CURRICULUM VITAE

NAME

Michael A. Werner, M.D.

TITLE

Medical Director, Maze Sexual & Reproductive Health
Board certified urologist with practice limited to Sexual Dysfunction, Male Infertility, Microsurgery

TELEPHONE

Westchester Office: (914) 997-4100
Manhattan Office: (646) 380-2600
Long Island Office: (646) 380-2600
Connecticut Office: (203) 831-9900

PROFESSIONAL ACTIVITIES

Private Practice Practice limited to Sexual Dysfunction, Male Infertility, Microsurgery Manhattan and Westchester, New York; Norwalk, Connecticut	1994-Present
Medical Director Maze Laboratories Westchester	1997-Present
Medical Director Maze Women's Sexual Health Manhattan, Long Island and Westchester, New York	2000-Present

RESEARCH STUDIES

Mereo *Protocol MBGS205* A phase IIb multicentre, double-blind, dose-ranginh,randomised, placebo-controlled study evaluating safety and efficacy of BGS649 in male obese subjects with hypogonadotrophic hypogonadism.	1/16-Present
Auxilium *Protocol AUX-CC-810* Long-term safety, curvature deformity characterization, and immunogenicity over time in subjects previously treated with AA4500 for Peyronie's disease instudies AUX-CC-802, AUX-cc-804, and AUX-cc-806	02/15-Present

Perrigo — 1/16-10/16
Protocol PRG-NY-007
A randomized, double -blind, vehicle-controlled, parallel-group, multicenter study to compare perrigo UK finko's estradiol vaginal cream 0.01% to estrace (estrodial) vaginal cream, USP, 0.01%
(Warner Chilcott (US), LLC) and both active treatments to a vehicle control In the treatment of vulvar and vaginal atrophy

Ferring Pharmaceuticals — 07/14-05/15
Protocol 000127
A Phase 3, Open -Label, Non-Randomized, Clinical Trial to Evaluate the Efficacy and Safety of FE 999303 (Testosterone Gel) in Adult Hypogonadal Males.

Abbvie — 10/15-03/15
Protocol A-8796-007
Psychometric Evaluation of the Hypogonadism Impact of Symptoms Questionnaire (HIS-Q)

BioActive — 01/13-03/22/13
Primary Investigator: Protocol SAL100
As single dose uptake study comparing Micronized Curcumin in a sustained-release matrix (MicroActive® Curcumin SR) and 95% Curcumin Powder

Clarus — 10/12-06/14
Primary Investigator: Protocol CLAR-12010
Phase IV, Open label study for oral testosterone undercanoate in hypogonadal men

Auxillium — 07/12-02/14
Primary Investigator: Protocol AUX-CC-806
Phase III, Open- label study of the safety and effectiveness of AA4500 administered twice per treatment cycle for up to four treatments (2 x 4) in men with Peyronie's Disease

Clarus — 06/19/13
Primary Investigator: Protocol CLAR-09007
Phase III, Active-Controlled, safety and efficacy trial of oral testosterone unecanoate (TU) In hypogonadal men

Trimel Biopharma SRL — 03/12-06/12
Primary Investigator: Protocol TBS-1-2011-03
A 90-day, randomized, dose-ranging study, including potential dose titration evaluating the efficacy and safety of intranasal TBS-1 in the treatment of male hypogonadism with sequential safety extension periods

Emotional Brain — 09/11-06/13
Primary Investigator: Protocol EB-82
A double-blind, randomized, placebo-controlled, dose-finding study to investigate the safety and efficacy of Lybrido in the domestic setting in healthy female subjects with hypoactive sexual desire disorder and low sensitivity for sexual cues. Phase II

Repros Therapeutics, Inc. — 12/10-1/12
Investigator: *Protocol Number ZA-202*
A randomized, parallel, double-blind, placebo-controlled exploratory study to evaluate the efficacy of androxal® in improving glycemic control in men with secondary hypogonadism or Adult-onset Idiopathic Hypogonadotropic Hypogo-nadism (AIHH) and type 2 diabetes mellitus with sub-optimum treatment.

Repros Therapeutics, Inc. 2/11-1/12
Investigator: *Protocol Number ZA-203*
A randomized, double-blind, placebo-controlled, parallel, multi-center Phase IIb study to evaluate normalization of morning testosterone levels in men with secondary hypogonadism with confirmed morning testosterone levels <250 ng/dL that wish to preserve their reproductive status and are not currently being treated with topical testosterone.

Allergan 7/10-4/11
Investigator, Phase 3: *Protocol Number 191622-095-01*
A multicenter, double-blind, randomized, placebo-controlled, parallel-group study of the safety and efficacy of a single treatment of BOTOX® (Botulinum Tox-in Type A) purified neurotoxin complex followed by a treatment with BOTOX® as applicable in patients with idiopathic overactive bladder with urinary inconti-nence.

Johnson & Johnson 5/09-8/09
Investigator: *Protocol Number KOYNAP00 06*
In vitro study on the effects of vaginal lubricant prototypes when mixed with human semen samples on sperm motility.

Graceway Pharmaceuticals 1/08-8/09
Investigator: *Protocol Number GW01-0801*
A Phase 3, randomized, double-blind, placebo-controlled, mulit-center, effica-cy and safety study of imiquimod creams in the treatment of external genital warts.

QuatRx Pharmaceuticals 8/07-8/09
Primary Investigator: *Protocol Number 15-50821*
Efficacy and safety of Ospemifene in the treatment of moderate to severe vaginal dryness and vaginal pain associated with sexual activity, symptoms of Vulvar and Vaginal Atrophy (VVA), associated with menopause: A 12-week, randomized, double-blind, placebo-controlled, parallel-group study comparing oral Ospemifene 60 mg daily dose with placebo in postmenopausal women.

Auxilium Pharmaceutics, Inc. - Hypogonadiasm Primary 3/08-8/09
Investigator: *Protocol Number AUX-TG-225*
Observational study to evaluate the effectiveness of Testim 1% in a large sam-ple of hypogonadal men from a variety of "real world" clinical practice settings by assessing sexual function, mood (depression), body mass index, and testos-terone levels.

Repros Therapeutics, Inc. - Secondary Hypogonadism 6/08-8/09
Primary Investigator: *Protocol Number ZA-201*
A Randomized, open-label, fixed dose, active-control, multi-center Phase IIB study to evaluate fertility in men with secondary hypogonadism comparing topical exogenous administration of testosterone and Androxal (Enclomiphene).

Biosante Pharmaceuticals - Hypoactive Sexual Desire Disorder 5/08-Present
Primary Investigator: *Protocol Number TEST WOO7*
A Phase III, randomized, double-blind, placebo-controlled, multi-center study of long-term safety and efficacy of LibiGel for the treatment of hypoactive sexual desire disorder in postmenopausal women.

Biosante Pharmaceuticals - Hypoactive Sexual Desire 5/08-Present
Disorder Primary Investigator: *Protocol Number TEST WOO8*

A Phase III, randomized, double blind, placebo controlled, multi center study of hypoactive sexual desire disorder in surgically menopausal women.

Medicis Pharmaceutical Corporation – Spermatogenesis 1/07-10/08
Primary Investigator: *Protocol Number MP-0104-18*
Randomized, double-blind, placebo-controlled study to examine the effects of Minocycline Extended-Release tablets on spermatogenesis in human males.

Bristol-Myers Squibb Company – Spermatogenesis 2/07-8/08
Primary Investigator: *Protocol Number CN148-014-017*
A multicenter, randomized, double-blind, placebo-controlled trial to evaluate spermatogenesis in healthy male subjects during administration of BMS-562086.

Palatin Technologies, Inc. – Female Sexual Dysfunction 8/06-8/08
Primary Investigator: *Protocol Number PT-141-2005-53FB*
A placebo-controlled, randomized, double-blind, parallel group, at-home exploratory study to evaluate the efficacy and safety ofintranasally administered PT-141 in subjects with female sexual arousal disorder.

Boehringer Ingelheim Pharmaceuticals, Inc. – Female Sexual Dysfunction 7/06-9/08
Primary Investigator: *Protocol Number 511.70*
A 24 week, randomized, double-blind, placebo-controlled, safety and efficacy trial of Flibanserin 25 milligrams twice daily and 50 milligrams once and twice daily in premenopausal women with hypoactive sexual desire disorder in North America.

Pfizer, Inc. – Sexual Dysfunction

Study #1082 10/02-12/03
A randomized, double-blind, placebo-controlled, fixed dose, multi-center study to evaluate the efficacy, safety and toleration of oral Sildenafil administered for 12 weeks to post menopausal women who have been diagnosed with female sexual arousal disorder.

Study #1123 10/02-12/03
A randomized, double-blind, double dummy, placebo-controlled, fixed dose, multi-center study to evaluate the efficacy, safety and toleration of oral Sildenafil citrate administered for 12 weeks to pre-menopausal women who have been diagnosed with female sexual arousal disorder.

Study #1133 7/03-2/04
An open-label, multi-center extension study to evaluate the safety, toleration and the sustained efficacy of oral Sildenafil administered to women who have been diagnosed with female sexual arousal disorder.

Study #1179 10/03-6/04
A multi-center open label flexible dose study to investigate the use patterns of Viagra and the ability of investigators to further optimize subject satisfaction with Viagra through customized instruction.

Bayer Pharmaceutical Corp. – Male Sexual Dysfunction

Study #100477 Version 19 11/03-1/04
REALISE – Real Life Safety and Efficacy - A post-marketing (Phase IV) surveil-lance study of Levitra.

EDUCATION

Boston University Medical Center, Boston, Massachusetts 1993-1994
Fellow in male infertility and erectile dysfunction with Robert D. Oates, M.D. and Irwin Goldstein M.D.

Mount Sinai Medical Center, New York, NY Urology resident 1989-1993

Beth Israel Medical Center, New York, NY Second and third year surgical resident 1987-1989

St. Luke's Hospital, New York, NY Medical internship 1986-1987

University of California, San Francisco Medical School Doctor of Medicine 1986

The Jewish Theological Seminary, New York, NY Coursework towards a Masters in Hebrew Letters 1984-1985

Harvard College, Cambridge, MA 1981
B.A. in Biology, Cum Laude.
Received the John Harvard and Detur Awards for academic achievement

HOSPITAL AFFILIATIONS

White Plains Hospital, White Plains, New York
Westchester County Medical Center, Valhalla, New York Montefiore Medical Center, Bronx, New York
New York Medical Center, New York, New York

ASSOCIATIONS

Society for the Study of Impotence
Society for the Study of Male Reproduction
American Urological Association
The American Society for Reproductive
Medicine Impotence World Association
American Society of Andrology
American Board of Bioanalysts
American Board of Urology
Society of Urologic Prosthetic Surgeons

PUBLICATIONS

Goldstein I, Nehra A, Werner M, Geffin M, Korn K, Krane R

Technique and follow-up of sharp corporal tissue excision procedure for prosthesis implantation with bilateral severe diffuse corporal fibrosis. Journal of Urology 1995; 4 (program Supplement); 360A. Abstract.

Goldstein I, Nehra A, Werner M, Geffin M, Korn K, Krane R
Technique and follow-up of sharp corporal tissue excision procedure for prosthesis implantation with bilateral severe diffuse corporal fibrosis. International Journal of Impotence Research, Sept. 6(1), Abstract A58, September, 1994.

Goldstein I, Nehra A, Werner M, Geffin M, Korn K, Krane R
Technique and follow-up of sharp corporal tissue excision procedure for prosthesis implantation with severe diffuse corporal fibrosis. Journal of Urology 1995; 4 (program Supplement); 44A. Video.

Goldstein I, Nehra A, Werner M, Geffin M, Korn K, Krane R
Technique and follow-up of sharp corporal tissue excision procedure for prosthesis implantation with bilateral severe diffuse corporal fibrosis. Journal of Urology 153(4). Abstract #V-17, April, 1995.

Goldstein, I., Geffin, M., Werner, M.A., Nehra, A
Technique and Follow-up of sharp corporal tissue excision procedure for prosthesis implantation with bilateral severe diffuse corporal fibrosis. Abstract No. 7, 63rd Annual New England Section, American Urological Association, Bermuda, September 29, 1994.

Gordon JW, Werner M, Champlin A, Schroeder A, Mobraaten L
Development of a fertilization microchamber that spontaneously concentrates motile sperm around oocytes and improves in vitro fertilization. Fertility and Sterility 1991; 56 (program Supplement): 567-568. Abstract.

Nehra A, Werner MA, Goldstein I
Reconstructive Penile Surgery. In: Pediatric and Adult Reconstructive Urologic Surgery. Edited by Libertino, JA. Baltimore: Williams and Wilkins. In press.

Nehra A, Werner MA, Title CI, Bastuba M, Oates RD
Vibratory stimulation and electroejaculation as therapy for spinal chord injured patients: semen pa-rameters and pregnancy rates. Fertility and Sterility 1994; 62 (Program Supplement): S59. Abstract

Nehra A, Werner MA, Title CI, Bastuba M, Oates RD
Vibratory stimulation and electroejaculation as therapy for spinal chord injured patients: semen parameters and pregnancy rates. Journal of Urology 155(2): 554-559, February, 1996.

Nehra, A., Werner, M.A., Krane, R. J., Goldstein, I
High resolution ultrasonography of the penis: a non-color duplex scanner with a 13.5 MHz pulsed wave probe (Proscan Excel). International Journal of Impotence Research, 6(1), Abstract D58, September, 1994.

Nehra, A., Werner, M.A., Title, C., Oates, R.D
Semen parameters and pregnancy rates in an ejaculatory spinal cord injured patients treated with vibratory stimulation and electroejaculation. Abstract No. 12, 63rd Annual New England Section, American Urological Association, Bermuda, September 29, 1994.

Nehra, A., Werner, M.A., Title, C., Oates, R.D.
Semen parameters and pregnancy rates in an ejaculatory spinal cord injured patients treated with vibratory stimulation and electroejaculation. Fertility and Sterility 62(suppl) Abstract#0-126, November, 1994.

Werner MA, Barnhard J, Gordon JW
The effects of aging on sperm and oocytes. Seminars in Reproductive Endocrinology 1991; 9: 231- 240.

Werner MA, Lipshultz LI
The new technology in male infertility: Is it practical? Contemporary Urology 1992; 4: 29-38.

Werner MA, Nehra A, Goldstein I
Duplex ultrasonography: the advantages of a 13.5 MHz probe (Proscan Excel). International Sympo-sium of Impotence Research. In press.

Werner MA, Oates RD
Male Infertility. In: Primary Care and General Medicine. Edited by Noble, J. St. Louis: Mosby-Year Book, 1996. 1764-1772.

Werner MA, Goldstein I, Krane RJ
Male Sexual Dysfunction. In: Primary Care and General Medicine. Edited by Noble, J. St. Louis: Mosby-Year Book, 1996, 1797-1803.