# CURRICULUM VITAE DONALD RUSSELL LOCKE, M.D.

Vantage Urologic Institute	
Medical Park at TimberRidge	
9401 SW Highway 200	
STE 502	
Ocala, Florida 34481-9650	
352.861.2115	
352.854.5726 (Fax)	
rlocke@vantagehealth.org	
www.vantageurology.com	
EDUCATION	
University of South Florida, Tampa, FL Associate of Arts	1976 – 1978
	1370 1370
Florida State University, Tallahassee, FL	
Program in Medical Sciences B.S., Biological Science	1979 – 1980
Basic Medical Sciences	1979 – 1980
University of Florida, Gainesville, FL	
College of Medicine	
Doctor of Medicine	1980 – 1983
POSTGRADUATE TRAINING	
Memorial Medical Center, Savannah, GA	1002 1004
Intern, Surgery	1983 – 1984
University of Florida, Gainesville, FL	
Department of Surgery	
Resident, Surgery	1984 – 1985
University of Florida, Gainesville, FL	
Department of Surgery	
Division of Urology	
Resident, Urological Surgery	1985 – 1987
University of Florida, Gainesville, FL	
Department of Surgery	
Division of Urology	
Chief Resident, Urological Surgery	1987 – 1988
ADVANCED TRAINING	
University of Florida, Gainesville, FL	
Department of Neurosurgery	
Theodore Gildred Microsurgery Course	1986
University of Florida, Gainesville, FL	
Department of Surgery	
Division of Urology	
Extracorporeal Shock Wave Lithotripsy Dornier HM-3 Certification	1986 – 1987
University of Florida, Gainesville, FL	
Department of Surgery	
Division of Urology	
Urologic Ultrasonography Transrectal Prostatic Ultrasonography	1987
Life-Tech, Inc., Boston, MA	

National Lithotripsy Association Extracorporeal Shock Wave Lithotripsy Siemens Lithostar Certification	1992
C. R. Bard, Inc., Orlando, FL Contigen Implant Training Program	1993
<pre>Phoenix, AZ Visual Laser Ablation of the Prostate (VLAP)</pre>	1994
Intuitive Surgical, Inc., Nashville, TN da Vinci Robotic-Assisted Laparoscopic Surgery	2003
American Medical Systems, St. Louis, MO Monarc Subfascial Hammock	2003
Focus Surgery, Inc., Indianapolis, IN High Intensity Focused Ultrasound (HIFU) Sonablate™ 500	2006
EDAP, Lyon, France High Intensity Focused Ultrasound (HIFU) Ablatherm	2006
American Medical Systems, Celebration, FL AdVance Male Sling System	2010
American Medical Systems, Orlando, FL GreenLight HPS Laser Therapy Advanced Concepts Workshop	2010
Medtronic, Minneapolis, MN InterStim® Sacral Neuromodulation Therapy	2011
Boston Scientific Corporation, Tampa, FL Cadaver Lab Training Program	2014
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC	2014
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC  Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy  Transperineal Laser Ablation of the Prostate (TPLA)	2014
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)	2014 2022
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION	2014 2022 1984
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners	2014 2022 1984 1990
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990)	2014 2022 1984 1990 1998
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998)	2014 2022 1984 1990 1998 2009
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)	2014 2022 1984 1990 1998 2009
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)	2014 2022 1984 1990 1998 2009 2018
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE	2014 2022 1984 1990 1998 2009 2018
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE  State of Florida (No. ME 44759)	2014 2022 1984 1990 1998 2009 2018
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE State of Florida (No. ME 44759) State of New York (No. 230900)	2014 2022 1984 1990 1998 2009 2018 1984 2003 2003
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE State of Florida (No. ME 44759) State of New York (No. 230900) State of Colorado (No. DR.0041449)	2014 2022 1984 1990 1998 2009 2018 1984 2003 2003
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE  State of Florida (No. ME 44759) State of New York (No. 230900) State of Colorado (No. DR.0041449) State of Arizona (No. 32381)	2014 2022 1984 1990 1998 2009 2018 1984 2003 2003 2004
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE  State of Florida (No. ME 44759) State of New York (No. 230900) State of Colorado (No. DR.0041449) State of Arizona (No. 32381) State of North Carolina (No. 200400907)	2014 2022 1984 1990 1998 2009 2018 1984 2003 2003 2004 2004
Cadaver Lab Training Program  American Medical Systems, Charlotte, NC Men's Health Advanced Course in Prosthetic Urology  Elesta SPA, Calenzano, Firenze, Italy Transperineal Laser Ablation of the Prostate (TPLA)  BOARD CERTIFICATION  National Board of Medical Examiners American Board of Urology (02/25/1990) American Board of Urology, Recertification (03/02/1998) American Board of Urology, Recertification (02/28/2009) American Board of Urology, Recertification (02/28/2018)  MEDICAL LICENSURE  State of Florida (No. ME 44759) State of New York (No. 230900) State of Colorado (No. DR.0041449) State of Arizona (No. 32381) State of North Carolina (No. 200400907) State of California (No. 87144)	2014 2014 2022 1984 1990 1998 2009 2018 1984 2003 2003 2004 2004 2004 2004 2004

<ul> <li>HealthCare Risk Manager (No. 267-33-4903)</li> </ul>	1994
PROFESSIONAL EMPLOYMENT	
Urology Center of Florida, Inc., Ocala, FL Founder, Urological Surgery	1988 - 2010
Vantage Urologic Institute, LLC, Ocala, FL Founder, Urological Surgery	2010 - Present
MEDICAL CENTER AFFILIATIONS	
Munroe Regional Medical Center, Ocala, FL	1988 – 2004
<ul> <li>Specialty Surgery of Ocala, LLC, Ocala, FL</li> </ul>	1991 – 2012
<ul> <li>Ocala Regional Medical Center, Ocala, FL</li> </ul>	1988 – Present
West Marion Community Hospital, Ocala, FL	2002 – Present
PROFESSIONAL APPOINTMENTS	
Specialty Surgery of Ocala, Medical Director	1991 – 2010
<ul> <li>Urology Center of Florida, Laboratory Director (Highly Complex)</li> </ul>	1993 – 2010
<ul> <li>State of Florida Agency for Health Care Administration, Special Expert Witness Program</li> </ul>	1996
LANGUAGES	
English – native language	
MILITARY SERVICE	
• None	
HONORS AND AWARDS	
University of South Florida, Tampa, FL President's Award for Academic Excellence	1976 – 1977
President's Award for Academic Excellence	1977 – 1978
INTERESTS	
<ul> <li>Alpine skiing, snow shoeing, hiking, golf, painting</li> </ul>	
PATENTS	
"Method of Medical Management for Lower Urinary Tract Symptoms and Beni Hyperplasia"	gn Prostatic
U.S. Patent Number: 6,200,573	2001
PEER REVIEWED JOURNALS	

- 1. Locke DR, Steinbock G, Salomom DR, Bezirdzian L, Peterson J, Newman RC, Kaude J, Finlayson B: Combination Extracorporeal Shock Wave Lithotripsy and Percutaneous Extraction of Calculi in a Renal Allograft. Journal of Urology, Volume 139, Issue 3, Pages 575-577, March, 1988.
- 2. Locke DR, Newman RC: Extracorporeal Shock Wave Lithotripsy of Calculi in Horseshoe Kidneys. Journal of Urology, Volume 35, Issue 5, Pages 407-411, May 1990.
- 3. Klimberg IW, Locke DR, Hawkins I, Drylie DM: Absolute ethanol renal angioinfarction for control of hypertension. Urology, Vol. 23, 2:153-158, 1989.
- 4. Klimberg IW, Locke DR, Leonard E, Madore RJ and Klimberg SR: "Outpatient Transurethral

- Resection of the Prostate at a Urologic Ambulatory Surgery Center". J. Urol., Vol. 151, Pg. 1547-1549, June, 1994.
- 5. Klimberg, IW, Locke DR, Dersch MW, Taub HC: "TURP as Same Day Surgery." Contemporary Urology, Vol. 8, Number 11, November 1996.
- Robertson, C, Sliwinski, A, Wallen, E, Ward, J, Orovan, W, Locke, D, Crawford, ED, Maroni, P, and others: "Efficacy of High Intensity Focused Ultrasound (HIFU) as a Primary Monotherapy for Low Risk Localized Prostate Cancer: Outcomes From the Enlight Trial". J. Urol., Vol. 195, Pg. 198-199, April, 2016.

## OTHER PUBLICATIONS/ABSTRACTS

- 1. Klimberg IW, Locke DR, Hawkins IF, Jr., Drylie DM: "Control of Hypertension by Ethanol Renal Ablation." American Urological Association, Southeastern Section, 1987, Abstracts.
- Klimberg IW, Linn R, Locke DR, Wajsman Z: "Long-Lasting, Postive Acid Fast Prostatic Granuloma in Patients Treated with Intravesical BCG." American Urological Association, Southeastern Section, 1988, Abstracts, p. 27.
- 3. Klimberg IW, Locke DR, Madore R, Harbater C, Klimberg S: Oral Enoxacin as a Prophylatic Agent for Ultrasound Directed Transrectal Needle Biopsy of the Prostate. American Urologic Association, Southeastern Section, 1991, Abstracts.
- 4. Klimberg IW, Locke DR, Madore R, Harbater C, Klimberg S: "Oral Enoxacin as a Prophylactic Agent for Ultrasound Directed Transrectal Needle Biopsy of the Prostate". American Urologic Association, Journal of Urology.
- 5. Klimberg IW, Locke DR, Madore R, Leonard E: "Autologous Blood Replacement (Pre-Deposit and Intraoperative Autotransfusion) in Radical Retropubic Prostatectomy." American Urologic Association, Journal of Urology, 1993.
- Klimberg IW, Locke DR, Leonard E, Madore R, Klimberg SR: "Outpatient Transurethral Resection of the Prostate at a Urologic Ambulatory Surgery Center." American Urologic Association, Journal of Urology, Vol. 149, Number 4, p. 321A, 1993.
- 7. Locke DR, Klimberg IW, Smith W, Madore R; "Outpatient Transurethral Resection of the Prostate; Three Year Experience". American Urological Association, 89th Annual Meeting, Journal of Urology, Vol. 151, Number 5, #1124, 1994.
- 8. Locke DR, Klimberg IW, Smith W, Madore R; "Transurethral Resection of the Prostate (TURP); Selection Criteria for Outpatient or Inpatient Status". American Urological Association, 89th Annual Meeting, Journal of Urology, 1994.
- 9. Madore R, Klimberg, IW, Locke DR, Smith W; "Autologous Blood Replacement (Predeposit and Intraoperative Autotransfusion) in Radical Retropubic Prostatectomy". American Urological Association, 89th Annual Meeting, Journal of Urology, 1994, #1169.
- 10. Klimberg IW, Locke DR, Hill C, Smith W, Madore R; "The Urologic Specialty Facility; A Cost Effective Model for the Delivery of Comprehensive Urologic Care in the 1990's". American Urological Association, 89th Annual Meeting, Journal of Urology, 1994.
- 11. Locke DR, Klimberg IW, Dersch M, Madore R, Smith W. "Outpatient Transurethral Resection of the Prostate; 350 Consecutive Cases." American Urologic Association, 90th Annual Meeting, Journal of Urology, 1995.
- 12. Lloyd D, Klimberg IW, Locke DR. "Outpatient TURP is Routine at Florida ASC." OR Manager, Vol. II, No. 12, December, 1995.

#### **MONOGRAPHS**

- 1. Locke DR: "The Emerging Role of Nutritional Supplementation the Management of Benign Prostatic Hyperplasia (BPH)" 1998.
- Locke DR: "ProstaTrac™" --- Benign Prostatic Hyperplasia (BPH) Assessment and Medical Management Program" 1998.
- 3. Locke DR: "The Emerging Role of High Antioxidant Multivitamin Supplementation in Chemoprevention of Urologic Cancers" 1998.
- 4. Locke DR: "The Emerging Role of The Emerging Role Proanthocyanidins in the Prevention

- of Urinary Tract Infection" 1998.
- 5. Locke DR: "The Emerging Role of Androgen Precursor Supplementation in the Management of Male Hypogonadism" 1998.
- 6. Locke DR: "da Vinci® Prostatectomy (dVP)—A Detailed Description of the Surgical Technique as performed at the Urology Center of Florida" 2004.

#### **PRESENTATIONS**

- "Extracorporeal Shock Wave Lithotripsy of Calculi in Horseshoe Kidneys." Southeastern Section, American Urologic Association, New Orleans, LA, 1987.
- "Absolute Ethanol Angioinfarction for Control of Hypertension." Southeastern Section, American Board of Urologic Association, New Orleans, LA, 1987.
- "Outpatient Transurethral Resection of the Prostate (TURP) at a Urologic Ambulatory Surgery Center." American Urologic Association, San Antonio, Texas, 1993.
- 4. "da Vinci Prostatectomy (dVP)." Pfizer, Inc., Topics in Urology, Orlando, Florida, 2003.
- 5. "Robotic Radical Prostatectomy." Mississippi Pharmacists Association, Destin, Florida, 2006.
- 6. "da Vinci Prostatectomy." Hospital Clínica Bíblica, San José, Costa Rica, 2007.

#### SPONSORED RESEARCH

- "A Multicenter, Dose Titration Study of Once-A-Day Administration of Terazosin in the Treatment of the Symptoms of Benign Prostatic Hyperplasia." (M87-012) Abbott Laboratories, Abbott Park, IL, 1989-1990.
- "A Multicenter, Dose Titration Study of Once-A-Day Administration of Terazosin in the Treatment of the Symptoms of Benign Prostatic Hyperplasia." (M87-012) Abbott Laboratories, Abbott Park, IL, 1989-1990.
- "A Phase III, Multicenter, Double-Blind, Parallel Group, Prospective, Randomized Comparative Study of Cefpodoxime Proxetil and Cefaclor in the Treatment of Outpatients with Uncomplicated Urinary Tract Infections", Sankyo, U. S. A. Corporation, New York, NY, 1989.
- 4. "A Double-Blind, Placebo-Controlled Efficacy & Safety Study of Ditropan SR Tablets for the Treatment of the Symptoms of Bladder Instability of Non-Neuropathic Origin." Marion Laboratories, Inc., Kansas City, MD 1989-1990.
- "Fleroxacin (R023-6240) in Complicated Urinary Tract Infections, An Open Label Randomized, Multidose, Comparative Study vs Ciprofloxacin", Roche Laboratories, Hoffman-LaRoche, Inc., Nutley, NJ 1990.
- 6. "An Open, Non-Comparative Study of Oral Enoxacin as a Prophylactic Agent for Ultrasound Directed Transrectal Needle Biopsy of the Prostate", Park-Davis Research Division, Warner-Lampert Company, Ann Arbor, MI 1990.
- "Long-Term Safety and Efficacy of Terazosin Administered Once-A-Day in the Treatment of the Symptoms of Benign Prostatic Hyperplasia", (M87-07) Abbott Laboratories, Abbott Park, IL 1990.
- 8. "A Double-Blind Randomized, Comparative Multicenter Study of Cefdinir CI-983 vs Trimethoprim/Sulfa Methaxazole in the Treatment of Urinary Tract Infections", Parke-Davis Pharmaceutical Research Division/Warner-Lambert Company, 1990-1991.
- 9. "A Dose Response Study of the Effect of Flutamide on Benign Prostatic Hypertrophy", C89-360-21. Schering-Plough Research, Kenilworth, NJ, 1991-1992.
- "A Double-Blind Randomized Placebo Controlled Dose Ranging Study of Atamestane to Evaluate the Efficacy, Safety and Endocrinological Effects in Symptomatic Patients with Benign Prostatic Hyperplasia (BPH)", 306-02A, Berlex Laboratories, Inc., Wayne, NJ, 1991-1992.
- "A Multicenter Comparison of the Safety and Efficacy of 3 Days of Lomefloxacin Therapy vs 3
   Days of Ofloxacin Therapy in the treatment of Women with Uncomplicated Urinary Tract
   Infections", S69-91-01-194. G. D. Searle & Co., Chicago, IL, 1991-1992.

- "Treatment I. N. D. Protocol for the Compassionate use of Elmiron (Pentosan Polysulfate Sodium) for Patients with Recurring Symptoms of Interstitial Cystitis", CE-001, Baker Cummins Pharmaceuticals, Inc., Miami, FL, 1991-1992.
- 13. "A Fourteen-Week Double-Blind, Placebo Controlled Dose Response Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Normotensive Patients." N-0488. Pfizer, Inc., New York, NY, 1991-1992.
- 14. "An Open Label Extension Study of Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia in Normotensive Patients", N-488, Pfizer, Inc., New York, NY, 1991-1993.
- 15. "A Multicenter Comparison in Intravenous Lomefloxacin vs Cefotaxime as Prophylactic Agents in Transurethral Surgery", S68-90-02-13, G. D. Searle, Chicago, IL, 1991-1992.
- 16. "Extended (Up to 15 Months) Double-Blind Evaluation of Atamestane and Placebo to Study the Long Term Efficacy, Safety and Endocrinological Effect in Patients with Benign Prostatic Hyperplasia", 306-04, Berlex Laboratories, Inc., Wayne, NJ, 1991-1992.
- 17. "A Randomized Comparative Trial of Casodex vs Flutamide used in Combination with Medical Castration in Patients with Untreated Metastatic Prostate Cancer", ICI Pharmaceuticals Group, Wilmington, DE, 1991-1993.
- "A Double-Blind, Randomized, Placebo Controlled Dose Ranging Study of Atamestane to Evaluate the Efficacy, Safety and Endocrinological Effects in Symptomatic Patients with Benign Prostatic Hyperplasia (BPH)", 306-02B, Berlex Laboratories, Inc., Wayne, NJ, 1992 -1993.
- 19. "A Multi-Center Comparison of the Safety and Efficacy of 3 Days of Lomefloxacin Therapy vs 10 Days of Trimethoprim/Sulfamethoxazole Therapy in the Treatment of Women with Uncomplicated Urinary Tract Infections", S69-91-02-190, G. D. Searle & Co., Chicago, IL, 1992.
- "Fosfomycin Tromethamine vs Trimethoprim/Sulfamethoxazole in Uncomplicated Urinary Tract Infections. A Double-Blind, Randomized Study", MON-US-002, Forest Laboratories, Inc., New York, NY, 1992-1993.
- 21. "A Multicenter, Prospective, Randomized, Double-Blind Comparison of Single Dose Ciprofloxacin vs Placebo Prophylaxis During Transrectal Prostate Biopsy," D91-019, Miles Inc., West Haven, CT, 1992.
- 22. "A Multicenter Comparison of the Safety and Efficacy of Lomefloxacin and Ofloxacin in the Treatment of Chronic Bacterial Prostatitis", 69-91-02-196, G. D. Searle & Co., Chicago, IL, 1992-1993.
- "Fleroxacin (R023-6240) in Urinary Tract Infections. An Open, Non-Comparative Trial," NI14127A, Roche Pharmaceuticals Hoffman-LaRoche, Inc., Nutley, NJ, 1992-1993.
- 24. "A Multicenter Prospective, Randomized Double Blind Comparison of Single Dose Oral Ciprofloxacin vs Single Dose Intravenous Cefotaxime Sodium vs Placebo for Antimicrobial Prophylaxis During Transurethral Surgery", D91-018, Miles, Inc., West Haven, CT, 1992 -1993.
- 25. "A Multicenter, Open Label Study of the Safety and Efficacy of Oral Lomefloxacin as a Prophylactic Agent in Transrectal Prostate Biopsy", S-69-92-02-221, G. D. Searle & Co., Chicago, IL, 1992-1993.
- 26. "A One-Year, Multicenter, Double-Blind Comparison of the Effects of Once-Daily Dosing with Three Dose Levels of SK&F 105647 or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia with Six-Month Untreated Follow-Up", Smith Kline, Beecham Pharmaceuticals, King of Prussia, PA, Study 017.
- 27. "A Multicenter, Randomized Study to Compare the Safety and Efficacy of Oral Levofloxacin with that of Lomefloxacin HCI in the Treatment of Complicated Urinary Tract Infections in Adults", Protocol L901159. R. W. Johnson Pharmaceutical Research Institute, Raritan, NJ., 1993 1994.
- 28. "Prospective, Randomized, Double-Blind Comparison of 100 mg Ciprofloxacin Tablets Twice Daily for Three Days, Trimethoprim/sulfamethoxazole 160/800 mg Twice Daily for Seven Days, and Nitrofurantoin (MACROBID) 100 mg Tablets Twice Daily for Seven Days in the Treatment of Patients with Acute Uncomplicated Lower Urinary Tract Infections", Protocol

- D92-033, Miles Pharmaceuticals, Inc., West Haven, CT, 1993 1994.
- 29. "Intravesical AD-32 in Patients with Carcinoma-in-Situ of the Bladder Who Have Failed or Have recurrence Following Treatment with BCG", A9301, Anthra Pharmaceuticals, Inc., Washington, DC, 1993 1994.
- 30. "Intravesical AD-32 in Patients with Transitional Cell Carcinoma of the Bladder", Protocol A9303, Anthra Pharmaceuticals, Inc., Washington, DC, 1993 1994.
- "A One-Year Multicenter, Double-Blind Comparison of the Effects of Once-Daily Dosing with Three Dose Levels of SK&F 105647 or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia, with Six Month Untreated Follow-Up", Protocol 105657, Study 018, SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1993 - 1994.
- 32. "A Twenty-Six Weeks, Double-Blind, Placebo-Controlled, Dose-Titration Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia", Protocol N-0606, Pfizer, Inc., New York, NY, 1993 1994.
- 33. "An Open-label Extension Study of the Twenty-Six Week, Double-Blind, Placebo-Controlled, Dose-Titration Study Using Doxazosin Tablets for the Treatment of Benign Prostatic Hyperplasia", Protocol N-0606, Pfizer, Inc., New York, NY, 1993 1994.
- 34. "A Randomized, Double-Blind, Multicenter Trial Comparing 7 Days of Oral Therapy with CP-99-219 (100 mg or 200 mg daily) or Ciprofloxacin Hydro-chloride (500 mg daily) for the Treatment of Uncomplicated Urinary Tract Infections", Protocol 154-013, Pfizer, Inc., New York, NY, 1993 1994.
- 35. "Two-Year, Open-Label, Multicenter Study of Oral Epristeride 80 mg Once Daily in the Treatment of Benign Prostatic Hyperplasia", 105657/052, SmithKline Beecham Pharmaceuticals, King of Prussia, PA., 1993 1995.
- 36. "A Randomized Control Trial of the Intra-Sonix TULIP System for Benign Prostatic Hyperplasia", Intra-Sonix, Inc., Burlington, MA, 1994.
- "Fosfomycin Tromethamine Versus Nitrofurantoin Monohydrate/Macrocrystals in Uncomplicated Urinary Tract Infections." A Double-Blind Randomized Study", MON-US-03, Forest Laboratories, Inc., New York, NY, 1994.
- 38. "A Prospective, Randomized, Double-Blind Study to Evaluate the Use of a Combination of Slow IV Push Midazolam with Low Dose Propofol vs Standard Dose Propofol During Induction and Maintenance of General Anesthesia for Outpatient Surgical Procedures Lasting Less Than 2 Hours", Protocol #124, Hoffmann-LaRoche, Inc., Nutley, NJ, 1994.
- 39. "A Prospective, Randomized, Double-Blind Study to Evaluate the Use of Slow IV Push Midazolam and Continuous Infusion Propofol in Outpatient diagnostic Surgical Procedures", Protocol #125, Hoffmann-LaRoche, Inc., Nutley, NJ, 1994.
- 40. "A One-Year, Open-label, Multicenter Study of Oral Epristeride 80 mg Once Daily in the Treatment of Benign Prostatic Hyperplasia", Protocol 105657, Study 051, SmithKline Beecham Pharmaceuticals, Inc., King of Prussia, PA, 1994-199
- 41. "Intra-Operative Autotransfusion in Urologic Oncology: Long Term Follow-Up." Cobe Cardiovascular, Inc., Arvada, CO, 1994.
- 42. "The Assessment of Health-Related Quality of Life in Patients with Stage D2 Prostate Cancer in Remission and Progression." P94-032-12, Schering Corporation, Kenilworth, NJ, 1994-1995.
- 43. "Evaluation of Biomarkers in the Diagnosis and Management of Prostate Disease." Bioclinical Partners, Inc., Sharon, MA, 1994-1995.
- 44. "Evaluation of Tumor Associated Biomarkers in the Diagnosis and Management of Prostate Cancer." Dianon Systems, Inc., Stratford, CT, 1995-1995.
- 45. "Chek-Stix® SG Lay Use." CTD-94-31, Miles, Inc. Diagnostics Division, Elkhart, IN, 1994-1995.
- 46. "Fleroxacin Syrup in the Treatment of Complicated or Recurrent Urinary Tract Infections in Elderly Patients. An Open-Label, Randomized, Comparative Multicenter Study vs. Ciprofloxacin Tablets." NR14556, Hoffman-La Roche, Inc., Nutley, NJ, 1995.
- 47. 46. "An Open Multicenter Trial Designed to Evaluate the Efficacy and Safety of CP-

- 116.517/CP-99.219 in the Treatment of Complicated Urinary Tract Infections." 154-118, Pfizer, Inc., Groton, CT, 1995.
- 48. "A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Fixed-Dose, Multicenter, Long-Term Dose-Response Study to Assess the Efficacy and Safety of UK-92-480 Administered Prior to Sexual Activity to Male Patients with Erectile Dysfunction." 148-101B, Pfizer, Inc., Groton, CT, 1995.
- 49. "Phase III of Oral Bropirimine vs. Intravesical BCG in Adult Patients with BCG Naive Bladder Carcinoma-In-Situ." M/1600/0015, The Upjohn Company, Kalamazoo, MI, 1995-1996
- 50. "Multicenter, Prospective, Double-Blind, Randomized, Comparative Trial to Evaluate the Treatment Effects of Ciprofloxacin for Seven Days, Compared with Standard Therapy for Fourteen Days, in Female Patients with Acute Uncomplicated Pyelonephritis." D93-037, Miles, Inc., West Haven, CT, 1995.
- 51. "Prospective, Randomized, Double-Blind, Controlled, Multicenter Comparative Trial to Evaluate the Clinical Effect of Ciprofloxacin vs. Ofloxacin vs. Placebo in the Treatment of Non-Bacterial Prostatitis." D92-022, Miles, Inc., West Haven, CT, 1995.
- 52. "Duloxetine for Urinary Incontinence: A Multiple-Dose Study for Efficacy and Safety." FIJ-MC-SAABCB, Eli Lilly and Company, Indianapolis, IN, 1995.
- 53. "A Randomized, Double-Blind Comparative Trial of Bicalutamide (CASODEX™) vs. Placebo in Patients with Early Prostate Cancer." 7054IL/0023, Zeneca Pharmaceuticals, Wilmington, DE, 1995.
- 54. "Chek-Stix® U.T.I. Clinical Utility Protocol." CTD-95-14, Bayer Corporation Diagnostics Division, Elkhart, IN, 1995.
- "A Three Month, Double-Blind, Placebo-Controlled, Randomized, Multicenter Study of the Effects and Safety of SB216469-S in Patients with Symptomatic Benign Prostatic Hyperplasia." SB 216469/S 009, SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1995.
- 56. "Ardito Incontinence Valve." Pri-Med International Corporation, Coon Rapids, MN, 1995.
- "A Randomized, Double-Blind, Multicenter Trial Comparing CP-116.517/CP-99.219 and Ciprofloxacin for the Treatment of Complicated Urinary Tract Infections." 154-117, Pfizer, Inc., Groton, CT, 1995.
- 58. "A Randomized, Multicenter, Double-Blind, Double-Dummy Comparative Trial of CP-99.219 (Trovafloxacin) and Ofloxacin for the Treatment of Bacterial Prostatitis." 154-119, Pfizer, Inc., Groton, CT, 1995.
- 59. "Randomized Prospective Study Comparing Intermittent vs. Continuous Androgen Deprivation with Lupron Depot in Clinical Stage D2 Prostate Cancer." M95-296, Tap Holdings, Inc., Deerfield, IL, 1995.
- 60. Evaluation of Biomarkers in the Diagnosis and Management of Prostate Disease." Bioclinical Partners, Inc., Sharon, MA, 1994-1995. "
- 61. Evaluation of Tumor Associated Biomarkers in the Diagnosis and Management of Prostate Cancer." Dianon Systems, Inc., Stratford, CT, 1995-1995.
- 62. "Chek-Stix® SG Lay Use." CTD-94-31, Miles, Inc. Diagnostics Division, Elkhart, IN, 1994-1995.
- 63. "Fleroxacin Syrup in the Treatment of Complicated or Recurrent Urinary Tract Infections in Elderly Patients. An Open-Label, Randomized, Comparative Multicenter Study vs. Ciprofloxacin Tablets." NR14556, Hoffman-La Roche, Inc., Nutley, NJ, 1995.
- 64. "An Open Multicenter Trial Designed to Evaluate the Efficacy and Safety of CP-116.517/CP-99.219 in the Treatment of Complicated Urinary Tract Infections." 154-118, Pfizer, Inc., Groton, CT, 1995.
- 65. "Phase III of Oral Bropirimine vs. Intravesical BCG in Adult Patients with BCG Naive Bladder Carcinoma-In-Situ." M/1600/0015, The Upjohn Company, Kalamazoo, MI, 1995-1996.
- 66. "Multicenter, Prospective, Double-Blind, Randomized, Comparative Trial to Evaluate the Treatment Effects of Ciprofloxacin for Seven Days, Compared with Standard Therapy for Fourteen Days, in Female Patients with Acute Uncomplicated Pyelonephritis." D93-037, Miles, Inc., West Haven, CT, 1995.

- 67. Prospective, Randomized, Double-Blind, Controlled, Multicenter Comparative Trial to Evaluate the Clinical Effect of Ciprofloxacin vs. Ofloxacin vs. Placebo in the Treatment of Non-Bacterial Prostatitis." D92-022, Miles, Inc., West Haven, CT, 1995.
- 68. "Duloxetine for Urinary Incontinence: A Multiple-Dose Study for Efficacy and Safety." FIJ-MC-SAABCB, Eli Lilly and Company, Indianapolis, IN, 1995.
- 69. "A Randomized, Double-Blind Comparative Trial of Bicalutamide (CASODEX™) vs. Placebo in Patients with Early Prostate Cancer." 7054IL/0023, Zeneca Pharmaceuticals, Wilmington, DE, 1995.
- 70. "Chek-Stix® U.T.I. Clinical Utility Protocol." CTD-95-14, Bayer Corporation Diagnostics Division, Elkhart, IN, 1995.
- "A Three Month, Double-Blind, Placebo-Controlled, Randomized, Multicenter Study of the Effects and Safety of SB216469-S in Patients with Symptomatic Benign Prostatic Hyperplasia." SB 216469/S 009, SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1995.
- 72. "Ardito Incontinence Valve." Pri-Med International Corporation, Coon Rapids, MN, 1995.
- 73. "A Randomized, Double-Blind, Multicenter Trial Comparing CP-116.517/CP-99.219 and Ciprofloxacin for the Treatment of Complicated Urinary Tract Infections." 154-117, Pfizer, Inc., Groton, CT, 1995.
- 74. "A Randomized, Multicenter, Double-Blind, Double-Dummy Comparative Trial of CP-99.219 (Trovafloxacin) and Ofloxacin for the Treatment of Bacterial Prostatitis." 154-119, Pfizer, Inc., Groton, CT, 1995.
- 75. "Randomized Prospective Study Comparing Intermittent vs. Continuous Androgen Deprivation with Lupron Depot in Clinical Stage D2 Prostate Cancer." M95-296, Tap Holdings, Inc., Deerfield, IL, 1995.
- 76. "Clinical Efficacy and Safety of Tolterodine Compared to Oxybutynin and Placebo." CTN 94-OATA-010 Part A, Pharmacia AB Pharmaceuticals, Uppsala, Sweden, 1995-1996.
- 77. "Long Term Safety, Tolerability and Clinical Efficacy of Tolterodine." CTN 94-OATA-010 Part B, Pharmacia AB Pharmaceuticals, Uppsala, Sweden, 1995-1996.
- 78. "A Two-year, Open-Label, Multicenter Study of Oral Epristeride 80 mg Once Daily in the Treatment of Benign Prostatic Hyperplasia." 105657/052 (Extension to 105657/017), SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1995-1997.
- 79. "A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Fixed Dose, Multicenter, Long Term Dose-Response Study of UK-92.480 Administered Prior to Sexual Activity to Male Patients with Erectile Dysfunction." 148-101, Pfizer, Inc., Groton, CT, 1995-1996.
- 80. "A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Fixed Dose, Multicenter, Long Term Dose-Response Study of UK-92.480 Administered Prior to Sexual Activity to Male Patients with Erectile Dysfunction." 148-101B, Pfizer, Inc., Groton, CT, 1995-1996.
- 81. "An Open, Non-Comparative Study to Assess the Long Term Safety of Sildenafil in Patients with Erectile Dysfunction." 148-101C, Pfizer, Inc., Groton, CT, 1995-1996.
- 82. "A Double-Blind, Randomized, Placebo Controlled, Parallel Group, Multicenter, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil Administered as Required to Male Patients with Erectile Dysfunction." 148-103, Pfizer, Inc., Groton, CT, 1996.
- 83. "An Open, Non-Comparative Study to Assess the Long-Term Safety of Sildenafil in Patients with Erectile Dysfunction. " 148-103C, Pfizer, Inc., Groton, CT, 1996.
- 84. "Duloxetine Hydrochloride vs. Placebo in Patients with Irritative Symptoms of Benign Prostatic Hyperplasia." F1J-MC-SAAI, Lilly Research Laboratories, Indianapolis, IN, 1995-1996.
- 85. "A Placebo-Controlled, Parallel-Group, Double-Blind Phase III Trial of 40 mg and 80 mg Oral Phentolamine in Patients with Erectile Dysfunction" Zon 301, Zonagen, Inc. The Woodlands, TX, 1996.
- 86. "A Double-Blind, Randomized, Comparative, Multicenter Study of Zagam® (Sparfloxacin) vs. Biaxin® (Clarithromycin) in the Treatment of Community-Acquired Pneumonia." 601, Rhône-Poulenc Rorer Pharmaceuticals, Collegeville, PA, 1996.
- 87. "A Multicenter Non-Drug Study to Develop an Irritable Bowel Syndrome Quality of Life

- Questionnaire and Diary." 137-454/96-CE 38-0686 Pfizer Central Research, New York, NY, 1996.
- 88. "A Methodology Trial to Assess the Reproducibility of Noninvasive Measurements used in the Diagnosis and Assessment of Treatment Outcome for Subject with Abnormal Voiding." 6169/0011 Zeneca Pharmaceuticals, Wilmington, NC, 1996.
- 89. "Efficacy and Safety of OROS ® Oxybutynin and TTS Oxybutynin in Middle-Aged and Elderly Women with Urinary Incontinence." C95-031-06 Alza Corporation, Palo Alto, CA, 1996.
- 90. "A One Year, Multicenter, Double-Blind Study of the Effects of Once Daily Dosing with Epristeride 80 mg or Placebo in the Treatment of Symptomatic Benign Prostatic Hyperplasia." Protocol 105657/070, SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1996-1997.
- 91. "An Open-Label, Multicenter Study of the Effects and Safety of SB216469-S in Patients with Symptomatic Benign Prostatic Hyperplasia." Protocol 216469/0010, SmithKline Beecham Pharmaceuticals, King of Prussia, PA, 1996-1997.
- 92. "An Open, Randomized Study In Patients to Determine the Penetration of Trovafloxacin (CP-99, 219) into Prostatic Tissue Following Multiple Dosing with Trovafloxacin (200 mg Qd)." Protocol 154-041, Pfizer, Inc., Groton, CT, 1996.
- 93. "A Randomized, Double-Blind, Multicenter Trial Comparing CP-99,219 and Ciprofloxacin for the Treatment of Complicated Urinary Tract Infections." Protocol 154-140(FR), Pfizer, Inc., Groton, CT, 1996.
- 94. "A Double-Blind, Placebo Controlled, Dose-Ranging Clinical Evaluation of GI198745 and Finasteride in Subjects with Benign Prostatic Hyperplasia." ARIA2001, Glaxo Wellcome, Inc., North Carolina, 1996.
- 95. "A Double-Blind, Randomized, Comparative Multicenter Study of Zagam® (Sparfloxacin) vs. Biaxin® (Clarithromycin) in the Treatment of Acute Bacterial Exacerbation of Chronic Bronchitis." 602, Rhône-Poulenc Rorer Pharmaceuticals, Inc., Collegeville, PA, 1996.
- 96. "A Double-Blind, Randomized, Placebo Controlled, Parallel Group, Multicenter, Flexible Dose Escalation Study to Assess the Efficacy and Safety of Sildenafil Administered as Required to Male Diabetic Patients with Erectile Dysfunction." 148-104, Pfizer, Inc., Groton, CT, 1996.
- 97. "An Open, Non-Comparative Study to Assess the Long-term Safety of Sildenafil in Diabetic Patients with Erectile Dysfunction." 104-C, Pfizer, Inc. Groton, CT 1996.
- 98. "A Three Month, Randomized, Double-blind, Placebo Controlled, Dose-Ranging, Multi-Center Study to Assess the Efficacy and Safety of RO 70-0004 in Patients with Benign Prostatic Hypertrophy." Protocol 70-000452730, Roche Global Development, Palo Alto, CA. 1996-1997.
- 99. "A Five Month, Double-Blind, Placebo-Controlled, Randomized Multi-Center, Cross-Over Study of the Effects and Safety of Testosterone Transdermal System (TTD System) in Men Presenting with Sexual Dysfunction and Serum Testosterone Levels ≤350 ng/dL." TT1000/002 Smith Kline Beecham Pharmaceuticals, King of Prussia, PA, 1996.
- 100."A Phase III Efficacy and Safety Study of Three Fixed Doses of Apomorphine SL Tablets versus Placebo in the Treatment of Male Erectile Dysfunction." M96-470, Tap Holdings, Inc., Deerfield, IL, 1996.
- 101."A Phase III Long-Term, Open-Label, Flexible Dose, Efficacy and Safety Study of Apomorphine SL Tablets in the Treatment of Male Erectile Dysfunction." M96-471, Tap Holdings, Inc., Deerfield, IL, 1996-1997.
- 102."A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Single Dose Ondansetron 8 mg and Single Dose Ondansetron 16 mg for the Treatment of Opioid-induced Nausea and Emesis in Subjects Experiencing Acute Pain. " S3AA3013 Glaxo Wellcome, Inc., Research Triangle Park, NC, 1996-1997.
- 103."Prospective, Randomized, Open Label Comparison of 250 mg Ciprofloxacin Suspension Twice Daily for Ten Days and 160/800 mg Bactrim (TMP/SMX) Suspension Twice Daily for Ten Days in the Treatment of Elderly Women with Acute Urinary Tract Infections." D96-011 Bayer Corporation, West Haven, CT, 1996-1997.
- 104."Phase IV Study Evaluating the Agonistic Stimulation of Serum Testosterone Following Reinjection with Lupron Depot 3 Month 22.5 mg and Lupron Depot 7.5 mg and Assessment of

- the Pharmacokinetic/Pharmacodynamic Relationship for Lupron Depot 22.5 mg. " M96-458, Tap Holdings, Inc., Deerfield, IL 1996-1997.
- 105."An Open-Label 24 Month Trial of 40 mg Oral Phentolamine in Patients with Minimal Erectile Dysfunction. " Zon 302, Zonagen, Inc., The Woodlands, TX, 1996-1997.
- 106. "Dose Ranging Study Comparing Best Medical Therapy With and Without ABT-627 for the Treatment of Pain in Men with Symptomatic Hormone Refractory Adenocarcinoma of the Prostate." M96-500 Abbott Laboratories, Abbott Park, Illinois; 1998.
- 107. "Development of a New Dyspepsia Impact Scale, (NDI Nepean Dyspepsia Index) Sponsored in Part by Abbott Laboratories on Behalf of the International Working Party on Dyspepsia chairman: Professor Dr. N. Talley, University of Sydney Australia." Abbott Laboratories, Abbott Park, Illinois; 1998.
- 108. "Phase 2 IDE Study of ACYST™ in the Treatment of Stress Urinary Incontinence." Advanced UroScience, Inc., St. Paul, Minnesota 1997-1998.
- 109. Safety and Efficacy Study of DUROS™ Leuprolide Implantable Therapeutic System in Patients with Prostate Cancer." C-97-010-01 Alza Corporation, Palo Alto, CA; 1997-1998.
- 110. "Phase III Randomized Study of a Single Adjunctive Instillation of Intravesical AD 32 (N-Trifluoroacetyladriamycin-14-valerate) versus No Adjunctive Therapy Immediately Following Transurethral Resection in Patients with Multiple Superficial ( $T_a/T_1$ ) Bladder Tumors." A9601, Anthra Pharmaceuticals, Inc., Princeton, NJ; 1997-1998.
- 111. "An Open, Non-Comparative Extension Study of Sildenafil in Patients with Erectile Dysfunction." 148-107, Pfizer Inc. Groton, CT, 1997-1998.
- 112. "Double-Blind, Placebo-Controlled Randomized, Multicenter Study to Evaluate the Efficacy and Safety of Two I.V. Infusions of 2, 4 and 6 mg. Ibandronate on Bone Pain in Patients with Prostate Cancer and Bone Metastases." MF 4309, Boehringer Mannheim GmbH, Mannheim Germany; 1997.
- 113. "Multicenter, Double-Blind, Placebo-Controlled, Randomized, Follow-up Study of the Efficacy and Safety of an Infusion of Ibandronate 2, 4, and 6 mg. Given as Required (Maximum Frequency Every 2 Weeks), for 6 Months, in Bone Pain in Patients with Prostate Cancer and Bone Metastases." MF 4429, Boehringer Mannheim GmbH, Mannheim Germany, 1997-1998.
- 114."A Randomized, Double-Blind, Double-Dummy, Active-Placebo Controlled, parallel Group Evaluation of Oral Sumatriptan (50 mg) compared to Oral Naproxen Sodium (275mg) on Migraine-Related Quality of Life." SUMA 4016, Glaxo Wellcome Research Triangle Park, North Carolina; 1997-1998.
- 115."A Randomized, Double-Blind, Placebo-Controlled, Two-Year Parallel Group Study of the Efficacy and Safety of GI198745 0.5mg in the Treatment and Prevention of Progression of Benign Prostatic Hyperplasia." ARIA 3002, Glaxo Wellcome, Research Triangle Park, North Carolina; 1997-2000.
- 116. "Clinical Trial with Autocath® 100 for the Long-Term Treatment of Stress Urinary Incontinence in Women." 97-002, HK Medical Technologies, Inc. San Antonio, Texas 1998.
- 117. "A Phase III Long-Term, Open-Label, Flexible Dose, Safety Extension Study of Apomorphine SL Tablets in the Treatment of Male Erectile Dysfunction." M97-682 Tap Holdings, Inc. Deerfield, Illinois, 1997-1998.
- 118. "An International Phase II Randomized, Double-Blind, Multicenter Study to Determine the Tolerability and Efficacy of Three Different Doses of Liarozole in Patients with Rising Prostate Specific Antigen Levels After Definitive Treatment. LIA-INT-26." Janssen Pharmaceuticals, Titusville, New Jersey, 1997.
- 119. "A Randomized, Double-Blind, Multicenter, Phase II/III Comparison of Gatifloxacin to Ciprofloxacin in the Treatment of Complicated Urinary Tract Infection and Pyelonephritis". AI1420-011 Bristol-Myers Squibb, Wallingford, Connecticut 1997-1998.
- 120. "A Randomized, Double-Blind Study (With Open-Label Treatment Extension) to Evaluate the Efficacy and Safety of Viagra™ (Sildenafil) in Men with Symptoms of Depression and Erectile Dysfunction." R-0538, Pfizer, Inc. Groton, Connecticut, 1998.
- 121. "Phase 2 Multi-Center, Open-Labeled Study of PPI-149, Administered as a Subcutaneous, Continuous Infusion for 57 to 85 Days (8 to 12 Weeks) in Patients Undergoing Radiation Therapy Interstitial Seed Implantation or Other Radiation Therapy." PPI 149-97-03, Praecis

- Pharmaceuticals, Inc. Cambridge, Massachusetts; 1997-1998.
- 122. "A Multi-Center, Open Label, Dose Escalation Study of the Safety and Therapeutic Effects of PPI-149-Depot, Administered as an Intramuscular (IM) or Subcutaneous (SC) Injection, in Prostate Cancer Patients who are Candidates for Initial Hormonal Therapy." PPI 149-97-04, Praecis Pharmaceuticals, Inc. Cambridge, Massachusetts, 1998.
- 123. "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy of SDZ HTF919 at Two Dose Levels and Placebo in Subjects with Constipation-Predominant Irritable Bowel Syndrome." HTFB 351-E-00, Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 1997-1998
- 124. Long-Term Safety, Tolerability and Clinical Efficacy of Tolterodine. A Phase III Open, Multinational Study in Patients with Detrusor Overactivity, Symptoms of Frequency, Urge Incontinence and/or Urgency. 96 OATA 032, Pharmacia & Upjohn, Kalamazoo, Michigan; 1997-1998
- 125. "An Open-Label 12 Month Trial of Oral Phentolamine in Patients with Mild to Moderate Erectile Dysfunction." Zon 303, Zonagen, Inc. The Woodlands, Texas, 1997-1998.
- 126. "Comparative Safety and Efficacy of Cefditoren Pivoxil and Cefpodoxime Proxetil in the Treatment of Community Acquired Pneumonia." CEF-97-002, Tap Holdings, Inc., Deerfield, Illinois; 1998.
- 127. A Double-Blind, Placebo Controlled, Parallel, Fixed Dose Study of Sertraline in the Treatment of Premature Ejaculation. 96CE21-0702, Pfizer, Inc., New York, New York, 1997-1998.
- 128. A Double-Blind, Randomized, Placebo-Controlled Phase II Clinical Trial of OPC-12759 (Rebamipide) for Treatment of Non-Ulcer Dyspepsia in Patients without Helicobacter Pylori. 37-97-531A, Otsuka America Pharmaceutical, Inc., Palo Alto, California, 1998.
- 129. A Double-Blind, Randomized, Placebo-Controlled Phase II Clinical Trial of OPC-12759 (Rebamipide) for Treatment of Non-Ulcer Dyspepsia in Patients with Helicobacter Pylori. 37-97-531B, Otsuka America Pharmaceutical, Inc., Palo Alto, California, 1998.
- 130."A Randomized Double-Blind Placebo-Controlled Multi-Center Study Measuring the Effects of Glyburide with the Addition of Troglitazone on Achieving Glycemic Control in Type II (Non-Insulin-Dependent) Diabetes Mellitus (NIDDM) Patients. 991-085-053." Park Davis, Morris Plains, New Jersey, 1997-1998.
- 131."A Phase 11/111, Double-Blind, Placebo-Controlled, Dose-Finding Study of the Safety and Efficacy of ABT-980 in Patients with Symptomatic Benign Prostatic Hyperplasia (BPH)". Protocol: M98-819, Abbott Laboratories, Abbott Park, Illinois, 1999.
- 132."A Phase II, Double-Blind, Randomized Placebo-Controlled Crossover Study of the Safety and Efficacy of Dapoxetine HCL in the Treatment of Premature Ejaculation". Protocol: GP-PE-98-01, GenuPro, Morrisville, North Carolina, 1999.
- 133." A Double-Blind, Multicenter, Parallel group Study to Compare the Efficacy and Safety of Oral FACTIVE 320 mg Once Daily Versus Oral Levofloxacin 250 mg Once Daily for 10 Days in the Treatment of Pyelonephritis or Complicated Urinary Tract Infections." Protocol: 265805/014, SmithKline Beecham, Collegeville, Pennsylvania, 1999.
- 134. "Long-Term Safety and Efficacy of Tolterodine Prolonged Release Capsules. An Open-Label, Uncontrolled, Multinational Study in Patients with Symptoms of Overactive Bladder." Protocol 98-TOCR-007B, Pharmacia & Upjohn Kalamazoo, Michigan, 1999-2000.
- 135."A Randomized, Double-Blind, Placebo Controlled, Parallel-Group Study of the efficacy and Safety of GI 198745 in the Treatment and Modification of Progression of Benign Prostatic Hyperplasia." Protocol ARIB 3003, Glaxo Wellcome, Research Triangle Park, NC, 1998-2000.
- 136. "Transdermal Oxybutynin in Patients with Urge Urinary Incontinence: A 12-Week Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study with a 12 Week Open-Label, Dose Titration, Safety Extension." Protocol 099009, Watson Laboratories Inc., Salt Lake City, Utah, 1999-2000.
- 137. A Phase III At Home Use Study Evaluating the Efficacy and Safety of Escalating Doses of Uprima, 2,3, and 4 mg in the Treatment of Patients with Erectile Dysfunction. Protocol M99-031 Tap Holdings, Inc., Deerfield, IL 1999.
- 138. A Phase III, Six-Month, Long-Term, Open-Label, Flexible Dose, Safety Extension Study of Uprima Tablets (2,3, and 4 mg) in the Treatment of Male Erectile Dysfunction. Protocol

- M99-038, Tap Holdings, Inc., Deerfield, IL, 1999-2000.
- 139. A Phase III, Multi-Center, Open-Label, Randomized Study of Abarelix-Depot vs Lupron Depot® 1-Month In Patients with Prostate Cancer Who Are Candidates for Initial Hormonal Therapy. Protocol 149-98-02, Praecis Pharmaceuticals, Cambridge, MA, 1998-2000.
- 140."A Phase 3, Multicenter, Open-Label Randomized Study of Abarelix-Depot 100 mg IM vs Lupron Depot® 7.5 mg IM in Patients with Prostate Cancer Who Are Candidates for Initial Hormonal Therapy. Protocol 149-99-03/990744, Praecis Pharmaceuticals, Cambridge, MA,/Amgen Inc., Thousand Oaks, CA 1999-2000.
- 141."A Rollover, Multicenter, Open-Label, Maintenance Study of Patients with Prostate Cancer Who Were Previously Treated with Abarelix-Depot 50 mg or 100 mg IM." Protocol 149-99-04/990789, Praecis Pharmaceuticals, Cambridge, MA, Amgen Inc., Thousand Oaks, CA, 2000.
- 142. "Efficacy and Safety of Alfuzosin Once-Daily Tablets at 2 Dosage Levels (10 mg and 15 mg) Versus Placebo in Patients with symptomatic Benign Prostatic Hyperplasia: A Placebo-controlled, Double-blind Study, Conducted in 3 Parallel Groups for Three Months Followed by Two (a 9-Month and a 12-Month) Open-Label Extensions of Alfuzosin OD (15 mg). Protocol ALFUS #2560, Sanofi-Synthelabo, Secaucus, New Jersey, 1998-2000.
- 143. "An Eleven-Week, Open-Label, Randomized, Multicenter, Parallel-Design, Placebo Lead-In Study of FLOMAX® Capsules, 0.4 mg Daily Versus HYTRIN® Capsules, 5 mg (with Titration) Daily in Patients with the Signs and Symptoms of Benign Prostatic Hyperplasia." Protocol 527.17, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, 1998-2000.
- 144."A Randomized, Double-Blind, Multicenter, Phase III Study of Gatifloxacin and Ciprofloxacin in the Treatment of Chronic Bacterial Prostatitis." Protocol AI420-063, Bristol-Myers Squibb, Wallingford, CT, 1998-2000.
- 145. "Extended Safety and Efficacy Study of DUROS™ Leuprolide Implant in Patients with Prostate Cancer." Protocol C-98-047-03, Alza Corporation, Mountain View, CA 1999-2000.
- 146."A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Comparative, Safety and Efficacy Study of Intravenous Zoledronate (4 and 8 mg) in Prostate Cancer Patients with Metastatic Bone Lesions Receiving Antineoplastic Therapy. Protocol 4244603039, Novartis Pharmaceuticals Corporation, East Hanover, NJ 1998-2000.
- 147. "A Randomized Double-Blind Placebo Controlled Phase III Trial Evaluating Zoledronate Plus Standard Therapy Versus Placebo Plus Standard Therapy in Patients with Recurrent Carcinoma of the Prostate who are Asymptomatic with Castrate Levels of Testosterone and having rising PSA levels without Radiologically-Evident Metastatic Disease." Protocol CZOL 0704, Novartis Pharmaceuticals Corporation, East Hanover, NJ, 1999-2000.
- 148."A Screening Protocol for Identification of Patients with Erectile Dysfunction for Participation in Schering Study POO186 (Twelve Week, Double Blind Efficacy and Safety of Oral Phentolamine, Oral Sildenafil Citrate vs. Placebo for the Treatment of Erectile Dysfunction)." Protocol POO244, Schering-Plough Research Institute, Kenilworth, NJ, 1999.
- 149. A Double-Bind Twelve-Week Comparative Efficacy and Safety Study of Oral Phentolamine Mesylate, Oral Sildenafil Citrate vs. Placebo in Patients with Erectile Dysfunction. Protocol P00186, Novartis Pharmaceuticals Corporation, East Hanover, NJ. 1999.
- 150."A Phase II Open Label Trial of Liposomal Amikacin (MIKASOME®) in Complicated Urinary Tract Infections." Protocol 107-13, NeXstar Pharmaceuticals, Inc., Boulder, CO 1998-1999.
- 151."A Double-Blind, Placebo-Controlled Safety and Efficacy Study of "On Demand" Therapy with IC351 for the Treatment of Male Erectile Dysfunction." Protocol DSD06, ICOS Corporation, Bothell, WA, 1998.
- 152."A Randomized, Double-Blind, Placebo-Controlled Trial of Cernitin for the Treatment of Benign Prostatic Hyperplasia." Protocol 201-697, Richardson Labs, Meridian, ID, 1998-1999.
- 153."An Evaluation on Effect of IC351 on Sperm Concentration in Normal Healthy Subjects or Subjects with Mild Erectile Dysfunction." Protocol H6D-MC-LVCD, Lilly ICOS LLC, Bothell, WA 2000.
- 154. Efficacy and Safety of I.D.D.S. Morphine Sulfate SR B.I.D. Compared to MS Contin Morphine Sulfate B.I.D. in Patients with Moderate to Severe Pain Due to Cancer: A Multicenter, Randomized, Parallel Group, Double Blind Study." Protocol MSU93021/006, I.D.D.S., Inc., Mount Laurel, NJ 1999-2000.
- 155."A Dose-Range Study to Evaluate (S)-Oxybutynin, Placebo and Racemic Oxybutynin When

- Administered to Female Subjects With Unstable Bladder Conditions." Protocol 332-004, Sepracor, Inc., Marlborough, MA 1999-2000.
- 156."A Phase III, Randomized, Multicenter, Placebo-Controlled, Double-Blind Clinical Trial to Study the Efficacy and Safety of CyPat® Cyproterone Acetate [CA] for the Treatment of Hot Flashes Following Surgical or Chemical Castration of Prostate Cancer Patients and Its Impact on the Quality of Life in These Patients." Protocol PCA-301, Barr Laboratories, Pomona, NY, 2000.
- 157. "A Long-Term, Open-Label Clinical Study Evaluating the Safety and Efficacy of ABT-980 in Subjects with Symptomatic Benign Prostatic Hyperplasia (BPH)." Protocol M98-989, Abbott Laboratories, Abbott Park, IL, 2000.
- 158."A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to assess the Safety and Efficacy of Tegaserod 12 mg/d and Placebo in Females with Constipation-Predominant Irritable Bowel Syndrome (C-IBS)." Protocol CHTF919 0358, Novartis Pharmaceuticals, East Hanover, NJ 2000.
- 159." A Double-Blind, Multicenter, Parallel group Study to Compare the Efficacy and Safety of Oral FACTIVE 320 mg Once Daily Versus Oral Levofloxacin 250 mg Once Daily for 10 Days in the Treatment of Pyelonephritis or Complicated Urinary Tract Infections." Protocol: 265805/014, SmithKline Beecham, Collegeville, Pennsylvania, 1999.
- 160. "Study in Patients with Erectile Dysfunction (ED) Comparing Two Different Formulations of Alprostadil (Prostaglandin  $E_1$  Pg $e_1$ ): Alprostadil Sterile Powder (S.PO.) vs Alprostadil/Alpha-Cyclodextrin." Protocol: CTN 98-Dual-001, Pharmacia & Upjohn, Kalamazoo, Michigan 1999.
- 161. "Clinical Efficacy and Tolerability Safety of Tolterodine Prolonged Release Capsules and Tolterodine Immediate Release Tablets vs Placebo. A Randomized, Double-Blind, Placebo-Controlled, Multinational Study in Patients with Symptoms of Overactive Bladder. Protocol: 98-TOCR-007, Pharmacia & Upjohn Kalamazoo, Michigan, 1998-1999.
- 162. "A Six-Month, Two-Part, Sequential, Open-Label, Fixed Dose Study to Evaluate the Safety, Tolerance, Pharmacokinetics and Endocrine Efficacy of Monthly Doses of LA-2500 in Patients with Advanced Prostate Cancer." Protocol AGL9904, Atrix Laboratories, Inc., Fort Collins, CO, 1999-2000.
- 163. "Randomized, Placebo-Controlled, Double-Blind, Parallel Design Trial of the Efficacy and Safety of Alprox TD® in Male Patients with Mild to Moderate Erectile Dysfunction." Protocol 99-002, NexMed, Inc., Robbinsville, NJ, 1999-2000.
- 164. "Double-Blind, Placebo-Controlled, Randomized, Multicenter, Parallel-Group Dose-Ranging Study to Investigate the efficacy and safety of Cilansetron in Non-Constipated Patients with Irritable Bowel Syndrome." Protocol S2412112, Solvay Pharmaceuticals, Marietta, GA, 1998-2000.
- 165. "Double-Blind, Placebo Controlled Long-Term Extension Study to Evaluate the Nine Month Safety Profile of Cilansetron in Non-Constipated IBS Patients." Protocol S2412114, Solvay Pharmaceuticals, Marietta, GA, 1999-2000.
- 166."A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Dose-Ranging Study to Assess the Safety and Efficacy of Daily administration of a Single Oral Dose of YM905 in Male and Female Patients with Urge Urinary Incontinence." Protocol 905-CL-006, Yamanouchi U.S.A, Inc., Paramus, NJ 1999-2000.
- 167. "Prospective, Randomized, Double-Blind Multi-Center, Comparative Trial To Evaluate The Efficacy and Safety of Ciprofloxacin Once Daily (QD) Modified Release (CIPRO MR) Tablets 1000 mg Versus Conventional Ciprofloxacin 500 mg Tablets BID in the 7-14 Day Treatment of Patients With Complicated Urinary Infections (cUTI) or Acute, Uncomplicated Pyelonephritis." Protocol 100275, Bayer Corporation, West Haven, CT, 2001-2002.
- 168. "Double-Blind, Placebo Controlled Study of Sustained Release (S)-Oxybutynin in Subjects with Symptoms of Overactive Bladder of Urgency, Frequency and Urinary Incontinence." Protocol 332-146, Sepracor, Inc., Marlborough, MA 2001.
- 169. "Open-Label Extension Study of Sustained Release (S)-Oxybutynin in Subjects with Symptoms of Overactive Bladder." Protocol 332-151, Sepracor, Inc. Marlborough, MA 2001.
- 170. "Prospective, Randomized, Double-Blind Study Comparing Faropenem Daloxate 300 mg PO BID for five days with Trimethoprim/Sulfamethoxazole 160/800 mg PO BID for five days in the treatment of patients with acute, uncomplicated lower urinary tract infections." Protocol 100286, Bayer Inc., West Haven, CT 2001.

- 171."A Phase III, Multicenter, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of Controlled Release Darifenacin Versus Tolterodine in the Treatment of Subjects with Overactive Bladder." Protocol A1371001, Pfizer, Inc., New London, CT, 2000-2001.
- 172."A Phase III Multi-Center, Open Label, Continuation Study of the Long-Term Safety, Toleration, Compliance and Efficacy of Controlled Release Darifenacin in Subjects with Overactive Bladder." Protocol A1371014. Pfizer, Inc., New London, CT, 2001.
- 173."A Multicenter, Fixed Dose Study with a Double-Blind, Randomized, Placebo-Controlled. Parallel Group Phase, and an Open Label Phase, to Investigate the Time to Onset of Activity of Viagra® (sildenafil citrate)." Protocol A1481122, Pfizer Inc., New York, NY, 2001-2002.
- 174. "Radiofrequency Energy Delivery to the Submucosa of the Bladder Outlet and Proximal Urethra for the Treatment of Stress Urinary Incontinence." Protocol 145-1384, Novasys Medical, Inc., Newark, CA., 2002.
- 175."A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study Comparing Oxybutynin Transdermal Systems versus Tolterodine Long Acting Capsules in Patients with Overactive Bladder." Watson Laboratories, Inc., Salt Lake City, UT, 2001 - 2002.
- 176, "A Multicenter, Double-Blind, Placebo-Controlled study of 20 mg, Twice Daily Trospium Chloride for 12 Weeks Followed by a 9-Month Open-Label Treatment Phase in Patients with Overactive Bladder." Protocol IP631-003, Interneuron Pharmaceuticals, Inc., Lexington, MA, 2001 - 2003.
- 177. A Multicenter, Open-Label Study of 20 mg, Trospium Chloride, Twice Daily, For Up To 9 Months To Characterize The Population Pharmacokinetics In Patients With Overactive Bladder Participating In The Open-Label Treatment Phase of Study IP631-003." Protocol IP631-004, Indevus Pharmaceuticals, Inc. (formerly Interneuron Pharmaceuticals, Inc.), Lexington MA 2002 - 2003.
- 178."A Single-Arm, Open Label Phase IV Study of Viadur™ (leuprolide acetate implant) in Community-based Patients with Advanced Prostate Cancer." Protocol 100331, Bayer Corporation, West Haven, CT, 2000 -2002.
- 179. "An Open-Label Comparison of Neoadjuvant Hormonal Therapy (NHT) with Abarelix Depot 100 mg IM or Lupron Depot® 7.5 mg IM in Patients with prostate Cancer Planned to Undergo Brachytherapy or External-beam Radiation Therapy." Protocol 200000170/149-01-03, Amgen Inc. & Praecis Pharmaceuticals, Inc., Waltham, MA, 2001 – 2002.
- 180."A Randomized Clinical Trial Comparing Goserelin Acetate (ZOLADEX™) 3.6-mg Depot and Goserelin Acetate (ZOLADEX) 10.8-mg Depot in Subjects with Prostate Cancer for Whom Hormonal Therapy is Indicated." Protocol 9393IL/0028, AstraZeneca, Mississauga, Ontario, Canada, 2000 - 2001.
- 181."A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study to Assess Efficacy and Safety of Daily Oral Administration of 10 mg YM905 Versus Placebo in Male and Female Subjects with Overactive Bladder." Protocol 905-CL-014, Yamanouchi USA Inc., Paramus, NJ, 2000 -2002.
- 182. "An Open-Label, Long-Term Tolerability Study of Daily Oral Administration of 10 Mg YM905 (Solifenacin Succinate) in Male and Female Subjects with Overactive Bladder." Protocol 905-CL-016 Yamanouchi USA Inc., Paramus, NJ, 2001.
- 183."A Randomized, Double-Blind, Parallel, Placebo-Controlled study to Evaluate the Efficacy and Safety of IC351 Administered "On Demand" to Men with Erectile Dysfunction." Protocol H6D-MC-LVEF, Lilly Research Laboratories, Indianapolis, IN, 2001.
- 184. "Comparison of the Efficacy and Tolerability of Ditropan XL® and Detrol® LA in the Treatment of Overactive Bladder." Protocol C-2001-019, Alza Corporation, Mountain View, CA 2001.
- 185. "Randomized, Double-Blind, Placebo-Controlled, Dose-finding study to Evaluate the Effects of a Partial Alpha 1A/1L Adrenoceptor Agonist, Ro115-1240, in women with Stress Urinary Incontinence and Mixed Urinary Incontinence." Protocol NN16378, Roche Global Development, Nutley, NJ 2001 - 2004.
- 186. "Open -Label Extension for Treatment of Incontinent Patients Who Have Completed a Ro115-1240 Study. Protocol NN16586, Hoffman-LaRoche, Inc. Nutley, NJ, 2002 - 2004.
- 187."A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase II Clinical Trial to Evaluate the Efficacy and Safety of Two Dosing Regimens of ML-04A in Subjects with

- Symptomatic Benign Prostatic Hyperplasia." Protocol ML-BPH-01, Milkhaus Laboratory, Inc., Providence, Rhode Island, 2001-2003
- 188."An Evaluation on Effect of 20 mg IC351 on Sperm Concentration in Normal Healthy Subjects or Subjects with Mild Erectile Dysfunction." Protocol H6D-MC-LVCZ Lilly ICOS LLC, Indianapolis, IN, 2000 -2001.
- 189. A Double-Blind Placebo-Controlled, Parallel-Group Safety and Efficacy Study Evaluating Three Dose Regimens of A10-8507L, A Selective Alpha-Adrenergic Antagonist, in the Treatment of Benign Prostatic Hyperplasia. Protocol AIO-8507L, Ono Pharmaceuticals, Co., Ltd., Osaka, Japan, 2001 –2002.
- 190."A Multicenter, Phase IIb, Four Arm, Dose Finding, Randomized, Placebo-Controlled Study to Determine the Long Term Prostate Cancer Chemoprevention Efficacy and Safety of 20 mg, 40 mg, & 60 mg Daily of GTx-006 in Men with High Grade Prostate Intraepithelial Neoplasia (PIN)." Protocol GTX-006-211, GTx, Inc., Memphis, TN 2001-2002.
- 191."A Randomized, Double-Blind, Placebo-Controlled, Dose Finding, Multicenter Study to Assess the Efficacy, Safety and Tolerability of Tegaserod Given Orally at Three Dose Levels (1.5 mg, 6 mg or 18 mg) and Placebo in Patients with functional Dyspepsia (FD) and Documented Normal Gastric Emptying." Protocol CHTF919D2204, Novartis Pharmaceuticals Corporation, East Hanover, NJ 2002-2002.
- 192."A Prospective, Randomized, Comparative Parallel Group Study of Coaptite and Contigen for Urethral Sphincter Augmentation in the Treatment Stress Incontinence In A Female Population." Protocol PO400028, BioForm, Inc., Franksville, WI, 2001-2005.
- 193."A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study Assessing the Efficacy and of MK-0869 in Postmenopausal Women with Urinary Incontinence." Protocol 079-00, Merck & Company Inc., Whitehouse Station, NJ, 2002.
- 194."A 12 Month, Open-Label, Fixed-Dose Study to Evaluate the Safety, Tolerance, Pharmacokinetics, and Endocrine Efficacy of Two Doses of LA-2580 45 mg in Patients with Advanced Prostate Cancer. Protocol AGL0205, Atrix Laboratories, Inc., Fort Collins, CO, 2002.
- 195."A Multi-Center, Double-Blind, Placebo-Controlled, Dose-Titration Study of Oxybutynin Transdermal Systems in Patients with Overactive Bladder." Protocol 002005, Watson Laboratories, Inc., Salt Lake City, Utah, 2003.
- 196."A Multicenter, Randomized, Parallel Group, Double-Blind, Placebo Controlled, Flexible Dose Escalation Study To Evaluate Sexual And Relationship Satisfaction In The Female Partner of Men With Erectile Dysfunction Treated With Viagra® (Sildenafil Citrate) In The United States." Protocol A1481177, Pfizer, Inc., New York, New York, 2003 2004.
- 197. "The Efficacy, Onset Of Effect, And Safety Of Benign Prostatic Hyperplasia: A Randomized Placebo-Controlled Trial Using An Acute International Prostate Score (Alf-Acute)." Protocol L8472 (ALF-ACUTE), Sanofi-Synthelabo, Inc., New York, New York, 2002.
- 198."A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating the Efficacy and Safety of Vardenafil Administered for 12 Weeks in a Flexible-Dose Regimen Compared to Placebo in Male Erectile Dysfunction Subjects of Broad Etiology Previously Unresponsive to Sildenafil Therapy by History." Protocol SB-782528-001, GlaxoSmithKline Pharmaceuticals, King of Prussia, 2002 2003.
- 199."A Phase 3B, Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study of Darifenacin in Subjects with Overactive Bladder." Protocol A1371047, Pfizer, Inc., New London, Connecticut, 2002-2003.
- 200."A Long-Term, Open Label, Multicenter Study of Darifenacin in Subjects with Overactive Bladder." Protocol A1371042, Pfizer, Inc., New London, Connecticut, 2002-2004.
- 201. "An Open-Label Trial on the Effect of I.V. Zometa 4 mg on Bone Mineral Density in Hormone Sensitive Prostate Cancer Patients with Bone Metastasis." Protocol CZOL446EUS24, Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 2002-2003.
- 202. "The Effect of Zometa Compared to Placebo on Bone Mineral Density in Patients Undergoing Androgen Deprivation Therapy." Protocol CZOL 446G US45, Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 2003 -2005
- 203."A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study of the Efficacy and Safety of Dutasteride 0.5 mg Administered Orally Once Daily for Four Years to Reduce the Risk of Biopsy-Detectable Prostate Cancer." Protocol ARI40006, GlaxoSmithKline, King of

- Prussia, Pennsylvania, 2003.
- 204. "Cipro® XR Excellence in Therapeutic Response and Activity (eXtRa) Assessing Symptom Relief in Urinary Tract Infections." Protocol 100544, Bayer Pharmaceuticals Corporation, West Haven, Connecticut, 2003-2004.
- 205."A Placebo-Controlled, Double-Blind, Randomized, Parallel Study of Efficacy and Safety of Dapoxetine HCl in the Treatment of Rapid Ejaculation." Protocol C-2002-012, Alza Corporation, Mountain View, California, 2002-2003.
- 206. "An open Label Study of the Long-term Safety of Dapoxetine HCI in the Treatment of Rapid Ejaculation." Protocol C-2002-014, Alza Corporation, Mountain View, California, 2003.
- 207. A Placebo-Controlled, Randomized, Double-Blind, Parallel-Group, Dose-Finding, At-Home Study to Evaluate the Efficacy and Safety of Intranasally Administered PT-141 in Subjects with Male Erectile Dysfunction. Protocol PT-141-2003-15, Palatin Technologies, Inc., Cranbury, New Jersey, 2003.
- 208."A Multicenter, Open Label, Flexible Dose Study to Investigate the Use of Patterns of Viagra® (sildenafil citrate) and the Ability of Investigators to Further Optimize Subject Satisfaction with Viagra® Through Customized Instruction." Protocol A1481179, Pfizer, Inc., New York, NY, 2003 2004.
- 209. "The Safety of Eszopiclone on Sperm Motility in Healthy Male Subjects." Protocol 190-029, Sepracor, Inc., 2003-2004.
- 210. "A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate AMG 162 in the Treatment of Bone Loss in Subjects Undergoing Androgen-Deprivation Therapy for Non-Metastatic Prostate Cancer." Protocol 20040138, Amgen, Thousand Oaks, CA 91320, 2004-2005.
- 211. "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of AZD 7371 in Patients 18-70 Years of Age with Symptoms of Overactive Bladder (GOBI Study)." Protocol D1801C00001, AstraZeneca, LP, Wilmington, DE, 2004-2005.
- 212. "Prospective, open label, non-comparative, multi-center study to evaluate the efficacy and safety of ciprofloxacin extended-release (Cipro XR) 1000 mg tablets given once daily for 7 to 14 days in the treatment of patients 18 years or older with complicated urinary tract infections caused by *Pseudomonas aeruginosa* and other common uropathogens." Protocol 11490, Bayer Pharmaceuticals Corporation, New Haven, CT, 2004-
- 213."A Protocol for Blood and Urine Sample Collection from Urologically Referred Subjects being evaluated for the Presence of Prostate Cancer and Other Prostate Conditions and Diseases to Aid in the Study of *in vitro* Diagnostic Devices." Protocol UREF COLL, Diagnostic Oncology CRO, Inc., Seymour, CT 2005-
- 214. "Multicenter, Randomized, Double-Blind, Study to Evaluate the Safety and Efficacy of Oxybutynin Vaginal Ring Releasing 4 Mg/Day versus 6 Mg/Day versus Placebo in Women Diagnosed with Overactive Bladder Who Have Symptoms of Predominant or Pure Urge Incontinence, Urgency and Frequency." Protocol BR-OXY-202, Duramed Research, Inc., Bala Cynwyd, PA, 2004.
- 215. "An Open-label, Randomized, Multi-center, Parallel Group Comparison of the Efficacy and Safety of Degarelix at Two Different Dosing Regimens in Patients with Prostate Cancer Dosed for Thirteen 28-day Cycles." Protocol FE200486 CS14, Ferring Pharmaceuticals, Inc., Suffern, NY, 2004 –2005.
- 216. "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Study of Toremifene Citrate for the Prevention of Prostate Cancer in Men with High Grade Prostatic Intraepithelial Neoplasia (PIN)." Protocol G300104, GTx, Inc., Memphis, TN 2004-
- 217. "A Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety Study of Toremifene Citrate for the Prevention of Bone Fractures in Men with Prostate Cancer on Androgen Deprivation Therapy," Protocol G300203, GTx, Inc. Memphis, TN, 2003 2005.
- 218."A Placebo-Controlled, Double-Blind, Randomized, Parallel Study of the Withdrawal Effects of Chronic Daily and As Needed Dosing with Dapoxetine in the Treatment of Premature Ejaculation." Protocol R096769-PRE-3002, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., Raritan, NJ, 2004—2005.
- 219. "An Evaluation of Semen Characteristics after 40 Weeks Daily dosing with 20 mg Tadalafil."

- Protocol H6D-MC-LVFE, Lilly ICOS LLC, Bothell, WA, 2003-2005
- 220."A Randomized, Double-Blind, Parallel, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Tadalafil (2.5 mg and 5 mg) Administered Once Daily to Men with Erectile Dysfunction." Protocol H6D-MC-LVFP, Lilly ICOS LLC, Bothell, WA, 2003 —
- 221."A Multicenter, Parallel-Arm, Placebo-Controlled, Double-blind Study to Evaluate the Efficacy and Safety of Tadalafil Administered Once Daily to Men with Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia." Protocol H6D-MC-LVGC, Bothell, WA 2004-2005
- 222. "Long Term Monitoring of Safety in Subjects Treated with Duloxetine for Stress Urinary Incontinence." Protocol F1J-MC-SBAY, Eli Lilly & Company, Indianapolis, IN, 2004-
- 223."A Placebo-Controlled Study Evaluating the Safety and Efficacy of Oxybutynin Chloride 3 mg and 5 mg in Women with Overactive Bladder." Protocol 14-101, McNeill Consumer & Specialty Pharmaceuticals, Fort Washington, PA, 2003 2005
- 224."A 12-week, randomized, open-label, parallel-group, multicenter study to evaluate the efficacy, safety and tolerability of Enablex® (darifenacin) (with voluntary up-titration from 7.5 mg o.d. to 15 mg o.d. at week 2) alone or in combination with Behavioral Modification Program for symptoms of overactive bladder." Protocol CDAR328AUS01, Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, 2005
- 225."A Phase III, Open-Label, Multicenter, Safety and Efficacy study of Oakwood Laboratories' Leuprolide Acetate for Injectable Suspension 22.5 mg in Patients with Advanced Prostate Cancer." Protocol OL-007, Oakwood Village, OH, 2004 2005
- 226."A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Effects of Rofecoxib in Decreasing the Risk of Prostate Cancer (VIP)." Protocol 201, Merck & Co., Whitehouse Station, NJ 2004
- 227. "A Multicenter, Double-Blind, Randomized Study to Compare the Efficacy and Safety of Levofloxacin 750 mg Once Daily for Five Days versus Ciprofloxacin Twice Daily for Ten Days in the Treatment of Complicated Urinary Tract Infection or Acute Pyelonephritis." Protocol CAPSS-349, Ortho-McNeil Pharmaceutical, Inc., Raritan, NJ, 2004.
- 228."A Randomized, Double-Blind, Placebo Controlled, Four Arm (Placebo, Tolterodine ER, Tamsulosin, and Tolterodine ER Plus Tamsulosin) Study to Evaluate the Clinical Efficacy and Safety of Tolterodine ER 4 mg in Men Who Have Frequency and Urgency, With or Without Urinary Urge Incontinence, With or Without Bladder Outlet Obstruction." Protocol A6121120, Pfizer, Inc., New York, NY, 2004.
- 229. "A Multicenter, Randomized, Parallel Group, Double-blind, Placebo Controlled Flexible Dose Study with an Open-Label Extension to Assess the Efficacy and Safety of Viagra® (sildenafil citrate) in the Treatment of men with Erectile Dysfunction (ED) AND Concomitant Lower Urinary Tract Symptoms (LUTS) Associated with Benign Prostatic Hyperplasia (BPH) in the United States." Protocol A1481217, Pfizer, Inc, New York, NY, 2004
- 230. "Evaluation of Patients Who Have Completed More Than 180 Days of Active Treatment with Ro 115-1240." Protocol NU18191, Hoffman-LaRoche, Inc. Nutley, NJ, 2005
- 231.A Phase 2 Randomized, Double-Blind, Dose-Ranging Efficacy and Safety Study of SCH446132 (10 Mg, 25 Mg, 50 Mg,), Sildenafil Citrate (50 Mg) Each Vs. Placebo in Subjects With Erectile Dysfunction." Protocol P03704, Schering-Plough Research Institute, Kenilworth, NJ 07033, 2004 –2005.
- 232. "A Phase 3, Parallel Group, Randomized, Double-Blind, Placebo Controlled Multicenter Trial to Investigate the Efficacy, Tolerability and Safety of Fesoterodine Sustained Release in Subjects with Overactive Bladder Syndrome." Protocol SP584, Schwarz Biosciences, Inc. Research Triangle Park, NC, 2003-2005
- 233. "Long-Term Open-Label Extension Trial for Subjects completing the Phase 3 Trial of Fesoterodine (SP584) for the treatment of Overactive Bladder Syndrome." Protocol SP739, Schwarz Biosciences, Inc. Research Triangle Park, NC, 2004-2005
- 234. "A Double-Blind, Randomize, Evaluation of the Safety and Efficacy of TA-1790 in Subjects with Erectile Dysfunction." Protocol TA-05, Vivus, Inc., Mountain View, CA 2004 2005
- 235."A Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel Evaluation of the Efficacy and Safety of Silodosin in the Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia." Protocol SI04010, Watson Laboratories, Inc. Salt Lake City, UT, 2005
- 236."A Phase 2, Randomized, Multicenter, Placebo-Controlled, Double-Blind, Dose-Ranging

- Clinical Trial To Study The Efficacy and Safety of 5, 15, or 25 mg/day CyPat™ (Cyproterone Acetate) for the Treatment of Hot Flashes Following Surgical or Medical Castration of Prostate Cancer Patients." Protocol DR-PCA-201, Duramed Research, Bala Cynwyd, PA, 2005.
- 237. "Evaluation of the Survivin Urine mRNA Assay to Estimate Risk of Bladder Cancer Found on Cystoscopy." Protocol FDI-01, Fujirebio Diagnostics, Inc., Malvern, PA, 2005.
- 238." A Twelve-Week Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Forced Titration, Proof of Concept Study to Assess the Efficacy, Safety and Tolerability as well as the Pharmacokinetic Profile of 60 mg and 120 mg of GW679769 Administered Once Daily vs Placebo in Women with Overactive Bladder." Protocol NKB105022, The GlaxoSmithKline Group of Companies, King of Prussia, PA, 2005.
- 239.A Multi-Center, Double-Blind Placebo Controlled, Flexible-Dose Study with and Open-Label Phase to Assess the Efficacy of Sildenafil Citrate on Erectile Function and Intercourse Satisfaction as well as to Validate the Sexual Experience Questionnaire and its Treatment Responsiveness in Men with Erectile Dysfunction." Protocol A1481236, Pfizer, Inc, New York, NY.
- 240. "A Randomized, Double-Blind, Placebo-Controlled, Dose Comparison Study of the Efficacy and Safety of Lonidamine for the Treatment of Symptomatic Benign Prostatic Hyperplasia." Protocol TH-CR-203, Threshold Pharmaceuticals, Inc, Redwood, CA, 2005.
- 241. A Multi-Center, Open-Label Evaluation of the Safety of Silodosin in the Treatment of the signs and Symptoms of Benign Prostatic Hyperplasia. Protocol SI04011, Watson Laboratories, Inc., Salt Lake City, UT, 2005.
- 242. "A Double-Blind, Multi-Center, International (US and Europe), Randomized, Placebo-Controlled Study of Safety and Efficacy of Trospium Chloride 60 mg Modified Release Capsules versus Placebo, Once Daily, for 12 Weeks Followed by a 9-Month, Open-Label Treatment Phase in Patients with Overactive Bladder." Protocol IP631-018, Indevus Pharmaceuticals, Inc. Lexington, MA, 2005.
- 243. "A Randomized, Placebo-Controlled, Double-Blind, Parallel Design Phase 2 Dose Ranging Trial to Assess the Safety and Efficacy of DA-8159 Tablets in Male Subjects with Erectile Dysfunction." Protocol DA-2005-001, Dong-A PharmTech, Co., Seoul, Korea, 2005.
- 244. "Ablatherm Integrated Imaging High Intensity Focused Ultrasound for the Indication of Low Risk, Localized Prostate Cancer." Protocol G050103, EDAP TMS S.A., Lyon, France, 2006.
- 245. "Phase III Multicenter Prospective Randomized Parallel-Group Placebo-Controlled Double Blind Clinical Evaluation of NX-1207 for the Treatment of BPH NX02-0018," Protocol NX02-0018, Nymox Corporation, Hasbrouck Heights, NJ, 2009.
- 246.PRX302-2-08 A Multi-Centre, Open Label, Phase IIb Study, Evaluating the Safety, Tolerability and Efficacy of Targeted Intraprostatic Administration of PRX302 to Treat Men with Histologically Proven, Clinically Significant, Localised, Low- to Intermediate-Risk Prostate Cancer that is Associated with an MRI Lesion. Sophiris, La Jolla, CA, 2017.

### **MEMBERSHIPS**

- American Medical Association
- · Florida Medical Association
- Marion County Medical Society
- American Urologic Association
- Southeastern Section American Urologic Association
- American Lithotripsy Society
- Florida Urologic Society
- American College of Surgeons
- European Association of Urology
- American Association of Clinical Urologists