DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 21, 2000

Dear Pediatric Subcommittee Ethics Session Speakers and Guests:

Enclosed please find the ethics background materials for the **September 11, 2000** meeting of the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee which will convene at 8:00 a.m. in the Haverford/Baccarat Ballroom of the Hyatt Hotel in Bethesda, Maryland. From 8:00 a.m. to 2:45 p.m. (with a lunch break from noon to 1:00 p.m.) we will be discussing the ethics of conducting placebo-controlled trials in children.

The following documents are included in this package:

- the Federal Register notice announcing the meeting;
- the draft Agenda (including case studies) for the day; and,
- a binder containing background materials from the Agency.

Please note that while the Subcommittee meeting is being held at the Hyatt Regency Hotel, we found it necessary to arrange for the meeting attendees to stay at the Holiday Inn Bethesda Hotel, a five (5) block walk away. We have arranged for shuttle bus service between the hotels if you choose not to walk. The shuttle bus will leave the Holiday Inn at approximately 7:30 a.m. on the morning of the 11th. If you wish to ride the shuttle, please meet at the front desk by 7:25 a.m. Also, if you are not staying over the night of the 11th, you will need to check out of the Holiday Inn that morning. If you bring your bags with you that morning to the Hyatt, we will arrange for storage of your bags.

Please do not hesitate to contact me if you have any general meeting questions. You should have already received meeting travel documents from this office. Questions specifically about travel can be directed to: Karen Graves. Our general telephone number is (301) 827-7001.

I look forward to a very interesting meeting.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Health Science Administrator/Executive Secretary
Advisors and Consultants Staff
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration
(301) 827-7001 (301) 827-6776 (FAX)

Enclosures

DMB

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 11, 2000, 8 a.m. to 5:30 p.m.

Location: Hyatt Regency, Baccarat/Haverford Rooms, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: at PETERSONJ@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 11, 2000, beginning at 8 a.m., the subcommittee will discuss ethical considerations in the conduct of placebo-controlled clinical trials in the pediatric population. Beginning at 3 p.m., the subcommittee will discuss the development of psychotropic drugs for use in young children.

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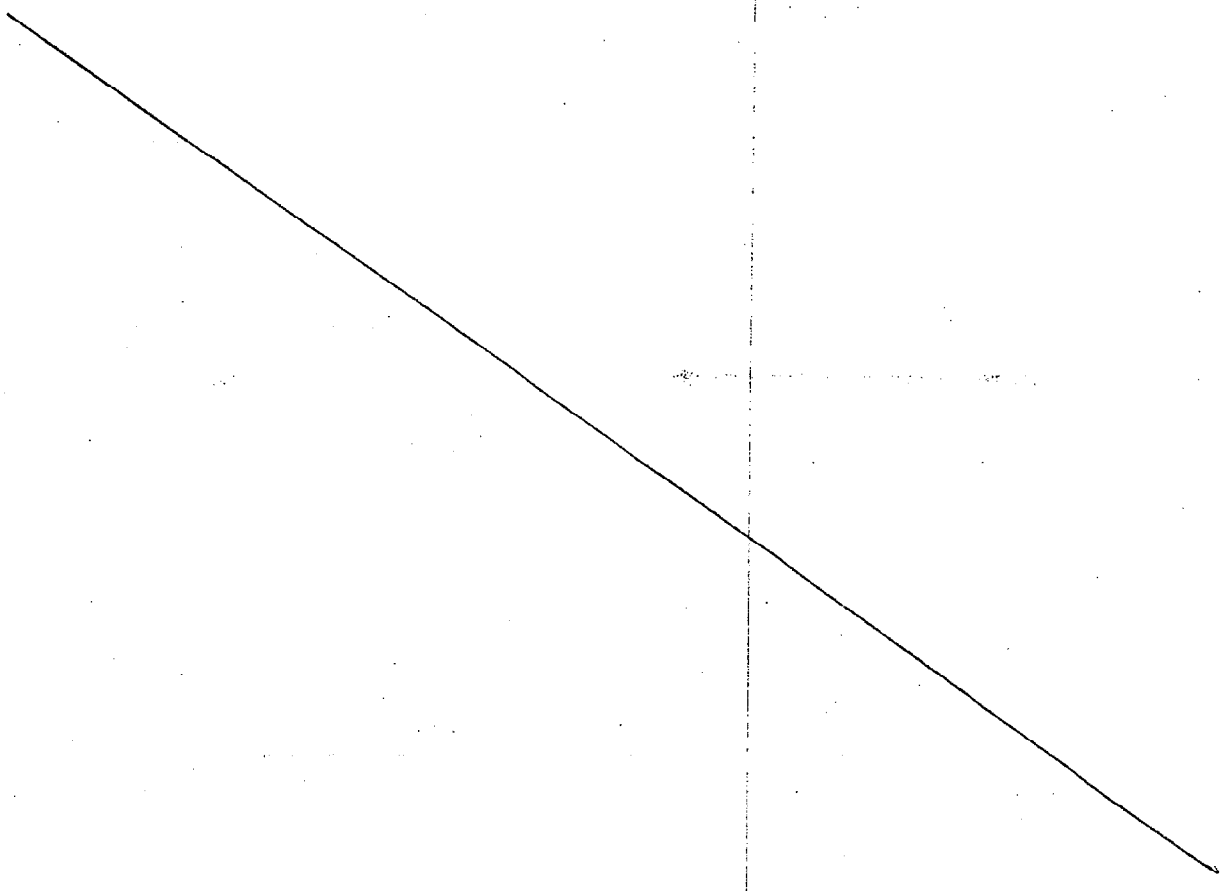
Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittee. Written submissions may be made to the contact person by September 5, 2000. On September 11, 2000, oral presentations from the public will be scheduled between approximately 8:15 and 8:45 a.m. and between approximately 3 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Pediatric Advisory Subcommittee

A Subcommittee of the Anti-Infective Drugs Advisory Committee
Food and Drug Administration
Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda,MD
September 11 and 12, 2000

DRAFT AGENDA
September 11, 2000

Morning Session - Ethical Issues

8:00 a.m. **Call to Order/Introductions**
P. Joan Chesney, M.D., Pediatric Advisory Subcommittee Chair

Conflict of Interest Statement
Jayne E. Peterson, R.Ph., J.D., Executive Secretary

8:05 a.m. **Welcome and Review of Meeting Agenda/ Background Information and Overview**

Dianne Murphy, M.D., Associate Director of Pediatrics, Center for Drug Evaluation and Research (CDER), FDA

8:15 a.m. **Presentations/Discussion:**
Part 1: The Ethics of Placebo-Controlled Clinical Trials in Children

Open Public Hearing
(**30 minutes allocated unless public participation does not last that long.)

8:45 a.m. **Overview of Placebo Control Trial Design: Benefits and Difficulties**
Robert Temple, M.D., Director, Office of Medical Policy, CDER

9:10 a.m. **International Perspective on Pediatric Placebo-Controlled Trials**
Dr. Barbara van Zwieten-Boot,
Efficacy Coordinator, Medicines Evaluation Branch

9:30 a.m. **Questions from the Subcommittee**

9:40 a.m. **Ethical Concerns in Pediatric Placebo-Controlled Trials**
Charles Weijer, M.D., Ph.D., Bioethicist and Asst. Prof. of Medicine, Dalhousie University

10:00 a.m. **Ethical Concerns in Pediatric Placebo-Controlled Trials from the European Experience**
Prof. Francis P. Crawley, Chairman, Ethics Working Party, European Forum for Good Clinical Practice & Member, Ethics Working Group, Confederation of European Specialists in Paediatrics

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10:20 a.m. **Questions from the Subcommittee**

10:30 a.m. **Break**

10:45 a.m. **Use of Drug Safety Monitoring Boards (DSMB) and their Role in Pediatric Clinical Trials**
Susan Ellenberg, Ph.D., Director, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), FDA

11:05 a.m. **Questions from the Subcommittee**

11:10 a.m. **Case Studies/Questions to the Committee**

A. Standard of Care plus placebo or investigational therapy
Assumptions are the following:
- The patient has the disease/condition
- The patient is receiving the standard of care therapy
- The disease/condition is stable but with exacerbations or inadequate control of sign/symptoms
- Examples to be given: seizures, asthma

Question: Is there a situation, population, disease/condition in which this type of placebo-controlled study would not be appropriate?

B. Placebo trial design where there is no approved therapy for the disease/condition in the pediatric population
Assumptions are the following:
- The patient has a chronic disease/condition and requires long term treatment
- Examples to be given: depression, hypertension

Question: Is there a situation, population, disease/condition in which this type of placebo-controlled study would not be appropriate?

C. Placebo trial design with withdrawal phase
Assumptions are the following:
- The patient has a chronic disease/condition and requires long term treatment
- There are limited therapeutic options available
- Examples to be given: hypertension, asthma

Question: In what situations, population, disease/condition is this type of placebo-controlled study appropriate? In what situations, population, disease/condition is this type of placebo-controlled study not appropriate?

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12:00 p.m. **Lunch**

1:00 p.m. **Subcommittee Discussion of Ethics Case Studies**

2:45 p.m. **Break**

Afternoon Session – Pediatric Psychotropic Drug Use Issues

3:00 p.m. **Part 2: A Proposed Approach to the Development of Psychotropic Drug Therapies for Pediatrics**
Introduction
Dianne Murphy, M.D.

3:05 p.m. **Open Public Hearing**
(**30 minutes allocated unless public participation does not last that long.)

3:35 p.m. **Current Regulatory Issues in Pediatric Psychopharmacology**
Thomas Laughren, M.D., Acting Deputy Director, Neuropharmacological Drug Products, CDER, FDA

3:50 p.m. **Pediatric Psychopharmacology: A Clinical Perspective**
Richard Malone, M.D., Eastern Pennsyl. Psychiatric Institute, Philadelphia, PA

4:05 p.m. **Pediatric Psychopharmacology: A Research Perspective**
Mark Riddle, M.D., Johns Hopkins Medical Institutions, Baltimore, MD

4:20 p.m. **NIMH Perspective on Pediatric Psychopharmacology**
Benedetto Vitiello, M.D., Chief, CATPIRB, DISR, NIMH

4:35 p.m. **Subcommittee Discussion of Questions/Issues**

5:25 p.m. **Closing Remarks**
Dianne Murphy, M.D.

5:30 p.m. **Adjourn**

Recommended references for the meeting of the:

Pediatric Subcommittee
of the Anti-Infective Drugs Advisory Committee

Ethics Session, September 11, 2000
8:00 a.m. – 2:45 p.m.

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