## **CURRICULUM VITAE**

### NAME:

Edward A. Zbella, M.D., CPI, FACOG, FACS

#### **PLACE OF BIRTH:**

Chicago, Illinois

## **BUSINESS ADDRESS/PHONE:**

Edward Zbella, M.D.

Florida Fertility Institute 2454 McMullen Booth Road, Suite 601 Clearwater, FL 33759 (727) 796-7705

Women's Medical Research Group, LLC 2454 McMullen Booth Road, Suite 609 Clearwater, FL 33759 (727) 724-9730

Florida Clinical Research Group 2454 McMullen Booth Road, Suite 610 Clearwater, FL 33759 (727)-724-9730

# **EDUCATION:**

## **UNDERGRADUATE:**

Illinois Benedictine College 5700 College Road Lisle, Illinois 60532 1972-1976

Major: Biochemistry

Degree: Bachelor of Science

# **GRADUATE:**

Abraham Lincoln School of Medicine The University of Illinois P.O. Box 5220, MC 503 Chicago, Illinois 60680 1976-1980

Degree: Doctorate of Medicine

Resident in Obstetrics and Gynecology

The University of Chicago 5841 S. Maryland Ave., MD 2050 Chicago, Illinois 60637 1980-1982, Chairman - Arthur Herbst, M.D.

Resident in Obstetrics and Gynecology

Mount Sinai Hospital Medical Center California Avenue at 15<sup>th</sup> Street Room F208 Chicago, Illinois 60608 1982-1984, Chairman - Norbert Gleicher, M.D. 1983-1984, Chief Resident 1983-1984, Chief Administrative Resident

Fellow in Reproductive Endocrinology

Michael Reese Hospital & Medical Center 2929 South Ellis Chicago, Illinois 60616 1984-1986, Chairman - Antonio Scommegna, M.D.

## PROFESSIONAL APPOINTMENTS:

Founder/Medical Director Florida Fertility Institute 2000-present

Chief of Staff, Women's Medical Center Seminole, Florida, 1989-1992

Director, Division of Gynecology Department of Obstetric and Gynecology Women's Medical Center, Seminole, Florida 1989-1994

Chairman, Laser Committee Women's Medical Center, Seminole, Florida 1989-1994 Faculty, Laser Centers of America Cincinnati, Ohio, 1990-1997

Member, Laser Committee Palms of Pasadena Hospital, St. Petersburg, FL 1990-1992

Medical Director Florida Cryobank, Seminole, Florida 1989-1997

Faculty, Department of Obstetrics and Gynecology - Bayfront Medical Center Director, Division of Reproductive

Endocrinology and Infertility 1991-present

Member, Clinical Improvement Committee Department of Obstetrics and Gynecology Bayfront Medical Center 1989-present

Member, Physician Advisory Council Community Health Systems Nashville, Tennessee, 1989-1992

Medical Director, Obstetrics and Gynecology Services AvMed Health Plan, Tampa Bay Area 1992-1996

Regional Medical Director CHR-Florida, 1996-2000

Senior Vice President GynCor, Inc., 1996-2000

Assistant Clinical Professor
Department of Obstetrics and Gynecology
University of South Florida
Tampa, Florida
1998-2010

Medical Director Women's Medical Research Group, LLC Clearwater, Florida 2003-present

Chief Medical Officer Medi Weight Loss Clinics Clearwater, Florida 2007-present

Clinical Professor Department of Obstetrics and Gynecology Ross University Miami, Florida 2013-present

# **MEDICAL LICENSURE:**

Florida – 48354

## **MEMBERSHIPS:**

American College of Obstetrics and Gynecology

American Fertility Society

Society of Reproductive Surgeons

Society for Reproductive Endocrinologists

American Association of Gynecologic Laparoscopists

Florida Society of Reproductive Endocrinologists

**Endocrine Society** 

Florida Obstetrics and Gynecology Association

Society of Laparoendoscopic Surgeons

The Obesity Society

# **SPECIALTY BOARDS:**

American Board of Obesity Medicine (Formerly ABBM), 2011 APPI: Certified Principle Investigator (CPI) 9/08/2007 Re-Certified 2011

Board Certified, American Subspecialty
Examination in Reproductive Endocrinology and
Infertility, 1988
Re-certified, 1997
Maintenance of Certification, Yearly
Fellow, American College of Surgeons, 1988
Board Certified, American Board of Obstetrics and
Gynecology, 1987
Re-certified, 1997
Maintenance of Certification, Yearly

Diplomat, American Board of Medical Examiners, 1981

## **AWARDS AND HONORS:**

Fellow, American College of Obstetrics and Gynecology

The Abbie Norman Prince Award of Merit from the Mt. Sinai Hospital Medical Center

American Association of Gynecologic Laparoscopist's Outstanding Resident in Gynecologic Endoscopy Award

The Physician Recognition Award of the American Medical Association

Junior Fellow Research Award Illinois Section of the American College of Obstetrics and Gynecology

#### PRESENTATIONS:

The Significance of the Class II PAP Smear in a High Risk Population. The American Society for Colposcopy and Cervical Pathology and the Gynecological Laser Society Combined Meeting; Orlando, Florida, March 7-10, 1984

The Significance of the Class II PAP Smear in a High Risk Population. The Chicago Gynecological Society Inaugural Thesis; Chicago, Illinois, May 18, 1984

- 3. The New Approach and Treatment of Premature Ovarian Failure. Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois, March 14, 1985
- 4. Study on Estradiol and Estriol Secretion by Cultured Human Choriocarcinoma (JEG-3) Cells Suggests a Single Aromatase Converting System. Chicago Association of Reproductive Endocrinologists, May 27, 1985

Study of Estradiol and Estriol Secretion by Cultured Human Choriocarcinoma (JEG-3) Cells Suggests a Single Aromatase Converting System. The Endocrine Society Annual Meeting, Baltimore, Maryland, June 20, 1985

- 6. Estrogen Steroidogenesis in Cultured Human Choriocarcinoma Cells (JEG-3) Suggests a Single Aromotase Converting System. District VI meeting of the American College of Obstetricians and Gynecologists, Milwaukee, Wisconsin, September 26, 1986
- 7. Precocious Puberty. Grand Rounds, Michael Reese Hospital and Medical Center, Chicago, Illinois, May 15, 1986
- 8. Puberty. Grand Rounds, University of Florida, Gainesville, Florida, April, 14, 1987
- 9. In Vitro Fertilization. Grand Rounds, Palms of Pasadena Hospital, St. Petersburg, Florida, July 15, 1987
- 10. Precocious Puberty. Grand Rounds, Mount Sinai Hospital and Medical Center, Chicago, Illinois, December 7, 1987
- 11. Alternative Reproductive Technology. Grand Rounds, Humana Hospital St. Petersburg, St. Petersburg, Florida, January 16, 1988
- 12. Estrogen Replacement Therapy. Grand Rounds, Humana Hospital Orlando, Orlando, Florida, February 16, 1988

13. GNRH Analogues in Gynecology. Grand Rounds, Palms of Pasadena Hospital, St. Petersburg, Florida, September 8, 1988

GNRH Analogues in Gynecology. Grand Rounds, Manatee County Hospital, Bradenton, Florida, November 15, 1988

- 15. Infertility Treatments 1989. Grand Rounds, Morton Plant Hospital, Clearwater, Florida, January 1989
- 16. Operative Laproscopy. CO2 Laser and Pelviscopy. Instructor, HCA Northwest Regional Hospital, Margate, Florida, May 11-12, 1989
- 17. Lasers in Gynecology. Instructor, Palms of Pasadena Hospital, St. Petersburg, Florida, May 26-27, 1990
- 18. Lasers in Gynecology. Instructor, Borgess Hospital, Kalamazoo, Michigan, June 23-24, 1990
- 19. Advanced Reproductive Technologies. Grand Rounds, Lee Memorial Hospital, Fort Myers, Florida, August 30, 1990
- 20. The Great Baby Chase. Nursing Seminar, Women's Medical Center, Seminole, Florida, August 25, 1990
- 21. The SLT Laser in Gynecology. Instructor, Bayfront Medical Center, St. Petersburg, Florida, September 15, 1990
- 22. Lasers in Gynecology. Instructor, Tampa Outpatient Surgery Center, Tampa, Florida, August 10, 1991
- 23. Laparoscopic Myomectomy. Instructor, Tampa Outpatient Surgery Center, Tampa, Florida, August 10, 199
- 24. Laparoscopic Assisted Vaginal Hysterectomy. Instructor, Tampa Outpatient Surgery Center, Tampa, Florida, August 10, 1991
- 25. Laparoscopic Treatment of Ectopic Pregnancy and Endometriosis. Instructor, Binghamton General Hospital, Binghamton, New York, August 24, 1991
- 26. Laparoscopic Lysis of Pelvic Adhesions and Appendectomy. Instructor, Binghamton General Hospital, Binghamton, New York, August 24, 1991

- 27. Lasers in Laparoscopy and Hysterectomy. Instructor, Overlook Hospital, Summit, New Jersey, September 22, 1991
- 28. Laparoscopic Assisted Vaginal Hysterectomy. Instructor, Butterworth Hospital, Grand Rapids, Michigan, January 12, 1992
- 29. Laparoscopic Assisted Vaginal Hysterectomy. Instructor, Indian Path Hospital, Kentucky, February 15, 1992

Endometriosis and Pelvic Pain. Endometriosis Symposia, Town and Country Hospital, Tampa, Florida, May 6, 1992

- 31. Laparoscopic Presacral Neurectomy. (Video) American College of Obstetrics and Gynecology Annual Meeting, Las Vegas, Nevada, April 28, 1992
- 32. Rupture of Benign Cystic Teratoma During Laparoscopy Does It Matter? American Association of Gynecologic Laparoscopists Annual Meeting, Chicago, Illinois. September 25, 1992
- 33. Supracervical Hysterectomy. American Association of Gynecologic Laparoscopists Annual Meeting, Chicago, Illinois, September 25, 1992
- 34. Presacral Neurectomy. American Association of Gynecologic Laparoscopists Annual Meeting, Chicago, Illinois, September 26, 1992
- 35. Surgery Versus Tubal Cannulation; The Pathology of Tubal Disease. American College of Surgeons Clinical Congress, October 13, 1992
- 36. Affect of Intrafollicular Insemination on the Formation of Sperm Antibodies. American College of Obstetricians and Gynecologists, District IV Meeting, San Juan, Puerto Rico, November 13, 1992
- 37. Gamete Intrafollicular Insemination Transfer as Treatment for Infertility Associated with Endometriosis. American College of Obstetricians and Gynecologists, District IV Meeting, San Juan, Puerto Rico, November 13, 1992
- 38. Chronic Pelvic Pain. Controversies in Gynecology, Meeting, University of Illinois and Bayfront Medical Center Combined Conference, St. Petersburg, Florida, February 12, 1993
- 39. Hysterectomy: Abdominal, Vaginal, Laparoscopic. Controversies in Gynecology Meeting, University of Illinois and Bayfront Medical Center Combined Conference, St. Petersburg, Florida, February 12, 1993

- 40. Operative Indications and Techniques for the KTP laser. Huntsville Hospital and the UAH School of Primary Medical Care, Huntsville, Alabama, May 15, 1993
- 41. Managed Care The Physician View. The American Association of Gynecologic Laparoscopists Annual Meeting, Chicago, Illinois, September 27, 1996
- 42. Evaluation of QD vs BID dosing of gonadotropins in patients undergoing IVF. 55<sup>th</sup> Annual Meeting at the Pacific Coast Reproductive Society; Rancho Mirage, California; April 18-22, 2007
- 43. Clinical Comparison of Ovarian Stimulation and Luteal Support Agents in Patients Undergoing GnRH Antagonist IVF Cycles. 66<sup>th</sup> Annual Meeting of American Society for Reproductive Medicine, Denver, Colorado, October 23, 2010
- 44. Pregnancy Outcome for Women with Endometriosis Undergoing IVF with Luteal Phase Support via Vaginal Gel: Pacific Coast Fertility Society, Palm Springs, CA, April 20, 2013

## **PUBLICATIONS:**

Deppe G, Zbella EA, Skorgerson K, Dumitru I: The rare indication for splenectomy as part of cytoreductive surgery in ovarian cancer. Jour Gynecol Oncol 16 (2): 282-287, 1983

Zbella EA, Deppe G, Elrad H: Gonococcal arthritis in pregnancy. Ob Gyn Sur 39 (1): 8-12, 1984

Deppe G, Zbella EA, Wall D: Outpatient cone biopsy of the cervix-surgical technique. Surg Gyn Ob 158 (6): 552-554, 1984

Deppe G, Zbella EA, Friberg J, Thomas W: Combination chemotherapy for mixed mullerian tumor of the fallopian tube. Cancer 54: 1517-1520, 1984

Zbella EA, Vermesh M, Friberg J, Deppe G: Coexistent Hydatidiform mole and fetus following human menopausal therapy. J Reprod Med 2 (10): 760-762, 1984

Deppe G, Zbella EA, Wall D, Dumitru I, Liu TL: Postmenopausal bleeding secondary to colorectal cancer. Am J Proct Gastroent Colon Tect Surg 36 (6): 13-16, 1984

Deppe G, Zbella EA, Malviya V, Pildes R: Limb Salvage in recurrent vulvar carcinoma after rupture of femoral artery. J Gynecol Oncol 19: 120-124, 1984

Deppe G, Zbella EA: Chemotherapy in endometrial cancer - A review. Wein Klin Wochenschr 96 (20): 747-756, 1984

Zbella EA, Vermesh M, Tiemstra J, Elrad H: Phenothiazines in pregnancy. Perinatology Neonatology (in press)

Zbella EA, Nemec L, Vermesh M: Vaginal douching pros, cons and proper technique. Postgrad Med 76 (8): 93-97, 1984

Vermesh M, Deppe G, Zbella EA: Nonpurpueral traumatic vulvar hematoma. Int J Gynecol Obstet 22: 217-219, 1984

Deppe G, Dolan T, Zbella EA: Synchronous multiple neoplasms of the breast, colon and vulva. J Reprod Med 29 (12): 878-880, 1984

Zbella EA, Scommegna A: Premature Menopause. Med Aspects Human Sexual March, 118-123, 1986

Zbella EA, Moise J, Carson SA: Noncardiogenic pulmonary edema secondary to intrauterine instillation of 32% Dextran 70. Fertil Steril 43 (3): 479-780, 1985

Confino E, Zbella EA, Eldayam U, Gleicher N: Cardiac drugs in pregnancy Drug Therapy March, 131-144, 1985

Zbella EA, Deppe G, Gleicher N: Outpatient versus inpatient cone biopsy of the cervix - economic factors. Mt Sinai Med J 53 (2): 1986

Zbella EA, AIP and the pregnant patient. (letter to editor) Contemp Obstet Gynecol 24 (5): 21-23, 1984

- 18. Vermesh M, Zbella EA, Menchaca A, Confino E, Lipshitz S: Vesical endometriosis following bladder injury. American J Obstet Gynecol, 153: 894-895, 1985
- 19. Zbella EA, Carson SA: Noncardiogenic pulmonary edema secondary to intrauterine instillation of 32% Dextran 70 (letter to editor). Fertility and Sterility 44 (4): 550-561, 1985
- 20. Bolar L, Zbella EA Gleicher N: Quantitation of proteinuria in pregnancy by use of single voided urine samples. Obstet Gynecol 70: 99-100, 1987
- 21. Deppe G, Zbella EA, Wall D, Smith P, Gleicher N: The significance of the Class II PAP Smear in high risk population. Colposcopy and Gynecol Laser Surg 2: 5-8, 1986
- 22. Zbella EA, Ilekis J, Scommegna A, Benveniste R: Competitive studies with dehydroepiandrosterone sulfate and 16 hydroxydehydroepiandrosterone sulfate in cultured human choriocarcinoma JEG-3 cells: effect on estrone, 17 Beta-estradiol, and estriol secretion. J Clin Endocrinol Metab 63: 751-757, 1986

- 23. Chatman D, Zbella EA: Pelvic peritoneal defects and endometriosis. further observations. Fertil Steril 46 (4): 711-714, 1986
- 24. Zbella EA, Vermesh M, Gleicher N: Contraceptive practices of female physicians. Contraceptive 33: 423-436, 1986
- 25. Chatman D, Zbella EA: Biopsy in laparoscopic diagnosed endometriosis. J Reprod Med 32: 855-857, 1987
- 26. Confino E, Zbella EA, Gleicher N: Abcess formation post-cesarean section due to a piece of latex glove. Int J Gynecol Obstet (in press)
- 27. Rezai P, Scommegna A, Zbella EA, Lessing J, Bronner S, Weiss G, Benveniste R: Free alpha-subunit response to gonadotropin releasing hormone in women with polycystic ovaries. Fertil Steril 47 (2): 249-254, 1987
- 28. Boler L, Zbella EA, Gleicher N: Quantitation of proteinuria in pregnancy by the use of single voided urine samples. (letter to editor) Obstet Gynecol 71: 90, 1988
- 29. Zbella EA: Diabetes mellitus, thyroid disease, and adrenal disease and their contribution to spontaneous and repetitive pregnancy loss. Seminar In Reproductive Medicine 7 (2): 130-137, 1989
- Zbella EA, Tarantino S, Wade R: Intrafollicular Insemination for Male Factor Infertility. Fertil Steril 58 (2): 442-443, 1992
- 31. Estevez A, Kunis S, Doran J, Zbella EA: Laparoscopic Adnexectomy of a Gonadoblastoma, J Gynecol Surg (8): 87-89, 1992
- 32. Zbella EA: The physician's view of managed care in reproductive medicine. Inf and Reprod Med Clinics of N America 9 (1): 1998
- 33. Godfrey CD, Zbella EA: Uterine necrosis after uterine artery embolization for leiomyoma. Obstet Gyn 98 (5): 2001
- 34. Zbella EA, Sanchez M: Complications of tubal reanastomosis. (letter to editor) Fertil Steril 80(3) 678-679, 2003
- 35. Ronald Hirth, M.D., Zbella EA, M.D., Mark Sanchez, MD., and Jose Prieto, M.D., M.P.H.: Microtubal Reanastomosis: Success Rates as Compared to in Vitro Fertilization: J Reprod. Med 161-165, 2010

- 36. Zbella, EA, Russell Foulk, M.D., Vicki Schnell, M.D., Said Daneshmand, M.D., Charles E. Miller, M.D., Vladimir Yankov, M.D., Jane Ruman, M.D., : Pregnancy Outcome for Women with Endometriosis Undergoing IVF with Luteal Phase Support via a Vaginal Gel: Fertility & Sterility P-16/S15, 2013
- 37. Miller CE, Zbella E, Webster BW, Doody KJ, Et Al: Clinical Comparison of Ovarian Stimulation and Luteal Support Agents in Patients Undergoing GNRH Antagonist IVF Cycles: J Reprod. Med. 58(4) 153-160, 2013

#### **CHAPTERS:**

- 1. Zbella EA, Gleicher N: The pineal gland. In Principles of Medical Therapy in Pregnancy. Gleicher N. (ed.) New York, Plenum Pub. Co., 1985
- 2. Zbella EA, Gleicher N: The oral cavity. In Principles of Medical Therapy in Pregnancy. Gleicher N. (ed.) New York, Plenum Pub. Co., 1985
- 3. Zbella EA, Gleicher N: Disorders of metals and metalloproteins. In Principles of Medical Therapy in Pregnancy. Gleicher N. (ed.) New York, Plenum Pub. Co., 1985
- 4. Carson SA, Zbella EA: Drugs and toxic agents in Pregnancy. In A Clinical Manual of Obstetrics: E.llis JW, Bechmann CRVS (ed.) Norwalk, Connecticut, Appleton-Century-Crofts, 1986
- 5. Zbella EA, Gleicher N: The pineal gland. In Principles of Medical Therapy in Pregnancy. Gleicher N. (ed.) New York, Plenum Pub. Co., 1990
- 6. Zbella EA, Gleicher N: Disorders of metals and metalloproteins. In Principles of Medical Therapy in Pregnancy. Gleicher N. (ed.) New York, Plenum Pub. Co., 1990
- 7. Zbella EA: Clinical Approach to Tubal Disease. In Tubal Catherization. Gleicher N. (ed.) 1992

# **ABSTRACTS**:

- 1. Zbella EA, Ilekis J, Moise J, Benveniste R: Study one estradiol and estriol secretion by cultured human choriocarcinoma (JEG-3) cells suggests a single aromatase converting system. Annual Meeting, the Endocrine Society, Baltimore, Maryland, 1985
- 2. Zbella EA, Wall D, Deppe G: The significance of the class II PAP smear in a high risk population. Annual Meeting, American Society of Colposcopy and Cervical Pathology and Gynecologic Laser Surgery, Lake Buena Vista, Florida, 1984

- 3. Zbella EA, Deppe G, Elrad II: Gonococcal arthritis in pregnancy. International Synopses, 1984
- 4. Soccia B, Zbella EA, Carson S, Gionfortoni J, Scommegna A, Prins G, Weidel L, Barnes R, Shangold G, Schreiber J, Marut EL: A comparison of hFSH (Metrodin) and HMG (Pergonal) for ovarian stimulation in an IVF-ET program. Annual Meeting, The American Fertility Society, Toronto, Canada, 1986
- 5. Blotner MB, Zbella EA, Brandt TD, Grant T, Scommegna A: Comparison of ultrasonic appearance and tissue biopsy of luteal phase endometrium. Annual Meeting, The American Fertility Society, Toronto, Canada, 1986
- 6. Tarantino S, Zbella EA, Yeko T: Rupture of Benign Cystic Teratoma During Laparoscopy Does it Matter? Annual Meeting, American Association of Gynecologic Laparoscopists, Chicago, Illinois, 1992
- 7. Zbella EA, Tarantino S: Presacral Neurectomy. Annual Meeting, American Association of Gynecologic Laparoscopists, Chicago, Illinois, 1992
- 8. Zbella EA, Tarantino S: Supercervical Hysterectomy. Annual Meeting, American Association of Gynecologic Laparoscopists, Chicago, Illinois, 1992
- 9. Wade R, Tarantino S, Zbella EA: Affect of Intrafollicular Insemination on the Formation of Sperm Antibodies, American College of Obstetricians and Gynecologists, District IV Meeting, San Juan, Puerto Rico, November, 1992
- 10. Zbella EA, Tarantino S, Wade R: Gamete Intrafollicular Transfer as Treatment for Infertility Associated with Endometriosis, American College of Obstetricians and Gynecologists, District IV Meeting, San Juan, Puerto Rico, November, 1992
- 11. Agrwal S, Hamrang C, Zbella EA, Tropin S, Judd H: Comparison of Efficacy and Safety of Nafarelin Intranasal with Leoprolide Depot Intramuscular for the Treatment of Endometriosis, American Society of Reproductive Medicine, November, 1996
- 12. Semo R, Zbella EA, Morgan F, Wininger S, Jimenez R, Johnson A, Nicholls A: The Safety and Efficacy of NBI-56418, an Oral, Nonpeptide, Gonadotropin Releasing Hormone (GnRH) Antagonist for the Treatment of Endometriosis, Lyons, France, July 3, 2007
- 13. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Changes in Body Composition with Weight Loss in a Physician Supported Weight Loss Program. Annual Meeting, American Society of Bariatric Physicians, Phoenix, AZ, 2013

- 14. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Screening for Diabetes and Diabetic Risk in a Weight Loss Program, Annual Meeting, American Society of Bariatric Physicians, Phoenix, AZ, 2013
- 15. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E. et al: Multicenter Study of Social Support and Patient Dyads in a Physicians Supervised Weight Loss Program, Annual Meeting, American Society of Bariatric Physicians, Phoenix, AZ, 2013
- 16. Tubens S, Sanchez M, Zbella E, Steele J: Pregnancy Rates after Tubal Re-Anastomosis; Tubo-occlusive Versus Standard Ligation. Annual Meeting, The American Society of Reproductive Medicine, Boston, MA, 2013
- 17. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Multicenter Study of Social Support and Patients Dyads in a Physicians Supervised Weight Loss Program. Annual Meeting, The Obesity Society, Atlanta, GA, 2013
- 18. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Screening for Diabetes and Diabetes Risk in a Weight Loss Program. Annual Meeting, The Obesity Society, Atlanta, GA, 2013
- 19. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Patients Adherence and Weight Loss in a Physician Supervised Weight Loss Program. Annual Meeting, The Obesity Society, Atlanta, GA, 2013
- 20. Guzman M, Nguyen J, Schram E, Holub CK, Zbella E, et al: Changes in Body Composition with Weight Loss in a Physician Supervised Program, Annual Meeting, The Obesity Society, Atlanta, GA, 2013
- 21. Gleicher N, Zbella E, Case Reports Spam or Ham? Fertility Sterility, 1998 Aug; 70(2):388-9.

# PRECEPTORSHIPS:

- 1. Laser Surgery and Operative Endoscopy. At Women's Medical Center. Sponsored by Tap Pharmaceutical.
- 2. Laparoscopic Assisted Vaginal Hysterectomy. At Women's Medical Center. Sponsored by Automated Instruments (U.S. Surgical)
- 3. Clinical Applications in General and Gynecologic Surgery. At Medical College of Georgia. Sponsored by Laser Committee and Laserscope, Inc.

#### **CLINICAL RESEARCH STUDIES:**

**1. STUDY TITLE:** Comparison of Nafarelin intranasal vs. Leuprolide Depot

intramuscular in patients with endometriosis.

PROTOCOL: LAB/NAF/610/USA

COMPLETION YEAR: 1992

**SPONSOR:** Syntex Laboratories **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**2. STUDY TITLE:** Estratest vs. Premarin study

PROTOCOL: 030.8.01 COMPLETION YEAR: 1992

**SPONSOR:** Solvay Pharmaceutical **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D

**3. STUDY TITLE**: Lupron Depot 3.75 vs Lo/Ovral in endometriosis requiring a

2<sup>nd</sup> look surgery.

PROTOCOL: M91-601 COMPLETION YEAR: 1993

**SPONSOR:** TAP Pharmaceutical

\* High enrollment, FDA audit – no deficiencies were found.

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**4. STUDY TITLE:** Treatment of bacterial vaginosis with Metronidazol Modified

Release Tablet.

**PROTOCOL:** N13-95-02-017

COMPLETION YEAR: 1994

**SPONSOR:** G.D. Searle & Company **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**5. STUDY TITLE:** Phase III Study comparing Miconazole Nitrate (4%) vaginal cream and Miconazole Nitrate (2.8%) vaginal cream to Monistat-7 (2%) vaginal cream in the treatment of vulvovaginal candidiasis.

**PROTOCOL**: 95-007-P **COMPLETION YEAR**: 1994

**SPONSOR:** Ortho Pharmaceutical Corporation

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**6. STUDY TITLE:** A randomized double-blind multicenter study comparing two dosing regimens of Fluconazole for the treatment of acute vaginal candidiasis in women with severe and/or recurrent infections.

PROTOCOL: R-0422 COMPLETION YEAR: 1995 **SPONSOR:** Pfizer Pharmaceutical **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**7. STUDY TITLE:** A randomized, double-blind, multicenter, placebo

controlled, menopausal symptom study of three doses of RPR Estradiol/Norethisterone Acetate

(NETA) patches in a continuous wear hormone replacement therapy (HRT) regimen.

**PROTOCOL**: RPR 106522-304

COMPLETION YEAR: 1995

**SPONSOR:** Rhone-Poulenc Rorer Pharmaceuticals, Inc.

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**8. STUDY TITLE:** Efficacy and safety comparison of Estrogel (17B-Estradiol in a topical gel) and the Climara 12.5 sq. cm patch system in the treatment of women with

menopausal symptoms.

PROTOCOL: CV141-002

COMPLETION YEAR: 1996

**SPONSOR:** Bristol Myers Squibb **PRINCIPAL INVESTIGATOR**: Edward Zbella, M.D.

**9. STUDY TITLE:** Fracture incidence reduction and safety of TSE-424

(Bazedoxifene Acetate) compared to placebo and Raloxifene in osteoporotic postmenopausal

women.

**PROTOCOL:** 3068A1-301-US

COMPLETION YEAR: 2001

**SPONSOR:** Wyeth-Averst Laboratories

**PRINCIPAL INVESTIGATOR**: Edward Zbella, M.D.

**10. STUDY TITLE:** An open label, randomized phase IV study of Gynazole 1

vs. Diflucan in patients with moderate to severe symptoms of vulvovaginal candidiasis.

PROTOCOL: 02-094 COMPLETION YEAR: 2002

**SPONSOR:** KV Pharmaceutical **PRINCIPAL INVESTIGATOR**: Edward Zbella, M.D.

**11. STUDY TITLE:** Safety and efficacy comparison of Clindamycin vaginal

cream versus placebo in patients with bacterial vaginosis. A multi-center, randomized,

double-blind, placebo-controlled, parallel group study.

PROTOCOL: 02-005 COMPLETION YEAR: 2003

**SPONSOR:** KV Pharmaceutical **PRINCIPAL INVESTIGATOR**: Edward Zbella, M.D.

**12. STUDY TITLE:** A Phase II, 6 month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 versus placebo in subjects with endometriosis.

PROTOCOL: M01-398 COMPLETION YEAR: 2004

SPONSOR: TAP Laboratories
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

**13. STUDY TITLE:** A Phase II, 3 month, randomized, double-blind study to evaluate the efficacy and safety of two doses of J867 versus placebo in subjects with uterine leiomyomata.

**PROTOCOL:** M02-408, Extension of M01-398

**COMPLETION YEAR:** 2005

**SPONSOR:** TAP Laboratories **PRINCIPAL INVESTIGATOR**: Edward Zbella, M.D.

**14. STUDY TITLE:** A Phase III, 12 month, randomized, double-blind

three doses of J867 versus placebo in subjects with uterine leiomyomata.

PROTOCOL: M01-390 COMPLETION YEAR: 2004

**SPONSOR:** TAP Laboratories **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**15. STUDY TITLE:** An Open Label Study of the Contraceptive Efficacy and Safety of Triphasic Norethindrone acetate 1 mg / Ethinyl Estradiol 0.005, 0.030, and 0.035 mg Oral Tablets Administered for 24 Days of a 28-day Cycle.

PROTOCOL: PR 10503 COMPLETION YEAR: 2005

SPONSOR: Warner Chilcott PRINCIPAL INVESTIGATOR: Edward Zbella

**16. STUDY TITLE:** A Phase III, 12 month, randomized, double-blind study to evaluate the efficacy and safety of three doses of J867 versus placebo in subjects with uterine leiomyomata.

**PROTOCOL:** M01-391, extension of M01-390

COMPLETION YEAR: 2005

SPONSOR: TAP Laboratories
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

**17. STUDY TITLE:** The Efficacy of Eszopiclone 3 mg Compared to

Placebo in the treatment of Insomnia Secondary to Perimenopause or Menopause.

**PROTOCOL**: 190-054

COMPLETION YEAR: 2005 SPONSOR: Sepracor

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**18. STUDY TITLE:** A Phase III, Continuation Study to Evaluate the

Safety of Asoprisinil Beyond 2 years in Subjects with Uterine Leiomyomata.

**PROTOCOL**: A-FB04-078

COMPLETION YEAR: 2006 SPONSOR: TAP

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**19. STUDY TITLE:** A safety and efficacy study of N,

O-carboxymethylchitosan (NOCC) when used for reduction of postoperative adhesion development in women undergoing laparoscopy.

PROTOCOL: Chito-03 COMPLETION YEAR: 2004

**SPONSOR:** Chitogenics, Inc. PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

**20. STUDY TITLE:** Efficacy Study Comparing 0.9 g and 1.25 g

EstroGel 0.03% Doses with Placebo in the treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Associated with Menopause.

PROTOCOL: \$1664003
COMPLETION YEAR: 2005
SPONSOR: Solvay

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**21. STUDY TITLE:** A Multi-Center, Randomized, Double-Blind, Comparative, Safety and efficacy study of a Single Dose of 400 mg Itraconazole Givenas Two 200 mg Film-Coated Tablets Versus a Single Dose of 150 mg Fluconazole Given as a Single Tablet in the Treatment of Vaginal Candidiasis.

PROTOCOL: BT0300C1-300-USA

**COMPLETION YEAR:** 2006

**SPONSOR:** Barrier Therapeutics **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**22. STUDY TITLE:** Evaluation of safety and efficacy of Prometrium Capsules in induction of secretory Conversion of endometrium and withdrawal bleeding in subjects with secondary amenorrhea.

PROTOCOL: \$1684002 COMPLETION YEAR: 2008 **SPONSOR:** Solvay Pharmaceuticals, Inc **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**23. STUDY TITLE:** A multicenter, double-phase, randomized,

double-blind, placebo controlled study evaluating the effect of tolterodine ER on urgency urinary incontinence, urgency, frequency, sexual quality of life and sexual function in women with overactive bladder.

PROTOCOL: A6121002
COMPLETION YEAR: 2006
SPONSOR: Pfizer

**PRINCIPAL INVESTIGATO**R: Edward Zbella, M.D.

**24. STUDY TITLE:** A multi-center, randomized, open-label,

parallel group study of vaginal micronized progesterone tablet (Endometrium) compared to Crinone 8% vaginal gel in female patients undergoing in-vitro fertilization (IVF).

**PROTOCOL**: 2004-02 (IVF)

**COMPLETION YEAR:** 2006

**SPONSOR:** Ferring Pharmaceutical **PRINCIPAL INVESTIGATOR:** Edward, Zbella, M.D.

**25. STUDY TITLE:** A multi-center, randomized, double-blind,

placebo-controlled study to assess the efficacy and safety of three dosage strengths of pulsatile GnRH administered intravenously or subcutaneously via portable infusion pump compared to oral treatment with Clomiphene Citrate in anovulatory or oligoovulatory infertile females.

**PROTOCOL:** Pulsatile GnRH 2004-05 (IV Pump)

**COMPLETION YEAR:** 2006

**SPONSOR:** Ferring Pharmaceuticals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**26. STUDY TITLE:** Randomized, double-blind, double-dummy, parallel group, multicenter study to compare the efficacy and safety of once-monthly oral administration of 150 mg ibandronate with once-weekly oral administration of 70 mg alendronate in postmenopausal osteoporosis-non-inferiority trial.

PROTOCOL: MM 17385

COMPLETION YEAR: 2006 SPONSOR: Roche

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**27. STUDY TITLE:** A multi-center, double-blind, placebo-controlled comparison of multiple doses of esterified estrogens and methyltesttosterone, in combination and alone, in relieving vasomotor symptoms on postmenopausal women.

PROTOCOL: SO202112

**COMPLETION YEAR:** 2007

**SPONSOR:** Solvay Pharmaceuticals PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**28. STUDY TITLE:** A randomized, double-blind, placebo-controlled, parallel-group study comparing clindamycin phosphate 2% butoconazole nitrate 2% combination vaginal cream with clindesse, gynazole-1, and placebo.

**PROTOCOL**: KV05-601-622467

**COMPLETION YEAR:** 2006

**SPONSOR:** KV Pharmaceutical Co. **PRINCIPAL INVESTIGATOR:** Edward Zbella. M.D.

**29. STUDY TITLE:** A double-blind randomized, placebo-controlled dose-ranging study of the effects of ERB-041 in the reduction of symptoms associated with endometriosis in reproductive aged women.

**PROTOCOL:** 3142A2-200-US

COMPLETION YEAR: 2006 SPONSOR: Wyeth

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**30. STUDY TITLE:** A Phase II, Randomized, Double-Blind,

Placebo-Controlled Study of NBI-56418 in Endometriosis. **PROTOCOL:** NBI-56418-0501

**COMPLETION YEAR:** 2006

**SPONSOR:** Neurocrine Biosciences **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**31. STUDY TITLE:** A phase II, randomized, double-blind, placebo-

controlled twice-daily dosing study of NBI- 56418 in endometriosis.

PROTOCOL: NBI-56418-0504

COMPLETION YEAR: 2007

SPONSOR: Neurocrine Biosciences
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**32. STUDY TITLE:** A double-blind, randomized, placebo-controlled, efficacy and safety study of bazedoxifene/conjugated estrogens combinations for treatment of vasomotor symptoms associated with menopause.

**PROTOCOL**: 3115A1-305-US

**COMPLETION YEAR:** 2007 **SPONSOR:** Wyeth

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.,CPI

**33. STUDY TITLE:** A double-blind, randomized, placebo controlled study to evaluate the safety and efficacy of 75 MG and 150 MG doses of ERB-041 on the reduction of symptoms associated with endometriosis during treatment and post treatment in reproductive-aged women.

**PROTOCOL**: 3142A2-203-WW

COMPLETION YEAR: 2007 SPONSOR: Wyeth

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**34. STUDY TITLE:** A randomized, placebo-controlled phase II study of multiple dosing regimens of intravaginally administered 851B gel for the treatment of cervical high risk HPV infection.

PROTOCOL: 1547-851B
COMPLETION YEAR: 2008
SPONSOR: Tekeda

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**35. STUDY TITLE:** A phase II, multi-center, double-blind, randomized, placebo-controlled study to evaluate two doses of a Danazol vaginal ring for the management of moderate to severe endometriosis-related non-menstrual pelvic pain.

**PROTOCOL**: DR-DZL-201

COMPLETION YEAR: 2007 SPONSOR: Duramed

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**36. STUDY TITLE:** A phase II, prospective, randomized, double- blind, multi-center, dose finding, comparative study for the evaluation of the Aromatase Inhibitor Anastrozole (Multiple-Dose) versus Clomiphene Citrate in stimulating follicular growth and ovulation in infertile women with ovulatory dysfunction.

PROTOCOL: 25550
COMPLETION YEAR: 2008
SPONSOR: Serono

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**37. STUDY TITLE:** A phase IV, multi-center, randomized, doubleblind, clinical trial to confirm the efficacy of the 75 IU dose of Luveris vs. placebo when administered with follitropin alfa for induction of follicular development and pregnancy in

hypogonadotropic hypogonadal women with profound LH deficiency, as defined by a baseline LH level <1.2 IU/L.

PROTOCOL: 26109
COMPLETION YEAR: 2012
SPONSOR: Serono

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**38. STUDY TITLE:** A randomized, multi-center, double-blind,

placebo-controlled trial to compare the effects of 12 weeks of treatment with DR-2041 vaginal cream vs. placebo vaginal cream on vulvovaginal atrophy in healthy postmenopausal women.

PROTOCOL: DR-CEN-302

COMPLETION YEAR: 2007 SPONSOR: Duramed

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**39. STUDY TITLE:** A multi-center validation study of the daily log of

sexual activities (DLSA) in postmenopausal women.

PROTOCOL: S0302108
COMPLETION YEAR: 2007

**SPONSOR:** Solvay Pharmaceuticals, Inc. **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**40. STUDY TITLE:** A multi-center, randomized, double-blind study to compare the efficacy and safety of patient-initiated Famciclovir 1000 mg B.I.D. X 1 day to Valacyclovir 500 mg b.i.d. X 3 days in immunocompetent adults with recurrent genital herpes.

PROTOCOL: CFAM810A2308

COMPLETION YEAR: 2006 SPONSOR: Novartis

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D.

**41. STUDY TITLE:** 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

**COMPLETION YEAR:** 2006

**SPONSOR:** GlaxoSmithKline PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

**42. STUDY TITLE:** An open label study of the contraceptive efficacy of

an extended regimen of norethindrone and ethinyl estradiol.

PROTOCOL: PR 00207 COMPLETION YEAR: 2008

SPONSOR: Warner Chilcott

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**43. STUDY TITLE:** A multi-center, double-blind, randomized, parallel-group, placebo-controlled, 7 cycle duration (196 days), phase III study of oral estradiol valerate/dienogest tablets for the treatment of dysfunctional uterine bleeding.

PROTOCOL: DUB 308960

COMPLETION YEAR: 2008 SPONSOR: Berlex

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**44. STUDY TITLE:** A phase II, randomized, double-blind, active-controlled study to assess the safety and efficacy of NBI-56418 in subjects with endometriosis

**PROTOCOL:** NBI-56418-0603

COMPLETION YEAR: 2009 SPONSOR: Neurocrine

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**45. STUDY TITLE:** A phase II clinical study evaluating the safety and efficacy of two regimens of danazol administered intravaginally for three months in women with moderate-to-severe pain associated with endometriosis.

**PROTOCOL**: DZ2-201-601-725036

**COMPLETION YEAR:** 2006

**SPONSOR:** KV Pharmaceutical PRINCIPAL INVESTIGATOR: Edward Zbella, M.D.

**46. STUDY TITLE:** A phase IIIb, randomized, open, multi-center study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' HPV-16/18 LI/AS04 vaccine co-administered intramuscularly with GlaxoSmithKline Biologicals Boostrix vaccine and/or Sanofi-Aventis' Menactra vaccine according

to different dose schedule combinations as compared to the administered of HPV vaccine, Boostrix or Menactra alone in healthy female subjects aged 11-18 years.

**PROTOCOL:** 107682 (HPV-018)

**COMPLETION YEAR:** 2010

SPONSOR: GlaxoSmithKline

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**47. STUDY TITLE:** A double-blind, randomized, controlled study to evaluate the immunogenecity and safety of GlaxoSmithKline Biologicals' herpes simplex candidate vaccine (gD2-AS04) in healthy HSV seronegative and seropositive female subjects aged 10-17 years.

**PROTOCOL**: 208141/040

**COMPLETION YEAR:** 2007

**SPONSOR:** GlaxoSmithKline Biologicals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**48. STUDY TITLE:** A phase III, multi-center, randomized, double-blind, placebo-controlled study of IoGen for the treatment of moderate or severe, periodic breast pain associated with symptomatic fibrocystic breast disease in otherwise healthy, euthyroid, pre-menopausal women.

PROTOCOL: SYM-CL-005

**COMPLETION YEAR:** 2007

**SPONSOR:** Symbollon Pharmaceuticals, Inc

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**49. STUDY TITLE:** Open label study of the safety and efficacy of a new

low dose oral contraceptive containing norethindrone acetate and ethinylestradiol.

PROTOCOL: PR 05806 COMPLETION YEAR: 2007

SPONSOR: Warner Chilcott

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**50. STUDY TITLE:** A randomized, double-blind, placebo controlled, parallel group, multi-center study investigating the efficacy and safety of a fast- dissolving ("Melt") formulation of desmopressin for the treatment of nocturia in adults.

PROTOCOL: FE-992026 CS-29

COMPLETION YEAR: 2007 SPONSOR: Ferring

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**51. STUDY TITLE:** A phase II, 18-Week, double-blind,

placebo-controlled, multi-center study evaluating the safety and efficacy of lidocaine/ diphenhydramine combination cream compared with lidocaine and placebo cream in the treatment of vulvar vestibulitis syndrome.

**PROTOCOL:** LDC-201-601-669020

**COMPLETION YEAR:** 2008

**SPONSOR:** KV Pharmaceuticals PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**52. STUDY TITLE:** Randomized, double-blind, parallel-group study evaluating the safety and efficacy of clindamycin/butoconazole vaginal cream in the treatment of mixed bacterial vaginosis/ vulvovaginal candidiasis infections.

**PROTOCOL**: CBC-302-602-622467

COMPLETION YEAR: 2009

**SPONSOR:** KV Pharmaceuticals PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**53. STUDY TITLE:** A phase IIII, multi-center, randomized, double-blind, placebo-controlled study to evaluate the effects of SCE-B on nocturnal vasomotor symptoms in Postmenopausal Women.

**PROTOCOL**: DR-ENJ-401

**COMPLETION YEAR:** 2009

**SPONSOR:** Duramed Research

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**54. STUDY TITLE:** A phase III, single-blind, randomized study to compare DR-2011 to a progesterone vaginal gel for Luteal phase supplementation for in vitro fertilization.

PROTOCOL: DR-PGN-302

**COMPLETION YEAR:** 2009

SPONSOR: Duramed Research
SUB. INVESTIGATOR: Edward Zbella, M.D., CPI

**55. STUDY TITLE:** A double-blind, randomized, multi-center study to investigate the endometrial safety of a continuous, combined oral estrogen/ progestin preparation (0.5 mg 17ß-estradiol [E2] / 0.25 mg drospirenone [DRSP]) and to compare the bleeding pattern of subjects treated With 0.5 mg E2 / 0.25 mg DRSP with the bleeding pattern of subjects treated with 1.0 mg E2 / 0.5 mg norethisterone acetate (NETA) when used for hormone therapy (HT) For 1 year in post-menopausal women.

PROTOCOL: 310523 COMPLETION YEAR: 2010 SPONSOR: Bayer

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**56. STUDY TITLE:** A randomized, double-blind, placebo-controlled, multi-center, 52-week study to evaluate the endometrial safety of transdermal testosterone (300 mcg/day) in naturally post-menopausal women with hypoactive sexual desire disorder.

PROTOCOL: 2007004 COMPLETION YEAR: 2007

**SPONSOR:** Proctor and Gamble **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**57. STUDY TITLE:** A phase II, randomized, double-blind, placebo controlled study to assess the efficacy and safety of NBI-56418 in subjects with endometriosis.

**PROTOCOL**: NBI-56418-0702

**COMPLETION YEAR:** 2009

**SPONSOR:** Neurocrine Biosciences **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**58. STUDY TITLE:** A multi-center extension study investigating the long term efficacy and safety of a fast-dissolving ("Melt") formulation of desmopressin for the treatment of nocturia in adults.

PROTOCOL: FE992026 CS31

**COMPLETION YEAR:** 2010

**SPONSOR:** Ferring Pharmaceutical **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**59. STUDY TITLE:** A multi-center, open-label, single-arm study to assess the efficacy and safety of the oral contraceptive SH TOO186D (0.02 mg ethinyl estradiol as betadex clathrate and 3 mg drospirenone) in a flexible extended regimen in 1356 healthy females for 1 Year.

PROTOCOL: 311642
COMPLETION YEAR: 2009
SPONSOR: Bayer

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**60. STUDY TITLE:** A placebo controlled randomized, 12-week, dose-ranging, double-blind study versus placebo using tolterodine as a study calibrator to evaluate efficacy and safety of SSR240600C in women with overactive bladder including urge urinary incontinence.

**PROTOCOL**: DRI6271 **COMPLETION YEAR**: 2008

**SPONSOR:** Sanofi-Aventis

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**61. STUDY TITLE:** A multi-center, randomized, controlled study to investigate the safety and tolerability of intravenous ferric carboxymaltose (FCM) vs. standard medical care in treating iron deficiency anemia in heavy uterine bleeding and postpartum patients.

PROTOCOL: 1VIT07017
COMPLETION YEAR: 2009
SPONSOR: Luitpold

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**62. STUDY TITLE:** A multicenter, randomized, double-blind, active-controlled, parallel group, 2-arm study to show superiority of the oral contraceptive SH T00658ID over Ortho Tri-Cyclen Lo on hormone withdrawal-associated symptoms after 6 cycles of treatment .

PROTOCOL: 13108

COMPLETION YEAR: 2011

**SPONSOR:** Bayer

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**63. STUDY TITLE:** A double-blind, randomized, placebo-controlled study assessing the safety and efficacy of DVS-SR for the treatment of vasomotor symptoms associated with menopausal.

**PROTOCOL:** 3151A2-3353-NA

**COMPLETION YEAR:** 2010 **SPONSOR:** Wyeth

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**64. STUDY TITLE:** Multi-center, double-blind, double-dummy, randomized, parallel-group study to evaluate cycle control, bleeding pattern, pressure, lipid and carbohydrate metabolism of the transdermal contraceptive patch vs. an oral comparator containing 20μg ethinylestradiol and 100μg levonorgestrel in a 21-day regimen for 7 cycles in 400 women.

PROTOCOL: 91556 COMPLETION YEAR: 2011

**SPONSOR:** Bayer HealthCare

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**65. STUDY TITLE:** A multicenter, open-label, randomized, controlled study, compare the effects on bone mineral density of DR-105 and a 28-Day cycle oral contraceptive regimen in healthy, postmedarchal, adolescent females.

PROTOCOL: DR-105-202

COMPLETION YEAR: 2013 SPONSOR: Duramed

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**66. STUDY TITLE:** A multicenter, open-label study to evaluate the efficacy and safety of a combination oral contraceptive regimen (DR-103) for the prevention of pregnancy in women.

PROTOCOL: DR-103-301

**COMPLETION YEAR**: 2011 **SPONSOR**: Teva

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**67. STUDY TITLE:** A Phase III randomized, double-blind, placebo control, multicenter study to investigate the efficacy and safety of SER120 nasal spray formulation in patients with Nocturia

PROTOCOL: SPC-SER120-DB1-200901

**COMPLETION YEAR:** 2010

**SPONSOR:** Serenity Pharmaceuticals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**68. STUDY TITLE:** A double-blind, randomized, placebo and active controlled efficacy and safety study of the effects of Bazedoxifene/conjugated estrogens combinations on endometrial hyperplasia and prevention of osteoporosis in postmenopausal women.

**PROTOCOL:** 3115A1-3307-WW

**COMPLETION YEAR:** 2011 **SPONSOR:** Wyeth

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**69. STUDY TITLE:** A phase IIIb open-label, multi-centre immunization study to evaluate the safety of GlaxoSmithKline Biologicals' HPV-16/18 L1 VLP AS04 vaccine administered intramuscularly according to a 0, 1, 6-month schedule in female American and Canadian subjects who received the active control hepatitis a vaccine in the 580299/008 study.

**PROTOCOL:** 111955 (HPV-057 EXT 008)

COMPLETION YEAR: 2011

**SPONSOR:** GlaxoSmithKline Biologicals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**70. STUDY TITLE:** A phase III open-label extension study to investigate the safety of SER120 nasal spray formulations in patients with nocturia

completing study SPC-SER120-DB1-200901 or Study SPC-SER120-DB2-200902.

PROTOCOL: SPC-SER120-OLI-200903

COMPLETION YEAR: 2011 SPONSOR: Serenity

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**71.** STUDY TITLE: A phase II, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of NBI-56418 Na in subjects with Endometriosis.

**PROTOCOL:** NBI-56418-0901

COMPLETION YEAR: 2010

**SPONSOR:** Neurocrine Biosciences **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**72. STUDY TITLE:** A multi-center, randomized, open-label evaluation of

MENOPUR versus FOLLISTIM in GnRH antagonist cycles. **PROTOCOL:** FPI MEN 2008-04

COMPLETION YEAR: 2009

**SPONSOR:** Ferring Pharmaceuticals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**73. STUDY TITLE:** A multi-center, randomized, open-label evaluation of

MENOPUR versus Follistim in polycystic Ovarian Syndrome (PCOS) patients.

**PROTOCOL:** FPI MEN 2008-05

**COMPLETION YEAR:** 2010

**SPONSOR:** Ferring Pharmaceuticals **SUB.INVESTIGATOR:** Edward Zbella, M.D., CPI

**74. STUDY TITLE:** A phase IIIb, multi-center, randomized, double-blind study of hydroxyprogesterone caproate injection, 250 mg/ml, versus vehicle

for the prevention of preterm birth in women with a previous singleton spontaneous preterm delivery.

PROTOCOL: 17P-ES-003

**COMPLETION YEAR:** 2010

**SPONSOR:** PRA International

**SUB. INVESTIGATOR:** Edward Zbella, M.D., CPI

**75. STUDY TITLE:** A randomized, assessor-blinded, multi-center study

investigating the efficacy, safety and tolerability of "Day Before" PicoPrep™ for oral administration versus HalfLytlely® for colon cleansing in preparation for colonoscopy.

PROTOCOL: 2009-02 COMPLETION YEAR: 2010

**SPONSOR:** Ferring Pharmaceuticals **SUB. INVESTIGATOR:** Edward Zbella, M.D., CPI

**76. STUDY TITLE:** A phase 3, multicenter, randomized, double-blind,

placebo controlled study to investigate the safety and efficacy of

Gabapentin Extended Release (G-ER) Tablets in the treatment of vasomotor symptoms in postmenopausal women.

PROTOCOL: 81-0064 COMPLETION YEAR: 2010

**SPONSOR:** Depomed, Inc.

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

77. STUDY TITLE: A multi-center, randomized, active controlled study to investigate the efficacy and safety of Intravenous Ferric Carboxymaltose (FCM) in patients with Iron Deficiency Anemia (IDA).

PROTOCOL: 1VIT09031
COMPLETION YEAR: 2010
SPONSOR: Luitpold

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**78. STUDY TITLE:** A phase 3, twenty four week, multicenter,

double-blind randomized, placebo-controlled, efficacy and safety study of Mesafem (Paroxetine Mesylate) capsules in the treatment of Vasomotor symptoms associated with menopause.

PROTOCOL: N30-004 COMPLETION YEAR: 2011

**SPONSOR:** Noven Pharmaceuticals, Inc. **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**79. STUDY TITLE:** A prospective, multi-center observational study with

blinded, nested case: control analyses to evaluate the performance of the Artemis Health

Prenatal Aneuploidy Diagnostic Test.

PROTOCOL: ART-0006
COMPLETION YEAR: 2011

**SPONSOR:** Artemis Health

**SUB INVESTIGATOR:** Edward Zbella, M.D., CPI

**80. STUDY TITLE:** A pivotal, multi-center in vitro-diagnostic study designed to establish the performance characteristic of the BD SurePath Plus Pap test to improve the cytological detection of high-grade cervical disease and cervical cancer.

PROTOCOL: TPO-10-06084

**COMPLETION YEAR**: 2012 **SPONSOR**: BD

**PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D., CPI

**81. STUDY TITLE**: A multi-center, open label study to evaluate the

efficacy and safety of a combination oral contraceptive regimen (DR-102) for the prevention of pregnancy in women

PROTOCOL: DSG-PPS-303

COMPLETION YEAR: 2013

**SPONSOR:** Teva Women's Health Research

**PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D., CPI

**82. STUDY TITLE:** A multi-center, randomized, double-blind,

placebo-controlled, parallel-group trial to demonstrate the efficacy and safety of desmopression orally disintegrating tablet for the treatment of Nocturia in adult females.

PROTOCOL: FE992026 CS40

COMPLETION YEAR: 2011

**SPONSOR:** Ferring Pharmaceuticals

**PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D., CPI

**83. STUDY TITLE:** A double blind, randomized, controlled, multicenter, efficacy and safety study of oral BGS649 vs. placebo (each co-administered with a combined oral contraceptive) assessing pain response in patients with refractory endometriosis.

PROTOCOL: CBGS649A2202

COMPLETION YEAR: 2012 SPONSOR: Novartis

**PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D., CPI

**84. STUDY TITLE:** An open-label, randomized, parallel group, phase 3 study of the contraceptive efficacy and safety of Agile transdermal contraceptive delivery system in comparison to a low-dose oral contraceptive containing 0.02 mg ethinyl estradiol and 0.1mg Levonorgestrel in a 21-day regimen.

PROTOCOL: ATI-CL12 COMPLETION YEAR: 2011

**SPONSOR:** Agile Therapeutics, Inc. **SUB INVESTIGATOR:** Edward Zbella, M.D., CPI

**85. STUDY TITLE:** Effect of WC3043 on Spermatogenesis and

Concentration of WC3043 in Semen: A double-blind, randomized, placebo-

controlled, parallel group study.

PROTOCOL: PR-00110 COMPLETION YEAR: 2011

**SPONSOR:** Warner Chilcott

**PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D., CPI

**86. STUDY TITLE:** A Multi-centre, Randomised, Double-blind, Placebo-controlled, Parallel-group Trial with an Open-label Extension to Demonstrate the Efficacy and Safety of Desmopressin Orally Disintegrating Tablets for the Treatment of Nocturia in Adult Males.

PROTOCOL: FE-992026 CS41

COMPLETION YEAR: 2011

**SPONSOR:** Ferring Pharmaceuticals PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**87. STUDY TITLE:** A Phase III, Randomized, Double-Blind, Placebo-Controlled Trial of Ferumoxytol for the Treatment of Iron Deficiency Anemia.

**PROTOCOL**: AMAG-FER-IDA-301

**COMPLETION YEAR:** 2012

**SPONSOR:** Amag Pharmaceuticals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

88. STUDY TITLE: Clinical Evaluation of Triage® hCG in Whole Blood

and Plasma (device) GOAL

PROTOCOL: STE-0134

**COMPLETION YEAR:** 2012

SPONSOR: Alere San Diego Inc.
PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**89. STUDY TITLE:** A Phase III, Open-Label Extension Trial of the Safety and Efficacy of Ferumoxytol for the Episodic Treatment of Iron Deficiency Anemia.

**PROTOCOL**: AMAG-FER-IDA-303

COMPLETIOION YEAR: 2012

**SPONSOR:** Amag Pharmaceuticals **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**90. STUDY TITLE:** A Randomized, Double-Blind, Vehicle-Controlled

Study of the Safety and Efficacy of WC3011 (estradiol vaginal gel) in the Treatment of

Symptoms of Vulvovaginal Atrophy in Postmenopausal Women.

PROTOCOL: PR-04409

COMPLETION YEAR: 2013

**SPONSOR:** Warner Chilcott

**PRINICIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**91. STUDY TITLE:** A Multicenter, Open-Label Extension Study to

Evaluate the Long-Term Safety and Efficacy of WC3011 (estradiol vaginal gel) in the Treatment of Symptoms of Vulvovaginal Atrophy in Postmenopausal Women

**PROTOCOL**: PR-04509

COMPLETION YEAR: 2013

**SPONSOR:** Warner Chilcott

**PRINICIPAL INVESITAGTOR:** Edward Zbella, M.D., CPI

**92. STUDY TITLE:** A Multicenter, Randomized, Open-Label,

Parallel-Group Study Comparing the Combination of Menopur® and Bravelle® with Menopur®

Alone in Subjects Undergoing Assisted Reproductive Technology (ART)

PROTOCOL: FE 999906 CS12

COMPLETION YEAR: 2012

**SPONSOR:** Ferring Pharmaceuticals PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**93. STUDY TITLE:** A Multi-Center, Randomized, Open-Label Study to

Evaluate the Implantation and Pregnancy Rates Following 24 Chromosome Aneuploidy

Screening With Parental Support in Patients Undergoing (IVF).

**PROTOCOL**: GSN-IVF006-D3

COMPLETION YEAR: 2012

**SPONSOR:** Gene Security Network **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**94. STUDY TITLE:** Exploratory, Non-Interventional Study to Identify and Validate Biomarkers in Follicular Fluid, Cumulus or Granulose Cells or Embryo Culture Medium for Prediction of Implantation and Pregnancy Outcome of Assisted Reproductive Technology Cycle.

PROTOCOL: EMR200497-001

COMPLETION YEAR: 2012

**SPONSOR:** EMD Serono Inc. USA **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**95. STUDY TITLE:** A Phase III, Multi-Center, Randomized,

Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Product 55394 in the Treatment of (BV) Bacterial Vaginosis.

PROTOCOL: MP-1601-01

COMPLETION YEAR: 2013

**SPONSOR:** Medicis Pharmaceutical Corp. PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**96. STUDY TITLE:** An Open-Label, Escalating Dose, 6-Month Phase III Safety Study of Enclomiphene Citrate in the Treatment Of Men with Secondary Hypogonadism.

PROTOCOL: ZA-300 COMPLETION YEAR: 2013

**SPONSOR:** Repros Therapeutics Inc. **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**97. STUDY TITLE:** A Randomized, Double Blind, Placebo Controlled Multi Center Phase III Study to Evaluate Normalization of Morning Testosterone Levels in Overweight Men with Acquired Hypogonadotropic Hypogonadism and Normal Sperm Concentration.

PROTOCOL: ZA-301 COMPLETION YEAR: 2013

**SPONSOR:** Repros Therapeutics Inc. **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**98. STUDY TITLE:** A Randomized, Double-Blind, Multi-Center,

Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Doses of NT100 Following In Vitro-Fertilization (IVF) in Women with a History of Repeated IVF Failure(Thrive-IVF).

PROTOCOL: NT-03
COMPLETION YEAR: Ongoing

SPONSOR: Nora Therapeutics, Inc PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**99. STUDY TITLE:** A Multicenter, 26-Week, Prospective, Observational

Study In Adult Patients With Pre-Diabetes Assessing

The Impact Of The PreDx Test On Patient Treatmen And Outcomes In Community-Based Clinical Practices.

PROTOCOL: TET2013-001A

**COMPLETION YEAR:** 2013

SPONSOR: Agility Clinical

PRINCIPAL INVESTIGATOR: Edward Zbella, M.D., CPI

**100. STUDY TITLE:** A Phase 1b/2a, Multi-center, Double-blind,

Randomized, Placebo-controlled Study to Evaluate the Safety, Tolerability, Immunogenicity and Efficacy in Preventing Vulvovaginal Candidiasis in Subjects with Recurrent Vulvovaginal Candidiasis Following Administration of a Single Dose of NDV-3A Vaccine, NDV-3 Vaccine or Placebo.

PROTOCOL: NDV3A-003 COMPLETION YEAR: Ongoing

**SPONSOR:** NovaDigm Therapeutics, Inc **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**101. STUDY TITLE:** A Randomized, Multicenter, Double-Blind,

Vehicle-Controlled Study to Evaluate the Safety and Efficacy of WC3011 in Postmenopausal Women with Dyspareunia.

PROTOCOL: PR-08112 COMPLETION YEAR: 2013

**SPONSOR:** Warner Chilcott, LLC **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**102. STUDY TITLE:** A Phase 2, Multi-Center, Three –Arm, Parallel

Designed, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of 6 and 12 mg Proellex® (Telapristone Acetate) Administered Orally in the Treatment of Premenopausal Women with Endometriosis Confirmed Within the Last Five Years and Who are Currently Using

Narcotics For Control of Symptomatic Pain. PROTOCOL:

ZPE-202

COMPLETION YEAR: Ongoing

**SPONSOR:** Repros Therapeutics Inc.

**PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**103. STUDY TITLE:** An Open Label, 6 Month Phase III Extension Study

of Enclomiphene Citrate in the Treatment of Men with Secondary Hypogonadism

**PROTOCOL:** ZA-301 ext.

COMPLETION YEAR: 2014

**SPONSOR:** Repros Therapeutics Inc. **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI

**104. STUDY TITLE:** A Randomized, Multicenter, Double-Blind,

Vehicle-Controlled Study to Evaluate the Safety and Efficacy of WC3011 in Postmenopausal

Women.

PROTOCOL: PR-05812 COMPLETION YEAR: 2013

**SPONSOR:** Warner Chilcott, LLC **PRINCIPAL INVESTIGATOR:** Edward Zbella, M.D., CPI