

Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD
GERD – Template

Agenda for June 11, 2002

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| 8:00 | Call to Order, Introductions: | Joan P. Chesney, M.D., Chair |
| | Meeting Statement: | Thomas H. Perez, R.Ph., M.P.H., Executive Secretary |
| | Opening Comments: | Dianne Murphy, M.D. |
| 8:15 | Introduction to the PPI Written Request Template | Hugo Gallo-Torres, M.D. |
| 8:30 | Pathologic Pediatric GER & Clinical Trial Design:
differences in infants < 1 & > 1 year | Eric Hassall, M.D. |
| 8:45 | Clinical trial design related to studies of PPIs in the neonate
& premature infant | Mark Hudak, M.D. |
| 9:00 | Ethical issues of using randomized, placebo-controlled withdrawal
trial design in pediatrics | Benjamin Wilfond, M.D. |
| 9:15 | Open Public Hearing | |
| 9:45 | Break | |
| 10:00 | Introduction to Questions & Charge to the Subcommittee | Dr. Victor Raczkowski |
| 10:10 | Discussion of Questions | |
| 12:00 | Lunch | |
| 1:00 | Introduction: Preliminary Priority List of Drugs | Dr. Anne Willoughby |
| 1:05 | Background | Dr. Rosemary Roberts |
| 1:25 | Development of the Preliminary Priority List of Drugs | Dr. William Rodriguez |
| 1:35 | NIH's Role in the Development of the Priority List | Dr. Anne Willoughby |
| 1:45 | Discussion of Preliminary Priority List of Drugs | Dr. Dianne Murphy |
| 2:00 | Open Public Hearing | |
| 2:30 | Break | |
| 2:45 | Presentation of Questions and Goals for Discussion | Dr. Dianne Murphy |
| 3:00 | Discussion | |
| 4:30 | Update from Europe | Dr. Julia Dunne
Dr. Agnes St. Raymond |
| 5:00 | Rule and Exclusivity Update | Peds Team |
| 6:00 | Close | |

Consultants (Voting)

Patricia Chesney, M.D., Professor of Pediatrics, University of Tennessee College of Medicine

Robert Fink, M.D., Chairman, Department of Allergy and Pulmonary Medicine, Children's National Medical Center

Mark Hudak, M.D., Professor and Chief, Division of Neonatology, University of Florida at Jacksonville

Victor Santana, M.D., Associate Professor, Dept. of Hematology/Oncology, St. Jude's Children's Research Hospital

Naomi Luban, M.D., Vice Chairman, Department of Laboratory Medicine, Children's National Medical Center

David Danford, M.D., Associate Professor of Pediatrics, University Nebraska Medical Center

Richard Gorman, M.D., FAAP, Pediatrician, Pediatric Partners

George D. Ferry, M.D., Professor of Pediatrics, Texas Children's Hospital

Eric Hassall, MBChB FRCP C FRCG, Division of Gastroenterology, BC Children's Hospital

Robert Nelson, M.D., Ph.D., Associate Professor of Anesthesia & Pediatrics, The Children's Hospital of Philadelphia

Guests (Non-voting)

Benjamin Wilfond M.D., Bioethics Research Section, National Institutes of Health

Robert M. Ward, MD., Director, Pediatric Pharmacology Program, University of Utah

Harland Winter, MD., Director, Pediatric IBD Center, MassGeneral Hospital for Children

Ben Gold, M.D., Director, Division of Pediatric Gastroenterology & Nutrition, Emory University School Medicine

Lillian R. Blackmon, M.D. Clinical Associate Professor, Pediatrics, University of Maryland School of Medicine

Ralph E. Kauffman, M.D. Professor, Pediatric Pharmacology, Children's Mercy Hospital

Laura James, M.D., Professor, Clinical Pharmacology, Arkansas Children's Hospital

John T. Walkup, M.D., Professor Clinical Psychopharmacology, Johns Hopkins Hospital

Julia Dunne, M.D., National Expert seconded to the European Commission

Agnes Saint Raymond, M.D., Head of Sector Scientific Advice and Orphan Drugs, The European Agency for the Evaluation of Medicinal Products (EMA)

Guest Industry Representatives (Non-voting)

Steven Spielberg, M.D., Johnson & Johnson Pharmaceutical