Version Date Nov 1st, 2016

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PERSONAL

Founder, CEO and Medical Director of Sermonix Pharmaceuticals

Director Emeritus of a Clinical Research Center with research interests in menopause, sexual dysfunction, hormone replacement therapy, SERMs, osteoporosis, contraception and gynecologic endocrinology. Conducted over 140 clinical trials in women's health.

Lectures nationally, internationally and consults widely on women's health issues, and is on numerous advisory boards. Board-certified Obstetrician/Gynecologist.

EDUCATION

B.A. in History and Premedicine, Northwestern University, Evanston, Illinois, 1984
M.D. The Ohio State University College of Medicine, Columbus, 1990
OB/GYN Post-Graduate Residency, Ohio State University Hospitals, Columbus, 1994

EMPLOYMENT

Present *Founder, CEO and Chief Medical Officer of Sermonix Pharmaceuticals, an Ohio LLC specialty pharmaceutical company with targeted focus towards bringing new and emerging late-stage women's health products through clinical development, regulatory approval, and commercialization.*

1997-Present *Founder, Director Emeritus, Principal Investigator, The Columbus Center for Women's Health Research - An independent private research center dedicated to innovation in the medical treatment of women, participating in Phase II-IV clinical trial research*

1994-2015 *Portman Obstetrics and Gynecology, Associates Private Practice*

1994-Present *Adjunct Instructor, Department of OB/GYN Wexner Medical Center at The Ohio State University* and *lecturer in the Department of Medical Humanities*

1995-2008 *Founder and President, Ob/Gyn Physician Services, Inc. - Provider of Obstetric and Gynecologic Emergency care for the under-insured and under-served of the East Columbus community.*

2003-2004 *Member, Pfizer National Women's Health Advisory Board*

2003-2014 *Teva Pharmaceuticals Advisory Board*

2007-2008 *Vice-Chairman, Mount Carmel East Hospital, Department of OB/Gyn*

2015-present *NAMS Corporate Liaison Council, Sermonix Pharmaceuticals*

2010-2014 *Eastside Surgery Center, Medical Advisory Committee*

2011-2014 *Editorial Peer-Review Referee, Journal of Sexual Medicine*

2011-2014 *Shionogi Pharmaceuticals Advisory Board*

2011-present *Palatin Technologies Advisory Board*

2011-2015 *Noven Pharmaceuticals Advisory Board*

2012-2014 *Board of Directors, International Society for the Study of Women's Sexual Health (ISSWSH)*

2012-2013 *Meda Pharmaceuticals Advisory Board*

2012-2014 *Education Committee, ISSWSH*

2012-2014 *Treasurer, Board of Directors, ISSWSH*

2012-1014 *TherapeuticsMD Advisory Board*

2012-present *Sprout Pharmaceuticals/Valeant Pharmacueticals—Co-Chairman of the Flibanserin Scientific Research Committee*

2013-2014 *Apricus Bioscience Advisory Board*

2013-2014 *Pfizer Duavee Advisory Board*

2014-present *Nuelle Advisory Board*

2013-2014 *Co-Chair ISSWSH/NAMS Consensus Conference on Vulvovaginal Atrophy: Definitions, Treatments and Nomenclature*

March 2013 Presented at Brisdelle Advisory Committee to FDA

June 2015 Presented at Flibanserin Advisory Committee to FDA

RESEARCH and PUBLICATIONS

RESEARCH

The Columbus Center for Women's Health Research, 1997-2015
Principal Investigator

-- A double-blind, randomized, parallel study comparing 17-Beta estradiol TD 7-day patch 20, 40, 60 and 80 μg/day with placebo in the treatment of vasomotor symptoms in postmenopausal women.

-- An open-label, non-comparative, multicenter study to evaluate contraceptive efficacy, cycle control and safety of a one-compartment all-EVA vaginal ring.

-- A randomized, double-blind, active- and placebo-controlled, parallel group, multicenter study assessing the safety and protective effect on the endometrium of 4 dosage combinations of norethindrone acetate plus ethinyl estradiol.

-- Phase II double-blind placebo-controlled trial of the safety, toleration and efficacy of the SERM CP-336,156 for the prevention of bone loss in postmenopausal women.

-- Efficacy and Safety of an OCP in the Treatment of Moderate Acne Vulgaris - A 6-Month Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study.

-- Phase II, Double-Blind, Placebo-Controlled Trial of the Safety, Toleration and Efficacy of a SERM and Raloxifene 60 mg/d for the Prevention of Bone Loss in Postmenopausal Women

--A Multicenter, Open Label Randomized, Crossover, Preference Study of Oral Alendronate Sodium 70 mg Once Weekly and 10 mg Once Daily in Postmenopausal Women with Osteoporosis

--A Phase III, Parallel, Randomized, Multicenter, Open Label Clinical Study to Evaluate the Efficacy and Safety of Extended Oral Contraceptive Therapy—84 Day Active Cycle
--Two year phase 3 extension study of extended-cycle OCs

-- Effects of Norethindrone Acetate (NA - 1 mg) Plus Ethinyl Estradiol (EE – 10micrgm) in Perimenopausal Women: A 6-Month Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study

-- A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Dose-Ranging Study to Assess the Effect of an investigational drug on Insulin and Ovarian Androgen Production in Obese Women with Polycystic Ovary Syndrome (PCOS)

--A Multi-Center, Randomized, Placebo-Controlled, Double-Blind Study to Assess the Effect of 500 and 1000mg of INS-1 on Ovulatory, endrocrine and

metabolic abnormalities in Obese Women with Polycystic Ovary Syndrome (PCOS).

--A Multi-Center, Randomized, Placebo-Controlled, Double-Blind Study to Assess the Effect of several doses of an investigational drug on Ovulatory, endrocrine and metabolic abnormalities in Obese Women with Polycystic Ovary Syndrome (PCOS).

--Genomic Substudy in Women with Polycystic Ovary Syndrome

--A Randomized, Placebo-controlled, double-blind clinical study to assess the Effect of D-Chiro-Inositol on Clomiphene Citrate induced Ovulation in Women with Polycystic Ovary Syndrome

--A Randomized, Placebo-Controlled, Double-blind, Parallel-group

--Study of the Relative Clinical Efficacy of Two 6.5% Tioconazole Vaginal Ointment Products: A Bioequivalence Study.

--Double-Blind, Randomized, Multicenter, Parallel Group Study Comparing the Therapeutic Equivalence and Safety of Miconazole Nitrate 4% Vaginal Cream with Monistat-3 Cream in the Treatment of Vulvovaginal Candidiasis.

-- Multicenter, Randomized, Double Blind, Placebo-Controlled, Safety and Efficacy Study of an OCP in Women with Dysmenorrhea.

-- Beyond Endorsed Lipid Lowering with EBCT Scanning - Atorvastatin 80 mg vs Pravastatin 40 mg.

--A 20-Week, Open-Label Assessment of the Safety and Efficacy Profile of Atorvastatin when used to Optimally Control Dyslipidemia in Postmenopausal Patients.

-- Impact of Progestogen Choice on Mood and the Quality of Life and Satisfaction of Women

-- Dose Range Finding and Efficacy Study of Estradiol (E_2) Administration with a GnRH agonist in Premenopausal Women with Uterine Leiomyomata and Eligible for Hysterectomy.

--A Randomized, Open-Label, Comparative Trial of Bone Mineral Density, Cognition, and Quality of Life with Norethindrone Acetate (NA - 1 mg) Plus Ethinyl Estradiol (EE – 10 μg), Evista® (Raloxifene), and PremPro™ in Women 5 to 15 Years Postmenopausal.

--A 12-Week, Randomized, Partially-Blinded, Active and Placebo-Controlled, Multicenter Study Assessing the Effect of Norethindrone Acetate (NA - 1 mg) Plus Ethinyl Estradiol (EE –5 and 10 μg) on Endothelial Dysfunction in Postmenopausal Women.

--A Study of the Safety and Efficacy of a SERM for the Prevention of Bone Loss and for Lipid Lowering in Postmenopausal Women at Risk for Osteoporosis

--A Randomized, Double blind Multicenter Study Evaluating and Comparing the Effects of Alendronate and Raloxifene on Bone Mineral Density in Postmenopausal Women

--Phase I/II Randomized, Placebo-controlled Proof of Concept Study to Evaluate the Effects of a SERM in Combination with Estradiol on Vasomotor Symptoms in Postmenopausal Women

--Multicenter, Multinational, Randomized, Double-Blind, Active Controlled Comparative Trial to Assess the Histological Profile Endometrial and Breast Endpoints Following Treatment with Tibolone versus Conjugated Estrogen plus Medroxyprogesterone Acetate in Postmenopausal Women

--Double-blind, Placebo Controlled Dose Ranging Trial to Evaluate the Efficacy of Atorvastatin on Bone Mineral Density and Markers of Bone Turnover in Postmenopausal Women

--Phase IIIb, Multicenter Trial Comparison of injectable progestin contraception on bone mineral density

--Prospective, Randomized Double-blind Comparative Trial to Evaluate the efficacy and safety of Ciprofloxacin 500mg once daily extended release 3 days vs. Ciprofloxacin 250mg BID 3 days for uncomplicated UTI in women

--A 6 month Randomized, Placebo-Controlled Study of the Safety and Efficacy of Lasofoxifene in the Treatment of Vaginal Atrophy in Postmenopausal Women with assessment of short term effects on bone mineral density

--A Phase III, Randomized, Multicenter, Clinical Trial to Evaluate the Efficacy and Safety of 91 Day Cycle Combination Oral Contraceptive Regimens Utilizing Ethinyl Estradiol During the Pill-Free Interval for the Prevention of Pregnancy in Women

--Up to 3 year phase 3 extention of 91 Day Cycle Oral Contraception
--Phase II/III multi-center Randomized study of the safety and efficacy of topical Estradiol gel in the treatment of vasomotor symptoms in postmenopausal women

--A 6 month open label randomized multicenter study to evaluate the comparative efficacy and safety of oral anti-viral in the episodic and suppressive treatment of recurrent genital herpes

--A 12 week phase 3 Study of the efficacy and safety of a SERM in the treatment of vaginal atrophy in postmenopausal women

--Randomized Multicenter, Double-blind controlled study to compare the effectiveness of a single dose anti-viral and Placebo in patient-initiated episodic treatment of recurrent Herpes Labialis

--Open-label non-randomized trial of the symptom specific effectiveness of an anti-muscarinic in adult patients with symptoms of overactive bladder

--Phase III randomized, placebo-controlled multi-center study of efficacy and safety of a non-hormonal agent for the treatment of postmenopausal vasomotor symptoms

--A prospective, open label, multi-center phase IIIb study to investigate patient satisfaction with montly Ibisphophonate in women with postmenopausal osteoporosis or osteopenia transitioned from once-weekly alendronate or risedronate.

--A prospective, randomized, parallel, double-blind controlled study of a multi-component medical food for the relief of breast pain associated with fibrocystic breast disease

--An open label multi-center study to determine level of adherence to monthly oral or every three month intravenous bisphosphonate treatment in postmenopausal women with osteoporosis or osteopenia who are GI intolerant of daily and/or weekly alendronate or risedronate

--A multi-center, double-blind, double-dummy, randomized, placebo-controlled study comparing a progestin-estradiol transdermal patch with a placebo patch in postmenopausal women to determine the lowest effective dose of estradiol for the relief of moderate to severe hot flushes

--A randomized, multi-center, double-blind study to evaluate the efficacy of an extended cycle combination oral contraceptive which utilizes ethinyl estradiol during the usual hormone-free interval, compared to conventional oral contraceptive therapy for the treatment of cyclic pelvic pain in women

--A randomized, multi-center, double-blind, placebo-controlled trial to evaluate the efficacy and safety of synthetic conjugated estrogens tablets for the treatment of vulvovaginal atrophy in healthy postmenopausal women

--A multi-center, double-phase, randomized, double-blind, placebo controlled (12-week double-blind followed by 12-week open label) study evaluating the effect of an anti-muscarinic on urgency urinary incontinence (UUI), urgency, frequency, sexual quality of life and sexual function in women with overactive bladder

--A prospective, open-label, multi-center extension study of a multi-component medical food for the relief of breast pain associated with fibrocystic breast disease

--Multi-Center Open-label Phase III study to evaluate the efficacy and safety of an extended cycle low dose combination oral contraception regimen, which utilizes ethinyl estradiol during the hormone-free interval for the prevention of pregnancy in women

--Double-blind randomized, placebo- and active-controlled efficacy and safety study of a SERM/estrogen combination for the treatment of moderate to severe vulvar/vaginal atrophy in post-menopausal women

--Double-blind, randomized, parallel, placebo-controlled multicenter trial to compare the effects of 12 weeks of treatment with an estradiol vaginal cream, USP, 0.01% vs Estrace® vaginal cream on vulvovaginal atrophy in healthy postmenopausal women

--Randomized, multicenter, double-blind placebo-controlled trial to demonstrate the safety and efficacy of daily synthetic conjugated estrogens for the treatment of vasomotor symptoms in postmenopausal women

--A 24-week, Randomized, Double-Blind Placebo Controlled, Safety and Efficacy Trial of an investigational centrally-acting drug in Premenopausal Women with Hypoactive Sexual Desire Disorder

--A 12-week randomized, multicenter, double blind placebo-controlled study to compare the effects of an investigational estrogen cream to placebo on vulvovaginal atrophy

--Phase IIB multi-center double-blind dose-ranging study evaluating the safety and efficacy of a non-hormonal investigational medication for the treatment of severe vasomotor symptoms associated with menopause

--A prospective, multicenter, open-label study to evaluate the safety and efficacy of a 21 day active combined OC and 7 days EE oral contraceptive regimen

--Open label Study of the Safety and Efficacy of a New Low Dose Oral Contraceptive Containing Norethindrone Acetate 1 mg and Ethinyl Estradiol 10mcg with a 2 day hormone free-interval

--A Phase II randomized Double-Blind Active –Controlled Study to Assess the Bone Density Safety and Treatment Efficacy of an Investigational Oral GnRH antagonist in Subjects with Endometriosis

--A partial double-blind. Placebo-controlled study to assess the efficacy and safety of an aromatase inhibitor on endometrial thickness in healthy premenopausal women when dosed at various times during the menstrual cycle

--A multiceneter, open-Label Study to evaluate the efficacy, cycle control and safety of a contraceptive vaginal ring delivering a daily dose of Nestorone and Ethinyl Esradiol

--Multi-center open-labeled randomized study to assess the safety and contraceptive efficacy of two doses of the ultra low dose contraceptive intrauterine system for a maximum of 3 years in women 18 to 35 years of age

--A multicenter, double-blind randomized placebo-controlled study to determine the lowest effective dose of an oral progestin and 17beta estradiol for the relief of

moderate to severe vasomotor symptoms in postmenopausal women over a treatment period of 12 weeks

--A prospective multicenter randomized double-blind study to evaluate hormone patterns and ovarian follicular with the oral contraceptive

--A phase III randomized double-blind placebo controlled multicenter study to determine the safety and efficacy of an investigational treatment for obesity in adults with BMI≥35

-- A phase III randomized double-blind placebo controlled multicenter study to detrermine the safety and efficacy of an investigational treatment for obesity in adults with obesity-related co-morbid conditions

--Phase II 12 week randomized double blind placebo controlled multicenter study of the efficacy and safety of a SERM in the treatment of severe vaginal dryness and vaginal pain associated with sexual activity, symptoms of vulvar and vaginal atrophy associated with menopause

--A 6 month phase III multicenter randomized double-blind placebo-controlled study to investigate the safety and efficacy of an extended release non-hormonal tablet in the treatment of vasomotor symptoms in post-menopausal women

--A multicenter, randomized double-blind active-controlled parallel group 2-arm study to show superiority of an oral contraceptive over Ortho Tri-Cyclen Lo on hormone withdrawal-associated symptoms after 6 cycles of treatment

--A randomized, double-blind placebo-controlled dose-ranging multicenter evaluation of a topically administered medication versus placebo in subjects with pain associated with fibrocystic breast disease

--Psychometric evaluation and validation of the symptoms of an endometriosis scale in electronic diary format

--A Phase 2, 16 week multicenter, randomized double blind placebo controlled, parallel group proof of concept study evaluating the safety and efficacy of an IgG2 monoclonal antibody directed against nerve growth factor for the treatment of pain associated with endometriosis

--Multicenter, open-label uncontrolled study to investigate the efficacy and safety of a transdermal contraceptive patch in a 21-day regimen for 13 cycles in healthy female subjects

--A 3 month Phase 3 multicenter randomized double-blind placebo controlled study to investigate the safety and efficacy of an extended release non-hormonal treatment of vasomotor symptoms in postmenopausal women

--Double blind randomized placebo and active controlled efficacy and safety study of the effects of SERM/estrogen combinations on endometrial hyperplasia and prevention of osteoporosis in postmenopausal women

--Phase III multicenter randomized placebo controlled trial investigating the safety and efficacy of a centrally acting drug for the treatment of HSDD in pre-menopausal women

--Phase III multicenter randomized placebo controlled trial investigating the safety and efficacy of a centrally acting drug for the treatment of HSDD in post-menopausal women

--Mulicenter open label single arm safety and efficacy pregnancy prevention trial of an extended cycle dose escalating oral combined contraceptive

--Phase III randomized multicenter placebo controlled trial of vaginal DHEA in the treatment of postmenopausal vaginal atrophy

--Phase III randomized controlled trial of safety and efficacy of vaginal DHEA in a 12 month study

--Phase III 6 month double-blind placebo controlled trial non-hormonal treatment using extended-release gabapentin for the treatment of post-menopausal vasomotor symptoms

--Phase III 6 month multi-center study of an SSRI for the treatment of post-menopausal vasomotor symptoms

--A Phase III pregnancy prevention and endometrial safety study of a 28-day cycle contraception with no hormone-free interval

--Phase III pregnancy prevention study of a new transdermal combined hormone contraceptive patch

--Phase III Multicenter randomized open-label study to evaluate user satisfaction with and tolerability of low-dose LNG IUS with 12µg LNG/day in comparison to a 30µgEE/3mg drosperinone OC in young nulliparous and parous women over 18 months

--Phase III 3 month multi-center study of a new SSRI for the treatment of post-menopausal vasomotor symptoms

---Phase III randomized multicenter placebo controlled trial of vaginal estrodiol gel in the treatment of postmenopausal vaginal atrophy

--Phase IIB placebo-controlled randomized parallel group, dose-finding trial to evaluate the efficacy and safety of subcutaneously administered bremelanotide in premenopausal women with FSAD and/or HSDD

--12 week phase 4, randomized double-blind placebo-controlled parallel group multicenter trial in overactive bladder subjects to conform the efficacy of 8 mg fesoteridine compared to 4 mg fesoterodine

--Phase III multi-center, randomized placebo-controlled trial investigating the safety and efficacy of two doses of an herbal therapy for the treatment of postmenopausal women with moderate to severe hot flashes

--A randomized, placebo-controlled, parallel group multicenter study to evaluate the efficacy and safety of a selective progesterone receptor modulator (SPRM) in women with anemia associated with uterine fibroids

--Bioequivalence study of 10microgram vaginal inserts and Vagifem® and compare both to a placebo control in female subjects with moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause

--Phase II multicenter randomized placeb-controlled double-blind parallel-group, dose finding trial to evaluate the efficacy and safety of an intranasal testosterone gel in pre-menopausal women with acquired female orgasmic disorder

--A phase IV evaluation of an electric pelvic floor muscle stimulator device in addition to Kegel exercises for the treatment of female stress urinary incontinence

--Validation of the Actionable MS Urinary Function Screening Tool (MS-UFST) in patients with urinary urgency incontinence due to overactive bladder

--Phase III randomized open-label active-controlled multicenter trial to study contraceptive efficacy and safety of nomegesterol acetate-17 Beta-estradiol tablets in healthy sexually active women aged 18-50 years

--Randomized, multicenter, double-blind, vehicle-controlled study to evaluate the safety and efficacy of a vaginal estrogen gel in postmenopausal women with dyspareunia

--Multicenter, double-blind, randomized, placebo-controlled Phase II study to assess the efficacy, safety, and dose-response of a botanical extract in the treatment of primary dysmenorrhea

--Open label Multicenter phase 3 efficacy and safety trial of a 5 microgram EE/NETA containing ultra-low dose chewable oral contraceptive for the prevention of pregnancy

--A randomized Double-Blind Active –Controlled Study Study to Evaluate the Safety and Efficacy of an Investigational Oral GnRH antagonist in Subjects with Moderate to Severe Endometriosis-Associated Pain

--A Phase 3, Double-Blind Placebo-Controlled Randomized Multicenter Study to Evaluate the Safety and Efficacy of Estradiol in Combination with Progesterone in Postmenopausal Women with an Intact Uterus: Estradiol to Reduce the Frequency and Severity of Vasomotor Symptoms and Progesterone to Manage the Incidence of Endometrial Hyperplasia

--Qualitative Study among Post-menopausal Women to Understand the Vulvovaginal Atrophy (VVA) Symptom Experience

--Symptomatic VVA: Item Development and Psychometric Validation of a Novel Patient Reported Outcome (PRO) Measure for Research and Clinical Application

--A single-arm, open-label, multicenter Phase 3 study of the contraceptive efficacy, safety and tolerability of a transdermal estrogen/progestin contraceptive delivery system

--Phase 3, randomized double-blind placebo-controlled multi-center trial to evaluate the safety and efficacy of estradiol softgel vaginal capsule in postmenopausal women with moderate to severe symptoms of VVA

--Phase III placebo-controlled double-blind randomized trial to evaluate the efficacy and safety of subcutaneously administered bremelanotide in premenopausal women with HSDD

Journal Articles, Abstracts, Presentations

One Year of Continuous Combined Hormone Therapy with 5µg EE/1 mg NETA and Endometrial protection in Postmenopausal Women

Poster Presentation North American Menopause Society Meeting *NAMS 2000*

Poster Presentation American Society of Reproductive Medicine *ASRM Orlando Fl 2001*

American Society for Reproductive Medicine Annnual Meeting Orlando 2001 *Symposium Co-Chair: The 50-Something Woman: What We Know, What We Think We Know, What We Need to Know*

Endometrial Hyperplasia and Proliferation in 2 pooled studies Abstract

NAMS Chicago Il 2002

3rd World Congress on Controversies in Obstetrics and Gynecology 2002

Poster presentation American Society for Reproductive Medicine 3/2001

American Association of Nurse Practitioners 2001

Effects of Low Dose Oral Contraception in Weight in Women with Moderate Acne Vulgaris Poster presentation 3rd World Congress in Obstetrics and Gynecology 2002

Poster NAMS Washington DC 2004: Lasofoxifene, but not Raloxifene, has beneficial effects on markers of vaginal atrophy

Review--HRT and The Human Genome Project: Trends In Formulation and Dose *The Female Patient* Dec. 2001

Effect of Chiro-Inositol on Insulin and Ovarian Androgen Production in Obese Women with Polycystic Ovary Syndrome (PCOS) Abstract *ASRM 2001*

Preference Study of Oral Alendronate Sodium 70 mg Once Weekly and 10 mg Once Daily Therapy in Postmenopausal Women with Osteoporosis
Poster presentation *NAMS 2001*

Lack of Effect of Raloxifene on markers of bone turnover compared to EE/NETA combined CCHRT Poster presentation *ACOG New Orleans, LA 2002*

A randomized, double-blind placebo-controlled multicenter study that assessed the endometrial effects of norethindrone acetate plus ethinyl estradiol versus ethinyl estradiol alone *American Journal of Ob/Gyn* FEB 2003

Vaginal Ph and MI changes with Lasofoxifene *ACOG Philadelphia 2004*

Comparison of lasofoxifene and raloxifene for the prevention of bone loss in postmenopausal women *ASBMR Seattle 2004*

Lasofoxifene vs placebo and objective measures of VVA
Beneficial effects of lasofoxifene vs placebo in patient reported symptom of irritation and burning
Posters *NAMS 2004 Washington DC:*

Efficacy and Safety of 91 Day Cycle Combination Oral Contraceptive Regimens Utilizing Ethinyl Estradiol During the Pill-Free Interval for the Prevention of Pregnancy in Women
Oral Presentation Association of Reproductive Health Professionals (ARHP) Annual Meeting, Tampa, FL 2005

3 year phase III extention of 91 Day Cycle Oral Contraception Poster Presentation, ARHP Annual Meeting, Tampa, FL 2005 *Contraception* 72 (2005) pg 238

A Review of Current Recommendations for Hormone Therapy 2006 *American Family Physician, American Journal for Nurse Practitoners*

Hormone Therapy Update: Current Recommendations for Menopausal Symptoms, *US Pharmacist 2006*

A Review of Current Recommendations for Hormone Therapy 8/2006 *Current Women's Health Reviews*

Long-term Safety of an Extended-regimen Oral Contraceptive (Seasonale): a Two-year Multicenter Open-label Extension Trial *American Journal of Ob/Gyn July* 2006

Safety and Efficacy of Extended Regimen Oral Contraception Utilizing Continuous Low-Dose Ethinyl Estradiol *Contraception* 2006;73:229-234

A One-Year Safety and Efficacy Trial of a low-dose extended cycle birth control regimen (Seasonale Lo®) and a Two-Year open label extension study of Seasonale Lo® *Ob/Gyn* April 2006 supplement

The Development of the Menopause Impact Tool. Supplement to *Contemporary Ob/Gyn* July 2006

The Development of the Menopause Impact Tool, Poster Presentation Annual Meeting of *The North American Menopause Society*, Nashville September 2006

A New Office-Based Menopause Assessment Questionnaire, Poster Presentation Annual Meeting of *The North American Menopause Society*, Nashville September 2006

Altering the Hormone-Free Interval with Extended-Cycle Contraception, *The Female Patient* September 2006 Supplement

Reproductive Dysfunction for Women with Epilepsy: Update and Directions for Research, *Epilepsy and Behavior* August 2007
Menopause Pharmacotherapeutic Development—CBI Second Annual Conference Review Drugs: The Investigational Drugs Journal March 2007

Ospemifene Improves the Clinical Signs of Vaginal Atrophy: Results from a Pivotal Phase 3 Study Poster Presentation *NAMS Orlando FL 2008*

The effectiveness of twice-weekly synthetic conjugated estrogens B on seven investigator-assessed clinical signs of vaginal atrophy Poster *NAMS Orlando 2008*

A comparison of Extended Cycle Oral contraception and Cyclic OCs for the treatment of cyclic pelvic pain Oral Presentation *ASRM San Francisco 2008*

Medication Adherence to Vaginal Estrogen Therapy: Implications for Clinical Practice *Journal of Women's Health* May 2008 17(4):569-578

Adding low-dose estrogen to the hormone free interval: Impact on bleeding patterns on Bleeding patterns in users of a 91-day regimen oral contraception *Contraception* 2009 79; 350-355

Low-dose synthetic conjugated estrogens, B exhibits early onset of action in the treatment of vasomotor symptoms and vulvovaginal atrophy asscociated with menopause

21st Annual Cardiovascular Invitation Lecture, August 2009: *Hormone Therapy and Cardiovascular Risk: Is There a Right Answer?*

Long-term effects of ospemifene on the clinical signs of vaginal atrophy
The Spectrum of Menopause: Symptom Impact Based on Age
NAMS Poster Session Annual Meeting San Diego 2009

Effects of Gabapentin Extended-Release on Hot Flashes in Post-Menopausal Women Oral Presentation *NAMS Chicago 2010*

The Effect of Orally Administered Synthetic Conjugated Estrogens-B on Vaginal Maturation Index Poster *NAMS Chicago 2010*

International Society for the Study of Female Sexual Dysfunction Annual Meeting Feb 2010 Scottsdale, AZ Plenary Lecture
Female Sexual Dysfunction Research: From Bench to Bedroom

Best Practices: Extended Cycles Contraception *ObGyn* News Feb 2011
Reduction in Dysmenorrhea Severity in Women Using a 91-Day extended-cycle oral contraceptive regimen compared to a 28-day regimen for the treatment of cyclic pelvic pain ASRM Orlando 2011

Ohio State University Cardiology Update: Lecture Title *Hormone Therapy—The Heart of the Matter*, September 14th 2011

Safety and Efficacy of ospemifene 60mg/day at 1 year for the Treatment of Postmenopausal Vulvovaginal Atrophy *ISSVD Annual Meeting*

Evaluation of the safety of daily ospemifene 60mg for up to 1 year when used for the treatment of vulvar and vaginal atrophy in postmenopausal women
Endometrial safety profile ospemifene 60 mg when used for the long-term treatment of vulvar and vaginal atrophy for up to 1 year
Efficacy of ospemifene when used in the treatment of vulvar and vaginal atrophy for up to 52 weeks in postmenopausal women
International Menopause Society IMS Annual Meeting Rome, Italy June 2011

Efficacy of a novel SERM, ospemifene, in the treatment of moderate-to-severe vaginal dryness symptoms of vulvovaginal atrophy associated with menopause
Oral Presentation *NAMS National Meeting Oct 2011 Washington DC*
Efficacy of a novel SERM, ospemifene, in the treatment of dyspareunia symptoms associated with postmenopausal vulvovaginal atrophy
Poster *NAMS National Meeting Oct 2011 Washington DC*

Safety and Efficacy of Ospemifene, a Selective Estrogen Receptor Modulator for the Treatment of Postmenopausal Women with Vulvovaginal Atrophy
Oral Presentation, *International Society for the Study of Women's Sexual Health Annual Meeting, Jerusalem Israel Feb 2012*

Multicenter Open-Label Study to Evaluate the Efficacy and Safety of an Ascending-Dose Extended-Regimen EE/Levonorgestrel Combination OC for Preventing Pregnancy in Women Poster presentation *ASRM Annual Meeting San Diego, CA 2012*

Efficacy of Gabapentin Extended-Release for the Treatment of Menopausal Hot Flashes: Results of the BREEZE 3 Study
Oral presentation *NAMS Annual Meeting Orlando, FL 2012*

Comparative Long-Term Safety and Efficacy in Pre- and Post-Menopausal Women with Hypoactive Sexual Desire Disorder Receiving 100 mg qHS Flibanserin Treatment
Poster presentation *NAMS Annual Meeting Orlando, FL 2012*

Ospemifene, a novel SERM for treating dyspareunia associated with postmenopausal vulvar and vaginal atrophy *Menopause* June 2013

Gastroretentive Gabapetin for Treatment of Moderate-to-Severe Hot Flashes in Menopause: Results of the Breeze 3 Study *Menopause* 2013

Low-dose Mesylate Salt of Paroxetine (7.5 mg) for Menopausal Vasomotor Symptoms: Two Randomized Controlled Trial *Menopause* October 2013

Outcomes of the Visual Evaluation of the Vagina in Phase 3 Stidies of Oral Ospemifene for Vulvar/Vaginal Atrophy Podium Presentation ISSWSH Annual Meeting February 28th-March 3rd, 2013 New Orleans, Louisiana

Efficacy of subcutatneous bremelanotide self-administered at home by premenopausal women with female sexual dysfunction: a placebo-controlled dose-ranging study Poster Presentation ISSWSH Annual Meeting February 28th-March 3, 2013 New Orleans, Louisiana

The Creeping Pearl: Why Has the Rate of Contraceptive Failure Increased in Clinical Trials of Combined Hormonal Contraceptive Pills Trussell J, Portman D *Contraception* 2013 published online

Overall Safety and Efficacy of Ospemifene for Vulvar and Vaginal Atrophy in Postmenpausal Women Poster Presentation ACOG Annual Meeting New Orleans May 2013

Vulvar and Vaginal Atrophy: Ospemifence, a New Treatment Option 2013 *The Journal for the Nurse Practitioner*

Ospemifene 12 Month Safety and Efficacy in Postmenopausal Women with Vulvar and Vaginal Atrophy *Climacteric* 2013

Effects of Low-dose Mesylate Salt of Paroxetine (7.5mg) on Weight and Sexual Function during Treatment of Vasomotor Symptoms Due to Menopause *Menopause* 2014

Low-Dose Ethinyl Estradiol and Levonorgestrel Contraceptive Patch and Pill: Results of Randomized Trial Comparing Efficacy, Safety, Cycle Control and Compliance *Obstetrics and Gynecology* 2013

Long-term safety of ospemifene (52-week extension) in the treatment of vulvar and vaginal atrophy in hysterectomized postmenopausal women
Maturitas epub ahead of print 2014

Abstracts presented at The North American Menopause Society Annual Meeting Dallas, Texas Oct 2013

Poster Presentations:

Treatment persistence with local estrogen therapy in postmenopausal women dealing with vaginal atrophy

Efficacy of Oral Ospemifene: Comparison in Subpopulations

Outcomes in most severe patients at baseline with treatment of LDMP for VMS

Persistence of benefit of LDMP for VMS out to 24 weeks of treatment

An alternative approach to calculating hot flash severity in a postmenopausal VMS trial

Patient Global Impression and Clinical Global Impression with LDMP in the treatment of VMS

Impact of patient baseline characteristics and the treatment of VMS with LDMP

Multiple secondary and exploratory outcomes in VMS trials with LDMP

Incremental Direct and Indirect Cost of VMS with high and lo-dose paroxetine

Oral Presentation:

Effects of Low Dose Mesylate Salt of Paroxetine (LDMP) for postmenopausal VMS on weight and libido

Incremental Direct and Indirect Cost of Untreated VMS

Efficacy and safety of bremelanotide for female sexual dysfunction
Controversies in Obstetrics and Gynecology (COGI) Conference, Vienna Austria October 2013

Society for Gynecologic Investigation Florence Italy March 2014

Subcutaneous Bremelantotide for Female Sexual Dysfunctions in Premenopausal Women: Minimum Clinically Important Differences and Responder Analyses Based on Receiver Operating Characteristics Curves
Poster Presentation

Efficacy of Self-Administered Bremelanotide in Premenopausal Women with Sexual Dysfunction: A Placebo-Controlled Dose-Ranging Study
Oral Presentation

Efficacy and Safety of an Ascending-Dose, Extended-Regimen Levonorgestrel/Ethinyl Estradiol Combined Oral Contraceptive *Contraception* Nov 2013

Women's Health 2014: The 22nd Annual Congress April 2014 Washington DC Safety of Subcutaneous Bremenlanotide Self-administered by Premenopausal Women with Female Sexual Dysfunction

ACOG Annual Meeting Chicago IL May 2014

Bremenalotide for Female Sexual Dysfunction: Responder Analyses from a Phase 2B Dose-Ranging Study Poster presentation

Bremelantotide for Hypoactive Sexual Desire Disorder: Analyses from a Phase 2B Dose-Ranging Study Poster presentation

International Menopause Society 14th World Congress on Menopause, Cancun, Mexico May 2014

Plenary presentation: SERMs and genitourinary effects

Oral Presentation: Efficacy and safety of ospemifene for postmenopausal VVA in various subgroups

Incremental direct and indirect costs of untreated vasomotor symptoms *Menopause* 2015 Mar;22(3):260-6

Female sexual function improved with ospemifene in postmenopausal women with vulvar and vaginal atrophy: results of a randomized, placebo-controlled trial *Climacteric* 2014;17:1-7

Ospemifene, a non-oestrogen selective receptor modulator for the treatment of vaginal dryness associated with postmenopausal vulvar and vaginal atrophy: A randomized, placebo-controlled, phase III trial *Maturitas* 2014;78:91-98

Genitourinary syndrome of menopause: new terminology for vulvovaginal Atrophy from the International Society for the Study of Women's Sexual Health and The North American Menopause Society Published simultaneously online in the *Journal of Sexual Medicine, Menopause, Climacteric*, and *Maturitas* August 25th, 2014 and in print of all three journals

New contraceptive patch wearability assessed by investigators and participants in a randomized phase 3 study Contraception 2015 Mar;91(3):211-6

Self-reported and verified compliance in a phase III trial of a novel low-dose contraceptive patch *Contraception* 2015 Mar;91(3):204-10

One-year treatment persistence with local vaginal therapy in postmenopausal women diagnosed as having vaginal atrophy *Menopause* 2015 May Epub ahead-of-print

Lack of effect of intravaginal DHEA (Prasterone) on the endometrium in postmenopausal women *Menopause* 2015 May

Prasterone has parallel beneficial effects on the main symptoms of vulvovaginal atrophy: 52-week open-label study *Maturitas* 2015 May;81(1):46-56

Treatment of pain at sexual activity (dyspareunia) with intravaginal DHEA (prasterone) Menopause 2015 Mar Epub ahead of print

Abstracts accepted at The North American Menopause Society Annual Meeting, Las Vegas NV Oct 2015

Oral presentations

Lasofoxifene, an estrogen agonist/antagonist favorably impacts lipid parameters: Results from the Osteoporosis and Lipid Lowering (OPAL) Study

Endometrial effects of lasofoxifene: Results from two phase 3 osteoporosis prevention trials

Lasofoxifene prevents postmenopausal bone loss: Pooled data from two pivotal 24 month osteoporosis prevention trials

Poster presentation

Lasofoxifene improves symptoms of genitourinary syndrome of menopause (GSM) and physiologic markers associated with vulvovaginal atrophy (VVA) in the Genitourinary symptoms and response to treatment (GARNET) studies

Poster presentation

Lasofoxifene 0.25mg compared to raloxifene 60mg for effects on bone mineral density and markers of bone turnover. Results from the Phase 3 Comparison Of Raloxifene and Lasofoxifene (CORAL) Trial American Society for Bone and Mineral Research ASBMR, Seattle, WA Nov 2015

Oral presentation Best Abstracts The Sexual Medicine Society of North America 21st Annual Meeting "Lasofoxifene, a selective estrogen receptor modulator, as a treatment for Sexual Dysfunction in Postmenopausal Women" Las Vegas, November 19-22, 201

Oral Presentations ISSWSH Annual Meeting Charleston, SC Feb 26-27, 2016

A Phase 2 Program on Female Sexual Arousal Disorder and Hypoactive Sexual Desire Disorder: Patient Characteristics and Implications for Diagnosis and Treatment of Female Sexual Dysfunction

Correlation of Physiologic Markers of Vulvovaginal Atrophy and Symptom Severity in Postmenopausal Women with Genitourinary Syndrome of Menopause

The Phase 3 Comparison of Raloxifene and Lasofoxifene (CORAL) Trial: Changes in Bone Markers and Bone Mineral Density Oral Podium Presentation World Congress on Osteoporosis Malaga, Spain April 14, 2016

Bremelanotide for female sexual dysfunctions in pre-menopausal women: a randomized, placebo-controlled dose-finding trial *Women's Health* Published Online ahead-of-print May 16 2016

ACOG Annual Meeting May 16th 2016 Washington DC ISSWSH Sponsored Symposium on Hypoactive Sexual Desire Disorder: Invited Speaker Treatment Lecture: Options for HSDD -WHERE is the evidence; WHEN should treatment be offered?

Reported sexual activity and orgasm frequency in a comparative study of the SERMs lasofoxifene and raloxifene in an osteoporosis trial *North American Menopause Society Annual Meeting* Orlando FL October 5-8, 2016 NAMS Selected Feature Poster

Flibanserin in postmenopausal women with hypoactive sexual desire disorder: Results of the Plumeria Study *North American Menopause Society Annual Meeting* Orlando FL October 5-8, 2016 NAMS Poster Prize Winner Runner-up

SOCIETIES

Fellow, American Congress of Obstetricians and Gynecologist

Diplomat, American Board of Obstetrics and Gynecology

Member, North American Menopause Society, Corporate Liaison Council

Member, International Menopause Society

Member, Association of Reproductive Health Professionals

Member, International Society for the Study of Women's Sexual Health, ISSWSH Fellow

Member, International Society for Sexual Medicine