HOFFMAN: I am Gary Hoffman. I am Professor and Chairman of Rheumatic and Immunologic Diseases at the Cleveland Clinic.

DR. DWORKIN: Hi. I am Bob Dworkin. I am Professor of Anesthesiology and Neurology at the University of Rochester School of Medicine.

DR. BOULWARE: I am Dennis Boulware, Professor of Medicine, and rheumatologist at the University of Alabama at Birmingham, and member of the Arthritis Advisory Committee.

DR. DOMANSKI: I am Mike Domanski. I am a cardiologist. I head the Clinical Trials Group at the National Heart, Lung and Blood Institute.

DR. FLEMING: Thomas Fleming, Chair of Biostatistics, University of Washington.

DR. FURBERG: Curt Furberg, Professor of Public Health Sciences, Wake Forest University. I am a member of the Drug Safety and Risk Management Advisory Committee.

DR. DAY: Ruth Day, Duke University, Director of the Medical Cognition Lab, and a member of the Drug Safety Committee.

DR. PLATT: I am Richard Platt. I am Professor and Chair of the Harvard Medical School, Harvard Pilgrim Healthcare Department, Ambulatory Care and Prevention. I am principal investigator of one of the HHRQ centers for education and research in therapeutics. I am a member of the Drug Safety Committee.

DR. GARDNER: I am Jacqueline Gardner, University of Washington School of Pharmacy and Pharmaceutical Outcomes Research Program. I am on the Drug Safety and Risk Management Committee.

DR. ELASHOFF: Janet Elashoff, Biostatistics, Cedars-Sinai and UCLA.

DR. NISSEN: I am Steve Nissen. I am the Medical Director of Cleveland Clinic Cardiovascular Coordinating Center. I am a cardiologist, and I am the Chair of the Cardiorenal Advisory Panel for the FDA.

DR. ABRAMSON: Steve Abramson, I am Chairman of Rheumatology at NYU and the Hospital for Joint Diseases.

DR. CRYER: I am Byron Cryer. I am a gastroenterologist from the University of Texas Southwestern Medical School in

Dallas, and the Dallas VA Medical Center. My role here today is as an FDA consultant to this group and as a member of the Gastrointestinal Drugs Advisory Committee.

DR. STEMHAGEN: I am Annette Stenhagen. I am an epidemiologist with Covance and I am the industry representative to the Drug Safety and Risk Management Committee.

DR. WOOD: I am Alastair Wood. I am the Associate Dean at Vanderbilt and Professor of Medicine and Professor of Pharmacology.

DR. WOOD: Thanks a lot. Two additional people have joined the cast of thousands that we have at the table, and perhaps it would be worth having them introduce themselves. Bob, you go first.

DR. TEMPLE: I am Bob Temple. I am Director of the Office of Medical Policy.

DR. WOOD: Stephanie?

DR. CRAWFORD: Thank you, Mr. Chair. Stephanie Crawford--good morning--University of Illinois at Chicago, College of Pharmacy; member of the Drug Safety and Risk Management Advisory Committee.

DR. SELIGMAN: Good morning. This is Paul Seligman. I am the Director of the Office of Pharmacoepidemiology and Statistical Science.