Larry Ereshefsky, Pharm.D., BCPP, FCCP
Follow the Molecule: CNS Consulting LLC
Chief Scientific Officer, Early Phase Development: Hassman Research Institute, LLC
Chief Scientific Officer, Early Phase Development: Collaborative Neuroscience Network, LLC
Retired Professor: The University of Texas Health Science Center

CONTACT INFORMATION:

Site Selection and Information:
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AFFILIATIONS:

Hassman Research Institute, LLC
175 Cross Keys Rd, Suite 300A
Berlin, NJ 08009

Collaborative Neuroscience Network, LLC
2600 Redondo Avenue, Suites 415 & 500
Long Beach, CA 90806

EDUCATION:

1976 – 1977 Post-Graduate Residency in Psychiatric Pharmacy/Psychopharmacology
University of Southern California, Los Angeles County Medical Center and Metropolitan State Hospital, Los Angeles, California

1972 – 1976 Doctor of Pharmacy
University of Southern California, Los Angeles, California

1969 – 1972 Undergraduate, Major: Biochemistry; Minor: Psychobiology
University of California, Los Angeles, California

CERTIFICATION:

Board Certified: BCPP, Psychiatric Pharmacy

LICENSURE:

California State Board of Pharmacy
Texas State Board of Pharmacy

PROFESSIONAL EXPERIENCE:

Consultant, Chief Scientific Officer, Early Phase Development, April 2018 – Present
Collaborative Neuroscience Network, LLC, Long Beach, CA

Consultant, Chief Scientific Officer, Early Phase Development, Mar 2017 – Present
Hassman Research Institute LLC, Berlin, NJ

Chief Scientific Officer and Owner, Jun 2016 – Present
Follow the Molecule: CNS Consulting LLC, Marina del Rey, CA

Clinical Research Consultant, Jan 2015 – Present
ProScience ResearchGroup (PsRG) LLC, Culver City, CA

VP, Principal Clinical Pharmacologist, and Global CNS Leader for Early Phase
Mar 2008 – Jun 2016
PAREXEL, Glendale, CA

Executive Vice President and Chief Scientific Officer, Sep 2003 – Mar 2008
California Clinical Trials Medical Group, Glendale/Paramount/San Diego, CA

Retired Professor, Department of Pharmacology and Psychiatry, and College of Pharmacy
Sep 2003 – Present
The University of Texas at Austin and UT Health Science Center (UTHSCSA), San Antonio, TX

Associate-Director Advanced Psychopharmacology Evaluation Laboratory and the Pharmacogenetics Lab at the McDermott Clinical Science Building
Sep 1988 – Sep 2003
The University of Texas at Austin and UT Health Science Center (UTHSCSA), San Antonio, TX

Professor of Pharmacy, Psychiatry and Pharmacology, 1977 – 2003
The College of Pharmacy, The University of Texas at Austin and the Departments of Pharmacology and Psychiatry, The University of Texas, Austin, TX

Glendale Adventist Medical Center, Glendale, California
Brotman Medical Center, Culver City, California
BMR Healthquest, San Diego
Paramount Long-term care nursing facility
San Antonio State Hospital and clinical research unit
Texas Department of Mental Health and Mental Retardation
Wilford Hall Air Force Medical Center
Bexar County Department of Mental Health
Audie Murphy Veterans Administration hospital

AWARDS AND HONORS:

2015 – Present	Chairman of the Behavioral and Psychiatric Symptoms in Dementia workgroup and workshop for the International Society for CNS clinical trials and methodology
2010 – Present	Member of the ADNI-FNIMH Biomarkers Task Force for Alzheimer's Disease
2011 – 2012	Member of the College of Psychiatric and Neurologic Pharmacists Foundation (CPNPF) Board
2010	Commencement speaker for the College of Pharmacy, The University of Texas at Austin's PharmD Graduation
2002 – 2015	NIMH and NIAAA Study Panel participation
2003	Elected, President-Elect, College of Psychiatric and Neurological Pharmacists
2004	President
2005 – 2006	Past-President
2005	Key note speaker for University of Southern California's First Annual Research Day for the School of Pharmacy
	Founding Member of the International Society for CNS Clinical Trials and Methodologies
2002 – 2004	Member of the Warfighters Counter-Fatigue Measures working group, USAF
2004	Listed in, Who's Who in the World
2003	Selected to serve on the Texas Small Business Advisory Task Force to President Bush
	Psychiatric Pharmacy Consultant to the Government of Lebanon, Department of Health
2001	Featured speaker at First International Conference of the Lebanese American University, Byblos, Lebanon 2001

Additional Awards and Honors available upon request

RESEARCH EXPERIENCE:

Sep 2003 – Jun 2016	California Clinical Trials/PAREXEL International
Sep 1988 – Sep 2003	UTHSCSA/San Antonio State Hospital
2003 – Present	The University of Texas at Austin and UT Health Science Center San Antonio
1977 – 2003	The University of Texas Health Science Center San Antonio, and The University of Texas at Austin

TEACHING - POST GRADUATE TRAINING:

July 2001 – 2005	Graduate Advisor for combined MS in Advanced Pharmacy Practice and Clinical Science and Specialty Practice Residency Program
July 1984 – 2005	Post-graduate Clinical Sciences Fellowship program in psychiatric pharmacy
July 1981 – 2005	Post-graduate Residency Training Program in Psychiatric Pharmacy Practice, including Psychopharmacologic Research. Co-funded by The University of Texas at Austin and San Antonio State Hospital. This is an accredited program with The American Society of Hospital Pharmacists (since 1981).
July 1978 – 2005	Psychiatric Pharmacy Residency incorporated into the 3 year Pharm.D. option at The University of Texas.

PROFESSIONAL SOCIETIES MEMBERSHIPS AND APPOINTMENTS:

The International Society for CNS Clinical Trials and Methodology (ISCTM) Founding Member, 2005

- Chair BPSD Working Group 2015 – Present
- Elected Board and Officer (Secretary and Treasurer) 2006 – 2013
- Scientific Program Committee 2006 – Present
- Chair, Finance Committee 2009 – 2014
- Member Finance Committee 2014 – Present

Foundation of the College of Psychiatric and Neurological Pharmacists

- Founding sponsor and Board Member, 2011-2014

American Society for Clinical Psychopharmacology (ASCP), 2005 ongoing member
Collegium Internationale Neuro-Psychopharmacologicum (CINP), 2000 ongoing member
College of Psychiatric and Neurological Pharmacists (CPNP) Founding Member 1995
Additional Professional Societies Memberships and Appointments available upon request

SCHOLARLY ACTIVITIES AND PRESENTATIONS:

Invited Presentations

1. January 2016: New Era of Drug Development in Central Nervous System Disorders. Presented at the PAREXEL India Symposium, Overcoming failure rates of drugs for CNS. Mumbai, India

2. December 2015: Brett English, Larry Ereshefsky (participant), Integrating fMRI into Early Development Clinical Trials. Presented at the Pennington Scientific Symposium, fMRI in Clinical Trials: State of the Science and Future Directions. Baton Rouge LA

3. June 2015: Part 2: New Approaches to Drug Development: Neurocircuitry Based Strategies Inspired by the Research Domain Criteria (RDoC) Initiative. CPNP University, (https://cpnp.org/ed/university/course/new-approaches-drug-development-neurocircuitry-based-strategies-inspired-0)

4. April 2015: Part 1: New Approaches to Drug Development: Neurocircuitry Based Strategies Inspired by the Research Domain Criteria (RDoC) Initiative. CPNP Annual Meeting. Tampa FL

5. March 2015: Robert Alexander (presenter), Larry Ereshefsky PharmD, BCPP (senior author). AZD3293, a novel BACE1 inhibitor: Pharmacokinetics, pharmacodynamics and safety/tolerability in healthy subjects and patients with Alzheimer's disease. Presented at the AD/PD Conference, Nice, France.

6. August 2015: Co-chair with Luca Panni, Workshop Leader, Behavioral and Psychiatric Symptoms of Dementia, ISCTM Fall Meeting, Amsterdam, Netherlands.

7. February 2015: Chairman Workshop Leader, Behavioral and Psychiatric Symptoms of Dementia, ISCTM 11th Annual meeting, Washington DC.

8. February 2015: PAREXEL Advisory Summit: Current and Future State of CNS Drug Development. Neurocircuity strategies to De-risk CNS POC. Waltham MA.

9. March 2014: CNS Early Phase Development Webinar, sponsored by FierceBiotech: What is the Problem with Early Phase CNS studies? Webcast scheduled for 62 minutes with Larry Ereshefsky, Michael Detke, and Elliot Ehrich.
Use of CNS biomarkers in early clinical trials
CNS imaging technologies in early phase studies
Clinical trial design and monitoring
Case Studies

Additional Invited Presentations available upon request

SCHOLARLY ACTIVITIES AND PRESENTATIONS (*continued*):

Accepted Papers – Research, Pharmacy and Medical Associations (Posters and Platform presentations)

1. Cohen, E. A., Hassman, H. H., Walling, D. P., Hoover, S., Wyka, K., Ball, R. R., Joseph, A. V., Lobb, J. M., Hazzard-Randolph, D., Ereshefsky, L. (2018, November). A first-time investigation of a subject intervention to reduce the placebo and nocebo effects: A multicenter, randomized, single-blind, all placebo study of a Placebo-Control Reminder Script for subjects with Major Depression. Poster presented at the Annual Meeting of the CNS Summit Conference, Boca Raton, FL.

2. May 2017: Kokuvi Atsou, Larry Ereshefsky, Clement Francois, Françoise Diamand, Melanie Brignone, Lisa Mucha, Natalya Danchenko. Cost-Effectiveness Evaluation of Vortioxetine in Patients With Major Depressive Disorder, Assessing the Effects of Cognition on Switching From First Antidepressant Therapy in the United States. ISPOR-US 22nd Annual International Meeting. Boston MA

3. March 2017: Kokuvi Atsou, Larry Ereshefsky, Clement Francois, Françoise Diamand, Melanie Brignone, Lisa Mucha, Natalya Danchenko. Cost-Effectiveness Evaluation of Vortioxetine in Patients With Major Depressive Disorder Switching From First Antidepressant Therapy in the United States. AMCP Managed Care & Specialty Pharmacy Annual Meeting Denver CO.

4. December 2016: John Alam, Hakop Gevorkyan, Stanford Jhee, Noel Alaka, Larry Ereshefsky. Clinical pharmacology study of p38 alpha MAP Kinase Inhibitor, Neflamapomid (VX-745), in Mild Cognitive Impairment Due to Alzheimer's Disease (AD) or Mild AD. Pending at the 8th Annual Trials on Alzheimer's Disease (CTAD). San Diego, CA.

5. September 2016: Karl Johe, Larry Ereshefsky, Brett English, Jack Johnstone, Lev Gertsik, Maurizio Fava, Marlene Freeman. Pharmacokinetics and Safety of NSI-189 in Healthy Subjects: First in Human Single Ascending Dose and Food Effect Study. American College of Clinical Pharmacology, ACCP Fall meeting. Bethesda, MD.

6. June 2016: Michael J. Detke, Gerald Koelsch, Larry Ereshefsky, John Ng, Raymond Ng, Geoffrey Bilcer, Terence A. Kelly. Preclinical and Initial Clinical Characterization of APN1125, an α7 nicotinic Acetylcholine Receptor Partial Agonist for the Treatment of Cognitive Disorders. Annual American Society of Clinical Psychopharmacology (NCDEU/ASCP). Scottsdale, AZ.

Additional Accepted Papers – Research, Pharmacy and Medical Associations (Posters and Platform presentations) available upon request

PUBLICATIONS:

Articles (peer reviewed)

1. Malú Tansey, Lori Eidson, George Kannarkat, Christopher Barnum, Jianjun Chang, Jae Gwon Chung, Chelsea Caspell-Garcia, Peggy Taylor, Brit Mollenhauer, Michael Schlossmacher, Larry Ereshefsky, Mark Yen, Catherine Kopil, Mark Frasier, and Vicki Hertzberg. Candidate inflammatory biomarkers display unique relationships with alpha-synuclein and correlate with measures of disease severity in subjects with Parkinson's disease, in press, npj Parkinson's Disease. 2017 (reference number: NPJPARKD-00142)

2. Matthew E. Kennedy, Andrew W. Stamford, Xia Chen, Kathleen Cox, Jared N. Cumming, Marissa F. Dockendorf, Michael Egan, Larry Ereshefsky, Robert A. Hodgson, Lynn A. Hyde, Stan Jhee, Huub J. Kleijn, Reshma Kuvelkar, Wei Li,, Hong Mei, John Palcza, Jack D. Scott, Michael Tanen, Matthew D. Troyer, Jack Tseng, Julie A. Stone3 Eric M. Parker and Mark Forman. The BACE1 inhibitor verubecestat (MK-8931) reduces CNS β-amyloid in animal models and in Alzheimer's disease patients. Science Translational Medicine 02 Nov 2016: Vol. 8, Issue 363, pp. 363ra150 DOI: 10.1126/scitranslmed.aad9704

3. Gvido Cebers; Robert C Alexander; Samantha Budd Haeberlein; David Han; Ronald Goldwater; Larry Ereshefsky; Tina Olsson; Naidong Ye; Laura Rosen; Muir Russel; Justine Maltby; Susanna Ekejall, Alan R Kugler;. AZD3293: Pharmacokinetic and pharmacodynamic effects in healthy subjects and patients with Alzheimer's disease. Brain (in press Oct 2016)

4. Fava M, Johe K, Ereshefsky L, Gertsik LG, English BA, Bilello JM, LThurmond LM, Johnstone J, Dickerson BC, Makris N, BHoeppner BB, Flynn M, Mischoulon D, Kinrys G, and Freeman MP. A Phase 1B, randomized, double blind, placebo controlled,multiple-dose escalation study of NSI-189 phosphate, a neurogenic compound, in depressed patients. Molecular Psychiatry advance online publication, 8 December 2015; doi:10.1038/mp.2015.178

5. Patrick C. May, Brian A. Willis, Stephen L. Lowe, Robert A. Dean, Scott A. Monk, Patrick J. Cocke, James E. Audia, Leonard N. Boggs, Anthony R. Borders, Richard A. Brier, David O. Calligaro, Theresa A. Day, Larry Ereshefsky, Jon A. Erickson, Hykop Gevorkyan, Celedon R. Gonzales, Douglas E. James, Stanford S. Jhee, Steven F. Komjathy, Linglin Li, Terry D. Lindstrom, Brian M. Mathes, Ferenc Martenyi, Scott M. Sheehan, Stephanie L. Stout, David E. Timm, Grant M. Vaught, Brian M. Watson, Leonard L. Winneroski, Zhiiang Yang, and Dustin J. Mergott. The Potent BACE1 Inhibitor LY2886721 Elicits RobustCentral Ab Pharmacodynamic Responses in Mice, Dogs, and Humans. Journal of Neuroscience, January 21, 2015 • 35(3):1199 –1210.

6. English BA, Thomas K, Johnstone J, Bazih A, Gertsik L, Ereshefsky L. Use of translational pharmacodynamics biomarkers in early-phase clinical studies for schizophrenia. Biomarkers Medicine (2014) 8 (1), 29-49

Additional Articles (peer reviewed) available upon request

BOOKS:

Photographic contributor "Moon Handbooks Jerusalem & the Holy Land, including Tel Aviv & Petra". This book will be published by Avalon Travel in January 2014.

Jhee SS, Rosenthal MH, Moran S, Ereshefsky L. Accelerating Global Drug Development: The Science and Practice of Ethnobridging.
Torrance: Classic Litho & Design, 2006.

Chapters, Brochures and Videos/DVDs

Ereshefsky L. Position Paper: Bioequivalence Study Design Considerations for Paliperidone Palmitate IM Suspention. PAREXEL submit to the FDA, January 2014.

Simon G, Diamond D, Ereshefsky L. "The Problem of NonAdherence". Wyeth Pharmaceuticals, 2006. Cardinal Health DVD.

DeVane CL, Ereshefsky L, Saklad SR. "Understanding Drug-Drug Interactions in Depression". Wyeth Pharmaceuticals, 2005. Cardinal Health DVD.

Ereshefsky L. Effects of Different Routes of Antipsychotic Administration on Pharmacokinetics and Pharmacodynamics. J Clin Psych JCP Visuals. Eds. Marder SR, Davis JM, Ereshefsky L, WW Fleischhacker WW, Kane JM, and Schooler NR. May 2003, pp 5-6.

Ereshefsky L. Effects of Different Routes of Antipsychotic Administration on Pharmacokinetics and Pharmacodynamics. In: The role of long-acting antipsychotics in improving partial compliance with medication treatment. Special issue of JCP Visuals. Eds. Marder SR, Davis JM, Ereshefsky L, Fleichhacker WW, Kane JM, and Schooler NP. August 2002, pp 4-5.

Ereshefsky L, Symposia Highlights: "Increasing the Utilization of Long-Acting Antipsychotics: How do we get there from here?",, American College of Clinical Pharmacy 2002 Annual Meeting, pp 7-8.

Lieberman DZ, Casey DE, Crismon ML, Ereshefsky L, Special Report: Medication Management Considerations in Schizophrenia, MD Version, The George Washington University Medical Center, American Pharmaceutical Association December 2002, pp 1–17.

Crismon ML, Banerji MA, Casey DE, Ereshefsky L, Special Report: Medication Management Considerations in Schizophrenia, Pharmacist's Version, The George Washington University Medical Center, American Pharmaceutical Association December 2002, pp 1-17.

Stephen R Marder, MD, John M Davis, MD, Larry Ereshefsky, Pharm D, BCPP, W Wolfgang Fleischhacker, MD, John M Kane, MD, Nina R Schooler, PhD. Partial Compliance: The Need for Long-Acting Antipsychotics; (49 minutes of Audio CD) J Clin Psych, August 2002

Additional Books available upon request

MICROCOMPUTER AND WEB BASED PROGRAMS, INTERVIEWS:

Denise Myshko, Ereshefsky L, Evans R. Diagnosing CNS Diseases. PharmaVoice May 2016. http://www.pharmavoice.com/article/2016-05-cns-diseases/

Ereshefsky L. Depression On Line: Internet consultations in psychopharmacology, sponsored by Organon Inc (Sept 2000-June 2001).

Ereshefsky L. Today's Antidepressants: A Pharmacist's Perspective. ACPE Accredited Computer based Learning Program, Wyeth-Ayerst Laboratories, 1998.

Ereshefsky L. Education 2000, Update: The Management of Depression in the Elderly. An Interactive CD-ROM Program for Consultant Pharmacists, Medical Communications Media, Inc., 1996.

Glazer WM, Ereshefsky L. Depot Neuroleptic Therapy: Rationale and Treatment Strategies. A Self-Assessment Review. Computer program on CD-ROM with accompanying 150 page workbook, McNeil Pharmaceuticals, 1991.

Saklad SR, Ereshefsky L. Dosing simulator for depot neuroleptics. American Psychiatric Association Annual Meeting, New York City, and San Francisco, 1990 and 1993

Ereshefsky L. Pharmacy Simulations. Wheels for the Mind. Apple Consortium. 1986 (Spring).

STANDARDS DEVELOPED AND PUBLISHED:

*Ereshefsky L (Chair) and Clinical Practice Affairs Committee for American College of Clinical Pharmacy. Minimum Practice Standards for Clinical Pharmacy Specialists with Interpretation for Organized Health Care Settings. Drug Intell Clin Pharm. 1987;21:645-647.

*Ereshefsky L (Chair) and Committee for Standards, Psychopharmacy SIG. ASHP Supplementary Standard and Learning Objective for Residency Training in Psychiatric Pharmacy Practice. Am J Hosp Pharmacy. 1980;37:1232-4.

Ereshefsky L. Chairman Psychopharmacy SIG, ASHP. Practice Standards for Clinical Pharmacy Specialists in Psychiatry. 1983.

ABSTRACTS:

Robert Aleander, MD, Samantha Budd Haeberlin, PhD, Laura Rosen, MD Muir Russell, Alan Kugler, PhD, Gvido Cebers MD, PhD, Naidong Ye, PhD, tina Olsson, PhD, David Han, MD, and Larry Ereshefksy PharmD, BCPP AD/PD Conference, March 2015 (accepted)

ABSTRACTS (*continued*):

Preskorn S, Ereshefsk L, Chiu Y, Poola N, Loebel A. Effect of food on the pharmacokinetics of lurasidone: results of two randomized, open-label, crossover studies. Human Psychopharmacology Clinical Exp, June 2013. Published online in Wiley Online Library (wileyonlinelibrary.com).

Earvin Liang, Pamela Garzone, Jesse M. Cedarbau1, Martin Koller, Thao Tran, Victor Xu, Brian Ross, Stanford S. Jhee, Larry Ereshefsky, Aleksandra Pastrak,and Susan Abushakra. Pharmacokinetic Profile of Orally Administered Scyllo-Inositol (Elnd005) in Plasma, Cerebrospinal Fluid and Brain, and Corresponding Effect on Amyloid-Beta in Healthy Subjects. Journal of Clinical Pharmacology 2013: 2 (2), 186-194.

Ereshefsky L, Frasier M, Yen M, Jhee S, Marek K, Taylor P, Sherman M, Caspell C, Coffey C, Schlossmacher M, Sherer T. Diurnal and inter-subject variability of cerebrospinal fluid biomarkers, Abeta-40/42, alpha-synuclein and DJ-1 in healthy volunteers. Presented at Alzheimers Association International Conference (AAIC/ICAD) 2012, Vancouver, British Columbia, Canada. July 2012.

Dogterom P, Thomson F, Hargreaves R, Hamill T, Sur C, Uslaner J, Eddins D, Vardigan J, Jayaraman S, Morrow J, Kleijn HJ, Schipper J, Ereshefsky L, Jhee S, Schoepp D. Characterization of the relationship between target occupancy/modulation and preclinical/clinical responses for the glycine transporter 1 (GlyT1) inhibitor, Org 25935. Presented at The American College of Neuropsychopharmacology Meeting (ACNP), December 2011.

Vanover K, Davis RE, Ereshefsky L, Gertsik L, Ettekal AE, Mates S. Safety, Pharmacokinetics and Early Signals for Efficacy with ITI-007, A Novel Investigational New Drug for the Treatment of Schizophrenia and Related Disorders. Presented at International Congress on Schizophrenia Research (ICOSR), Colorado Springs, April 2011. Schizophrenia Bulletin (2011) 37, Page 32, March 20115.

Carsten Hofmann, Alberati D, Banken L, Boetsch C, Ereshefsky L, Jhee S, Moran S, Martin-Facklam M, Backholer Z, Boutouyrie-Dumont B. Glycine Transporter Type 1 (GLYT1) Inhibitor RG1678: Proof of Mechanism of Action in Healthy Volunteers. Presented at International Congress on Schizophrenia Research (ICOSR), Colorado Springs, April 2011. Schizophrenia Bulletin (2011) 37, Page 306, March 2011.

Little J, DeMartinis N, Ereshefsky L, Rapaport M, Targum SD. Use of audio-digital recordings for external monitoring to improve subject selection in a schizophrenia trial. Poster presentation at NCDEU Submission Abstract # 358, Boca Raton, FL, June 2011.

Additional Abstracts available upon request

LETTERS, EDITORIALS:

Ereshefsky L. All Guidelines are Not the Same. Am J Health-Syst Pharm 1999; 56(18):1829.

Ereshefsky L. Drug Interactions with Venlafaxine. American Family Physician 1997; 56(8): 1964-1970.

Ereshefsky L. Update on Clozapine. ACCP Report, 1990.

Ereshefsky L, Wilcox R. New Conceptual Models of Schizophrenia: Diagnostic and Treatment Issues. Psychopharmacy Newsletter. 1988; 7:3-4.

Ereshefsky L. Progress Report of The Long Range Planning Committee. ACCP Report. 1988.

Ereshefsky L. Progress Report of The Clinical Practice Affairs Committee. ACCP Report 1987; 6:2-3.

Ereshefsky L. Application of Antipsychotic Pharmacokinetics to Patient Care. Psychopharmacy Newsletter 1986; 4:3-4.

Ward ME, Saklad SR, Ereshefsky L. Use of Lorazepam for Treatment of Aggressive Behavior in Schizophrenia. Am J Psychiatry. 1986;143 1195-6.

Ereshefsky L. Progress Report of The Clinical Practice Affairs Committee. ACCP Report 1986; :2-3.

Grothe DL, Ereshefsky L, Jann MW, Fidone G. Clinical Drug Interactions Between Neuroleptics and Opioids. Drug Intel Clin Pharmacy. 1986;20:75.

Ereshefsky L. Nomifensine: An Antidepressant With a Difference? Clinical Pharmacy 1985; 4:673-674.

Ereshefsky L. Buspirone's Advantages over Benzodiazepines Anxiolytics. Clinical Pharmacy 1984; 3(6):654-655.

Jann MW, Saklad SR, Ereshefsky L. Carbamazepine Treatment of Psychiatric Inpatients with Affective Symptoms. Drug Intel and Clin Pharm 1984; 18:81.

Ereshefsky L. Toxicities of Amoxapine. Clinical Pharmacy 1983; 2:104-108.

Ereshefsky L, Lehmann CR, Saklad SR. Refractory Patients and Loxapine. Am J Psychiatry 1982; 139:701-702.

Additional Letters, Editorials available upon request

BOOK REVIEWS:

Ereshefsky L. Clinical Pharmacology of Psychotropic Agents. (Ed) Hollister LE. Stanford Press, Palo Alto, 1984. Clinical Pharmacy 1984; 3:326.

Ereshefsky L. Current Developments in Psychopharmacology, Vol. 5 (Ed) Essman WB, Medical Scientific Books, NY, 1979. Drug Intel Clin Pharm. 1981;15:138-139.

Ereshefsky L. Psychopharmacology of Affective Disorders. (Ed) Paykel R, Oxford University Press, NY, 1979. Drug Intel Clin Pharmacy. 1979;13:701.

Ereshefsky L. Lithium in Medical Practice. (Ed) Johnson FN, Baltimore, University Park Press, NY, 1978. Drug Intel Clin Pharmacy. 1979;13:239.

EDITORIAL RESPONSIBILITIES AND BOOK EDITOR:

Referee responsibilities: American Journal of Psychiatry (since 1992), Schizophrenia Bulletin (since 2001), Biological Psychiatry (since 1986), Annals of Pharmacotherapy (since 1985), Journal Clinical Psychiatry (since 1989), Pharmacotherapy (since 1988), Psychopharmacology (since 1985), and Journal of Clinical Psychopharmacology (since 1985).

September 1994 - 2005: Editorial Board, Drug Therapy Perspectives, Adis press.

December 2000-2005: Editorial Board, Pharmacy Practice News.

August 2001-2004: Editorial Board, Current Psychiatry

July 1987 - 2002: Reviewer of Hospital Pharmacy.

March 2001: Guest Editor, Journal of Clinical Psychiatry, supplement on the Bioequivalence of Generic versus Branded Clozapine.

2001 – 2004: Editorial Board, TSHP Journal.

1999 – 2004: Editorial Board, T.E.N., The Journal of Pharmacoeconomic Outcomes and Decision Making

September 1994 - 1999: Editorial Board, Primary Psychiatry.

December 1998: Editor, Supplement to U.S. Pharmacists

1994 - 1998: Editor, Neural Network

1994 - 1998: Editorial Board, American Journal of Hospital Pharmacy

Additional Editorial Responsibilities and Book Editor available upon request

APPENDIX OF PROFESSIONAL EXPERIENCE:

A. Faculty Appointments

September 2003 – 2012: Adjunct Clinical Professor of Psychiatry, at The University of Texas Health Science Center at San Antonio.

September 1988-2003 (retired, 2003): Professor of Pharmacy, Psychiatry and Pharmacology, at The College of Pharmacy, The University of Texas at Austin and the Departments of Pharmacology and Psychiatry, The University of Texas Health Science Center at San Antonio. Held the Regent's Professorship in Psychiatric Pharmacy, at the College of Pharmacy.

September 1982-1988: Associate Professor of Pharmacy, Psychiatry and Pharmacology, at The College of Pharmacy, The University of Texas at Austin and the Departments of Pharmacology and Psychiatry, The University of Texas Health Science Center at San Antonio.

April 1978-2003: Member of the graduate faculty, The University of Texas at Austin.

September 1977-August 1982: Assistant Professor of Pharmacy, Psychiatry and Pharmacology at The College of Pharmacy, The University of Texas at Austin and The University of Texas Health Science Center at San Antonio.

July 1976-June 1977: Clinical Instructor, School of Pharmacy, University of Southern California.

B. University-related Appointments and Administrative Responsibilities

September 2005-present: Member of the College of Pharmacy's Dean's Advisory Council for Research and Education, The University of Texas at Austin.

September 2002 – 2005: Member of the Center for Biomedical Neuroscience (CBN), University of Texas Health Science Center at San Antonio.

May 2002 – 2003: Accreditation Self-Study Committee on Mission, Goals & Systematic Planning, College of Pharmacy, The University of Texas at Austin.

September 1995-2003: Associate Director, Clinical Research Unit, San Antonio State Hospital.

July 1981-2003: Director of the Psychiatric Pharmacy Practice Program, College of Pharmacy, The University of Texas at Austin.

September 1989-2003: College Budget Council, College of Pharmacy, The University of Texas at Austin.

Additional Appendix of Professional Experience available upon request

TEACHING EXPERIENCE:

A. Teaching-Clinical

Provide staff inservice presentations and continuing education to research and medical personnel of PAREXEL International (2003-present). Inservice Training provided to Medical and Research Staff includes:

Interview techniques for Mental Status Examination\
Inter-rater reliability for PANSS and Simpson Angus rating scales training
Drug Interactions
Titration strategies for patients with schizophrenia
Psychopharmacology

Coordinated all aspects of psychiatric pharmacy practice training programs. Role model and structured supervision of clinical pharmacy residents, clinical sciences fellows, Pharm.D. students, and Baccalaureate pharmacy students. Case conferences, verbal and written examinations, video taped interactive sessions, rounds, and role play are used when appropriate. Facilities used as clinical training sites include:

San Antonio State Hospital	Audie Murphy Veterans Administration Hospital
San Antonio State School	Bexar County Mental Health and Mental Retardation Clinics
Brady Green Mental Health Clinic	Private practice sites in child psychiatry and adult psychiatry
Southwest Neuropsychiatric Institute	Bexar County Jail and Psychiatric Evaluation Unit
Villa Rosa Psychiatric Hospital	Alamo Mental Health Group
Wilford Hall U.S.A.F. Medical Center	South Texas Epilepsy Foundation Clinic

Internship Programs for Pfizer Pharmaceuticals, AstraZeneca and Bristol Myers Squibb: All day training program for CNS field force representatives on schizophrenia, antipsychotics, and health care delivery systems, 2001-2004.

B. Teaching Didactic

Graduate Coursework up through 2003:

a. Developed new coursework for the implementation of a Ph.D. in Clinical Pharmacy Sciences. Research Methodologies: Pharmacokinetic and Pharmacodynamic modeling are part of the 4-credit hour course in the approved program.

b. Course Coordinator and Developer of Graduate School coursework, Advanced Neuro- and Psychopharmacology, PHR 488U and PHR 289F.

c. Course Coordinator and Developer of PHR 285T, Advanced Pharmacotherapeutics and PHR 185U, Laboratory for Advanced Applied Therapeutics. 1994-present.

Additional Teaching Experience available upon request

POST-DOCTORAL COURSEWORK:

a. August 1992-2003: Course Coordinator and Developer of, Advanced Neuro- and Psychopharmacology, PHR 488U; also, clinical rotations for residents now are graduate experiential components with course credits assigned.

b. August 2000-2003: Co-coordinator of the Department of Psychiatry, PG-4 seminar on Neurophysiology.

c September 1989-1994: Coordinating faculty for Seminars in Psychopharmacology, team taught with Pharmacy and Psychiatry Faculty to Post-doctoral trainees in Psychiatric Pharmacy, Psychopharmacology, and Psychiatry.

d. September 1987-2003: Faculty for "Advanced Topics in Psychopharmacology", Department of Psychiatry Residency Program, UTHSCSA.

e. January 1985-1994: Annual 12-hour Psychopharmacology Series to psychiatric residents at Wilford Hall U.S.A.F. Medical Center.

f. July 1981-2003: Two-way teleconference seminars via microwave on advanced topics in psychopharmacology and psychiatric pharmacy practice between Austin and San Antonio residency training program.

OTHER COURSEWORK:

a. September 1999-2003: Consult and Liaison Attending rounds, WHAFMC and Department of Psychiatry, at University Hospital and VAH. Developed role for PharmD residents as a member of the C&L team.

b. September 1997-1999: Physical Therapy student Pharmacology Coursework for Psychiatric Disorders.

c. April 1978-1995: Nursing and Dental student Pharmacology Coursework, Case Conferences and Lectures to the Psychiatry and Psychology Residents and house staff at San Antonio State Hospital/State School.

d. July 1987-1992: Psychopharmacology Seminar Series for Texas Department of Mental Health and Mental Retardation, provided 9 hours of lecture which were professionally video-taped and now used to train all physicians within the state system. Periodic ComNet updates provided.

Psychopharmacy core 1977: Clinical lecturer, University of Southern California

INVESTIGATOR EXPERIENCE:

Anxiety Disorder

A 28-Day, Multicenter, Randomized, Placebo-controlled, Double-blind, Efficacy and Safety Study of XXX in Patients with Generalized Anxiety Disorder

A 4-Week, Double-Blind, Randomized, Multicenter, Fixed Dose, Placebo-Controlled, Parallel Group Study of XXX and XXX in Patients With Generalized Anxiety Disorder: Assessment of A New Instrument Intended to Capture Rapid Onset.

Alzheimer's Disease

XXX Augmentation of Cholinesterase Inhibitor Therapy in Patients with Alzheimer's Disease.

Long-term Safety and Efficacy of Open-label XXX, 80 mg b.i.d. in the treatment of probable Alzheimer's Disease: A 6-month follow-up after completion of study XXX .

A Multi-center, Randomized, Open-label Study Evaluating the Effects of XXX, 80 mg b.i.d., vs. XXX, 5 or 10 mg, on Adrenal Function in Patients with Mild Alzheimer's Disease.

A prospective, randomized, parallel-cohort, multicenter, 13-week, open-label comparative study of the effects of XXX, XXX, and XXX on CSF cholinesterase activity in patients with mild to moderate Alzheimer's disease.

A 24-week, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group Evaluation of the Efficacy, Safety, and Tolerability of the Once-daily XXX Patch Formulation in Patients with Probable Alzheimer's Disease (MMSE 10-20).

Post-text supplement: An Open-label, 28-week Extension to a 24-week, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled, Parallel-group Evaluation of the Efficacy, Safety, and Tolerability of the Once-daily XXX Transdermal Patch Formulation in Patients with Probable Alzheimer's Disease (MMSE 10-20).

An open-label, parallel group, dose proportionality study evaluating XXX 5 cm2, 10 cm2, 15 cm2, and 20 cm2 (FMI) transdermal patches and 1.5 mg, 3 mg, 4.5 mg and 6 mg b.i.d. capsules at steady state in patients with mild-to-moderate Alzheimer's Disease.

An 80-week, randomized, multi-center, parallel-group, double-blind study of the efficacy and safety of XXX 80 mg plus an acetylcholinesterase inhibitor versus an acetylcholinesterase inhibitor alone in the treatment of mild to moderate Alzheimer's disease.

Comparison of Serum and Cerebrospinal Fluid Pyruvate Concentrations in Subjects with Alzheimer's Disease (AD), Subjects with Mild Cognitive Impairment (MCI) and Healthy Elderly Subjects.

INVESTIGATOR EXPERIENCE (*continued*):

Single Dose Escalation Safety Study of XXX in Patients with Mild-Moderate Alzheimer's Disease.

A Dose-Ranging Placebo-Controlled Study of XXX at the doses of 0.5 mg, 2 mg and 8 mg for 12 Weeks in Patients with Mild-to-Moderate Alzheimer's Disease.

A Multicenter, Randomized, Third-Party Unblinded, Placebo-Controlled, Safety, Tolerability, and Pharmacokinetic Study of Single Ascending Doses of XXX in Patients With Mild To Moderate Alzheimer's Disease.

Bipolar Disorder

A 21-Day, Double-Blinded, Placebo-Controlled, Parallel-Group Evaluation of the Efficacy and Safety of XXX ER in the Treatment of the Manic Phase of Bipolar Disorder.

A Multicenter, Randomized, Parallel-group, Double-blind, Phase III Comparison of the Efficacy and Safety of XXX (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Lithium or Divalproex) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients.

Healthy

Protein Profiling of Plasma and Cerebrospinal Fluid in Healthy Subjects.

A Multiple-Dose, Dose-Escalation Study with XXX to Evaluate the Safety and the Pharmacokinetics of XXX and XXX in the Plasma and Cerebrospinal Fluid in Healthy Subjects.

A Randomized, Open-label, Crossover Study to Evaluate the Effect of Food on the Pharmacokinetics of XXX in Healthy Japanese Subjects.

Pharmacokinetic Evaluation of XXX in Healthy Volunteers.

Safety, Pharmacodynamic and Pharmacokinetic Study of Oral Single Doses of XXX in Healthy Young Male Japanese Volunteers and Their Matching Healthy Caucasian Male Volunteers (Double-Blind, Randomized, Placebo Controlled, Escalating Doses Study).

Safety,Pharmacodynamic and Pharmacokinetic Study of Oral Multiple Doses of XXX in Healthy Young Male Japanese Volunteers and Their Matching Healthy Caucasian Male Volunteers. Double-Blind, Randomized, Placebo Controlled, Escalating Doses Study.

INVESTIGATOR EXPERIENCE (*continued*):

Parkinson's Disease

A Randomized, Double-blind, Placebo-controlled, Multiple Oral Dose Escalation Study to Demonstrate the Safety, Tolerability, and Pharmacokinetics of XXX in Patients with Parkinson's Disease.

An open label, up-titration study to assess the dose proportionality of XXX CR and to demonstrate the bioequivalence of XXX CR (1 X 8 mg) compared to XXX CR (4 X 2 mg) in Parkinson's Disease patients not receiving other dopaminergic therapies.

An Open-Label, Multi-Site, Randomized Trial of the Pharmacokinetics and Cardiac Safety of XXX Transdermal Patch (18.0MG) in Subjects with Early-Stage, Idiopathic Parkinson's Disease.

An Open-Label, Multi-Site, Extension Trial to Assess the Long-Term Safety and Tolerability of XXX Transdermal Patch in Subjects with Early-Stage, Idiopathic Parkinson's Disease.

Schizophrenia

A Randomized, Double-Blind Study of the Safety and Efficacy of XXX ER plus an Atypical Antipsychotic vs. an Atypical Antipsychotic Alone in the Treatment of Schizophrenia

A Multicenter, Randomized, Double-Blind, Placebo Controlled Stydy of Three Fixed Doses of XXX in the Treatment of Patients with Acute Schizophrenia.

A Randomized, Double-Blind Comparison of the Efficacy and Safety of XXX Intramuscular Formula, XXX, or Placebo in the Treatment of Acutely Agitated Patients with a Diagnosis of Schizophrenia or Schizoaffective Disorder.

Assessment of the In Vivo Release Characteristics and Safety of an Intramuscular Depot Formulation of XXX in Subjects with Schizophrenia or Schizoaffective Disorder.

A Multicenter, Randomized, Double-Blind, Placebo Controlled Stydy of Three Fixed Doses of XXX in the Treatment of Patients with Acute Schizophrenia.

Insulin Sensitivity in Patients with Schizophrenia or Schizoaffective Disorder Treated with XXX and XXX.

An Open Label, Parallel Group, Randomised, Single Sequence Study to Characterise the Pharmacokinetics of XXX (200mg twice daily and 400mg once daily) Administered as Single and Repeat Doses for 14 days in Patients With Schizophrenia and Healthy Volunteers.

Pharmacokinetics, Tolerability, and Safety of Paliperidone after Repeated Intramuscular Injection of XXX in the Arm or Buttock of Subjects with Schizophrenia.

INVESTIGATOR EXPERIENCE (*continued*):

A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 and 100 mg-eq of XXX in Subjects With Schizophrenia.

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study With an Open-Label Extension Evaluating Extended Release XXX in the Prevention of Recurrence in Subjects With Schizophrenia.

An Open-Label Extension to study XXX (A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study With an Open-Label Extension Evaluating Extended Release XXX in the Prevention of Recurrence in Subjects With Schizophrenia).

A Randomized, Double-Blind, Placebo-Controlled, In-Patient and Multi-Center Trial with Two Sequential Cohorts, Each Receiving Repeating Doses and Dose Escalation Within Each Patient, to Evaluate the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of XXX in Sustained Release Formulation for the Treatment of Schizophrenic Disease.

A 6-week, multicenter, double-blind, randomized, placebo-controlled trial to assess the efficacy and safety of qd and bid dose regimens of up to 30 mg/day XXX versus placebo in subjects suffering from an acute exacerbation of schizophrenia.

A multicenter, double-blind, placebo-controlled, two-arm, flexible-dose efficacy and safety trial with XXX (250-750 mg b.i.d.) in subjects with acutely exacerbated schizophrenia.

A Four-Week Double Blind Multi-Center Study Comparing the Efficacy and Safety of XXX to XXX in Subjects With Schizophrenia or Schizoaffective Disorder Needing Inpatient Care.

A Double-Blind, Parallel, Multicenter Study to Assess the Effect of XXX, XXX, and Placebo on the QTc Interval in Patients with Schizophrenia.

A Double-Blind, Eight-Week, Placebo- and XXX-Controlled, Dose-Finding Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in the Treatment of Patients with Schizophrenia or Schizoaffective Disorder.

A Randomized, Double-Blind, Placebo-Controlled and XXX-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of XXX in the Treatment of Schizophrenia.

A Randomized, Double-Blind, XXX-Referenced, Parallel-Group Safety and Efficacy Study of Flexible Doses of XXX in the Long-term Treatment of Schizophrenia (Extension of Protocol XXX).

A Randomized, Double-Blind, Placebo-Controlled and XXX-Referenced, Parallel-Group Efficacy and Safety Study of Two Fixed Doses of XXX in the Treatment of Schizophrenia.

INVESTIGATOR EXPERIENCE (*continued*):

A Randomized, Double-Blind, XXX-Referenced, Parallel-Group Safety and Efficacy Study of Flexible Doses of XXX in the Long-term Treatment of Schizophrenia (Extension of Protocol XXX).

Other Indications

An Open-Label Study to Compare the Cytochrome P450-mediated Metabolizing Ability Among First and Third Generation Japanese Residing Outside of Asia and Caucasians.

A Study to Compare the Steady-State Pharmacokinetics, Safety and Tolerability of XXX in Children, Adolescents and Adults with Selected Psychotic Disorders.

An Exploratory Study of XXX Effects on Plasma and CNS Biomarkers of Norepinephrine Transporters (NET) Inhibition.

A Placebo-Controlled Study of the Electrophysiological Effects of Supratherapeutic Doses of XXX on the QT Interval

Double-Blind, Single-Rising-Dose Safety, Tolerability, Pharmacokinetic and Pharmacodynamic Study of XXX in Postmenopausal Women after Oral Administration of 50, 75, 100, 150, 200, 250, 300, 350 mg of XXX.

INVESTIGATOR INITIATED/CONTRACT STUDIES AT THE UNIVERSITY OF TEXAS:

Ereshefsky L and Miller A (PI), Co-Investigators: Jerry G. Olsen, M.D., Albana Dassori, M.D., Marisa Flores, B.A., Michael Butler, Recruiter, Rochelle Javors, B.S., Regina Tabor, R.Ph., Joseph Peters, Research Coordinator, Pharmacokinetics, Tolerability and Safety of Paliperidone after Repeated Intramuscular Injection of Paliperidone Palmitate (R092670) in the Arm or the Buttock of Subjects with Schizophrenia, Protocol R092670-USA-3, Johnson & Johnson $364,900, 2003 – 05.

Ereshefsky L, Pharm D and Dassori A, M.D (PI), Co-Investigators Alexander L. Miller, M.D., Jerry G. Olsen, M.D., Faye Lytle, M.S., Miguel Herrera, LVN, Michael E. Butler, Recruiter, Efficacy of High Dose Olanzapine in a Controlled Fixed Dose-Response Trials for the Treatment of Schizophrenia and Schizoaffective Disorder, Protocol F1D-US-HGLF, Lilly Research Laboratories $146,973, 2003 – 05.

Additional Investigator Initiated/Contract Studies at the University of Texas available upon request

Biosketch May, 2018
Larry Ereshefsky, Pharm.D., BCPP, FCCP
Follow the Molecule: CNS Consulting LLC
Chief Scientific Officer, Early Phase Development: Hassman Research Institute, LLC
Chief Scientific Officer, Early Phase Development: Collaborative Neuroscience Network, LLC
Retired Professor: The University of Texas Health Science Center

Larry Ereshefsky over his 40 years' career applies his experience as a clinician, scientist and investigator, to develop treatments and innovate clinical methodologies to make a difference in the lives of patients with Neurodegenerative and Psychiatric Disorders. He has contributed significantly to several drug approvals spanning neurology and psychiatry, including drug development planning, PK/PD evaluation, and methodological innovation for Parkinson's (PD) and Alzheimer's Diseases (AD), as well as numerous psychiatric indications including Schizophrenia, TRD, Bipolar and Anxiety Disorders. He has designed, implemented, supervised, and conducted more than 80 CNS clinical trials ranging from first into patient through to proof of concept, implements Asian Bridging strategies, and oversees large global Phase III registration trials. He is a leader in the use of signal detection strategies to minimize placebo response and insuring study designs preserve statistical power while preserving the blinding. Larry has a proven track record as an investigator, translational CNS scientist, and clinical advisor in designing and performing Phase I/IIA and clinical pharmacology studies.

He is a retired Regents Professor of Pharmacy, Psychiatry, and Pharmacology from The University of Texas/UT Health Science Center (UT). Subsequently, he was the CSO and Exec VP for California Clinical Trials, acquired by PAREXEL International where his role was VP, Principal Pharmacologist and Therapeutic Area Leader for CNS Early Phase with Global responsibilities. Throughout he continued as a clinical investigator actively involved in supporting the study teams at CCT and PAREXEL's research facilities in Southern California, Baltimore, London, Berlin, and Bloemfontein. Currently, he is the owner of Follow the Molecule: CNS Consulting, providing services to pharma, CROs, and technology vendors. He is a consultant for a number of pharma, as well as supporting clinical research sites (ProScience Research Group's later phase psychiatry programs, as well as Chief Scientific Officer, Early Phase Development, for Hassman Research Institute and CNS Network).

He has been a leader in the application of translational drug development tools including neurocircuitry/biomarker based (RDoC) strategies, i.e., continuous CSF sampling, QEEG, ERP, PSG, sMRI, fMRI, PET, and cognitive and behavioral paradigms. He has worked with Michael J Fox Foundation on validating inflammatory markers and alpha-synuclein in PD, and with Washington University and the NIH in validating CSF Amyloid and Tau targets, including publishing data on most of the targets now in development for AD, i.e., beta-, gamma-secretase inhibitors, small molecules targeting a variety of inflammatory and protein trafficking pathways, as well as experience with several neurotrophic active compounds. He has extensive experience with antibody, immunological modulation, and other large molecule strategies for AD, PD, and MS. He has particular expertise and skill in supporting complex, integrated (umbrella) and adaptive Phase I-II studies, including extensive experience using enriched and first generation Asian population and biomarker strategies. He was an early investigator of CYP studies evaluating ethnicity and drug-drug interactions, as well as glucose-insulin clamp/metabolic studies for atypical antipsychotic safety evaluations.

He was head of the UT laboratory applying the pharmacogenetics and pharmacokinetics of drugs to improve dosing and outcomes, and sub-investigator on *in vitro* and animal neuropharmacology studies. Credentialed as a clinical specialist for patient care and served as a Principal Investigator in over 50

clinical trials (sub-I in an additional 70). Dr. Ereshefsky's unique perspective helps to guides preclinical development, PK/PD modeling, and clinical drug development plans informed by animal behavioral markers, and safety signals. He efficiently de-risks early phase drug development.

He served twice on the FDA Psychopharmacological Drugs Advisory Committee. His PharmD and Residency in Psychopharmacology and Clinical Pharmacy were at the University of Southern California and LA County Medical Center. His first grant support, while an undergraduate at UCLA, was from the Atomic Energy Commission studying the kinetics of organic Cobalt compounds.

Larry Ereshefsky, Pharm.D., F.C.C.P., B.C.P.P.