



DR. IRA J. GOTTLIEB
CURRICULUM VITAE

General Information

Place of Birth: Washington, D.C.
Date of Birth: August 29, 1959

Education

1977-1981	B.S. Microbiology	University of Maryland College Park, Maryland
1981-1985	Doctor of Podiatric Medicine	Pennsylvania College of Podiatric Medicine Philadelphia, Pennsylvania
1986-1987	Surgical Resident	Lutheran Hospital Baltimore, Maryland

Certifications

1990	Fellow, American College of Foot and Ankle Surgeons
1990	Diplomate, American Board of Podiatric Surgeons
1988	Associate, American Academy of Podiatric Sports Medicine

Practice Experience

1987-present	Chesapeake Foot and Ankle Centers, PA Private group practice with two locations in Maryland: <ul style="list-style-type: none">- The Horizons - Anne Arundel County, Pasadena- Mercy Medical Center - Baltimore City
1993-present	Chesapeake Ambulatory Surgery Center, LLC Office based ASC specializing in surgery of the foot and ankle. Clinical Research based on surgical models of the foot and ankle.
1999-2003	Scirex Corporation Clinical Trial Site Principal Investigator/Sub Investigator
2004-present	Chesapeake Research Group, LLC Medical Director/ Principal Investigator/Sub Investigator

Clinical research specializing in the following areas:

- Acute Pain Services (Bunionectomy correction, hammertoe correction and other surgical procedures of the foot and ankle).
- Chronic Pain Services (Neuropathic and OA pain)
- Skin and Skin Structure Infections (Fungal and bacterial infections, wound healing, Diabetic ulcers)
- Device trials- Prosthetic and implantable devices

Honors

2002 Maryland Podiatric Medical Association - **“Maryland Podiatrist of the Year Award”**

Clinical Research Experience

**** QRx Pharma Q8003-022 (2011)**

A Randomized, Double-Blind, Multicenter, Repeat-Dose Comparison of the Effects of Q8003 to the Morphine-Equivalent Doses of Oxycodone and of Morphine on the Opioid-Related Adverse Events of Moderate to Severe Nausea, Emesis, and Dizziness in Subjects with Acute Moderate-to-Severe Postoperative Pain Following Bunionectomy

**** Keraderm KD-PV01 (2010)**

A multi-Center, Randomized, Double-Blinded, Pivotal Study of the Safety, Local Tolerability and Efficacy of XXX for the Treatment of Onychomycosis

Johnson & Johnson PRD R331333-PAI-3027 (2010)

A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety and Tolerability of (the study drug) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy

Eli Lilly F1J-US-HMGL (2009)

A Randomized, Placebo-Controlled Trial of (the study drug) added to Nonsteroidal Anti-Inflammatory Drugs in Patients with Knee Pain due to Osteoarthritis who have Suboptimal Response to Nonsteroidal Anti-inflammatory Drug Treatment

**** Abbott Nutrition BK15 (2009)**

Evaluation of a Medical Food for Chronic Wounds

**** QRx Pharma Q8003-008 (2009)**

A Randomized, Double-Blind, Multicenter, Repeat-dose Comparison of Analgesic Efficacy and Safety of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery

**** QRx Pharma Q8003-021 (2009)**

A Double-Blind, Randomized, Multi-Center, Repeat Dose, Comparison of the Analgesic Efficacy and Safety of the (the study drug) to each of the Individual Milligram Components (Oxycodone and Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery

Abbott Laboratories M10-277 (2009)

A Phase 3, Open-Label Period Followed by a Randomize, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

**** Javelin Pharmaceuticals DFC-005 (2008)**

A randomized, double-blind, active- and placebo-controlled study of the analgesic efficacy and safety of repeated dosing of DIC075V relative to parenteral ketorolac and placebo in patients with acute moderate to severe post-surgical pain following mixed elective general orthopedic surgery

**** Innocoll Technologies INN-TOP-002 (2008)**

A Phase II, Randomized, Parallel, Double-blind, Placebo-controlled Study to Assess Prevention of Infection Using (the study drug) in Diabetic Patients with Uninfected Lower Extremity Skin Ulcers

**** Innocoll Technologies INN-TOP-001 (2008)**

A Randomized, Controlled, Open-Label Study to Investigate the Safety and Efficacy of (the study drug) Compared to Levofloxacin in Diabetic Patients with a Mild Infection of a lower Extremity Skin Ulcer

**** Abbott Laboratories M10-421 (2008)**

A Randomized, Multicenter, double-blind Study comparing the Analgesic Efficacy and Safety of (the study drug) to Placebo in Subjects with Acute Pain Following Bunionectomy

**** Hisamitsu Pharmaceuticals HKT-500-US10 (2008)**

A Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of HKT-500 in the Treatment of Pain Associated with Grade I or Grade II Ankle Sprain

Abbott Laboratories/Skye Pharma SKY2028-1-003 (2008)

A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel Group, 6-Week Study to Evaluate the Effect of Multiple Doses of (the study drug) twice daily, Prednisone and Placebo on the Hypothalamic-Pituitary-Adrenal Axis in Adult Subjects with Mild to Moderate Asthma

**** Javelin Pharmaceuticals KET-017 (2008)**

A randomized, multiple-center, double-blind, placebo-controlled study of the safety and analgesic efficacy of repeated dosing of PMI-150 to treat acute post-operative pain following orthopedic trauma, injury or surgery

**** Johnson & Johnson PRD R331333PAI3018 (2008)**

A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of (the study drug) in the Treatment of Acute Pain From Bunionectomy

**** QRx Pharma Q8003-010 (2007)**

A Double-Blind, Multi-Center Extension Study to Evaluate the Safety and Efficacy of Q8003 in Patients with Acute Moderate to Severe Pain

**** QRx Pharma Q8003-007 (2007-2008)**

A Placebo-Controlled, Randomized, Double-Blind Study of the Safety and Efficacy of Q8003 in the Management of Post-Bunionectomy Pain

ABBO2814 M06-850 (2007-2008)

A Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of ABT-894, Duloxetine and Placebo in Subjects with Diabetic Neuropathic Pain

**** Grunenthal KF5503/37 (2007)**

A Phase 3, Randomized, Double-Blind, Parallel-Group, Multi-Center, Active- and Placebo-Controlled Trial to Evaluate the Analgesic Efficacy and Safety of Multiple Doses of (the study drug) for Postoperative Pain Following Bunionectomy

**** Hospira, Inc 2005-005 (2007)**

A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of (the study drug) for Sedation During Monitored Anesthesia Care

**** Hospira, Inc 2005-008 (2007)**

A Randomized, Phase 2, Double-blind, Parallel Group, Multicenter Lockout Determination Study of Hydromorphone Hydrochloride Administered by a Patient Controlled Analgesia (PCA) Pump for the Treatment of Post-Operative Pain Following Elective Bunionectomy Surgery

ABBO2814 M04-697 (2007)

A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of (the study drug) to Placebo in Subjects With Osteoarthritis

Eli Lilly H7U-MC-IDAW (2006)

A Phase 3, Open-Label, Parallel Group Treatment Concordance Study to Compare Insulin Use and Its Effect on Glycemic Control in Patients with Type 2 Diabetes Mellitus: Two Populations with Different Insulin Treatment Options

**** Johnson & Johnson PRD R331333PAI3003 (2006)**

A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of (the study drug) Immediate Release Formulation in the Treatment of Acute Pain From Bunionectomy Followed by a Voluntary Open-Label Extension

**** Xanodyne Pharmaceuticals XP21L-301 (2006)**

A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) in Subjects with Pain Following Bunionectomy Surgery.

ABBO2814 M05-790 (2006)

A Phase 3, Open-Label Period Followed by a Randomized, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy and Safety of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

**** Endo Pharmaceuticals EN3269-301 (2006)**

A Randomized, Double Blind, Placebo Controlled Parallel Group Phase III Study of the Efficacy Tolerability and Safety of (study drug) in the Treatment of Pain Associated With Grade 1 or Grade 2 Ankle Sprain or Strain

**** MGI Pharma 3000-0523 (2006)**

A Phase 3 Open-Label, Single Arm Study to Assess the Safety of (study drug) For Minimal-To- Moderate Sedation in Patients Undergoing Minor Surgical Procedures

**** Genentech VGF3554g (2006)**

A Phase II, Double Blind, Randomized, Placebo Controlled Study to Assess the Effect of (study drug) for Induction of Diabetic Foot Ulcers

**** GSK SB767905/014 (2005-06)**

A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase 3 Study to Evaluate the Long-Term Safety of (the study drug) for 12 Months for the Treatment of Opioid-Induced Bowel Dysfunction in Adults taking Opioid Therapy for Persistent Non-Cancer Pain.

Hisamitsu HKT-500-US05 (2005)

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Two-Week Study to Assess the Safety and Efficacy of HKT-500 in Subjects with pain from Moderate Lateral Epicondylitis.

Hisamitsu HKT-500-US06 (2005)

An Open Label Safety Study with Intermittent Use of HKT-500 in Subjects with Lower Back Pain, Pain from Osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain.

ABBO2814 M03-666 (2005)

An Open Label Study Evaluating the Safety and Tolerability of Long Term Administration of (the study drug) in Subjects with Moderate to Severe Chronic Non-Malignant Pain.

**** Guilford Pharmaceuticals, Inc. 3000-0412(2005)**

A Phase III, Randomized, Open Label Study to Assess the Safety and Efficacy of (Study drug) Versus Midazolam HCL for Sedation in Patients Undergoing Minor Surgical Procedures.

**** Anesiva, Inc (formerly AlgoRx Pharmaceuticals, Inc.) 4975-2-003-1(2004-5)**

Randomized, Double-Blind, Placebo-Controlled Dose Ranging Trial of (the study drug) in Subjects Undergoing Bunionectomy with First Metatarsal Osteotomy Surgery.

ABBO2814 M03-643 (2004)

A Randomized, Multi-Center Double-Blind Study Comparing the Analgesic Efficacy of (the study medicine) Extended Release and Placebo in Subjects with Osteoarthritis.

ABBO2814 M03-609 (Nov03-Mar04)

A Randomized, Double-Blind, Placebo-controlled Study Comparing the Analgesic Activity of (the study medicine) Extended Release and Placebo in Subjects with Pain Following Bunionectomy Surgery

SCIR0301 SCIREX 0005 (Sep03)

Clinical Protocol For A Multi-Center, Single Dose, Double-blind, Placebo-Controlled, Randomized, Pilot Study To Investigate the Assay Sensitivity of Single Digit Hammertoe Surgery As A Model For The Study Of Analgesic Drugs In Acute Pain.

**** PHAR2719 (089) PARA-0505-089-P-1 (May03-Jul03)**

Revised Clinical Protocol for a Randomized Multiple Dose Assessment of the Safety of the (study med) Ready to Use (RTU) Formulation Compared to Parecoxib Sodium Lyophilized Preparation in Patients in Pain Following Bunionectomy

PHAR2564 PARA 0505 078 P (Oct02 - Feb 03)

Clinical Protocol for a Randomized, Double-Blind, Placebo Controlled, Multiple Dose Assessment of the Analgesic Efficacy of the Dosing Regimen of (study med name) Compared to Placebo Patients in Pain Following Bunionectomy

**** PHAR 2563 PARA 0505 077 P (Oct 02 - Jan 03)**

Clinical Protocol for a Multiple Dose Randomized, Double-Blind, Placebo Controlled Study of the Analgesic Efficacy and Safety of (study med name) Compared to Placebo in Patients for Treatment of Post-Surgical Pain from Bunionectomy Surgery

**** KF0151Y/03 (01-02)**

A Randomized, Double-Blind, Parallel-Group Study Assessing the Analgesic Efficacy and Safety of Four Dose Levels of GRT0151Y (50 mg, 100 mg, 150 mg and 200 mg) compared to Ibuprofen 400 mg, Morphine 60 mg and Placebo in Patients with acute Pain Following Orthopedic Surgery (Bunionectomy).

Merck 052-00 (2001)

A randomized double-blind, Placebo and active comparator controlled parallel group multi-center study of study medication and naprelan in the treatment of post-bunionectomy surgery pain

**** KF5503-05 (2001)**

A Randomized, Double-Blind, Parallel-Group, Dose-Ranging Study Assessing the Analgesic Efficacy and Safety of Five Dose Levels of CG5503 (25 mg, 50 mg, 75mg, 100 mg, and 200 mg) compared to Morphine 60mg, Ibuprofen 400 mg, and Placebo in patients following Orthopedic Surgery (Bunionectomy).

SKB 14777/277 (2000-2001)

Analgesic Efficacy of Single doses of Investigational Medication (900mg, 1350mg, 1800mg) and Multiple Doses of Investigational Medication (900mg UID or 450 mg BID) Compared with Single and Multiple doses of Naproxen Sodium 500mg or placebo in Patients with Pain from Outpatient Orthopedic surgery (Bunionectomy)

**** SKB 14777/276 (2000)**

Comparative Analgesic Efficacy of Single and Multiple Doses of Investigational Medication (900mg, 1350mg, 1800mg), Naproxen Sodium 550mg or Placebo in Pain Following Outpatient Orthopedic surgery (Bunionectomy)

GD Searle & Co. N91-99-02-072 (1999-2000)

Clinical Protocol for A Double blind Placebo and Active-Controlled Comparison of the Analgesic Activity of Investigational Medication 40mg Oxycodone 10mg/acetaminophen 1000mg (Tylox) and Placebo in Post Bunionectomy Surgical Patients

**** Principal Investigator**

Hospital /Surgical Center Affiliations

North Arundel Hospital
 Mercy Medical Center
 Harbor Hospital Center
 Chesapeake Ambulatory Surgery Center

Appointments

2002-present President, Maryland State Board of Podiatric Medical Examiners
 Appointed by Governor, Robert Ehrlich
 2010-2011 Clinical Associate Professor (Adjunct), Temple University School of Podiatric
 Medicine, Department of Podiatric Surgery
 Appointed by Dean, John A. Mattiacci, D.P.M.

Elected Positions

1994-2002 Executive Board, Maryland Podiatric Medical Association
 Committees- Legislative, Membership and Newsletter
 1998-2002 Peer Review Committee/Podiatrist Recovery Network- Chairman
 1998-2002 Editor, Maryland Memo, The Official Publication of the Maryland
 Podiatric Medical Association.

Advanced Training And Professional Development

June 2008 Poster Presentation “A Single Intra-Operative Administration of
 Adlea™ Decreases Postoperative Pain and Analgesic Use After
 Bunionectomy Surgery^a” AOFAS 24th Annual Summer Meeting-
 Denver, CO

July 2008 Poster Presentation “Safety and Tolerability of Tapentadol
 Immediate Release in Patients With Pain After Bunionectomy”
 2008 Annual Meeting of the American Podiatric Medical Association-
 Honolulu, Hawaii

July 2008 Poster Presentation “Efficacy of Tapentadol Immediate Release
 in Patients With Pain After Bunionectomy” 2008 Annual Meeting of the American
 Podiatric Medical Association-Honolulu, Hawaii

July 2008 Lecture “A Single Intra-Operative Administration of Aldea™
 Decreases Postoperative Pain and Analgesic Use After Bunionectomy
 Surgery^a” 2008 Annual Meeting of the American Podiatric Medical
 Association-Honolulu, Hawaii

October 2008 Poster Presentation “The Efficacy of Diclofenac Potassium Soft Gelatin Capsules for
 Postbunionectomy Pain” 2009 American Academy of Pain Management Meeting-
 Phoenix, Arizona

October 2008 Poster Presentation “Diclofenac Potassium Soft Gelatin Capsules Reduce
 Postbunionectomy Opioid Use” 2009 American Academy of Pain Management
 Meeting-Phoenix, Arizona