# DR. IRA J. GOTTLIEB
# CURRICULUM VITAE

## Education

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

## Certifications

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| 1990 | Fellow, American College of Foot and Ankle Surgeons |
| 1990 | Diplomate, American Board of Podiatric Surgeons |
| 2009 | Fellow, American Society of Podiatric Surgeons |
| 1988 | Associate, American Academy of Podiatric Sports Medicine |

## Clinical Research Experience

2004-present **Chesapeake Research Group, LLC**
**Founder - President/Owner**
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

1999-2003 **Scirex Corporation**
Clinical Trial Site
Principal Investigator/Sub Investigator

8030B Ritchie Highway
Pasadena, MD 21122
Phone: (410) 761-0118 Fax: (410) 761-5118
www.chesapeakeresearchgroup.com
igottlieb@crgmd.com

## Practice Experience

2011-present **Foot and Ankle Specialists of the Mid-Atlantic, LLC**
**Partner – Executive Board, Secretary**
Private group practice with nine locations in the Maryland/DC area

1987-2011 **Chesapeake Foot and Ankle Centers, PA**
**Founding Partner**
Private group practice with two locations in Maryland:
- The Horizons - Anne Arundel County, Pasadena
- Mercy Medical Center - Baltimore City

1993-present **Chesapeake Ambulatory Surgery Center, LLC**
**Founding Partner**
Office based ASC specializing in surgery of the foot and ankle.
Clinical Research based on surgical models of the foot and ankle.

## Honors

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

## Clinical Research Experience

****Protocol HTX-011-301 (2017)**
A Phase 3, Randomized, Double-Blind, Saline Placebo- and Active-Controlled, Multicenter Study of (the study drug) via Local Administration for Postoperative Analgesia and Decreased Opioid Use Following Unilateral Simple Bunionectomy

****Protocol AVE-901-102 (2017)**
A Phase 3, Multicenter, Randomized, Double Blind, Three-Arm Study to Evaluate the Efficacy and Safety of (the study drug) versus Placebo in the Management of Postoperative Pain Following Bunionectomy

****Protocol CLCT-018 (2017)**
A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Determine the Efficacy and Safety of (the study drug) as a Treatment for Moderate-to-Severe Acute Pain and the Prevention of Opioid-Induced Nausea and Vomiting (OINV) Following Orthopedic Surgery

****Protocol ESTEVE-SUSA-301 (2017)**
A Randomized, Double-blind, Active- and Placebo-controlled, Parallel Groups, Phase 3 Clinical Trial to Establish the Efficacy of (the study drug) for the Management of Moderate to Severe Post-surgical Pain after Bunionectomy

****Protocol AFT-MXIV-07 (2016)**
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

**Protocol CP130-3002 (2016)**
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Abdominoplasty

****Protocol CP130-3001 (2016)**
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Bunionectomy

**Protocol HTX-011-C2015-203 (2016)**
A Phase 2, Randomized, Controlled Evaluation of the Efficacy and Safety of (the study drug) for Post-Operative Analgesia Following Abdominoplasty Surgery

****Protocol HTX-011-C2016-208 (2016)**
A Phase 2, Randomized, Controlled, Multicenter, Evaluation of the Efficacy and Safety of Locally Administered (study drug) for Postoperative Analgesia Following Bunionectomy

****Protocol REC-15-016 (2016)**
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of (the study drug) Following Bunionectomy

****Protocol INS005-16-062 (2016)**
A Phase 3, Randomized, Double Blind, Multiple Dose, Parallel Group, Placebo Controlled Study of (the study drug) for the Treatment of Moderate to Severe Pain

****Protocol 4975-MN-203 (2015)**
An Open-Label, Multiple-Dose Extension Study to Evaluate the Safety and Efficacy of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

****Protocol TV46763-CNS-30031 (2015)**
A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Analgesic Efficacy and Safety of (study drug) Every 4 to 6 Hours in Patients with Moderate to Severe Pain Following Bunionectomy

****Protocol REC-15-014 (2015)**
A Phase 2, Single-Center, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety, Efficacy, and Pharmacokinetics of (the study drug) Following Bunionectomy

****Protocol ELI-200-003-2014 (2015)**
A Multi-Center, Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of (the study drug) for the Treatment of Adults with Moderate to Severe Pain Following Bunionectomy Surgery

****Protocol 4975-MN-202 (2014)**
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

****Protocol CP130-2001 (2014)**
A Phase 2, Multicenter, Randomized, Double-Blind, Multiple-Dose, Adaptive, Placebo-and Active-controlled Study of (the study drug) for the Treatment of Acute Post-Operative Pain After Bunionectomy

****Protocol MN-201 (2014)**
An Open Label, Ascending Dose Study to Evaluate the Safety and tolerability of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

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**Protocol JN-NM-002 (2013)**
A Phase 2, Randomized, Controlled, Double Blind Multi-Center Study to Evaluate Safety and Immunogenicity of (the study vaccine) compared with Menactra

****Protocol TCO2-2012-01 (2012)**
A Prospective, Randomized, Double-Blind Multicenter Study Comparing (the study device) standard Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Ulcers

****Protocol COV15010232-US (2012)**
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of (the study drug) in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open-Label Extension

****Protocol RBI.2012.003.P.2 (2012)**
A Multicenter, Randomized, Sham-Controlled, Double-Blinded Study to Evaluate the Analgesic Efficacy and Safety of (the study device) in Bunionectomy Surgery for the Treatment of Post-Operative Pain

****Protocol IND3-10-06 (2012)**
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

****Protocol COV15000182-US (2012)**
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of (the study drug) in Moderate to Severe Post-Operative Bunionectomy Pain followed by an Open Label Extension

****Protocol IND3-08-04b (2012)**
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

****Protocol DIC3-08-04 (2011)**
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

**Protocol M12-807 (2011)**
A Phase 2, Randomized Withdrawal Study of the Analgesic Efficacy and Safety of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

****Protocol Q8003-022 (2011)**
A Randomized, Double-Blind, Multicenter, Repeat-Dose Comparison of the Effects of (the study drug) 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

****Protocol KD-PV01 (2010)**
A multi-Center, Randomized, Double-Blinded, Pivotal Study of the Safety, Local Tolerability and Efficacy of (the study drug) for the Treatment of Onychomycosis

**Protocol 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

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**Protocol 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

**** Protocol BK15 (2009)**
Evaluation of a Medical Food for Chronic Wounds

**** Protocol Q8003-008 (2009)**
A Randomized, Double-Blind, Multicenter, Repeat-dose Comparison of Analgesic Efficacy and Safety of (the study drug) with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery

**** Protocol 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

**Protocol 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

**** Protocol DFC-005 (2008)**
A randomized, double-blind, active- and placebo-controlled study of the analgesic efficacy and safety of repeated dosing of (the study drug) relative to parenteral ketorolac and placebo in patients with acute moderate to severe post-surgical pain following mixed elective general orthopedic surgery

**** Protocol 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

**** Protocol 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

**** Protocol 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

**** Protocol HKT-500-US10 (2008)**
A Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of (the study drug) in the Treatment of Pain Associated with Grade I or Grade II Ankle Sprain

**Protocol 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

**** Protocol KET-017 (2008)**
A randomized, multiple-center, double-blind, placebo-controlled study of the safety and analgesic efficacy of repeated dosing of (the study drug) to treat acute post-operative pain following orthopedic trauma, injury or surgery

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**** Protocol 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

**** Protocol Q8003-010 (2007)**
A Double-Blind, Multi-Center Extenstion Study to Evaluate the Safety and Efficacy of (the study drug) in Patients with Acute Moderate to Severe Pain

**** Protocol Q8003-007 (2007-2008)**
A Placebo-Controlled, Randomized, Double-Blind Study of the Safety and Efficacy of (the study drug) in the Management of Post-Bunionectomy Pain

**Protocol M06-850 (2007-2008)**
A Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of (the study drug), Duloxetine and Placebo in Subjects with Diabetic Neuropathic Pain

**** Protocol 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

**** Protocol 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

**** Protocol 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

**Protocol 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

**Protocol 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

**** Protocol 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

**** Protocol 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.

**Protocol 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

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**** Protocol EN3269-301 (2006)**
A Randomized, Double Blind, Placebo Controlled Parallel Group Phase III Study of the Efficacy Tolerability and Safety of (the study drug) in the Treatment of Pain Associated With Grade 1 or Grade 2 Ankle Sprain or Strain

**** Protocol 3000-0523 (2006)**
A Phase 3 Open-Label, Single Arm Study to Assess the Safety of (the study drug) For Minimal-To- Moderate Sedation in Patients Undergoing Minor Surgical Procedures

**** Protocol VGF3554g (2006)**
A Phase II, Double Blind, Randomized, Placebo Controlled Study to Assess the Effect of (the study drug) for Induction of Diabetic Foot Ulcers

**** Protocol 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.

**Protocol HKT-500-US05 (2005)**
A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Two-Week Study to Assess the Safety and Efficacy of (the study drug) in Subjects with pain from Moderate Lateral Epicondylitis.

**Protocol HKT-500-US06 (2005)**
An Open Label Safety Study with Intermittent Use of (the study drug) in Subjects with Lower Back Pain, Pain from Osteoarthritis of the Knee, Shoulder Pain or Lateral Epicondylitis Pain.

**Protocol 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.

**** Protocol 3000-0412(2005)**
A Phase III, Randomized, Open Label Study to Assess the Safety and Efficacy of (the study drug) Versus Midazolam HCL for Sedation in Patients Undergoing Minor Surgical Procedures.

**** Protocol 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.

**Protocol M03-643 (2004)**
A Randomized, Multi-Center Double-Blind Study Comparing the Analgesic Efficacy of (the study drug) Extended Release and Placebo in Subjects with Osteoarthritis.

**Protocol M03-609 (Nov03-Mar04)**
A Randomized, Double-Blind, Placebo-controlled Study Comparing the Analgesic Activity of (the study drug) Extended Release and Placebo in Subjects with Pain Following Bunionectomy Surgery

**Protocol 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.

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**** Protocol PARA-0505-089-P-1 (May03-Jul03)**
Revised Clinical Protocol for a Randomized Multiple Dose Assessment of the Safety of (the study drug) Ready to Use (RTU) Formulation Compared to Parecoxib Sodium Lyophilized Preparation in Patients in Pain Following Bunionectomy

**Protocol 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 (the study drug) Compared to Placebo Patients in Pain Following Bunionectomy

**** Protocol 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 (the study drug) Compared to Placebo in Patients for Treatment of Post-Surgical Pain from Bunionectomy Surgery

**** Protocol KF0151Y/03 (01-02)**
A Randomized, Double-Blind, Parallel-Group Study Assessing the Analgesic Efficacy and Safety of Four Dose Levels of (the study drug) (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).

**Protocol 052-00 (2001)**
A randomized double-blind, Placebo and active comparator controlled parallel group multi-center study of (the study drug) and naprelan in the treatment of post-bunionectomy surgery pain

**** Protocol KF5503-05 (2001)**
A Randomized, Double-Blind, Parallel-Group, Dose-Ranging Study Assessing the Analgesic Efficacy and Safety of Five Dose Levels of (the study drug) (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).

**Protocol SKB 14777/277 (2000-2001)**
Analgesic Efficacy of Single doses of Investigational Medication (900mg, 1350mg, 1800mg) and Multiple Doses of (the study drug) (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)

**** Protocol SKB 14777/276 (2000)**
Comparative Analgesic Efficacy of Single and Multiple Doses of (the study drug) (900mg, 1350mg, 1800mg), Naproxen Sodium 550mg or Placebo in Pain Following Outpatient Orthopedic surgery (Bunionectomy)

**Protocol N91-99-02-072 (1999-2000)**
Clinical Protocol for A Double blind Placebo and Active-Controlled Comparison of the Analgesic Activity of (the study drug) 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

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**Appointments**

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|---|---|
| 2002-2010 | President, Maryland State Board of Podiatric Medical Examiners<br>Appointed by Governors, Robert Ehrlich, Martin O'Mally |
| 2010-2013 | Clinical Associate Professor (Adjunct), Temple University School of Podiatric Medicine, Department of Podiatric Surgery<br>Appointed by Dean, John A. Mattiacci, D.P.M. |

**Elected Positions**

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|---|---|
| 1994-2002 | Executive Board, Maryland Podiatric Medical Association<br>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

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| 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 |

**Community Awareness/Professional Volunteer Work**

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|---|---|
| 2010-2012 | Anne Arundel Counties' Homeless Resource Day |

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