



Women's Health

Women are complex in physical makeup and sexual function. Women have the unique ability to bear children, which requires a highly sophisticated reproductive system complete with unique sexual hormones and organs. Hormones have a major role to play in a woman's body, directing puberty, the development of eggs and menstruation, and later, to menopause. At each step of a woman's life, hormones change and, in some sense, define the stage of life in which the woman finds herself. Due to the complex interplay between the reproductive system and the rest of the body, many women must undergo some form of hormone monitoring and adjustment to ensure proper body function. Treatments aid in the achievement of total balance in a woman's body.

Contraception

Women today have many options available to them when it comes to birth control. Many of these options involve hormones, and can be oral (the “pill”), implanted (either in the uterus or under the skin), injected, or absorbed (from vaginal devices or patches worn on the skin). Most hormone contraceptives are combinations of estrogen and progesterone, and work in two ways: they prevent the monthly release of an egg from the ovaries, and they thicken the mucous in the cervix and vagina (making it difficult for sperm to get through, in case an egg is accidentally released). All of these options are reversible—if a woman decides she wants to become pregnant, she can simply stop using whatever method of contraception she has chosen. There are also permanent methods of preventing pregnancy, known as sterilization. The oldest approved method involves surgically blocking the fallopian tubes, the passage through which eggs move from the ovaries into the uterus. Newer methods do not require surgery, and involve coaxing the body to build up scar tissue to naturally block the fallopian tubes.

	COMPANY	PRODUCT	PHASE
Contraception	Berlex	Levlite Tablets (levonorgestrel/ethinyl estradiol)	M
	Berlex	Mirena (levonorgestrel-releasing intrauterine system)	M
	Berlex	Tri-Levlen/Triquilar	M
	Berlex	Yasmin (drospirenone/ethinyl estradiol)	M
	Berlex	Yaz (drospirenone and ethinyl estradiol)	M

Female Sexual Dysfunction

Due to medications and various therapies for other illnesses, some women will experience problems becoming aroused for sexual intercourse. This can cause psychological and emotional stress for the both the woman and her partner. Treatments are being developed to increase blood flow to the genitalia to help increase arousal and other bodily processes involved in sexual stimulation.

	COMPANY	PRODUCT	PHASE
Female Sexual Dysfunction	VIVUS, Inc.	Alista (topical alprostadil)	II

Libido

Libido is commonly defined as sexual desire and is affected by many things. Obesity, being underweight, oral contraceptives, SSRIs and beta blockers can all affect a woman’s desire for sexual activity. Usually, if the cause of reduced libido (in women this is called female androgen deficiency) is determined, it can be removed and libido will return to normal. There are instances, however, in which libido slows down to the point where desire for sexual contact is strongly reduced. In these cases, treatments, both psychological and medicinal, can be sought to help return libido to its normal level.

	COMPANY	PRODUCT	PHASE
Libido	VIVUS, Inc.	Testosterone MDTs	II

Menopause

Menopause-related changes women experience are due to declining levels of the hormones estrogen and progesterone. Menopause happens to all women and usually begins around age 40, as they shift out of the reproductive stage of their lives. (It can also happen to women of any age who have undergone removal of their ovaries, which produce estrogen and progesterone, or their uterus, which helps regulate the body's hormone levels).

Every woman is affected differently by menopause. Symptoms may include hot flashes, changes in the menstrual cycle, insomnia, mood changes, sexual and urinary problems, and bone loss (which can lead to osteoporosis). Some women may experience many symptoms; others, almost none at all. Women who are particularly bothered by their symptoms may consider hormone replacement therapy (HRT). This treatment involves taking estrogen and progestin (or only estrogen, for those women who have had their uterus removed), and can help ease symptoms like hot flashes, help prevent uterine cancer, and reduce bone loss. There are some risks involved with extended use, so as with any treatment, the benefits and risks of HRT should be thoroughly discussed with a doctor before beginning.

COMPANY	PRODUCT	PHASE	
Bionovo, Inc.	MF101	II	Menopausal Symptoms
VIVUS, Inc.	Evamist (Estradiol MDTs)	III	
Berlex	Estradiol/Levonorgestrel Transdermal Combination Patch	PA	
Berlex	Angeliq (drospirenone and estradiol)	A	
Berlex	Climara (estradiol transdermal system)	M	Postmenopausal Osteoporosis
Berlex	Climara Pro (estradiol/levonorgestrel transdermal system)	M	
Berlex	Menostar (estradiol transdermal system)	M	

Faces of Osteoporosis: A Look at Bone Disease Through Patients' Eyes

"I can still remember my first fracture." Randi, a fifty year old Bay Area woman has been affected by fragile bone health since early 1995. In an interview for a new collection of stories, Faces of Osteoporosis by Amelia Davis, Randi tells her story. "I was 39 years old and a birthday well-wisher whisked me around and gave me a very gregarious bear hug. I never told him that two of my ribs were broken that night."

Although she kept quiet at the party, Randi immediately called her doctor and was referred to the Foundation for Osteoporosis Research & Education (FORE) for a bone density test. FORE, a nonprofit voluntary health organization based in Oakland, CA, identified severe bone loss and a high potential for fracture of other bones. Osteoporosis often appears in older men and women; studies suggest that over 44 million Americans are affected by osteoporosis; but in Randi's case, extenuating factors played into her early diagnosis. Not only had she been taking medications for lupus since her early 30's, which can leech bones of their calcium, but Randi also had a family history of osteoporosis and a petite frame – two of the risk factors for the disease.

FORE

Foundation for Osteoporosis
Research and Education

Each year FORE screens thousands of men and women, especially those in underserved, high-risk communities. Often, over half of those screened have undiagnosed osteoporosis and a history of fracture. Luckily for Randi and the millions of others with severe bone loss, there are options for fracture prevention including drug therapies, exercise and increased intake of calcium with vitamin D. “As the years have passed my fractures have been fewer and fewer.” Reflects Randi, “I’m fighting osteoporosis one day at a time”.

Pelvic Tissue Damage (Pelvic Floor Prolapse)

The pelvic diaphragm is made of connective tissue and muscles located underneath the pelvis. It is vital for providing support to the pelvic organs (e.g., the bladder, intestines, uterus) and maintaining continence as part of the urinary and anal sphincters. After childbirth, especially in the case of C-sections, the muscles may be weakened or cut due to hysterectomy. Pelvic floor exercises, known as Kegel exercises, can help strengthen the muscles for women who suffer from urinary incontinence. Lost neural support to either the urinary sphincter, pelvic muscles, or vagina can contribute to an individual woman’s urinary incontinence problems.

Unfortunately, pelvic floor damage can also lead to organ prolapse in which the pelvic organs protrude into or outside of the vagina. The causes can include inappropriate (asymmetrical, excessive, insufficient) muscle tone and asymmetries caused by trauma to the pelvis. Age, childbirth, family history, and hormones all contribute to potential prolapse. Treatments include strengthening the muscles via surgical and non-surgical means.

	COMPANY	PRODUCT	PHASE
Pelvic Tissue Damage	Mentor Corporation	Axis	M
	Mentor Corporation	EvaCare	M
	Mentor Corporation	NovaSilk	M
	Mentor Corporation	Suspend	M

Premenstrual Dysphoric Disorder (PMDD)

Premenstrual dysmorphic disorder (PMDD) is a chronic condition that can severely impact a woman’s life and requires medical evaluation and treatment. It is estimated that 3 percent to 8 percent of women have PMDD during their reproductive years.

During her monthly menstrual cycle, a woman’s hormones generally rise and fall, and often lead to premenstrual symptoms (PMS). Symptoms of PMDD are like those of PMS, but much worse. These include breast tenderness, acne, headaches, gastrointestinal discomfort, hot flashes, mood swings, increased appetite, difficult concentrating and oversensitivity. To be classified as PMDD, there must be a general feeling of intense emotionality. Drug therapy is the usual treatment.

	COMPANY	PRODUCT	PHASE
Premenstrual Dysphoric Disorder	Pherin Pharmaceuticals, Inc.	PH80	II
	Berlex	Yaz (drospirenone and ethinyl estradiol)	A

Vaginal Dryness

Vaginal dryness occurs when the vagina does not produce enough naturally occurring lubricant. It is normal for the amount and consistency of the lubricant to vary during a woman's menstrual cycle, but certain medications, diets, and illnesses can decrease the amount produced. This can lead to discomfort during sexual intercourse. Treatments seek to restore natural moisture levels to a woman's vagina.

COMPANY	PRODUCT	PHASE	
Parnell Pharmaceuticals, Inc.	Feminease	M	Vaginal Dryness

Vaginal Infections

Vaginitis is an inflammation of the vagina and falls into one of three categories based on the cause: hormonal, irritant, or infectious. Most infections are due to external irritants such as allergies to condoms, spermicides, soaps, perfumes, tampons, or topical medications and infectious irritants such as yeast, Chlamydia, herpes, and gonorrhea. Vaginitis is usually harmless; however, if it is caused by an infectious organism such as Chlamydia, the infection can spread to the fallopian tubes or ovaries and lead to infertility. Symptoms include irritation and/or itching of the genital area, inflammation of the genitals, vaginal discharge, foul odor, and discomfort upon urinating. Treatments usually include topical ointments and antibiotics.

COMPANY	PRODUCT	PHASE	
Osel, Inc.	Lactin-V	II	Vaginal Infections

