

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510-6200

February 24, 2009

Via Electronic Transmission

The Honorable Daniel R. Levinson
Inspector General
Department of Health and Human Services
Office of Inspector General
330 Independence Ave, SW
Washington, DC 20201

Dear Inspector General Levinson:

The United States Senate Committee on Finance (Committee) has jurisdiction over, among other things, the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under those programs. In this capacity, I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the National Institutes of Health (NIH/Agency). Specifically I am committed to ensuring that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the public funding provided for medical studies. This research often forms the basis for action taken by the Medicare and Medicaid programs.

Over the last year, I have been investigating the lack of oversight regarding the almost \$24 billion that the NIH spends annually for extramural grants. I have found that NIH provides very little oversight to ensure that conflicts of interest are adequately reported and/or managed by institutions receiving these grants.

My inquiry revealed several problems at Emory University (Emory) concerning Dr. Charles Nemeroff, chair of the department of psychiatry. A number of those concerns are outlined below.

1. Possible Violation of NIH Conflict of Interest Rules

My concerns regarding Dr. Charles Nemeroff were outlined in two letters that I sent to Emory^[1]. In those letters, I noted that that Dr. Nemeroff may have violated NIH conflict of interest (COI) rules for several Agency grants. In fact, Emory's own COI Committee concluded in 2004 that Dr. Nemeroff failed to disclose his potential financial

^[1] Letters to James Wagner, President of Emory University, dated September 16, 2008 and October 2, 2008.

conflicts of interest in his Annual Disclosure Form for 2002-2003.^[2] Under current regulations, Emory is required to report conflict of interests to the NIH. But I have learned from the NIH that it was generally not aware of Dr. Nemeroff's conflicts until I made the issue public last fall.

2. Possible Violations of IRB Protocols, and Failure to Report IRB violations to the Office of Human Subject Research Protection (OHRP)

According to publically available documents, Emory's COI Committee concluded in 2004 that Dr. Nemeroff failed to report his conflicts of interest on his Institutional Review Board (IRB) forms.^[3] When my staff contacted the Office of Human Research Protection (OHRP), they explained that Emory never notified them of these violations of IRB policies.

3. Possible Violations of Federal Contracting Rules regarding Commitment of Time for NIH grants

Dr. Nemeroff has been the primary investigator for several NIH grants from which he has been paid a portion of his annual salary in return for committing a percentage of his professional time to the NIH effort. However, I do not understand how Dr. Nemeroff could have complied with his commitments to these federal grants while, at the same time, spending hundreds of days on the road giving promotional talks for, among others, drug companies. Accordingly, I would appreciate a review of, among other things, Dr. Nemeroff's NIH grants, Emory's employment policies, as well any information on the promotional talks that Dr. Nemeroff gave to third parties. In particular, I am seeking an assurance that NIH received the time and efforts expected under each NIH grant involving Dr. Nemeroff.

4. Possible Misleading Information Provided to the NIH

In a December 5, 2008 letter to me, Emory stated that Dr. Nemeroff's talks for GlaxoSmithKline were "focused on substantive medical educational topics such as depression and bipolar disorder and were not product specific or promotional." In response, I asked GSK to clarify the nature of the information that I made public on September 16, 2008, regarding Dr. Nemeroff's promotional talks for its drugs. GSK responded that the public document "contained information for product talks." Other activities such as National Advisory Board meetings were also identified, but GSK did not identify Dr. Nemeroff's promotional talks as "substantive" or "focused on medical education." Indeed, Emory and Dr. Nemeroff have continued to maintain that these talks by Dr. Nemeroff were educational in nature and "CME-like."

^[2] Internal Emory documents related to the Senate Finance Committee investigation were made public at a Finance Committee hearing on September 16, 2008. The documents can be found online at: <http://finance.senate.gov/sitepages/hearing091608.htm>

^[3] Confidential Memo to Dr. Charles B. Nemeroff, MD, PhD, from Conflict of Interest Committee, dated June 24, 2004.

Furthermore, according to GSK documents made public last December, Dr. Nemeroff was involved in a GSK program called PsychNet. GSK created this program of trained doctors to “help build Paxil advocacy.” It is my understanding that each doctor involved in PsychNet signed a confidentiality agreement; agreeing not to disclose or share information about PsychNet including compensation levels or copies of the materials provided to them by GSK. GSK noted further that PsychNet doctors were “educated on the positive data for Paxil in depression, social anxiety disorder, OCD and panic disorder.” The guest speaker who trained PsychNet doctors in Paxil advocacy was Dr. Charles Nemeroff. I have attached a copy of the PsychNet program to this letter for your review and consideration.

Finally, I would like to request that the OIG conduct a further accounting of this issue to ensure that Emory did not, either directly or indirectly, mislead the NIH about the nature of Dr. Nemeroff’s promotional talks for GSK and advocacy on behalf of Paxil.

In closing, I am requesting that your office examine the allegations set forth in this letter. I request further that my staff be briefed as to your findings upon completion of the review. Thank you for your attention to this important matter. Should you have any questions regarding this request, please contact me, or your staff may call Paul Thacker of my staff at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

cc: Raynard Kington, M.D., PhD.
Acting Director
National Institutes of Health

Attachment



PSYCHnet

PAXIL® CLINICIANS SPEAKER COUNCIL

Program Workbook

MARCH 10-12, 2000

The Registry Resort • Naples, Florida



Program Workbook

March 10-12, 2000
Naples, Florida

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Design/Art Direction by Jon A. Bjornson

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Consultant Resource Manual



Introduction

*This booklet is provided to you as a guide to help plan PsychNet programs in your region. **PsychNet: Paxil® Clinicians Speaker Council** provides trained physician speakers for programs in each region. PsychNet is a new resource for all consultants to use for dinner programs, round tables or any speaker engagement (excluding CME such as CD Rounds: Hidden Diagnosis). PsychNet physicians have all been educated on the benefits of Paxil® (paroxetine HCl) and its effective treatment on mood and anxiety disorders.*

Purpose

PsychNet: Paxil® Clinicians Speaker Council is one of many physician programs the Paxil team has developed for 2000 to engender solid relationships with influential physicians in each region. The goals of the program are to:

- Develop and/or solidify relationships with key influential psychiatrists and primary care physicians*
- Develop these physicians into knowledgeable and engaging speakers on Paxil and its effective treatment on mood and anxiety disorders*
- Build advocacy amongst PsychNet physicians by creating speaking opportunities*

PsychNet is an ideal way for key opinion leaders to influence clinicians in your region on the benefits of Paxil versus competitors.

PsychNet Speakers – Selection and Training

Each region selected several physicians who are influential in their communities, credible and interested in speaking on behalf of Paxil. Specifically, the physicians met the following criteria:

- Local key opinion leaders*
- Educated on the benefits of Paxil*
- Strong communication skills*

A list of regional speakers can be found at the back of this booklet



Each physician was invited to a weekend training session and educated on the efficacy of *Paxil* and the PsychNet presentations. The PsychNet Advisory Board reviewed all of the presentations and were closely involved with the training process.

The PsychNet Advisory Board includes:

Daniel D. Christensen, MD, *Clinical Professor of Psychiatry, Clinical Professor of Neurology, Adjunct Professor of Pharmacology, Neuropsychiatric Institute, University of Utah*

Prakash S. Masand, MD, *Professor of Psychiatry, Director, Psychopharmacology Consultation, Training, and Research Program, SUNY Upstate Medical University*

Peter J. Panzarino, MD, *Chairman, Department of Psychiatry, Cedars-Sinai Medical Center*

David V. Sheehan, MD, MBA, *Professor of Psychiatry, University of South Florida College of Medicine, Director, Clinical Research*

Guest Speakers at Training Session:

Charles Nemeroff, MD, PhD, *Reunette W. Harris Professor and Chairman, Department of Psychiatry and Behavioral Sciences, Emory University School of Medicine*

Rajinder Kumar, MD, *Vice President and Director Neurosciences Clinical Research, Development and Medical Affairs of North America, SmithKline Beecham Pharmaceuticals*

PsychNet Presentations and Slide Kits

Each PsychNet speaker has been trained on a total of 5 presentations. The PsychNet speaker has been provided with 35 MM slides and CD-ROMs with the following five Power Point presentations:

- **Contemporary Issues in Depression** – *Discusses major depression, SSRI treatment, the efficacy of Paxil in treating depression versus other SSRI/SNRIs, and briefly discusses the serotonin/norepinephrine dual action effect of Paxil.*
- **Contemporary Issues in Anxiety Spectrum Disorders** – *Reviews the prevalence of anxiety spectrum disorders, current treatment options and the efficacy of Paxil to treat anxiety.*

-
- **Antidepressants and Managed Care: Issues and Solutions** – *Discusses the efficacy of Paxil in treating mood and anxiety disorders and the importance of treating these disorders and reviews the cost of treatment of SSRIs.*
 - **The Role of Norepinephrine in Depression** – *A high science presentation that identifies the theory of NET and 5-HT neurotransmitters, reviews the roles of each, and discusses the potential norepinephrine effect of Paxil at higher dosages.*
 - **Controversial Issues in SSRI Therapy: A Critical Review** – *Highlights the importance of understanding clinical data and looks at issues that affect all SSRIs such as weight gain, sexual dysfunction, drug interaction and discontinuation.*

PsychNet speaker slide kits also have a Q&A section. This section contains additional data on PTSD, GAD, and PMDD and on special populations (i.e., elderly, adolescent). These should not be incorporated into a promotional *Paxil* PsychNet talk. The speakers have been informed that in accordance with FDA regulations, these slides are only to be used in response to a specific question during the Q&A period of the talk.

Each of your RMAs and PsychNet Regional Contacts have copies of the slide kit presentations. They will not be available for consultants to order on Powerline.

Compensation and Payment

For every PsychNet presentation, the PsychNet physician will be paid an enhanced honorarium of \$2500. If the PsychNet speaker gives more than one presentation in a day, the PsychNet speaker will be paid \$1000 for each successive presentation delivered in that day.

Your health care education budget will be charged the customary \$750 (the average cost of a physician speaker honorarium) for that physician and the supplemental honorarium of \$1750 will be charged against the marketing budget allotted to your region budget for PsychNet. For a secondary \$1000 PsychNet presentation, \$500 will be charged to your health care education budget and \$500 will be charged to the regional PsychNet budget.



To ensure that your PsychNet physician gets paid properly and in a timely fashion, you must:

- Write "PsychNet Presentation" in the "NOTES" section of your speaker request form and indicate \$2500 for the honorarium.
- Send in your Speaker Request form as quickly as possible, no later than 30 days prior to the speaking engagement.
- Work with the physician to ensure that he/she submits his/her expense form as quickly as possible after the speaking engagement.

Management of this process will be quicker and easier once the Regional Meeting Planners have been established.

How PsychNet Works:

- There are a total of 65 PsychNet speakers available to speak at engagements nationwide.
- Each speaker has agreed to do a minimum of 4 and no more than 15 talks per year. A final number of talks depends on scheduling and SB's regional need.
- PsychNet speakers have signed a confidentiality agreement to not disclose or share information about the PsychNet program, including compensation and content of materials.
- Speakers will be available to begin speaking engagements after the March 10-12 training meeting.
- Each region has a limited number of PsychNet talks that will be managed by the RBA or someone designated by your RVP. This person will notify all Paxil consultants in the region if the number of PsychNet talks has been or is close to being completely utilized. (Consult your PsychNet Regional Contact to confirm who will manage the PsychNet budget and number of talks in your region.)

NOTE: Once Regional Meeting Planners (RMPs) have been established and set up in your region, they will be in charge of managing the number of PsychNet talks that are available. It is important to consult with them as they have the information on how many talks the region can support financially.

The Process: How to Begin

1. The consultant should notify his/her PsychNet Regional Contact that he/she is interested in using a PsychNet speaker and make sure that the region is able to support the PsychNet engagement.
2. The consultant should contact the selected speakers to confirm a date for the presentation.
3. Before the program, the consultant and speaker discuss the objectives of the program and select the appropriate presentation.
4. The consultant should provide the PsychNet Regional Contact with the name of the PsychNet speaker and date of the presentation. Copies of the physician's Curriculum Vitae and hotel/travel and food preferences will be available for your review from the PsychNet Regional Contact.

NOTE: The Regional Meeting Planners will have this responsibility once they are established for the region.

5. The consultant or RMP will coordinate all travel and accommodations for the speaker, arrange the location and manage the invitation process.
6. After the program, the consultant should provide feedback to the Regional Contact on each program.

Questions and Answers

1. One of my PsychNet doctors also gives Hidden Diagnosis talks. Does he receive a \$2500 honorarium for a Hidden Diagnosis talk?
No. PsychNet physicians only receive \$2500 for a PsychNet speaking engagement: a promotional *Paxil* talk based on one of the PsychNet presentations. It is against CME regulations for SmithKline Beecham or any pharmaceutical company to enhance the honorarium for any CME-related talk. In addition, it is important to realize that the PsychNet honorarium payment is based on the speaker delivering a promotional *Paxil* presentation, which CME should not be.
2. Does \$2500 include travel and dinner expenses?
No. As with normal speaker engagements, speaker travel and dinner expenses come from your health education and/or field funds.



3. Do I have to use only the PsychNet speakers from my region or can I use PsychNet speakers in other regions?

You can use PsychNet speakers from any region. Note, however, that each region has a certain number of speaking engagements that they can fund. It is important to keep your PsychNet Regional Contact informed of the speaker you use and how many engagements you set up in your area.

4. Who do I contact if I have questions about the PsychNet program, a speaker or the content of the slide kits?

All of your RMAs will have a PsychNet slide kit available to them. In addition, there is a DSM or RMA PsychNet contact for each region. He/she is available to answer any questions you may have regarding the PsychNet program. See the back of this booklet for your Regional Contact for PsychNet.

5. My speaker has already done 9 presentations and he wants to do more, but our region has no more money available to support his honorarium. Can we make an exception?

No. Each region has been allocated a set number of funds for this program that is fixed. We cannot exceed this budget for 2000.

While we strongly encourage the use of PsychNet speakers as many times as possible, you should not feel obligated to offer each PsychNet physician 15 speaking engagements if that is not necessary for your region. The confidentiality agreement clearly states that only "a minimum of 4 up to 15. The number of presentations will be determined by scheduling and SB's regional need."

6. How will the program work when the Regional Meeting Planner is appointed to our region?

In terms of coordination, PsychNet will operate the same way most speaker programs will. Your RMP will coordinate the travel and accommodations for the speaker, send out invitations, and set up the meeting, and disburse payment. In addition, the RMP will monitor the number of PsychNet talks done in the region.

7. Can I order a copy of the slide presentations and distribute them to other speakers that are not a part of the PsychNet Council?

No. PsychNet slide kits are not available at this time for consultant use, nor are we distributing them to physicians not a part of the PsychNet Council. If it is necessary for you to review the presentations, contact your RMA or the PsychNet Regional Contact.

8. I know a PsychNet physician that could not make the March 10-12 weekend training session. Can I still have him speak?

Yes, but only after he has been trained. All PsychNet physicians that could not make the training meeting will be trained by the Regional Contact at a later date. Please contact your Regional Contact to obtain the date after which the PsychNet speaker will be trained and available to make PsychNet engagements.

9. Why should I use a PsychNet physician rather than any other physician?

There are many advantages for using a PsychNet speaker:

- *They have been educated on the positive data for Paxil in depression, social anxiety disorder, OCD and panic disorder.*
- *Regardless of the cost of a speaker's regular honorarium, you pay only \$750 from your budget to grant the speaker an enhanced honoraria of \$2500.*
- *You help build Paxil advocacy from the PsychNet key opinion leader.*

PsychNet is an ideal way for key opinion leaders to influence clinicians in your region on the benefits of *Paxil* versus competitors.



Regional Contact List

REGION	CONTACT	PHONEMAIL#
New England	John Cosseboom (DSM)	3128357
Shore Region	Lee Drosdak (DSM) Mary Sotirhos (RMA)	3433406
Northern Lights	Marcelo Ferreyra (DSM)	5124783
PA/West Virginia	Jim Glavin (RMA)	3341971
Desert Mountain	Cindy McKinney (DSM)	1625779
Mid-America	Sheri Mullen (DSM)	1326845
Pacific Sun	Judy Parsons (DSM)	5427735
South Central	Norm H. Rutz (DSM)	1411120
South West	Karen Schaefer (RMA)	1543107
Empire State	Laura Shostak (RMA)	3243971
Pacific Northwest	Andrew Smith (RMA)	5744045
River Valley	Sheldon Thomas (DSM)	3540814
Florida	John Weiner (RMA)	1127791
South East	Chris Wilkinson (DSM)	3621087
Blue Ridge	Sonny Woodruff (DSM)	1210239



FLORIDA REGION (LA)

Beatriz Currier, MD
Department of Psychiatry
University of Miami
1611 NW 12 Avenue
Miami, FL 33125
Phone: 305 585 6115

Joseph Henry, MD
1400 NW 10th Avenue
Room 304-A
Miami, FL 33136
Phone: 305 243 4060
Fax: 954 437 7654

David Sheehan, MD, MBA
3315 E. Fletcher Avenue
University of South Florida
College of Medicine
Department of Psychiatry
3rd Floor
Tampa, FL 33613
Phone: 813 974 4544
FAX: 813 974 4575

MID-AMERICA REGION (LC)

Emil Coccaro, MD
University of Chicago
5841 South Maryland Avenue
Chicago, IL 60637
Phone: 773 834 2660

Moises Gaviria, MD
912 Wood Street
Chicago, IL 60612
Phone: 312 996 6139
Fax: 312 996 1587

Bennett Leventhal, MD
University of Chicago
5841 South Maryland Avenue
Chicago, IL 60637
Phone: 773 702 6751

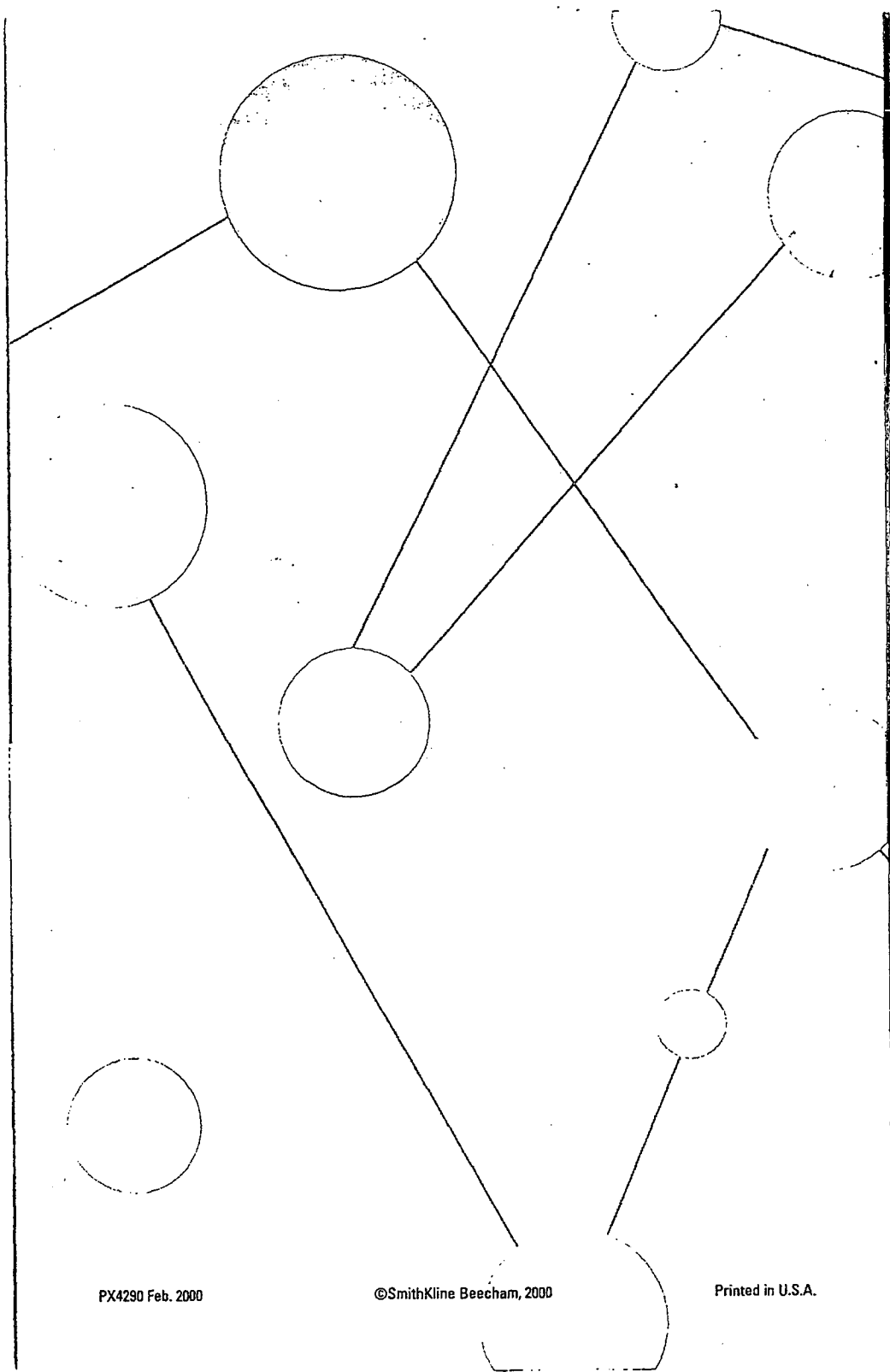
Anatha Shekhar, MD
IU Medical Center
550 University Boulevard
3rd Floor
Indianapolis, IN 46202





PSYCHnet

PAXIL® CLINICIANS SPEAKER COUNCIL



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FLORIDA REGION (LA)

Beatriz Currier, MD
Department of Psychiatry
University of Miami
1611 NW 12 Avenue
Miami, FL 33125
Phone: 305 585 6115

Joseph Henry, MD
1400 NW 10th Avenue
Room 304-A
Miami, FL 33136
Phone: 305 243 4060
Fax: 954 437 7654

David Sheehan, MD, MBA
3315 E. Fletcher Avenue
University of South Florida
College of Medicine
Department of Psychiatry
3rd Floor
Tampa, FL 33613
Phone: 813 974 4544
FAX: 813 974 4575

Michael Ware, MD
2831 NW 41 Street
Gainesville, FL 32606
Phone: 352 373 1332

BLUE RIDGE REGION (LB)

Guy Brannon, MD
1002 Highland Avenue
Shreveport, LA 71101
Phone: 215 413 7892

Ross Gallow, MD
824 Elmwood Park Suite 135
New Orleans, LA 70123
Phone: 215 413 7892

David L. Snow, MD
Associate Medical Director
Emotional Health & Recovery
Center
Blount Memorial Hospital
659 Morganton Square Drive
Maryville, TN 37801
Phone: 865 984 9933
Fax: 865 982 9428

MID-AMERICA REGION (LC)

Emil Cocco, MD
University of Chicago
5841 South Maryland Avenue
Chicago, IL 60637
Phone: 773 834 2660

Moises Gaviria, MD
912 Wood Street
Chicago, IL 60612
Phone: 312 996 6139
Fax: 312 996 1587

Bennett Leventhal, MD
University of Chicago
5841 South Maryland Avenue
Chicago, IL 60637
Phone: 773 702 6751

Anatha Shekhar, MD
IU Medical Center
550 University Boulevard
3rd Floor
Indianapolis, IN 46202
Phone: 317 274 1246

John Zajacka, MD
1725 Harrison #955
Chicago, IL 60612
Phone: 312 942 4000

SOUTH-CENTRAL REGION (LD)

Dale Anderson, MD
1035 Bellvue Suite 412
St. Louis, MO 63117
Phone: 314 645 1567

Donald Chesler, MD
1000 North Lee
Oklahoma City, OK 73101
Phone: 405 272 6716

Ray Clark, MD
5 St. Vincent Circle Suite 301
Little Rock, AR 72205
Phone: 501 666 4266
Fax: 501 666 2149

Jerold J. Kreisman, MD
12255 DePaul Drive Suite 500
Bridgeton, MO 63044
Phone: 314 344 7575
Fax: 314 344 7571



H. Mykel Thomas, MD
5701 West 119th, #407
Overland Park, KS 66209
Phone: 913 323 3801

SOUTHWEST REGION (LE)

Stephen Kyle Brannan, MD
Department of Psychiatry
UTHSCSA
7703 Floyd Curl Drive
San Antonio, TX 78284
Phone: 210 567 5450
Fax: 210 567 6941

Doyle Carson, MD
777 Walter Reed Boulevard
Suite 305
Garland, TX 75042
Phone: 972 276 0755
Fax: 972 494 3062

Mary Ann Ty, MD
7324 SW Freeway Suite 610
Houston, TX 77074
Phone: 713 779 8963
Fax: 713 777 8963

Jean-Joseph Vanderpool, MD
6151 Dew Drive
El Paso, TX 79912
Phone: 915 833 5855

Nishendu Vasavada, MD
560 West Main Suite 101
Lewisville, TX 75057
Phone: 972 221 1741

DESERT MOUNTAIN REGION (LF)

Alvin Burstein, MD
2701 Camelback Suite 203
Phoenix, AZ 85016
Phone: 602 957 2368

Robert Davies, MD
4200 East 9th Avenue
Denver, CO 80262
Phone: 303 315 0452

Steve Methner, MD
501 South Chipeta Way
Salt Lake City, UT 84108
Phone: 801 584 2096

Neil Weiner, MD
4770 East Iliff Avenue Suite 229
Denver, CO 80222
Phone: 303 756 4608

Robert Winski, MD
2033 East Speedway Boulevard
Tucson, AZ 85719
Phone: 520 319 3607

NORTHERN LIGHTS REGION (MA)

Chalakudy Ramakrishna, MD
15645 Farmington Road
Livonia, MI 48154
Phone: 734 422 4748

Jeffrey Simon, MD
9275 North 49th Street Suite 200
Brown Deer, WI 53223
Phone: 414 357 9444
Fax: 414 357 9422

Reid Taylor, DO
720 Goldenrod Avenue
Holland, MI 49423
Phone: 616 847 5145
Fax: 616 842 1495

Scott Yarosh, MD
2550 University Avenue West
Suite 229N
St. Paul, MN 55114
Phone: 651 645 3115
Fax: 651 645 2752

PACIFIC COAST REGION (MC)

Robert Hales, MD
2230 Stockton Boulevard
Sacramento, CA 95817
Phone: 916 734 2980

Allen K. Louie, MD
UCSF/Langley Porter
Psychiatric Institute
401 Parnassus Avenue
Box F Room 367
San Francisco, CA 95143
Phone: 415 476 7017

Michael Resnick, MD
3491 Northwest Raleigh
Portland, OR 97210
Phone: 503 784 8539

Dane Wingerson, MD
325 9th Avenue
Box 359896
Seattle, WA 98104
Phone: 206 731 3425

PACIFIC SUN REGION (MD)

Vivian Burt, MD
UCLA
Neuropsychiatric Institute
760 Westwood Plaza
Los Angeles, CA 90024
Phone: 310 206 5135

Amir Kalali, MD
Quintiles
10201 Waterridge Circle
San Diego, CA 92121
Phone: 858 646 2541

Sidney Zisook, MD
Department of Psychiatry
9500 Gilman Drive
La Jolla, CA 92093
Phone: 858 534 4040
Fax: 858 552 8585

NEW ENGLAND REGION (RA)

Amjad Bahnassi, MD
198 Russell Street
Worcester, MA 01609
Phone: 508 753 5554
Fax: 508 752 7245

Robert J. Birnbaum, MD
One Deaconess Road
Boston, MA 02115
Phone: 617 632 0100

Michael E. Hirsch, MD
Associate Director of
Psychopharmacology
Department of Psychiatry
One Deaconess Road First Floor
Boston, MA 02215
Phone: 617 632 0103
Fax: 617 632 7721

Craig Nelson, MD
Professor of Psychiatry
Director of Inpatient Services

Yale University School of
Medicine
333 Cedar Street
New Haven, CT 06520
Phone: 203 688 2157

Mark Pollack, MD
15 Parman Street
Boston, MA 02114
Phone: 617 726 3488

EMPIRE STATE REGION (RB)

George Alexopoloulos, MD
22 Bloomingdale Road
White Plains, NY 10605
Phone: 914 997 5767

Jeremy Copeland, MD
75-59 263rd Street
Glen Oaks, NY 11005
Phone: 718 470 8000

Manuel B. Montes De Oca, MD
22 Mountainview Avenue
Suffern, NY 10901
Phone: 914 368 4384

Robert Weisman, DO
1650 Elmwood
Rochester, NY 14620
Phone: 716 275 0300

Richard Wolin, MD
295 Essjay Avenue
Williamsville, NY 14221
Phone: 716 630 1204

**PENNSYLVANIA/WEST VIRGINIA
REGION (RC)**

M. Khalid Hasan, MD
Raleigh Psychiatric Services
24 Mallard Court
Beckley, WV 25801
Phone: 304 252 8409
Fax: 304 252 0022