

CURRICULUM VITAE

NAME:

Edward A. Zbella, M.D., CPI

DATE AND PLACE OF BIRTH:

February 7, 1954, Chicago, Illinois

BUSINESS ADDRESS/PHONE:

Edward Zbella, MD, PA
DBA: Florida Fertility Institute

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

3268 66th Street N
St. Petersburg, FL 33710
(727) 341-1991

Women's Medical Research Group, LLC
2454 McMullen Booth Road, Suite 609
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Neuro-Psych Medical Research, LLC
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Clearwater, FL 33759
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Florida Clinical Research Group
2454 McMullen Booth Road. Suite 610
Clearwater, FL 33759
(727)-724-9730

HEALTH:

Excellent

EDUCATION:

UNDERGRADUATE:

Illinois Benedictine College
5700 College Road
Lisle, Illinois 60532
(708) 960-1500
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
(312) 996-3500
1976-1980

Degree: Doctorate of Medicine
Resident in Obstetrics and Gynecology
The University of Chicago
5841 S. Maryland Ave., MD 2050
Chicago, Illinois 60637
(312) 702-1939
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
(312) 542-2000

INTERNSHIP:

OB/GYN: 1980-1982

GRADUATE CONTINUED:

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
(312) 791-2000
1984-1986
Chairman - Antonio Scommegna, M.D.

PROFESSIONAL APPOINTMENTS:

Director, Florida Fertility Institute, Suite 601
Clearwater, Florida, 1986-1988

Director, IVF-GIFT Program,
Palms of Pasadena, 1987-1989

Owner/Medical Director
Edward Zbella, MD, PA
DBA: Fertility Institute of West Florida, 1988-1992
DBA: The Center of Reproductive Endocrinology, 1992-1996
DBA: University Fertility Associates, 1996-2000
DBA: 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 Center 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-present

Medical Director
Women's Medical Research Group, Suite 609 (2008)
Clearwater, Florida 2003-present

Chief Medical Officer
Medi Weight Loss Clinics
2007-present

MEDICAL LICENSURE:

Florida – 48354

CERTIFICATION:

APPI: Certified Principle Investigator (CPI)
9/08/2007

MEMBERSHIPS:

American College of Obstetrics and
Gynecology

American Fertility Society

Society of Reproductive Surgeons

Society for Reproductive Endocrinologists

Society for Assisted Reproductive Technology

American Association of Gynecologic
Laparoscopists

Gynecologic Laser Society

International Society for Gynecologic
Endoscopy

Florida Society of Reproductive
Endocrinologists
Society for Study of Reproduction

American Medical Association

Southern Medical Association

International Society for Gynecologic
Endocrinology
Endocrine Society

Society of Laparoscopic Surgeons

Pinellas County Medical Association

Florida Obstetrics and Gynecology Association

Society of Laparoendoscopic Surgeons

SPECIALTY BOARDS:

Diplomat, American Board of Medical
Examiners, 1981

Board Certified, American Board of Obstetrics
and Gynecology, 1987
Re-certified, 1997

Board Certified, American Subspecialty
Examination in Reproductive Endocrinology
and Infertility, 1988
Re-certified, 1997

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:

1. 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
2. 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
5. 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, 1985
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
14. 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, 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
30. 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.

PUBLICATIONS:

1. 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
2. Zbella EA, Deppe G, Elrad H: Gonococcal arthritis in pregnancy. Ob Gyn Sur 39 (1): 8-12, 1984
3. Deppe G, Zbella EA, Wall D: Outpatient cone biopsy of the cervix-surgical technique. Surg Gyn Ob 158 (6): 552-554, 1984
4. Deppe G, Zbella EA, Friberg J, Thomas W: Combination chemotherapy for mixed mullerian tumor of the fallopian tube. Cancer 54: 1517-1520, 1984
5. 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
6. 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

7. 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
8. Deppe G, Zbella EA: Chemotherapy in endometrial cancer - A review. *Wein Klin Wochenschr* 96 (20): 747-756, 1984
9. Zbella EA, Vermesh M, Tiemstra J, Elrad H: Phenothiazines in pregnancy. *Perinatology Neonatology* (in press)
10. Zbella EA, Nemeč L, Vermesh M: Vaginal douching pros, cons and proper technique. *Postgrad Med* 76 (8): 93-97, 1984
11. Vermesh M, Deppe G, Zbella EA: Nonpurpueral traumatic vulvar hematoma. *Int J Gynecol Obstet* 22: 217-219, 1984
12. Deppe G, Dolan T, Zbella EA: Synchronous multiple neoplasms of the breast, colon and vulva. *J Reprod Med* 29 (12): 878-880, 1984
13. Zbella EA, Scommegna A: Premature Menopause. *Med Aspects Human Sexual March*, 118-123, 1986
14. Zbella EA, Moise J, Carson SA: Noncardiogenic pulmonary edema secondary to intrauterine instillation of 32% Dextran 70. *Fertil Steril* 43 (3): 479-780, 1985
15. Confino E, Zbella EA, Eldayam U, Gleicher N: Cardiac drugs in pregnancy. *Drug Therapy March*, 131-144, 1985
16. Zbella EA, Deppe G, Gleicher N: Outpatient versus inpatient cone biopsy of the cervix - economic factors. *Mt Sinai Med J* 53 (2): 1986
17. 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: 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
30. 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

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: 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

PUBLISHED 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 Leuprolide 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.

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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
2. **STUDY TITLE:** Estratest vs. Premarin study
PROTOCOL: 030.8.01
COMPLETION YEAR: 1992
SPONSOR: Solvay Pharmaceutical
PRINCIPLE 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.
PRINCIPLE 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
PRINCIPLE 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: Advanced Care Products
Ortho Pharmaceutical Corporation
PRINCIPLE 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
PRINCIPLE 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.
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
14. **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:** M01-390
COMPLETION YEAR: 2004
SPONSOR: TAP Laboratories
PRINCIPLE 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
- PRINCIPLE 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
- PRINCIPLE 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
- PRINCIPLE 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
- PRINCIPLE 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.
- PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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.
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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

- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Serono
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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.
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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

- PRINCIPLE 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
PRINCIPLE 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: Ongoing
SPONSOR: Warner Chilcott
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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: Ongoing
SPONSOR: Neurocrine
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
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: Ongoing
SPONSOR: KV Pharmaceutical
PRINCIPLE 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:**
- SPONSOR:** GlaxoSmithKline
- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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:** Ongoing
- SPONSOR:** GlaxoSmithKline Biologicals
- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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, premenopausal women.
- PROTOCOL:** SYM-CL-005
- COMPLETION YEAR:** Ongoing
- SPONSOR:** Symbollon Pharmaceuticals, Inc
- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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:** Ongoing
- SPONSOR:** Warner Chilcott
- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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:** Ongoing
SPONSOR: Ferring
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: KV Pharmaceuticals
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: KV Pharmaceuticals
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Duramed Research
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Duramed Research
SUB. INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Bayer

- PRINCIPLE INVESTIGATOR:** Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Proctor and Gamble
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Neurocrine Biosciences
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Ferring Pharmaceuticals
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Bayer
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.
- 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: Ongoing
SPONSOR: Sanofi-Aventis
PRINCIPLE INVESTIGATOR: Edward Zbella, M. D.
- 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: Ongoing
SPONSOR: Luitpold
PRINCIPLE INVESTIGATOR: Edward Zbella, M. D.

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: Ongoing
SPONSOR: Bayer
PRINCIPLE INVESTIGATOR: Edward Zbella, M.D.

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: Ongoing
SPONSOR: Wyeth
PRINCIPLE INVESTIGATOR: Edward Zbella, M. D