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Talking with Your Patients About Hypoactive Sexual Desire Disorder and Advances in its Treatment

Sheryl A. Kingsberg, PhD
David J. Portman, MD

Identified or perceived conflict of interest has been resolved in accordance with ACCME guidelines.

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Faculty Disclosures

Dr. Kingsberg has the following disclosures:

Consulting Fees: AMAG Pharmaceuticals, Dare, Emotional Brain, Endoceutics, Lupin Pharmaceuticals, Inc., Sprout, Strategic Science Technologies, Therapeutics MD, IVEX
Commercial Interest Speakers Bureau: AMAG Pharmaceuticals, Therapeutics MD

Contracted Research: AMAG Pharmaceuticals, Dare, Endoceutics, Palatin

Ownership Interest: Viveve

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Faculty Disclosures

Dr. Portman has the following disclosures:

Grant/Research Support: Boehringer Ingelheim, Endoceutics, Palatin Technologies, QuatRx Pharmaceuticals, Shionogi Pharmaceuticals, TherapeuticsMD

Consultant/Advisory Board: AMAG Pharmaceuticals, Agile Therapeutics, Duchesnay Pharmaceuticals, ITF Pharma

Commercial Interest Speakers Bureau: AMAG Pharmaceuticals

Salary and Stockholder: Sermonix Pharmaceuticals

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Objectives

- Define hypoactive sexual desire disorder (HSDD)
- Address barriers that inhibit the appropriate diagnosis and management of HSDD
- Identify the screening tools that allow for diagnosis of HSDD
- Identify current therapeutic modalities to manage HSDD

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Hypoactive Sexual Desire Disorder (HSDD)

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Hypoactive Sexual Desire Disorder (HSDD): DSM-IV

- Persistent or recurrent deficiency or absence of sexual thoughts, fantasies and/or desire for, or receptivity to, sexual activity
  - Accompanied by clinically significant personal distress or interpersonal difficulties
  - Not otherwise accounted for by another medical disorder, drug/medication, or psychiatric condition

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 4th ed., Text Revision. Washington, DC: American Psychiatric Press; 2000.

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ISSWSH Consensus Nomenclature for HSDD

Any of the following for >6 months:

- Lack of motivation for sexual activity manifested by either:
  - Reduced or absent spontaneous desire (sexual thoughts, fantasies)

    OR
  - Reduced or absent responsive desire to erotic cues and stimulation or inability to maintain desire
- Loss of desire to initiate or participate, including behavioral responses such as avoidance, not secondary to a sexual pain disorder

+

Clinically significant personal distress that includes frustration, grief, incompetence, loss, sorrow, or worry

ISSWSH = International Society for the Study of Women's Sexual Health

Parish SJ, et al. J Sex Med. 2016;13:1888-1906.

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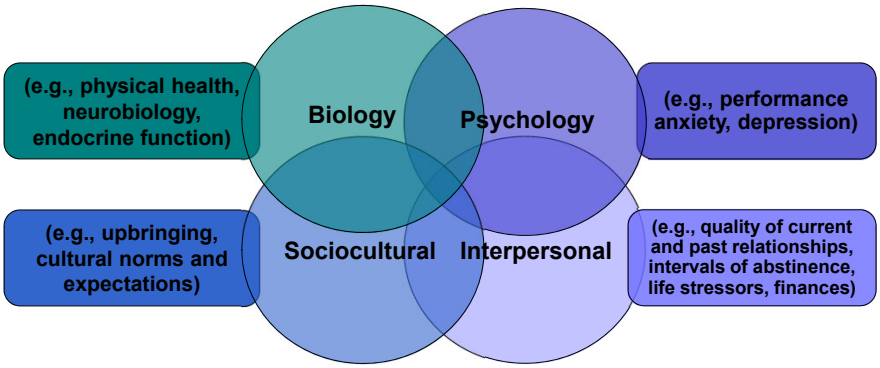
Biopsychosocial Model of Female Sexual Response



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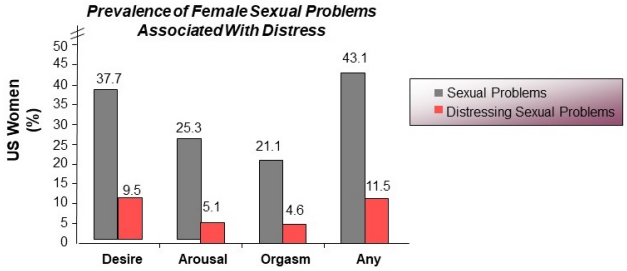
Prevalence of FSD: PRESIDE

- **OBJECTIVES:** Estimate the prevalence of self-reported sexual problems (any, desire, arousal, and orgasm), the prevalence of problems accompanied by personal distress, and describe related correlates
- **POPULATION:** 31,581 US female respondents ≥18 years of age from 50,002 households
- **RESULTS:** Response rate was 63% (n=31,581/50,002)



Shifren JL, Monz BU, Russo PA, Segreti A, Johannes CB. Obstet Gynecol. 2008;112(5):970-978.

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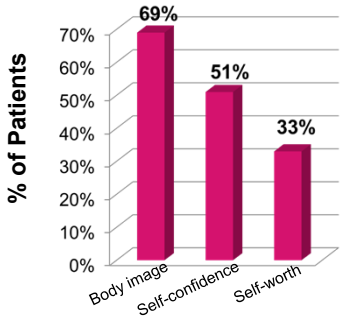
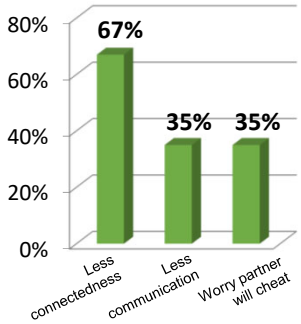
Low Sexual Desire Negatively Affects Self-image and Partner Relationships

Online Survey: Premenopausal women with self-described low sexual desire (n=306)

Affect your personal life?



Affect relationship with your partner?



Kingsberg SA. J Women's Health 2014;23(10):817-23.

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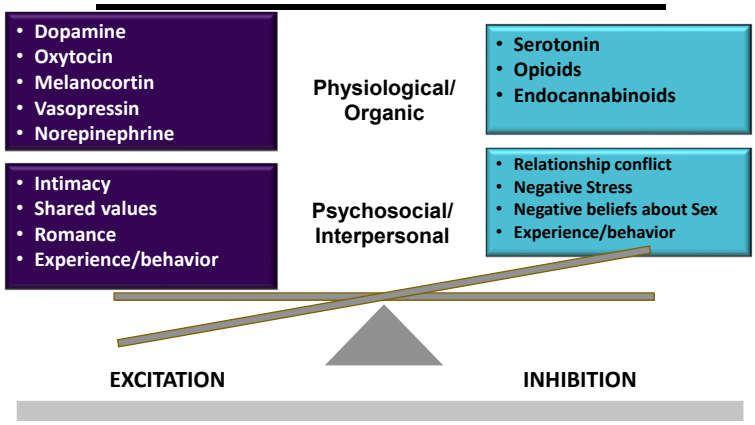
Etiology of HSDD Imbalance Between Excitation/Inhibition



Bancroft J, et al. J Sex Res. 2009;46:121-142.
Perelman MA. J Sex Med 2009;6:629-32.

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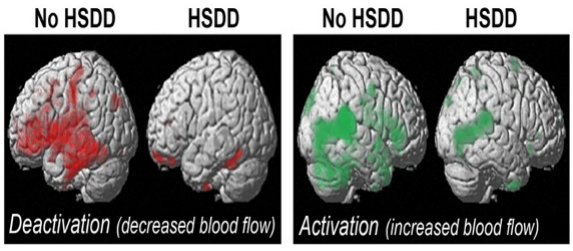
PET Scan Changes in Neural Activity in Response to Erotic Video



- Women with HSDD have weaker activation in cerebral cortex in right hemisphere
- Possibly representing muted response to sexual cues
- Women with HSDD have less deactivation in left hemisphere possibly representing inability to deactivate higher order processing and perpetuates inhibitory neural pathways

Holstege G. Sex Med Rev. DOI:
http://dx.doi.org/10.1016/j.sxmr.2016.04.002

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Evaluating Sexual Desire: Are Patients Asking? Are Ob/Gyns Asking?

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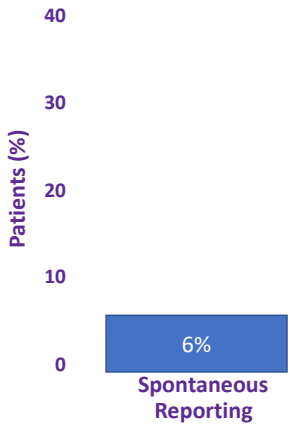
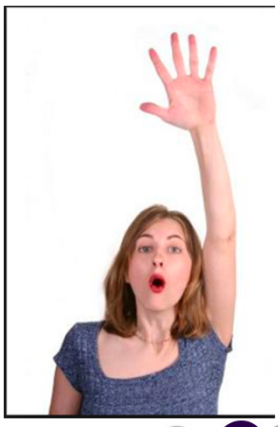
Are Patient's Asking?





3,239 women with self-reported sexual problems of desire, arousal, and/or orgasm

Shifren JL, et al. Obstet Gynecol. 1989:73:425-427.

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Reporting of HSDD

- 80% of women with self reported HSDD did not mention it to a health care provider
- 50% reported that discomfort or embarrassment contributed to their unwillingness to seek treatment

Kingsberg S.A. J Womens Health (Larchmt) 2014;23:817–823.
Shifren J.L., Johannes C.B., Monz B.U. J Womens Health (Larchmt) 2009;18:461–468.

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Are Physicians Asking?

- 53 primary care physicians completed questionnaire about their experience asking about low libido[1]
  - 86.3% had not screened for low libido
  - 90% had not diagnosed low libido
    - 53% felt not confident at all
    - 38% little confidence

1. Harsh et al., J Sex Med 2008.

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Are Ob-Gyns Asking?

- 63% Routinely Ask About Sexual Activities
- 40% Routinely Ask About "Problems"
- 13.8% Ask About Pleasure During Sexual Activity
- Females doctors twice as likely to ask

*1,154 practicing U.S. ob/gyns (53% male; mean age 48 years) was surveyed regarding their practices of communication with patients about sex

What We Don't Talk about When We Don't Talk about Sex1: Results of a National Survey of U.S. Obstetrician/Gynecologists Janelle N. Sobecki, MA, Farr A. Curlin, MD, Kenneth A. Rasinski, PhD, Stacy Tessler Lindau, MD, MAPP The Journal of Sexual Medicine Volume 9, Issue 5, Pages 1285-1294 (May 2012) DOI: 10.1111/j.1743-6109.2012.02702.x.

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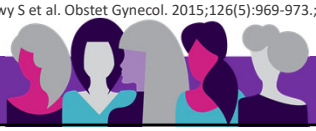
Physician-Based Barriers

- Lack of Training-Inadequate Knowledge of Solutions
- Lack of awareness of associated co-morbidities
- HCP embarrassment
- Fear of embarrassing patient
- "Improving quality of life" not a high priority
- Time constraints
- Underestimation of prevalence
- Consider other issues as higher priorities

Broekman CPM, et al. Int J Impot Res. 1994;6:67-72.; Eid JF, et al. Cliniguide® to Erectile Dysfunction. Lawrence DellaCorte Publications, Inc; 2001.; Baum N, et al. Patient Care. Spring 1998(suppl):17-21.; Parish SJ et al. Int J Women's Health. 2013;5:437-447.; Shahawy S et al. Obstet Gynecol. 2015;126(5):969-973.; Kingsberg SA. Sex Reprod Menopause. 2004;2:199-203.



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Written Screening Tools

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Validated Tools to Assess FSD

Validated Tool	Assessment Area
Decreased Sexual Desire Screener (DSDS)[1]	Brief diagnostic tool for Hypoactive Sexual Desire Disorder (HSDD)
Female Sexual Function Index (FSFI)[2,3*]	Desire, arousal, orgasm, and pain
Female Sexual Distress Scale-Revised (FSDS-R)[4]	Distress

*FSFI questionnaire and scoring key available at: www.fsfi-questionnaire.com

1. Clayton AH, et al. J Sex Med. 2009;6:730-738.
2. Meston CM. J Sex Marital Ther. 2003;29:39-46.
3. Rosen R, et al. J Sex Marital Ther. 2000;26:191-208.
4. DeRogatis L, et al. J Sex Med. 2008;5:357-364.

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Decreased Sexual Desire Screener (DSDS)

1	In the past, was your level of sexual desire or interest good & satisfying to you?	Yes / No
2	Has there been a decrease in your level of sexual desire or interest?	Yes / No
3	Are you bothered by your decreased level of sexual desire or interest?	Yes / No
4	Would you like your level of sexual desire or interest to increase?	Yes / No

5. Please check all the factors that you feel may be contributing to your current decrease in sexual desire/interest:

A. An operation, depression, injuries, or other medical condition	No ☐ Yes
B. Medications, drugs or alcohol you are currently taking	No ☐ Yes
C. Pregnancy, recent childbirth, menopausal symptoms	No ☐ Yes
D. Other sexual issues you may have (pain, decreased arousal, orgasm)	No ☐ Yes
E. Your partner's sexual problems	No ☐ Yes

If "NO" to Q1, 2, 3, or 4 = Not generalized acquired HSDD

If "YES" to all Q1–4 and "NO" to all Q5 factors = clinician to use best judgment to confirm a diagnosis of generalized acquired HSDD

If "YES" to all Q1–4 and "YES" to any Q5 factor = clinician to use best judgment to determine diagnosis*

Co-morbid conditions such as arousal or orgasmic disorder do not rule out a concurrent diagnosis of HSDD

Clayton AH, Goldfischer ER, Goldstein I, et al. J Sex Med. 2009;6(3):730-738.

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HSDD Management: Types of Interventions

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Types of Interventions

- Psychotherapy/counseling
- Pharmacologic therapies
- Combined therapy
- Treatment determined by etiology

Kingsberg SA, Janata JW. Urol Clin North Am. 2007;34:497-506.
Simon JA, Reape KZ, Wininger S, Hait H. Fertil Steril. 2008;90:1132-1138.

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Psychotherapy Goals and Techniques

1. Lessen performance anxiety
2. Cognitive restructuring
3. (Re)gain confidence in their sexual performance
4. Redirect focus from performance to sensuality and pleasure
5. Surmount barriers to intimacy
6. Resolve interpersonal issues that cause/maintain HSDD
7. Improve communication skills
8. Predict in order to prevent relapse

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FDA-Approved Pharmacologic Options for Generalized, Acquired Hypoactive Sexual Desire Disorder (HSDD)

Flibanserin
Bremelanotide

David J. Portman, MD
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Adjunct Faculty, The Ohio State University
Department of Obstetrics and Gynecology
Founder and CEO, Sermonix Pharmaceuticals
Columbus, OH

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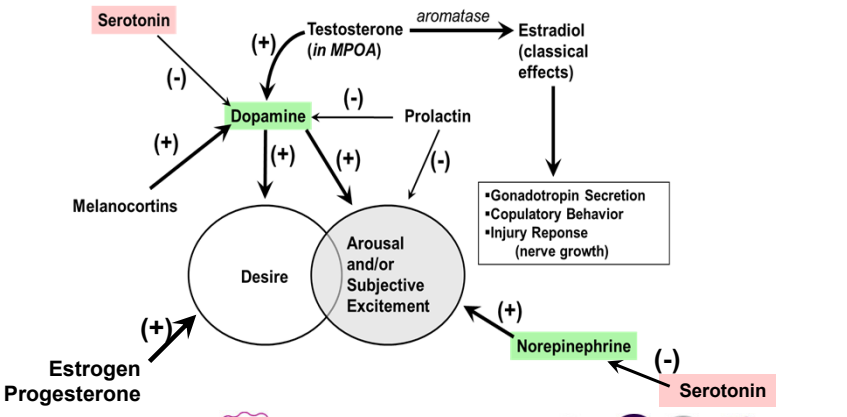
Neurotransmitters and Central Regulation of Desire/Arousal



Clayton et al., Obstet Gynecol Clin North Am. 2009;36(4):861-876.

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Flibanserin: FDA approved for Generalized, Acquired Pre-Menopausal HSDD August 2015

- Once nightly oral medication
- Mixed post-synaptic 5HT1A agonist and 5HT2A antagonist
  - **5HT1A agonists** could have **pro-sexual effects**
  - **5HT2A antagonists** could have **pro-sexual effects**
- Activity at dopamine D4 receptors
- Thought to produce region-specific elevations in dopamine and norepinephrine which offset inhibitory serotonergic activity
- Flibanserin is believed to work on brain function by enhancing excitatory elements and lessening the inhibitory response to sexual cues

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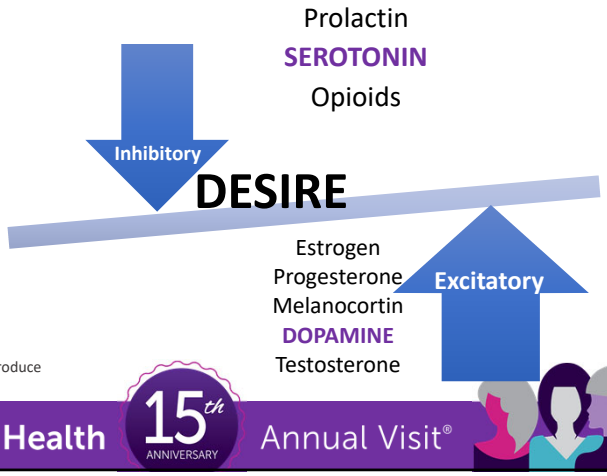
Excitatory and Inhibitory Effects of Neurotransmitters and Hormones on Sexual Desire



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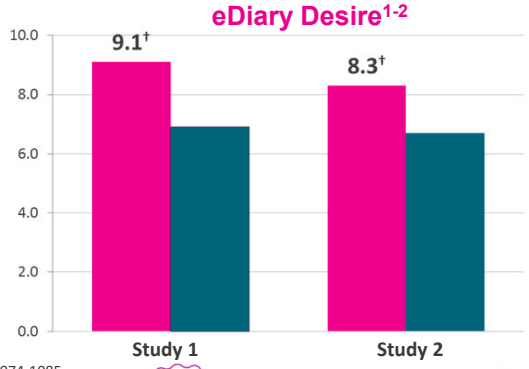
Flibanserin Increased Sexual Desire on Daily eDiary vs. Placebo

Mean Change from Baseline at Week 24

eDiary Desire[1-2]



† P = Not significant

Flibanserin

Placebo

While subjects responding to Flibanserin showed an increase in sexual desire as measured by the eDiary, the difference did not reach statistical significance

1. Derogatis LR, et al. J Sex Med. 2012;9(4):1074-1085.
2. Thorp J, et al. J Sex Med. 2012;9(3):793-804.

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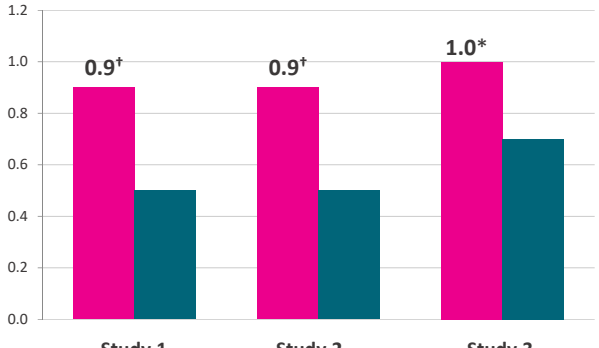
Flibanserin Increased Sexual Desire on FSFI-D vs. Placebo

Mean Change from Baseline at Week 24

FSFI-D Desire[1-3]



* P < 0.0001

Flibanserin

Placebo

† P-value not reported for secondary endpoints in study 1 and 2 because the trials did not meet eDiary co-primary efficacy endpoint

1. Derogatis LR, et al. J Sex Med. 2012;9(4):1074-1085.
2. Thorp J, et al. J Sex Med. 2012;9(3):793-804.
3. Katz M, et al. J Sex Med. 2013;10(7):1807-1815.

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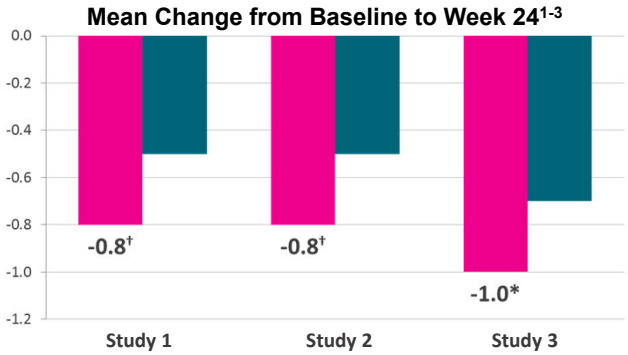
Flibanserin Showed a Decrease in Distress vs. Placebo Across All 3 Studies



* P < 0.0001

Flibanserin

Placebo

† P-value not reported for secondary endpoints in study 1 and 2 because the trials failed to meet the eDiary co-primary efficacy endpoint

1. Derogatis LR, et al. J Sex Med. 2012;9(4):1074-1085.
2. Thorp J, et al. J Sex Med. 2012;9(3):793-804.
3. Katz M, et al. J Sex Med. 2013;10(7):1807-1815.

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Flibanserin Adverse Reactions

Adverse reactions reported in clinical trials in ≥2% of patients receiving 100 mg of flibanserin at bedtime and at a higher incidence than placebo-treated patients

	Flibanserin (n=1543)	Placebo (n=1556)
Dizziness	11.4%	2.2%
Somnolence	11.2%	2.9%
Nausea	10.4%	3.9%
Fatigue	9.2%	5.5%
Insomnia	4.9%	2.8%
Dry mouth	2.4%	1.0%

The majority of these adverse reactions began within the first 14 days of treatment

Discontinuation

- Adverse reactions leading to discontinuation of ≥1% of patients receiving flibanserin 100 mg at bedtime and at a higher incidence than placebo-treated patients were: dizziness, nausea, insomnia, somnolence, and anxiety
- Discontinuation rate due to adverse reactions was 13% for flibanserin 100 mg and 6% for placebo

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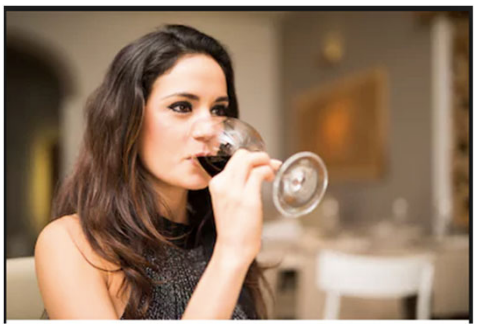
Prescribing Flibanserin

- Continuous bedtime dosing
- Boxed warning for:
  - Hypotension, syncope in certain settings:
    - Alcohol within 2 hours of dosing and contraindicated with moderate or strong CYP3A4 inhibitors, hepatic impairment
- REMS program—Pharmacy and prescriber certification
- Labeling changes August 2019
  - FDA removed alcohol contraindication
  - Remains a warning and precaution



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FDA-Approved Pharmacologic Options for Hypoactive Sexual Desire Disorder (HSDD)

Bremelanotide

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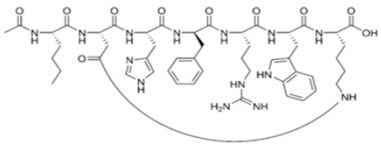
Bremelanotide (BMT): Approved for Premenopausal HSDD June 2019

- Novel cyclic 7-amino acid **melanocortin-receptor agonist**, with high affinity for the type-4 melanocortin receptor, an analog of α-melanocyte-stimulating hormone (MSH)



- BMT is delivered via an auto-injector on an "as needed" basis 45 minutes before sexual activity
- BMT demonstrated significant efficacy vs. placebo in measures in increasing sexual desire and decreasing distress

Data presented at ISSWSH annual meeting Feb 2017 by Simon, J.
Clayton AH, Althof SE, Kingsberg S, DeRogatis LR, Kroll R, Goldstein I, Kaminetsky J, Spana C, Lucas J, Jordan R, Portman DJ. Womens Health (Lond). 2016 Jun;12(3):325-37. doi: 10.2217/whe-2016-0018. Epub 2016 May 16.Clayton AH, Kingsberg SA, Goldstein I. Evaluation and Management of Hypoactive Sexual Desire Disorder. Sex Med 2018;6:59–74.

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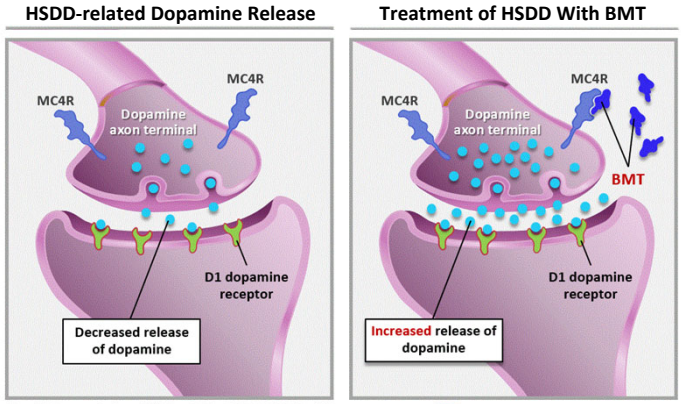
BMT MOA: Potential to Modulate Brain Pathways Involved in Sexual Desire



- Bremelanotide (BMT): an investigational, novel cyclic 7-amino acid melanocortin-receptor-4-agonist (MC4R)[1]
- BMT (Vyleesi™) acts on the physiological and neurobiological components of female sexual function
  - Potential to modulate brain pathways involved in sexual desire and arousal in women with HSDD[2]

1. Molinoff PB, et al. Ann N Y Acad Sci. 2003;994:96-102.
2. Pfaus J. J Sex Med. 2007;4(suppl 4):269-279.

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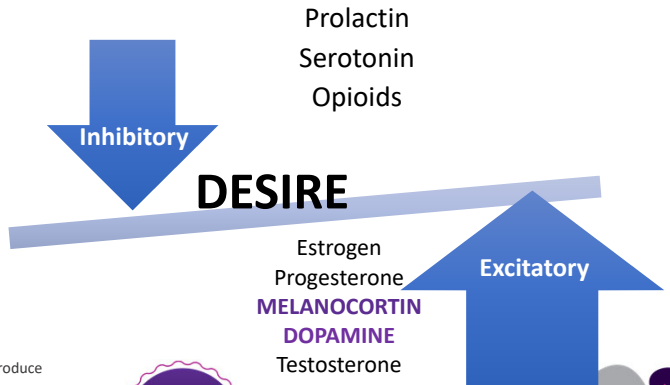
Excitatory and Inhibitory Effects of Neurotransmitters and Hormones on Sexual Desire



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The RECONNECT Study

Placebo-controlled, phase 3 studies of BMT administered as-desired for the treatment of HSDD

- Healthy, premenopausal, nonpregnant women, ≥18 years of age, currently in a stable (≥6 months) relationship
- Diagnosed with HSDD (with/without decreased arousal) for ≥6 months
- Experienced "normal" sexual function in the past for ≥2 years
- Willing to engage in sexual activities ≥1X/month during the study
- Had ALL of the following at screening:
  - Patient Health Questionnaire-9 total score <10 and a score of 0 on question 9
  - Female Sexual Function Index (FSFI) total score ≤26 (if diagnosed with HSDD with/without symptoms of decreased arousal) OR
  - FSFI desire domain (FSFI-D) score ≤5 (if diagnosed with HSDD without decreased arousal) regardless of total FSFI score
  - Female Sexual Distress Scale-Desire/Arousal/Orgasm (FSDS-DAO) total score >18

Efficacy of Bremelanotide for HSDD in Women: RECONNECT Open-Label Extension Phase Results [8Q]
Clayton, Anita H., MD; Kingsberg, Sheryl A., PhD; Simon, James A., MD, CCD, NCMP, IF; Jordan, Robert; Lucas, Johna, MD Obstetrics & Gynecology: May 2018 - Volume 131 - Issue - p 186S
doi: 10.1097/01.AOG.0000533221.21767.0a

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Key Outcome Measures

- Co-primary Efficacy Endpoints
  - Change in the FSFI-D and FSDS-DAO Item 13 scores among women who completed the double-blind treatment phase of the RECONNECT study
- Responder Analysis Based On
  - Participants self-reporting a score of ≥5 (on a 7-point Likert scale) in response to question 3 on the General Assessment Questionnaire "To what degree do you think you benefited from taking the study drug?"
  - The proportion of participants meeting or exceeding the following predefined minimal clinically important differences (MCIDs)
    - FSFI-D score (MCID=0.6)
    - FSDS-DAO Item 13 score (MCID=-1.0)

Efficacy of Bremelanotide for HSDD in Women: RECONNECT Open-Label Extension Phase Results [8Q]
Clayton, Anita H., MD; Kingsberg, Sheryl A., PhD; Simon, James A., MD, CCD, NCMP, IF; Jordan, Robert; Lucas, Johna, MD Obstetrics & Gynecology: May 2018 - Volume 131 - Issue - p 186S
doi: 10.1097/01.AOG.0000533221.21767.0a

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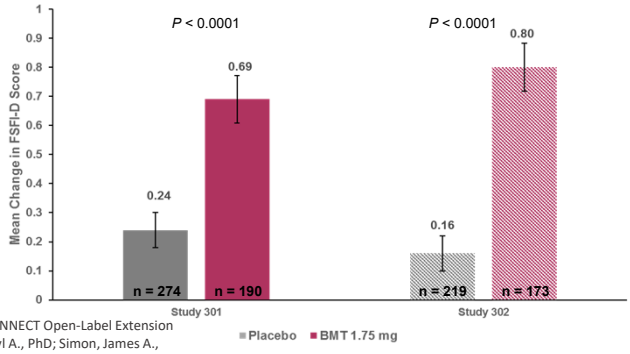
Efficacy Results: FSFI-D

Compared with those taking placebo, women taking BMT had significantly increased scores on the desire domain of the FSFI at 6 months, indicating an increase in desire

Figure 2. *Change in FSFI Desire Domain Score from Baseline to End of Core (Double-Blind) Phase*



P values determined by unadjusted Wilcoxon rank-sum test. Error bars are standard error of the mean.

Efficacy of Bremelanotide for HSDD in Women: RECONNECT Open-Label Extension Phase Results Clayton, Anita H., MD; Kingsberg, Sheryl A., PhD; Simon, James A., MD, CCD, NCMP, IF; Jordan, Robert; Lucas, Johna, MD Obstetrics & Gynecology: May 2018 - Volume 131 - Issue - p 186S
doi: 10.1097/01.AOG.0000533221.21767.0a

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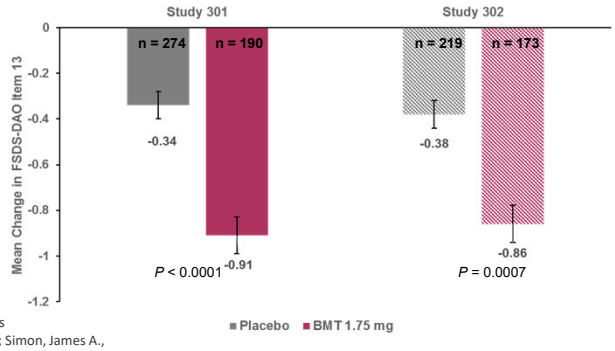
Efficacy Results: FSDS-DAO Item 13

Compared with those taking placebo, women using BMT had a significant reduction in their FSDS-DAO Item 13 score at 6 months, indicating a reduction in distress related to low sexual desire

Figure 4. Change in FSDS-DAO Item 13 from Baseline to End of Core (Double-Blind) Phase



P values determined by unadjusted Wilcoxon rank-sum test. Error bars are standard error of the mean. FSDS-DAO, Female Sexual Distress Scale-Desire/Arousal/Orgasm.

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Defined Anchor Analysis

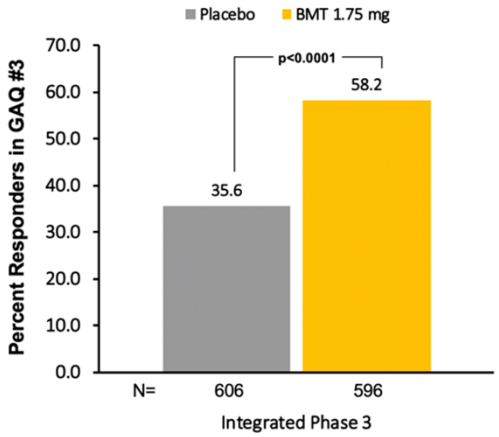
Global Assessment Questionnaire Q3 for Co-Primary

"Compared with the start of the study (prior to taking the study drug), to what degree do you think you benefited from taking the study drug?"

Very Much Worse			No Change			Very Much Better
1	2	3	4	5	6	7

Responder defined as score of ≥5

Percent Responders Defined by a Score of ≥5 on GAQ Question #3



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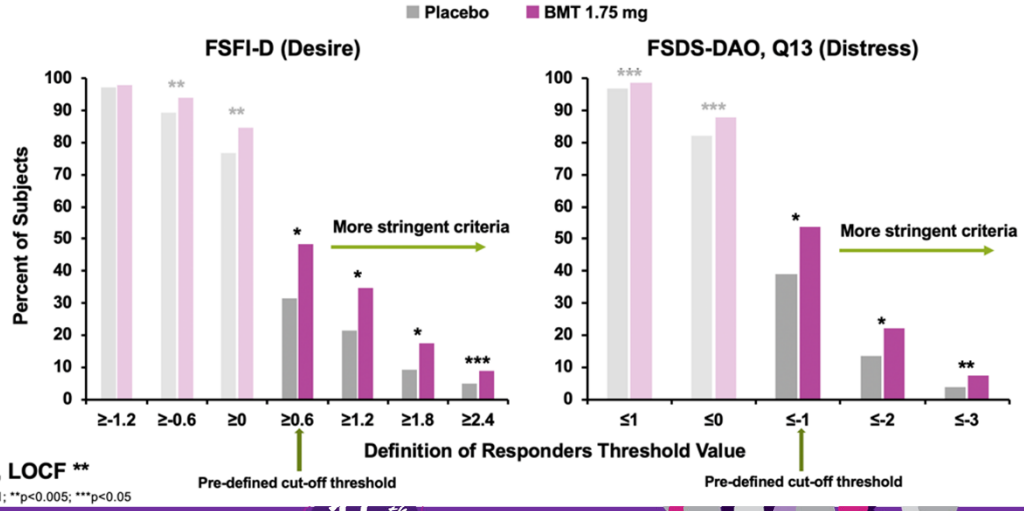
Cumulative Distribution of Responder Results: Integrated Efficacy Data



MITT, LOCF **

*p<0.0001; **p<0.005; ***p<0.05

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Safety

- Bremelanotide: an on-demand auto-injector has a favorable safety profile
- Most AEs were mild or moderate in nature
  - Nausea, vomiting most common: 40%
  - 8% discontinued due to N/V
- TEAEs led to treatment discontinuation/interruption in approximately 18% of women taking bremelanotide (vs. 2% in placebo)
  - Most of the bremelanotide AEs causing withdrawal were gastrointestinal (11.1% in Study 301 and 7.6% in Study 302)
- Contraindication: uncontrolled hypertension or known CVD
- No interaction with alcohol

Efficacy of Bremelanotide for HSDD in Women: RECONNECT Open-Label Extension Phase Results [8Q]
Clayton, Anita H., MD; Kingsberg, Sheryl A., PhD; Simon, James A., MD, CCD, NCMP, IF; Jordan, Robert; Lucas, Johna, MD Obstetrics & Gynecology: May 2018 - Volume 131 - Issue - p 186S
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Off-Label Therapy

- Testosterone
- Estrogen
- Bupropion
- PDE-5 Inhibitors

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Testosterone

- A 2017 systematic review and meta-analysis included 7 randomized controlled studies of transdermal testosterone (with or without concomitant estrogen therapy) that was composed of more than 3,000 postmenopausal women with HSDD.
- Postmenopausal women treated with the transdermal testosterone patch experienced significant increases in sexual desire, sexual activity, SSE, and orgasms and a significant decrease in personal distress compared with women in the placebo group.
- No testosterone product is approved in the U.S. for women

Achilli C, Pundir J, Ramanathan P, et al. Fertil Steril 2017;107:475-482.e415.

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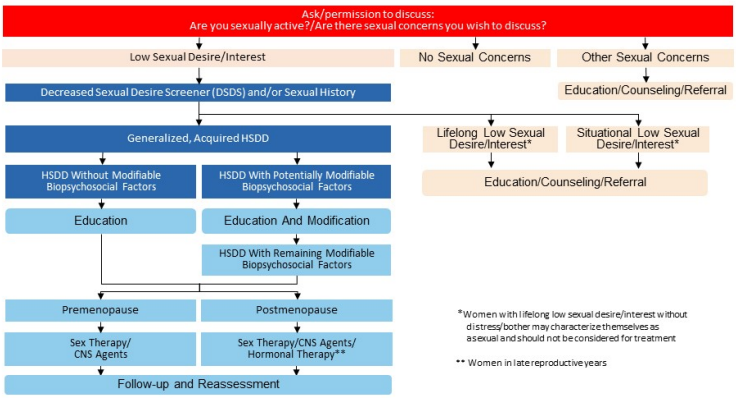
ISSWSH Process of Care for Management of Hypoactive Sexual Desire Disorder (HSDD) in Women



Adapted from Clayton AH, et al. Mayo Clin Proc. 2018;93:467-487.

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Conclusions

- HSDD is highly prevalent and presents a huge burden to the quality of life of women who suffer from this condition
- It is the responsibility of the HCP to initiate discussion of sexual concerns with all patients
- There are safe and effective treatments for HSDD.

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Talking with Your Patients About Hypoactive Sexual Desire Disorder and Advances in its Treatment