

PAXIL ADVISORY BOARD MEETING
A PROPOSAL FOR ONE PSYCHIATRIST ADVISORY BOARD MEETING

Program Date: November 5-7, 1993

Proposed to:

Bonnie Rossello
SmithKline Beecham

Proposed by:

John A. Romankiewicz, PharmD
Scientific Therapeutics Information, Inc

Revised
October 1, 1993

WB 085320

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PURPOSE

The purpose of this proposal is to outline a description, services, timing, and costs for organizing and running one psychiatrist advisory board meeting with members of the PAXIL Advisory Board. The first meeting will be held from November 5-7, 1993 in Palm Beach Florida.

The purpose of the Advisory Board Meeting is to assemble the members of the PAXIL Advisory Board to provide an exchange of scientific and marketing information regarding PAXIL and related topics. Comments on the information concerning quality, application, and practical suggestions on the best vehicle for distribution, will be solicited. In addition, helpful ideas and advice on issues faced by the PAXIL Marketing Team will be sought.

The information obtained at these meetings will be recorded in a report that will highlight key points and will serve as a reference source for future use.

COST SUMMARY

●	Developmental fees, attendance time, estimated travel expenses for STI.	\$37,400
●	Meeting with Chairman, October 11	\$2,800
●	Slide development, estimated	\$13,000
●	Advisory Board airfares, estimated	\$40,000
●	Meeting Report	\$12,500
●	Background paper preparation: 4 topics	\$12,000
	TOTAL:	<u>\$117,700</u>

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DESCRIPTION

A description of the key components of the Advisory Board Meeting include:

1. The meeting will be held over a three-day period. Day I will be a travel day with a dinner reception held in the evening. Day II and Day III will each have a half-day session held in the morning, concluding with lunch. Departure will be scheduled for the afternoon of Day III.
2. The meeting program will consist of a combination of lectures and discussions. Ample opportunity will be provided for discussion of concepts, new research, and new areas of direction for PAXIL.
3. Selected Advisory Board members may be asked to prepare a presentation relevant to the specific meeting.
4. Each meeting will be a closed meeting. The audience will consist of the Advisory Board members (up to 15), individuals from SmithKline Beecham, and two editors from STI.
5. Each Advisory Board member will receive an honorarium.

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AGENDA AND FACULTY

A formal agenda for each meeting will be prepared in advance of each meeting after consultation with SmithKline Beecham. The agenda included below is a sample agenda for the 1993 Advisory Board Meeting. Topics are included without faculty. Briefings on the data available with PAXIL and issues that SmithKline Beecham wants to address are necessary. This agenda will be completed after consultation with the sponsor.

SMITHKLINE BEECHAM PSYCHIATRIST ADVISORY BOARD MEETING**November 5 - 7, 1993****Ritz Carlton Hotel
Palm Beach, Florida****Friday, November 5**

Afternoon Arrival and Hotel Check-in

7:00 PM Cocktail Reception

8:00 PM Dinner
 Welcoming Remarks by
 David Brand, Vice President,
 SmithKline Beecham

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AGENDA AND FACULTY (continued)

Saturday, November 6

- 7:00 AM Breakfast
- 8:00 AM Agenda and Objectives
Charles B. Nemeroff, MD, PhD, Chairman
- Strengthen Paxil profile
 - Identify competitor deficits/strengths
 - Evaluate clinical research/promotional programs
 - Generate information for use in promotion/education
 - Strategize to reach primary care physicians
- 8:10 AM Overview of Paxil Market Experience and Success
Bonnie Rossello, Paxil Senior Product Manager, SmithKline Beecham
- 8:30 AM Comparison of Paxil with Marketed and Investigational SSRIs
Jerrold F. Rosenbaum, MD (suggested)
- Pharmacology
 - Pharmacokinetics
 - Indications/efficacy
 - Adverse effects
- 9:00 AM Advisory Board Reaction and Comment
Charles B. Nemeroff, MD, PhD, Chairman, Moderating
- Comments
 - Controversies
 - Summarize strengths/weaknesses of all agents
- 9:30 AM Coffee Break

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AGENDA AND FACULTY (continued)

Saturday, November 6 (continued)

- 10:00 AM Review of Paxil Clinical Research Program
 David E. Wheadon, MD, Vice President,
 SmithKline Beecham
- Recently completed studies
 - Ongoing studies
 - Future studies
- 11:00 AM Advisory Board Reaction and Comment
 Charles B. Nemeroff, MD, PhD, Chairman, Moderating
- Assessment of research program
 - Suggestions for use of data
 - Recommendations for future studies, indications
- 11:30 AM Review of Paxil Promotion
 Brian Lortie, Paxil Product Manager,
 SmithKline Beecham
- Overview of Paxil promotional program
 - Compare/contrast with competitors' promotional efforts
- 12:00 PM Advisory Board Reaction and Comment
 Charles B. Nemeroff, MD, PhD, Chairman, Moderating
- Assessment of promotional program - by psychiatrists versus primary care physicians
 - Assessment of competitors' promotion
 - Suggestions for additional programs/future directions
- 12:30 PM Luncheon

AGENDA AND FACULTY (continued)

Sunday, November 7 (continued)

- Workshop 3 Reaching the Primary Care Physician
Facilitated by *Psychiatrist with knowledge of
primary care and presentation of depression in
this setting
Goals: Generate recommendations for educating
primary care physicians about depression,
appropriate treatment, and use of Paxil
- 8:00 AM Workshop 1: Paxil versus Competitors (Group A)
Workshop 2: Profile of Paxil Patients (Group B)
- 9:15 AM Break
- 9:30 AM Workshop 3: Reaching the Primary Care Physician (Group A)
Workshop 1: Paxil versus Competitors (Group B)
- 10:45 AM Break
- 11:00 AM Workshop 2: Profile of Paxil Patients (Group A)
Workshop 3: Reaching the Primary Care Physician (Group B)
- 12:15 PM Luncheon
- 1:30 AM Departure for all

* For these sessions, STI in conjunction with SmithKline Beecham and the Moderator will develop a series of questions on key issues with PAXIL that are aimed at acquiring information.

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ADVISORY BOARD MEMBERS***ADVISORY BOARD OF PSYCHIATRISTS**

(confirmed as of September 29, 1993)

James C. Ballenger, MD
 Chairman, Dept of Psychiatry
 Director, Institute of
 Psychiatry
 Medical University of South
 Carolina
 Charleston, SC 29425

John G. Csernansky, MD
 Gregory B. Couch Associate
 Professor
 Department of Psychiatry
 Washington University Medical
 School
 St. Louis, MO 63110

Joseph Deltito, MD
 Director, Anxiety and
 Mood Disorders Program
 Assoc Professor of Clinical
 Psychiatry
 New York Hospital
 Cornell Medical Center
 White Plains, NY 10605

David L. Dunner, MD
 Professor and Vice Chairman
 for Clinical Services
 Dept of Psychiatry and
 Behavioral Sciences
 University of Washington
 Seattle, WA 98105

Robert Hirschfeld, MD ✓
 Chairman
 Dept of Psychiatry and
 Behavioral Sciences
 University of Texas -
 Medical Branch
 Galveston, TX 77555

Charles B. Nemeroff, MD, PhD
 Professor and Chairman
 Dept of Psychiatry and
 Behavioral Sciences
 Emory University School of Medicine
 Atlanta, GA 30322

Charles F. Reynolds, III, MD
 Director, Sleep Evaluation Center
 Professor of Psychology
 and Neurology
 Western Psychiatric Institute
 and Clinic
 Pittsburgh, PA 15213

Jerrold F. Rosenbaum, MD
 Associate Professor of Psychiatry
 Harvard Medical School
 Chief, Clinical
 Psychopharmacotherapy Unit
 Massachusetts General Hospital
 Boston, MA 02114

Steven Schleifer, MD
 Professor and Chairman
 Dept of Psychiatry
 UMDNJ
 Newark, NJ 07103

David V. Sheehan, MD
 Professor of Psychiatry
 Director, Clinical Research
 University of South Florida
 Psychiatry Center
 Tampa, FL 36613

* Additional Advisory Board Members are being recruited.

SERVICES

The services and costs for this Advisory Board meeting assume that SmithKline Beecham will provide all logistical arrangements. STI will provide program design and content, editorial development, and faculty liaison services.

STI Editorial Services

STI will work in conjunction with SmithKline Beecham to provide the following:

- Identify and develop program content/agenda.
- Identify and recruit Advisory Board Members
- Research and prepare background material for mailing to Advisory Board prior to meeting.
- Provide slide services as needed for presenters.

MEETING EDITORIAL COSTS

Our costs are based on program development work, editorial activity, writing, proofreading, correspondence (usually express mail) with Advisory Board members, SmithKline Beecham and others as needed to insure a high quality, credible, and useful program for SmithKline Beecham and Advisory Board members. Costs are as follows:

<u>Editorial Development:</u>	Liaison with board members including recruitment and travel arrangements of board members and SmithKline Beecham, content outline development, preparation of moderator for meeting, authoring one presentation (Rosenbaum) and discussion questions (fee).	COST:	\$30,000
<u>STI Airfare Expenses:</u>	Two STI editors (coach).	COST:	\$2,000†
<u>Per Diem Expenses:</u>	Two STI editors: 3 days each.	COST:	\$1,500
<u>STI Meeting Attendance and Travel Time:</u>	Two editors onsite, plus travel time (fee). Assumes three days.	COST:	\$3,900
<u>Consulting Fee:</u>	Up to 20 Advisory Board members as follows: Chairman - \$5,000; 3 presenters/moderators @ \$4,000 each; 16 (estimated) @ \$2,500 each.		(SB TO PAY)
<u>Slide Development</u>	STI will work with the faculty to develop high quality and professional presentation slides. Our costs for slides are \$130.00 per slide if we have 2 weeks or more to work with and \$170.00 if we have less than two weeks to work. We estimate 100 slides for this program.	COST:	\$13,000*

† Pass through cost

* STI will bill for the actual number of slides developed.

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MEETING EDITORIAL COSTS (continued)

<u>Meeting with Chairman:</u>	One visit with Chairman in Atlanta on October 11, 1993. Two editors @ \$650 each (fee) plus travel expenses estimated at \$1,500 (air and ground transport)	COST:	\$2,800
<u>Board Travel Expenses:</u>	First Class air travel for 20 Advisory Board Members.	COST:	\$40,000†
	TOTAL (Editorial development costs):		<u>\$93,200</u>

† Pass through cost.

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MEETING REPORT

STI will transcribe the audiotapes (meeting plus one of each workshop) and provide a synopsis of the key points from the meeting. The report will be issued within one month of the meeting. We estimate the report to be up to 50 doublespaced typewritten pages. An executive summary will be included.

COSTS: \$12,500

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BACKGROUND PAPERS

Purpose: We propose to develop succinct background papers that will provide a literature based review of the facts regarding issues associated with Paxil. These papers will outline the information needed to come to a consensus on the specific issues that will be discussed in the workshops.

Description:

Each background paper will be up to 10 typewritten, double spaced pages in length and will include pertinent references. A statement of the issue will initiate the paper with a detailed analysis of data supporting or refuting the issue to follow. Background papers will be developed on the following topics:

1. P450 and drug interactions with SSRIs
2. Identification of patient types for Paxil therapy
3. Dose titration needs with SSRIs
4. Sedation and SSRIs

Costs: The costs associated with development of these background papers include literature research, technical writing and editing, client review and comments, preparation of two drafts, timing (one month), word processing, copy editing and proofreading, distribution to advisory board members in advance of meeting, and management needed to develop these background papers on a timely schedule.

COST (per paper):	\$3,500
COST (4 papers):	\$12,000*

* A discount is provided for development of all four developed simultaneously because we can take advantage of economies of scale.

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PAYMENT SCHEDULE

To be invoiced immediately	\$58,850
To be invoiced upon completion of the meeting November 4-5, 1993	<u>\$58,850</u>
	\$117,700

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