

CURRICULUM VITAE

ROBERT W. BAKER, M.D.

CURRENT POSITION: Vice President, Clinical Program Design

9/19 - present

- The senior cross-functional/cross-therapeutic area role to oversee and lead innovation in design of clinical development programs and protocols
- Chairs council of Lilly's senior development leaders. Responsible to advise Lilly Executive Committee's decisions for product commercialization or major development investment
- Leader of Lilly's Exploratory Medicine and Pharmacology (EMP) and direct supervisor of EMP Senior Medical Director and Senior Director of Operations
 - EMP designs and implements Lilly's Phase 1 studies, Biopharmaceutical studies, and (in partnership with the Early Phase Therapeutic Medical teams) most phase 2 work up to proof of concept. EMP includes a large Lilly-owned and run inpatient and outpatient clinic in Singapore, dedicated to early phase research
- Leader of Lilly's Design Hub and direct supervisor of Senior Directors of its Therapeutic Area sleeves (Diabetes, Neuroscience, Immunology, Oncology) and Design Hub Foundation Senior Director (program/protocol infrastructure support, business analytics, co-labs, and design innovation). Dotted line supervisor to advanced analytics and clinical design statistics teams
 - Design hub is integral to clinical development at Lilly. It is a co-located, cross-functional, integrated team dedicated to improving clinical development expertise and leading development innovation. The hub provides high-contrast options for all development programs and designs and authors all clinical protocols for Phase 2-3 studies at Lilly (with input from product development teams). In addition to developing the protocols, the design hub is responsible for the associated complete trial package (e.g., investigators' brochures, investigator selection, clinical laboratory plans).
- Stand in for Lilly's Chief Medical Office if required due to CMO travel/vacation

11/17 – 8/19

Vice President
Clinical Pharmacology

- Direct supervisor of Clinical Pharmacology Senior Medical Directors/Therapeutic Area Leaders (now renamed as Exploratory Medicine and Pharmacology)

REVISED NOVEMBER 2019

- 11/17 – 8/19 Vice President
Design Hub
- Leader of Lilly’s Design Hub and direct supervisor of Senior Directors of three Therapeutic Area sleeves (Diabetes, Neuroscience, Immunology) and Design Hub Foundation Senior Director. Dotted line supervisor to advanced analytics and clinical design statistics teams
- 2/14 - 8/19: Vice President
Global Patient Safety
- Direct supervisor for Senior Director, Clinical Case Management; Senior Director, Surveillance, Senior Director, Pharmacoepidemiology; Senior Medical Director for Therapeutic Areas and Benefit-Risk Management (supervisor of the Senior Medical Directors); European Union Qualified Person for Pharmacovigilance, and Senior Medical Safety Fellows.
 - Oversees Lilly Safety System and Global Pharmacovigilance Processes and Regional Safety Centers (Indianapolis; Sao Paulo, Brazil; London, UK; Bengaluru, India; Kobe, Japan)
 - Accountable for safety core data sheet, determination of adverse drug reactions, and benefit-risk management for entire Lilly portfolio

PREVIOUS LILLY POSITIONS

- 11/12 – 1/14 Vice President, Global Medical Affairs
Lilly Bio-Medicines Business Unit
- Direct supervisor of Senior Medical Leaders of Lilly USA and Lilly Europe and Senior Medical Directors of Lilly Australia and Lilly Canada; Senior Director of Lilly medical affairs capabilities and Global Medical Information, and Medical Affairs chief operating officer; non-reporting supervision for Senior Medical Director of Lilly Japan
 - Accountable for medical affairs teams and strategies supporting Bio-Medicines products (Cardiovascular, Autoimmune Diseases, Osteoporosis, Men’s Health, Psychiatry, Pain Disorders, Alzheimer disease).
 - Led country-level medical organizations supporting Lilly portfolio and local safety/regulatory needs for US, Canada, Australia, New Zealand, and all European countries
 - Business Unit chair, Lilly Neuroscience Research and Development steering committee
- 10/08 – 10/12 Global Development Leader (Vice President)
Psychiatry and Pain Disorders Program
- Direct supervisor of Global Senior Medical Directors, Distinguished

Research Fellow, and Chief Operating Officers; oversight of their team of development physicians and scientists; indirect oversight and budget holder for teams (e.g., clinical operations, statistics, regulatory affairs, clinical pharmacology) and clinical trials supporting development

- Accountable for psychiatric disorder and pain disorder novel treatment development (e.g., pomaglumed, edivoxetine, Hypnion, galcanezumab) and global coordination/stewardship of marketed products (Prozac, Zyprexa, Symbiax, Strattera, Cymbalta).
- Lilly chair for Cymbalta partnerships (Boehringer Ingelheim, Shionogi)

4/08 – 9/08

Global Development Leader (Vice President)
Psychotic Disorders Program

- Direct supervisor of Global Senior Medical Director and Chief Operating Officer; oversight of their team of development physicians and scientists; indirect oversight and budget holder for teams (e.g., clinical operations, statistics, regulatory affairs, clinical pharmacology) and clinical trials supporting development
- Accountable for Psychotic Disorder novel treatment development (e.g., pomaglumed) and global coordination/stewardship of marketed products (Zyprexa, Symbiax).

11/06 – 3/08

Group Medical Director, Global Patient Safety

- Direct supervisor for Product Safety Medical Directors and Senior Medical Directors leading the physician/clinical research scientist teams accountable for product-level pharmacovigilance, safety assessment (adverse drug reaction determination), benefit-risk management, and product core data sheet safety content for all Lilly products in clinical development and/or on the market globally. Accountable for design and implementation of scientific safety processes within the recently formed Global Patient Safety organization.

4/05 – 10/06

Medical Director, US Neurosciences
U.S. Medical Division

- Direct supervisor for Neuroscience Associate Medical Directors and Research Manager.
- Oversight of all US Neuroscience physicians, clinical research scientists, clinical project management associates, and clinical development associates responsible for marketed products (Cymbalta, Prozac, Strattera, Symbiax, Zyprexa). Strategic (non-supervisory) leadership for US Neuroscience statisticians, writers, medical information associates, outcomes scientists, and medical liaisons. Responsible for US

Neuroscience medical strategy and activities including clinical plan development, budget, execution; all US Phase 4 strategy, study design, execution, and publication; US execution of global Phase 2/3 studies; Promotional material medical review; and US Medical Affairs for Neuroscience.

5/03-3/05 Associate Medical Director, US Neurosciences
(promoted 1/04 from Senior CRP to Medical Fellow I)
U.S. Medical Division

Direct supervisor for physicians and clinical research scientists responsible for US medical support to Symbyax and Zyprexa.

9/99-4/03 Clinical Research Physician/Senior Clinical Research Physician
(promoted 1/02)
U.S. Medical Division

US Medical Affairs lead for Bipolar Disorder-associated indications for the atypical antipsychotic olanzapine, for design/conduct of phase 4 studies; also part time commitment to global product development team, designing/executing Phase 3 studies and US/Global submissions for Bipolar Mania and Maintenance indications.

PREVIOUS RELEVANT JOB EXPERIENCE (Non-Lilly)

ACADEMIC APPOINTMENTS:

1986-1988 Clinical Instructor of Psychiatry
Department of Psychiatry
University of Pittsburgh School of Medicine, Pittsburgh, PA

1988-1996 Assistant Professor of Psychiatry
Department of Psychiatry
University of Pittsburgh School of Medicine, Pittsburgh, PA

1997-1999 Associate Professor of Psychiatry and Pharmacology
Department of Psychiatry and Human Behavior
University of Mississippi Medical School, Jackson, MS

1999-2005 Clinical Associate Professor of Psychiatry (volunteer appointment)
Department of Psychiatry and Human Behavior
University of Mississippi Medical School, Jackson, MS

WORK ASSIGNMENTS:

- 1986-1989 Mayview State Hospital, Commonwealth of PA, Bridgeville PA
Attending Physician and Admissions Director (1987-89)
- 1989-1996 Western Psychiatric Institute and Clinic, Pittsburgh, PA
Director of Special Studies Center (Schizophrenia Research) at Mayview
State Hospital and Attending Psychiatrist WPIC Schizophrenia, Geriatric,
and Emergency Psychiatry Divisions
- 1996 EPICS Research Program Medical Director (Psychotherapeutic,
Cognitive, and Rehabilitative Research in Schizophrenia: Program
Director: Gerard Hogarty)
Western Psychiatric Institute and Clinic
Pittsburgh, PA
- 1997-1999 Adult Inpatient Psychiatric Services Director; Residency Training Director
(1998-9); and Clinical Psychopharmacology Research Director (1998-9)
University of Mississippi Medical Center, Jackson, MS

EDUCATION AND TRAINING

UNDERGRADUATE:

- 1976-1978 Northwestern University, Evanston, IL (Honors Program in Medical Education)
Degree: B.S. in Medical Sciences, 1980

GRADUATE:

- 1978-1982 Northwestern University Medical School, Chicago, IL
Degree: M.D., 1982

POSTGRADUATE:

- 1982-1983 Intern in Internal Medicine
University of Pittsburgh School of Medicine
Montefiore Hospital, Pittsburgh, PA
- 1983-1986 Resident in General Psychiatry
University of Pittsburgh School of Medicine
Western Psychiatric Institute and Clinic, Pittsburgh, PA

LICENSURE AND CERTIFICATION

MEDICAL LICENSURE:

- 1984 Commonwealth of Pennsylvania, license # MD-031571-E (inactive)
1996 State of Mississippi, license # 15116

CERTIFICATION:

- 1983 National Board of Medical Examiners
1987 Psychiatry, certificate # 29352
American Board of Psychiatry and Neurology
1991-2001 Added Qualifications in Geriatric Psychiatry, certificate # 17
American Board of Psychiatry and Neurology (10 year certificate)
1998-2008 Subspecialty in Addiction Psychiatry, certificate # 1445
American Board of Psychiatry and Neurology (10 year certificate)

SELECTED AWARDS AND HONORS

- 1981 Elected to Alpha Omega Alpha Medical Honor Society
1992 Exemplary Psychiatrist Award
National Alliance for the Mentally Ill
1998 Fellow
American Psychiatric Association
2004 Distinguished Fellow
American Psychiatric Association

SELECTED TASK FORCES/COMMITTEES/SERVICE (Non-Lilly)

EDITORIAL BOARD:

- 1998-1999 Associate Editor, The Journal of Psychotic Disorders: Reviews and Commentaries

OTHER SERVICE (selected):

1988- 2004	Examiner, Part II Psychiatry Certification Exam American Board of Psychiatry and Neurology
1992-1999	Member, Psychiatry Minor Committee for Part I Certification Exam American Board of Psychiatry and Neurology (prepare and select neurology questions for psychiatry board exam)
1997-1999	American Psychiatric Association Assembly Deputy Representative from the Mississippi Psychiatric Association
1997-1999	Executive Council Mississippi Psychiatric Association
1999- 2001	Member, Psychiatry Recertification Examination Committee American Board of Psychiatry and Neurology
1999	American Psychiatric Association Assembly Representative from the Mississippi Psychiatric Association
1999- 2005	Scientific Program Committee Council on Medical Education and Career Development American Psychiatric Association
1999- 2005	Symposia Subcommittee Scientific Program Committee American Psychiatric Association
2014	Clinical and Preclinical Development Committee Pharmaceutical Research and Manufacturers of America
2015-16	Clinical Chair, Clinical and Preclinical Development Committee Pharmaceutical Research and Manufacturers of America
2017-19	Workstream Leader, Interpretation of Pharmacovigilance Guidance And Regulations and member, Pharmacovigilance Steering Committee

MEMBERSHIPS IN PROFESSIONAL SOCIETIES

1979-1982	American Medical Student Association
1986-2012	American Psychiatric Association
1986-1996	Pennsylvania Psychiatric Association
1997-2005	Mississippi Psychiatric Association

2005-2012 Indiana Psychiatric Society

1998-1999 American Association of Directors of Psychiatry Residency Training

PUBLICATIONS:

PUBLISHED PEER-REVIEWED MANUSCRIPTS:

1. Zipursky RB, **Baker RW**, Zimmer B: Alprazolam withdrawal delirium unresponsive to diazepam: Case report. *J Clin Psychiatry* 46:344-5, 1985.
2. Conley RR, Schulz SC, **Baker RW**, Collins JF, Bell JA: Clozapine efficacy in schizophrenic nonresponders. *Psychopharmacol Bull* 24: 269-74, 1988.
3. Trzepacz PT, **Baker RW**, Greenhouse J: A symptom rating scale for delirium. *Psychiatry Res* 23:89-97, 1988.
4. Conley RR, **Baker RW**: Family response to improvement by a relative with schizophrenia. *Hosp and Community Psych* 41:989-901, 1990.
5. Birmaher B, **Baker R**, Kapur S, Quintana H, Ganguli R: Clozapine for the treatment of adolescents with schizophrenia. *J American Academy of Child and Adolescent Psychiatry* 31:160-164, 1992.
6. **Baker RW**, Chengappa KNR, Baird JW, Steingard S, Schooler N, Christ MA: Emergence of obsessive-compulsive symptoms during treatment with clozapine. *J Clin Psychiatry* 53:439-442, 1992.
7. Chengappa KNR, Shelton MD, **Baker RW**, Schooler NR, Baird J, Delaney J: The prevalence of akathisia in patients receiving stable doses of clozapine. *J Clin Psychiatry* 55:142-145, 1994.
8. Chengappa KNR, **Baker RW**, Kreinbrook SB, Adair D: Clozapine use in female geriatric patients with psychoses. *J Geriatric Psychiatry* 8: 12-15, 1995.
9. Chengappa KNR, **Baker RW**, Sirri C: The successful use of clozapine in ameliorating self mutilation in a patient with borderline personality disorder. *J Personality Disorders*, 9:76-82, 1995.
10. Chengappa KNR, **Baker R**, Pelucio M, Cole D: Recurrent pancreatitis on clozapine rechallenge. *J Psychopharmacology*, 9: 367-368, 1995.
11. John JP, Chengappa KNR, **Baker RW**, Gupta B, Mortimer MT: Assessment of changes in both weight and frequency of use of medications for the treatment of gastrointestinal symptoms among clozapine-treated patients. *Ann Clin Psychiatry*, 7: 119-125, 1995.
12. **Baker RW**, Ames D, Umbricht DSG, Chengappa KNR, Schooler NR: Obsessive-compulsive symptoms in schizophrenia: A comparison of olanzapine and placebo. *Psychopharmacol Bull*, 32: 89-93, 1996.

13. Chengappa KNR, Gopalani A, Haught MK, McChesney K, **Baker RW**, Schooler NR: The treatment of clozapine-associated agranulocytosis with granulocyte colony-stimulating factor (G-CSF). *Psychopharmacol Bull*, 32: 111-121, 1996.
14. Ames D, Wirshing WC, **Baker RW**, Umbricht DSG, Sun AB, Carter J, Schooler NR, Kan JM, Marder SR: Predictive value of eosinophilia for neutropenia during clozapine treatment. *J Clin Psychiatry* 57: 579-581, 1996.
15. **Baker RW**, Bermanzohn PC, Wirshing DA, Chengappa KNR: Obsessions, compulsions, clozapine, and risperidone. *CNS Spectrums* 2: 26-36, 1997.
16. Thompson J, Chengappa KNR, Good CB, **Baker RW**, Kiewe RP, Bezner J, Schooler NR: Hepatitis, hyperglycemia, pleural effusion, eosinophilia, hematuria, and proteinuria occurring early in clozapine treatment. *International Clinical Psychopharmacology* 13: 95-98, 1998.
17. Sanders RD, Forman SD, Pierri JN, **Baker RW**, Kelley ME, Van Kammen DP, Keshavan MS. Inter-rater reliability of the neurological examination in schizophrenia. *Schizophrenia Research* 29: 287-292, 1998
18. Ahmed S, Chengappa KNR, Naidu VR, **Baker RW**, Parepally H, Schooler NR: Clozapine withdrawal-emergent dystonias and dyskinesias: a case series. *J Clin Psychiatry*, 59: 472-477, 1998
19. Chengappa KNR, Sheth S, Brar JS, Parepally H, Marcus S, Gopalani A, Palmer A, **Baker RW**, Schooler NR: Risperidone use at a state hospital: A clinical audit 2 years after the first wave of risperidone prescriptions. *J Clin Psychiatry*, 60: 373-378, 1999
20. Rush CR, **Baker RW**, Wright K: Acute physiological and behavioral effects of oral cocaine in humans: A dose-response analysis. *Drug and Alcohol Dependence*, 55: 1-12, 1999
21. Rush CR, **Baker RW**, Wright K: Trazodone, zolpidem, and triazolam in humans: Acute behavioral effects and abuse potential. *Psychopharmacology*, 144: 220-233, 1999
22. Rush CR, **Baker RW**, Rowlett JK: Discriminative-stimulus effects of zolpidem, triazolam, pentobarbital, and caffeine in zolpidem-trained humans. *Experimental & Clinical Psychopharmacology*, 8:22-36, 2000
23. Rush CR, **Baker RW**: Zolpidem and triazolam interact differentially with a delay interval on a digit-enter-and-recall task. *Hum Psychopharmacol Clin Exp*, 16: 147-157, 2001
24. Rush CR, Essman WD, Simpson CA, **Baker RW**: Reinforcing and subject-rated effects of methylphenidate and d-amphetamine in non-drug-abusing humans. *Journal of Clinical Psychopharmacology*, 21: 273-86, 2001
25. Kane JM, Marder SM, Schooler NR, Wirshing WC, Umbricht D, **Baker RW**, Wirshing DA, Safferman A, Ganguli R, McMeniman M, Borenstein M: Clozapine and haloperidol in moderately refractory schizophrenia: a six-month randomized double blind comparison. *Arch Gen Psychiatry* 58: 965-72, 2001.

26. Rush CR, **Baker RW**: Behavioural pharmacological similarities between methylphenidate and cocaine in cocaine abusers. *Experimental and Clinical Psychopharmacology*, 9: 59-73, 2001.
27. Kennedy JS, Bymaster FP, Schuh L, Calligaro DO, Nomikos G, Felder CC, Bernauer M, Kinon BJ, **Baker RW**, Hay D, Roth HJ, Dossenbach M, Kaiser C, Beasley CM, Holcombe JH, Effron MB, Breier A: A current review of olanzapine's safety in the geriatric patient: from pre-clinical pharmacology to clinical data. *International Journal of Geriatric Psychiatry*, 16: S33-61, 2001.
28. Chengappa KN, Vasile J, Levine J, Ulrich R, **Baker R**, Gopalani A, Schooler R: Clozapine: its impact on aggressive behavior among patients at a state psychiatric hospital. *Schizophrenia Research*, 53:1-6, 2002
29. Tohen M, Chengappa KNR, Suppes TR, Zarate CA, Calabrese JR, Bowden CL, Sachs GS, Kupfer DJ, **Baker RW**, Risser RC, Keeter EL, Feldman PD, Tollefson GD, Breier A: Efficacy of olanzapine in combination with valproate or lithium in the treatment of mania in patients partially nonresponsive to valproate or lithium monotherapy. *Arch Gen Psychiatry*, 59: 62-69, 2002
30. **Baker RW**, Goldberg JF, Tohen M, Milton DR, Stauffer VL, Schuh LM: The impact of response to previous mood stabilizer therapy on response to olanzapine versus placebo for acute mania. *Bipolar Disorders* 4(1), 43-49, 2002.
31. Tohen M, **Baker RW**, Altshuler L, Zarate CA, Suppes T, Ketter TA, Milton DR, Risser R, Gilmore JA, Breier A, Tollefson GA: Olanzapine versus divalproex in the treatment of acute mania. [erratum appears in *Am J Psychiatry*. 2005 Feb;7(1):102] *Am J Psychiatry* 159(6): 1011-1017, 2002.
32. Rush CR, Kelly TH, Hays LR, **Baker RW**, Wooten AF. Acute behavioral and physiological effects of modafinil in drug abusers. *Behavioral Pharmacology* 13(2) 105-112, 2002.
33. **Baker RW**, Milton DR, Stauffer VL, Gelenberg A, Tohen M: Placebo-controlled Trials Do Not Find Association of Olanzapine with Exacerbation of Bipolar Mania. *J Affective Dis* 73: 147-53, 2003
34. Chengappa KNR, **Baker RW**, Shao L, Yatham LN, Tohen M, Gershon S, Kupfer D: Rates of response, euthymia, and remission in two placebo-controlled olanzapine trials for bipolar mania. *Bipolar Disorders* 5:1-5, 2003
35. **Baker RW**, Tohen M, Swann AC, Fawcett J, Risser RC, Schuh LM, Stauffer VL, Tollefson GD: Acute dysphoric mania: treatment response to olanzapine versus placebo. *J Clin Psychopharmacol* 23: 132-7, 2003
36. Tohen M, Ketter TA, Zarate CA, Suppes T, Frye M, Altshuler L, Zajecka J, Schuh LM, Risser RC, Brown E, **Baker RW**. Olanzapine versus divalproex sodium for the treatment of acute mania and maintenance of remission: a 47-week study. *Am J Psychiatry*, 160: 1263-1271, 2003

37. **Baker RW**, Kinon BJ, Maguire GA, Liu H, Hill AL. Effectiveness of rapid initial dose escalation of up to 40 mg per day oral olanzapine in acute agitation. *Journal Clinical Psychopharmacol* 23: 342-348, 2003
38. Baldessarini RJ, Hennen J, Wilson M, Calabrese J, Chengappa R, Keck PE Jr, McElroy SL, Sachs G, Vieta E, Welge JA, Yatham LN, Zarate CA Jr, **Baker RW**, Tohen M. Olanzapine vs. placebo in acute mania: treatment responses in subgroups. *J Clinical Psychopharmacology* 23: 370-376, 2003
39. Tohen M, Vieta E, Calabrese J, Ketter TA, Sachs G, Bowden C, Mitchell PB, Centorrino F, Risser R, **Baker RW**, Evans AR, Beymer K, Dubé S, Tollefson GD, Breier A. Efficacy of olanzapine and olanzapine-fluoxetine combination in the treatment of bipolar I depression [erratum appears in *Arch Gen Psychiatry*. 2004 Feb;61(2):176]. *Arch Gen Psychiatry*, 60: 1079-1088, 2003
40. Tohen M, Goldberg JF, Gonzalez-Pinto Arrillaga AM, Azorin JM, Vieta E, Hardy-Bayle M-C, Lawson WB, Emsley RA, Zhang F, **Baker RW**, Risser RC, Namjoshi MA, Evans AR, Breier A: A 12-week double-blind comparison of olanzapine versus haloperidol in the treatment of acute mania. *Archives Gen Psychiatry*, 60: 1218-1226, 2003.
41. Haga JL, **Baker RW**, Rush CR. Behavioral and physiological effects of cocaine in humans following triazolam. *Pharmacology, Biochemistry & Behavior*. 76(3-4):383-92, 2003
42. Shi L, Namjoshi MA, Swindle R, Yu X, Risser R, **Baker RW**, Tohen M. Effects of olanzapine alone and olanzapine/fluoxetine combination on health-related quality of life in patients with bipolar depression: A secondary analysis of a double-blind, placebo-controlled, randomized clinical trial. *Clinical Therapeutics*, 26:125-134, 2004.
43. Tohen M, Chengappa KNR, Suppes T, **Baker RW**, Zarate CA, Bowden C., Sachs GS, Kupfer DJ, Ghaemi SN, Feldman PD, Risser RC, Evans AR, Calabrese JR. Relapse prevention in bipolar I disorder: 18-month comparison of olanzapine plus mood stabiliser v. mood stabiliser alone. *British Journal of Psychiatry*. 184:337-45, 2004
44. Lindenmayer JP, Brown E, **Baker RW**, Schuh LM, Shao L, Tohen M, Ahmed S, Stauffer VL. An excitement subscale of the Positive and Negative Syndrome Scale. *Schizophrenia Research*. 68(2-3):331-7, 2004
45. Kinon BJ, Liu-Seifert H, Ahl J, Ahmed S, **Baker RW**. Longitudinal effect of olanzapine on fasting serum lipids: a randomized, prospective, 4-month study. *Annals of the New York Academy of Sciences*. 1032:295-6, 2004.
46. **Baker RW**, Brown E, Akiskal HS, Calabrese JR, Ketter TA, Schuh LM, Trzepacz PT, Watkin JG, Tohen M. Efficacy of olanzapine combined with valproate or lithium in the treatment of dysphoric mania. *British Journal of Psychiatry*. 185:472-8, 2004
47. Chengappa KNR, Hennen J, Baldessarini RJ, Kupfer D., Yatham LN, Gershon S, **Baker RW**, Tohen M. Recovery and functional outcomes following olanzapine treatment for bipolar I mania. *Bipolar Disorders*. 7(1):68-76, 2005

48. Zhu B, Tunis S., Zhao Z, **Baker RW**, Lage MJ, Shi L, Tohen M. Service utilization and costs of olanzapine versus divalproex treatment for acute mania: results from a randomized, 47-week clinical trial. *Current Medical Research & Opinion*. 21(4):555-64, 2005
49. Tohen M, Greil W, Calabrese JR, Sachs GS, Yatham LN, Oerlinghausen BM, Koukopoulos A, Cassano GB, Grunze H, Licht RW, Dell'Osso L, Evans AR, Risser R, **Baker RW**, Crane H, Dossenbach MR, Bowden CL. Olanzapine versus lithium in the maintenance treatment of bipolar disorder: a 12-month, randomized, double-blind, controlled clinical trial. *American Journal of Psychiatry*. 162(7):1281-90, 2005
50. Suppes T, Brown E, Schuh LM, **Baker RW**, Tohen M. Rapid versus non-rapid cycling as a predictor of response to olanzapine and divalproex sodium for bipolar mania and maintenance of remission: post hoc analyses of 47-week data. *Journal of Affective Disorders*. 89(1-3):69-77, 2005
51. Kennedy J, Deberdt W, Siegal A, Micca J, Degenhardt E, Ahl J, Meyers A, Kaiser C, **Baker RW**. Olanzapine does not enhance cognition in non-agitated and non-psychotic patients with mild to moderate Alzheimer's dementia. *International Journal of Geriatric Psychiatry*. 20(11):1020-7, 2005.
52. Micca J, Hoffmann VP, Lipkovich I, Ahl J, **Baker RW**, Hardy TA. Retrospective analysis of diabetes risk in elderly patients with dementia in olanzapine clinical trials. *American Journal of Geriatric Psychiatry*. 14(1):62-70, 2006 .
53. Tohen M, Calabrese JR, Sachs GS, Banov MD, Detke HC, Risser R, **Baker RW**, Chou JC, Bowden CL. Randomized, placebo-controlled trial of olanzapine as maintenance therapy in patients with bipolar I disorder responding to acute treatment with olanzapine. *American Journal of Psychiatry*. 163(2):247-56, 2006.
54. Perlis RH, Brown E, **Baker RW**, Nierenberg AA. Clinical features of bipolar depression versus major depressive disorder in large multicenter trials. *American Journal of Psychiatry*. 163(2):225-31, 2006
55. Williamson D, Brown E, Perlis RH, Ahl J, **Baker RW**, Tohen M. Clinical relevance of depressive symptom improvement in bipolar I depressed patients. *Journal of Affective Disorders*. 92(2-3):261-6, 2006
56. Perlis RH, **Baker RW**, Zarate CA Jr., Brown EB, Schuh LM, Jamal HH, Tohen M. Olanzapine versus risperidone in the treatment of manic or mixed states in bipolar I disorder: A randomized, double-blind trial. *Journal of Clinical Psychiatry*. 67 (11): 1747-53, 2006
57. Houston JP, Lipkovich IA, Ahl J, Rotelli MD, **Baker RW**, Bowden CL. Initial symptoms of manic relapse in manic or mixed-manic bipolar disorder: post hoc analysis of patients treated with olanzapine or lithium. *Journal of Psychiatric Research*. 41(7):616-21, 2007
58. Tamayo JM, Mazzotti G, Tohen M, Gattez WF, Zapata R, Castillo JJ, Fahrer RD, Gonzales-Pinto AM, Vieta E, Azorin JM, Brown E, Brunner E, Rovner J, Bonnett-Perrin E, **Baker RW**. Outcomes for Latin American versus White patients suffering from acute mania in a randomized, double-blind trial comparing olanzapine and haloperidol. *Journal of Clinical Psychopharmacology*. 27(2): 126-34, 2007
59. Piletz J, **Baker R**, Halaris A. Platelet imidazoline receptors as a state marker for depressive symptomatology. *Journal of Psychiatric Research*. 42 (1); 41-9, 2008

60. Ascher-Svanum H, Nyhuis AW, Faries DE, Kinon BJ, **Baker RW**, Shekhar A. Clinical, functional, and economic ramifications of early non-response to antipsychotics in the naturalistic treatment of schizophrenia. *Schizophrenia Bulletin*. 34(6) 1163-71, 2008
61. Spann M, Lindborg S, Seaman J, **Baker R**, Dunayevich E, Breier A. Bayesian adaptive non-inferiority with safety assessment: Retrospective case study to highlight potential benefits and limitations of the approach. *Journal of Psychiatric Research*, 2009 Feb;43(5):561-7. doi:10.1016/j.jpsychires.2008.07.009. Epub 2008 Sep 18.
62. Marder SR, Sorsaburu S, Dunayevich E, Karagianis JL, Dawe IC, Falk DM, Dellva MA, Carlson JL, Cavazzoni PA, Baker RW. Case reports of postmarketing adverse event experiences with olanzapine intramuscular treatment in patients with agitation. *J Clin Psychiatry*. 2010 Apr;71(4):433-41.
63. Schooler NR, Marder SR, Chengappa KN, Petrides G, Ames D, Wirshing WC, McMeniman M, Baker RW, Parepally H, Umbricht D, Kane JM. Clozapine and risperidone in moderately refractory schizophrenia: a 6-month randomized double-blind comparison. *J Clin Psychiatry*. 2016 May;77(5):628-34.

PEER-REVIEWED LETTERS:

1. **Baker RW**, Conley RR: Seizures during clozapine therapy. *Am J Psychiatry* 148:1265-1266, 1991.
2. **Baker RW**: Fluoxetine and schizophrenia in a patient with obsessional thinking. *Journal of Neuropsychiatry* 4:232-3, 1992.
3. Steingard S, Chengappa KNR, **Baker RW**, Schooler NR: Clozapine, obsessive symptoms, and serotonergic mechanisms. *Am J Psychiatry* 150:1435, 1993.
4. Chengappa KNR, **Baker RW**, Baird J: Iron for chronic and persistent akathisia? *J Clin Psychiatry* 54:320-321, 1993.
5. Chengappa KNR, **Baker RW**, Harty I: Seizures and clozapine dosing schedule. *J Clin Psychiatry* 55: 456, 1994.
6. **Baker RW**, Chengappa KNR: Further study of Neuroleptic Malignant Syndrome. *Am J Psychiatry* 152: 1831, 1995.
7. **Baker RW**: Possible dose-response relationship for risperidone in obsessive-compulsive disorder. *J Clin Psychiatry* 59: 134, 1998.
8. **Baker RW**, Chengappa KNR: Clozapine and gastro-esophageal reflux. *J Clin Psychiatry* 59: 257, 1998.
9. Singh, A; Twomey K; **Baker R**: Global pharmacovigilance regulations: Call for re-harmonization. *Clinical Trials* 15: 631-32, 2018.

NON-PEER-REVIEWED PUBLICATIONS:

Books:

Trzepacz PT, **Baker RW**, The Psychiatric Mental Status Examination, Oxford University Press, 202 pp., New York, 1993.

Also published as Portuguese Translation: Trzepacz PT, **Baker RW**, Exame Psiquiátrico do Estado Mental. Climepsi Editores, Lisbon, Portugal, 2001

Chapters:

1. Schulz SC, Kahn EM, **Baker RW**, Conley RR: Lithium and carbamazepine augmentation in treatment refractory schizophrenia. Chapter in The Neuroleptic Nonresponsive Patients: Characterization and Treatment: Angrist, B and Schulz SC. (Eds), pp. 109-136. American Psychiatric Press, Washington, 1990.

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