Sex, Drugs and (Hold the Rock-‘n-Roll)

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Everyone’s doing it! It’s how we all got here! You can’t drive down the interstate without seeing a billboard with sexual overtones. Why then do we all “blush” when it comes to discussions about sex and sexual dysfunction. Even in our pharmacies and clinics we get nervous when it comes to discussions about anorgasmia, female hypoactive sexual desire disorder, erectile dysfunction and premature ejaculation. Join our Professor Pete for a thoughtful and professional discussion about sexual concerns as well as the drugs that can cause them and pharmacotherapy for the treatment of these conditions.

Learning Objectives

<table>
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<tr>
<th>Pharmacist</th>
<th>Pharmacy Technician</th>
<th>Nurse</th>
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<tbody>
<tr>
<td>1. Identify treatment options for treatment of Vaginal Dryness</td>
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<td>2. Recognize treatment options for erectile dysfunction and premature ejaculation, including drug therapy that may cause those conditions</td>
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Target Audience
Pharmacists, Pharmacy Technicians, Nurses

Universal Activity Number

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Credit Hours
1.25 Hour

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Knowledge-Based

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SEX, DRUGS, AND (HOLD THE ROCK-N-ROLL)  Pete Kreckel  RPh

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Identify treatment options for treatment of vaginal dryness

Recognize treatment options for erectile dysfunction and premature ejaculation, including drug therapy that may cause those conditions.

State treatment options for female sexual disorders including Female Hypoactive Sexual Desire Disorder and anorgasmia

At the family practice clinic, one of our female PA’s read a patient’s chief complaint of “anorgasmia”. We started discussions and she immediately blushed. Even health care professionals struggle with these discussions. This webinar we will be discussing sex and pharmacotherapy. If there are younger people in your family listening, perhaps headphones might be appropriate.
“LET’S TALK ABOUT . . .”

• Everyone talks about sex!
• It’s how we all got here
• Sex is everywhere... billboards, TV, internet etc.
• Why are we so uncomfortable??

NOTE: All faculty honoraria from the production and presentation of this webinar will be donated to the Centre Volunteers In Medicine (CVIM) to be used for the health needs of women who visit that clinic.

WOMEN’S HEALTH

Dr. Kristine Charles
FACOG

Special thanks to Dr. Charles for her insight and review of the women’s health portion of this webinar.
SENIOR CITIZENS ARE “DOING IT”

- Adults over age 60 diagnosis rates for herpes simplex, gonorrhea, syphilis, hepatitis B, trichomoniasis and chlamydia rose 23 percent between 2014 and 2017
  - Compared to an 11 percent increase among the entire population over age 13.
  - May be due to lack of barrier method use
    - Traditionally thought of for pregnancy prevention
    - May not like the feel or texture
    - “At our age does it matter?”

FOR HIM AND HER—CHECK THE THYROID!

For her:
- Thyroid disease can lower vaginal lubrication
- May make sex uncomfortable, painful, or unsatisfying.

For him:
- Hypothyroidism increases the chances of low sexual desire, erectile dysfunction and delayed ejaculation
- Hyperthyroidism increases the chance of premature ejaculation (up to 50% of men)

For him and her:
Hypothyroidism lowers testosterone, which can lower libido.
May cause depression in both sexes.

Source: https://www.sexhealthmatters.org/sex-health-blog/thyroid-disorders-and-mens-sexual-health/single

VAGINAL DRYNESS

- Etiology: anything that caused decrease in estrogen
  - Menopause
  - Oophorectomy
- Sjogren’s syndrome (90% are female)
- Smoking
- Consider other causes:
  - Caffeine and alcohol consumption
  - Bubble bath, soaps, lotions
  - Douching

Source: https://www.sexhealthmatters.org/sex-health-blog/thyroid-disorders-and-mens-sexual-health/single
In a cross-sectional study of 1922 heterosexual women aged 18–60 years in the United States, 61% of women reported having used a lubricant and 25% had used a lubricant in the past month.

Prescriptions known to cause vaginal dryness:

- Tamoxifen
- Anastrozole, Letrozole, Exemestane
- Oral contraceptives
- Anticholinergics
- Calcium Channel Blockers
- Beta Blockers
- Benzodiazepines
**RX TREATMENT OF DYSpareunia-SERM**

**Osphena®** (ospemifene) 60mg tablets  (~$700/month)
- **Dose:** Take (1) tablet daily
- **Mechanism:** estrogen agonist on vaginal tissue. Minimal effect in uterine tissue and serves as an estrogen antagonist in breast tissue. Ospemifene may have a positive effect on bone tissue. Up to 45% of postmenopausal women can experience vulvovaginal atrophy due to estrogen loss.
- **Indications:** approved by the FDA to treat moderate to severe dyspareunia (painful intercourse) due to menopause
- **USE:** being promoted for its estrogenic effect on vaginal symptoms.
- **May make hot flashes worse.**
- **Watch for CYP450-3A4 interactions**

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**UROGENITAL ATROPHY**

At least **50%** of post-menopausal women suffer symptoms of urogenital atrophy, caused by estrogen deficiency.

Atrophy of the vaginal mucosa results in vaginal dryness, and dyspareunia.

Symptoms may include urethritis, recurrent UTI, urinary frequency and urgency.
DYSPAREUNIA: TOPICAL ESTROGENS

Tablets, rings & creams are used for urogenital atrophy.

However, this treatment has more than a local effect. Local application can reverse atrophic vaginal changes and avoid significant systemic absorption. Estrogen receptors have been demonstrated in the lower genito-urinary tract.

- Cream: conjugated estrogens (Premarin®),
- Cream: estradiol (Estrace®)
- Rings: estradiol (Estring®) (works for 90 days)
- Tablets: estradiol (Vagifem®)

DYSPAREUNIA: PRASTERONE (INTRAROSA®)

- Indication: Moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.
- Mechanism: Prasterone, an endogenous steroid, gets converted by enzymes to estradiol and testosterone.
- Dose: Place one insert (6.5mg) into the vagina at bedtime. May take up to 12 weeks to see results
TOPICAL PRODUCTS FOR VAGINAL DRYNESS

Water based lubricants
- Are absorbed and do not last as long
- Originally developed as surgical lubricants
- Examples: K-Y® jelly, Astroglide®
- Are safe for latex condoms

SILICONE BASED LUBRICANTS
- Last longer, not absorbed through skin
  - May be more difficult to “wash-up”
- Safe for condoms
- May be preferable for “water activities”
- Examples: Astroglide-X® premium, Gun Oil®
- No water; fewer than four ingredients
  - Liquid silicones: Cyclomethicone; Cyclopentasiloxane
OIL BASED LUBRICANTS

- Last longer, may be difficult to remove
- May damage condoms
- Mineral oil, Baby oil, Petroleum jelly.
  - Avoid Petroleum jelly, due to increase likelihood of candida albicans infection.

TRYING TO CONCEIVE?

Surgical gels, saliva, olive oil, and glycerin and leading personal lubricants, such as Astroglide® and K-Y® jelly, are detrimental to sperm motility and chromatin integrity. These coital lubricants caused a remarkable decrease in sperm motility. (pH is “slightly acidic”)
Pre-Seed® is marketed as a lubricant for couples trying to conceive. It is glycerin free, the correct tonicity for sperm, and ideal pH for sperm motility. Normal pH 7.1-8.0

• Some lubricants may cause tissue irritation
**ERECTILE DYSFUNCTION HOW COMMON?**

**Definition:** Erectile dysfunction (ED) is the inability to develop and maintain an erection for satisfactory sexual intercourse.

**Complete erectile dysfunction:** About 5 percent of men (1/20) that are 40 years old have complete erectile dysfunction.
- About 15 percent of men at age 70 have complete ED.

**Mild and moderate erectile dysfunction** affects approximately **10 percent** of men per decade of life:
- 50 percent of men in their 50’s
- 60 percent of men in their 60’s
- 70 percent of men in their 70’s

Source: uwhealth.org

**OTHER RISK FACTORS (ASIDE FROM AGE!)**

- **Diabetes mellitus:** improve glycemic control.
- **Dyslipidemia:** improve control with diet, exercise and statins.
- **Hypertension:** appropriate selection of anti-hypertensive medications. Diet and exercise.
- **Obesity:** associated with erectile dysfunction with an approximately 50% increase in ED in obese men as compared with normal weight men.
OTHER DISEASES MAY SIGNAL ED

Incidence of erectile dysfunction (ed) in men with other diseases:
- Cerebrovascular disease 70%
- Coronary artery disease 60%
- Coronary artery bypass graft 60%
- Diabetes mellitus 50%
- Peripheral vascular disease 70%
- Untreated hypertension 10%

MEDICATIONS CAUSING ERECTILE DYSFUNCTION

Classes of Drugs Implicated with ED
- Major antipsychotics (typical)
- Tricyclic antidepressants
- SSRI antidepressants
- Anxiolytics (benzodiazepines)
- Anticholinergics (as antispasmodics & anti-Parkinson’s drugs)
- Antihistamines (especially sedating)
- Muscle relaxants
- Antiarrhythmic (disopyramide) (amiodarone) (mexiletine)

ANTIHYPERTENSIVES
### MECHANISMS OF DRUGS CAUSING ED

<table>
<thead>
<tr>
<th>Medication</th>
<th>Mechanism Proposed</th>
<th>Modified Libido/ Sexual Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihypertensives, anxiolytics, ethanol, muscle relaxants, narcotics, neuroleptics sedatives</td>
<td>Sedation</td>
<td>Decreased libido</td>
</tr>
<tr>
<td>Cimetidine, Marijuana, Digoxin, excess Ethanol, Ketoconazole, Spironolactone</td>
<td>Testosterone antagonism</td>
<td>Libido</td>
</tr>
<tr>
<td>Metoclopramide, Narcotics, Antipsychotics</td>
<td>Prolactin elevation</td>
<td>Libido</td>
</tr>
<tr>
<td>Anticholinergic Agents, TCAs, antihistamines (1st generation)</td>
<td>Parasympathetic dysfunction</td>
<td>Penile tumescence</td>
</tr>
<tr>
<td>Diuretics, methyldopa, beta-blockers</td>
<td>Decreased blood flow to corpora</td>
<td>Penile tumescence</td>
</tr>
</tbody>
</table>

### ALTERNATIVE THERAPIES FOR DRUGS CAUSING ED

<table>
<thead>
<tr>
<th>DRUG causing sexual dysfunction</th>
<th>Possible alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticonvulsants</td>
<td>Valproic acid (Depakote)</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Imipramine and desipramine Buproprion</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>ACE inhibitors &amp; Calcium Channel Blockers, ARBS, alpha-blockers</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>Loxapine</td>
</tr>
<tr>
<td>Diuretics</td>
<td>Furosemide</td>
</tr>
<tr>
<td>Anti-ulcer drugs</td>
<td>Pepcid (avoid Cimetidine)</td>
</tr>
<tr>
<td>Nonsteroidal anti-inflammatory</td>
<td>Diclofenac (Voltaren)</td>
</tr>
<tr>
<td>Antihistamines</td>
<td>Second generation antihistamines</td>
</tr>
</tbody>
</table>
LOW TESTOSTERONE?

Chronic drugs that LOWER testosterone levels:
• Prednisone 5mg/day and greater, or
• Morphine 100mg/day or greater AND their equivalents.
  • Testosterone levels drop by 50% within hours of dosing.

ORAL AND INJECTABLE TESTOSTERONE

Testosterone oral tablets: Offers little value because of extensive first pass metabolism.
  • Hepatotoxicity
  • G.I. upset, edema, weight gain

Testosterone injection: every 2 weeks
  • cypionate 100mg and 200mg/ml
    • (DepoTestosterone)
    • Oily solution given deep IM
  • enanthanate 200mg/5ml
    • (Delatestryl)
    • More expensive. In short supply
TOPICAL TESTOSTERONE: CLASS EFFECTS

• **Advantages:** Provides therapeutic testosterone levels without large fluctuations, easier to use and less skin irritation than patches.

**Disadvantages:** Transfer of gel or solution from one person to another -- avoid this by washing hands after application and wearing clothing over application site. Fortesta® (thighs) and Axiron® (underarms) minimize transfer.

**Comments:** Do not apply to genitals.

**Testosterone Monitoring:** Check testosterone level at least 7 to 14 days after initiation of therapy. (Wait at least 14 days for Axiron®).

PAPAVERINE PENILE INJECTION

• **Smooth muscle relaxer**
  - Relaxes blood vessels and allows increased blood flow to the penis.
  - Possibly inhibits phosphodiesterases and it may have direct actions on calcium channels.
  - A natural opiate from the poppy plant.

• **Onset:** 10 minutes. Intercourse should be attempted within 2 hours. Maximum 3 times per week.

• **Dose:** 30 to 60mg : slowly inject over one or two minutes to completely inject the dose. This minimizes serious adverse effects such as arrhythmias.
ALPROSTADIL (CAVERJECT®) (JULY 1995)

Mechanism: direct injection of vasoactive prostaglandins onto the corpora cavernosum.

- First injection should be done in a clinician’s office with trained personnel.
  - Must stay in office until complete detumescence occurs. If no response next higher dose may be given in 1 hour. If response, wait at least one day for subsequent dose. Generally reserved for patients who have failed other regimens.
- May be used only twice a week.
- Side effects: May cause: Penile fibrosis, priapism, penile pain, hematoma, ecchymosis.

ALPROSTADIL URETHRAL SUPPOSITORY (MUSE®) (NOV 1996)

Mechanism: alprostadil inserted via suppository into the urethra. Apply post urination, residual urine disperses the medicated pellet permitting alprostadil to be absorbed by the urethral mucosa.

- Erection occurs in 5 to 10 minutes and lasts 30-60 minutes. Can be used up to twice daily.

Muse® (alprostadil): 100mcg, 250mcg, 500mcg urethral suppositories. Are small pellets one time use applicator/injector containing the alprostadil dose, about 30mm into the urethra. (cost= about $70/dose)
ALPROSTADIL URETHRAL SUPPOSITORY (MUSE®)  
(NOV 1996)

**Warnings/Precautions and Adverse effects**

- May cause transient penile pain, and hypotension, headache and dizziness, testicular pain
- Usually does not cause priapism
- Possible urethral abrasions and bleeding
- Do NOT use if partner is pregnant, unless using a condom

PHOSPHODIESTERASE TYPE-5 INHIBITORS:

**Mechanism:** Enhances the effect of nitric oxide by inhibiting phosphodiesterase type 5 (PDE5). When sexual stimulation causes the local release of nitric oxide, inhibition of PDE5 by Phosphodiesterase-5 inhibitors produces increased levels of cGMP in the corpus cavernosum. This results in smooth muscle relaxation and inflow of blood into the penile tissues, which in turn produces an erection.

- Sildenafil (Viagra®): released 1998
- Sildenafil (Revatio®): released 2005
PDE-5 INHIBITORS—SIDE EFFECTS

• **Color disturbances:** (blue/green) important for pilots (PDE-6 found in retina) can be affected at higher doses
• **Headache** (16%), facial flushing, dyspepsia
• **Hypotension:** 8-10mm decrease in systolic & 5-6 mm in diastolic
• **Hearing loss:** ISMP-2016: reports a strong association between PDE5 drugs and hearing loss. PDE5 caused hearing loss 21.5 times higher than similar comparators

PDE-5 INHIBITORS

WARNINGS AND PRECAUTIONS

Due to the risk of hypotension, caution should be used in patients using alpha blockers (Tamsulosin, alfuzosin, terazosin & doxazosin) for prostate hyperplasia

- Caution with other antihypertensive medications and alpha blockers, which should not be co-administered with PDE5 inhibitors.
- In patients who take 50 mg of sildenafil or more: separate PDE-5 inhibitor from alpha blocker by 4 hours.

**Nitrates:** PDE-5 inhibitors are contraindicated in combination with nitrates due to the risk of severe hypotension and death

**CYP-3A4 inhibitors** (azole antifungals, protease inhibitors, clarithromycin): caution due to increased side effects due to decreased metabolism
PDE-5 INHIBITORS: REPRESENTATIVE PRODUCTS

<table>
<thead>
<tr>
<th>Brand</th>
<th>Generic</th>
<th>Dose mg</th>
<th>Onset min.</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viagra®</td>
<td>sildenafil</td>
<td>25, 50, 100</td>
<td>30 min</td>
<td>4 hours</td>
</tr>
<tr>
<td>Levitra®</td>
<td>vardenafil</td>
<td>2.5, 5, 10, 20</td>
<td>20 min</td>
<td>4 to 5 hours</td>
</tr>
<tr>
<td>Cialis®</td>
<td>tadalafil</td>
<td>5, 10, 20</td>
<td>30 min</td>
<td>36 hours (weekend)</td>
</tr>
<tr>
<td>Cialis®</td>
<td>Tadalafil</td>
<td>2.5mg or 5mg</td>
<td>once daily</td>
<td></td>
</tr>
<tr>
<td>Stendra®</td>
<td>avanafil</td>
<td>50, 100, 200mg</td>
<td>15 min</td>
<td>4 hours</td>
</tr>
</tbody>
</table>

Dosage: “On demand” dosing. Usually dosed ½ to 1 hour before sexual activity. **Tadalafil (Cialis®)** continuous dosing: **2.5 to 5mg daily.** The low-dose daily dosing provides an option for men with ED who want a medication that can be taken without regard to timing of sexual activity and who anticipate sexual activity at least twice weekly.

BEFORE WE HAD VIAGRA®….. YOHIMBINE

**Mechanism:** blocks presynaptic alpha-2 adrenergic receptors. Increases parasympathetic and decreases sympathetic activity. Erection is linked to cholinergic activity, and alpha-2 blockade, which theoretically results in increased penile blood inflow, decreased outflow or both.

- Widely used as an aphrodisiac to improve sexual drive.

**Warnings/Precautions and Adverse effects/Drug Interactions:**
- May cause: anxiety, insomnia, tachycardia and hypertension
- American Urological Society has cautioned **against** the use of yohimbine
- NO FDA sanctioned indications
- Contraindicated with antidepressants

Representative Products and Dosages: found frequently in male enhancement or natural products for ED.
MALE DYSPAREUNIA: PAINFUL EJACULATION

• Prostatitis
• Structural abnormalities
  • Peyronie's disease
  • Compression of pudendal nerve
• STI's: chlamydia and trichomoniasis
• Neurological problems- due to diabetes
• Antidepressants
• Selective Alpha blockers for BPH (especially Tamsulosin)

1 in 5 men will complain...
YES, IT REALLY HAPPENS: 3 DIFFERENT MEN

While reviewing the profile of a 75 year old man, I noticed he was adherent to all of his medications, except for Tamsulosin (Flomax) for his BPH.

• He is sexually active, with his 48 year old female partner.
• I had a female student pharmacist in the examination room. I asked if he would be more comfortable without a female in the room. He relied "Heck no—I’m comfortable if she is."
• He said that the Tamsulosin was causing painful ejaculation, and would rather deal with BPH than the pain from intercourse.

WHAT CAN WE DO TO HELP...

• I consulted Dr. Gates to switch the tamsulosin (Flomax®) to alfuzosin (Uroxatral®). Alfuzosin is least likely of alpha blockers to cause ejaculatory problems. Does not require dosage titration.
  • Dr Gates question--- ok, but what does it cost
    Tamsulosin: Cost is around $7.00/ 100
    Alfuzosin : Cost is around $12.00/100
    Dr Gates approved switch and Rx sent to pharmacy.
  • Uroxatral (alfuzosin) 10mg tablets #30  SIG: one tablet at bedtime
• RESULTS: Christmas party about 3 months later— big hug, and: “Thanks Pete for stepping in... the drug works better for me, and no side effects. Haven’t missed a dose yet!”
Prevalence is consistently around 30% in men age 18-59 in the United States

IELT: Intravaginal Ejaculatory Latency Time

A measure of the time from intromission until ejaculation

Sex therapists' opinions regarding an length for ejaculatory latency was:

- Too Short: 1-2 minutes
- Adequate: from 3 to 7 minutes;
- Desirable: from 7 to 13 minutes
- Too long: from 10 to 30 minutes.

Source: Journal of Sexual Medicine: May 2005
**PREMATURE EJACULATION—TREATMENT**

Non-pharmacological measures:
- Start-Stop technique
- Kegel exercises- to strengthen pelvic floor
- Pause squeeze technique

Pharmacological measures:
SSRI: Paroxetine (Paxil ®) is far superior to Prozac (fluoxetine) and other SSRI, due to short half life.
- For improvement of IELT it requires chronic daily dosing which patients find inconvenient and laden with unpleasant side effects.
- SSRI have a slow onset of action and adverse effects including: nausea, drowsiness, cognitive impairment and sexual side effects.

**SSRI AND OTHER OPTIONS FOR PREMATURE EJACULATION**

- **SSRI**: Will take at least 5-10 days for benefit. Full effect within 21 days.
  - Unwanted side effects of antidepressants might include nausea, perspiration, drowsiness and decreased libido
  - Dapoxetine (Priligy)- on demand 1-3 hours before sex. (half life=1-1.5hr)
    - Not available in US
- **Clomipramine** (Anafrani®)
- **Tramadol** (Ultram®): needs to be used for 8-12 weeks. (respiratory depression, addiction?, possible ED)
- **PDE-5 inhibitors** might be of benefit, especially in combo with SSRI
Approximately 40% of women in the U.S. have sexual concerns.
  - May include lack of sexual desire, impaired arousal, inability to achieve orgasm, or pain with sexual activity.

Sexual response cycle:
  - *Desire* (libido) → *Arousal* (excitement) → *Orgasm* → *Resolution*
FEMALE SEXUAL DYSFUNCTION

- **Risk Factors:** depression, anxiety, psychotic disorders, benzodiazepines, SSRIs
- **Treatment:** treat underlying cause, lifestyle modifications (weight loss, diet, sleep)

HSDD (FEMALE HYPOACTIVE SEXUAL DESIRE DISORDER)

**Estrogen** - (alone or in combination with progestin) for peri/postmenopausal atrophic vaginitis
- May improve vaginal environment - less dryness, improved mucosa, reduced pH

**Testosterone** - NOT FDA approved, often prescribed off label w/ or w/o estrogen
- May be effective for short-term treatment but limited evidence for treatment >6 months
- Increases # sexually satisfying events (SSE) by around 1.2 events/month
- Formulations: tablet, transdermal spray, patch
- Contraindications: presence/high risk of breast/endometrial cancer, VTE, CV disease
- Adverse events: hirsutism/virilization, acne, CV complications, breast cancer

**Bupropion** - norepinephrine-dopamine reuptake inhibitor
- May increase sexual arousal and orgasm (may or may not improve desire) in HSDD
OTHER FEMALE SEX DISORDERS

- **Female Orgasmic Disorder** - mainstay of treatment is psychotherapy
- **Sexual Pain Disorder** - conduct pelvic exam, consider hormonal treatments (estrogen, ospemifene)

MEDICATIONS AND FEMALE SEX DISORDERS

Watch for female sexual dysfunction caused by meds:

- Antidepressants:
  - Highest risk antidepressants (>30%): fluoxetine, fluvoxamine, paroxetine, sertraline
  - Medium risk (10-30%): citalopram, duloxetine, escitalopram, venlafaxine
  - Lowest risk: bupropion, mirtazapine, desvenlafaxine, vilazodone, vorioxetine
ADDYI® (FLIBANSERIN) (APPROVED 2015)

Serotonin receptor 1A agonist/serotonin receptor 2A antagonist

- #30 tablets $480.00
- 100 mg tablet, once daily at bedtime (NOT PRN) in premenopausal women. Not for use in post-menopausal women
- Increases # SSEs by approximately 0.5 events/month
- Can cause dizziness, somnolence, nausea, fatigue, insomnia, dry mouth
- Interacts with CYP3A4 inhibitors, alcohol CONTRAINDICATED with use (can cause severe hypotension/syncope)
- Not for those with HSDD due to medical/psych conditions, medications or other drug substance, or relationship problems

ADDYI® (FLIBANSERIN)

- ADDYI® is available only through a restricted program under a REMS called the ADDYI® REMS Program, because of the increased risk of severe hypotension and syncope due to an interaction between ADDYI and alcohol

The REMS Program:

- Prescribers must be certified with the program by enrolling and completing training
- Pharmacies must be certified with the program and must only dispense to patients pursuant to a prescription from a certified prescriber

AddyiREMS.com or 844-746-5745.
**BREMELANOTIDE (VYLEESI®)**

(Approved June 21, 2019)

- Vyleesi activates melanocortin receptors, but the mechanism by which it improves sexual desire and related distress is unknown.
- The First FDA-Approved **As-Needed Treatment** for Premenopausal Women Experiencing Distress or Interpersonal Difficulty Due to Low Sexual Desire
- 1 in 10 Premenopausal Women in the U.S. (Approximately 6 Million Women) Suffer From HSDD

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**Efficacy?**

- There was no difference between treatment groups in the change from the start of the study to end of the study in the number of satisfying sexual events. Vyleesi does not enhance sexual performance. (source: FDA)
- **25%** of patients treated with Vyleesi had an increase of 1.2 or more in their sexual desire score (scored on a range of 1.2 to 6.0, with higher scores indicating greater sexual desire) compared to about **17%** of those who took placebo
BREMELANOTIDE (VYLEESI) DOSING

- Inject SQ at least 45 minutes prior to sex
- Only one dose per 24 hours
- Maximum of 8 doses per month
- Only for use in pre-menopausal women
- Available as an auto-injector 1.75mg dose (per .3ml)
- STOP: treatment after eight weeks if they do not report an improvement in sexual desire and associated distress.

BREMELANOTIDE (VYLEESI) SIDE EFFECTS

- Nausea (40%) and vomiting, (13% needed meds to control N & V)
- flushing
- injection site reactions
- Headache
- Hypertension- usually resolves in 12 hours, not recommended for uncontrolled hypertension or cardiac patients
MAJOR DRUG INTERACTION WITH BREMELANOTIDE (VYLEESI)

• **Naltrexone (Revia)** if taken by mouth, Vyleesi may significantly decrease the levels of naltrexone in the blood. Patients who take a naltrexone-containing medication by mouth to treat alcohol or opioid dependence should not use Vyleesi because it could lead to naltrexone treatment failure.

FEMALE ANORGASMIA

• Only 25 percent of women are *consistently* orgasmic during vaginal intercourse.
• About half of women *sometimes* have orgasms during intercourse.
• About 20 percent *seldom or ever* have orgasms during intercourse. And about 5 percent *never* have orgasms.
• Most women's erotic pleasure does not come from the penis.
FEMALE ANORGASMIA - VIBRATORS

Who's using: Australia (46%) U.S.A. (45%) India (3%)
- Women in a relationship are more inclined to use a vibrator than women who are single.
- 46% reported using vibrators most during self-pleasure
- 37% reported regularly using a vibrator with their sexual partner during intercourse.

Age of first use:
- 17% were under age 20
- 50% were in their 20s
- 22% to 27% were in their 30s
- 10% were 40 or older

THE PHARMACIST AND SEXUAL HEALTH

Pharmacists are the drug experts...
- Numerous drug therapies affects sex drive and sexual performance

Markets for medications for ED, PE, libido, dyspareunia, HSDD, as well as lubricants are in the pharmacist’s realm of expertise.

Sexual health is an approachable topic with all of your patients. Provide confidential, compassionate, clinical care!
QUESTIONS?

- Please type your questions into the chat box