

Ronald R. Bowsher, Ph.D.

**Partner & President
Bowsher Brunelle Smith, LLC
(B2S Consulting)**

**Chief Scientist
BioPharma Services
Millipore Corporation**

Fellow of the American Assoc. of Pharmaceutical Scientists

	Work	Home
Address	70 south 12 th Avenue, Beech Grove, IN 46107	
Telephone	317-787-2213	317-786-4770
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Professional Experience

President and Partner

Jan. 2003 – Current

B2S Consulting, Beech Grove, IN 46107, USA

- Provide strategic, operational and marketing leadership for B2S Consulting.
- Provide bioanalytical (Ligand binding assays for biopharmaceuticals, novel biomarkers and anti-drug antibodies) & drug development consulting expertise (preclinical and clinical ADME of protein therapeutics and immunogenicity) to pharmaceutical and biotech clients.
- Market and promote B2S statistical consulting, data analysis and data management capabilities and solutions to pharmaceutical/biotech and K-12 educational clients.
- Provide scientific leadership for development and support of new business opportunities

Consultant and Chief Scientist, Regulatory Compliant Laboratory

Nov. 2006 – Current

MILLIPORE Corporation, St. Charles, MO 63304, USA

Consultant and Chief Scientific Officer

May 2006 – Oct. 2006

LINCO Diagnostics, Inc., St. Charles, MO 63304, USA

Vice-President and Chief Scientific Officer

Jan. 2006 – Apr. 2006

LINCO Diagnostics, Inc., St. Charles, MO 63304, USA

- Provide strategic, scientific and technical leadership for bioanalytical business, including support for discovery research, regulatory-compliant studies and clinical diagnostics
- Serve as scientific and technical advisor to scientists/staff for the design, development, validation, trouble-shooting and application of ligand binding assays (immunoassays) for biotherapeutics, conventional drugs, novel biomarkers and anti-drug antibodies (immunogenicity testing). Aid clients by providing interpretation of bioanalytical data.
- Provide leadership for efforts to implement policies, procedures and infrastructure to ensure compliance with Good Laboratory Practices (GLP) and other global regulatory requirements

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for pharmaceutical bioanalysis (OECD).

- Promote company and encourage business by serving a leadership role in external professional organizations and providing consultation to external clients
- Provide external leadership and advise Biotec clients for the development, delivery and ADME of biotherapeutics

Vice-President and Laboratory Director
LINCO Diagnostics, Inc., St. Charles, MO 63304, USA

Mar. 2003 – Dec. 2005

- Provide strategic, scientific and technical leadership for bioanalytical business, including support for discovery research, regulatory-compliant studies and clinical diagnostics
- Serve as scientific and technical advisor to scientists/staff for the design, development, validation, trouble-shooting and application of ligand binding assays (immunoassays) for biotherapeutics, conventional drugs, novel biomarkers and anti-drug antibodies (immunogenicity testing). Aid clients by providing interpretation of bioanalytical data.
- Provide leadership for efforts to implement policies, procedures and infrastructure to ensure compliance with Good Laboratory Practices (GLP) and other global regulatory requirements for pharmaceutical bioanalysis (OECD).
- Promote company and encourage business by serving a leadership role in external professional organizations and providing consultation to external clients
- Provide external leadership and advise Biotec clients for the development, delivery and ADME of biotherapeutics
- Provide scientific leadership for development and support of new business opportunities

Senior Research Scientist

1999 - 2003

Department of Diagnostic and Experimental Medicine

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Serve as a technical advisor in the Laboratory for Experimental Medicine for the development, validation and application of *in vitro* assays for novel biomarkers
- Provide strategic, operational and scientific leadership within LRL for clinical safety assessments of immunogenicity of therapeutic proteins
- Advise LEM associates and contract organizations on development, validation and application of assays to quantify anti-drug antibodies
- Serve as a technical advisor to Clinical Diagnostic Services (CDS) for clinical application of *in vitro* ligand binding assays, insulin and endocrinology.
- Advise LRL colleagues on development and validation of ligand binding assays, bioanalysis of macromolecules, and the disposition of therapeutic proteins

Senior Research Scientist, Protein Team Group Leader

1996 - 1999

Department of Drug Disposition Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Serve as leader of the Drug Disposition Protein Team
- Advise team members on development, validation and application of immunoassays for macromolecular therapeutics and biomarkers
- Advise team members on investigations to assess the pharmacokinetics and disposition of therapeutic proteins
- Provide bioanalytical support for Toxicology studies to assess the safety of new therapeutics

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- Provide bioanalytical support for clinical studies to assess the safety and efficacy of new therapeutics
- Prepare IND and NDA documents to support global registration of Eli Lilly compounds
- Advise LRL colleagues on development and validation of immunoassays

Research Scientist, Protein Team Group Leader

1995 - 1996

Department of Drug Disposition Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Serve as leader of the Drug Disposition Protein Team
- Advise team members on development, validation and application of immunoassays for macromolecular therapeutics and biomarkers
- Advise team members on investigations to assess the pharmacokinetics and disposition of therapeutic proteins
- Provide bioanalytical support for Toxicology studies to assess the safety of new therapeutics
- Provide bioanalytical support for clinical studies to assess the safety and efficacy of new therapeutics
- Prepare IND and NDA documents to support global registration of Eli Lilly compounds
- Advise LRL colleagues on development and validation of immunoassays

Research Scientist, Group Leader

1991 - 1995

Dept. of Drug Disposition and Bioanalytical Research, Lilly Lab. for Clinical Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Serve as leader of the Drug Disposition Team responsible for clinical ADME investigation of therapeutic proteins
- Advise team members on development, validation and application of immunoassays for macromolecular therapeutics and biomarkers
- Advise team members on investigations to assess the pharmacokinetics and disposition of therapeutic proteins
- Provide bioanalytical support for clinical studies to assess the safety & efficacy of new drugs
- Provide bioanalytical support for pharmacodynamic assessments of new drugs entities
- Prepare NDA documents to support global registration of Eli Lilly compounds
- Advise LRL colleagues on development and validation of immunoassays
- Serve as Lilly Clinical Radiation Safety Officer

Senior Biochemist

1986 - 1991

Dept. of Drug Disposition Research, Lilly Lab. for Clinical Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Serve as leader of the Drug Disposition Team responsible for clinical ADME investigation (PK and disposition) of therapeutic proteins and advise clinical teams.
- Advise team members on development, validation and application of immunoassays for macromolecular therapeutics and biomarkers
- Provide bioanalytic support for clinical studies to assess the safety and efficacy of new drugs
- Provide bioanalytical support for assays to assess drug pharmacodynamics in clinical studies of new drug entities
- Prepare NDA documents to support global registration of Eli Lilly compounds

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- Advise LRL colleagues on development and validation of immunoassays
- Serve as Lilly Clinical Radiation Safety Officer

Chemist

1978 - 1985

Dept. of Drug Disposition Research, Lilly Lab. for Clinical Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Perform assays for catecholamines and other biogenic amines in biological fluids to support clinical development of new drug entities
- Purify reagent enzymes for use in radioenzymatic assays of biogenic amines
- Conduct studies on the human metabolism of new drug entities
- Develop, validate and perform novel in vitro assays to quantify new drugs and metabolites
- Advise graduate students on general laboratory techniques

Technician

1973 - 1978

Dept. of Drug Disposition Research, Lilly Lab. for Clinical Research

Lilly Research Laboratories, Eli Lilly and Company, Indianapolis, IN, USA

- Perform assays for catecholamines and other biogenic amines in biological fluids to support clinical development of new drug entities
- Purify reagent enzymes for use in radioenzymatic assays of biogenic amines
- Conduct studies on the human metabolism of new drug entities
- Develop, validate and perform novel in vitro assays to quantify new drugs and metabolites
- Advise graduate students on general laboratory techniques

Marketed Eli Lilly Compounds Supported

Permax (pergolide), Humatrope (human growth hormone), Humulin (human insulin), Humalog (insulin lispro), Humulin Fixed Mixtures (70:30 & 50:50), Humalog and Fixed Mixtures (70:30 & 50:50), Evista, Forteo' (hPTH 1-34), rDNA-glucagon, Xigris (rhAPC)

Education

Ph.D., 1986

Indiana University School of Medicine, Indianapolis, IN

Department of Biochemistry (Pharmacology minor)

Thesis: Cytosolic Rat Brain Tyrosine Transaminase: Purification, Characterization and Identification as Glutamine Transaminase-K

M.S., 1981

Indiana University School of Medicine, Indianapolis, IN

Department of Biochemistry

Thesis: Purification and Characterization of Mammalian Tyrosine Decarboxylase Activity

B.S., 1977

Indiana University, Indianapolis, IN

Department of Chemistry (Biology – minor)

Continuing Education

- July 2001 SAS Institute, JMP Software: Statistical Quality Control (G. Hobbs) Indpls., IN
July 2001 SAS Institute, JMP Software: Design and Analysis of Experiments (G. Hobbs)
Indpls, IN
May 2001 SAS Institute, JMP Software: ANOVA and Regression Analysis (Paul Marovich)
Indpls, IN
May 2001 SAS Institute, JMP Software: Statistical Data Exploration (P. Marovich) Indpls, IN

Jan. 1999 FDA Requirements for Immunoassay Testing in the Pharmaceutical Industry (Jon
P. Kimball, PhD) 25th Annual Meeting of Clinical Ligand Assay Society, Phil., PA
Jan. 1995 Pharmacokinetics for Pharmaceutical Scientists, UCSF, San Francisco, CA
June 1987 The Endocrine Society Fourteenth Annual Training Course on Hormonal Assay
Techniques, Bethesda, MD

Professional Societies & Organizations

- American Association of Pharmaceutical Scientists (AAPS)
- American Society for Pharmacology & Experimental Therapeutics (ASPET)
- The Endocrine Society
- American Association for Clinical Chemistry (AACC)
- American Association for the Advancement of Science (AAAS)
- Sigma Xi

Awards

- Nov. 2004 Elected Fellow of American Assoc. Pharmaceutical Sciences (AAPS)

Sept. 1999 Lilly Research Laboratories - Presidential Award. Investigation of Luminex
Multiplexing Technology for the Simultaneous Determination of Multiple
Cytokines in biological Samples

Nov. 1994 Lilly Research Laboratories - John L. Emmerson Award for Excellence in
Toxicology: Investigation of the mechanism of fialuridine toxicity following
chronic oral administration of fialuridine

April 1983 Sigma Xi Graduate Research Competition - 2nd Place: Rat Histamine N-Methyl-
transferase: Distribution, Purification to Homogeneity & Immunologic Properties

Committees and Offices

- 2007-Present AAPS 2008 National Biotechnology Conference, Past-Chair
2007-Present AAPS Ligand Binding Assay – Biomarker Subcommittee
2007-Present Group Leader, USP Chapter – Assay Design, Quality Control, and Data
Analysis; USP Ad Hoc Advisory Committee for Immunological Test Methods
2006-Present USP Ad Hoc Advisory Committee for Immunological Test Methods
2007-Present Chair-Elect, AAPS Fellows Selection Committee
2004-2007 AAPS Fellows Selection Committee
2004-2005 AAPS Biotechnology Section, Past-Chair
2006-2007 AAPS Member Groups Coordination Committee (MGCC)
2006-2007 AAPS Program Coordination Committee (PCC)
2006-2007 AAPS 2007 National Biotechnology Conference, Chairman
2005-2006 AAPS 2006 National Biotechnology Conference, Co-Chair
2004-2005 AAPS Biotechnology Section, Chair
2004-Present American Diabetes Assoc. Committee for the Standardization of Insulin Assays

Committees and Offices – cont'd.

2003-2004	AAPS Biotechnology Section, Chair Elect.
2003-2005	AAPS Section / Focus Group Coordination Committee
2003-2004	AAPS Short Course Program Review Team
2003-Present	AAPS Training Program Task Force
2003-Present	AAPS Annual Meeting Program (AMPC) Review Team
2003-Present	AAPS 2004 National Biotechnology Conference, Planning Committee
2003-2004	2004 Bioval Meeting, London, UK., Organizing Committee
2003-Present	2003 AAPS Annual Meeting, Program Committee
2003	AAPS Biotec Section, Vice-Chairman Elect.
2002-2003	14 th International Symposium on Pharmac. & Biomedical Analysis (PBA 2003), Orlando FL, Planning Committee
2001-Present	AAPS Biotec Section Executive Comm.
2001-2002	2002 AAPS Natl. Biotechnology Conference, Planning Comm., San Diego, CA.,
2000-2002	AAPS Ligand Binding Assay Bioanalytical Focus Group, Founder & Chairman,
1999-2000	FDA & AAPS Planning Committee for Crystal City Workshop on the Bioanalysis of Macromolecules
1993-1995	American Diabetes Assoc. Committee for the Standardization of Insulin Assays
1986-1995	IUPUI Radionuclide Radiation Safety Committee
1986-1995	IUPUI Radioactive Drug Research Committee
1986-1992	Eli Lilly & Company Corp. Radiation Safety Committee

Invited Lectures

Oct. 2007	Insights into Regulated Bioanalysis of Biotherapeutics: <i>The Search for Improved Insulins</i> , Butler University, School of Pharmacy, Indianapolis, IN
Sept. 2007	Bioanalytical Method Validation of Ligand Binding Assays (LBAs) for Supporting Bioanalysis of Macromolecules: <i>The Challenge of Human Insulin Analogs</i> , 2007 BSAT-Applied Pharmaceutical Conference, Boston MA
June 2007	Perspectives on Biomarker Assay Translation from Drug Discovery to Clinical Diagnostics-Moderator, 2007 AAPS Natl. Biotechnology Meeting, San Diego, CA
June 2007	Technical & Regulatory Challenges for Bioanalysis of Biopharmaceuticals & Biomarkers by Ligand Binding Assays, Ambrx, San Diego, CA
June 2007	AAPS Ligand Binding Assay Training Course: Development and Validation of Quantitative Ligand Binding Assays, 2007 AAPS National Biotechnology Meeting, San Diego, CA
Apr 2006	Developmental Considerations for Biopharmaceuticals: <i>The search for Improved Insulins</i> , Purdue Univ. School of Pharmacy, Lafayette, IN.
Oct 2006	Preanalytical and Sample Prep Considerations for Assays to Support PK/TK Assessments of Biopharmaceuticals. Short Course - Bioanalytical and Pharmacokinetic Considerations in Developing Biotechnology-Derived Products, 2006 AAPS Annual Meeting, San Antonio, TX.

Invited Lectures – cont'd.

- Oct 2006 Challenges of Biomarker Assays. Roundtable – Road Test of “Fit-for-Purpose” Approach of Biomarker Method Validation, 2006 AAPS Annual Meeting, San Antonio, TX.
- Aug 2006 Issues in the Application of Commercial Kits for Quantitative Determination of Biomarkers in Support of Clinical Drug Development, Amgen Inc., Thousand Oaks, CA
- June 2006 Strategies for Developing and Validating Biomarker Assays in the Presence of Endogenous Levels, Sunrise Session, 2006 AAPS National Biotechnology Meeting, Boston, MA
- June 2006 AAPS Ligand Binding Assay Training Course: Development and Validation of Quantitative Ligand Binding Assays, 2006 AAPS National Biotechnology Meeting, Boston, MA
- June 2006 Statistical Considerations in the Evaluation of Validation Data for Immunogenicity Assays to Detect Anti-Drug Antibodies, Moderator, 2006 AAPS National Biotechnology Meeting, Boston, MA
- May 2006 Common Issues Between Large and Small Molecule Analysis, 2006 AAPS/FDA Third Bioanalytical Methods Validation Workshop, Arlington, VA
- May 2005 Impact of Modern Biotechnology on Laboratory Medicine (symposium organizer). 31st International Meeting of the Clinical Ligand Assay Society, San Diego, CA
- May 2005 Analytical Issues of Assays for Novel Biomarkers in Support of Clinical Drug Development. 31st Int. Meeting of the Clin. Ligand Assay Soc., San Diego, CA.
- Nov 2004 Macromolecular reference stds. for assays of novel biomarkers. AAPS Annual Meeting, Baltimore, MD
- Oct 2004 Bioanalytical method validation of assays for novel biomarkers in support of clinical drug development. Amgen Pharmaceuticals, Inc. Thousand Oaks, CA
- Sept 2004 The importance of statistically valid data analysis in educational data-driven decision-making. ISBA Annual meeting. Indianapolis, IN.
- June 2004 Bioanalytical validation of assays for novel biomarkers in support of clinical drug development. BioScience Forum on Application of Biomarkers to the drug discovery and development process. San Francisco, CA
- Mar 2004 Analytical validation of assays for novel biomarkers. Delaware Valley Drug Metabolism Discussion Group. Langhorne, PA
- Sept 2003 The importance of statistically valid data analysis in educational data-driven decision-making. ISBA Annual meeting. Indianapolis, IN.

Invited Lectures – cont'd.

- Sept 2003 Development of ligand binding assays for drug bioanalysis. Short course at 14th International Symposium on Pharmaceutical & Biomedical Analysis. Orlando, FL
- May 2003 Current issues in the validation and application of immunoassays for bioanalysis of macromolecules. AAPS workshop for bioanalytical method validation for macromolecules in support of pharmacokinetic studies. Washington DC
- Feb. 2003 Biomarker assay validation: a pharmaceutical perspective for clinical drug development. Barnett Conference. Philadelphia, PA
- June 2002 Application of biomarkers in clinical drug development (symposium moderator). AAPS National Biotechnology Meeting, San Diego, CA
- Feb. 2002 Biomarker assay validation: a pharmaceutical perspective for clinical drug development. BIOVAL 2002, London, UK
- Oct. 2001 AAPS 'Hot Topic:' Harmonization and interpretation of bioanalytical method validation guidance and workshop/conference reports. A perspective on validation of ligand binding assays for small molecules. AAPS Ann. Meeting Denver, CO
- Oct. 2001 Application of multiplexing binding assays in the quantification of biomarkers (symposium organizer). AAPS Annual Meeting, Denver, CO.
- Nov. 2000 AAPS Open Forum on Bioanalytical Methods Validation for macromolecules. AAPS Annual Meeting, Indianapolis, IN.
- Oct. 2000 Biomarker analytical validation-biological issues. DIA Workshop for new approaches for assessing efficacy and safety in drug development, 3rd Annual Clinical Trial Lab. and Biomarker Symposium, Arlington, VA.
- Mar. 2000 Current Issues in the Validation and Application of Immunoassays for Macromolecules. FDA/AAPS Workshop on Validation of Bioanalytical Methods for Macromolecules. Crystal City Meeting, Arlington, VA
- Jan. 2000 Calibration Curve Issues in Validation of Immunoassays. FDA/AAPS Workshop on Bioanalytical Methods Validation. Crystal City Meeting, Arlington, VA
- Nov. 1998 Immunoassay Issues in the Bioanalysis of 2nd Generation Therapeutic Proteins. AAPS Roundtable, San Francisco CA
- May 1997 Development of Therapeutic Proteins: A Drug Metabolism Perspective. Midwestern Biopharmaceutical Statistics Workshop, Muncie IN
- Oct. 1993 An improved RIA for the determination of Insulin-like growth factor-II in biological fluids and rat tissues. Dept. of Biochemistry & Molecular Biology, Ind. Univ. School of Medicine

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Consultant

- Jan 2008 - Present Emisphere; Tarrytown, NY. Bioanalysis of biopharmaceuticals
- Oct 2007 - Present Halozyme Inc.; San Diego, CA. Bioanalysis of biopharmaceuticals
- Oct 2007 - Present Alkermes, Cambridge, MA. Immunogenicity of biopharmaceuticals
- Apr 2007 - Present Ambrx Inc.; La Jolla, CA USA; Bioanalysis of biopharmaceuticals and immunogenicity testing
- Apr 2007 – Present TheraTechnologies; Montreal Quebec, Canada; Immunogenicity Consultant
- Jan. 2006 – Present Marcadia Biotec, Carmel IN, Bioanalysis & ADME of Biopharmaceuticals
- Sept 2006 - Present BioRexis Pharmaceuticals, King of Prussia, PA; Bioanalysis of biopharmaceuticals and immunogenicity testing
- July 2006 – Present Savient Pharmaceuticals, East Brunswick NJ; Immunogenicity Consultant
- May 2006 – Present Amgen Pharmaceuticals, Thousand Oaks, CA; Biomarker Assays
- Apr. 2006 – Present Millipore / Serologicals, Inc., St. Charles, MO USA
- 2006 - 2007 ConjuChem Inc., Montreal Quebec, Canada; Immunogenicity Consultant
- 2005 – Present Luminex Corp., Austin TX; Scientific Advisory Board
- Feb. 2005 ConjuChem, Montreal Quebec, Canada; Immunogenicity Advisory Board Meeting
- Oct. 2007, Aug. 2005 & Apr 2003 Hoffman-La Roche Pharma. Inc., Nutley, NJ
- Nov. 1999 National Cancer Institute, Epidemiology and Biostatistics Program, RFP-0500-27. Assays to determine C-peptide, leptin and prolactin in a case-control study of premenopausal breast cancer.
- Mar. 1995 National Cancer Institute, Epidemiology and Biostatistics Program, RFP-0500-04. Radioimmunoassays for C-peptide

Patents

- Mar. 1987 4,649,107 - Radioenzymatic Assay for Norepinephrine, Eli Lilly and Company
- Apr. 1986 4,582,806 - Purification of Phenylethanolamine N-methyltransferase for Use in Radioenzymatic Assays, Eli Lilly and Company

Other Professional Experience

- 1992-Present Adjunct Assistant Professor, Department of Biochemistry and Molecular Biology, Indiana University School of Medicine
- 1992-Present Affiliate Member, Indiana University Graduate School Faculty
- 1989-1991 Adjunct Instructor, Dept. of Biochemistry, Indiana Univ. School of Medicine
- 1986-1995 Lecturer in Methods in Protein Chemistry, B841; Dept. of Biochemistry & Molecular Biology
- 1986-2000 Lecturer in Physiological Disposition of Drugs, F836; Dept. of Pharmacology
- 1980 – 2000 School Board member, Beech Grove City Schools

Post-Doctoral Advisor

- 1999-2000 Ying (Robert) Cao, Drug Disposition, Lilly Research Laboratories Investigation of chemiluminescence as a routine detection method in ELISAs for the bioanalysis of Therapeutic Proteins

Graduate Student Committees

- 1999-2006 Chad A. Ray, Department of Pathology, Indiana University School of Medicine. Ph. D. Thesis: Pneumocystis Pneumonia Induces Caspase-9 Mediated Apoptosis in Rat Alveolar Macrophages (Oct. 2006).
- 1993-1997 Jing Zhang, Department of Biochemistry, Indiana University School of Medicine. Ph. D. Thesis: Expression and Distribution of Tissue Carboxyl-esterases that Catalyze Drug Ester Metabolism (Dec. 1997).

Education-Related Publications and Presentations

- Sept 2004 The importance of statistically valid data analysis in educational data-driven decision-making. ISBA Annual meeting. Indianapolis, IN.
- Sept 2003 The importance of statistically valid data analysis in educational data-driven decision-making. ISBA Annual meeting. Indianapolis, IN
- July 2003 Data Driven Decision-Making. A comprehensive integrated strategy for K-12 education. Beech Grove City Schools.
- Bowsher RR, Brunelle RL and Smith WC. *The Importance of Statistically Valid Data Analysis in Educational Data-Driven Decision-Making*. Indiana School Boards Association Journal, 48(4): 16-18 (2002).

MANUSCRIPTS AND BOOK CHAPTERS

1. Dean RA, Henry DP, **Bowsher RR** and Forney RB. A sensitive radioenzymatic assay for the simultaneous determination of dopamine and salsolinol. *Life Sci* 27:403-413 (1980).
2. **Bowsher RR** and Henry DP. Decarboxylation of p-tyrosine: A potential source of p-tyramine in mammalian tissues. *J Neurochem* 40:992-1002 (1983).
3. Verburg KM, **Bowsher RR** and Henry DP. A new radioenzymatic assay for histamine using purified histamine N-methyltransferase. *Life Sci* 32:2855-2867 (1983).
4. **Bowsher RR**, Verburg KM and Henry DP. Histamine N-methyltransferase: Quantification, tissue distribution, purification and immunologic properties. *J Biol Chem* 258:12215-12220 (1983).
5. Verburg KM, **Bowsher RR** and Henry DP. Kinetic analysis of the histamine N-methyltransferase reaction as used in the histamine radioenzymatic assay: Optimization of assay specificity. *Life Sci* 35:241-251 (1984).
6. Herman KS, **Bowsher RR** and Henry DP. Synthesis of N- π -Methyl-histamine and N- α -Methylhistamine by purified rabbit lung indolethylamine N-methyl-transferase. *J Biol Chem* 260:12336-12340 (1985).
7. **Bowsher RR** and Henry DP. Aromatic L-amino acid decarboxylase: Biochemistry and functional significance. In *Neurochemical Techniques and Analyses*. Vol. 5, pps. 33-78 (Boulton, AA, Baker GF and Yu PH, eds.) Humana Press, Clifton, NJ (1986).
8. Henry DP and **Bowsher RR**. An improved radioenzymatic assay for plasma norepinephrine using purified norepinephrine N-methyltransferase. *Life Sci* 38:1473-1483 (1986).
9. Verburg KM, **Bowsher RR**, Zerbe RL and Henry DP. The effect of hypertonic saline administration or stalk transection on histamine and histamine N-methyltransferase in the rat posterior pituitary. *Agents and Actions* 18:494-498 (1986).
10. Pratt JH, Turner DA, **Bowsher RR** and Henry DP. Dopamine in rat adrenal glomerulosa. *Life Sci* 40:811-816 (1987).
11. Becker GW, **Bowsher RR**, Mackellar WC, Poor ML, Tackitt PM and Riggin RM. Chemical, physical and biological characterization of a dimeric form of biosynthetic human growth hormone. *Biotechnol and Appl Biochem* 9:478-487 (1987).
12. Van Huysse JW, **Bowsher RR**, Willis LR and Henry DP. A radioenzymatic assay for p-tyramine and p-octopamine. *Biochem Med and Metabol Biol* 40:50-60 (1988).
13. Verburg, KM, **Bowsher RR** and Henry DP. Quantification of urinary histamine by a new radioenzymatic assay: Documentation of assay specificity and establishment of normal excretion rates. *J Allergy Clin Immunol* 82:339-347 (1988).

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14. Van Huysse JW, **Bowsher RR**, Willis LR and Henry DP. The simultaneous measurement of multiple urinary aralkylamines. *Biogenic Amines* 6:279-288 (1989).
15. Apathy JM and **Bowsher RR**. A sensitive immunoradiometric assay for the quantification of murine monoclonal antibodies in human serum. *J Pharm Biomed Anal* 7:593-600 (1989).
16. Schneck D, Butler F, Dugan W, Littrel D, Dorrbecker S, Peterson B, **Bowsher R**, DeLong A and Zimmerman J. Phase I studies with a murine monoclonal antibody vinca conjugate (KS1/4-DAVLB) in patients with adenocarcinoma. *Antibody Immunoconj Radiopharm* 2:93-100 (1989).
17. **Bowsher RR**, Riggin RM, Apathy JM, Ferguson AL and Henry DP. Cross-reactivity of monomeric and dimeric biosynthetic human growth hormone in commercial immunoassays. *Clin.Chem* 36:362-366 (1990).
18. Schneck D W, Butler F, Dugan W, Littrell D, Petersen B, **Bowsher RR**, DeLong A, Dorrbecker SH, Littrell D, Butler F and Dugan W. Disposition of a murine monoclonal antibody vinca conjugate (KS1/4-DAVLB) in patients with
19. Lepor H, Shapiro E, **Bowsher RR** and Henry DP. Determination of norepinephrine levels in the adult human prostate. *J Urology* 144(5):1263-1266 (1990).
20. Schneck DW, Butler F, Dugan W, Littrel D, Dorrbecker S, Petersen B, **Bowsher, RR**, DeLong A, Zimmerman J and Bumol TF. Phase I studies with a murine monoclonal antibody-vinca conjugate in patients with adenocarcinoma of the lung, colon or ovary. In *Monoclonal Antibodies and Immunoconjugates*, pps. 127-142 (Baldwin, R. W., Byers, V. S. & Mann, R.D.J., eds.) The Parthenan Publ. Group, Park Ridge, N J (1990).
21. Brier ME, **Bowsher RR**, Mayer PR and Henry DP. Conversion of tyrosine to p-tyramine in the isolated perfused rat kidney: Modulation by perfusate tyrosine concentration. *Life Sci* 48: 901-907 (1991).
22. **Bowsher RR**, Russell WL., Apathy JM, O'Brien PJ, Ferguson AL and Henry DP. Measurement of insulin-like growth factor-II in physiological fluids and tissues. I: An improved extraction procedure and RIA for human and rat fluids. *Endocrinology* 128:805-814 (1991).
23. Russell WL, **Bowsher RR**, Smith MC, Apathy JM and Henry DP. Measurement of insulin-like growth factor-II in physiological fluids and tissues. II: Measurement in rat tissues. *Endocrinology* 128:815-822 (1991).
24. Henry DP, **Bowsher RR** and Verburg KM. Radioenzymatic assay for histamine: Development and validation. *Scand J Gastroenterol.* 26(Suppl. 180):26-31 (1991).
25. Taber LD, O'Brien PJ, **Bowsher RR** and Sportsman JR. A competitive particle concentration fluorescence immunoassay of 5,10-dideaza-5,6,7,8-tetrahydrofolic acid, an antifolate agent with broad-spectrum antitumor activity. *Clin Chem* 37(2):254-260 (1991).

26. Hooper SD, **Bowsher RR**, and Howey DC. Pharmacokinetics and pharmacodynamics of intravenous regular human insulin, In Peptides, peptoids, and proteins, Pharmacokinetics and Pharmacodynamics, vol 3, pps. 128-137, (Grazone, P. D., Colburn, W. A. and Mokotoff, M., eds.) Harvey Whitney Books, Inc., Cincinnati, OH (1991).
27. Hsu-Fang C, Ipp E, **Bowsher R**, Berman N, Ezrin C and Griffiths S. Sustained, pulsatile insulin secretion from adenomatous human beta cells: Synchronous cycling of insulin, C-peptide and proinsulin. *Diabetes* 40:1453-1458 (1991).
28. Pratt JH, Manatunga AK, **Bowsher RR** and Henry, D. P. The interaction of norepinephrine excretion with blood pressure and race in children. *J Hypertension* 10:93-96 (1992).
29. Galloway JA, Spradlin CT, Howey DC, Frank BH, **Bowsher RR** and Anderson JH. Human proinsulin: review of chemistry, in vitro and in vivo receptor binding, animal and human pharmacology studies, and clinical trial experience. *Diabetes Care* 15:666-692 (1992).
30. Ipp E, Griffiths SM, **Bowsher RR**, Tarris RH, Zhou DB and Terlecki ME. Fluctuations in plasma proinsulin in an insulinoma. *Diabetes Care* 15:931-933 (1992).
31. **Bowsher RR**, Wolny JD and Frank BH. A rapid and sensitive radioimmunoassay for the quantification of proinsulin in human serum. *Diabetes* 41:1084-1090 (1992).
32. **Bowsher RR**, Apathy JM, Compton JA, Wolen RL, Carlson KH and DeSante KA. A sensitive, specific radioimmunoassay for quantifying pergolide in plasma. *Clin Chem* 38(10):1975-1980 (1992).
33. Schwertschlag US, Cerimele BJ, McNay J, **Bowsher RR** and Rowe H. Effect of Tibenelast (a phosphodiesterase inhibitor) and Theophylline on Isoproterenol stimulated heart rate, cyclic AMP and norepinephrine levels. *Pharmacol* 46: 142-47 (1993).
34. Haffner SM, Mykkanen L, Stern MP, Valdez RA, Heisserman JA and **Bowsher RR**. Relationship of proinsulin and insulin to cardiovascular risk factors in nondiabetic subjects. *Diabetes* 42:1297-1302 (1993).
35. Shekhar A, Sims LS and **Bowsher RR**. GABA receptors in the region of the dorsomedial hypothalamus of rats regulate anxiety in the elevated plus-maze test: II. Physiological measures. *Brain Res* 627:17-24 (1993).
36. Woodworth JR, Howey DC and **Bowsher RR**. Establishment of time-action profiles for regular and NPH insulin using pharmacodynamic modeling. *Diabetes Care* 17(1):64-69 (1994).
37. Howey DC, **Bowsher RR**, Brunelle RL and Woodworth JR. [Lys(B28),Pro(B29)]-Human insulin: a rapidly-absorbed analogue of human insulin. *Diabetes* 43(3): 396-402 (1994).

38. Woodworth JR, Howey DC. **Bowsher RR**, Brunelle RL, Rowe HM, Compton JA and Cerimele B. Comparative pharmacokinetics and glucodynamics of two human insulin mixtures: 70/30 and 50/50. *Diabetes Care* 17:336-41 (1994).
39. Voelker JR, Cobb SL and **Bowsher RR**. An improved HPLC-RIA method for the quantification of angiotensin II in human plasma. *Clin Chem* 40(8):1537-1543 (1994).
40. **Bowsher RR**, Compton JA, Kirkwood JA, Place GD, Jones CD, Mabry TE, Hyslop DL, DeSante KA and Hatcher BL. A sensitive and specific RIA for fialuridine: initial assessment of pharmacokinetics after a single dose in healthy volunteers. *Antimicrob Agents Chemother* 38(9):2134-2142 (1994).
41. Richardson FC, Engelhardt JA and **Bowsher RR**. Fialuridine (FIAU) accumulates in DNA of dogs, monkeys and rats following long-term oral administration. *Proc Natl Acad Sci, USA* 91: 12003-12007 (1994).
42. Haffner SM, **Bowsher RR**, Mykkanen L, Hazuda HP, Mitchell BD, Valdez RA, Gingerich R, Monterossa A and Stern MP. Proinsulin and specific insulin concentrations in high and low risk populations for NIDDM. *Diabetes* 43(12): 1490-1493 (1994).
43. Haffner SM, Mykkanen L, Valdez R, Stern MP, Holloway DL, Monterrosa A and **Bowsher RR**. Disproportionately increased proinsulin levels are associated with the insulin resistance syndrome. *J Clin Endocrinol Metab* 79:1806-1810 (1994).
44. Birnbaum RS, **Bowsher RR** and Wiren KM. Changes in Insulin-like growth factor-I expression and secretion during the proliferation and differentiation of normal rat osetoblasts. *J Endocrinol* 144:251-259 (1995).
45. Haffner S, Mykkanen L, Robbins D, Valdez R, Miettinen H, Howard B., Stern MP and **Bowsher RR**. A Preponderance of Small Dense LDL is Associated with Specific Insulin, Proinsulin and the Components of the Insulin Resistance Syndrome in Non-Diabetic Subjects. *Diabetologia* 38:1328-1336 (1995).
46. Holloway DL, Santa PS, Compton JA, and **Bowsher RR**. Validation of the Diagnostic Products Coat-A-Count insulin radioimmunoassay for the quantification of humalog, a rapidly absorbed analog of human insulin. *Clin Chem* 41(12):1777-1778 (1995).
47. Howey DC, **Bowsher RR**, Brunelle RL, Rowe HM, Santa PS, Downing-Shelton J and Woodworth JR. [Lys(B28), Pro(B29)]-human insulin: effect of injection time on postprandial glycemia. *Clin Pharmacol Ther* 58:459-469 (1995).
48. Haffner SM, Stern MP, Miettinen H, Gingerich R and **Bowsher RR**. Higher proinsulin and specific insulin are both associated with a parental history of diabetes in non-diabetic mexican american subjects. *Diabetes* 44:1156-1160 (1995).
49. Robbins DC, Anderson L, **Bowsher RR**, Chance R, Dinesen B, Frank, B. et al. Report of the american diabetes association's task force on standardization of the insulin assay. *Diabetes* 45:242-256 (1996).

50. Burge MR, McLeod J, **Bowsher RR**, and Schade DS. Validity of Count Coat-A-Insulin RIA kit for quantifying total and free humalog. *Clin Chem* 42(5):777 (1996).
51. Kasperska-Czyzyk T, Jedynasty K, **Bowsher RR**, Stradowska I, Stepien K, Nowaczyk R, Szymczak W and Czyzyk A. Difference in the influence of maternal and paternal non-insulin-dependent diabetes (NIDDM) on pancreatic beta-cell activity and blood lipids in normoglycaemic non-diabetic adult offspring. *Diabetologia* 39(7):831-837 (1996).
52. Liechty EA, Boyle DW, Moorehead H, Lee W-H, **Bowsher RR** and Denne SC. Effects of circulating IGF-I on glucose and amino acid kinetics in the ovine fetus. *Am J Physiol, Endo & Metabol* 271:E177-E185 (1996).
53. Sinha MK, Opentanova I, Ohannesian JP, Heiman ML, Hale J, Becker GW, **Bowsher RR**, Stephens TW and Caro JF. Evidence of free and bound leptin in human circulation: studies in lean and obese subjects during short-term fasting. *J Clin Invest* 98(6):1277-1282 (1996).
54. Grinspoon S, Gulick T, Askari H, Landt M, Lee K, Anderson E, Zhongmin M, Vignati L, **Bowsher R**, Herzog D and Klibanski A. Serum leptin levels in women with anorexia nervosa. *J Clin Endocrinol Metab* 81(11):3861-3863 (1996).
55. Lee W-H, Gaylord TD, **Bowsher RR**, Hlaing M, Moorehead H and Liechty EA.. Nutritional regulation of circulating insulin-like growth factors (IGFs) and their binding proteins in the ovine fetus. *Endocrine J.* 44(1):163-173 (1997).
56. Rotimi C, Luke A, Li Z, Compton JA, **Bowsher RR** and Cooper RS. Heritability of plasma leptin in a population sample of african-american families. *Genetic Epidemiology* 14:255-263 (1997).
57. Chou JZ, Place GD, Waters DG, Kirkwood JA and **Bowsher RR**. Development of a radioimmunoassay for LY315902, an analog of glucagon-like insulinotropic peptide, and its application in the study of canine pharmacokinetics. *J. Pharmac Sci* 86(7):768-773 (1997).
58. Berman N, Genter P, Chou H-F, Cortez C, **Bowsher RR** and Ipp E. Erratic oscillatory characteristics of plasma insulin concentrations in patients with insulinoma: mechanism of unpredictable hypoglycemia. *J Clin Endocrinol Metab* 82(9):2899-2903 (1997).
59. Coleman DL, Place GD, Canak N, Shih C and **Bowsher RR**. A sensitive and specific radioimmunoassay for LY309887, a potent inhibitor of glycinamide ribonucleotide formyltransferase. *Clin Cancer Res* 4(1):157-163 (1998).
60. Radziuk J, Pye S, Bradley B, Braaten J, Vignati L, Roach P, **Bowsher RR**, Dimarchi R and Chance R. Basal activity profiles of NPH and [N^Σ-palmitoyl-Lys(B29)] human insulins in subjects with IDDM. *Diabetologia* 41(1):116-120 (1998).
61. Luke AH, Rotimi CN, Cooper RS, Long AE, Forrester TE, Wilks R, Bennet FI, Olufemi O, Compton JA and **Bowsher RR**. Leptin and body composition of Nigerians, Jamaicans and US blacks. *Am J Clin Nutr* 67(3):391-396 (1998).

62. Ambrosius WA, Compton JA, **Bowsher RR** and Pratt JH. Relation of race, age, and sex hormone differences to serum leptin concentrations in children and adolescents. *Horm Res* 49(5):240-246 (1998).
63. Tennat BC, Baldwin BH, Graham LA, Ascenzi MA, Hornbuckle WE, Rowland PH, Tochkov IA, Yeager AE, Erb HN, Colacino JM, Lopez C, Engelhardt JA, **Bowsher RR**, Richardson FC, Lewis W, Cote PJ, Korba BE and Gerin JL. Antiviral activity and toxicity of fialuridine in the woodchuck model of hepatitis B virus infection. *Hepatology* 28(1):179-191 (1998).
64. Meetze W, **Bowsher RR**, Compton J and Moorehead H. Hyperglycemia in extremely-low-birth-weight infants. *Biol of the Neonate* 74(3):214-221 (1998).
65. Boyle DW, Denne SC, Moorehead H, Lee W-L, **Bowsher RR**, and Liechty EA. Effect of recombinant human insulin-like growth factor-I (rhIGF-I) on whole fetal and fetal skeletal muscle protein metabolism in sheep. *Am J Physiol* 275 (Endocrinol Metab 38):E1082-1091 (1998).
66. **Bowsher RR**, Lynch RA, Brown-Augsburger P, Santa PS, Legan WE, Woodworth JR and Chance RE. Sensitive RIA for the specific determination of insulin lispro. *Clin Chem* 45(1):104-110 (1999).
67. Jovanovic L, Ilic S, Petitt DJ, Hugo K, Gutierrez M, **Bowsher RR** and Bastyr III EJ. Metabolic and immunologic effects of insulin lispro in gestational diabetes. *Diabetes Care* 22(9):1422-1427 (1999).
68. Liechty EA, Boyle DW, Moorehead H, Lee W-H, **Bowsher RR** and Denne SC. Glucose and amino acid kinetic response to graded infusion of rhIGF-1 in the late gestation ovine fetus. *Am J Physiol (Endocrinol Metab)* 40):E537-E543 (1999).
69. Graf CJ, Woodworth JR, Seger ME, Holcomb JH, **Bowsher RR** and Lynch R. Pharmacokinetic and glucodynamic comparison of recombinant and animal-source glucagon after IV, IM and SC injection in healthy volunteers. *J Pharm Sci* 88(10):991-995 (1999).
70. Findlay JWA, Smith WC, Lee JW, Nordbloom GD, Das I, Desilva BS, Khan MN, and **Bowsher RR**. Validation of immunoassays for bioanalysis: A pharmaceutical industry perspective. *J Pharm Biomed Anal* 21(1): 1249-1273 (2000).
71. Wolff RK, Allen DL, Hughes BL, Smith HW, Chou JZ, **Bowsher RR**, Francis PC, and Vahle JL. The case for route-dependent toxicology comparisons: using large animal models to speed clinical development of inhaled proteins. *Respiratory Drug Deliv* 7:163-170 (2000).
72. Brown-Augsburger P, Masnyk M, Santa P, Gingerich RL, and **Bowsher RR**. An immunoadsorption strategy to produce specific antisera against analogs of human proteins: Development of sensitive and specific RIAs for two analogs of human leptin. *J Pharm Biomed Anal* 21(4): 687-696 (2000).

73. Shah VP, Midha KK, Findlay JWA, et al. Workshop Report: Bioanalytical method validation - a revisit with a decade of progress. *Pharmac. Res.* 17(12):1551-1557 (2000).
74. Urae A, Maeda A, **Bowsher RR**, Wordworth JR. Pharmacokinetics and pharmacodynamics of fast-acting insulin, LY275585, a phase I study – comparison with regular human insulin (Humulin R). *J Clin Therap and Med* 16(11):1601-1611 (2000). [*Japanese*]
75. Budman DR, Johnson R, Barile B, **Bowsher RR**, Vinciguerra V, Allen RL, Kolitz J, Ernest II CS, Kreis W, Zervos P and Walling J. Phase I and pharmacokinetic study of LY309887: a specific inhibitor of purine biosynthesis. *Cancer Chemother Pharmacol* 47(6):525-531 (2001).
76. Cao Y, Smith WC and **Bowsher RR**. A sensitive chemiluminescent enzyme immunoassay for the bioanalysis of carboxyl-terminal B-chain analogues of human insulin. *J Pharm Biomed Anal* 26(1):53-61 (2001).
77. Miller KJ, **Bowsher RR**, Celniker A, et al. Workshop on bioanalytical methods validation for macromolecules: summary report. *Pharmac. Res.* 18(9):1373-1383 (2001).
78. **Bowsher RR** and Smith WC. Analytical validation of assays for novel biomarkers: a practical approach for clinical drug development. *AAPS Newsmagazine* 5(6):18-24 (2002).
79. Lee JW, Nordbloom GD, Smith WE and **Bowsher RR**. Validation of bioanalytical assays for novel biomarkers: practical recommendations for clinical investigation of new drug entities, in *Biomarkers in Clinical Drug Development* (Bloom JC and Dean RA, eds.), Marcel Dekker, NY (2002).
80. Woodworth JR, Howey DC, **Bowsher RR** and Brunelle RL. Relating glucose clamp profiles to reduction of blood glucose after insulin administration. *Diabetes Technology and Therapeutics* 6(2):147-153 (2004).
81. Ray CA, **Bowsher RR**, Smith WC, Devanarayan V, Willey MB, Brandt JT, Dean RA. Development, validation, and implementation of a multiplex immunoassay for the simultaneous determination of five cytokines in human serum. *J Pharm Biomed Anal* 36(5):1037-44 (2005).
82. Lee JW, Weiner RS, Sailstad JM, **Bowsher RR**, Knuth DW, O'Brien PJ et al. Method validation and measurement of biomarkers in nonclinical and clinical samples in drug development: a conference report. *Pharmac Res* 22(4):499-511 (2005).
83. Smolec J-M, DeSilva B, Smith WC, et al. Workshop Report: Bioanalytical method validation for macromolecules in support of pharmacokinetic studies. *Pharmac Res* 22(9):1425-31 (2005).
84. Fill JA, Brandt JT, Wiedemann HP, Rinehart BL, Lindemann CF, Komara JJ, **Bowsher RR**, Spence MC and Zeiher BG. Urinary desmosine as a biomarker in acute lung injury. *Biomarkers* 11(1):85-96 (2006).

Ronald R. Bowsher, Ph.D. CV

85. Marcovina S, **Bowsher RR**, Miller WG, Staten M, Myers G, Caudill SP, Campbell SE and Steffes MW. Standardization of insulin immunoassays: Report of the American Diabetes Association's workgroup. *Clin Chem* 53:711-716 (2007).
86. Nowatzke W and **Bowsher RR**. A macromolecule perspective on the 3rd AAPS/FDA Workshop/Conference –report – Quantitative bioanalytical methods validation and implementation: Best practices for chromatographic and ligand binding assays. *AAPS Newsmagazine* 10(6): 21-23 (2007).
87. Shankar G, Devanarayan V, Smith H, Barrett YC, **Bowsher R** et al. Recommendations for the validation of immunoassays used for detection of host antibodies against biotechnology products. (*submitted*)
88. **Bowsher RR** and Sailstad JM. Bioanalysis of circulating concentrations of receptor activator of nuclear factor κ B ligand (RANKL): Insights in the application of research-grade diagnostic kits for biomarker assessments in support of clinical drug development. *J Pharma Biomed Anal* (*in preparation*).
89. **Bowsher RR** and Santa PS. Differential stability of proinsulin in human serum and plasma: evidence for the proteolytic formation of B-C junctional split forms in serum. *Diabetes* (*in preparation*).
90. Howey, DC, **Bowsher RR**, Brunelle RL, Woodworth JR, and Seger M. [Lys(B28), Pro(B29)]-Human insulin: a rapidly-absorbed analogue of human insulin. A comparison with regular insulin over a range of doses. (*in preparation*).
91. DeSilva B and **Bowsher RR**. A phased approach for validation of ligand binding assays for bioanalysis of therapeutics, *in* *Ligand-Binding Assays: Development, Validation and Implementation in the Drug Development Arena* (Khan M and Findlay JW, eds.) (*in preparation*).

ABSTRACTS

1. Dean RA, Henry DP, **Bowsher RR** and Forney RB. A sensitive radioenzymatic assay for the simultaneous determination of dopamine and salsolinol. Soc of Toxicology, New Orleans, Louisiana (1979).
2. **Bowsher RR** and Henry DP. Purification and characterization of mammalian tyrosine decarboxylase activity. Fed Proc 40:300 (1981).
3. Verburg KM, **Bowsher RR** and Henry DP. Purification of histamine N-methyltransferase for use in histamine radioenzymatic assays. Fed Proc 41:1709 (1982).
4. Verburg KM, Henry DP, Callaghan JT and **Bowsher RR**. Gastric secretion of histamine after gastrin administration in normal human subjects. Clin Res 30(4):726A (1982).
5. **Bowsher RR**, Verburg KM and Henry DP. Histamine N-methyltransferase: Purification to homogeneity, characterization and immunologic properties. Fed Proc 42:907 (1983).
6. Verburg KM, **Bowsher RR** and Henry DP. Kinetic analysis of the HNMT reaction: Effect on the histamine radioenzymatic assay. Fed Proc 42:907 (1983).
7. Henry DP, **Bowsher RR**, Myers MJ, Zerbe RL and Petersen BH. Immunocytochemical localization of histamine N-methyltransferase in rat kidney. Fed Proc 42:709 (1983).
8. Verburg KM, **Bowsher RR**, Zerbe RL and Henry DP. Characterization of neurohypophyseal histamine: Effect of saline-induced dehydration and stalk-sectioning. Soc for Neurosci 9:705 (1983).
9. Van Huysse JW, **Bowsher RR**, Henry DP and Willis LR. *In vivo* renal synthesis of para-tyramine in the rabbit. Fed Proc 43:452 (1984).
10. **Bowsher RR**, Verburg KM and Henry DP. Guinea-pig and rat histamine N-methyltransferase: A comparative study. The Pharmacologist 26:222 (1984).
11. Verburg KM, **Bowsher RR**, Israel KS, Black HR and Henry DP. Histamine release by vancomycin in humans. Fed Proc 44:1247 (1985).
12. Brier GL, **Bowsher RR**, Black HR and Henry DP. Production of histamine by organisms associated with upper respiratory tract infections. Fed Proc 44:1247 (1985).
13. **Bowsher RR** and Henry DP. Purification and characterization of soluble tyrosine transaminase from rat brain. Fed Proc 44:1632 (1985).
14. Henry DP, Van Huysse JW and **Bowsher RR**. A new class of radioenzymatic assay for the Quantification of p-Tyramine and phenylethylamine. Fed Proc 45:158 (1986).
15. Brier ME, **Bowsher RR**, Mayer PR and Henry DP. Tyramine production by the isolated perfused rat kidney: Modulation by perfusate tyrosine concentration. Fed Proc 45:419 (1986).

16. **Bowsher RR** and Henry DP. An improved radioenzymatic assay for plasma norepinephrine using purified phenylethanolamine N-methyltransferase. *Fed Proc* 45:434 (1986).
17. Phebus LA, Russell WL, **Bowsher RR**, Henry DP and Clemens JA. Striatal extracellular phenethylamine and p-tyramine measured by *in vivo* microdialysis and radioenzymatic assay. *Neuroscience Abst* 12(2):994 (1986).
18. Schneck DW, Rubin A, Knadler MP, **Bowsher RR** and Apathy JM. Efficacy disposition of a new calcium antagonist. *Clin Pharmacol and Therapeutics* 41(2):234 (1987).
19. Brier GL, Apathy JM, **Bowsher RR**, Counter FT and Henry DP. The *in vivo* production of histamine by haemophilus influenza, *ASM Abstracts* 39 (1987).
20. **Bowsher RR**, Apathy JM, Ferguson AL and Frank BH. An improved radioimmunoassay for proinsulin in human serum and plasma. *Diabetes* 36 (Suppl. 1):94A (1987).
21. Howey DC, Dorrbecker SH, **Bowsher RR**, Kreigh TM, Hatcher BL and Rowe H R. The bioavailability of human proinsulin is greater and its absorption is less variable than regular insulin. *Diabetes* 36 (Suppl.1):63A (1987).
22. Henry DP, Nyhart EH and **Bowsher RR**. Pharmacokinetics of humatrope (biosynthetic human growth hormone) in man: iv, im, subcutaneous administration. *Endocrine Soc Abst* 69:252 (1987).
23. Brier ME, **Bowsher RR**, Mayer PR and Henry DP. Dose dependent renal conversion of tyrosine to tyramine in the isolated perfused rat kidney. *Clin Res* 35:A373 (1987).
24. **Bowsher RR**, Apathy JM, Ferguson AL, Riggin RM and Henry DP. Cross-reactivity of monomeric and dimeric biosynthetic human growth hormone in commercial immunoassays. *Endocrine Soc Abst* 70:122 (1988).
25. Dorrbecker SH, **Bowsher RR** and Howey DC. Pharmacokinetics and pharmacodynamics of intravenous human regular insulin in healthy men. *Pharm Res* 5:S-153 (1988).
26. Shukla SB and **Bowsher RR**. Production of affinity-purified antibodies and development of an immunoassay for LY253351, a potent α -1-antagonist. *Pharm Res* 5:S-229 (1988).
27. Apathy JM, Henry DP and **Bowsher RR**. The purification and characterization of an IGF-2 specific binding protein from human urine. *David Gibson Symposium*, A25 (1988).
28. Schneck DW, Petersen B, **Bowsher RR**, DeLong A, Dorrbecker S, Littrell D, Butler F and Dugan W. Disposition of a monoclonal antibody vinca conjugate in patients with cancer. *ASCPT* (1989).

Ronald R. Bowsher, Ph.D. CV

29. **Bowsher RR**, Apathy JM, Ferguson AL and Henry DP. An improved extraction method and RIA for insulin-like growth factor-2 (IGF-2). *Endocrine Soc.* 71:1340 (1989).
30. Russell WL, Smith MC and **Bowsher RR**. Development of a new extraction method and RIA for the quantification of insulin-like growth factor-2 (IGF-2) in rat tissues. *Endocrine Soc* 71:1341 (1989).
31. Chou HF, Berman N, **Bowsher RR** and Ipp E. Human beta cells secrete insulin in pulsatile fashion. *Diabetes* 38(2):97A (1989).
32. Henry DP, **Bowsher RR**, Apathy JM and Russell W-L. Binding of radiolabeled IGF-I and II by human plasma, urine, CSF as assessed by FPLC. *Endocrine Soc Abst* 71:277 (1989).
33. Dorrbecker SH, **Bowsher RR** and Howey DC. Pharmacokinetic and pharmacodynamic modeling of iv human proinsulin in healthy men. *Pharm Res* 6:S-240 (1989).
34. Dorrbecker SH, **Bowsher RR** and Howey DC. Pharmacokinetics and pharmacodynamics of iv human regular insulin. *Pittsburgh Pharmacodynamic Conf.* (1989).
35. Russell W-L, Apathy JM, **Bowsher RR** and Henry DP. Regional distribution of insulin-like growth factor-2 in rat brain. *Soc for Neurosci Abst* 15(1):231 (1989).
36. Singh SP, Russell W-L, **Bowsher RR**, Henry DP, Snyder AK and Harms KA. Fetal IGF-II levels following ethanol exposure. *Res Soc Alcoholism Abst.*(1990).
37. Young C, Currie V, Baltzer L, Trochanowski B, Eton O, Dyke R, **Bowsher R**. Phase I and clinical pharmacologic study of LY264618, 5,10-dideaza-tetrahydrofolate. *Am Assoc for Cancer Res* 31:1053 (1990).
38. Henry DP, **Bowsher RR**, Cerimele BJ and Nyhart EH. The administration of recombinant-derived insulin-like growth factor-II (IGF-II) to normal human subjects. *Endocrine Soc Abst* 72:1150 (1990).
39. O'Brien PJ, Donahue J and **Bowsher RR**. Characterization of a new binding protein for insulin-like growth factor-II (IGF-II) in human amniotic fluid. *Endocrine Soc Abst* 72:185 (1990).
40. Sessa C, Gumbrell L, Hatty S, Kern H, Cavalli F, **Bowsher R** and Woodworth J. Phase I study of 5,10-dideazatetrahydrofolic acid (LY264618; DDATHF) given daily for three consecutive days. *European Soc Med Oncol* (1990).
41. Schwertschlag US, Cerimele BJ, McNay JL, **Bowsher RR** and Rowe HM. Effect of Tibenelast, a PDE inhibitor, and theophylline on baseline and isoproterenol stimulated heart rate, cAMP and norepinephrine levels. *ASCPT* (1991).
42. Howey DC, Hooper SA and **Bowsher RR**. [Lys(B28), Pro(B29)]-human insulin: An equipotent analog of human insulin with rapid onset and short duration of action. *Diabetes* 40(Suppl. 1):423A (1991).

43. **Bowsher RR**, Compton JA, Apathy JM, Wolen RL and Henry DP. A sensitive and specific radioimmunoassay (RIA) for the quantification of pergolide. Soc for Neurosci Abst 17(2):1261 (1991).
44. Howey DC, Brunelle RL, **Bowsher RR**, Woodworth JR and Vignati L. Des (64,65)-human proinsulin: a potent insulin-agonist with intermediate action. Diabetes 41(Suppl. 1) (1992).
45. Haffner SM, Stern MP and **Bowsher RR**. The relationship of proinsulin and insulin to obesity, body fat distribution, lipids and lipoproteins. Circulation 86(Suppl. 1):I-200 (1992).
46. Satterwhite JH, **Bowsher RR**, Callaghan JT, Cerimele BJ and Levine LR. Nizatidine: lack of drug interaction with Naproxen. Clin Res 40(3):706A (1992).
47. Woodworth JR, **Bowsher RR**, Howey DC, Rowe HM and Ferguson AL. Pharmacokinetic and pharmacodynamic comparisons of [LYS B28, PRO B29] human insulin to Humulin R. Pharm Res (1992).
48. Lee W-H, Liechty EA, Murff-Maxey AY, Moorehead H, Santa PF, **Bowsher RR**. Regulation of circulating IGFBPs by glucose in ovine fetus independent of insulin. Endocrine Soc Abst. 75:422 (1993).
49. **Bowsher RR**, Henry DP, Santa PF, Wolny JD, Murff-Maxey AY and Lee W-H. Validation of formic acid/acetone in the extraction of IGF-I and -II from rat. Endocrine Soc Abst. 75:334 (1993).
50. **Bowsher RR** and Wolny JD. Differential stability of proinsulin in human serum and plasma. Diabetes 42(Suppl. 1):238A (1993).
51. Woodworth JR, Howey DC, **Bowsher RR**, Lutz S, Santa PF and Brady P. [Lys(B28),Pro(B29)]Human insulin: Dose-ranging vs Humulin R. Diabetes 42 (Suppl. 1):54A (1993).
52. Bergman NG, Genter P, Chou HF, Cortez C, **Bowsher RR** and Ipp E. Plasma insulin oscillations in patients with insulinomas. Endocrine Soc Abst 75:236 (1993).
53. Birnbaum RS, Wiren KM and **Bowsher RR**. Changes in insulin-like growth factor-I expression and secretion during osteoblast proliferation and differentiation. Am Soc for Bone and Mineral Research (1993).
54. Haffner S, Stern M and **Bowsher RR**. Increased proinsulin levels are associated with the insulin resistance syndrome. Am Heart Assoc (1993).
55. Gaylord T, Lee W-H, Liechty EA, Moorehead H, Santa PF and **Bowsher RR**. Regulation of insulin-like growth factors and the binding proteins in the ovine fetus. Clin Res 41(N3):A673 (1993).
56. Woodworth JR, Howey DC, Lutz S, Santa PF, Brady P and **Bowsher RR**. [Lys(B28),Pro(B29)]Human insulin: Dose-ranging vs Humulin R. Diabetologia 36(Suppl. 1):155A (1993).

57. Gaylord T, Lee W-H, Liechty EA and **Bowsher RR**. Regulation of insulin-like growth factors and the binding proteins in the ovine fetus. *Ped Res* 94(N4):A67 (1994).
58. Haffner S, Mykkanen L and **Bowsher RR**. Proinsulin, insulin and proinsulin/insulin ratio in non-diabetic mexican americans and non-hispanic whites. *Diabetes* 43(Suppl. 1):151A (1994).
59. Fineberg SE, Barrett-Conner E, Hufferd S, **Bowsher RR** and Fineberg NS. Can increments in insulin levels with progressive carbohydrate intolerance be explained on the basis of hyperproinsulinemia? *Diabetes* 43(Suppl. 1) (1994).
60. Goldberg MJ, Rowe HM, Cerimele BJ, Woodworth JR, **Bowsher RR** and Santa PF. Withdrawal effects in humans of LY228729, a 5HT_{1A} agonist. 5HT third IUPHAR Meeting on Serotonin (1994).
61. Haffner S, Mykkanen L and **Bowsher RR**. Increased proinsulin levels are associated with the insulin resistance syndrome. *Diabetologia* 37(Suppl. 1):A74 (1994).
62. Haffner S, Stern M and **Bowsher RR**. Increased proinsulin relative to specific insulin in impaired glucose tolerance and non-insulin dependent diabetes (NIDDM). 15th International Diabetes Fed.; Kobe, Japan (1994).
63. **Bowsher RR** and Santa PF. Serum catalyzes the in vitro formation of B-chain-C-peptide junctional split forms of proinsulin. International Diabetes Fed. 15th International Diabetes Fed.; Kobe, Japan (1994).
64. Kasperska-Czyzyk T, Jedyndasty K, **Bowsher RR**, Stradowska I, Stepien K and Nowaczyk R. Difference between the influence of maternal and paternal non-insulin-dependent diabetes on body mass, pancreatic β -cell activity and blood lipids of normoglycemic offspring. 15th International Diabetes Fed.; Kobe, Japan (1994).
65. Levine ES, Colacino JM, **Bowsher RR**, Sallie R and Lewis W. FIAU incorporates into DNA from human liver and from human hepatoblastoma cells. Am Assoc for the Study of Liver Diseases. *Hepatology* 94(20):A189 (1994).
66. Santa PF, **Bowsher RR**, Sittampalam GS, O'Bannon DD, Wheeler WJ and Flaugh ME. A sensitive, specific radioimmunoassay (RIA) for the quantification of LY228729. *FASEB J* 9(3):2364 (1995).
67. Place GD, Coleman DL, Kirkwood JA and **Bowsher RR**. Preparation and characterization of rabbit antisera specific for LY309887. *Pharmac Res* 12(9): S-379 (1995).
68. Haffner S, Stern M, Miettinen H, Gingerich R, Mitchell B, **Bowsher RR**. Proinsulin and true insulin in nondiabetic mexican-americans with a personal history of diabetes. *Diabetes* 44(Suppl. 1):A159 (1995).
69. Richardson FC, Horn DM, Scheuring JC, Huffman DM, Oakes DW, Engelhardt JA, Kirkwood JA and **Bowsher RR**. Kinetics of accumulation of fialuridine (FIAU) in the F-344 rat during long-term oral administration. *Cancer Res* 36:A2131 (1995).

Ronald R. Bowsher, Ph.D. CV

70. Farid NA, Perrin KA, Santa PF, **Bowsher RR** and Johnson TR. The disposition of [N-palmitoyl lys(B29)]-human insulin (LY309132) in rats and dogs. ISSX Meeting abstract (1996).
71. Chou J, Place G, Waters D, Kirkwood J and **Bowsher RR**. Development of an immunoassay for LY315902, an analog of glucagon-like insulinotropic peptide, and its application in the study of canine pharmacokinetics. AAPS Meeting abstract, Seattle WA (1996).
72. Gongola JA, Compton JA, Place GD, Shipley LA and **Bowsher RR**. Preparation and characterization of rabbit antisera specific for LY156735, a potent melatonin agonist. AAPS Meeting abstract, Seattle WA (1996).
73. Howey DC, Woodworth JR, **Bowsher RR** and Reviergo J. Pharmacokinetic and glucodynamic assessments of N-palmitoyl, Lys(B29) human insulin in healthy volunteers. IDF Abstract, Diabetologia 40(Suppl. 1):A354 (1997).
74. **Bowsher RR**, Woodworth J, Wilke A, Smith W, Yordy R and Lynch R. Characterization of dose, gender, and temporal response differences for recombinant glucagon in dogs. IDF Abstract, Diabetologia 40(Suppl. 1): A240 (1997).
75. Chou JZ, Hoffman JA and **Bowsher RR**. *In vitro* metabolism of native GLP-1 peptides and its analog LY307161 in rat and human serum. AAPS Abst. (1997).
76. Chou JZ, Ackermann BL, Waters DG, Lozano EP and **Bowsher RR**. In vitro metabolism and determination of parathyroid hormone (PTH) (1-34) in canine and human saliva. AAPS Abst. (1997).
77. Brown-Augsburger P, Lynch RA, Santa PS, Holloway DL, Legan W.E and **Bowsher RR**. Production of polyclonal guinea pig antisera specific for insulin lispro. AAPS Abst 4211 (1997).
78. Santa PS and **Bowsher RR**. An optimized immunocapture-amidolytic assay for the quantification of LY203638 (activated protein C). AAPS Abst 4159 (1997).
79. Waters DG, Chou JZ, Koenig MC and **Bowsher RR**. Development and optimization of an immunoassay to measure the immunoreactive serum concentration of human parathyroid hormone (hPTH) in rats. ISSX Abst. (1997).
80. **Bowsher RR**, Lynch RA, Brown-Augsburger P, Santa PF, Legan WE and Chance RE. A sensitive radioimmunoassay for the specific determination of insulin lispro. Diabetes 47(Suppl. 1):A95 (1998).
81. Woodworth JR, Howey DC and **Bowsher RR**. Pharmacokinetic and pharmacodynamic results from a dose-ranging and test meal trial of LY355101, a novel leptin analogue, in healthy volunteers. Diabetes 47(Suppl. 1) (1998).
82. Woodworth JR, Howey DC, **Bowsher RR**, Trautmann M and Caro J. The pharmacokinetics and acute effects of LY355101, a novel antiobesity protein, in healthy volunteers. 8th Int Congress on Obesity (1998).

Ronald R. Bowsher, Ph.D. CV

83. Gongola J and **Bowsher RR**. Comparison of C-peptide antisera specificity among commercial radioimmunoassay kits. AAPS Abst (1998).
84. Gillespie T, Barbuch R, Berna M, **Bowsher R** and Jensen C. LC/MS/MS identification and profiling of pergolide mesylate metabolites in human, rat and dog liver slices. Proc. 46th Ann. Conf. of ASMS. Orlando, FL, 706 (1998).
85. Cao Y, Smith WC, **Bowsher RR**. A sensitive chemiluminescent enzyme immunoassay for the bioanalysis of B-chain analogs of human insulin. AAPS Abst 3149, Indianapolis, IN (2000).
86. Ray C, Willey M, Dean RA, **Bowsher RR**, Brandt JT. Validation of a multiplex immunoassay for the simultaneous determination of Five cytokines. GLIIFCA Abst, Detroit MI, (2000).
87. Sittampalam G, Cox KL, Viswanath D, Chen X-Y, Ray C, **Bowsher RR**, Dean RA, and Marder P. Analytical chemistry in high throughput screening and drug discovery. Pharmac & Biomedical Anal Conference 2001, Montrey, CA (2001).
88. Pham K, Woo J, Calamba D, Nowatzke W, Freeman M, Sailstad J, **Bowsher RR** and Castaigne J-P. Validation of an Immunoradiometric Assay (IRMA) for the Detection of Anti-CJC-1295 Antibody in Monkey serum. AAPS National Biotechnology Conference, San Francisco CA (June 2005).
89. Pham K, Roumeliotis P, Nguyen L, Nowatzke W, Baganoff M, Sailstad J, **Bowsher RR**, and Castaigne J-P. Validation of an Immunoradiometric Assay (IRMA) for the Detection of Anti-CJC-1131 Antibody in Monkey serum. AAPS National Biotechnology Conference, San Francisco CA (June 2005).
90. Sailstad J, Pham K, Nowatzke W, Iordanova V, Castaigne J-P, Wen S, and **Bowsher RR**. Evaluation of Binding of Protein LA to Rabbit, Monkey, Dog, and Human Immunoglobulins. AAPS National Biotechnology Conference, San Francisco CA (June 2005).
91. **Bowsher RR**, Pham K, Salfen B, Baganoff M, Sailstad J, and Nowatzke W. Investigation of Three Immunogenicity Methods to Detect Antibodies to CJC-1295. AAPS National Biotechnology Conference, San Francisco CA (June 2005).
92. Pham K, Roumeliotis P, Nguyen L, Nowatzke W, Baganoff M, Sailstad J, **Bowsher RR**, and Castaigne J-P. Validation of an immunoradiometric assay (IRMA) for the detection of anti-CJC-1131 antibodies (IgG, IgM, IgA, and IgE) in monkey serum. 2005 AAPS Annual Meeting, Nashville TN (Nov. 2005).

Ronald R. Bowsher, Ph.D. CV

93. Sloan JH, Butler RC, Nowatzke WL, Konard R, **Bowsher RR**. Development and validation of an endpoint assay for quantitative determination of dipeptidyl peptidase IV (DPP-IV) activity in human serum. AAPS 2006 National Biotech Conference, Boston, MA. (June 2006)
94. Nowatzke WL, Delhaye R, Reinacher S, Green N, Gingerich RL and **Bowsher RR**. Stability of insulin in human serum and plasma. AAPS 2006 National Biotech Conference, Boston, MA. (June 2006)
95. Bourdage J, Konrad R, O'Dell M, Sloan J, **Bowsher R** and Dean R. Development of a novel RIA to detect serum autoantibodies against amyloid-beta peptides in patients treated with LY2062430, a fully-human monoclonal antibody directed against the amyloid-beta peptide mid-region. AAPS 2007 National Biotech Conference, San Diego, CA (June 2007).
96. Freeman MM, Tajkowski P, Sloan J, Bowsher RR, Kamerud J, Shaw H, Ellis B and Vick A. Development of a novel immunoassay for the determination of insulin glargine and its active metabolites in human serum. AAPS 2007 National Biotech Conference, Toronto CA (*submitted*).