

**Forum on Drug Discovery, Development, and Translation
Addressing the Barriers to Pediatric Drug Development**

**June 13, 2006
8:00 am–4:30 pm
The National Academies**

Workshop Agenda

- 7:30 am Breakfast
- 8:00 am Opening Remarks by Discussion Moderator
Michael Katz, MD
March of Dimes Birth Defects Foundation

8:10 am Current Development Procedures and Impact on Clinical Practice

- 8:10 am Richard Gorman, MD
American Academy of Pediatrics
- 8:25 am Wayne Snodgrass, MD, PhD
American Academy of Pediatrics Committee on Drugs
- 8:40 am Discussion

9:10 am Regulatory Perspective

- 9:10 am Lisa Mathis, MD
U.S. Food and Drug Administration
Historical and Regulatory Background
- 9:25 am William Rodriguez, PhD, MD
U.S. Food and Drug Administration
Relabeling of Existing Drugs
- 9:40 am Dianne Murphy, MD
U.S. Food and Drug Administration
Lessons Learned and Future Directions
- 9:55 am Discussion

10:25 am Break

10:40 am Incentives and Disincentives for Pediatric Drug Development

10:40 am Robert Nelson, MD, PhD
Children's Hospital of Philadelphia

Ethical Issues Concerning Testing of New Drugs in Children

10:55 am Natasha Jarrett
Hoffman-LaRoche

11:10 am Thomas Hassall, RPh, MS
Abbott Laboratories

11:25 am Discussion

12:00 pm Lunch

1:00 pm Dose Finding and Bioavailability Guessing

1:00 pm Robert Ward, MD
University of Utah

1:15 pm George Giacoia, MD
National Institute of Child Health and Human Development
National Institutes of Health, U.S. Department of Health and Human Services

Best Pharmaceuticals for Children Act: Pediatric Formulation Issues

1:30 pm Discussion

2:00 pm Could Vaccines Be a Possible Model for Pediatric Drug Development?

2:00 pm Walter Orenstein, MD
Vaccine Adverse Event Reporting System

2:15 pm Discussion

2:45 pm Break

3:00 pm Current Models and Alternative Approaches

3:00 pm Annic Weyersberg, MD
European Agency for the Evaluation of Medicinal Products

European Union Legislation

3:15 pm William Evans, PharmD
St. Jude Children's Research Hospital

*St. Jude's Approach to Addressing the Institute of Medicine Report
Making Better Drugs for Children with Cancer*

3:30 pm Discussion

4:00 pm	Identification of Actions
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4:00 pm Conclusions and Next Steps for the Institute of Medicine Drug Forum

4:30 pm Adjourn