

## **DIVISION OF CLINICAL THERAPEUTICS**

The division of Clinical Therapeutics was officially created on July 1, 2007, by joining the following divisions and units: Anxiety Disorders Clinic, Anxiety Genetics Unit, Biological Studies Unit/ Clinical Psychobiology, Center for Neuroinflammatory Disorders and Biobehavioral Medicine/ Lyme Disease, Clinical Psychopharmacology, Depression Evaluation Service and the Eating Disorders Research Unit. Therefore, this summary report reflects the activities of those units between July 1, 2006 and June 30, 2007.

### **ANXIETY DISORDERS CLINIC**

#### **1. Professional Staff**

*Helen Blair Simpson, MD, Director, Psychiatrist II*  
*Donna Vermes, MS, NPP, Administrator, Psychiatric Nurse II*  
*Lawrence Amsel, MD, Assistant Professor of Clinical*  
*Ivan Balan, PhD, Research Project Manager III*  
*Carlos Blanco, MD, PhD, Psychiatrist II*  
*Raphael Campeas, MD, Research Psychiatrist II*  
*Elizabeth Jackson, MD, Research Interviewer*  
*Ronit Kishon, PhD, Senior Research Worker*  
*Eve Leehman, MD, Psychiatrist II*  
*Roberto Lewis-Fernandez, MD, Psychiatrist II Spanish Language*  
*Michael, Maher, PhD, Research Scientist II*  
*Randall Marshall, MD, Psychiatrist III*  
*Michael McKee, PhD, Research Scientist III*  
*Yuval Neria, PhD, Research Scientist VI*  
*Jessica Page, PhD, Research Scientist III*  
*Sapana Patel, PhD, Assistant Professor of Clinical Psychology (in Psychiatry)/Research Scientist II*  
*Daniel Pilowsky, MD, Psychiatrist II*  
*Anthony Pinto PhD, Research Project Manager III*  
*Jose Arturo Sanchez-Lacay, MD, Psychiatrist II Spanish Language*  
*Franklin Schneier, MD, Research Psychiatrist II*  
*Smit Sinha, MD, Assistant Professor of Clinical Psychiatry*  
*Eun Jung Suh, PhD, Research Scientist II*

#### **2. Overview**

The Anxiety Disorders Clinic (ADC) was established in 1982 to study the diagnosis, pathophysiology, and treatment of anxiety disorders. The clinic has grown over the years and now includes programs in obsessive-compulsive disorder, posttraumatic stress disorder and related traumatic conditions (Trauma and PTSD program), generalized anxiety disorder, anxiety and depression in Hispanic Americans (Hispanic Treatment Program), pathological gambling, and anxiety and depression in patients seen in primary care and other medical specialties. Studies include effectiveness trials in community settings, efficacy trials in specialty clinics, and brain imaging studies investigating pathophysiology.

Our mission is to improve the outcome of our patients by the development and study of new therapeutic strategies, the dissemination of evidence-based practices to clinicians and patients, and the elucidation of the brain mechanisms underlying their symptoms. We are examining pharmacotherapy, psychotherapy (cognitive-behavioral therapy, interpersonal therapy, motivational interviewing), and complementary medicine approaches. We are also conducting epidemiological and services research.

### **3. Current Research**

***OCD program:*** Dr. Simpson runs an interdisciplinary research program dedicated to improving the outcome of patients with OCD. She is currently using clinical trials methodology to study whether motivational interviewing can improve adherence to evidence-based OCD treatments (R34 funded by NIMH and NARSAD) and which augmentation strategies can lead to remission in OCD (R01 funded by NIMH). She is also using brain imaging methodology to determine whether patients with OCD have serotonergic abnormalities in specific brain areas (R01 funded by NIMH). New directions include developing translational models of OCD in collaboration with Dr. René Hen.

***Anxiety, Medical Illness and Addictions:*** Dr. Blanco runs a program that integrates epidemiology, treatment development, and efficacy and effectiveness studies in depression, anxiety, and addictive disorders, with a focus on Hispanics. Funding for this program is provided by NIH, OASAS, and private foundations. In collaboration with Dr. Grann (Herbert Irving Comprehensive Cancer Center) he is conducting a study to treat depressed women with breast cancer with interpersonal psychotherapy (IPT).

***Generalized Anxiety Disorder:*** Dr. Schneier is studying sequential treatment with cognitive-behavioral therapy and escitalopram.

***Social Anxiety Disorder:*** Drs. Liebowitz and Blanco continued a multi-site study of cognitive-behavioral therapy and paroxetine. Dr. Schneier began a study of brain circuitry responses to direct versus indirect eye gaze, before and after paroxetine treatment (R21 funded by NIMH), and he continued a collaboration with Dr. Gorenstein (Surgery) to study social anxiety in hyperhidrosis patients.

***Depression:*** Dr. Schneier is studying D2 receptors and dopamine release in depressed patients (NARSAD Independent Investigator Award).

***Trauma and PTSD program:*** Dr. Neria, the new director of the program obtained funding from the:

1) SPUNK fund to conduct the first clinical trial of Complicated Grief Treatment (CGT) among 9/11 Bereaved, 2) SPUNK fund to be the lead editor of a comprehensive volume about Disaster Mental Health (to be published in Cambridge University Press), 3) CHUM center to study the relationships between exposure to trauma and bipolar illness among poor ethnic minorities, 4) NIMH to conduct year III of an RO1 study R01 (MH072833-03) study aiming to assess the long term impact of 9/11 attacks in primary care

***The Hispanic Treatment Program:*** Dr. Lewis-Fernandez continued to conduct a) an R34 from NIMH on a novel approach based on the DSM-IV Cultural Formulation to help bridge the care of depressed Hispanic patients from primary care to specialty mental health services, and b) a project funded by the American Red Cross to provide medication and psychotherapy services to

Hispanics still suffering from anxiety and depressive disorders as a result of 9/11. We also received an R01 to test an intervention based on motivational interviewing to improve retention and treatment outcome in depressed Hispanics on antidepressant therapy. In addition, we were granted an award from the NYC Division of Mental Hygiene to evaluate early adopter clinics of a City program to enhance diagnosis and treatment of depression in primary care.

#### **4. Education and Training**

Dr. Sinha finished his fourth year of his NIMH K23 Career Development Award, “The Neuroendocrinology of Panic Disorder.” As a group, we also participate actively in the teaching and supervision of PGY-2, PGY-3, and PGY-4 psychiatric residents, and medical students, organizing and running several core classes (e.g., Anxiety Disorders Class for PGY-2 residents) and providing lectures (e.g., psychopharmacology of anxiety disorders, cognitive-behavioral therapy of anxiety disorders) in other core classes. Drs. Simpson, Amsel, and Schneier also delivered lectures for the Departmental Annual Review of Psychiatry. After receiving an encouraging first round review from the NIMH Services Committee, Dr. Patel resubmitted her K23 application, “Patient Centered Care for Underserved Minorities in Primary Care,” in November 2007 and has continued her pilot study of mindfulness meditation therapy for anxiety disorders funded by the Frontier Fund award of Columbia University. Dr. Blanco received a score of 125 in the resubmission of his K02 award “Bridging Efficacy and Effectiveness in Drug Abuse Treatment,” which is expected to be funded in early 2008.

#### **5. Awards and Honors**

Dr. Simpson was invited by Dr. Thomas Insel to speak to the National Advisory Mental Health Council of the NIMH (one of five new investigators chosen nationally)

Blair Simpson, MD, was Co-Chair of Annual meeting of the Anxiety Disorders Association of America.

Publication of the first Practice Guidelines for the Treatment of OCD produced by the American Psychiatric Association (Dr. Blair Simpson as one of the workgroup members)

Carlos Blanco, MD, was appointed to NIDA’s Health Services Review Committee (NIDA-F)

Roberto Lewis-Fernandez, MD, was invited to join the American Psychiatric Association Committee on Psychiatric Diagnosis and Assessment, which oversees the development of DSM-V.

Yuval Neria, MD received the 2007 NARSAD Klerman Award for **Outstanding Clinical Research** (Honorable Mention)

Franklin Schneier, MD was appointed to the Scientific Advisory Board of the Anxiety Disorders Association of America.

#### **6. Appointments**

Blair Simpson, MD, was promoted to Associate Professor of Clinical Psychiatry

Carlos Blanco, MD, was promoted to Associate Professor of Clinical Psychiatry

Sapana Patel, PhD, was appointed to Assistant Professor of Clinical Psychology (in Psychiatry).

## 7. New Grant Support

2 R01 MH071570-01A2 (Simpson) Maximizing Treatment Outcome in OCD

1 R01 (Simpson) Imaging the Serotonin System In OCD

1 R01 MH 077226-01 A2 (Lewis-Fernández) Motivational Antidepressant Therapy for Hispanics

R01 DA019606-01A2 (Blanco) Substance Abuse in Hispanics: A National Study

R01 DA020783 (Blanco) Substance Abuse in Hispanics, SMART: Improving Detection and Outcome of Psychiatric Comorbidity in Drug Abuse Treatment

R21 (Schneier) Neural circuitry of submissive behavior and treatment response in social anxiety disorder

Eszopiclone for the Treatment of Chronic Insomnia Induced by Trauma: A Randomized, Placebo Controlled Study (Sinha)

ASFP (Blanco): A National Study of Ethnic Differences in Suicidal Ideation and Attempts.

## 8. Publications

Blanco C, Cohen O, Luján J, Wulfert E. Substance Abuse and Pathological Gambling. In: Substance Dependence and Co-Occurring Psychiatric Disorders: Best Practices for Diagnosis and Treatment. Nunes E, Selzer J, Levounis P, eds. Civic Research Institute, Inc., (in press)

Blanco C, Harford T, Grant BF, Nunes EV, Hasin DS. The Latent Structure of Marijuana and Cocaine Use Disorders. *Drug Alcohol Depend*, 2007; 91: 91-96.

Blanco C, Markowitz JC, Weissman MM. Interpersonal Psychotherapy. In: Gelder MG, Andreasen N, Lopez-Ibor JJ, eds. *The New Oxford Textbook of Psychiatry*. Oxford: Oxford University Press (in press).

Blanco C, Ogburn E, Alderson D, Grant BF, Nunes EV, Hasin DS. National trends in non-medical use, abuse and dependence of controlled prescription drugs: 1991-1992 and 2001-2002. *Drug and Alcohol Dependence* 2007;90:252-260

Blanco C, Okuda M, Rosenthal H, Lewis-Fernández R. Duloxetine in the Treatment of Major Depressive Disorders and other Psychiatric Disorders. *Expert Review of Clinical Pharmacology* (in press).

Blanco C, Olfson M, Goodwin RD, Ogburn E, Nunes E, Liebowitz MR, Hasin DS. Generalizability of clinical trials for depression to community samples. *J Clin Psychiatry* (in press)

Blanco, CB, Patel SR, Liu, L, Jiang, H, Lewis-Fernandez, R, Schmidt AB, Liebowitz, MR, Olfson, M. National Trends in Ethnic Disparities in Mental Health Care, *Medical Care*, 2007;45 (11).

- Blanco C, Patel SR, Liu L, Jiang H, Lewis-Fernández R, Schmidt AB, Liebowitz MR, Olfson M. National trends in ethnic disparities in mental health care. *Med Care*. 2007;45:1012-1019.
- Blanco C, Schneier FR, Vesga O, Liebowitz MR. Pharmacological treatment of social phobia. In: Stein DJ, Hollander E, Rothbaum BO, eds. *APA Textbook of Anxiety Disorders*, 2nd edition. Washington, DC: American Psychiatric Publishing, Inc (in press)
- Choy C, Schneier FR, Heimberg RG, Oh K-S, Liebowitz MR: Features of the Offensive Subtype of *Taijin-Kyofu-Sho* in U.S. and Korean patients with DSM-IV Social Anxiety Disorders, *Depression and Anxiety*, 2007 Mar 5.
- Daughters SB, Braun AR, Sargeant MN, Reynolds EK, Hopko DR, Blanco C, Lejuez CW. Effectiveness of a brief behavioral treatment for inner-city illicit drug users with elevated depressive symptoms: The Life Enhancement Treatment for Substance Use (LETS ACT!). *J Clin Psychiatry* (in press)
- Patel, S.R., Carmody, J., Simpson, H.B. Adapting Mindfulness Based Stress Reduction for the treatment of Obsessive Compulsive Disorder: A case report. *Cognitive and Behavioral Practice*, 2007; 14, 375-380.
- Lewis-Fernández R, Blanco C, Mallinckrodt CH, Wohlreich MM, Watkin JG, Plewes JM. Duloxetine in the treatment of major depressive disorder: Comparisons of safety and efficacy in US Hispanic and majority Caucasian patients. *Journal of Clinical Psychiatry*, 2006, 67:1379-1390.
- Moadel, A.B., Shah, C., Wylie-Rosett, J., Harris, M.S., Patel, S.R., Hall, C.B., Sparano, J.A. Randomized controlled trial of Yoga among a multiethnic sample of breast cancer patients: Effects on quality of life. *Journal of Clinical Oncology*, 2007; 25 (28): 4387-4395.
- Moreno C, Laje G, Blanco C, Jiang H, Schmidt AB, Olfson M. National trends in the outpatient diagnosis and treatment of bipolar disorder in youth. *Arch Gen Psychiatry*, 2007; 64: 1032-1039.
- Perez-Rodriguez MM, Baca-Garcia E, Oquendo MA, Blanco C. Ethnic Differences in Suicidal Ideation and Attempts. *Primary Psychiatry* (in press)
- Pietrzak RH, Morasco BJ, Blanco C, Grant BF, Petry NM. Gambling level and psychiatric and medical disorders in older adults: results from the National Epidemiologic Survey on Alcohol and Related Conditions. *Am J Geriatr Psychiatry*. 2007;15:301-313.
- Schneier FR. Clinical Practice: Social anxiety disorder: *New England Journal of Medicine* 2006;355:1029-1036.
- Schneier FR, Martinez D, Abi-Dargham A, Zea-Ponce Y, Simpson HB, Liebowitz MR, Laruelle M: Striatal dopamine D<sub>2</sub> receptor availability in OCD with and without comorbid social anxiety disorder: Preliminary findings. *Depression and Anxiety*, 2007 Jan 24.
- Schneier FR, Mellman LA, and Spiegel D (Section Eds.): Anxiety disorders, dissociative disorders, and adjustment disorders. In Gabbard GO (ed.) *Treatment of Psychiatric Disorders*, Fourth Edition. 2007; pp. 479-582. *American Psychiatric Press*, Washington, D.C.

Schultz LT, Heimberg RG, Rodebaugh TL, Schneier FR, Liebowitz MR, Telch MJ: The Appraisal of social Concerns Scale: Psychometric validation with a clinical sample of patients with social anxiety disorder. *Behavior Therapy* 2006;37:392-405.

Sinha SS, Goetz RG, Klein DF. Physiological and Behavioral effects of naloxone and lactate in normal volunteers with relevance to the pathophysiology of panic disorder. *Psychiatry Research* 149 (2007) 309-314.

Vesga O, Blanco C. IPT and medication. In: Gabbard GO, ed. American Psychiatric Association Textbook of Psychotherapy. Washington, D.C.: American Psychiatric Publishing, Inc. (in press).

## **ANXIETY GENETICS UNIT**

### **1. Professional staff:**

*Abby J. Fyer, MD, Director, Psychiatrist II*  
*Joshua Lipsitz, PhD, Associate Professor*  
*Lindsey Nederlander, PhD, Research Associate*  
*Merav Gur, PhD, Assistant Professor*

### **2. Overview**

The Anxiety Genetic Unit originated as the component of the NYSPI Anxiety Disorders Clinic responsible for diagnostic and family studies. In collaboration with Jean Endicott we developed research instruments for lifetime assessment of anxiety disorders and symptoms and conducted some of the first family studies of social and specific phobias. In 1987 we expanded our work to include a DNA marker linkage study of panic disorder and have since become a separate research group with a specific focus on understanding genetic contributions to human anxiety and anxiety disorders. Our work involves both collaborations on traditional family/linkage studies and neurobiologically based “endophenotypic” and “translational” approaches genetic studies of anxiety.

### **3. Current Research**

Abby Fyer, MD, continued sample collection and began analyses on a genetic study of fear learning, began pilot studies of a psychophysiological paradigm for safety learning in collaboration with colleagues in the Center for Neurobiology and Behavior, and continued her work as part of collaborative linkage studies of panic and obsessive compulsive disorders.

Merav Gur, PhD, with support from the ACISR of NYSPI's Department of Child Psychiatry is piloting of a psychosocial intervention for youngsters with ongoing chest pain.

Joshua Lipsitz, MD, completed an NIMH-funded study of children and adolescents with unexplained chest pain. Results indicate that there is considerable distress and psychopathology in this previously unstudied population.

### **4. Education and Training**

A research fellow, Dr. Yujuan Choy graduated in June 2006. Dr. Fyer co-taught with Dr. Rieder a short course on Research Methods for PGY IV residents.

## 5. Appointments

Abby J. Fyer, MD, became Treasurer of the Anxiety Disorders Association of America (ADAA)

Joshua Lipsitz, PhD, was promoted to Associate Professor of Clinical Psychology.

## 6. Publications

Choy, Y, Fyer, AJ, Goodwin RD. Specific phobia and comorbid depression: a closer look at the National Comorbidity Survey data. *Comprehensive Psychiatry*, 2007; 48(2): 132-6.

Choy, Y, Fyer AJ, Lipsitz, JD. Treatment of specific phobia in adults. *Clinical Psychology Review*, 2007; 27(3):266-86.

Cullen B, Samuels JF, Pinto A, Fyer AJ, McCracken JT, Rauch SL, Murphy DL, Greenberg BD, Knowles JA, Piacentini J, Bienvenu OJ 3rd, Grados MA, Riddle MA, Rasmussen SA, Pauls DL, Willour VL, Shugart YY, Liang KY, Hoehn-Saric R, Nestadt G. Demographic and clinical characteristics associated with treatment status in family members with obsessive-compulsive disorder. *Depression and Anxiety*, 2007 Mar 7;

Fyer AJ, Hamilton SP, Durner M, Haghghi F, Heiman GA, Costa R, Evgrafov O, Adams P, de Leon AB, Taveras N, Klein DF, Hodge SE, Weissman MM, Knowles JA. A third-pass genome scan in panic disorder: evidence for multiple susceptibility loci. *Biological Psychiatry*. 2006; 60(4): 388-401.

Hasler G, Pinto A, Greenberg BD, Samuels J, Fyer AJ, Pauls D, Knowles JA, McCracken JT, Piacentini J, Riddle MA, Rauch SL, Rasmussen SA, Willour VL, Grados MA, Cullen B, Bienvenu OJ, Shugart YY, Liang KY, Hoehn-Saric R, Wang Y, Ronquillo J, Nestadt G, Murphy DL; OCD Collaborative Genetics Study. Familiality of factor analysis-derived YBOCS dimensions in OCD-affected sibling pairs from the OCD Collaborative Genetics Study. *Biological Psychiatry*, 2007; 61(5):617-25.

Lipsitz JD, Gur M, Miller NL, Forand N, Vermes D, Fyer AJ. An open pilot study of interpersonal psychotherapy for panic disorder (IPT-PD). *Journal of Nervous and Mental Disease*. 2006; 194(6):440-5.

Samuels JF, Bienvenu OJ 3rd, Pinto A, Fyer AJ, McCracken JT, Rauch SL, Murphy DL, Grados MA, Greenberg BD, Knowles JA, Piacentini J, Cannistraro PA, Cullen B, Riddle MA, Rasmussen SA, Pauls DL, Willour VL, Shugart YY, Liang KY, Hoehn-Saric R, Nestadt G. Hoarding in obsessive-compulsive disorder: results from the OCD Collaborative Genetics Study. *Behavior Research and Therapy*. 2007; 45(4): 673-86

Shugart YY, Samuels J, Willour VL, Grados MA, Greenberg BD, Knowles JA, McCracken JT, Rauch SL, Murphy DL, Wang Y, Pinto A, Fyer AJ, Piacentini J, Pauls DL, Cullen B, Page J, Rasmussen SA, Bienvenu OJ, Hoehn-Saric R, Valle D, Liang KY, Riddle MA, Nestadt G.

Genomewide linkage scan for obsessive-compulsive disorder: evidence for susceptibility loci on chromosomes 3q, 7p, 1q, 15q, and 6q. *Molecular Psychiatry*. 2006 Aug;11(8):763-70.

Samuels J, Shugart YY, Grados MA, Willour VL, Bienvenu OJ, Greenberg BD, Knowles JA, McCracken JT, Rauch SL, Murphy DL, Wang Y, Pinto A, Fyer AJ, Piacentini J, Pauls DL, Cullen B, Rasmussen SA, Hoehn-Saric R, Valle D, Liang KY, Riddle MA, Nestadt G. Significant linkage to compulsive hoarding on chromosome 14 in families with obsessive-compulsive disorder: results from the OCD Collaborative Genetics Study. *American Journal of Psychiatry*, 2007; 164(3):493-9.

## **BIOLOGICAL STUDIES UNIT/CLINICAL PSYCHOBIOLOGY**

### **1. Professional Staff**

*Laszlo Papp, MD, Director, Psychiatrist II*

*Aley Karyat, RN*

*Ethan Gorenstein, PhD*

*Felice Trager, PhD*

*Arlene King, PhD*

### **2. Overview**

The Biological Studies Unit (BSU), directed by Dr. Laszlo Papp, in addition to conducting its own research program (BSU Clinical Psychobiology), also maintains a centralized research laboratory, serving the need of investigators throughout the Medical Center.

Current protocols at the BSU Psychobiology Program include a sequential treatment study, including both psychotherapy and medications guided by patient choice, sponsored by NIMH for older patients with Generalized Anxiety Disorder. Another project is designed to develop a novel administration of an anti-panic drug using a laboratory paradigm. The immediately acting form of this medication could potentially prevent panic attacks in patients with panic disorder.

Pharmacological treatment trials and biological challenge studies with levetiracetam and tiagabine have been completed during the reporting period and the results have been presented at national and international scientific meetings and are being prepared for publication.

### **3. Grants**

Alexza Pharmaceuticals

Development of a Multimodal Treatment for Late Life Generalized Anxiety Disorder

Escitalopram for patients with comorbid anxiety/mood disorder and Irritable Bowel Syndrome  
Forest

Investigation of a Single Dose of Staccato™ Alprazolam for Inhalation in Doxapram-Induced Panic Attack in Patients with Panic Disorder

NIMH Levetiracetam and CO2 Sensitivity in Panic Disorder.

Open Label Levetiracetam in Panic Disorder.

UCB Pharma

#### **4. Publications**

Dunlop BW, Papp LA, Garlow SJ, Weiss PS, Knight BT, Ninan PT: Tiagabine for Social Anxiety Disorder. *Human Psychopharmacology: Clinical & Experimental*, 2007; 22(4): 241-244.

Gorenstein EE, Papp LA: Cognitive-behavioral therapy for anxiety in the elderly. *Current Psychiatry Reports* 2007; 9(1):20-5.

Papp LA: Generalized Anxiety Disorder; Evaluation and Diagnosis. In Barnhill (ed.) *Approach to the Psychiatric Patient*. American Psychiatric Press, Washington DC (in press).

Papp LA: Pharmacological approach to the management of stress and anxiety disorders. In Lehrer, Woolfolk (eds.) *Principles and Practice of Stress Management* (Third Edition) 2007; The Guilford Press, New York

Papp LA: Safety and efficacy of levetiracetam for patients with panic disorder: results of an open-label, fixed-flexible dose study. *Journal of Clinical Psychiatry* 2006; 67(10): 1573-6.

Papp LA: Sedative-hypnotic agents. In Lieberman, Tasman (eds.) *Handbook of Psychiatric Drugs*. (Second Edition). 2006 (pgs 155-172) John Wiley & Sons, England.

Papp LA, Goetz R, Reynoso MB: Benefits of venlafaxine in late-life anxiety. (in review)

Papp LA, Ray S: The SGRI tiagabine for the treatment of generalized anxiety disorder. (in review)

### **CENTER FOR NEUROINFLAMMATORY DISORDERS AND BIOBEHAVIORAL MEDICINE / LYME DISEASE**

#### **1. Professional Staff**

*Brian A. Fallon, MD. Director (CNDBBM & LTBDRC), Psychiatrist II*  
*Kathy Corbera, MD. Co-Director Lyme & Tick-Borne Diseases Research Center*  
*John Keilp, PhD. Neuropsychology Consultant*  
*Kelli Harding, MD. Research Fellow, Principal Investigator*  
*Ella Doctoroff, OD, MD. Research Fellow*  
*Rafal Tokarz, PhD. Research Fellow, Microbiologist*  
*Michael McKee, PhD. Research Scientist II*  
*Samantha Luk, BA. Study Coordinator (Lyme)*  
*Emily Doherty, BA. Study Coordinator (Hypochondriasis)*  
*Katy Harper, MS. Study Coordinator (Psychosis)*  
*Jordan Slavov, PhD. Statistician*  
*Natalia Skritskaya. PhD. Candidate*

#### **2. Overview**

The Center for Neuroinflammatory Disorders and Biobehavioral Medicine (CNDBBM) was established in 2007, with historical predecessors to 1994 when the Somatic Disorders Program and the Lyme Disease Research Program were established. The CNDBBM studies diseases that fall within the domain of neuroinflammatory disorders, biobehavioral medicine, and neuropsychiatry. Also in 2007, the University-wide Lyme and Tick-borne Diseases Research Center was established – a joint effort among Columbia University, Time for Lyme, Inc, and the Lyme Disease Association, Inc. The opening of the Center was celebrated by a symposium with speakers including C. Ben Beard (Chief, Vector Borne Diseases, CDC) and Ian Lipkin (Director, Laboratory for Immunopathogenesis and Infectious Diseases). Primary areas of disease focus have been Lyme disease, hypochondriasis, and most recently refractory psychosis. Targets of study include humans and ticks. Studies include efficacy trials and diagnostic, biomarker, neuroimaging, and molecular research.

### **3. Current Research**

***Hypochondriasis:*** Jointly with Dr. Arthur Barsky at Harvard University, we continue to conduct a five-year NIH-funded, dual-site treatment study of hypochondriasis, comparing CBT, Fluoxetine alone, FLX+CBT, and Placebo. We are also conducting, with Dr. Kelli Harding as PI and Dr. Brad Peterson as Co-Investigator, a fMRI study of information processing using a virtual reality maze among patients with hypochondriasis versus healthy controls.

***Lyme Disease:*** Several studies have continued during this year. (1) A study assessing the potential utility for differential diagnosis associated with brain SPECT imaging comparing Lyme disease, depression, and healthy controls. (2) A study evaluating the specificity of laboratory testing for Lyme disease at four different laboratories; this is both a laboratory comparison study and a specificity study. (3) A study initiated with Dr. James Moeller to determine whether there is a neuro-imaging biomarker associated with Lyme encephalopathy. (4) A study examining what other micro-organisms exist within Ixodes Scapularis ticks. (5) A study conducted collaboratively with Dr. Steven Schutzer of UMDNJ to examine whether Bb-specific immune complexes are present in patients with chronic symptoms and whether they are biomarkers of disease severity or treatment response.

***Psychosis:*** Given recent pre-clinical work demonstrating that the antibiotic IV ceftriaxone is one of the most powerful up-regulators of the GLT1 glutamate transporter, Dr. Fallon, in collaboration with Dr. Lieberman and the Schizophrenia Research Unit, began a NARSAD-funded placebo-controlled study to investigate the potential efficacy of IV ceftriaxone as a treatment for refractory psychosis. This study also has a MR spectroscopy component that is being conducted with Dr. Larry Kegeles, Dr. Shungu, and Dr. Peterson to look for changes in the glutamate/gaba spectra before and after treatment.

### **4. Education and Training**

Dr. Fallon continues to chair the annual National Research Conference on Lyme and Tick-Borne Diseases run jointly by Columbia University and the Lyme Disease Association.

Dr. Kelli Harding (Somatoform Disorders) and Dr. Ella Doctoroff (Lyme) were Research Fellows during this interval. We also participate in the teaching and supervision of medical

students and PGY-IV residents. Specifically, during the summer of 2006, we had two P&S medical students who spent 6-8 weeks with us learning about Lyme and tick-borne diseases.

## **5. Grants**

NARSAD Independent Investigator award (Fallon) for “IV ceftriaxone for refractory psychosis: a controlled study”

RO1 MH071456-02 (Fallon, PI): “Treatment of Hypochondriasis with CBT and/or SSRI”  
Time for Lyme, Inc. (Training Gift for Lyme Tick Fellowship given to Lyme Center)

## **6. Publications**

Fallon BA. Mystery Diagnosis: Treatment of Neuropsychiatric Lyme Disease. In *DSM-IV-TR® Casebook*, Volume 2. Experts Tell How They Treated Their Own Patients. Edited by Robert L. Spitzer, M.D., Michael B. First, M.D., Janet B. W. Williams, D.S.W., and Miriam Gibbon, M.S.W. Washington D.C., American Psychiatric Publishing, Inc, 2006. Pages 39-52.

Fallon BA, Barsky A. Hypochondriasis. *Gabbard's Treatments of Psychiatric Disorders*, Fourth Edition. Edited by Glen O. Gabbard, M.D. APPI Press, 2007.

## **Clinical Psychopharmacology**

### **1. Professional Staff**

*Alexander H. Glassman, M.D., Chief*

*Steven P. Roose, MD, Psychiatrist Research II*

*Lirio S. Covey, Ph.D., Research Scientist V*

*Joel Sneed, Ph.D, Post-doctoral Research Fellow*

*Bret Rutherford, MD, Post-doctoral Research Fellow*

### **2. Overview**

Our research efforts have focused on depression, reward systems, and their comorbidity. Areas of interest include: biological characteristics and treatment modalities in patients with late-life depression; the relationship of depression to the development of cardiac mortality/morbidity; and smoking dependence, with special interest in the relationship between nicotine addiction and depression, as well as the prevention of smoking relapse.

### **3. Current Research**

Alexander Glassman, in association with the Department of Medicine and School of Public Health, is completing a five-year follow-up of patients who participated in the study of an SSRI vs. placebo in major depression following myocardial infarction. The initial results of this study were republished in JAMA in 2002. Although there was a trend for a reduction in life-threatening events the number of such events that occurred in six months was limited. With five

years of follow-up over 25% of the sample will have died. This study involves examining potential predictors of death.

Important new developments in the Late-Life Depression Clinic include that Dr. Bret Rutherford, a research fellow, has begun a series of new studies to understand the impact of patient expectancy on outcome in antidepressant clinical trials. Joel Sneed continues projects as part of his K award to study diagnostic criteria for vascular depression. As part of this project we have developed a collaboration with the Geriatric Division of Harlem Hospital and are going to be part of a NIMH multi-center study on the use of calcium channel blockers in patients with vascular depression. Unique meta-analyses by Drs. Sneed and Rutherford, both in press, have shown that study design, e.g. whether a patient is in a comparator study in which both patient and doctor know they are receiving an active treatment or are in a placebo-controlled study where they do not know whether they are receiving an active treatment, has a greater impact on outcome than medication itself. Drs. Gregory Pelton, Devangere Devanand, and Steven Roose are close to completing the first study of whether the combination antidepressants and cognitive enhancers will decrease the rate of conversion of depressed patients with cognitive impairment to dementia.

Dr. Lirio Covey reported the main finding from her completed 5-year grant “Maintenance treatment for preventing smoking relapse,” funded by the National Institute on Drug Abuse (NIDA), in the journal *Addiction*. Compared to the standard, eight-week duration of bupropion use as a smoking cessation aid, an additional 16 weeks of bupropion treatment prolonged time to relapse; the effect was modest (hazard ratio=0.59) but statistically significant. The study also found, however, that the relapse preventive effect did not last long after terminating bupropion use.

There are several other publications from Dr. Covey’s investigation in press or under review. One involves the marked disparity by race/ethnicity in treatment response to eight weeks of combined bupropion and nicotine patch treatment, since proportionately fewer African-American and Hispanic smokers stopped smoking compared to White smokers. Another compares participants according to the core symptoms of Attention Deficit Hyperactivity Disorder (ADHD) and shows that smokers with hyperactivity/impulsivity symptoms have significantly poorer treatment response to combined bupropion and nicotine patch compared with both smokers with inattention symptoms only and with smokers without ADHD symptoms. This finding is consistent with pre-clinical findings that nicotine exerts divergent effects on inattention and response inhibition/impulsivity. A third forthcoming publication reports on a comparison of nicotine dependence characteristics, psychiatric history, and smoking cessation outcome among smokers who report homosexual versus heterosexual. There is scant knowledge regarding this relationship.

In collaboration with Dr. Edward Nunes of the Long Island Node of NIDA’s Clinical Trial Network, Dr. Covey and her colleagues continued their participation as the NYSPI site for a six-site, large-scale (N=255) placebo-controlled pilot trial of OROS-methylphenidate as a smoking cessation aid for adult smokers with ADHD. The main study objective is to investigate the ability of OROS-MPH to improve smoking cessation outcome among smokers with ADHD when used as an adjunct to standard smoking cessation treatment, i.e., nicotine patch and individual behavioral counseling. Three types of treatment facilities were selected for this pilot trial: community-based drug treatment, ADHD clinic, or smoking cessation clinic. The NYSPI site was selected, along with the Mayo Clinic’s Nicotine Dependence Center, as a prototype of a smoking cessation facility.

#### 4. Training

Continuing to collaborate with CUMC's School of Dentistry, Dr. Covey served as the mentor for a pre-doctoral student interested in nicotine dependence research. Fellows gain first-hand experience with research subjects in smoking cessation trials and participate in data analysis and preparation of scientific publications.

#### 5. Publications

Covey L, Gardiner P, Howard JM, Thompson A. Race/ethnicity and smoking. Program Notes, 2<sup>nd</sup> Annual Conference in Health Disparities Research, March 8-9, 2007, Teachers College, Columbia University, New York, NY.

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#### DEPRESSION EVALUATION SERVICE

## **1. Professional Staff**

*Patrick J. McGrath, MD, Co-Director, Depression Evaluation Service, Professor of Clinical Psychiatry*

*Jonathan W. Stewart, MD, Co-Director, Depression Evaluation Service, Professor of Clinical Psychiatry*

*Judith G. Rabkin, PhD, Director HIV Program, Professor of Clinical Psychology in Psychiatry*

*Edward V. Nunes Jr, MD, Director NIDA Clinical Trials Network, Research Psychiatrist, Professor of Clinical Psychiatry*

*Deborah Deliyannides, MD, Research Psychiatrist, Assistant Clinical Professor of Psychiatry*

*Stephen Donovan, MD, Research Psychiatrist, Assistant Professor of Clinical Psychiatry*

*David Hellerstein, MD, Research Psychiatrist, Associate Professor of Clinical Psychiatry*

*Richard Rabkin, MD, Research Psychiatrist*

*Vito Agosti, CSW, Research Scientist, Senior Staff Associate*

*Sarai Batchelder, PhD, Clinical Program Manager*

*Manuel de la Nuez, Research Scientist I*

*Martin McElhiney, PhD, Research Scientist III*

*Donna O'Shea, MsEd, Clinical Researcher Level III*

*Monica Alvarez-Goldman, Study Coordinator*

*Carmen Prieto, Senior Laboratory Technician*

*Amanda West, Research Assistant*

*Ming Zhu, Study Coordinator*

## **2. Overview**

The Depression Evaluation Service (DES) was begun in 1977 by Dr. Frederick Quitkin, who sadly succumbed to cancer in October 2005. Drs. Patrick J. McGrath and Jonathan W. Stewart have been appointed Co-Directors to succeed Dr. Quitkin. Dr. Quitkin's vision was to study diagnosis, pathophysiology, and treatment in mood disorders using therapeutic response as a nosologic tool. His legacy includes the development of an evidence base for the diagnosis of "atypical" subtype of mood disorders which resulted in its being included in DSM-IV as a validated sub-type. Other major studies conducted under his direction have included: prediction of relapse after successful treatment with serotonin reuptake inhibitor antidepressant medication, treatment of depression which co-occurs with alcohol or drug dependence, innovative treatment of explosive mood disorder in adolescents, genetic predictors of antidepressant medication response, and brain imaging to subtype depressive disorders.

The DES participated in the design of a major NIMH clinical trial entitled "Sequenced Treatment Alternatives to Relieve Depression" (STAR\*D) and was one of the Regional Centers in that recently completed landmark study. The DES has also embarked on collaborations in pharmacogenetics and in functional magnetic resonance imaging and positron emission tomography to assist in studying pathophysiology and moderators of therapeutic response in depressive disorder.

This year, Drs. David Hellerstein and Sarai Batchelder joined the DES to expand our work further into the study of dysthymia, an area in which Dr. Hellerstein is a nationally known expert.

## **3. Highlights, Awards, and Honors**

The NIMH funded Depression Treatment Network initiated a study at the Columbia University Regional Center, "Suicide Assessment Methodology Study," which has enrolled over 250 patients to date and is designed to examine the emergence of any suicidal impulses or behavior during antidepressant treatment with SSRI antidepressants, a critical public health issue.

Dr. Jonathan Stewart began recruitment for an exciting new translational research NIMH-funded clinical trial of combination of antidepressant medications to maximize both rapid response and higher remission rate. (NIMH #1R01MH076961-01A2: Combining Antidepressants to Hasten Remission from Depression)

Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) and its ancillary studies were completed and have generated many contributions to the psychiatric literature.

The Department welcomed David Hellerstein, M.D., an expert in the assessment and treatment of dysthymia and his Project Coordinator, Sarai Batchelder, Ph.D., to the department in July 2006

The DES has opened a midtown location at 1775 Broadway under the Direction of David Hellerstein, M.D., which will be a new resource of patients to access clinical trials without traveling to the CUMC site.

Dr. Hellerstein has begun recruitment for a state of the art study of dysthymia which includes fMRI imaging of patients with dysthymia before and after treatment with medication to examine the psychobiology of this disorder in a way never before explored.

Dr. Stephen Donovan has been funded to conduct a new clinical trial of lisdextroamphetamine in subjects with ADHD who have drug abusing adolescent siblings to examine the effect of such treatment on both the subjects and their siblings.

Dr. Rabkin, as co-author, published an invited essay in JAMA on palliative care in amyotrophic lateral sclerosis.

Drs. J. Rabkin, R. Rabkin and McElhiney are completing a placebo controlled randomized study of modafinil to treat fatigue in ALS patients, with promising results.

Dr. McElhiney is conducting a study of the overlap between depression and fatigue, and the role of illness markers, in a sample of 250 ALS patients.

Dr. Edward V. Nunes was elected to the Board of Directors of the College on Problems of Drug Dependence

#### **4. Publications**

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## **EATING DISORDERS RESEARCH UNIT**

### **1. Professional Staff**

*B. Timothy Walsh, MD, Psychiatrist III, Professor of Psychiatry*

*Michael J. Devlin, MD, Psychiatrist II, Associate Professor of Clinical Psychiatry*

*Evelyn Attia, MD, Psychiatrist II, Associate Professor of Clinical Psychiatry*  
*Allegra Broft, MD, Assistant Professor of Clinical Psychiatry*  
*Diane Klein, MD, Assistant Professor of Clinical Psychiatry*  
*Lisa Kotler, MD, Assistant Professor of Clinical Psychiatry*  
*Laurel Mayer, MD, Psychiatrist II, Herbert Irving Assistant Professor of Psychiatry*  
*Joanna Steinglass, MD, Assistant Professor of Clinical Psychiatry*  
*Ellen Zimmerli, PhD, Assistant Clinical Professor of Psychology in Psychiatry*  
*Juli A. Goldfein, PhD, Assistant Clinical Professor of Psychology in Psychiatry*  
*Nicole Barbarich-Marsteller, PhD, Instructor of Clinical Psychology in Psychiatry*  
*Pamela Raizman, PhD, Instructor of Clinical Psychology in Psychiatry*  
*Janet Schebendach, RD, Project Coordinator*

## **2. Current Research**

***New York State Center of Excellence:*** The New York State Department of Health renewed its grant for an additional year to the Eating Disorders Research Unit of New York-Presbyterian Hospital, directed by Dr. Evelyn Attia; NYSPI; and Schneider Children's Hospital. These three organizations make up one of the three New York State Centers of Excellence for eating disorders. This Center improves coordination of clinical services for patients with anorexia nervosa, bulimia nervosa and ED-NOS.

***Bulimia Nervosa:*** We have continued our work aimed at examining psychobiological concomitants of bulimia nervosa: eating behavior, stomach functioning, and levels of CCK, a hormone that is released into the blood after eating to signal "fullness." We published the results of a pilot clinical trial of baclofen, a novel class of medication, for the treatment of BN. We continue a collaborative, translational research grant among several groups studying various aspects of eating regulation: researchers studying drug abuse/dependence (Dr. Richard Foltin), researchers studying peripheral controls of appetite and satiety in animals (Drs. Gary Schwartz, and Gerard Smith), and CNS reward mechanisms involved in eating (i.e. "sugar addiction") in animals (Dr. Bart Hoebel). The purpose of this grant is to apply the concepts and methodology used by these other groups to study dysregulation of eating in humans.

***Anorexia Nervosa:*** We completed a pilot treatment trial for weight gain in women with AN comparing treatments of differing levels of intensity: standard inpatient treatment compared to a sequenced care approach – initial inpatient treatment, with a transition to day-treatment when appropriate. Preliminary results suggest successful weight gain can occur with a stepped-level of care. We are nearing completion of a double blind trial of olanzapine for the outpatient treatment of AN. We (Steinglass) were awarded a two-year grant from the Hilda and Preston Davis Foundation to develop exposure therapy and response prevention as a new treatment for relapse prevention in AN. The above mentioned translational research grant is examining the phenomenon of exercise dependence in women with anorexia nervosa. We published the results of one study in patients with AN of the relative reinforcing value of exercise. This study applied paradigms developed and proven useful with patients with substance abuse and serves as a successful example of the benefits of the translational approach to the study of eating disorders.

***Binge Eating Disorder:*** We are continuing to conduct laboratory studies of eating behavior in obese women with and without binge eating disorder. Finally, we are continuing to study the relationship between eating disorders, such as binge eating and night eating, and outcome in patients who have gastric bypass surgery for obesity.

**Adolescent Obesity:** In collaboration with the Department of Pediatrics and Pediatric Surgery we are continuing to study the psychological effects of bariatric surgery in overweight teens.

### **3. Education & Training**

The unit staff is active in a broad range of training programs. The educational objectives for all residents are to learn how to recognize and treat major eating disorders. We currently have one research fellow. We graduated two research fellows in the past year.

### **4. Awards**

B. Timothy Walsh, MD, received the Price Family Award for Research Excellence, National Eating Disorders Association.

Nicole Barbarich-Marsteller, MD, was awarded a Laureate Young Investigator's Grant, National Eating Disorders Association for her study entitled Serotonergic dysfunction in activity-based anorexia: Treatment implications.

Dr. Barbarich-Marsteller also received research grants from the Frontier Fund and the Sackler Institute of College of Physicians and Surgeons of Columbia University towards her study of the neurochemical-behavioral alterations in reward in activity-based anorexia.

Allegra Broft, MD, was awarded a Janssen Fellowship for her study: Imaging of dopamine systems in bulimia nervosa.

Dr. Broft was also awarded a 3-year, K12, CTSA Career Development Award to study dopamine function in patients with Bulimia Nervosa.

Michael J. Devlin, MD, was awarded Teacher of the Year by the Association for Academic Psychiatry, Region 2.

Diane Klein, MD, was awarded a NARSAD Young Investigator Award to study Effects of Mifepristone in the Treatment of Anorexia Nervosa

Joanna Steinglass, MD, was awarded a NARSAD Young Investigator Award to study D-Cycloserine and Exposure Therapy: A Novel Treatment Approach in Anorexia Nervosa.

### **5. Appointments**

B. Timothy Walsh, MD, continued to serve as a member to the Committee on Gulf War and Health: Physiologic, Psychologic, and Psychosocial effects of Deployment Related Stress, Institute of Medicine, National Academy of Science, 2005 - 2007.

Allegra Broft, MD, was promoted to Assistant Professor of Clinical Psychiatry.

Michael J. Devlin, MD, served on the work group that developed APA Practice Guideline for Treatment of Patients with Eating Disorders. The Guidelines were published this year.

Joanna Steinglass, MD, was promoted to Assistant Professor of Clinical Psychiatry.

## 6. Publications

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