

JOHN ANTHONY BILELLO, Ph.D

APPOINTMENTS

Principal
Innovalyst Intellectual Capital Network
10117 Tipperary Road
Baltimore, MD 21234

SUMMARY

Dr. John Bilello has extensive experience in academia, the pharmaceutical industry, biotechnology sector, and government laboratories both in the US and Europe. He received his Ph.D. in molecular biology from the Albert Einstein College of Medicine (New York) and did post-doctoral research at the University of Hamburg (Germany) and the Johns Hopkins School of Medicine. Dr. Bilello was an Associate Professor of Medicine at the University of Maryland School of Medicine (MD) and Albany Medical College (New York). He was Chief of the Molecular Biology Laboratory at the VA Medical Center, Baltimore, MD. Currently, Dr. Bilello is Principal and Consultant at Innovalyst ICAN a Life Science small business accelerator. He was Scientific Officer Atlantic Diagnostic Laboratories and Chief Scientific Officer of Ridge Diagnostics (RidgeDx). John co-founded Ridge Dx a biotechnology company developing diagnostic tests for mood disorders and label-free point-of-care biomarker detection technology. From 2002-2006 he was the Director of Technology Development in Translational Medicine and Genetics at GlaxoSmithKline (GSK) Research and Development (R&D). As an outgrowth of these activities, he has authored over seventy publications in refereed journals and more than ten book chapters. He is an inventor on multiple US and international patents and processes. John was a member of the editorial board of the American Society for Microbiology journal Antimicrobial Agents and Chemotherapy (1995-2012).

In addition to an established track record of innovative basic and clinical research, Dr. Bilello has experience in both project and organizational management. John was a co-founder and Managing Partner of Innovalyst LLC a life science consulting company initially based in Research Triangle Park, NC. During his tenure at Innovalyst, he worked with companies from small businesses to Fortune 500 companies as well as “Invest NI” Northern Ireland’s regional economic development agency.

EDUCATIONAL BACKGROUND

1966 B.S., Biology, The City College of
 The City University of New York,
 New York, New York

- 1969 M.A., Microbiology, Southern Illinois University, Carbondale, Illinois
- 1972-1977 NIH Pre-Doctoral Fellow, Albert Einstein College of Medicine, Bronx, New York
- 1974 Tumor Virology Course, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY
- 1977 Ph.D., Molecular Biology, Albert Einstein College of Medicine, Bronx, NY

ACADEMIC AND EMPLOYMENT EXPERIENCE

- 2018-Present Principal, Innovalyst Intellectual Capital Network (ICAN)
- 2017-2018 Scientific Officer Atlantic Diagnostic Laboratories, Bensalem, PA
- 2009-2015 President & CSO, Ridge Diagnostics Inc. Research Triangle Park, NC
- 2008-2012 Managing Partner Innovalyst LLC. Research Triangle Park, NC
- 2006-2008 Chief Scientific Officer, Ridge Diagnostics Inc. Durham, NC
- 2002-2006 Director Technology Development, Translational Medicine and Genetics, Clinical Pharmacology and Discovery Medicine. GlaxoSmithKline, Research Triangle Park, NC.
- 2002 Senior Therapeutic Area Advisor for Antivirals, Clinical Pharmacology and Experimental Medicine, GlaxoSmithKline
- 2000-2001 Director, Preclinical Research and Development, VIRCO Lab Inc. Rockville, MD.
- 1998-2000 Director, Preclinical Research and Development, SRA Life Sciences. Rockville, MD.
- 1992-1998 Associate Professor, Department of Medicine, Associate Professor, Department of Pharmacology, Albany Medical College, Albany, New York
- 1993-1998 Director, HIV Laboratories, Department of Medicine, Division of Clinical Pharmacology Albany Medical College, Albany, NY
- 1985-1992 Chief, Molecular Biology Laboratory VA Medical Center, Baltimore, MD
- 1988-1992 Head, Antiviral Pharmacology Section

Retrovirus Research Center
Baltimore VAMC

- 1989-1992 Associate Professor Program in
Oncology, School of Medicine
University of Maryland at Baltimore,
Baltimore, Maryland
- 1981-1983 Instructor in Oncology,
The Johns Hopkins University,
School of Medicine
- 1977-1980 Wissenschaftlicher Assistant,
Department of Molecular Biology
Institute of Physiological Chemistry
University of Hamburg
Hamburg, West Germany
- 1970-1972 Assistant Biochemist
Dept. of Chemotherapy
Virus Biochemistry Section
Hoffman-La Roche Inc.
Nutley, NJ

HONORS

- 1961-1965 New York State Regents Scholarship
- 1969-1970 Special Doctoral Fellowship, Southern Illinois University
- 1973-1977 NIH Pre-doctoral Fellowship,
Albert Einstein College of Medicine
- 1977-1979 Volkswagen Foundation Award
University of Hamburg
- 1983-1985 Frank Bressler Research Award
University of Maryland

SUMMARY OF RECENT R&D EXPERIENCE (Decending Chronological Order)

Development of detection methods for colon polyps based upon PolypDx™ and cancer specific proteins in urine.

Studies on the interaction between Chronic Pain states and Major Depressive Disorder, Ridge Dx and Atlantic Diagnostic Laboratories (ADL)

Use of Biomarker Panels in both Phase I and Phase II of new antidepressant drugs.

Development of a Biomarker Panel for Detecting Adolescent Depression. NIH, NIMH
Small Business Catalyst Award for Accelerating Innovative Research

Development of Ridge Diagnostics' Human Biomarker Library and Unipolar Depression panel

Development of Molecular Interaction Measurement System for detection of multiple analytes. National Science Foundation Phase I and Phase II SBIR grants

Project Team Leader and Joint Steering Committee Member: Oxford Glycosciences-GSK Collaboration on Analysis of Differential Protein Expression in Six Therapeutic Areas.

Project Team Leader: Alzheimer's Disease Biomarkers, GSK

Translational Medicine's Representative, Technology Investment Board, GSK

Disruptive Technology Innovation Team, Discovery Research, GSK

Clinical Development Team Member, Migraine Candidate, GSK

Clinical Development Team(s) Member, Multiple HIV Therapeutics, GSK

Protein Microarray Applications in Biomarker Discovery and Validation GSK

Development of Hollow Fiber Bioreactor models for pharmacodynamic analysis of anti-infective agents. Application of this model system to clinical studies of agents effective against HIV infection

Establishment of Reporter Gene Based Assays for HIV and CMV infection of human cells

Co-investigator on the NIAID HIV Immune Surveillance Contract with SRA Life Sciences

Molecular studies of retrovirus replication in cultured lymphoid, macrophage-monocyte, neuronal, and endothelial cells.

SELECTED REVIEW BOARDS AND COMMITTEE MEMBERSHIPS

Member Organizing Committee Neurologic Biomarkers Meeting GTCBio 2013, 2014

Member Editorial Board, Antimicrobial Agents and Chemotherapy, ASM, 1/95-12/12.

Member, IMST-12 SBIR, Devices and Detection Systems Review Panel, NIH, 2009

Member, NIH Challenge Grants Review Panel, NIMH, NIH 2009

Member, HIV/AIDS Clinical Trial Network Review Panel, NIAID, NIH, 2006

Member, HIV/AIDS Prevention Trials Network Review Panel, NIAID, NIH. 2005

Member, SBIR/STTR SSS-2 Study Section on Proteomic Technologies, CSR, NIH 2004-2005

PATENTS

GRANTED

US 8,158,374 - Materials and Methods related to diagnosing a clinical condition in a subject, or determining the subject's predisposition to develop the clinical condition, using a multi-parameter system to measure a plurality of parameters and an algorithm to determine a disease score.

US 8,450,077 - Materials and methods related to materials and methods for diagnosing or assessing a clinical condition in a subject, or determining a subject's predisposition to develop a clinical condition, using algorithms to determine a disease score based upon a combination of parameters.

US 8,440,418 - Materials and methods for using combinations of metabolic syndrome and HPA axis biomarkers for monitoring major depressive disorder.

JAPAN 5663314- Materials and Methods for Diagnosing and Monitoring Major Depressive Disorder assessing a clinical condition in a subject,.

JAPAN 5658571- Inflammatory Biomarkers for Monitoring Depression Disorders assessing a clinical condition in a patient with a depression disorder.

JAPAN 5540000- Human Biomarker Hypermapping for Depressive Disorders. Materials and Methods for Hypermapping patient data in 3-Dimensional Space.

JAPAN 5767973- Metabolic Syndrome and HPA Axis Biomarkers for Monitoring Major Depressive Disorders. Using multiple biomarkers (MSX and HPA) to monitor the response of patients to treatment of Major Depressive Disorder.

JAPAN 5744063- Multiple Biomarker Panels to Stratify Disease Severity and Monitor Treatment of Depression

JAPAN 5675771- Biomarkers for Monitoring Neuropsychiatric Diseases

WIPO 2337866 - Human Biomarker Hypermapping for Depressive Disorders. Materials and Methods for Hypermapping patient data in 3-Dimensional Space.

PUBLICATIONS (Selected from 75)

1. **Bilello, J.A. and Tennant, F.S.** Patterns of chronic inflammation in extensively treated patients with arachnoiditis and chronic intractable pain. Postgraduate medicine, 129(1), pp.87-91. (2017)
2. **Bilello, J.A.** Seeking an Objective Diagnosis of Major Depressive Disorder. Biomarkers in

- Medicine, 10, 861-875 (2016).
3. Fava M, Johe K, Ereshefsky L, Gertsik LG, English BA, **Bilello JA**, Thurmond LM, Johnstone J, Dickerson BC, Makris N, Hoepfner BB. (A Phase 1B, randomized, double blind, placebo controlled, multiple-dose escalation study of NSI-189 phosphate, a neurogenic compound, in depressed patients. *Molecular Psychiatry*. (2015) Dec 8.
 4. **Bilello, J. A.**, Thurmond, L. M., Smith, K. M., Pi, B., Rubin, R., Wright, S. M. Taub, F. Henry, M.E. Shelton, R.C. & Papakostas, G. I. MDDScore: confirmation of a blood test to aid in the diagnosis of major depressive disorder. *The Journal of Clinical Psychiatry*, 76(2), e199-206. (2015).
 5. Papakostas, G, Shelton RS, Kinrys G, Henry ME, Bakow BR, Lipkin SH, Pi B, Thurmond L, **Bilello JA**. Assessment of a Multi-Assay, Serum-Based Biological Diagnostic Test for Major Depressive Disorder: A Pilot and Replication Study. *Molecular Psychiatry*, 18: 332-339 (2013)
 6. Smith, KM, Renshaw, PF, **Bilello, J**, The diagnosis of depression: current and emerging methods. *Comprehensive Psychiatry* 54:1-6 (2013)
 7. Ashina M, Tvedskov JF, Lipka K, **Bilello J**, Penkowa M & Olesen J. Matrix metalloproteinases during and outside of migraine attacks without aura. *Cephalalgia* 30: 303-310 (2009).
 8. Pinto-Plata, V., Toso, J., Lee, K., Park, D. **Bilello, J.A.**, Mullerova, H. De Souza, M.M., Vessey, R., and Celli, B., Profiling Serum Biomarkers in Patients with COPD: Associations with Clinical Parameters *Thorax* 62:595-601 (2007: e-published 3-13-07)
 9. Pinto-Plata, V., Toso, J., Lee, K., Park, D. **Bilello, J.A.**, Mullerova, H. De Souza, M.M., Vessey, R., and Celli, B., Use of Proteomic Patterns of Serum Biomarkers in Patients with Chronic Obstructive Pulmonary Disease: Correlation with Clinical Parameters. *Proceedings of the American Thoracic Society* 3:465-466 (2006)
 10. **Bilello, J.A.** ‘Omics’ in Translational Medicine: are they Lost in Translation? In *SEB-Comparative Genomics* ed. Coward, K. and Parrington, J.. Taylor Francis Group UK, pp.133-141 (2006)
 11. **Bilello, J.A.**, The Agony and Ecstasy of “OMIC” Technologies in Drug Development. *Current Molecular Medicine* 5: 39-52,(2005)
 12. Preston, S.L., Piliero, P.J., **Bilello, J.A.**, Symonds, W. T Stein, D. S., and Drusano, G.L. In vitro-in vivo model for evaluating the antiviral activity of amprenavir in combination with ritonavir administered at 600 and 100 milligrams, respectively, every 12 hours. *Antimicrob. Agents Chemother.* 47:3393-99. (2003).
 13. Drusano, G. L.. Bilello, P. A. Symonds, W. T Stein, D. S., McDowell, J., Bye, A. and **Bilello J.A.**, Pharmacodynamics of Abacavir in an In Vitro Hollow-Fiber Model System *Antimicrob. Agents Chemother.* 46: 464-470 (2002).
 14. Drusano, G.L., **Bilello, J.A.**, Preston, S.L., O’Mara, E., Kaul, S., Schnittman, S. and Echols, R. Hollow Fiber Unit Evaluation of BMS232632, a New HIV-1 Protease Inhibitor, for the Linked Pharmacodynamic Variable. *J. Infectious Diseases*. 183:1126-1129, (2001).
 15. Snyder, S., D’Argenio, D.Z., Weislow, O., **Bilello, J.A.**, and Drusano, G.L. The triple

- combination indinavir-zidovudine-lamivudine is highly synergistic. *Antimicrob Agents Chemother.* 44:1051-1058. (2000).
16. Drusano G.L., D'Argenio, D.Z., Preston, S.L., Barone, C., Symonds, W., LaFon, S., Rogers, M., Prince, W., Bye, A., and **Bilello, J.A.** Use of drug effect interaction modeling with Monte Carlo simulation to examine the impact of dosing interval on the projected antiviral activity of the combination of abacavir and amprenavir. *Antimicrob Agents Chemother.* 44:1655-1659. (2000).
 17. Skowron ,G., Stein,D., Drusano, G., Melbourne, K., **Bilello, J.**, Mikolich, D., Rana, K., Agosti, J.M., Mongillo, A., Whitmore , J., and Gilbert, M.J. The safety and efficacy of granulocyte-macrophage colony-stimulating factor (Sargramostim) added to indinavir- or ritonavir-based antiretroviral therapy: a randomized double-blind, placebo-controlled trial. *J. Infect. Dis.* 180:1064-1071 (1999).
 18. Drusano, G.L., D'Argenio, D.Z., Symonds, W., Bilello, P.A., McDowell, J., Sadler, B., Bye, A. and **Bilello, J.A.** Nucleoside analog 1592U89 and human immunodeficiency virus protease inhibitor 141W94 are synergistic in vitro. *Antimicrob Agents Chemother* 42:2153-215(1998).
 19. Landay, A.L., Bethel, J., and Schnittman, S., for the DATRI 003 Study Group. Phenotypic variability of lymphocyte populations in peripheral blood and lymph nodes from HIV-infected individuals and the impact of antiviral therapy. *AIDS Research and Human Retroviruses.* 14:445-451 (1998).
 20. Drusano, G.L., **Bilello, J.A.**, Stein, D.S., Nessly, M., Meibohm, A., Emini E.A., Deutsch, P. Condra, J., Chodakewitz and Holder, D.J. Factors influencing the emergence of resistance to Indinavir: Role of virologic, immunologic and pharmacologic variables. *J Infect Dis* 178: 360-367 (1998).
 21. Stein DS, Lyles RH, Graham NM, Tassoni CJ, Margolick JB, Phair JP, Rinaldo C, Detels R, Saah A, and **Bilello J.** Predicting clinical progression or death in subjects with; early-stage human immunodeficiency virus (HIV) infection: a comparative analysis of quantification of HIV RNA, soluble tumor necrosis factor type II receptors, neopterin, and beta2-microglobulin. Multicenter AIDS Cohort Study. *J Infect Dis* 176:1161-1167 (1997).
 22. **Bilello, J.A.**, Stellrecht, K.S., Drusano, G.L. and Stein, D.S. Soluble Tumor Necrosis Factor Receptor type II (sTNF RII) Correlates with HIV RNA Copy Number in HIV-infected Patients. *J. Infect. Diseases,* 173:464-468 (1996).
 23. Cohen, O.J., Pantaleo, G., Holodniy, M., Fox, C.H., Orenstein, J., Schnittman, S., Niu, M., Graziosi, C., Pavlakis, G.N., Lalezari, J., Bartlett, J.A., Steigbigel, R.T., Cohn, J., Novak, R., McMahon, D., **Bilello, J.**, and Fauci, A.S. Antiretroviral Monotherapy in Early Stage Human Immunodeficiency Virus Disease has no Detectable Effect on Viral Load in Peripheral Blood and Lymph Nodes. *J. Infect. Diseases,* 173:849-856 (1996).
 24. Stein, D.S. Fish, D.G., **Bilello, J.A.**, Preston, S.L., Martineau, G.L. and Drusano, G.L. A 24 Week Open Label Phase 1 Evaluation of the HIV Protease Inhibitor MK-639. *AIDS* 10:485-492 (1996).
 25. Drusano, G.L., Pritchard, MN, Bilello, P.A. and **Bilello, J.A.** A Method to Guide Regimen Choice for Clinical Trial Evaluation Through Modeling of the Interaction of Combinations of

- Antiretroviral Agents In Vitro. *Antimicrob. Agents Chemother.* 40:1143-1147 (1996).
26. **Bilello, J.A.**, and Drusano, G.L. Relevance of Plasma Protein Binding to Antiviral Activity and Clinical Efficacy of Inhibitors of Human Immunodeficiency Virus Protease. *J. Infect. Diseases*, 173:1524-1525 (1996).
 27. **Bilello, J.A.**, Bilello, P.A., Stellrecht, K.S., Leonard, J., Norbeck, D.W., Kempf, D.J., Robins, T., and Drusano, G.L. Human Serum α 1-Acid Glycoprotein Reduces the Uptake, Intracellular Concentration and Antiviral Activity of A-80987, an inhibitor of the Human Immunodeficiency Virus Type I (HIV-1) Protease. *Antimicrob. Agents Chemother.* 40:1491-1497 (1996).
 28. **Bilello, J.A.**, Bilello, P.A., Prichard, M., Robins, T. and Drusano, G.L. Reduction of the in vitro activity of A77003, an inhibitor of the human immunodeficiency virus protease, by human alpha 1-acid glycoprotein. *J. Infect. Diseases*, 171:546-551 (1995).
 29. **Bilello, J.A.**, Bilello, P.A., Kort, J.J., Dudley, M.N., Leonard, J. and Drusano, G.L., Efficacy of constant infusion A77003, an inhibitor of the HIV-1 protease, in limiting acute HIV-1 infection in vitro. *Antimicrob. Agents Chemother.* 39:2523-2527 (1995).
 30. **Bilello, J.A.**, Eiseman, J.L., Standiford, H.C., and Drusano, G.L. Impact of Dosing Schedule Upon Suppression of a Retrovirus in a Murine Model of AIDS Encephalopathy *Antimicrob. Agents Chemother.* 38:628-631 (1994).
 31. **Bilello, J.A.**, Bauer, G., Dudley, M.N., Cole, G.A. and Drusano, G.L. The effect of 2',3' dideohydro- 3' deoxythymidine (D4T) in an in vitro hollow fiber pharmacodynamic model system correlates with results of dose ranging clinical studies. *Antimicrob. Agents Chemother.* 38:1386-1391 (1994).
 32. Kort, J.J., **Bilello, J.A.**, Bauer, G., and Drusano, G.L. Preclinical Evaluation of Antiviral Activity and Toxicity of Abbott (A)77003, an Inhibitor of the Human Immunodeficiency Virus Type 1 Protease. *Antimicrob. Agents Chemother.* 37:115-119 (1993).
 33. **Bilello, J.A.**, MacAuley, C., Kort, J.J., Yetter, R.A., Fredrickson, T.N. and J.L. Eiseman. ZDV Delays but does not Prevent the Transmission of MAIDS by LP-BM5 MuLV Infected Macrophage-Monocyte Cells. *J. AIDS*, 5:571-576 (1992).
 34. Martin, S.J., O'Neill, T.J. **Bilello, J.A.** and Eiseman, J.L. Lymphocyte Transformation Abnormalities in Bovine Immunodeficiency-Like Virus Infected Calves. *Immunology Letters*, 27:81-84 (1991).
 35. Eiseman, J.L., Yetter, R.A., Fredrickson, T.N., MacAuley, C., Shapiro, S.G. and **Bilello, J.A.** Effect of 3'Azidothymidine Administered in Drinking Water or by Continuous Infusion on the Development of MAIDS. *Antiviral Research*, 16:307-326 (1991).
 36. **Bilello, J.A.**, MacAuley, C., Frederickson, T., Bell, M.M., McKissick, C., Shapiro, S.G., Personette, R., and Eiseman, J.L. Use of a Neonatal Murine Retroviral Model to Evaluate the Long-term Efficacy and Toxicity of Antiviral Agents. *Annals of the New York Academy of Science*, 616:238-251 (1990).
 37. Kitchen, L.W., Mather, F.J., Chapple, F.E. and **Bilello, J.A.** Effect of the Administration of

- Diethylcarbamazine on Murine Leukemia Virus (Cas-Br-M) Infected Mice. *Journal of Clinical and Laboratory Immunology*, 33:97-105 (1990).
38. Robbins, D., **Bilello, J.A.** and Hoffman, P.M. Pathogenesis and Treatment of Neurotropic Murine Leukemia Virus Infections. In *Neurology and Neurobiology*, Vol. 51 "HTLV-I and the Nervous System" Roman, G.C., Vernant, J.C. and Osame, M. eds., Alan R. Liss Inc., New York. pp. 575-587 (1989).
 39. Hoffman, P.M., Pitts, O.M., **Bilello, J.A.** and Cimino, E.F., Retrovirus Induced Neuron Degeneration. *Rev. Neurol. (Paris)* 144:111-121 (1988).
 40. Hoffman, P.M., MacAuley, C., **Bilello, J.A.**, Morse, H.C., III, and Rohwer, R.G. Transmission of Spongiform Encephalopathies in Inbred NFS/N Mice. *Proc. Nat. Acad. Sci.* 84: 3866-3870 (1987).
 41. Pitts, O.M., Powers, J.A., **Bilello, J.A.** and Hoffman, P.M. Ultrastructural Changes Associated with Retroviral Replication in Central Nervous System Capillary Endothelial Cells. *Lab Investigation*, 56: 401-407 (1987).
 42. **Bilello JA**, Pitts OM, Hoffman PM. Characterization of a progressive neurodegenerative disease induced by a temperature-sensitive Moloney murine leukemia virus infection. *J Virol.* 59: 234-241 (1986).