EXHIBIT A

MARVIN A. HEUER, M.D. F.A.A.F.P.

6001 Vineland Road Suite 104
Orlando, Florida 32819
Phone: 407-574-5650
Email: mheuer@heuermd.com

CHIEF EXECUTIVE OFFICER ~ CHIEF SCIENCE OFFICER ~ MEDICAL PHYSICIAN

Internationally Accomplished Medical Research Physician and Executive. More than 30 years experience in international and domestic clinical research, pharmaceutical and nutraceutical development. Extensive experience and interaction with FDA and FTC in pharmaceutical and nutraceutical industries. Along with the practice of medicine has served as Chief Science Officer for Iovate Health Sciences, VP of Clinical Research, IntegraMed America, VP & Director Worldwide of R&D, SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline), VP of R&D, Wallace Laboratories (now Meda AB), and VP & Medical Director Worldwide, Ayerst Laboratories (now Pfizer).

- *Product Formulation and Development*
- *FDA / FTC / Regulatory Compliance*
- *Clinical Trials / R&D*
- *Public and Media Relations*
- *Nutraceutical Supplement Company*
- *Skincare Company*
- *Preventative Medicine*
- *Author*

Medical Licenses ▪ Arizona ▪ California ▪ Florida ▪ Minnesota ▪ NRCME DOT

MD Degree ▪ University of Minnesota Medical School 1973 Board Certified Family Practice 1975

Bachelor of Science ▪ Biology / Chemistry ▪ Mankato State University ▪ Graduated Cum Laude 1969

Heuer M.D. Research, Inc. June 2002 to Present.
Orlando, FL
Chief Executive Officer
Founder and Chief Executive

- Founder of a private SMO clinical research organization.
- Principal Investigator for ongoing pharmaceutical clinical research trials.
- Consultant to nutraceutical / pharmaceutical / cosmetic industries.
- Nutraceutical / cosmetic research and product development company, formulation, studies, author .
- Nutraceutical / cosmetic product testing and clinical trial development.
- GRAS / NDI dossiers and submission.
- FDA / FTC, regulatory reviews and representation.
- Expert report compilation / Expert witness services

Walt Disney World Resorts August 2014 to Present
Orlando, FL
Physician
Occupational Health and Safety Physician

- Perform DOT commercial driver medical examinations.
- Assess employees with medical illnesses and emergencies and take appropriate action according to established protocol.
- Maintain HIPAA and Occupational Safety and Health Administration (OSHA) compliance standards.
- Administer the company's Drug-Free Workplace Program.

Iovate Health Sciences Inc. February 2004 to December 2008
Oakville, ON
Chief Scientific Officer
Senior Operating Executive with full strategic planning and product development responsibility.

- Formulated over 70 new nutraceutical and health products increasing annual revenues from $50 million to over $500 million in two years.
- Fostered small inexperienced R&D into highly productive unit generating extensive novel IP and finished products totaling over 200 applied and approved patents.
- Transformed young bodybuilding supplement company into the industry leader in nutraceuticals and homeopathic and OTC development.
- Anticipated external legislative, regulatory policy and political environments in short, mid, long term.
- Championed, structured and initiated first pharmacovigilance oversight in the nutraceutical industry.
- Liaison with FTC, FDA, Health Canada and other various regulatory agencies.
- Oversaw product manufacturing and quality control, monitor plant facilities domestically and abroad to ensure U.S. federal regulations are met and instructed on manufacturing processes.

Clin Sci International, Inc. (CRO) October 1998 to July 2003
Gainesville, FL
Sole Owner / Chief Executive Officer

- Founder of a private mini SMO clinical research and family practice organization / clinic.
- Consultant to several major pharmaceutical companies and regulatory agencies.
- Principal investigator on over 13 clinical trials in diverse therapeutic areas.

Florida Medical and Research Institute September 1998 to May 2001
Gainesville, FL and Ocala, FL
President

- Revived a failing clinical research organization increasing it from 6 studies to 21 studies.
- Transformed organization from severe financial peril to profitable position in less than three years.
- Conducted clinical trials Phases I through IV on up to 24 clinical research studies at a time.

IntegraMed America Women's Health Fertility and Family Medicine March 1997 – August 1998
Gainesville, FL
Vice President

Women's Medical and Diagnostic Center March 1997 – August 1998
Gainesville, FL and Ocala, FL
Director of Family Practice and Clinical Research

Heuer Associates 1991 - 1996
President

- Consultant to medical practitioners and researchers for developing and running clinical trials for pharmaceutical and device research, and IND and NDA submissions.
- Coordinator of plans, facilities and financing for important Phase I, II trials unit in Minneapolis / St. Paul area.

Medical Valley Biotechnology Westview Clinic, PA November 1991 – March 1997
West St. Paul, Minnesota
Executive Consultant/Family Practice Physician

- Managed medical care of the entire patient and family unit.
- Conducted research on devices and drugs in multi-center trials.

SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline) April 1989 – December 1991
King of Prussia, Pennsylvania
Vice President & Director Worldwide Clinical Investigation, Therapeutic Unit
Research & Development Pharmaceuticals

- Managed activities of clinical representatives worldwide in the formulation and execution of the overall product development plans.
- Cultivated corporate process and implemented necessary systems to allow rapid worldwide product development with an R&D budget of over $40 million.
- Supervised the safety of compounds with worldwide databases for Phases I, II, III, and IV.
- Fostered drug development skills and raised morale to 40 + direct reports.

Wallace Laboratories Division of Carter -Wallace, Inc. September 1987 – March 1989
(now Medpointe Pharmaceuticals)
Cranbury, New Jersey
Vice President Research & Development

- Led the development of the new cardiovascular, pulmonary, analgesics, central nervous system and antibiotic compounds with staff of 200+ and a budget of $25 million.
- Directed all preclinical and clinical research, including bench chemistry and manufacturing.
- Revived the R&D organization with new talent infusion, project management controls, revised budgets, and state-of -the-art communication, database systems and equipment.

Ayerst Laboratories Division of American Home Products Corp. July 1986 – September 1987
(now Wyeth Pharmaceuticals)
New York, New York
Vice President Clinical Research Worldwide and Medical Director

- Directed clinical programs of all drugs in development with staff of 200+ and a budget of $47 million.
- Implemented and managed worldwide systems for rapid development of Tolrestat and other drugs in diabetes, cardiovascular disease, and HRT.
- Launched major campaign to protect the Inderal franchise against generics.

SmithKline and French laboratories 1980 - 1986
Philadelphia, Pennsylvania
Vice President & Director of Operations R&D Clinical Investigations Worldwide
Group Director R&D Clinical Investigations
Associate Director R&D Clinical Investigations

- Managed Phase I, II, III drug development, IND and NDA submissions, worldwide safety and data network for all clinical trials and protocols.
- Successfully brought an arthritis drug to market.
- Developed and mentored staff who now occupy senior industry positions.

General Medicine and Surgery and OB 1974-1980
Park Rapids, Minnesota
Family Practice

TEACHING APPOINTMENTS

University of Central Florida — 2010 – Present
Orlando, Florida
Adjunct Clinical Faculty

University of Florida Department of Family Medicine — 1998 - 2004
Gainesville, Florida
Adjunct Clinical Associate Professor

University of Minnesota Department of Family Medicine — 1992 - 2005
Minneapolis, Minnesota
Clinical Associate Professor

University of Iowa Physician Assistant Programs — 1993-1999
Iowa City, Iowa
Assistant Professor/Preceptor

Rutgers Biomedical and Health Sciences — 1984-1992
(University of Medicine and Dentistry of New Jersey)
Department of Family Medicine
Camden, New Jersey
Clinical Associate Professor

Cooper Medical Center Department of Family Medicine — 1981-1992
Camden, New Jersey

University of Minnesota School of Nursing — 1977-1979
Minneapolis, Minnesota

PATENTS AND PATENT APPLICATIONS

Accelis	Compositions and Methods for Weight-loss and Weight-loss maintenance
Adistat	Composition and method for weight loss
Adistat	Composition and method for weight loss
Allergy HP	Homeopathic Composition for Alleviating Allergy Symptoms
Allergy MD	Composition and Method for Reducing Inflammation
Anthocyanins	Nutritional Composition for Increasing Muscle Mass and Strength, Improving Athletic Performance and/or Recovery, and/or Reducing Body fat in an Individual
Aplodan H Blocker	Nutritional Composition for Promoting Muscle Performance and Acting as a Hydrogen (H+) Blocker
BUGBITE MD	Oral composition for warding off insects
Caplet with holes	Solid Oral Dosage Form with Increased Surface Area
Capsule Shell	Capsule Shell with Incorporated Active Agent
CEE-Pro	Supplemental dietary Composition for Increasing Muscle Size, Strength, Athletic Performance and/or Exercise Capacity
Cell Tech RTD	Dietary Supplment Having Improved Efficacy at Time of Consumption
CellTech Hardcore	Nutritional Composition and Method for Increasing Creatine Uptake and Retention in Skeletal Muscle, Increasing Muscle Mass and Strength, Increasing Exercise Capacity and for Aiding Recovery Following Exercise.

Cholesterol MD	Composition for improving blood cholesterol levels
Cirsimarin	Cirsimarin for lipolytic pathway signaling support
Cold HP	Composition for Treatment of Colds and Associated Symptoms
Creatine Hydroxycitric Acid AKA Tricreatine HCA	Creatine Hydroxycitric Acid Salts and Methods for Their Production and Use in Individuals
Creatinol Aplodan	Composition and Method for Increasing Lean Muscle Mass, Decreasing Muscle Loss, Increasing Muscle Strength and Improving Athletic Performance
Creatinol Fatty Acid Ester	Creatinol Fatty acid ester
Cylaris	Diet Supplement for Causing Weight Loss
Diet Effervescent	Method for enhancing delivery and uniformity of concentration of dietary ingredients
Everslim	Supplemental Dietary Compositions for Causing Rapid Weight Loss, Improving Day-Time Energy, Promoting Night-Time Relaxation and Sleep, Controlling Appetite , and/or Increasing Metabolism
GAKIC Improve	Supplemental Dietary Composition for Enhancing Muscle Performance and/or Recovery from Fatigue
Gelcap Beads OTC	Particles in a capsule
Geranylgeranylacetone & Glutamine	Compositions and methods for enhancing protein accretion in skeletal muscle
Germ MD Immune	Composition for Improving Immune System Health
Germ MD Vitamin C	Composition for Enhancing Immunity and Reducing Inflammation Related to Infections

GLUT4	Nutritional Composition for Enhancing Skeletal Muscle Mass, Increasing Muscle Fatigue Resistance and Recovery, Augmenting Muscle Glycogen Deposition Rate, Preventing Skeletal Muscle Protein Catabolism and/or Reducing Muscle Soreness and Inflammation
Hammerhead	Supplemental Dietary Composition Including Caffeine, Taurine and Ginseng Supplemental Dietary Composition Including Caffeine, Taurine And Antioxidant
Hydroxycut	Nutritional Composition Which Promotes Weight Loss, Burns Calories, Increases Thermogenesis, Supports Energy Metabolism and/or Suppresses Appetite
Hydroxycut Hardcore	Compositions and Methods for Increasing Adipose Metabolism or Lipolysis or Lipolytic Metabolism via Thermogenesis
Improved ALA	Alpha Lipoic Acid Based Food Supplement for Increasing Lean Muscle Mass and Strength
Inositol & Theanine	Composition and methods for reducing stress
Insulinogen (NitroTech Hardcore)	Composition and Method for enhancing or promoting the activity of insulin, enhancing skeletal muscle growth, reducing skeletal muscle loss, and increasing the energy supply to skeletal muscle
Joint MD	Compositions and Methods for the Alleviating Joint Pain and Improving Joint Flexibility
Leanbalance	Supplemental Dietary Compositions for Promoting Weight Loss
Leukic	Supplemental Dietary Composition for Turning on Anabolic Switches in Muscle, Stimulating and/or Optimizing Protein Synthesis, and/or Potently Signaling Muscle Building and/or Growth

Melatonin	Composition for Increasing Growth Hormone, Muscle Development, Fat Loss, Protein Synthesis IGF-I and Improving Exercise Performance and Recovery
Melatonin	Method of Increasing Growth Hormone Secretion
Musclebuilding Kit	Kit Comprising Three Independent Compositions and Methods for Building Muscle, Increasing Strength, Increasing Muscle Size and Increasing Muscle Performance and Reducing Muscle Fatigue
Nano Experiments - Amino Acids	Fast Dissolution Amino Acid Composition
NanoDiffuse	Compositions and method for increasing bioavailability of compositions for performance improvement.
NanoDiffuse	Method for Increasing the Rate and Consistency of Bioavailability of Supplemental Dietary Ingredients
NanoDiffuse Multi-Phase	Method for a Supplemental Dietary Composition Having a Multi-Phase Dissolution Profile
NanoSlim	Fat β-oxidation Enhancing and Carbohydrate Absorption Inhibition Supplement
NanoSlim	Fat β-oxidation Enhancing and Carbohydrate Absorption Inhibition Supplement
naNOvaopr Nitric Oxide	Composition for improving blood flow in working muscles
naNOvaopr Nootropic	Composition for promoting cognitive attributes
naNOvaopr Sensory-Stimulating Effect	Method for producing a sensory stimulating effect
naNovapor Thermo	Composition and method for supporting thermogenesis and lipid oxidation
NanoX9	Rapidly Dissolving Solid Oral Dosage Form for Delivery of Composition for Increasing Nitric Oxide Activity

No Fast Loss - GBB + Cissus	Composition and Method for Increasing The Metabolism of Free Fatty Acids and Facilitating a Favouravle Blood Lipid Profile
No Fast Loss - GBB + Cissus	Composition and Method for Increasing The Metabolism of Free Fatty Acids and Facilitating a Favouravle Blood Lipid Profile
No Fast Loss GBB + Green Tea	Composition and Method for Inducing Lipolysis and Increasing The Metabolism of Free Fatty Acids
No Fast Loss GBB + Green Tea	Composition and Method for Inducing Lipolysis and Increasing The Metabolism of Free Fatty Acids
Orlistat	Composition and Methods for Weight Loss in a Mammal
ProCho	Compositions and Methods for Activating Protein Synthesis and Deactivating Catabolic Processes in Skeletal Muscle
	Optimization of Whole Body Creatine Retention in Healthy Human Subjects
Pump-Tech	Nutritional Composition for Enhancing Lean Muscle Stimulus, Growth, Strength and Recovery, Creating and Prolonging Muscle Pumps, Supporting Endurance, Strength, Performance, Size and Stamina, Providing a Transducer Effect for Nitric Oxide, Increasing Nutrient Delivery and or Promoting Increased Vascular Response in an Individual
	NUTRITIONAL COMPOSITION FOR FACILITATING MUSCLE PUMPS
	Nutritional Composition for Promoting Lean Muscle Mass - Pump/Nitroxy3/Six Stat NO
Red Wine	Compositions and Methods for Increasing Muscle Mass and Strength. Improving Athletic Performance, and or Reducing Body Fat Mass
Resveratrol MD	Resveratrol Containing Compositions for General Health and Vitality

Satellite Cell	Composition for Promoting the Maintenance and Function of Muscle-Spcific Progenitor Cells
Six Star Protein	Supplemental Dietary Composition for Supporting Muscle Growth, Recovery and Strength
Sleep MD	Compositions and Methods for the Induction and Maintenance of Quality Sleep
SleepGel	Melatonin-based Composition for Improved Sleep
SmartBurn	Supplemental Dietary Compositions for Causing Rapid Weight Loss, Controlling Appetite, Managing Stress, Supporting Relaxation, Combating Fatigue and or Supporting Mental Well-Being
	Diet supplement comprising Hoodia Gordonii for weight loss and mental well-being
Thermogain	Nutritional Composition for Increasing Creatine Uptake in Skeletal Muscle
ThermoShred	Compositions and Methods for Increasing Metabolism, Thermogenesis and/or Muscular Definition
TriSleep Calm	Composition for a Feeling of Calmness
TriSleep Relaxing	Composition for a Feeling of Relaxation
TriSleep Sleep	Composition for Supporting Restful Sleep
Trometamol ALA	Method for Improving the Oral Administration of Alpha-Lipoic Acid
VivaBody	Supplemental Dietary Composition for Burning Additional Calories, Providing sustained Energy, Supporting Weight Loss, and/or Improving Mental Focus

HONORS AND AWARDS

Fellow of the American Academy of Family Physicians
1981-present

Diplomat American Board of Family Physicians
1976
Re-certified 1983
Re-certified 1994
Re-certified 2001

AMA Physicians Recognition Award
1976, 1979, 1982, 1983, 1984, 1987, 1990, 1992, 1993, 1994, 1997, 2000, 2003, 2010

University of Minnesota Residency Teaching Award
1977, 1979, 1980, 1993, 1994

Graduated Cum Laude with Honors
Mankato State University 1969

Marquis Who's Who in the US
1998, 2000, 2001, 2003, 2006

Marquis Who's Who in Science and Engineering
1992-1993, 1993-1994, 1995-1997, 2000

Marquis Who's Who of Emerging Leaders in America
1993-1994, 1994-1995, 2000, 2003, 2006

ASSOCIATIONS

Academy of Pharmaceutical Physicians and Investigators
American Academy of Family Physicians
American Association for the Advancement of Science
American Society Clinical Pharmacology Therapeutics
Arizona Medical Board
Association of Clinical Research Professionals
Canadian Health Food Association
Council for Responsible Nutrition
Drug Information Association

Florida Department of Health
International Bone & Mineral Society
ISSN - International society of sports Nutrition
Medical Board of California
Minnesota Board of Medical Practice
National Strength and Conditioning Association
Natural Products Association
North American Menopause Society
Pennsylvania State Board of Medicine
Proliant Scientific Advisory Board

ADMINISTRATIVE SERVICES

International Olympic Committee (IOC) Federation International Gymnastics (FIG) Associate Physician Member Bahamas Delegation	2003 to Present
Medical Director Fertility Services Clear Passage Physical Therapy Gainesville, FL	1999 to present
Pharmacy Committee Nature Coast Regional Hospital Williston, FL	2001 to 2006
Clinical Associate Professor University of Minnesota Medical School Minneapolis, MN	1992 to 2005
Mankato State University Biotechnology Advisory Council Mankato, MN	1986 to present
Member, HealthSpan Integrated Provider Steering Committee LifeSpan/Health One Provider Network Minneapolis, MN	1992 to 1997

Minnesota State Board of Medical Examiners — 1995 to 1997
Physician Assistant Advisory Committee
St. Paul, MN

Minnesota Medical Association — 1992 to 1997
Drug Utilization Review Board
Minneapolis, MN

Minnesota Academy of Family Physicians — 1993 to 1995
Practice Research Steering Committee
PRN Monthly Newsletter
St. Paul, MN

Chair Education & Research Committee — 1994
United Hospital
St. Paul, MN

Chair Pharmacy and Therapeutics Committee — 1995
United Hospital
St. Paul, MN

Member Executive Committee — 1994 to 1995
United Hospital
St. Paul, MN

Member IPN Finance Committee — 1993 to 1997
Allina IPN
Minneapolis, MN

Medical Alley — 1994 to 1997
Committee on Research
Minneapolis, MN

Clinical Associate Professor — 1983 to1992
University of Medicine and Dentistry
Camden, NJ

Mayo Medical School — 1977 to 1983, 1997 to present
Curriculum Advisor
Rochester, NY

Minnesota Academy of Family Physicians Credentials Committee — 1977 to 1996

Minnesota Academy of Family Physicians Delegate — 1977 to 1980, 1995

President – Elect Upper Mississippi Medical Association	1978, 1980
St. Joseph's Hospital Park Rapids, Minnesota	
Chief of Staff	1979 to 1980
Chief of Obstetrics	1975 to 1980
Chief of Pediatrics	1976 to 1980
Joint Commission Committee	1977 to 1980

COMMUNITY SERVICES

Harn Museum Committee University of Florida Gainesville, FL	1998 to 2003
Chamber Orchestra Committee Gainesville, FL	1998 to 2003
Gainesville Area Innovation Network Gainesville, FL	2000 to 2003
Finance Committee Incarnation Lutheran Church St. Paul, MN	1993 to 1997
Property Committee Incarnation Lutheran Church St. Paul, MN	1992 to 1997
Youth Committee Incarnation Lutheran Church St. Paul, MN	1992 to 1997
Trustee Committee St. Matthews Lutheran Church Morrestown, NJ	1983 to 1992
Pulpit Committee St. Matthews Lutheran Church Moorestown, NJ	1983 to 1985

Church Council St. Matthews Lutheran Church Morrestown, NJ	1981 to 1985
Youth Advisor (Junior and Senior High) St. Matthews Lutheran Church Moorestown, NJ	1981 to 1985
Member, Advisory Board Wadena Vo-Tech Institute Medic and Paramedic Training Park Rapids, MN	1977 to 1980
City Health Officer Park Rapids, MN	1978 to 1980
City Health Officer Nevis, MN	1977 to 1980
Deputy Country Coroner Hubbard County, MN	1977 to 1980
Civil Air Patrol Advisor Hubbard County, MN	1977 to 1980
Parents Prenatal Classes Instructor Hubbard County, MN	1976 to 1980
Hubbard County Emergency Service Advisor Hubbard County, MN	1977 to 1980
Hubbard County Law Enforcement Committee Hubbard County, Minnesota	1977 to 1980

MEDICAL LICENSURE

Florida	ME 72101
Arizona	13070
California	G-46189
Minnesota	021412-6
NRCME DOT	6151028149

GRADUATE TRAINING

St. John's Hospital ▪ St. Paul, Minnesota ▪ Internship 1974

CERTIFICATION

American Board of Family Practice 1976 Re-certified

BIBLIOGRAPHY

Wurn, B., Wurn, L., King, R., Heuer, M., Roscow, A., Scharf, E., Shuster, J. "Treating Female Infertility and Improving IVF Pregnancy With a Manual Physical Therapy Technique". Medscape 6/18/04

Heuer, M., Scharf. E., Cometa, A., "A Review of Worldwide Experience with IV Immune Globulin Archives of Internal Medicine". Submitted for Publication (2001).

Scharf, E., Wurn, L., Heuer, M., "Clinical Infertility Reversal Using Massage Therapy". Submitted for Publication. (2001).

Heuer, M., Pietrusko, R., Morris, R., Scheffler, B., "An Analysis of Worldwide Safety Experience with Auranofin", The Journal of Rheumatology 12:4 (1985), pp. 474-503

Heuer, M., Morris, R., "SmithKline and French Worldwide Clinical Experience with Auranofin: A Review: Excerota Medica of Amsterdam, Excerpta" , Medica (1983)

Flagg, A., Stokes, A., Pietrusko, R. Heuer, M., Blodgett, R. "Infrequent Occurrence of Thromocytopenia During Auranofin Internal Therapy" (Accepted for Publication Archives of Medicine)

PRN Practice Research Network, Research Newsletter of MAFP Steering and Editorial Committee 1993 to Present

Heuer, M., Auranofin, Early Clinical Experience, "Bioinorganic Chemistry of Gold Coordination Compounds", (1983) – Symposium Proceeding

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ABSTRACTS

Wurn, L., Heuer, M., Massage Therapy for Infertility. Journal of American Medical Society. (2001)

Heuer, M.A. Intravenous Immunoglobulin Therapy: Review of Clinical Applications, Efficacy and Safety. Clin Sci International, Inc. Gainesville, Fl. (2001)

Heuer, M., Wright, C. Trough Serum Levels of Estradiol, Estrone, and FSH Following Topical Application of ESTRASORB™ in a Phase III Clinical Trial. (2002)

D. Craig Wright, D; Joan Brisker, BS (ASCP); Larry R. Muenz, PhD; Harold Boyenbaum, PhD; Marvin A. Heuer, MD Maria Gutierrez, MD. A Phase I Safety and Pharmacokinetic Study in Estradiol and Testosterone Deficient Postmenopausal Women of MaxANDRASORB™ - A Topical Sustained-Release Testosterone Emulsion. (2001)

Heuer, M., MD; Wright, D.C., MD. A Phase I Pharmacokinetic Study of ESTRASORB™ Lotion, a Topical, Sustained-Release Estradiol Emulsion for Treatment Relief of Postmenopausal Vasomotor Symptoms. (2001)

Heuer, M., MD; Brisker, J.; Micellar Nanoparticles: A New Novel Topical Drug Delivery System for Systemic Delivery of Estradiol and Testosterone. (2001)

Wright, DC, MD; Brisker, J; Heuer, M: The Safety of ESTRASORB™, a New Topical Emulsion Technology for Systemic Delivery of Estradiol. (2001)

Brisker, J; Heuer, M, MD: Clinical Response as an Endpoint in Studies of Estrogen Replacement Therapy in Postmenopausal Women. (2001)

Pietrusko, R., Blodgett, R., Heuer, M., Proteinuria in Gold Treated Rheumatoid Arthritis. Submitted for Publication

Scheffler, B., Pietrusko, R., Heuer, M., Blodgett, R., Safety Profile Auranofin in the Elderly, Submitted for Publication

Scheffler, B., Hurley, J., Heuer, M., X-Ray Evaluation of Erosion Progression in RA: Double-Blind Study of Auranofin vs. Placebo, Submitted for Publication

Pietrusko, R., Shirley, D., Heuer, M., Blodgett, R.: Blood Gold Levels During Chronic Auranofin Therapy. Submitted for Publication.

Schumacher, H, Heuer, M., Blodgett, R., Friedman, R. Effect of IM Gold and Other Disease Modifying Agents for Rheumatoid Arthritis After Treatment Failure on Auranofin. Submitted for Publication.

PRESENTATIONS

BIT Annual World Congress of Nutrition and Health 2013. Sports and Health Nutrition, The Need for Human Clinical Trials.
Dalian, China 2013

Lectures in Research and Medicine General Topics (Arthritis, HRT, Osteoporosis, Hypertension, Erectile Dysfunction, OC, etc.) Women's Health
Gainesville, Florida 1997 to present

Conducting Clinical ResearchCME Allina Health Systems Course Phillips Eye Institute
Minneapolis, Minnesota 1995 - 1997

Clinical Research From Start to Finish CME Allina Health Systems Course
St. Paul, MN 1994

Lectures in Research and Medicine General Topics Allina and Health East and Local Groups
St. Paul, MN 1992 to 1997

Presentations Covering Research and Development and New Drug Approvals SmithKline Beecham Pharmaceuticals
Philadelphia, PA 1990 to 1992

Presentations Covering Development and Research Projects Wallace Laboratories
Cranbury, NJ 1987 to 1989

Multiple Presentations Covering Development Projects Ayerst Laboratories
New York, NY 1984 to 1987

Press Launches for New Ayerst Products (as required) Ayerst Laboratories
New York, NY 1984 to 1987

DIA Labeling Workshop How to Unify Adverse Reaction Listings on Product Labels
Philadelphia, PA January 1986

"The Medical Degree – A Golden Ticket!" Cooper Medical School, University of Medicine and Dentistry of New Jersey
Camden, NJ 1985, 1986, 1987, 1988, 1992

Multiple Presentations Covering Development Projects SmithKline and French Laboratories
Philadelphia, PA 1984

"The Development of New Pharmaceuticals" University of Minnesota, Alumni Meeting
Minneapolis, MN 1984

"Experience with Auranofin Therapy: A Review of Worldwide Date, European Congress of Rheumatology"
Moscow, Russia 1983

"Safety Profile of Auranofin in the Elderly" Western Regional American Rheumatism Association
Tucson, AZ 1983

"X-Ray Evaluation of Erosion Progression in RA: Double-Blind Study of Auranofin vs. Placebo"
Philadelphia, Pennsylvania 1983

"Auranofin – Worldwide Safety Review"
Portugal 1983

"The Clinical and Safety Profile of Auranofin"
Singapore, Thailand, Malaysia 1983

"Auranofin, Early Clinical Experience"
Philadelphia, PA 1982

FUNDED RESEARCH SUPPORT

1. AstraZeneca (Protocol D5896C00027) "A 26 week, randomized, double-blind, parallel-group, active controlled, multicenter, multinational safety study evaluating the risk of serious asthma-related events during treatment with Symbicort®, a fixed combination of inhaled corticosteroid (ICS) (budesonide) and a long acting β2-agonist (LABA) (formoterol) as compared to treatment with ICS (budesonide) alone in adult and adolescent (≥12 years of age) patients with asthma."

2. AstraZeneca (Protocol D3250C00017) "A 62 week, Randomized, Double-blind, Parallel Group, Placebo-controlled, multicenter, multinational, Phase III Efficacy and Safety Study of Benralizumab (MEDI-563) Added to High-dose Inhaled Corticosteroid Plus Long-acting β2 Agonist in Patients with Uncontrolled Asthma."

3. SmithKline Beecham, 1981-1984
   Diagnostic Bioequivalence Studies and Reformation
   Monoacid Injectable Antibiotic Development Protocols
   Paxil Antidepressant Studies UK and US
   Obsessive Compulsive Studies US
   Relafen Full Development Plan and All Protocols
   RA and OA; Pain
   Pharmacokinetic Studies
   Ridawra – OA and RA Study Program
   Topical Use Eczema Program
   Tagamet – Ulcer Peptic and Gastric Studies
   Various Ophthalmologics Topical – Antibiotics, Steroids

4. Ayerst Laboratories, 1982-1986
   Altromid-S Protocols
   Inderal – Product Line Extension Hypertension
   Effexor – Antidepressant Study Program
   Lodine Development RA, OA Protocols
   PremPro Development Plan and Protocols
   Premarin Osteoporosis Program Development
   Prem Phase Development Plan and Protocols
   Various Oral Contraceptive Studies

5. Wallace Laboratories, 1987-1990
   Felbamate Development Program for Lennox Gasteau Syndrome, Seizures Organidin Reformulation Studies – cough / cold

6. SmithKline Beecham, 1990-1991
   Paxil, Carvedelol, Asthma, Arthritis

7. Scherrng Laboratories, 1981-1982
   Topical and Transdermal Delivery Systems

8. Upjohn Laboratories, 1981-1983
   Depression, Hypertension

9. Nautilus, Inc. 1982-1990
   Exercise Physiology and Osteoporosis

10. Ayerst Laboratories 1982
    Premarin, GNRH

11. FL Dept. of Health & Rehabilitative Services I, 1983

12. FL Dept. of Health & Rehabilitative Services II, 1983-1984

13. Bruner Foundation, 1983-1985

14. Schering Laboratories, 1983-1984

15. Ciba-Geigy, 1983-1984
    Opthalmologics, Antihypertensives

16. Ayerst Laboratories, 1985

17. Wyeth Laboratories, 1985

18. Nuclear Data, 1985-1986

19. Lederle Laboratories, 1986

20. Florida Department of Health and Rehabilitative Services III, 1986

21. Abbott Laboratories, 1986

22. Ayerst Laboratories, 1987

23. NIH (Co-Investigator with Dan Martin, Ph.D.) Walking and Bone Mass, 1988-1990

24. Ayerst Estrogen, Exercise and Lipid Study, 1988-1990

25. Reid-Rowell Estratab and Estratest and Effects on Lipids and Bone Mass, 1988-1990

26. Bartor Estrapel and Effects of Estradiol Production Levels, 1989

27. Columbia Laboratories, Inc. Vaginal Moisturizing Gel Study, 1989

28. Organon, Inc. Desogestrel O.C. CTR-04 Study, 1990

29. Health & Sciences Research, Inc. Noven Patch Study , 1990

30. 3M/Bio –Pharm Estradiol Patch Study, 1990

31. Wyeth-Ayerst Laboratories: Trigonitis, 1992

32. Miles, Inc.: Clotrimazole 2% Vaginal Cream, 1993

RESEARCH EXPERIENCE

Asthma

AstraZeneca (Protocol D3250C00021) A Multicentre, Randomized, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-actingβ2 Agonist. 2015

AstraZeneca (Protocol D2210C00008) A 52-Week, Multicentre, Randomized, Double-Blind, Parallel Group, Placebo Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Tralokinumab in Adults and Adolescents with Asthma Inadequately Controlled on Inhaled Corticosteroid Plus Long-Acting β2-Agonist. 2015

COPD

AstraZeneca (Protocol D3251C00003) A randomised, double-blind, placebo-controlled, parallel group, multicentre, phase III study to evaluate the efficacy and safety of 2 doses of benralizumab (MEDI-563) in patients with severe to very severe Chronic Obstructive Pulmonary Disease (COPD) with a history of COPD exacerbations. 2014

Type 2 Diabetes & Hypertension

Johnson and Johnson (Study #28431754DIA4002) A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Blood Pressure Reduction With Ambulatory Blood Pressure Monitoring (ABPM), Safety, and Tolerability of Canagliflozin in the Treatment of Subjects with Hypertension and Type 2 Diabetes Mellitus. 2014

Cardiovascular

AstraZeneca (Protocol D513BC00001) Multinational, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor 90 mg twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus. 2014

Ankle Strain / Sprain

Kowa (Protocol K-103-IP-3.01US) Randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of K-103-IP compared with placebo for the treatment of mild to moderate acute pain associated with ankle strain or sprain. 2014

Asthma

AstraZeneca (Protocol D3250C00016) "A 62 week, Randomized, Double-blind, Parallel Group, Placebo-controlled, multicenter, multinational, Phase III Efficacy and Safety Study of Benralizumab (MEDI-563) Added to Medium-dose Inhaled Corticosteroid Plus Long-acting β2 Agonist in Patients with Uncontrolled Asthma." 2014

AstraZeneca (Protocol D3250C00017) "A 62 week, Randomized, Double-blind, Parallel Group, Placebo-controlled, multicenter, multinational, Phase III Efficacy and Safety Study of Benralizumab (MEDI-563) Added to High-dose Inhaled Corticosteroid Plus Long-acting β2 Agonist in Patients with Uncontrolled Asthma." 2013

AstraZeneca (Protocol D5896C00027) "A 26 week, randomized, double-blind, parallel-group, active controlled, multicenter, multinational safety study evaluating the risk of serious asthma-related events during treatment with Symbicort®, a fixed combination of inhaled corticosteroid (ICS) (budesonide) and a long acting β_2-agonist (LABA) (formoterol) as compared to treatment with ICS (budesonide) alone in adult and adolescent (≥12 years of age) patients with asthma." 2013

Hormone Replacement Therapy

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994

Kabi Pharmacia: Comparison of a Continuous Low Dose of Estradiol Released From a Vaginal Ring vs. Conjugated Equine Estrogen in a Vaginal Cream in the Treatment of Postmenopausal Women with Signs and Symptoms of Urogenital Atrophy, 1992.

Zeneca Pharmaceuticals Group: Comparison of 3.6 mg ZOLADEX therapy with or without hormone replacement therapy for the treatment of endometriosis, 1992.

Novo Nordisk Pharmaceuticals, Inc.: Evaluation of Estrofem® 0.25, 0.5, 1.0, and 2.0 mg on relief of vasomotor and other symptoms of the menopause, 1993.

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterified Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Solvay Pharmaceuticals, Inc.: Study of the Effects of Estratest H.S.®,

Estratest®, and Premarin® in Surgically Menopausal women, 1992.
Solvay Pharmaceuticals, Inc.: Study of Estrafied Estrogens Plus Methyltesterone (Estratest®) and Esterified Estrogens (Estratab® 1.25 mg) in Surgically Postmenopausal Women: Symptoms, Psychometric Assessments, Serum and Saliva Hormone Levels, 1993.

ClinTrials Research Inc./TheraTech, Inc.: Comparison of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) with Placebo Matrix Transdermal Delivery System I the Treatment of women with Postmenopausal Symptom, 1994.

Novo Nordisk Pharmaceuticals, Inc. (Protocol VAG/PD/9/USA) “A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Multicenter Study Comparing the Efficacy and safety of Vagifem 10 μg and 25 μg doses in Treatment of Estrogen Deficiency Derived Atrophic Vaginitis.”

Ostex International, Inc. (Protocol OST-C2) :A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women”

ClinTrials Research, Inc. TheraTech, Inc. (Protocol E94001A) “An Open-Label, Multicenter Extension of Protocol No. E94001 to Describe the Use of Two Doses of an Estradiol Matrix Transdermal Delivery System (EMTDS) in the Treatment of Women with Postmenopausal Symptoms.”

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/PD/7/USA) "A Double-Blind, Randomized, Parallel Group, Multicenter, Dose Finding Study Comparing the Efficacy and Safety of 1 mg 17β-Estradiol in Combination With Low Doses of Norethindrone Acetate with that of 1 mg 17β-Estradiol Alone on the Endometrium in Postmenopausal Women."

Rhone-Poulace Rorer (Protocol RPR 106522-303) "A Randomized, Double-Blind, Multicenter, Placebo-Controlled, Menopausal Symptom study of Three Doses of RPR Estradiol Norethisterone Acetate (NETA) Patches in a Sequential Wear Hormone Replacement Therapy (HRT) Regimen."

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis."

The Upjohn Company (Protocol M5410/0336) "Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving (OGEN/PROVERA) Hormone Replacement Therapy (HRT)."

Eli Lilly & Company (Protocol H3S-MC-GGHG) "Comparison of Raloxifene HCl, Estrogen and Placebo on the Uterus in Healthy Postmenopausal Women."

R.W. Johnson PRI (Protocol ESTNRG-CHRT-102) "A Multicenter, Randomized, Double-Blind, Parallel Group, Dose-Ranging Study to Evaluate the Safety of a CYCLOPHASIC Hormone Replacement Therapy Regimen of Estradiol and Norgestimate and its Effects on Endometrial Histology, Vaginal Bleeding and Metabolic Parameters in Postmenopausal Women."

R.W. Johnson (Protocol ESTNRG-CHRT-104) "A Multicenter, Double-Blind, Randomized Parallel Group, Placebo Controlled Study to Evaluate the Safety and Efficacy of Oral 17β-Estradiol for the Treatment of Vasomotor Symptoms and Genital Atrophy in Postmenopausal Women."

Eli Lilly & Company (Protocol H3S-MC-GGHD) "Comparison of Raloxifene HCL, Continuous Combined Hormone Replacement Therapy and Placebo in Early Postmenopausal Women: Once a Week Estradiol-Levonorgestrel Combination Transdermal System (TDS).

Novo Nordisk Pharmaceuticals, Inc. (Protocol KLIM/USA/1/USA) "Bleeding Profile with Continuous0Combined Hormone Replacement Therapy: A Randomized, Double-Blind, Multicenter, Comparative Trial of 1 mg 17B-Estradiol in Combination with 0.25 mg Or 0.5 mg Norethindrone Acetate and Prempro®."

Procter & Gamble Pharmaceuticals (Protocol 1996023) A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging , Multicenter Study Protocol Comparing EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women."

Ethical Pharmaceuticals (UK) Ltd. (Protocol EPCOUS02) "A Clinical Evaluation of the Effects of Estradiol TD and Combi TD, Used Continuously, on Estradiol-Induced Endometrial Hyperplasia."

Berlex Laboratories, Inc. (Protocol 96097) "A Multicenter, Double-Blind, Randomized Comparison of Continuous Oral Estradiol-Drospirnone Combinations and Continuous Oral Estradiol, Examining the Effects on the Endometrium, Symptom, and Bleeding Patterns in Postmenopausal Women."

RW Johnson Pharmaceuticals Research Institute (Protocol ESTRNG-CHRT-106) "A Multicenter, Randomized, Double-Blind Exploratory Study Investigating the Pharmacodynamic Profile of Two Different Hormone Replacement Therapy Regimens: Conjugated Estrogens plus Medroxyprogesterone Acetate vs. Micronized Estradiol plus Cyclophasic Addition of Norgestimate (Cyclophasic HRT) vs. Placebo in Postmenopausal Women."

Procter & Gamble Pharmaceuticals / TheraTech (Protocol 1998049) "A 12-week, Randomized, Parallel Group, Multicenter, Wear Study to Assess skin Tolerance With a 40-Week safety Extension Period

Comparing Three Continuous Dose Regimens (0.1, 0.2, and 0.4 mg/day NETA Combined with 0.05 mg/day Estradiol) Under Condition of Routine Clinical Use."

Wyeth-Ayerst Research (Protocol 0802D1-324-US) "A Randomized, Double-Blind, Placebo and Active-Controlled, Parallel, Multicenter Study to Assess the Safety and Efficacy of 3 ½ Day Combinations of 17β-Estradiol/Norethindrone Acetate Transdermal Delivery Systems for Relief of Menopausal Vasomotor Symptoms and Reduction of Endometrial Hyperplasia."

Oral Contraceptives

Organon, Inc./Pharmaco LSR (Protocol 086-001) "An Open Label, Multicenter, Non-Comparative Safety and Efficacy Study of the Desogestrel Containing Oral Contraceptive CTR 25." Organon, Inc./Pharmaco LSR (Protocol 092-001) "An Open-Label, Randomized, Parallel, Comparative,

Multicenter, Safety and Efficacy Study of Triphasic Combination Oral Contraceptives, CTR 99 and CTR 77, versus Ortho-Novum 777).

Organon, Inc./Quintiles, Inc. (Protocol 069-001) "An Open-Label Noncomparative Efficacy and Safety Study of Implanon, a one-Rod Contraceptive Implant Containing 3-Ketodesogestrel in Healthy Female Volunteers, With subsets For Pharmacokinetic Measurements, Ophthalmological Assessments, Carbohydrate Metabolism, Lipid Metabolism and Endometrial Morphology."

Ortho-McNeil Pharmaceutical (Protocol CAPSS022) "A Comparison of Two Oral Contraceptives: Oral Tri-Cyclen® vs. Loestrin® Fe 1/20."RW Johnson Pharmaceutical Research Institute (Protocol NRGEEP-CONT-004) "An Open-Label Study to Evaluate Contraceptive Efficacy ad Safety of the Transdermal Contraceptive System of 17-Deacetylnorgestimate and Ethinyl Estradiol with the Oral Contraceptive Triphasil."

Organon, Inc. (Protocol 147-001) "A Randomized, Open-Label, Comparative, Multicenter Trial to Evaluate Contraceptive Efficacy, Cycle Control, Safety and Acceptability of a Monophasic COC Containing 200μg EE, Compared to a COC Containing 100μg Levonorgestrel and 20μg EE."

Osteoporosis

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (Protocol RPE 002494) "A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Compare the Efficacy and Safety of Risedronate (NE-58095) plus Estrogen versus Estrogen Only in the Prevention of Bone Mineral Mass and No Vertebral Fractures."

Sterling Winthrop Pharmaceuticals (Protocol SR 41319B-005) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Post-Menopausal Women with Low Bone Mineral Mass and No Vertebral Fractures."

Ostex International, Inc. (Protocol OST-C2) :A Study of the Use of Osteomark in the Quantitation of Cross-Linked N-telopeptides of a Type I Collagen as an Aid in Monitoring the Effect of Therapies Used for the Prevention and Management of Bone Loss in Postmenopausal Women"

Mead Johnson Laboratories: Evaluation of the Effect of the 0.5 mg Estrace Compared to Placebo on Biochemical Markers of Bone Resorption in Postmenopausal Women, 1994

Solvay Pharmaceuticals, Inc.: Investigation of Three Doses of Esterifield Estrogens (Estratab®) on Bone Mineral Density and Parameters of Bone Metabolism in Postmenopausal Women, 1992.

Sterling Winthrop Pharmaceuticals (Protocol SR41319B-004) "A Phase III Study of Intermittent Cyclical Tiludronate in the Treatment of Established Post-Menopausal Osteoporosis."

Organon, Inc. (Protocol 010-006) "A Dose-Finding Efficacy & Safety Study of Tibolone (Org OD 14) for Prevention of Osteoporosis in Postmenopausal Women."

The Upjohn Company (Protocol M5410/0336) "Evaluation of Endometrial Histology and Bone Mineral Density (BMD) in Postmenopausal Women Receiving (OGEN/PROVERA) Hormone Replacement Therapy (HRT)."

Procter & Gamble Pharmaceuticals/G.H. Besselaar Associates (protocol RVN008993) "A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Parallel Group Study to Determine the Efficacy and Safety of Risedronate (NE-58095) in the Treatment of Postmenopausal Women with Established Osteoporosis-Related Vertebral Deformities."

Procter & Gamble Pharmaceuticals / Quintiles Inc. (Protocol RHN009193) "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group study to Determine the Efficacy and Safety of Risedronate in the Treatment of Osteoposoris in Elderly Women."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/15/USA) "A Double-Blind, Randomized Placebo Controlled Trial of Three Doses of Levomeloxifene and Prempro® for the Prevention of Postmenopausal Osteoporosis."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/16/USA) "A Double Blind, Randomized, Multicenter, Placebo-Controlled Trial of 1.25 and 2.5 mg of Levormeloxifene for the Treatment of Postmenopausal Osteoporosis."

Novo Nordisk Pharmaceuticals, Inc. (Protocol LEV/PD/17/USA) "A Double-Blind, Placebo Controlled Trial To Study the Safety and Efficacy of 2.5, 10, and 40 mg of Levormeloxifene for the Prevention of Postmenopausal Bone Loss."

Boehringer Manheim Pharmaceuticals Corporation (Protocol MF4380) "Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate (BM 21.0955)

During Three Years Treatment in Patients with Postmenopausal Osteoporosis Using an Intermittent (every 3 months) I.V. Injection Regimen of 1 mg."

Roche Pharmaceuticals (Protocol MF4492) "Double-Blind, Placebo-Controlled, Randomized, Multicenter Study on the Efficacy and Safety of Ibandronate During an Extended Two Year Partial Crossover Study of Patients Enrolled in MF4380 Using an Intermittent I.V. Injection Regimen of 0.5 mg and 1 mg Every 3 Months."

Eli Lilly & Company (Protocol H3S-MC-GGGK) "Comparison of Raloxifene HCl and Placebo in the Treatment of Postmenopausal Women with Osteoporosis."

Eli Lilly & Company (Protocol H3S-MC-GGHF) "Raloxifene HCl Versus Placebo Versus Hormone Replacement Therapy: Histomorphologic Effects in Bone Loss."

Pfizer, Inc. (Protocol 174-106) "A Randomized, Double-Blind, Placebo Controlled Study of the Effects of Droloxifene 40 mg/d, 60 mg/d, and 80 mg/d on BMD in Osteopenic, Postmenopausal Women."

Procter & Gamble Pharmaceuticals (Protocol 1996023) A Randomized, Double-Blind, Placebo-Controlled 24 Month, Dose Ranging , Multicenter Study Protocol Comparing EMTDS to Placebo in the Prevention of Bone Loss in Hysterectomized Postmenopausal Women."

Pfizer, Inc. (Protocol 174-113) "A Study of the Safety and Efficacy of Droloxifene for Preventing Bone Loss in Normal, Early Postmenopausal Women."

Pfizer, Inc. (Protocol A2181003-5045) "A Study of the Safety and Efficacy of Lasofoxifene for the Prevention of Bone Loss and for Lipid Lowering in Postmenopausal Women at Risk for Osteoporosis."

Overactive Bladder and Urinary Incontinence

Eli Lilly & Company (Protocol H3S-MC-SAAL) "Duloxetine Versus Oxybutnin in Patients with Urge Incontinence: A Multiple-Dose Study for Efficacy and Safety."

Pharmacia & Upjohn Pharmaceuticals (Protocol 97 OATA 039) "Dose Escalation Study with Tolterodine in Patients with Overactive Bladder. A Single-Blind Study in Patients with Symptoms of Overactive Bladder Including Urinary Urgency and Frequency With or Without Urge Incontinence."

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007) "Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder."

Pharmacia & Upjohn Pharmaceuticals (Protocol 98-TOCR-007B) "Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder."

Candidiasis

Bayer Corporation (Protocol S95-003) "A Multicenter, Prospective, Randomized, single-Blind, Parallel-Group Comparison of the Clotrimazole 1-Day (One 500 mg Vaginal Insert) and the Clotrimazole 3-Day Regimens (One 200 mg Vaginal Insert Daily for 3 Days) with Clotrimazole 7-Day

Regimen (One 100 mg Vaginal Insert Daily for 7 Days) for the Treatment of Vulvovaginal Candidiasis."

Advance Care Products, Ortho Pharmaceutical Corporaqtion (Protocol 94-007P) "Phase III Study Comparing Micanzole Nitrate (4%) Vaginal Cream and Mixanozole Nitrate (2.8%) Vaginal Cream to MONISTAT® 7 (2%) Vaginal Cream in the Treatment of Vulvovaginal Candidiasis."

Urinary Tract Infection

Bayer (Protocol 100398) "Prospective, randomized, double-blind, multicenter, comparative trial to evaluate the efficacy and safety of ciprofloxacin once daily extended release 500mg tablets QD for 3 days *versus* conventional ciprofloxacin 250mg tablets BID for 3 days in the treatment of patients with uncomplicated urinary tract infections".

Acute Exacerbation of Chronic Bronchitis

Abbott Laboratories, Inc. (Protocol M97-766) "Comparative Study of the Efficacy of Clarithromycin and Azithromycin for the Treatment of Patients with Acute Exacerbation of Chronic Bronchitis."

Community Acquired Pneumonia

Abbott Laboratories, Inc. (Protocol M98-939) "Comparison of the Safety of Clarithromycin IR (250 mg) BID to Levofloxacin (500 mg OD) for the Treatment of Community-Acquired Pneumonia."

TAP Holdings (Protocol CEF-97-002) "A Comparative Study on the Safety and Efficacy of CefditorenPivoxil and Cefpodoxime Proxetil in the Treatment of Community-Acquired Pneumonia."

Endometriosis

IBAH / Searle Research and Development (Protocol N65-97-02-001) "Clinical Protocol for a Dosing Optimazation Study of Syneral® for Endometriosis: Safety and Efficacy of a Single 400μG Daily Dose for 6 Months and a Step-Down Dose from 200μG BID for 2 Months to 200μG

Daily for 4 Months. A Double-Blind, Placebo-Controlled, Randomized Comparison to the Currently Recommended Regimen of 200μG BID Daily for 6 Months, IND # 18,138."

Hypertension

GD Searle & Company (Protocol IE3-98-02-01) "A Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the safety and Efficacy of Ranging Doses of Eplernone Relative to Placebo, Hydrochlorothiazide and Daily Dose Combinations of Eplernone and Hydrochlorothiazide For the Treatment of Mild to Moderate Hypertension."

ALLHAT National Trial on Hypertension Agents and Heart Disease. 5-year NIH trial

Arthritis

Merck Industries (Protocol 088-001) "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUB's During Chronic Treatment with MK-0966 or Naproxen in Patients with Rheumatoid Arthritis."

GD Searle & Company (Protocol N49-98-02-102) "Clinical Protocol for a Multicenter, Double-Blind, Parallel Group Study Comparing the Incidence of Clinically Significant Upper Gastorintestinal Adverse Events Associated with SC-58635 400 mg BID to That of Diclofenac 75 mg BID in Patients With Osteoarthritis or Rheumatoid Arthritis, IND # 48,395."

Diabetes

Insmed Pharmaceuticals (Protocol INS1-DM-28) "A Randomized, Multicenter, Double-Blind, Parallel-Group Clinical Study to Compare the Effects of INS1 (D-Chiro-Inositol) Versus Placebo as Initial Oral

Therapy in Subjects with Type 2 Diabetes Mellitus Who Fail to Achieve Adequate Glycemic Control with Diet and Exercise Alone."

Bristol-Myers Squibb US Pharmaceuticals (Protocol CV 138-002) "Comparative Outcomes Study of Metformin Invention Versus Conventional Approach: The Cosmic Approach Study."

Lipid Lowering

Pharmacia Corporation (Protocol NB4-00-02-009) "Clinical Protocol for a Randomized, Double-blind, Placebo-controlled Study of SD-5613 as Monotherapy in Patients with Primary Hypercholesterolemia (Monotherapy Assessment of Reducing Cholesterol [MONARCH]), IND #58,482."

Sinusitis

Abbott Laboratories (Protocol M00-225) "Comparative Study of the Safety and Efficacy of ABT-773 150 mg QD vs. 150 mg BID for the Treatment of Acute Bacterial Sinusitis."

Migraine

Wyeth-Ayerst Inderol LA in Chronic Severe Migraine. Inderol LA 160mg vs. Inderol 40mg TID vs. Calcium Channel Blocker.

Glaxo Welcome. Imitrex Injection in the Treatment of Acute Migraine and Cluster Migraine.

Glaxo Welcome. Imitrex Injection vs. Imitrex Tablets in Chronic Severe Migraine.