

MICHAEL MARKOWITZ, MD, MBA, MSPH

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PHARMACEUTICAL MEDICAL EXECUTIVE

Optimize Drug Development Through Integration of Clinical and Real World Evidence

Innovative medical research leader with expertise in clinical and health outcomes studies and impactful communication of results with important stakeholders. Known for building strong collaborations with external partners that maximize the patient perspective in drug development. Skilled presenter, educator, and mentor.

CORE COMPETENCIES

- **Therapeutic Areas of Expertise:** Neurology, Psychiatry, Pain Management, Gastroenterology
- **Medical Affairs:** medical director, medical liaison, publication planning
- **Clinical Development:** medical advisor, protocol design, safety monitoring, data analysis
- **Evidence Generation:** registries, observational data bases, real-world clinical studies, modeling
- **Benefit Risk Assessment and Patient Preference Studies**

EXPERIENCE

University of North Carolina, Chapel Hill, NC

2006-current

Adjunct Associate Professor, School of Public Health and School of Pharmacy

Course director and teacher for pharmaceutical health policy and drug development course. Teach additional independent study classes, serve as guest lecturer in several classes, mentor and advise students, participate in masters paper review committees.

Peachtree Bioresearch Solutions, Atlanta, GA

2023-current

Chief Scientific Advisor

- Leads and directs recruiting, developing, training, and retaining the medical and scientific team; ensures prioritization of activities and resourcing is in line with clinical development programs. Drives for operational excellence; fosters a collaborative, highly integrated culture
- Develops and maintains relationships with KOLs and other key medical experts. Collaborates with, and directs, internal and external medical, scientific and operational experts to keep abreast of industry standards; provides clinical operations strategic and technical perspective to decisions
- Drives the creation of department standards, systems, and processes across the trials; ensures compliance with regulatory and other applicable standards and guidelines
- Reviews enrollment data and competitive landscape for potential projects

Independent Medical Director Consultant

2022-current

Provide medical affairs, health outcomes, and clinical development medical consulting services to the biopharmaceutical industry including evidence generation activities, clinical trial and real world evidence study design and review, publication planning, medical liaison team functional design and management, benefit-risk assessment and patient preference study design and implementation.

JAZZ PHARMACEUTICALS, Cary, NC**2021-2022****Senior Director/Global Molecule Lead, Global Medical Affairs**

Oversee medical strategy for movement disorders franchise. Responsibilities include development and implementation of medical strategy, tactical plan, and evidence generation plan. Design and implement RWE studies to support development of Phase 2 asset in several indications. Coordinate KOL strategy, advisory boards, and steering committees. Medical lead on several cross-functional teams including : Global Molecule Team, Clinical Development Team, Commercial Strategy Team, Medical Core Team, and Publications Team.

THERAVANCE BIOPHARMA, Durham, NC**2019 – 2020****Executive Director, Head, Neurology Clinical Development**

Oversee a phase 3 rare disease clinical program in subjects with neurogenic orthostatic hypotension who have **Parkinsons** Disease, MSA, or PAF. Responsibilities include: protocol development, regulatory responses, medical and safety oversight, strategic plan for life cycle development and management of a team of nine physicians and scientists.

UCB BIOSCIENCES, Raleigh, NC**2013 – 2019****Head of Physician Faculty**

2017 – 2019

Promoted to oversee professional development, training, governance, recruitment, and medical ethics / health policy initiatives for 200+ UCB physicians world-wide including all functional and therapeutic areas. Headed UCB / UNC / Duke Neurology Drug Development Fellowship program. Directed Quantitative Benefit-Risk and Preference Study Initiative. Reported to Vice President of Clinical Development and Medical Affairs.

- Initiated training and professional development program for physicians, contributing to 50% reduction in turnover the following year.
- Designed and directed novel clinical development fellowship for neurology clinical development – 1 of only 2 known in the US.
- Developed interactive HR database that identified physician pharmaceutical and clinical expertise, facilitating optimized, efficient utilization of company physician's skill sets

Medical Director, CNS Clinical Development

2013 – 2016

Served as lead physician for Parkinson's Disease program providing medical oversight and strategic input into clinical trial design and implementation. Chaired safety signal detection team and core member of the benefit-risk and data generation teams. Developed Patient Preference Study capacity at UCB.

- Led medical oversight as study physician for novel Parkinson's disease biosensor proof of concept study.
- Developed and implemented multi-functional Patient Preference Study Initiative at UCB, resulting in a broad educational initiative, the implementation of several studies, and incorporation of preference study and quantitative benefit-risk consideration at many high-level corporate committees.

JOHNSON & JOHNSON, Titusville, NJ**2001 – 2013****Director, CNS Epidemiology and Medical Affairs**

2010 – 2013

Managed and designed epidemiology and outcomes studies including post-hoc clinical trial analyses, observational data base analyses, benefit-risk analyses, and preference studies. Authored more than 15 posters and 7 manuscripts published in leading peer-reviewed scientific journals.

- Developed and led projects focusing on structured benefit-risk analysis and preference studies for a novel psychiatry product, resulting in 4 publications and multiple presentations at scientific conferences.
- Led pharmacovigilance working team that established new safety processes for investigator-initiated trials and observational studies.
- Started Epidemiology function within Medical Affairs to employ rigorous methodologies on medical affairs studies that addressed important strategic data gaps.
- Epidemiologist for Alzheimer's Disease program for Bapineuzumab. Designed instruments for trials focusing on co-morbidities and lifestyle factors as well as risk factor modelling.

Regional Scientific Director, Medical Affairs: CNS, Pain, Internal Medicine

2001 – 2009

Managed all strategic and operational functions of field medical teams in CNS, Internal Medicine, and Managed Care. Responsibilities included personnel decisions, mentoring, budget management, development of metrics and management of health care compliance policies. Provided strategic direction for investigator-initiated trials process.

- Spearheaded field medical launches for tramadol ER (pain), Risperdal Consta (schizophrenia), and Ionsys (pain).
- Co-led start-up of 50-person Internal Medicine MSL team that supported new Cardiovascular product.
- Developed innovative process that improved efficiency and effectiveness of scientific conference activities for medical staff.
- Developed Alzheimer's key opinion leader support, facilitated investigator initiated trials, and provided disease specific and product training for Alzheimer's Disease product Razadyne.

GLAXO WELLCOME, Research Triangle Park, NC**1997 - 2001****Senior Clinical Research Physician, GI Medical Affairs**

1999 – 2001

Served as medical advisor for 1st Irritable Bowel drug responsible for protocol design, clinical study implementation, promotional review, MSL and sales rep training, and strategic design of phase 3B/4 clinical trials.

- Developed and managed Glaxo Wellcome / academic collaborative IBS advisory board which resulted in several published health outcomes manuscripts.
- Chaired company-wide GI publication / communication committee, leading to prestigious commercial strategy award.
- Launched first irritable bowel (IBS) drug.
- Developed and led first IBS patient registry.

Senior Regional Medical Scientist, CNS Medical Affairs

1997 – 1999

EDUCATION

Preventive Medicine Residency, University of North Carolina, Chapel Hill, NC

Medical Internship, St. Vincent Medical Center, Indianapolis, IN

Pharmacoeconomics Post-doctoral Fellow, University of North Carolina, NC

Medical Doctor (MD), University of Illinois, Medical Scholar's Program

Master of Business Administration (MBA), University of Illinois Medical Scholars Program, Urbana, IL

Master of Science in Public Health (MSPH), Health Policy / Admin, University of North Carolina, Chapel Hill, NC

Bachelor of Arts (BA), Political Science, Carleton College, Northfield, MN

CERTIFICATION, LICENSURE

NC Medical License

Board Certification, Preventive Medicine

PROFESSIONAL SOCIETY MEMBERSHIPS/ACADEMIC APPOINTMENTS

- Academy of Pharmaceutical Physicians and Investigators: **board of trustees** (2005 – 2009)
- Association of Clinical Research Professionals **education committee member** (2006–2010)
- American College of Preventive Medicine (2009 – 2014)
- International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (2018-): **academic advisory council**
- **University of North Carolina, School of Public Health, Adjunct Associate Professor (2006-current)**
- **University of North Carolina, School of Pharmacy, Adjunct Associate Professor (2010-current)**

PEER REVIEWED ARTICLES

- Boroojerdi B, Ghaffari R, Mahadevan N, Markowitz M, et al. Clinical feasibility of a wearable conformable sensor patch to monitor symptoms in Parkinson's Disease. *Parkinsonism and Related Disorders*. Nov 2018. <https://doi.org/10.1016/j.parkreldis.2018.11.024>.
- Effects of using a wearable device on clinical decision making and motor symptoms in patients with Parkinson's Disease starting transdermal rotigotine patch: a pilot study. Isaacson S, Boroojerdi B, Waln O. et al. *Parkinsonism and Related Disorders*. Jan 28, 2019. <https://doi.org/10.1016/j.parkreldis.2019.01.025>.
- Muller T, Tolosa E, Badea L, Asgharnejad M, Grieger F, Markowitz M, et al. An Observational study of rogtigotine transdermal patch and other currently prescribed therapies in patients with Parkinson's disease. *Journal of Neural Transmission* (2018): 125: 953-963.
- Levitan B, Markowitz M, Turkoz I, Fu DJ, Gopal S, and Alps L. Benefit-risk assessment of paliperidone oral extended-release tablet versus monthly injectable for maintenance treatment of schizophrenia. *International Clinical Psychopharmacology* 2016, 00:000-000.
- Markowitz M, Levitan B, Mohamed AF, Johnson FR, Bridges JFP, Alphs L, et al. Psychiatrists' judgments around antipsychotic benefit and risk outcomes and formulation in schizophrenia treatments. *Psychiatric Services*. Epub: 10.1176/appi.ps.201300290.
- Levitan B, Markowitz M, Mohamed A, Johnson R, Alphs L, Citrome L, and Bridges J. Patients preferences related to benefits, risks, and formulations of schizophrenia treatment. *Psychiatric Services in Advance*. March 16, 2015. Doi: 10-1176/appi. ps. 201400188.
- Lafeuille MH, Dean J, Fastenau J, Panish J, Olson W, Markowitz M, Duh MS, Lefebvre P. Burden of schizophrenia on selected co-morbidity costs. *Expert Review Pharmacoecon Outcomes Research*. Early online 1-9 (2014).
- Karve S, Markowitz M, Fu DJ, Lindenmayer JP, Wang CC, Candrilli S, Alphs L. Assessing Medication Adherence and Healthcare Utilization and Cost Patterns Among Hospital-Discharged Patients with Schizoaffective Disorder. *Appl Health Econ Health Policy*. 2014 Apr 23

- Markowitz M, Fu DJ, Levitan B, Gopal S, Turkoz I, Alphas L. Long-acting injectable paliperidone palmitate versus oral paliperidone extended release: a comparative analysis from two placebo-controlled prevention studies. *Ann Gen Psychiatry*. 2013; 12:22.
- Markowitz M, Karve S, Panish J, Candrilli SD, Alphas L. Antipsychotic adherence patterns and health care utilization and costs among patients discharged after a schizophrenia-related hospitalization. *BMC Psychiatry*. 2013 Oct 5;13(1):246.
- Olden K, DeGarmo RG, Jhingran P, Bagby B, Decker C, Markowitz M, Carter E, Bobbitt W, Dahdul A, DeCastro E, Gringeri L, Johanson J, Levinson L, Mula G, Poleynard G, Stoltz RR, Truesdale R, Young D; Lotronex Investigator Team. Patient satisfaction with alosetron for the treatment of women with diarrhea-predominant irritable bowel syndrome. *Am J Gastroenterol*. 2002 Dec;97(12):3139-46.
- Legorreta AP, Ricci JF, Markowitz M, Jhingran P. Patients diagnosed with irritable bowel syndrome: medical record validation of a claims-based identification algorithm. *Disease Management & Health Outcomes*. 2002 10(11): 715-722.
- Markowitz M., Mauskopf J., Halpern M. Cost-effectiveness model of adjunctive Lamotrigine for the treatment of epilepsy. *Neurology* 1998 51(4):1026-33.
- Markowitz M., Gold M., Rice T. Determinants of health insurance status among young adults. *Medical Care* 1991; 29:1, p. 6-19.

ADDENDUM**PEER REVIEWED POSTERS, PRESENTATIONS, AND LETTERS TO THE EDITOR**

- M. Markowitz, B. Levitan, A. F. Mohamed, F. R. Johnson, J. F. P. Bridges, L. Alphas, L. Citrome, "Psychiatrist and Patient Preferences for Benefit and Risk Outcomes and Formulation in Schizophrenia Treatments: Comparison of Two Conjoint Analyses," *APA Annual Meeting*, San Francisco, 2013.
- M. Markowitz, B. Levitan, A. F. Mohamed, F. R. Johnson, J. F. P. Bridges, L. Alphas, L. Citrome, "Psychiatrists' Preferences for Benefit and Risk Outcomes and Formulation in Schizophrenia Treatments: A Conjoint Analysis Study," *APA 64th Institute on Psychiatric Services Meeting*, New York City, NY, Oct, 2012
- Markowitz M, Karve S, Fu D, Lindenmayer JP, Wang CC, Candrilli SD, Alphas L. Assessing Medication Adherence and Healthcare Utilization and Costs Patterns among Hospital Discharged Patients with Schizoaffective Disorder. Poster presentation at the 2012 165th annual *American Psychiatric Association* conference, Philadelphia, PA.
- Karve S, Markowitz M, Panish J, Candrilli SD. Assessing healthcare utilization and costs among hospital discharged patients with schizophrenia. Poster presentation at the 21st *US Psychiatric and Mental Health Congress*; November 2011.
- Markowitz M, Karve S, Fu D, Lindenmayer JP, Wang CC, Candrilli SD, Alphas L. Patterns of Medication Adherence and Resource Utilization Among Patients with Schizoaffective Disorder. Poster presentation at the 2012 52nd annual *New Research Approaches for Mental Health Interventions* conference, Phoenix, AZ.
- Levitan B, Markowitz M, Turkoz I, Fu DJ, Gopal S, Alphas L. Benefit-risk assessment of maintenance therapy with an oral versus a long-acting injectable agent in schizophrenia. *13th International Congress of Schizophrenia Research* April 2-6, 2011. Colorado Springs, Co
- Crivera C, Dirani R, Markowitz M, Durkin M, Ma Y-W, McCarner K, Martin M. Evaluation of patient hospital readmission rates following the initiation of paliperidone palmitate in patients with schizophrenia. *US Psychiatric and Mental Health Congress* Nov 18-21, 2010. Orlando FL
- McCarrier K, Durkin M, Dirani R, Markowitz M, Slabaugh SL, Martin M. Innovative design for a comparative effectiveness study of schizophrenia treatments: Analysis of record review data incorporating randomization and propensity score matching. *International Society of Pharmacoeconomics and Outcomes Research* May 15-19, 2010. Atlanta, GA.
- Markowitz M, Levitan B, Fu DJ, Turkoz I, Gopal S, Hough D, Coppola D, Alphas, L. Benefit-risk assessment of maintenance therapy in schizophrenia comparing long-acting injectable (LAI) paliperidone palmitate with paliperidone ER. *164th Annual Meeting of the American Psychiatric Association*. May 14-18, 2011. Honolulu, HI.
- Markowitz M, Turkoz I, Levitan B, Simpson G, Alphas, L. Post-hoc comparative effectiveness study of paliperidone palmitate vs paliperidone ER: An indirect comparison from placebo-controlled relapse prevention studies. *American College of Neuropsychopharmacology* 49th Annual Meeting. Dec 5-9, 2010. Miami Beach, FL.
- Markowitz M, Karve S, Panish J, Candrilli SD, Cosmatos I, Alphas L. Evaluating anti-psychotic adherence patterns among Medicaid enrolled hospital discharged patients with schizophrenia. *US Psychiatric and Mental health Congress* Nov 7-10, 2011. Las Vegas, NV.
- Karve S, Markowitz M, Panish J, Candrilli SD, Cosmatos I, Alphas L. Assessing health care utilization and costs among hospital discharged patients with schizophrenia. *US Psychiatric and Mental Health Congress* Nov 7-10, 2011. Las Vegas, NV.
- Markowitz M, Levitan B, Fu DJ, Turkoz I, Gopal S, Alphas L. Designing a benefit-risk assessment of maintenance therapy with an oral versus a long acting injectable agent in schizophrenia. *International Society for CNS Clinical Trials and Methodology* Autumn Conference. Oct 13-14, 2010. Baltimore MD.
- Markowitz M, Jhingran P, Gordon S, Wentz A, Asgharian A, Carter E. Irritable Bowel Syndrome (IBS) subtypes: Differences in Qol impairment, productivity, and resource use. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
- Ricci JF, Jhingran P, Harris W, Asgharian A, Markowitz M, Carter E. Impact of differences in severity of Irritable Bowel Syndrome (IBS) on patient's well-being and resource use. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
- Jhingran P, Ricci JF, Markowitz M, Gordon S, Asgharian A, Carter E. Differences in productivity, Qol, and resource use in newly diagnosed and established Irritable Bowel Syndrome (IBS) patients. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.

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- Markowitz M, Harris W, Ricci JF, Harrison C, Gordon S, Wentz A, Carter E. Comorbid conditions in patients with Irritable Bowel Syndrome: Data from a national IBS awareness registry. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
 - Markowitz M, Jhingran P, Harris W, Wentz A, Gordon S, Ricci JF, Carter E. Symptom patterns in Irritable Bowel Syndrome (IBS) patients. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
 - Jhingran P, Bagby B, Carr B, Gordon S, Markowitz M, Carter E. Validation of global improvement scale in Irritable Bowel Syndrome (IBS) symptoms as an endpoint in IBS clinical trials. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
 - Malone T, Ameen V, Markowitz M, Carter E. Retrospective review of ischemic colitis (IC) in gastroenterology (GI) and internal medicine practices over a 5-year period. *DDW Annual Meeting*, Atlanta GA. May 20-23, 2001.
 - Markowitz MA, Jhingran P, Asgharian A, Harris WA, Brod M, Wentz AL, Gordon SH, Carter E. IBS prevalence: results from a community-based registry based on the Rome II Criteria. *Am J Gastrol* 2000; 95(9): 2634, A 766.
 - Jhingran P, Bagby BA, Decker C, Gordon S, Markowitz MA, Carter E. Patient satisfaction in Lotronex (Alosetron HCL) treated non-constipated Irritable Bowel Syndrome (IBS) females. *Am J Gastrol* 2000; 95(9): 2631, A758.
 - Markowitz MA, Bagby BA, Gordon S, Decker C, Jhingran P, Carter E. Satisfactory control of bowel urgency and global improvement in Irritable Bowel Syndrome (IBS) with Lotronex (Alosetron HCL) therapy. *Am J Gastrol* 2000; 95(9): 2543, A451.
 - Jhingran P, Bagby BA, Gordon S, Markowitz MA, Thompson C, Carter E. Impact of Lotronex (Alosetron HCL) on workplace productivity and activity time in females with non-constipated Irritable Bowel Syndrome (IBS). *Am J Gastrol* 2000; 95(9); 2537, A432.
 - Markowitz M, Mauskopf J, Halpern M. Cost-effectiveness model of adjunctive Lamotrigine for the treatment of epilepsy [Correspondence]. *Neurology* 1999; 53(3): 657-658.
 - Mauskopf, J., Markowitz, M., Halpern, M., and Murray, M. A Cost-effectiveness model for estimating the value of Lamotrigine, a new drug for epilepsy treatment. *Neurology* February 1996, 46; p.A323.
 - Halpern, M., Bryant-Comstock, L., Lee J., Markowitz, M., Cramer, J., Risner, M. The impact of Lamotrigine adjunctive therapy on seizure severity and associated economic effects. *Epilepsia* 1996, 37: Suppl 5: p. 10.