CURRICULUM VITAE

DANIEL PAUL H. WERMELING

I. GENERAL INFORMATION

Home Address: 3732 Wembley Lane
Lexington, KY 40515

Telephone:: (859) 221-4138

Personal Email: dpwermeling@gmail.com

Certificate of Specialty Licensure: Registered Pharmacist
State of Kentucky - 1983
Pharmacy License #8933
Certified-Naloxone Dispensing

Marital Status: Married to Susan H. Wermeling, M.D.

Adult Children: Benjamin Scott Wermeling
Alexander David Wermeling

II. EDUCATION

Fellowship: Drug Product Evaluation Unit
1985-87 College of Pharmacy
University of Kentucky
Lexington, Kentucky

Residency: University Hospital
1983-85 Albert B. Chandler Medical Center
University of Kentucky
Lexington, Kentucky

Doctor of Pharmacy: College of Pharmacy
1977-83 University of Kentucky
Lexington, Kentucky

III. PROFESSIONAL EXPERIENCE

Emeritus Professor, University of Kentucky. April 2018 - Present

Professor (with tenure – Special Title Series)
College of Pharmacy, University of Kentucky
2011 to 2018

CEO and Founder, AntiOp Inc., 2009 - Present

Associate Professor (with tenure – Special Title Series)
College of Pharmacy, University of Kentucky
1998 – 2011

Chief Scientist
Intranasal Therapeutics, Inc.
2004-2006

Senior Vice President and Chief Operating Officer
Intranasal Technology, Inc.
2002 – 2004 (unpaid leave of absence)

Scientific Director, Kentucky Center for Clinical Research & Investigator Services,
University of Kentucky Medical Center
1997 – 2000

Director, Investigational Drug Service
Department of Pharmacy
A B Chandler Medical Center
1990 – 2000

Associate Research Professor and Director
Drug Product Evaluation Unit
Center for Pharmaceutical Science and Technology
College of Pharmacy, University of Kentucky
1994 – 1998

Assistant Research Professor and Director
Drug Product Evaluation Unit
Center for Pharmaceutical Science and Technology
College of Pharmacy, University of Kentucky
1990 – 1994

Clinical Research Associate
Merrell Dow Research Institute
Cincinnati, Ohio
1988 – 1990

Coordinator - Bristol-Myers Industrial Clerkship
Investigational Drug Pharmacist
Assistant Director of Hospital Pharmacy

University of Kentucky Medical Center
1987 – 1988

Research Fellow – Drug Product Evaluation Unit, College of Pharmacy University of Kentucky
1985 – 1987

Pharmacy Resident - University of Kentucky Medical Center
1983 – 1985

IV. ACADEMIC APPOINTMENTS

Emeritus Professor, University of Kentucky, 2018 - Present

Professor (with tenure – Special Title Series)
Full Member Graduate School Faculty
College of Pharmacy
University of Kentucky
902 Rose Street
Lexington, KY 40536
2011 – 2018

Associate Professor (with tenure – Special Title Series)
Full Member Graduate School Faculty
College of Pharmacy
University of Kentucky
902 Rose Street
Lexington, KY 40536
1998 – 2011

Associate Research Professor
Associate Member of the Graduate School Faculty
Division of Pharmacy Practice & Science
College of Pharmacy
University of Kentucky
902 Rose Street
Lexington, KY 40536
1994 – 1998

Assistant Research Professor
Associate Member Graduate School Faculty
Division of Pharmacy Practice & Science
College of Pharmacy
University of Kentucky
907 Rose Street
Lexington, KY 40536
1990 – 1994

V. HOSPITAL OR CLINICAL APPOINTMENTS

Assistant Director of Pharmacy – Obstetrics and Psychiatry
Investigational Drug Pharmacist
University Hospital
Albert B. Chandler Medical Center
Lexington, KY
1987 – 1988

Director, Investigational Drug Service
Department of Pharmacy
University Hospital
Albert B. Chandler Medical Center
Lexington, KY
1990 – 2000

VI. Consulting History

Scientific Consulting

NX Development Corporation – 2018 - Present

Alltech Inc. – 2011 – 2014
Alzheimer's Disease Early Stage Product Development

LiPoint Inc. 2008-2009
Nasal Drug Development

Celgene and Novartis – 2008 - 2009
Patent Analysis

Apotex Pharmaceuticals 2007-2008
Patent Analysis

The Round Table Group 2007-
Drug Development Consulting

Biovail Corporation 2006
Drug Delivery for Pain Management

Boston Life Sciences – 2005–6
Intrathecal Analgesia Delivery

Cydex Corporation – 2005
Nasal Formulation Approach

Intranasal Technology, Inc. 2004 - 2008
Nasal Drug Delivery

Purdue Pharma – 2003 – 2004

Oxycodone Pharmacokinetics & Pharmacodynamics

Intranasal Technology Inc.
1998 – 2001

Pain Care Incorporated
1994 – 1995

NIH Master Agreement for the Clinical Evaluation of
Investigational Anti-Epileptic Drugs - Co-Investigator
1993 – 1999

Health Economics Research
Propofol Pharmacoeconomic Evaluation
1992 – 1994

Hoffman LaRoche Pharmaceuticals
TAT Antagonist – Antiretroviral Pharmacokinetics
1992

Evaluation of Drug Interactions
Chapter 2 Anesthetic Drug Interactions
1988 – 1998

Litigation Consulting History

I have testified as an expert at trial or by deposition in the following matters:

- *GlaxoSmithKline Inc. v. Apotex Inc.*, No. T-1780-07 (Canada Fed. Ct.)
- *Estate of Vivian Caudill v. Sarah Belhausen*, No. 08-CI-00252 (Johnson Circuit Court, Kentucky)
- *Estate of Arthur C. McChesney, Jr. v. Saint Joseph Healthcare Inc.*, No. 08-CI-872 (Fayette Circuit Court, Kentucky)
- *Estate of Bonnie Cocanougher v. Saint Joseph Healthcare, Inc.*, No. 07-CI-2897 (Fayette Circuit Court, Kentucky)
- *Wyeth and Cordis Corp. v. Abbott Labs and Boston Scientific*, C.A. No, 3:08-CV-00230-JAP-TJB, District of New Jersey
- *Wyeth and Cordis Corp. v. Medtronic and Abbott*, C.A. No. 08-1021-JAP-TJB, District of New Jersey

VII. TEACHING ACTIVITY

Graduate Program Teaching

2007- 2009	CME 599/PS 760 Buccal and Nasal Drug Delivery, 2 contact hours
2004 - 2018	PPS 764 Drug Development Regulation and Clinical Research Methods, Primary Instructor, 3 credit course 26 of 43 contact hours. This is a required course for Clinical and Experimental Therapeutics Ph.D. program students.
2004	PHR 760-009 Introduction to Translational Research (Co-instructor), 2 credit course, 8 contact hours
2001	PHR 760 Introduction to Drug Development and Clinical Research – (Primary Instructor)
2001	NIH K-30 Elective Course in Clinical Research

Professional Program Courses

2015- 2018	PHR 914 – Clinical Reasoning. Course Designer and Instructor
2012- 2017	PPS 946 Introduction to Therapeutics– PY2 Course Director and Pain Management Module Leader
2012- 2017	PPS 895 – Independent Problems in Pharmacy Practice Emma Hatfield Amanda Robinson Abbey Bailey Elizabeth Riner Leann Hewlett
2008-11	PS 924 – The Drug Development Process – 3 contact hours
2006 - 2018	PPS 564 Introduction to FDA & the Drug Development Process – 2 credit hours elective – Primary Instructor
2006- 2012	PPS 946 - PY 2 Spring Semester Pain Management Module Leader – 23 contact hours
2004-05	PHR 956-7 Fall Semester, Pain Management Module Leader and Primary Lecturer PY 3 Therapeutics, 23 contact hours
1994-1999	Pharmacy Seminar (PHR 890)
1993-2002	Nervous Systems (PHR 851)
1992-2001	Pharmacy Practice Clerkship (PHR 866)
1991-1999	Advanced Institutional Practice Management (PHR 833)
1991-2001	Independent Problems in Clinical Pharmacy (PHR 895)
1988	Implications of Drug Therapy for Nurses (NUR 866)
1987-1988	Bristol-Myers Industrial Clerkship
1986-1988	Institutional Pharmacy Practice (PHR 880)
1986-1988	Applied Therapeutics I & II (PHR 866-868)
1986-1988	Clinical Orientation Clerkship (PHR 870)

Hospital Pharmacy Residency

Supervise 6-7 pharmacy residents per year (1 – 2 month rotations) who participate in a Clinical Drug Development Rotation. Residents obtain first hand experience in clinical research administration and conduct. 1990 – 1998

Post-Doctoral Fellow Training

Carinda Field, Pharm.D. (fellow)
1991 – 1993

Charles Xie, M.D., Ph.D. (fellow)
1996 – 1997

Graduate Students

Anna Hitron, Pharm.D., Masters Degree Candidate 2009-10, Committee Member

Ben Chamberlain, BS, mentor for NIH GCRC mentored student program. 2007-08

Committee Member for Jennifer King, Ph.D., Department of Gerontology
2004-2009

Committee Member for Jennifer Oh, Pharm.D., (thesis masters student and fellow) 2004-06

Mentor for Jodi L. Miller, Pharm.D., M.S. (non-thesis masters student and fellow)
2000 – 2002

Committee Member for Doug Hiser, D.D.S., M.S. (non-thesis masters student in College of Dentistry) 1998 – 1999

Mentor for Lance Piecoro, Pharm.D., M.S. P. H. (non-thesis masters student and fellow)
1995 – 1998

VIII. ADVISING ACTIVITY

2 new PYI students per year – 1990-1998

IX. ADMINISTRATIVE ACTIVITY AND UNIVERSITY, STATE AND NATIONAL SERVICE

University of Kentucky

University Senate Council - 2011
University Senator – 2008-2011
Senate Academic Program Committee 2008-2010

College of Pharmacy Committees

Conflict of Interest Committee 2017- 2018
College Accreditation Subcommittee Chair – 2014-15
Student Affairs Committee – 2013-15
Academic Performance Committee – 2012- 2018
Nominations Committee - 2011
Conflict of Interest Committee 2009-2018
Faith Pharmacy Student Advisory Committee 2009 – 2011
Curriculum Committee (Chair) 2009
PPS Department Graduate Education and Research Committee 2006 - 2009
Appointment, Promotion and Tenure 2005 - 2008
Practice Plan Committee 2005 – (chair 2009-10)-2009
Advisor to Associate Dean for Research on Clinical Research 2004-2009
College of Pharmacy Executive Committee, 2000 – 2001
Nominations Committee, 1999 –2001
College Practice Plan Committee, 1997 – 1999
PPS Division Practice Plan Expenditure Committee, 1997 – 1999
Clinical Pharmacology Oversight Committee, 1994 – 1999
Division Research/Computer Equipment Committee, 1993 – 1997
Co-Advisor Pre-pharmacy Club, 1994 – 1996
Co-Advisor Pre-pharmacy Club, 1994 – 1996
Residency and Seminar Committee, 1990 – 1991
Student Advisor Committee, 1984 – 1985
Curriculum Committee, 1983 – 1985

Hospital Committees

Corporate Compliance Committee 1999-2000
Research Subcommittee, 1999 – 2000
Integrated Clinical Information System, 1998 – 1999
Clinical Research Reengineering Task Force, 1995 – 1997
Health Enterprise Research Information Committee, 1997
Residency Research Committee, 1995 – 2000
Resident Advisor Committee, 1990 – 1991
Resident Advisor Committee, 1990 – 1991
Obstetric Service Task Force, 1987 – 1988
Resident Advisor Committee, 1985 – 1987
Pharmacy Computer Search Committee, 1985 – 1986

College of Medicine Committees

NIH Clinical Research Center Clinical Trials Scientific Review Committee – 2008-14
NIH Scientific Advisory Committee, Center for Clinical and Translational Research, University of Kentucky Medical Center, 2008-
NIH General Clinical Research Center Scientific Advisory Committee 2005 - 2008
NIH General Clinical Research Center/Advisory Committee, 1996 – 2001

NIH General Clinical Research Center/Drug Product Evaluation Unit Space Committee, 1993 – 2001
NIH General Clinical Research Center/Drug Product Evaluation Unit Operations Subcommittee, 1993 – 2001

University Committees

CCTS Drug Development Advisory Committee, Therapeutics Advisory Committee 2012- 2018
CCTS Data Safety and Monitoring Board 2010 - 15
Clinical and Translational Science Award (CTSA), Therapeutics Advisory Committee 2009-15
Clinical Research Task Force – 2004 - 2006
Institutional Bio-safety Committee – Ex-Officio, 1998 – 2000
KCCRIS Advisory Committee – Ex-Officio, 1997 – 2000
Research Process Planning Committee, 1997 – 2000
Medical Institutional Review Board – Ex-Officio Member, 1993 – 2000

Commonwealth of Kentucky

6th Congressional District Drug Abuse Task Force sponsored by US Congressman Andy Barr. 2015 - 2017

Kentucky Life Science Organization – State science and development leaders advising the Governor on life science economic development policy, 2004 - 2007

KLSO Executive Committee and Founding Board Member, 2004 - 2007

National Committees

American College of Clinical Pharmacy – Research Institute Fund Committee - 2010 - 2016

American College of Clinical Pharmacy – Credentials Committee – Fellowship Evaluation Subcommittee 2009 - 15

American College of Clinical Pharmacy – Blue Ribbon Task Force on Pharmacometrics. 2008-2009

American College of Clinical Pharmacy, Research Affairs Committee, Chair, Sub-committee on national pharmacy practice based research networks. 2007-08

National Institutes of Health, Gene and Drug Delivery Systems Study Section for SBIR/STTR Grants, July 10, 2006

National Institutes of Health, Gene and Drug Delivery Systems Study Section for SBIR/STTR Grants, November 28, 2005.

National Institutes of Health, Gene and Drug Delivery Systems Study Section Review Committee, November 17-18 2005

American College of Clinical Pharmacy, Task Force on Research in Special Populations, 2005-6

American College of Clinical Pharmacy, Research Committee, 1998 – 1999

American Society of Health-System Pharmacists, PALS Program, 1997 – 1999

American Society of Health-System Pharmacists, Council on Professional Affairs, 1996/97 & 1997/98 & 1998/99

University Health System Consortium Benchmarking Committee, 1997 – 1999

American Society of Health-System Pharmacists, Facilitator – Section of Clinical Specialists – Investigational Drugs and Clinical Research, 1995 – 1997

American College of Clinical Pharmacy, Credentials Committee, 1995
Chair, 1996-1997, 1997 – 1998
Chairman, 1995 – 1996

American College of Clinical Pharmacy, Women's Health Care PRN
Chairman Elect, 1994 – 1995

American College of Clinical Pharmacy, Special Task Force on Women's Health & Education Issues, 1991 – 1993
Vice Chairman, 1993 – 1994

American College of Clinical Pharmacy, Research Affairs Committee, 1991 – 1992, Vice Chairman, 1992 – 1993

American Society of Hospital Pharmacists Nominee for Position on FDA OTC Drug Advisory Committee, October 1991

Liaison, University Health-System Consortium Clinical Research & Investigator Services, 1990 – 1999

ASHP Drug Therapy Research Awards Program Selection Panel, 1999 – 2000

X. SPECIAL ASSIGNMENTS

Senator – University of Kentucky 2008-2011, Senate Council 2011

University of Kentucky Human Gene Therapy Task Force, 1998 – 1999

Special Assistant to the Dean, 1999-2001

XI. HONORS

William T. Miles Award – May 2017

Thomas S. Foster Lecturer – September 2015

WR Martin Mentoring Senior Resident Research Award, Department of Psychiatry, University of Kentucky, 2009

Recipient, American College of Clinical Pharmacy Research Institute Award, 2007

Fellow, American College of Clinical Pharmacy (FCCP), October 2006

Kentucky Colonel, from Governor Ernie Fletcher, for research entrepreneurship in the Commonwealth of Kentucky, January 2006

Fellow, American Society of Health System Pharmacists (FASHP), June, 1998

Kentucky Society of Hospital Pharmacists
Research Pharmacist of the Year, 1988

XII. PROFESSIONAL ACTIVITY AND PUBLIC SERVICE

Organizations

American College of Clinical Pharmacology 2008-14
American College of Clinical Pharmacy 1990-
Kentucky Society of Hospital Pharmacy 1990 -
Phi Delta Chi (Pharmaceutical Fraternity) 1990-94
American Pharmaceutical Association 1990 - 2000
American Society of Health-System Pharmacists 1983-
Society of Research Administrators – 1990-97
American College of Research Professionals – 1994-97
Drug Information Association – 1994-97
American Association of Pharmaceutical Scientists 2000-2003

Journal Reviewer

Addiction 2018 x 2
Pharmacotherapy 2017
Pediatrics 2017
Addiction 2017
Pediatrics 2016
Expert Opinion in Drug Delivery 2016
Alcohol and Drug Dependence 2016
Addiction 2016
Journal of Clinical Pharmacology 2015
Pharmacotherapy 2015

Journal of Opioid Management 2015
Journal of Opioid Management 2014
Therapeutic Delivery 2014
Pediatrics 2014
Journal of Opioid Management 2013
Pharmacotherapy 2013
Currents in Pharmacy Teaching and Learning 2013
Annals of Internal Medicine 2012
Journal of Opioid Management 2012
Advanced Drug Delivery Reviews 2012
Advanced Drug Delivery Reviews 2011
Pharmacotherapy 2011
Journal of Pharmacy and Pharmacology 2011
Lancet 2010
Expert Opinion in Drug Delivery 2010
Journal of Clinical Pharmacology 2010 x2
Journal of Clinical Anesthesia 2009
European Journal of Pain 2009
Journal of Drug Targeting 2009
The Journal of Pain 2009 x 2
Journal of Pain and Symptom Management 2009
Pharmacotherapy 2009
Journal of Clinical Pharmacology 2009 x 2
Clinical Therapeutics 2009
Epilepsy Research 2008
BMC Pharmacology 2008
Expert Opinion on Pharmacotherapy 2008 x2
Journal of Pharmacy Practice and Research 2008
Pharmacotherapy 2008
Drug Benefit Trends 2007
The Journal of Pain 2007
Yonsei Medical Journals 2007
Expert Opinion in Drug Discovery 2007
Pharmacotherapy 2007
Biopharmaceutics and Drug Disposition 2007
Journal of Clinical Anesthesia 2006
BMC Clinical Pharmacology 2006
Pharmacotherapy – 2006
Johns Hopkins Advanced Studies in Medicine 2006
Journal of Pharmacy and Pharmacology 2006
Drugs of Today 2006
Drug Profiles 2006
Journal of the American Board of Family Practice 2005 -
The Annals of Pharmacotherapy – 1987-
American Journal of Hospital Pharmacy 1987-
Drug Intelligence and Clinical Pharmacy 1987- 1995
The Journal of Pharmacy Technology 1990-91
Journal of Pharmaceutical Sciences – 1990-91

Reviewer of Proposals

ACCP Women's Education Foundation – Foundation Awards Program Selection Panel 1997-2000
ASHP Foundation Award – Innovative Clinical Pharmacy Research – 1997-2000

Reviewer of Abstracts

Judge: Best poster submission. ACCP Spring Meeting April 27, 2009.

For ACCP for publication in Journal of Pharmacology, Pharmacotherapy 1991-2001, 2004 – 2017

XIII. INVITED SPEAKING ENGAGEMENTS

International

2013 International Conference on Opioids. Expand Access to Naloxone for High Risk Patients. June 10, 2013, Boston, MA.

2012 International Nasal and Buccal Delivery, 2012. Intranasal Delivery of Pharmaceuticals for Systemic Drug Administration. April 22, 2012, London, UK

2012 FDA/CDC/NIDA Conference on Expanded Access to Naloxone. Intranasal Delivery of Naloxone for Treatment of Suspected Opioid Overdose. April 12, 2012. Bethessa, MD

2010 International Nasal Drug Delivery 2010. Intranasal Delivery of Opioid Antagonists. April 14th, 2010. London, UK

2008 International Nasal Drug Delivery 2008. "Intranasal Delivery of Analgesic Compounds: Experience with Hydromorphone in Acute Trauma Pain. April 8th, 2008, London, UK

2008 New Horizons in the Development of Antiepileptic Drugs: Non-traditional Approaches to Treat Epilepsy Conference. "Intranasal Delivery of Anti-epileptic Medications". March 7, 2008, Dublin, Ireland

2007 10th Annual Nasal Drug Delivery Conference. "Where is Nasal Delivery Research Headed? " February 8, 2007, London, UK.

2006 Biovail Pain Management Forum. "Drug Delivery Approaches Employed in Pain Management Pharmacotherapy." December 15, 2006. New York, NY.

2005 ATACCC 2005 Conference – Advanced Technology for Combat Casualty Care. "Needle-Free, Self-Administered Nasal Hydromorphone for the Rapid Treatment of Moderate to Severe Acute Pain." Sponsored by the

Army and Navy Casualty Care Research Programs and the Air Force Surgeon General. Tampa, FL, August 16, 2005

2005 Eighth Annual Anti-epileptic Drug Conference, "Intranasal Delivery of Benzodiazepines for the Treatment of Seizure". March 2005, Biscayne, FL

2004 Practical Approaches to Nasal and Pulmonary Drug Delivery II, "Nasal Delivery of Analgesics for Acute and Break-Through Cancer Pain", Valois Nasal and Pulmonary Delivery Conference, Delray Beach, Florida

2003 Management Forum LTD – Sixth International Conference Exploring the Rapidly Developing Area of Nasal Drug Delivery, "Nasal Drug Delivery Opportunities in Pain Management Therapeutics", London, England

2002 Technology Catalysts – 19th Annual International Technology Transfer Forum, "Nasal Delivery of Medications for the Central Nervous System", Reston, Virginia

2002 Management Forum LTD – Fifth International Conference Exploring the Rapidly Developing Area of Nasal Drug Delivery, "Design of Products for Acute, Subacute, and Chronic CNS Medical Indications", London, England

2001 Strategic Research Institute – 6th International Drug Delivery Technologies and Deal Making Summit, "Nasal Drug Delivery: A Leading Edge Technology for Systemic Delivery", Princeton, New Jersey

National

2016 National Drug Abuse Summit. Drug Product Selection Considerations for New Naloxone Products. Atlanta GA Apr 2016

2014 Collaborative Perspectives on Addiction. Opioid Overdose: Intervention Efforts and Challenges. Atlanta, GA March 1, 2014.

2013 Feasibility and Due Diligence in Drug Development. National SBIR Meeting, October 25, 2013, Souix Falls, SD.

2009 University of Colorado College of Pharmacy. Leadership in Academic Departments of Clinical Pharmacy. Denver, CO May 21, 2009.

2007 Medical University of South Carolina. Nasal Drug Delivery of Medications for the Treatment of Alcoholism. January 5, 2007. Charleston, SC.

2006 National Institute of Alcohol Abuse and Alcoholism – Nasal Drug Delivery as an Interventional Approach to Alcohol Drug Therapy, NIH, June 20, 2006, Rockville, MD

2006 University of Chicago College of Medicine – “Nasal Drug Delivery – Pharmacotherapy Option and Research Tool”. May 12, 2006, Chicago, Il

2005 American College of Clinical Pharmacy – Spring Research and Practice Meeting, Navigating Research: “Patient Safety, Privacy and Funding Issues”, April 7, 2005 Myrtle Beach, SC.

2001 Institute for International Research – Inhalation Technology Conference, “Nasal Drug Delivery: A Leading Edge Technology for Systemic Delivery”, Boston, Massachusetts

2001 MedTech Insight, Investment in Innovation – A Preview of Early-Stage Medical Technology Companies, “Nasal Drug Delivery: A Leading Edge Technology Platform for Drug Delivery”, New York, New York

2000 American College of Clinical Pharmacy, “Pharmacokinetics (PK) of Intranasal Hydromorphone (HM) in Healthy Subjects”, Los Angeles, California

1999 Massachusetts Society of Health-System Pharmacists, “Managing Issues Related to Clinical Research”, Boston, Massachusetts

1999 Corporate Compliance and Clinical Research, University Health System Consortium, Chicago, Illinois

1998 Society of Research Administrators, “Addressing the Investment in Clinical Research”

1998 American Society of Health-System Pharmacists, “Is Your Pharmacy Ready for Gene Therapy?”

1997 American Society of Health System Pharmacists Annual Meeting, “Clinical Research: Regulatory Issues”

1996 Society of Research Administrators, “How to Prepare for a Successful FDA Audit for a Clinical Investigator or IRB”

1995 American Society of Health-System Pharmacists, “New NIH and FDA Guidelines Regarding Women’s Participation in Clinical Research”

1993 Auburn University, Annual Clinical Practice and Research Forum, “Development of a Clinical Research Unit”

1992 Burroughs Wellcome Company, Inc., “First Time in Man Drug Trials”

1991 American Society of Hospital Pharmacists, “Managing Grant Funds: The University Perspective”

1991 Applied Research Ethics National Association (ARENA), “Handling Equitable Selection”

1991 American College of Clinical Pharmacy, “Women’s Participation as Research Subjects”

1988 St. Louis Society of Hospital Pharmacists, “Pharmacy Considerations for Implementing a PCA Program in Your Hospital”

1987 American Society of Hospital Pharmacists, “Evaluation of the Travenol Infusor with Patient Control Module as a PCA Device for Treatment of Postoperative Pain”

1987 Georgia Society of Hospital Pharmacists, “Pharmacy Considerations for Implementing a PCA Program in Your Hospital”

1986 Intravenous Nurses Association of Northwest Florida, “Patient-Controlled Analgesia and the Cancer Patient”

1986 Indiana Society of Hospital Pharmacists, “Patient-Controlled Analgesia: Implementation of a Clinical Service Program”

1986 American Society of Hospital Pharmacists, “Patient-Controlled Analgesia: Implications for Patient Care and Pharmacy Services”

1986 Butorphanol Tartrate Symposium: Research Advances in Multiple Clinical Settings, “Patient-Controlled Analgesia for Postoperative Pain: Streamlining Drug Delivery for Pain Management”

1985 American Society of Hospital Pharmacists. “Patient-Controlled Analgesia: Parallel Development of the Research Tool and Clinical Service Program”

1985 Ohio Conference on Clinical Pharmacy and Clinical Pharmacology, “Patient Controlled Analgesia”

1984 Southeastern Residents Conference, “Pentobarbital Coma in Refractory Cerebral Edema”

1984 American Society of Hospital Pharmacists, “Osmolality of Injectable Drugs in Minibags: Predicted vs. Actual Value”

State

2016 Increasing Access to Naloxone in your Community. Continuous program given 1-2 times per month in the Commonwealth of KY. March 2016 -

2015 Factors to Consider When Starting A Pharmaceutical Company – a Regulatory Perspective. KSTC Regulatory Summit, Lexington, KY November 19, 2015

2014 Harm Reduction Involving Expanding Access to Opioid Antidote Naloxone. AHEC May 28, 2014. Morehead, KY.

2013 A Harm Reduction Strategy: Expand Access to the Opioid Antidote Naloxone. The Good, The Bad and The Ugly. UKMC CE Central and Department of Justice, Commonwealth of Kentucky. August 3, 2013.

2012 College of Pharmacy Continuing Education Series and Alumni Weekend October 19, 2012. Opioids and Risk Evaluation and Risk Mitigation Strategies (REMS): Collaborative Professional, Patient Education, and Patient Care Activities

2012 OVALS (Ohio Valley Life Science Associates) October 2, 2012. "Observations of Academic Pharmaceutical Start Up Companies".

2008 University of Kentucky College of Pharmacy Continuing Education Series, Fall Meeting, October 17, 2008. "Emerging Drug Delivery Systems for the Treatment of Pain."

2006 University of Kentucky College of Pharmacy Continuing Education Series, Fall Meeting, October 6, 2006. "Multi-modal, Mechanism Based Approaches to Treatment of Chronic Non-Malignant Pain".

2004 University of Kentucky, Health and Medical Care Delivery Systems – HSM 241, "Intranasal Technology, Inc.: A Leading Edge Specialty Pharmaceuticals Company", Lexington Kentucky

2003 University of Cincinnati, Biotechnology and Pharmaceutical Management Course, "Intranasal Technology, Inc.: A Leading Edge Specialty Pharmaceuticals Company", Cincinnati Ohio

2001 The Entrepreneurship Committee of the Greater Louisville Health Enterprises Network, Life Sciences Investor Forum "Intranasal Technology, Inc. A Leading Edge Drug Delivery Company", Louisville Kentucky

1996 Sanders-Brown Center on Aging, Conference for Pharmacists, "Considerations in Conducting Clinical Trials with Alzheimer's Disease Patients"

1986 Kentucky Pharmacists Association, "Patient-Controlled Analgesia: Implementation of a Clinical Service Program"

1985 Kentucky Pharmacists Association, "New Concepts in Pain Management"

1984 Intravenous Therapy and Nutrition Technology Update for 1984, University of Kentucky College of Pharmacy Continuing Education Program, "Preparing Drugs in the Pharmacy for Patient Administration – Concern for pH, Osmolality, and Drug Concentration"

Local

2016 Opioid Overdose Recognition and Training on Naloxone Administration. Trips to local agencies for in-service training and naloxone dispensing (Numerous) March 2016 - 2018

2015 Thomas S. Foster Lectureship. "Living The Dream". UK College of Pharmacy, September 25, 2015

2015 Video CE Lecture. Naloxone for Opioid Overdose Prevention. Department of Justice, Commonwealth of KY. September, 2015

2015 CCTS Clinical Research Update. Research and Commercialization of Naloxone Nasal Spray. November 10, 2015.

2015 Chrysalis House. Use of Naloxone At Home for Opioid Overdose Prevention. April 10, 2015, Lexington, KY

2014 Naloxone for Community Opioid Overdose Prevention: Radio Interview WUKY March 26, 2014

2014 Pharmacists Role in Expanding Access to Naloxone. Bluegrass Pharmacists Association. March 25, 2014

2008 "The Drug Approval Process". Transylvania University, Lexington, KY Pre-professional Degree Student Forum, May 12, 2008

2007 "Drug Development in the United States". NIH GCRC Mentored Student Lecture Series, July 23, 2007.

2007 "Nasal Drug Delivery for Treatment of Alcoholism". NIH General Clinical Research Center lecture, March 12, 2007.

2006 "Translational Research in Nasal Drug Delivery". Center for Drug and Alcohol Translational Research, University of Kentucky, March 6, 2006

2001 "Making New Drugs in the Bluegrass: Public-Private Partnership" Fasig-Tipton, Lexington Kentucky, Sponsored by the Lexington Rotary Club

2001 Start Up @ 5, Sawyers Downtown, Lexington Kentucky, Sponsored by Kentucky Science and Technology Corporation

2000 "Evolution of Faculty Research into a New Economy Business" Hyatt Regency, Lexington, Kentucky, Sponsored by UK Board of Trustees

1996 Channel 36-TV interview with Sandy Gray, "Making Sense of Medications Today"

1994 Department of Psychiatry Grand Rounds

1994 Investigational Drugs for Treatment of Sepsis at the University of Kentucky Medical Center, Radisson Hotel, Lexington, Kentucky, September 12, 1994

1993 "Drug Development Opportunities: Psychiatric Drug Evaluation"

XIV. PATENTS ISSUED

Intranasal Naloxone Compositions and Methods of Using Same.
AntiOp Patent 9,289,425
Date of Patent: March 22, 2016
Issued To; AntiOp

Intranasal Naloxone Compositions and Methods of Using Same.
AntiOp Patent 9,192, 570
Date of Patent: November 24, 2015
Issued To; AntiOp

"Intranasal Opioid Compositions"
Patent no. US 8,198,291 B 2
Date of Patent: June 12, 2012
Issued to: Daniel Wermeling and Assigned to University of Kentucky

"System and Method for Intranasal Administration of Lorazepam"
Patent No.: US 6,610,271
Date of Patent: August 26, 2003
Issued to: Daniel Wermeling

"Programmable Multi-Dose Intranasal Drug Delivery Device"
Patent No.: US 6,948,492
Date of Patent: September 27, 2005
Issued to: Daniel Wermeling and co-inventors

"Programmable Multi-Dose Intranasal Drug Delivery Device"
Notice of Allowance March 9, 2009
US Patent Application No.: 11/204,611
Patent No. 7,559,321
Date of Patent: July 14, 2009
Issued to: Daniel Wermeling and co-inventors

Patents Submitted / Pending as Primary Inventor

Pharmaceutical Compositions Comprising an Opioid Receptor Antagonist and Methods for Using Same.
US2007/0212307

Intranasal Delivery of Antipsychotic Drugs
WO 2006/023497A2
US20060039869A1

Composition & Methods for Intranasal Delivery of Tricyclic Canabinoids
US-2007-0060639-A1
PCT/US2006/034562

"System and Method for Intranasal Administration of Opioids"
Pub. No.: US 20030077300 A1
Pub. Date: April 24, 2003

"Intranasal Benzodiazepine Compositions "
Pub. No. US 20040176359

"Intranasal Opioid Compositions"
Pub No. US 20040115133

XV. INDs NDAs SUBMITTED TO THE FDA

INDs

Cimetidine Injection 1991 (SKB contract)

DSPC Liposome 1994 (The Liposome Company contract)

Ondansetron Nasal Spray 1996 (GSK contract)

Hydromorphone Nasal Spray 1998 (Intranasal Technology Inc. contract)

Butorphanol Nasal Spray 1998 (Intranasal Technology Inc. contract)

Lorazepam Nasal Spray 1999 (Intranasal Technology Inc. contract)

Midazolam Nasal Spray 1999 (Intranasal Technology Inc. contract)

Haloperidol Nasal Spray 2000 (Intranasal Technology Inc. contract)

Naloxone Nasal Spray 2012 (AntiOp Inc., f/k/a Alcomed Inc.)

NDAs

Naloxone Nasal Spray # 205678

XVII. PEER REVIEWED RESEARCH AND CREATIVE PRODUCTIVITY

Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access. Daniel Wermeling. Therapeutic Advances and Drug Safety. 2015, 6(1) 20-31.

Prescribe Naloxone to Reduce Opioid Mortality. Daniel Wermeling, Catherine Martin. Journal of American Academy of Child and Adolescent Psychiatry. Jan 2915 Page 256.

Intranasal Administration of Naloxone Injection for the Treatment of Opioid Overdose. Amanda Robinson, **Daniel Wermeling** American Journal of Health System Pharmacy. 2014 71: December 15 2014

Naloxone for Opioid Overdose Prevention: Pharmacists Role in Community Based Practice Settings. Abby Bailey, **Daniel Wermeling**. Annals of Pharmacotherapy 2014, 48 (5) 601-606.

Survey of Naloxone Legal Status in Opioid Overdose Prevention. Lee Ann Hewlett, **Daniel Wermeling.** J Opioid Mgmt. 2013 Sep-Oct 9(5) 369-377.

A Response to the Opioid Overdose Epidemic: Naloxone Nasal Spray. Daniel Wermeling. Drug Delivery and Translational Research, 2014, Volume 3, Issue 1, 63-74.

Comparison of the Behavioral and Cardiovascular Effects of Intranasal Dextroamphetamine. Joshua A. Lile, Shanna Babalonis, Cleeve Emurian, Catherine A. Martin, **Daniel P. Wermeling** and Thomas H. Kelly. Journal of Clinical Pharmacology, 2011, 51 Jun; 888-898.

Opioid Harm Reduction Strategies: Focus on Expanded Access to Intranasal Naloxone. Wermeling, DP. Pharmacotherapy 2010; 30 (7).

A Multicenter, Open-Label, Dose-Ranging Trial of Intranasal Hydromorphone for Managing Acute Pain from Traumatic Injury. Wermeling, DP, Clinch TC, Rudy AC, Dreitlein D, Sumer S, LaCouture P. The Journal of Pain 2010 11 (1) 24-31.

Intranasal Delivery of Antiepileptic Medications for the Treatment of Seizures. Wermeling DP. Neurotherapeutics 2009 Apr; 6: (2) 352-358.

A Pharmacokinetic and Pharmacodynamic Study, in Healthy Volunteers, of a Rapidly Absorbed Intranasal Midazolam Formulation. Wermeling, DP, Record KE, Archer SM, Rudy AC. Epilepsy Research 2009 83: 124-132.

Clinical Research in Special Populations: ACCP White Paper. Cheang KI, Ott C, Garnber S, Cambell H, Hansen L, Ma Q, Nazeri E, Gunning K, **Wermeling DP.** Pharmacotherapy 2008 28 (9) 1203-1206.

A Pharmacokinetic Profile of Intranasal Hydromorphone in Emergency Room Trauma Patients. Lacotoure P, Dreitlein D, Suner S, Hefti F, Clinch T, Pike D, **Wermeling, D.** The Journal of Pain 2008 9 (4) suppl (2) 36-41.

A Pilot Pharmacokinetic Study of Nasally Delivered Haloperidol Compared to Intravenous and Intramuscular Administration. Wermeling D, Ashford W, Archer S, Rudy A, Miller J. Pharmacotherapy 2008; 28: 875-882.

Microneedles Permit Transdermal Delivery of a Skin-Impermeable Medication to Humans. Wermeling DP, Banks SA, Hudson DA, Gill HS, Prausnitz M, Stinchcomb AS. Proceedings of the National Academy of Sciences 2008, Feb 12, 108: (6) 2058-63.

Intranasal Absorption of Delta 9 tetrahydrocanabinol and WIN 55,212-2mesylate in rats. Valiveti S, Agu RU, Hammell DC, Paudel KS, Earles DC, **Wermeling DP**. Stinchcomb AS. Eur J Pharm Biopharm 2006, Aug 23.

Pharmacokinetics and Pharmacodynamics of a New Intranasal Midazolam Formulation in Healthy Volunteers. Wermeling DP, Record K, Kelly TH, Archer SM, Clinch T, Rudy AC. Anesthesia and Analgesia 103 (2) August 2006

Ziconotide Infusion for Severe Chronic Pain: A Case Series of Patients with Neuropathic Pain. Wermeling DP, Berger JR., Pharmacotherapy 2006: 26 (3), 395-402.

Pharmacokinetics, Bioequivalence and Dose Reproducibility of Intranasal Butorphanol After Administration with Two Different Nasal Spray Pumps. Wermeling DP, Miller JL, Archer SM, Rayens MK, Rudy AC., Journal of Clinical Pharmacology August 2005; 45 (8): 969-73.

A Review of Ziconotide, an N-Type Calcium Channel Antagonist, Delivered by Intrathecal Adminsitration for the Treatment of Chronic Pain. Wermeling, DP. Pharmacotherapy 2005: 25 (8) 1084-94.

A Randomized, Double-Blind, Parallel-Group Study Comparing the Analgesic Effects of Intranasal Butorphanol Tartrate to Placebo, Using a Unit Dose Nasal Spray Device, in the Dental Impaction Pain Model. Wermeling, DP, Grant GM, Lee A, Alexander N, Rudy AC. Clinical Therapeutics 2005; 27 (4): 430-440.

Bioavailability of Intranasal Butorphanol Administered from a Single-dose Sprayer. Davis GA, Rudy A, Archer SM, **Wermeling, DP**. American Journal of Health System Pharmacy 2005 62 (1): 48-53

A Multiple Dose Phase 1 Study of Intranasal Hydromorphone Hydrochloride in Healthy Volunteers. Rudy AC, Coda BA Archer SM, **Wermeling DP**. Anesth Analg 2004 99 (5): 1379-86.

Bioavailability of Intranasal Butorphanol Using Unit-Dose Spray Pump in Healthy Volunteers. Davis GA, Rudy AC, Archer SM, **Wermeling DP**. Am J Health Syst Pharm 2004; 62; Jan 1, 48-53

Bioavailability and Pharmacokinetics of Intranasal Hydromorphone in Patients With Allergic Rhinitis. Davis GA, Rudy AC, Archer SM, **Wermeling DP**, McNamara PJ. Pharmacotherapy 2004; 24 (1) 26-32

Intranasal Delivery of recombinant human parathyroid hormone hPTH 1-34, teripartitide in rats. Agu R, Valiveti S, earles DC, Klausner M, Hayden PJ, **Wermeling DP**, Stinchcomb AL. Endocrine Research 2004; 30 (3), 455-467

"Pharmacokinetics of Butorphanol Tartrate Administered from Single-Dose Intranasal Sprayer", Davis GA, Rudy AC, Archer SM, **Wermeling DP**, *American Journal of Health-Systems Pharmacists* 2004;61:261-266

"Effect of Fluticasone Propionate Nasal Spray on Bioavailability of Intranasal Hydromorphone Hydrochloride in Patients with Allergic Rhinitis", Davis GA, Rudy AC, Archer SM, **Wermeling DP**, McNamara PJ, *Pharmacotherapy* 2004;24(1):26-32

"Pharmacokinetics and Pharmacodynamics of Intrathecal Ziconotide in Chronic Pain Patients", **Wermeling DP**, Drass M, Ellis D, Mayo M, McGuire D, O'Connell D, Hale V, Chao S, *The Journal of Clinical Pharmacology* 2003;43:624-636

"**Hydromorphone Transfer Into Breast Milk After Intranasal Administration"**, Edwards JE, Rudy AC, **Wermeling DP**, Desai N, McNamara PJ, *Pharmacotherapy* 2003;23(2):153-158

"Pharmacokinetics and Bioavailability of Single-Dose Intranasal Hydromorphone Hydrochloride in Healthy Volunteers", Coda BA, Rudy AC, Archer SM, **Wermeling DP**, *Anesthesia and Analgesia* 2003;97:117-123

"Systemic Intranasal Drug Delivery: Concepts and Application", **Wermeling DP**, Miller JL, Rudy AC, *Drug Delivery Technology* 2002;2:56-61

"Appearance of Impropriety?" **Wermeling DP**, Lamposona V. Hosp Health Netw 2002; 76 (10): 28.

"The Bioavailability and Pharmacokinetics of Lorazepam After Intranasal, Intravenous, and Intramuscular Administration", **Wermeling DPH**, Miller JL, Archer SM, Manaligod JM, Rudy AC, *The Journal of Clinical Pharmacology* 2001;41(11): 1225-1231

"**Hospital and Pharmacy Departmental Policies and Procedures for Gene Therapy at a Teaching Institution"**, Armitstead JA, Zillich AJ, Williams KL, Sitzlar SC, **Wermeling D,** *Hospital Pharmacy* 2001 January;36(1):56-66

"The Clinical Pharmacist as Principal Investigator", Ujhelyi MR, Bayat M, Davis L, Knoell D, Korth-Bradley J, Munger M, Shaefer M, Vlasses P, **Wermeling D**, ACCP White Paper, *Pharmacotherapy* 2000;20:599-608

"Pharmacokinetics of Flunisolide Administered via Metered Dose Inhaler with and without a Spacer Device and Following Oral Administration", Dickens GR, **Wermeling DP**, Matheny CJ, John W, Abramowitz W, Sista SM, Foster T, Choudhury S, *Ann Allergy Asthma and Immunol* 2000 May;84(5):528-32

"Ziconotide, A New N-Type Calcium Channel Blocker, Administered Intrathecally for Acute Postoperative Pain", Atanassoff PG, Hartmannsgruber MW, Thrasher J, **Wermeling D**, Longton W, Gaeta R, Singh T, Mayo M, McGuire D, Luther RR, *Reg Anesth Pain Med* 2000 May-Jun;25(3):274-8

"Clinical Research: Regulatory Issues", **Wermeling, DP** *American Journal of Health-System Pharmacy* 1999 Feb 1;56:252-6

"A comparison of the efficacy, safety, and patient satisfaction of ondansetron versus droperidol as antiemetics for elective outpatient surgical procedures", Fortney JT, Gan TJ, Graczyk S, Wetchler B, Melson T, Khalil S, McKenzie R, Parrillo S, Glass PS, Moote C, **Wermeling D**, Parasuraman TV, Duncan B, Creed MR, *Anesth Analg* 1998;86:731-738

"**Guidelines for the Use of Pharmaceuticals in Clinical Research**", **Wermeling DP**, *American Journal of Health-System Pharmacists* 1998; 55:369-76

"Seizures in Patients Receiving Concomitant Antimuscarinics and Acetylcholinesterase Inhibitor", Piecoro LT, **Wermeling DP**, Schmitt FA, Ashford JW, *Pharmacotherapy* 1998;18(5):1129-1132

"Pharmacokinetics, Pharmacodynamics, and Safety of Metrifonate in Patients with Alzheimer's Disease", Pettigrew LC, Bieber F, Lettieri J, **Wermeling DP**, Schmitt FA, Tikhtman AJ, Ashford JW, Smith CD, Wekstein DR, Markesbery WR, Orazem J, Ruzicka BB, Mas J, Gulanski B, *Journal of Clinical Pharmacology* 1998;38:236-245

"Financial Impact of Clinical Research on a Health System", **Wermeling DP**, Piecoro LT, Foster T, *American Journal of Health System Pharmacy* 1997 August;54(15):1742-1751

"**Phase I Pilot Study of Trovafloxacin (CP-00,219), on the Pharmacokinetics of Theophylline in Healthy Male Volunteers"**, Dickens G, **Wermeling D**, Vincent J, *The Journal of Clinical Pharmacology* 1997 March;37(3):248-252

"Gender-related Considerations in Clinical Pharmacology and Drug Therapeutics." Xie CX, Piecoro LT, **Wermeling, DP**. Crit Care Nurs Clin North Am 1997. 9 (4): 459-68.

"Gender Differences in Pharmacokinetics", Piecoro L, **Wermeling DP**, *Pharmaguide to Hospital Medicine* 1996*;*9(4):1-4

"**Dirithromycin Increases Ethinyl Estradiol Clearance Without Allowing Ovulation: A Novel Approach to Antibiotic**", **Wermeling DP**, Chandler MHH, Sides GD, Collins D, Muse K, Oral Contraceptive Interaction, *Obstetrics & Gynecology* 1995;86(1):78-84

"**Frontal Lobe Phosphorus Metabolism and Neuropsychological Function in Aging and in Alzheimer's Disease**", Smith CD, Pettigrew LC, Avison MJ, Kirsch JE, Tinkhtman AJ, Schmitt FA, **Wermeling DP**, Wekstein DR, and Markesberry WR, *Annals of Neurology* 1995;38:194-201

"Single Oral Dose Fluconazole Compared with Conventional Clotrimazole Topical Therapy of Candida Vaginitis", Sobel JD, Stein GE, Brooker D, **Wermeling DP**, Thomason JL, Wekstein L, Bradley B, Pancorbo S, Gilbert G, *Am J Obstet Gynecol* 1995 Apr;172:1263-1268

"Single-Dose Pharmacokinetics of S-Atenolol Administered Orally as a Single Enantiomer Formulation and the Racemic Mixture (Tenormin)", **Wermeling DP**,

Clementi WA, Clifton DG, Garvey TQ, McCoy RA, Brandt SG and Schwartz S, *Chirality* 1994;6:169-174

"**Computer-Assisted Investigational Drug Information and Testing Mechanism for Nurses"**, **Wermeling DP**, Nowak-Rapp M, and Sitzlar S, *Hospital Pharmacy* 1994;29:745-750

"**Pharmacokinetics and Pharmacodynamics of a New Cardiotonic – Vasodilator Agent** – **349U85**", Clifton GD, Harrison MR, **Wermeling DP,** Long RA, Fleck RJ, Rolleri RL, and Weller MS, *Clinical Pharmacology and Therapeutics* 1994;55:55-63

"**Effects of Chronic Oral Carvedilol On the Steady-State Pharmacokinetics of Oral Digoxin In Patients With Mild To Moderate Hypertension"**, **Wermeling DP**, Field CJ, Smith DA, Chandler MH, Clifton GD, Boyle DA, *Pharmacotherapy* 1994;14(5):600-686

"A Dose Response Study of Orally Administered Torsemide In Patients With Ascites Due To Cirrhosis", Applefeld JJ, Kasmer RJ, Botti RE, Hak L, Dukes GE, **Wermeling DP**, McClain CJ, *Alimentary Pharmacology and Therapeutics* 1994;8:397-402

"**Pharmacodynamics of Racemic and S(-) Atenolol in Man**", McCoy RA, Clifton GD, Clementi WA, Smith WD, Garvey TQ, **Wermeling DP**, Schwartz SE, *Journal of Clinical Pharmacology* 1994;34:816-822

"Current Issues Surrounding Women and Minorities In Drug Trials", **Wermeling DP**, Selwitz AS, *The Annals of Pharmacotherapy* 1993 July-August;27:904-911

"Value of Investigational Drugs", **Wermeling DP**, *American Journal of Hospital Pharmacy* 1993 August;50(8):1576

"Ethical Issues Related to Clinical Pharmacy Research", Rutledge DR, Stewart C, **Wermeling DP**, ACCP White Paper *Pharmacotherapy* 1993 September 10;13(5):523-530

"Women As Research Subjects", Sagraves R, Raebel MA, Jermain DM, O'Connell MB, **Wermeling DP**, ACCP White Paper *Pharmacotherapy* 1993 Sep/Oct;13(5):534-542

"Multi-Center Evaluation of Patient-Controlled Analgesia Device for the Treatment of Post-Operative Pain", **Wermeling DP**, Greene SA, Boucher FA, Lehman ME, Briggs GG, Bezarro ER, and Foster TS, *Clinical Pharmacy* 1992 April;11:342-346

"IRB Policies and Practices: Review of Subject Populations", Selwitz AS, **Wermeling DP**, *National Institutes of Health Personal Services Report*, May 1992

"A Randomized Comparison of Analgesic Requirements In Patients Undergoing Cholecystectomy: Patient-Controlled Delivery Vs Standard Intramuscular Injection", Kenady DE, Wilson JF, Schwartz RW, Bannon CL, **Wermeling DP**, *Surgery,Gynecology, and Obstetrics* 1992 March;174:216-220

"Advances in Preventive Medical Therapy for Osteoporosis", **Wermeling DP**, *Clinical Trends in Hospital Pharmacy* 1988;2(3):50-54

"Patient-Controlled Analgesia Using Butorphanol for Postoperative Pain Relief: An Open-Label Study", **Wermeling DP**, Foster TS, Witt WO, Farrington EA, McPherson D, *Acute Care* 1987 August 15;875-78

"**Evaluation of a Disposable, Non-Electronic, Patient-Controlled Analgesia Device for Postoperative Pain"**, **Wermeling DP**, Foster TS, Rapp RP, Kenady DE, and Munson ES, *Clinical Pharmacy* 1987 April;6:307-314

"**Pentobarbital Pharmacokinetics in Patients with Severe Head Injury**", **Wermeling DP**, Blouin RA, Porter RH, Rapp RP, and Tibbs PA, *Drug Intelligence and Clinical Pharmacy* 1987 June;21:459-463

"Patient-Controlled Analgesia in Gynecologic Oncology", Gallion HH, **Wermeling DP**, Van Nagel JR, Donaldson ES, Rowley KC, and Kryscio RJ, *Gynecology Oncology*, October 1987

"Patient-Controlled High Dose Morphine Therapy in a Patient with Electrical Burns", **Wermeling DP,** Record KE, Foster TS, *Clinical Pharmacy* 1986 October;5:832-35

"Osmolality of Small-Volume Intravenous Admixtures", **Wermeling DP**, Rapp RP, DeLuca PP, Piecoro JP, *American Journal of Hospital Pharmacy* 1985;42:173917-44

"Hemodialysis of Pentobarbital During Continuous Infusion", **Wermeling DP**, Record KE, Bell RM, Blouin RA, *Therapeutic Drug, Monitoring* 1985 December;7:485-487

"Guidelines for the Administration of Commonly Used Intravenous Drugs", Rapp RP, **Wermeling DP,** Piecoro JP, *Drug Intelligence and Clinical Pharmacy* 1984 March;18(3):218-232

Non Peer Reviewed Manuscripts

Opioid Harm Reduction Strategies – Expanded Access to the Opioid Antidote Naloxone; Daniel Wermeling, Pharm.D., Anna Hitron, Pharm.D., Val Adams, Pharm.D. Kentucky Society of Health System Pharmacy Newsletter March 2010.

Redistribution of Controlled Substances: Laws and Regulations Governing Take-Back Anna Hitron, Pharm.D., Val Adams, Pharm.D., Dan Wermeling, Pharm.D. Kentucky Society of Health System Pharmacy Newsletter March 2010.

Abstracts and Posters

Naloxone Based Harm Reduction: Implementation in the State of Kentucky. Elizabeth Riner, **Daniel Wermeling.** American Pharmaceutical Association Meeting, March 30, 2014.

Intranasal administration of naloxone injection for the treatment of opioid overdose. Amanda Robinson, **Daniel Wermeling**. University of Kentucky College of Pharmacy Rho Chi Student Research Day.

Naloxone Nasal Spray for the Treatment of Suspected Opioid Overdose. Daniel Wermeling. International Conference on Opioids. Boston, MA June 12, 2012.

Neurobehavioral Effects of Intranasal d-Amphetamine. Presented to the College on Problems of Drug Dependence, Kelly, T.H., Babalonis, S., Emurian, C.S., Corbly, C.R., Martin, C.A., **Wermeling, D.P**., Joseph, J.E., and Lile, J.A. Scottsdale, AZ, 2010.

A Pilot Study of the Effects of Intranasal Oxytocin and Desmopressin on Aggressive Social Interaction. Royce Lee, M.D.; Michael McCloskey, Ph.D.; Vernon Leo Towle Ph.D.; Daniel Wermeling, Pharm.D.; Rosemary McCarron; Jessica Hempel; Bing Chen, M.S.; Emil F. Coccaro, M.D. American College of Neuropsychopharmacology, Ft. Lauderdale December 2009.

A Pilot Study of the Effects of Intranasal Oxytocin and Vasopression on a Laboratory Measure of Human Aggression. Lee R, Coccaro E, **Wermeling D**, McCloskey M. American Society of Neuropsycholopharmacology, Scottsdale, AZ, December 2008.

A Pharmacokinetic Profile of Intranasal Hydromorphone in Emergency Room Trauma Patients. Lacotoure P, Dreitlein D, Suner S, Hefti F, Clinch T, Pike D, Wermeling, D. 27**th** Meeting of the American Pain Society, Tampa FL May 9, 2008.

Acute Pain Management Research in the Emergency Department – Considerations for Model Development. Lacotoure P, Dreitlein D, Suner S, Hefti F, Clinch T, Pike D, Wermeling, D. 27th Meeting of the American Pain Society, Tampa FL May 9, 2008.

An In Line Filter to Remove Aluminum from Intravenous Feeding Solutions. Harris W, Kuhn R, Spillng C, Wermeling D, Yokel R, Zhan CG. 4th Kentucky Innovation and Enterprise Conference, April 11, 2008, Louisville, KY.

Behavioral and cardiovascular effects of intranasal d-amphetamine in humans. Lile JA, Phillips TR, Babalonis S, Wermeling, DP, Joseph JE, Martin CA, Kelly TH. February 2008, 70th Annual Scientific Meeting, College on Problems with Drug Dependence, San Juan Puerto Rico.

Microneedle Enhanced Skin Permeation of Naltrexone Hydrochloride in Human Volunteers. Banks SA, Wermeling DP, Hudson DA, Gill HS, Prausnitz M, Stinchcomb AS. American Association of Pharmaceutical Scientists Annual Meeting, Nashville, TN, November, 2007.

Succesful Transdermal Delivery of a Skin Impermeable Molecule Using Microneedles. Wermeling, DP, Banks SA, Hudson DA, Gill HS, Prausnitz M, Stinchcomb AS. American College of Clinical Pharmacy, Denver, CO October 15, 2007.

"Absorption of THC and WIN 55,212-2 mesylate in rats." Paudel KS, Valveti S, Agu RU, Hamell DC, Wermeling DP, Stinchcomb AL. AAPS Fall meeting 2004**.**

Pilot Dose Ranging Study of Unit Dose Intranasal Butorphanol Tartrate in Dental Pain Model. Rudy AC, Wermeling DP, AAPS Pharm Sci 2003 5 (4) Abstract W4185.

"Bioavailability of Intranasal Butorphanol Using Unit-Dose Sprayers in Healthy Volunteers", Davis GA, Rudy AC, Archer SM, Wermeling DP, Presented at 31st (2002) Annual Meeting of American College of Clinical Pharmacology. *J Clin Pharmacol* 2002;42:1058. Abstract 35. Presented at American College of Clinical Pharmacy 2002 Annual Meeting. Encore poster. *Pharmacotherapy* 2002;22(10):1363. Abstract 249E.

"Single and Multiple Dose Pharmacokinetics Of 1.0 mg Or 2.0 mg of Intranasal Butorphanol Tartrate Using Single Dose Sprayers in Healthy Volunteers", Davis GA, Rudy AC, Wermeling DP, Archer SM, Presented at 2002 American Society of Health-System Pharmacists Midyear Clinical Meeting. *Int Pharmaceut Abst* November 2002;39(21):2270-2271. Abstract P-446E.

"Bioavailability and Pharmacokinetics of Intranasal Midazolam", Rudy AC, Record KE, Archer SM, Wermeling DP, Presented at 2002 AAPS Annual Meeting. *AAPS pharmSci* 2002;4(4). Abstract W4175.

"Pharmacokinetics of Lorazepam After Intranasal, Intravenous, And Intramuscular Administration", Wermeling DP, Miller JL, Archer SM, Manaligod J, Rudy AC, Presented at American College of Clinical Pharmacy 2001 Spring Practice and Research Forum. (Finalist Best Poster Award Competition).

"Pharmacokinetics (PK) and Bioavailability of Hydromorphone HCl (HM HCl) After Intranasal (IN) And Intravenous (IV) Administration", Rudy AC, Wermeling D, Coda BA, Jay M, Archer S, Presented at 2001 AAPS Annual Meeting. *AAPS pharmSci* 2001;3(3). Abstract T3742.

"Bioavailability and Pharmacokinetics of Intranasal Hydromorphone in Treated and Untreated Allergic Rhinitis Patients", McNamara PJ, Davis GA, Miller JL, Rudy AC, Wermeling DP, Presented at American College of Clinical Pharmacy 2001 Annual Meeting. *Pharmacotherapy* 2001;21(10):1265.

"The Distribution Of Hydromorphone Into Human Milk", Edwards JE, Rudy A, Wermeling D, McNamara PJ, Presented at 2001 AAPS Annual Meeting. *AAPS pharmSci* 2001;3(3). Abstract T3404.

"Accuracy Of Intranasal (IN) Butorphanol Tartrate (BT) Delivery In 2 Nasal Spray Pumps Used In Clinical Study", Rudy AC, Wermeling DP, Archer SM, Rayens MK, Jay M. Presented at 2000 AAPS Annual Meeting. *AAPS pharmSci* 2000;2(2). Abstract 913.

"Bioavailability and Pharmacokinetics of Intranasal Hydromorphone in Treated and Untreated Allergic Rhinitis Patients", McNamara PJ, Davis GA, Miller JL, Rudy AC, Wermeling DP, *ACCP Pharmacotherapy*, October 2001

"Pharmacokinetics of Lorazepam After Intranasal, Intravenous, and Intramuscular Administration", Wermeling DP, Miller JL, Archer SM, Manaligod J, Rudy AC, *ACCP Pharmacotherapy* March 2001

"Pharmacokinetics (PK) of Intranasal Hydromorphone (HM) in Healthy Subjects", Wermeling D, Rudy A, Archer S, Rayens MK, Jay M, *American College of Clinical Pharmacy*, November 2000

"Pharmacokinetic-Pharmacodynamic Relationship of Ziconotide, A Novel Analgesic, Following Intrathecal Administration to Patients with Chronic Pain", Hale V, Ngo L, Chao S, O'Connell D, Ellis D, Mayo M, Wermeling D, for presentation at the American Association of Pharmaceutical Sciences Annual Meeting, October 2000

"Analgesic Efficacy of Epidural Ziconotide in Acute Postoperative Pain," Wendel D, Wermeling DP, Neurex Division of Elan Pharmaceuticals 1998

"Successful Use of SNX-111, A Novel N-Type Neuronal Calcium Channel Blocker, In the Treatment of Severe Aids Neuropathic Pain: A Case Report", Wermeling DP, Pfeifer B, Berger J, Piecoro L, Luther R, and McGuire D*, Neuroscience of HIV Infection, Basic Research and Clinical Frontiers*, March 6-9 1996

"Advantages of the "Time-Index" Method for Measurement of Severity in Alzheimer Dementia: Assessment of the Benefit of Metrifonate", For presentation in Nice, France 1996

"Intrathecal SNX-III, A Novel Peptide for Treating Malignant and Neuropathic Pain", Piecoro L, Wermeling DP, Pfeifer B, Berger J, Luther R, McGuire D, Tich N, for presentation at the American College of Clinical Pharmacy Annual Meeting, Nashville, Tennessee 1996

"A Double-Blind Placebo-Controlled Clinical Trial of Subcutaneous Recombinant Human Ciliary Neurotrophic Factor (rHCNTF) in Amyotrophic Lateral Sclerosis", ALS CNTF Treatment Study [ACTS] Study Group, American Association of Neurology, 1995

"Resource Utilization and Patient Outcomes for Propofol Verses Thiopental/Isoflurane Anesthesia in Gineral Abdominal Surgery", Wermeling DP, Suver J, Wilson J, Winter Practice & Research Forum, American College of Clinical Pharmacy, Orlando Fl 1995

"**Results of a Phase II Clinical Trial with Metrifonate**", Pettigrew L, Mas J, Schmitt F, Wermeling D, Bieber F

"Dirithromycin Increases Ethinyl Estradiol Clearance Without Allowing Ovulation: A Novel Approach to Antibiotic-Oral Contraceptive Interactions", Wermeling DP, Sides G, Chandler MHH, Collins DC, Curry TE, Muse KN, *American Fertility Society*, November, 1994

"Analysis of Medications Administered to Patients With Sepsis Syndrome: Likelihood of Adverse Drug Interactions", Shedlofsky SL, Blouin RA, McClain CJ, Johnson SB, Wermeling DP, *American Association of Liver Diseases*, Chicago, Illinois, June 22, 1994

"Cerebral Energy Metabolism and Cognitive Performance in Alzheimer's Disease", Pettigrew LC, Smith CD, Schmitt FA, Wermeling DP, Tikhtman AJ, et al. *American Association of Neurology*, Washington, D.C., May 3, 1994

"IRB Communication With A University Hospital Regarding Investigational Drug Research", Wermeling DP, Martin LA, Nowak-Rapp M, *American Society of Hospitals* December 9, 1993

"A Randomized, Comparative, Multi-Center, Study of the Efficacy and Safety of Fluconazole Administered As A Single Oral Dose and Seven Day of Clotrimazole Intravaginal Therapy in the Treatment of Vaginal Candidiasis", Sobel J, Brooker D, Thomason J, Wermeling D, Bradley B, Wekstein L. Gilbert G, Pancorbo S, and the Fluconazole Vaginitis Study Group, *American College of Obstetrics and Gynecology*, Washington, D.C., May 3-6, 1993

"Investigational Drug Information and Testing Mechanism For Nurses", Wermeling DP, Nowak-Rapp M, Sitzlar S, *American Society of Hospital Pharmacists*, December 7, 1992

"Investigation of Intravenous Infusion Monitoring System: Site Guard", Rockich AK, Rapp RP, Liter MF, Wermeling DP, *American Society of Hospital Pharmacists*, December 9, 1992

"Clinical Pharmacology of a New Inotrope/Vasodilator in Healthy Males", Clifton GD, Harrison MR, Wermeling DP, Rolleri RL, Fleck RJ, Weller MS, Long RA, *American Society of Clinical Pharmacology and Therapeutics*, February, 1992.

"Intrathecal SNX-III, A Novel Peptide for Treating Malignant & Neuropathic Pain", Piecoro LT, Wermeling DP, Pfeifer B, Berger J, Luther R, McGuire D, Tich N, *American College of Clinical Pharmacy*

Book Chapters

"**Intranasal Drug Delivery**", Wermeling DP, Miller JL. In Modified-Release Drug Delivery Technology, edited by Rathbone, MJ, Hadgraft, J, Roberts, MS. New York/Basel: Marcel Dekker, Inc. 2002

Editor

Open Pharmacology Journal, Editorial Board Member 2008 - 2010

Controlled Release Society Advisory Board – Textbook on Nasal Drug Delivery 2008-14

Current Pharmaceutical Design – Executive Guest Editor 2007 - 2010

Evaluation of Drug Interactions
Chapter 2 Anesthetic Drug Interactions
1988 – 1998

Grant Activity

Funded Grants

University of Kentucky eLii Teaching Enhancement Grant. May 2015. $ 4000

NIH NIDA. Grant Number**:** 2R42DA030001-04. May 1 2013 – April 30 2016. $2.97 M Total. University of Kentucky Sub-Award of $ 300,000 per year for 3 years.
Role: Principal Investigator

Kentucky Science and Technology Corporation (KSTC). Matching Award to Phase 2 of NIDA 2 R 42DA0300001-01 – April, 1 2012. $ 500,000
Role: Principal Investigator

Kentucky Science and Technology Corporation (KSTC). Matching Award to Phase 1 of NIDA 1 R 42DA0300001-01 – Feb, 1 2011. $ 150,000
Role: Principal Investigator

NIH NIDA 1R42DA030001-01 – "Intranasal Naloxone: An Opioid Overdose Antidote". $1,451,714 in total/2 years. UK Contract Portion $ 430,055. 2010-2012.
Role: Principal Investigator

Clinical and Translational Science Award (CTSA), Therapeutics Advisory Committee 2009-2011, 5% effort.

ACCP Frontiers Award – "fMRI Imaged Neuroactivation and Craving in Alcoholics is Modulated by Ondansetron". American College of Clinical Pharmacy, $ 30,000, August 2007. Role: Principal Investigator.

NIH MO1RR02602 – Priority Score 150 – Alcohol Related fMRI Imaged Neuroactivation and Craving: Part A Imaging Validation; Part B Medication Administration. October 2007, Role: Principal Investigator.

NIH – R41HD055009-01, A Device Containing Immobilized Chelator to Remove Aluminum in TPN Solutions. October 2007, 2.5% effort, Role: Subinvestigator

NIH 1R41AA016500-01, Priority Score 161, Nasal Delivery of Naltrexone for the Treatment of Alcoholism: Role: Principal Investigator 10% effort. National Institute on Alcoholism and Alcohol Abuse, $ 100,000, June 2006.

NIH P20 RR15592. Nasal Delivery of Dextroamphetamine by the Nasal Route and to Evaluate Effects on Human Cognition, Mood and Brain Function. NCRR 2.5% effort. Role: Subinvestigator.

The Effects of Intranasal Corticotropin Releasing Hormone on Cortical and Subcortical Information Processing. PI Royce Lee, M.D. $ 1000 per year for 2 years. Role – Co-Investigator on grant from Brain Foundation and subcontract from University of Illinois Chicago. April 2006.

A Pilot Study of the Effect of Intranasal Corticotropin-Releasing Hormone on Emotion Processing in Remitted Depression. PI: Royce Lee, M.D. $ 30,000 over 2 years. Role – Co-investigator $ 3000/yr. NARSAD Foundation and University of Illinois subcontract. April 2006

Microneedle Assisted Naltrexone Hydrochloride Transdermal Delivery for the Treatment of Addictions. Role: Principal Investigator. NIH GCRC and UK Internal Competition. Pilot Research Project $29,500. April 2006

An Open Label Study Asssessing the Pharmacokinetics and Pharmacodynamics of Cangrelor Bolus Plus Infusion in Healthy Volunteers, The Medicines Company. Role: Co-investigator, $ 367,618. 2005.

Nasal Drug Delivery Development. Intranasal Technology, Inc. $ 18,000/yr. 2004

A Double Blind, Randomized, Placebo-Controlled, Crossover Study to Investigate the Safety, Tolerability and Pharmacokinetics of Single Oral Escalating Doses of GW572016 Ditosylate Monohydrate in Healthy Volunteers, Glaxo EFG10001(Co-Principal Investigator)
$379,970 1999

A Double Blind, Randomized, Placebo-Controlled, Parallel Study to Investigate the Safety, Tolerability and Pharmacokinetics of Multiple Oral Doses of GW572016 in Healthy Volunteers, Glaxo EFG10002 (Co-Principal Investigator)
$671,627 2000

ITI Infrastructure, Project #4 (DPEU). Inhalation Technology, Inc. (Principal Investigator)
$2,177,587 2000-1

A Single-Dose, Open-Label, Three Way Crossover, Randomized, Pilot Bioavailability Study of Lorazepam Comparing Intranasal Administration to Intravenous and Intramuscular Administration in Healthy Human Volunteers, Inhalation Technology, Inc. (Principal Investigator)
$116,174 2000

A Single and Multiple Dose Pharmacokinetic Study of 2.0 mg Intranasal Hydromorphone Hydrochloride in Healthy Volunteers, Inhalation Technology, Inc. (Principal Investigator)
$160,896 1998

Absolute Bioavailability of Intranasal Hydromorphone HC1 in Patients with Rhinitis and Rhinitis Treated with Oxymetazoline, Inhalation Technology, Inc. (Sub-Principal Investigator)
$118,454 1999

A Single-Dose Milk Transfer Study of Hydromorphone Hydrochloride Following Intranasal Administration in Healthy Human Volunteers, Inhalation Technology, Inc. (Sub-Principal Investigator)
$55,633 1999

A Pharmacokinetic, Bioavailability and Safety Study of 1.0mg Hydromorphone Hydrochloride Following Intranasal Administration and Intravenous Administration in

Children and Adolescents with Existing Central Venous Access Catheters, Inhalation Technology, Inc., (Sub-Principal Investigator)
$74,374 1998

Absolute Bioavailability of Intranasal Hydromorphone HC1 in Patients with Perennial or Seasonal Allergic Rhinitis and with Perennial or Seasonal Allergic Rhinitis Treated with Flonase, Inhalation Technology, Inc., (Sub-Principal Investigator)
$81,236 2000

A Single and Multiple Dose Pharmacokinetic Study of 2.0mg Intranasal Hydromorphone Hydrochloride in Healthy Volunteers. Inhalation Technology, Inc. (Principal Investigator), 2000
$146,381

A Single Dose, Open Label, Three Way Crossover Bioavailability Study of 1.0 and 2.0 mg Intranasal hydromorphone HC1 in Healthy Volunteers. Inhalation Technology Inc. (Principal Investigator), 1999
$142,173

Open-Label Extension Study of Continuous Subcutaneous Infusion of Sufentanil Citrate for the Treatment of Chronic Pain. Pacific Research Assoc. (Principal Investigator), 1999
$99,918

Application to FDA for Notice of Suitability. Inhalation Technology, Inc. (Principal Investigator), 1999
$49,832

A Single Blind, Open-Label, Three Way Crossover, Randomized Pilot Bioavailability of Hydromorphone. Inhalation Technology, Inc. (Principal Investigator), 1999
$56,283

ITI-Project #3 Nasal Spray (DPEU). Inhalation Technology, Inc. (Principal Investigator), 1999
$914,201

Continuous Epidural Infusion of Ziconotide in Patients with Severe Chronic Pain: Open Label, Safety and Feasibility Study. Elan Pharm./Clinimetrics (Principal Investigator), 1999
$76,802

A Single-Dose, Open-Label, Three Way, Incomplete Block Crossover, Randomized, Pilot Study of Butorphanol Tartrate Comparing Intranasal Administration via Multi-Dose Spray pump Versus Single-Dose Sprayer in Healthy Human Volunteers. Inhalation Technology, Inc. (Principal Investigator), 1999 $79,931

A Single Blind, Open-Label, Three-Way Crossover Pilot Bioavailability Study of Hydromorphone HCL Comparing IN to IV and IM Administration in Healthy Human Volunteers. Inhalation Technology, Inc. (Principal Investigator), 1998
$56,283

Open-Label Dose-Filtration Study of Continuous Infusion of Sufentanil Citrate for the Treatment of Chronic Pain. Durect Corp. (Principal Investigator), 1998
$38,054

A Phase II Pilot Study of Ziconotide (SNX-111) Administered by Bolus Epidural Injection in Patients with Chronic Pain. Neurex/Elan Pharmaceuticals (Principal Investigator), 1998
$116,713

A Single Dose, Open Label, Three-Way Crossover, Randomized Pilot Bioavailability Study of Ondansetron, Hydrochloride Comparing Intranasal Aqueous and Gel Formulations to Intravenous Administration in Healthy Human Volunteers. Glaxo-Wellcome (Principal Investigator), 1998
$50,000

Alza E-Trans (Fentanyl) Protocol C-94-057. Paraxel (Principal Investigator), 1998
$17,800

A Prospective, Randomized Single-Blind Crossover Comparison Study of the Safety and Efficacy of Apothecon-Warfarin and DuPont-Warfarin in the Treatment of Patients with Atrial Fibrillation. Apothecon/UHC (Sub-Investigator), 1998
$75,045.47

Single-Site, Phase II, Open-Labeled, Rising Dose, Feasibility, Safety & Efficacy Study of SNX-111 Administered Intrathecally in Bolus Doses for Chronic Pain. Neurex (Principal Investigator), 1998
$136,754

An Open-Label, Long-Term Safety and Tolerability Study of Ziconotide® Administered Intrathecally to Patients with Chronic, Severe Pain. Elan Pharmaceuticals (Principal Investigator), 1998
$117,200

Multidisciplinary Clinical Research Training Program. National Institutes of Health (Sub-Investigator)
$1,080,000 (5 yr. budget – approx. $216,000 each year) submitted

A Four-Way Crossover, Dose Study of Flunisolide Administered Through Intravenous Injection, Oral Solution, and Oral Inhalation System (AEROBID) With and Without the Spacer (AEROCHAMBER) in Normal Healthy Male or Female Volunteers. Forest Laboratories(Principal Investigator, 1997)
$148,000

A Double-Blind, Parallel Group, Placebo-Controlled Study of Intravenous Kytril (Granisetron Hydrochloride) in the Treatment of Post-Operative Nausea and Vomiting in Patients Undergoing Elective Surgery with General Anesthesia. Smith-Kline Laboratories (Principal Investigator), 1996-1997
$20,000

A Multicenter, Phase II, Placebo-Controlled Pilot Study of SNX-111 Administered Intrathecally to Patients with Acute Postoperative Pain. Neurex (Co-Principal Investigator)
$36,000

The Effects of Renal Dysfunction on the Pharmacokinetics and Pharmacodynamics of Suramin in Cancer Patients. Parke-Davis Laboratories (Co-Principal Investigator)
$19,000

Investigation of the Influence of Topical Application of Glycolic Acid on the Percutaneous Penetration of Model Penetrants Through Human Skin in Vivo. Hilltop Research (Co-Principal Investigator)
$27,120

A Double-Blind, Placebo Controlled Trial of Metrifonate in Patients with Probable Alzheimer's Disease. Bayer, Inc. (Principal Investigator)
$152,400

An Open Label Extension Trial of Metrifonate in Patients with Probable Alzheimer's Disease. Bayer, Inc. (Co-Investigator)
$98,400

A Phase I/II Open Label, Rising Dose, Safety and Feasibility Study of SNX-111 Administered Intrathecally to Patients With Intractable Chronic Pain. Neurex (Co-Principal Investigator)
$33,500

A Trial of Recombinant Methionyl Human Brain Derived Neurotrophic Factor Given By Daily SQ Injection to Patients With Amyotrophic Lateral Sclerosis. Amgen (Co-Investigator)
$318,500

Multicenter, Double-Blind, Randomized, Placebo-Controlled, Dose-Finding, Safety and Tolerability Trial of R-IGF-1 in Patients With Acute Kidney Failure. Chiron (Co-Investigator)
$117,400

Double-Blind, Randomized, Placebo-Controlled, Parallel Group Trial of the Efficacy and Safety of Enlimomab Compared to Placebo Administered Within 6 Hours of Onset of Stroke Symptoms for Treatment of Acute Ischemic Stroke. Boehringer-Ingelheim (Co-Investigator)
$109,200

Cervene Modification of Outcome in Patients with Acute Ischemic Stroke: a Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Dose Comparison Study by 24 Hour Infusion. Baker-Norton Pharmaceuticals (Co-Investigator)
$86,400

A controlled pilot study of 1,25(OH)D-3 (calcitriol) in the treatment of Alzheimer's Disease. NIH Program Project Grant - Specific Aim 2 (Co-Investigator)
Salary savings, 7.5% FTE (approx. $9,000/yr)

A Double-Blind, Placebo-Controlled Trial of Anti-Tumor Necrosis Factor in Patients with Severe Sepsis. Bayer (Co-Investigator)
$158,000

A Multi-Center, Pharmacokinetic and Pharmacodynamic Study of Dofetilide in Subjects With Stable Atrial Fibrillation (AF) and Reduced Left Ventricular Ejection Fraction, Pfizer (Co-Investigator)
$128,931

A Double-Blind, Randomized, Placebo-Controlled, Dose-Response, Study of Inhaled Nitric Oxide 9OHM-11771) in the Treatment of Acute Respiratory Distress Syndrome (ARDS) Ohmeda (Co-Investigator)
$175,240

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Intravenous Ondansetron for the Treatment of Postoperative Emesis in Pediatric Patients Undergoing Outpatient Surgery -Glaxo (Co-Investigator)
$30,000

An Open-Label Study of the Pharmacokinetics of Venlafaxine in Extensive and Poor Metabolizers of Dextromethorphan-Phase I Phenotype Study Wyeth-Ayerst (Co-Investigator)
$144,888

A Double-Blind Comparison of Sertindole and Haldol^{R}: An Assessment of the Chronic Safety, Efficacy, Quality of Life and Relapse in Stable Schizophrenic Patients (M93-132) Outpatient-Abbott Labs (Co-Investigator)
$174,019

A Double-Blind, Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of Sertindole and Three Doses of Haldol^{R} in Schizophrenic Patients (M93-113) Inpatient Abbott Labs (Co-Investigator)
$106,192

Tricyclic Versus Serotonin Specific Reuptake Inhibitor Anti-Depressant in Low Back Pain, Pain Care Inc. (Co-Investigator)
$12,243

A Trial of Recombinant Methionyl Human Brain-Derived Neurotrophic Factor (f-tHuBDNF) Given By Daily Subcutaneous Injection to Patients with Amyotrophic Lateral Sclerosis (ALS) Amgen (Co-Investigator)
$136,500

Phase I Pilot Study Evaluating the Effect of Study-State CP- 99219 On the Pharmacokinetics of Theophylline in Healthy Male Subjects Pfizer (Co-Investigator)
$77,113

A Randomized, Double-Blind, Multi-Center Trial Comparing 7 Days of Oral Therapy With CP-99219 (100 mg or 200 mg daily) or Ciprofloxacin Hydrochloride (500 mg daily) for the Treatment of Uncomplicated Urinary Tract Infections Pfizer (Principal Investigator)

$35,973

Erythromycin Citrate: Bioequivalency Study-Baxter Healthcare Corporation (Principal Investigator)
$110,664

Randomized, Placebo-Controlled Trial of E5 Antiendotoxin Monoclonal Antibody in Patients With Severe Sepsis Pfizer (Co-Investigator)
$55,000

A Placebo-Controlled Study to Determine the Effects of 500mg, 1000mg and 2000mg Citicoline in Ischemic Stroke Patients Parexel (Co-Investigator) $83,460

The Safety and Efficacy of Tiagabine HCL Monotherapy in the Treatment for Partial Seizures: High Dose Versus Low Dose Abbott (Co-Investigator)
$90,809

A Double-Blind, Placebo-Controlled, Dose Finding Study to Evaluate the Safety and Efficacy of Three Different Doses of Metrifonate (BAY A 9826) in Patients with Probable Alzheimer's Disease Miles (Co-Investigator)
$221,000

Prospective, Double-Blind, Placebo-Controlled, Randomized, Multi-Center, North American Study of the Safety and Efficacy of Murine Monoclonal Antibody to Tumor Necrosis Factor (TNFMAb) for the Treatment of Patients With Septic Shock Miles (Co-Investigator)
$162,073

A Randomized, Double-Blind, Placebo-Controlled Study of Intravenous Ondansetron Versus Droperidol For the Prevention of Post-Operative Nausea and Vomiting In Outpatient Surgery. Glaxo (Principal Investigator)
$75,000

A Phase III Study of r-metHuG-CSF in the Treatment of Severe Community Acquired Pneumonia (CAP) Amgen (Co-Investigator)
$78,750

A Randomized, Double-Blind, Placebo-Controlled Trial Testing the Efficacy of Tirilazad Mesylate in Patients With Acute Ischemic Stroke (RANTTAS) (The Upjohn Company) NIH (Co-Investigator)
$75,000

A Double-Blind, Randomized, Multi-Center Study of the Safety and Recovery Profiles of Tracrium, Norcuron, and Pavulon in Intensive Care Patients Who Require Neuromuscular Blocking Agents to Facilitate Mechanical Ventilation. Burroughs Wellcome (Co-Investigator)
$46,803

Phase I Safety and Tolerance Study of IP-AD-32 in Patients with Refractory Cancer Confined to the Peritoneal Cavity. Theradex (Co-Investigator)
$24,155

A Double-Blind, Placebo-Controlled, Randomized, Single-Center Study of the Safety, Tolerability, and Pharmacokinetics of Metrifonate. Miles (Co-Principal Investigator)
$352,898

A Phase II/III Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Safety and Efficacy Study of Recombinant Human Ciliary Neurotrophic Factor. Regeneron (Co-Investigator)
$107,100

Open-Label, Multiple-Dose, Pharmacokinetic/Pharmacodynamic Study of Dirithromycin and Oral Contraceptives (On - 7/7/7/28). Lilly Research Laboratories (Principal Investigator)
$111,460

A Double-Blind, Placebo-Controlled, Study to Determine Whether Procrit Can Reduce Peri-Operative Transfusion Requirements In Subjects Undergoing Major Orthopedic Surgery. R. W. Johnson Research Institute (Co-Investigator)
$89,031

A Study to Evaluate the Safety and Efficacy of Human r-IL1ra in Increasing Survival in Patients With Severe Sepsis. Synergen (Co-Investigator)
$68,250

Induction and Maintenance of General Anesthesia: An Economic Evaluation of Propofol and Thiopental/Isoflurane in Patients Undergoing Elective Intra-Abdominal Surgery. Health Economics Research (Principal Investigator)
$181,480

A Placebo-Controlled Trial to Evaluate the Safety, Tolerability, and Potential Efficacy of Initiating IV Administration of CGS-19755 to Serious Head Trauma Patients Prior to Surgery. Ciba-Geigy (Co-Investigator)
$98,000

A Multi-Center Phase I Evaluation of AD-32 Administered by Intravesical Instillation in Patients with Superficial Transitional Cell Carcinoma of the Urinary Bladder. Anthra Pharmaceuticals (Co-Investigator)
$18,192

The Safety of Intravenous Valproate Abbott Laboratories (Co-Investigator)
$7,182

The Effects of Subcutaneous r-HuEPO in Patients with Chronic Lymphocytic Leukemia R.W. Johnson Pharmaceuticals Research Institute (Co-Investigator) $30,000

An Open Study to Determine the Safety and Efficacy of Procrit Sterile Solution in Correcting Anemia in Renal Transplant Patients with Chronic Graft Dysfunction, R.W. Johnson Pharmaceuticals Research Institute (Co-Investigator)
$36,070

A One Year Multi-Center Double Blind Comparison of the Effects of Once Daily Dosing with Three Dose Levels of SKF 105657 or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia with Six Month Untreated Follow-Up SmithKline Beecham (Co-Investigator)
$111,082

Dose Tolerance of DSPC Liposome in Healthy Volunteers The Liposome Company (Principal Investigator)
$162,389

A Controlled Trial of Intravenous Plus Oral RS-87476 in Acute Non-Hemorrhagic Cerebral Infarction Syntex Research (Co-Investigator) $30,000

Investigation of Intravenous Infusion Monitoring System: Site Check IMED Corporation (Co-Investigator)
$14,592

A Study to Evaluate the Safety and Efficacy of Human Recombinant Interleukin-1 Receptor Antagonist (IL-1RA) in the Treatment of Sepsis Syndrome Synergen, Inc. (Co-Investigator)
$153,000

A Double-Blind Comparison of the Efficacy of a Two-Dose Regimen of Oral Granisetron (1 mg twice, 2 mg once) in Preventing Active Nausea and Emesis in Patients Receiving Moderate Emetogenic Chemotherapy SmithKline Beecham (Co-Investigator)
$61,920

Kinetics of Edatrexate and Its Metabolites after Single 40 and 80 mg/m^2 Intravenous Doses in Cancer Patients with Varying Degrees of Renal Insufficiency Ciba-Geigy (Co-Investigator)
$97,750

Measurement of Muscle Strength and Abilities to Perform Activities of Daily Living in Patients with Amyotrophic Sclerosis Regeneron Pharmaceuticals (Co-Investigator)
$20,000

A Relative Bioavailability Study of RO 24-7429 (TAT Antagonist) Tablets (With and Without Food) vs. Oral Solution (Fasting) in Normal Volunteers Hoffman-LaRoche (Principal Investigator)
$72,487

Acute Dose Tolerance and Pharmacokinetics of Oral 1045U85/HCL in Healthy Male Volunteers Burroughs Wellcome (Co-Investigator) $237,754

Evaluation of Gastric pH Control in Head Trauma Patients by Continuous IV Infusion of Cimetidine SmithKline Beecham - (Co-Investigator)
$23,161

Evaluation of Streptokinase Infusion Kit for the Emergency Room Delivery of Thrombolytic Therapy Baxter Healthcare Corporation - (Co-Investigator)
$48,000

Investigation of Intravenous Infusion Monitoring System: Gemini IMED Corporation - (Co-Investigator)
$18,958 Part A, $12,500 Part B

Transurethral Resection of Prostatic Tissue Using an Endoscopic Ultrasonic Surgical Aspirator System Valleylab, Inc. (Co-Investigator)
$204,286

Pharmacokinetic Analysis of Lidocaine Administered by the Baxter Infusor Baxter Healthcare Corporation (Co-Investigator)
$26,059

MK 787/791 vs. Ampicillin Plus Clindamycin plus Gentamicin in the Treatment of Serious Gynecological and Lower Abdominal Infections in Female Patients Merck Sharp & Dohme Research Laboratories (Co-Investigator)
$112,500

IRB Equitable Selection Survey ARENA (Co-Investigator)
$800

Single Oral Dose Pharmacokinetic and Pharmacodynamic Comparison of S-Atenolol and Racemic Atenolol (Termorin) in Healthy Adults Sepracor, Inc. (Co-Investigator)
$75,000

Pivotal Study of Human MAB-T88 in Patients with Gram-Negative Sepsis. Cetus Corporation (Co-Investigator)
$70,000

A Study to Assess the Effects of Chronic Oral Carvedilol on the Steady-State Pharmacokinetics of Oral Digoxin in Patients with Mild to Moderate Hypertension. SmithKline Beecham Pharmaceuticals (Principal Investigator)
$83,000

Double-Blind, Placebo-Controlled Study of the Effect of Ceftizoxime Sodium in the Management of Patients with Preterm, Premature Rupture of Membranes. Fujisawa Pharmaceutical Company (Co-Investigator)
$77,000

A Randomized Multi-Center Study of a Single Dose Oral Fluconazole Tablet Compared with Seven Days of Miconazole Vaginal Cream in the Treatment of Acute Candidal Vaginitis in Women 18-65 Years of Age. Pfizer Pharmaceuticals (Principal Investigator)
$35,000

A Randomized Multi-Center Study of a Single Dose Oral Fluconazole Tablet Compared with Seven Days of Clotrimazole Vaginal Tablets in the Treatment of Acute Candidal Vaginitis in Women 18-65 Years of Age. Pfizer Pharmaceuticals (Principal Investigator)
$70,000

A Phase II Dose Finding Placebo Controlled Study of YM617 in Patients with Signs and Symptoms of Benign Prostatic Hyperplasia. Yamanouchi Pharmaceuticals (Co-Investigator)
$95,000

A Phase II Open-Label, Randomized Controlled Study of rhIGF-1 in Patients with Severe Head Injury. Genentech (Co-Investigator)
$199,000

The Comparison of Sulbactam/Ampicillin (Unasyn) and Ampicillin/Gentamicin in the Treatment of Chorioamnionitis. Pfizer (Co-Investigator)
$116,000

Double-Blind, Placebo-Controlled Pilot Study Evaluating Safety and Tolerability of Two Intravenous Bolus Doses of CGS-19755 in the Treatment of Patients with Acute Stroke. Ciba-Geigy (Co-Investigator)
$84,000

A Placebo Controlled, Double Blind, Crossover, Dose/Response Study of Oral Torsemide in Patients with Ascites Due to Cirrhosis. Boehringer Mannheim Pharmaceuticals (Principal Investigator)
$59,200

Acute Dose Tolerance, Pharmacokinetics, and Pharmacodynamics of Oral 349U85 in Healthy Male Volunteers. Burroughs Wellcome (Co-Investigator)
$270,000

Comparative Clinical Efficacy of Two Tablet Strengths of Deflazacort in the Treatment of Steroid Dependent Asthma. Merrell Dow Pharmaceutical (Co-Investigator)
$52,278

Long Term Safety and Efficacy Study of Deflazacort in Patients with Chronic Steroid Dependent Asthma. Merrell Dow Pharmaceutical (Co-Investigator)
$21,356

Comparative Safety and Efficacy of Clarithromycin and Suprax in the Treatment of Lower Respiratory Tract Infections. Abbott Laboratories (Co-Investigator)
$24,000

Unasyn - Pharmacy Surveillance Project. Pfizer Pharmaceuticals (Co-Investigator)
$275,000

A Double-Blind, Placebo Controlled Study to Determine the Safety of r-HuEPO and Whether r-HuEPO can Reduce the Postoperative Transfusion Requirements in Subjects Undergoing Orthopedic Surgery. R.W. Johnson Foundation (Co-Investigator)
$79,000

Assessment of Time to Study State After Multiple Dose Nefazodone in Extensive and Poor Metabolizers of Dextromethorphan. Bristol-Myers (Co-Investigator)
$150,000

Infusion Device for Lidocaine Administration. Baxter Laboratories (Co-Investigator)
$70,000

Evaluation of the Travenol Infusor/Patient Control Module for the Treatment of Postoperative Pain Travenol Laboratories (Co-Investigator)
$25,000

Evaluation of Stadol with the Travenol Infusor and Patient Control Module for Patient-controlled Analgesia. Bristol-Myers (Co-Investigator)
$12,500

An Evaluation of the Bioavailability of BW825C and Pseudoephedrine from 825C/Pseudoephedrine Combination Capsules and Syrup in Normal Male Volunteers. Burroughs Wellcome Company (Co-Investigator)
$52,108

A Randomized Comparative Trial of Morphine Administered by Patient-Controlled Analgesia vs. Intramuscular Injection for the Treatment of Pain in Postoperative Patients. Bard Medsystems (Principal Investigator)
$8,000

Multi-Institutional Study of Patient-Controlled Analgesia. Travenol Laboratories (Principal Investigator)
$100,050

A Comparative Study Of CGS-15849 vs. Its Components and Placebo on Intraocular Pressure in Normal Subjects. Ciba-Geigy (Co-Investigator)
$65,678

A Multiple Dose Placebo Double-Masked Comparative Tolerability Study of Diclofenac Sodium vs. Placebo in Normal Subjects. Ciba-Geigy (Co-Investigator)
$84,114

Other Creative Activity

National

"Advent IV Medication Delivery Systems Implementation Guide." A reference manual for pharmacists preparing small volume parenteral using a gravity-feed syringe system. Sponsored by Quest Medical.

"Patient-Controlled Analgesia Device Inservice." A VHS tape describing methods for pharmacy preparation, nurse monitoring and patient utilization of a novel PCA device. Sponsored by Baxter.

"Electronic Research Administration Binder." An asserted copyright computer program for research administration. 1998

Intranasal Therapeutics Inc.

Address: Intranasal Therapeutics, Inc.
Coldstream Research Campus
1513 Bull Lea Boulevard
Lexington KY 40511-1200
www.intranasal.com

- Co-founder and consultant for a university-based start-up specialty pharmaceutical and drug delivery company – 1996 - 1999
- Senior Vice President and Chief Operating Officer – 1999-2004
- Chief Scientist 2004 - 06
- Technology based on University of Kentucky research in nasal transmembrane delivery of pharmaceuticals to the systemic circulation
- From 1996-2003 ITI funded over $6 million into University of Kentucky research programs. The research funding supported major programs at UK and led to scholarly productivity by faculty
- Patents have been submitted and issued to UK from this research
- ITI has licensed the technology from UK and is partnering with larger pharmaceutical companies for finance and marketing support
- ITI has moved initial operations in the University incubator facility to the UK Coldstream Research campus where a research and development and manufacturing plant has been constructed
- ITI was the first private company to receive equity and debt financing from the Commonwealth of Kentucky Economic Development Cabinet. Total investment was $3.5 million
- In July 2006 ITI closed a $ 39 million venture capital financing for clinical and basic research and physical plant expansion

AntiOp Inc. (f/k/a Alcomed Inc.)
3732 Wembley Lane
Lexington, KY 40515

- Founder, President and Chief Executive Officer
- Incorporated in Kentucky as a University of Kentucky spin-off May 2009
- Focused on developing nasal delivery technology for treatment of opioid overdose
- Virtual pharmaceutical company
- Completed NDA and Submission
- Assets sold to Indivior (f/k/a Reckitt Benckiser Pharmaceuticals)