# 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

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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
8	Background paper preparation: 4 topics	\$12,000

TOTAL: \$117,700

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

- 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.
- 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.

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

# 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

### 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

# Saturday, November 6 (continued)

Open Forum: Long-Term Outlook for Depression Treatment 1:30 PM Charles B. Nemeroff, MD, PhD, Chairman

- Unmet needs in therapy
- Impact of health care reform
- Role of psychiatrists, primary care physicians
- What is industry involvement?
- Future treatment of depression

2:15 PM Adjourn

2:30 PM Afternoon at leisure

7:00 PM Cocktails

8:00 PM Dinner

# Sunday, November 7

Breakfast 7:00 AM

Breakout into Workshops 8:00 AM

Workshop 1 Paxil versus Competitors

Facilitated by Charles B. Nemeroff, MD, PhD Goals: Differentiate Paxil from competitors on

basis of P450, dose titration, sedation,

activation, weight loss/gain, sexual dysfunction

Workshop 2 Profile of Paxil Patients

Facilitated by James C. Ballenger, MD Goals: Identify 4 or 5 patient subtypes

suitable for treatment with Paxil

### 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 Workshop 1: Paxil versus Competitors (Group A) 8:00 AM Workshop 2: Profile of Paxil Patients (Group B) 9:15 AM Break Workshop 3: Reaching the Primary Care Physician (Group A) Workshop 1: Paxil versus Competitors (Group B) 9:30 AM 10:45 AM Break Workshop 2: Profile of Paxil Patients (Group A) 11:00 AM Workshop 3: Reaching the Primary Care Physician (Group B) Luncheon 12:15 PM Departure for all 1:30 AM

<sup>\*</sup> 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.

#### 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

<sup>\*</sup> Additional Advisory Board Members are being recruited.

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.

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:

Editorial Development:	Liaison with board members including travel arrangements of board members Beecham, content outline development moderator for meeting, authoring one (Rosenbaum) and discussion questions	s and Smith t, preparat e presentat	Kline ion of					
		COST:	\$30,000					
STI Airfare Expenses:	Two STI editors (coach).	COST:	\$2,000†					
Per Diem Expenses:	Two STI editors: 3 days each.	COST:	\$1,500					
STI Meeting	Two editors onsite, plus travel time (fee).							
Attendance and Travel Time:	Assumes three days.	COST:	\$3,900					
Consulting Fee:	Up to 20 Advisory Board members as Chairman - \$5,000; 3 presenters/mod @ \$4,000 each; 16 (estimated) @ \$2,	erators 500 each.	B TO PAY)					
<u>Slide</u> <u>Development</u>	STI will work with the faculty to d quality and professional presentati costs for slides are \$130.00 per sl weeks or more to work with and \$170 than two weeks to work. We estimat this program.	on slides. ide if we l .00 if we l	Our nave 2 nave less					
	F3	COST:	\$13,000*					

t Pass through cost

<sup>\*</sup> STI will bill for the actual number of slides developed.

# MEETING EDITORIAL COSTS (continued)

Meeting with

Chairman:

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

Board Travel Expenses:

First Class air travel for 20 Advisory Board

Members.

COST:

\$40,000†

TOTAL (Editorial development costs):

\$93,200

t Pass through cost.

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

#### 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:

- P450 and drug interactions with SSRIs
- 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\*

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

# PAYMENT SCHEDULE

To be invoiced immediately \$58,850

To be invoiced upon completion of the meeting

November 4-5, 1993 \$58,850

\$117,700

