

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 15th 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

American Society of Bariatrics Physicians

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 Aromatase 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 Laparoscopy. 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, 1991

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. 55th 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. 66th 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, Nemeč 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, Ileki 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: Abscess 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. Ellis 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, Ileakis 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 2nd 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: S1664003
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 Given as 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: S1684002
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 INVESTIGATOR: 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 methyltestosterone, 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, double-blind, 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 immunogenicity 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 loGen 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 ethinyl estradiol.

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 III, 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 17 β -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 desmopressin 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
COMPLETION 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
PRINCIPAL 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
PRINCIPAL INVESTIGATOR: 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 Granulosa 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 Treatment 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