

Challenging Medicalization: Women's Health Movement Strategies

Cindy Pearson

National Women's Health Network

www.nwhn.org

Women's Health Movement Victories

- No more quotas in medical schools
- Partners & support people in the delivery room
- Written information about prescription drugs
- Informed decision-making model of contraceptive counseling
- Nurse practitioners as independent clinicians with prescribing authority
- Dalkon Shield
- High dose oral contraceptives
- VBACs
- SWAN (natural history of menopause)
- Defeating Premarin's cardiovascular indication
- Making NIH do the WHI – results helped women safely stop using HT and avoid breast cancer & heart disease
- WomanCare study (ocs & breast cancer)
- Consumer representatives on FDA advisory committees & open mike at the meetings
- Federal sterilization abuse regulations
- Reversible long-acting contraception
- Coverage for maternity care, breast feeding supplies and contraception in almost all health insurance plans
- Drug Snapshots with information about how many women and people of color were in pivotal trials
- Office of Research on Women's Health at NIH

Challenging Medicalization

- PMDD
- Estrogen deficiency
- Osteopenia
- HSDD

Strategies

- Expose conflicts of interest
- Challenge legitimacy of invented conditions
- Press for independently-funded research
- Use the FDA process to point out safety concerns, efficacy concerns
- Inform consumers about what the science shows
- Engage the media

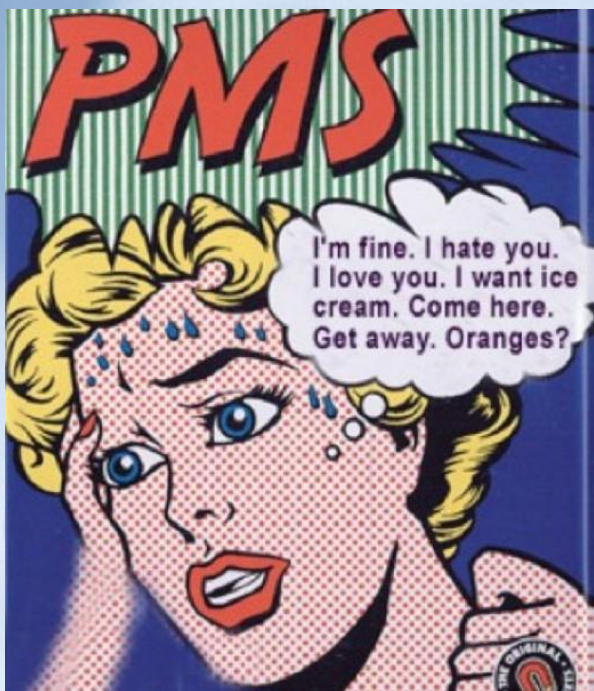
Challenging Medicalization

Premenstrual Dysphoric Disorder

PMDD: Sarafem (fluoxetine)



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After Prozac lost patent exclusivity, Sarafem provided new life to the patent.

Medicalization

Estrogen Deficiency

1959



“Difficult family situations can often be wholly remedied by estrogen therapy for the woman involved.”

Wilson, Feminine Forever, 1966

The whole family likes “Premarin”

IN a sense, when you prescribe “Premarin” for a wife and mother who is suffering in the menopause, chances are you’re treating the whole family. Junior, Sis, and Dad, just like Mom, can tell the difference right off.

Mother isn’t just more tranquil on “Premarin” therapy. Hundreds of published reports tell us she takes a

positive outlook on life. She feels good. And we all know that’s the single most important factor for a happy home.

Women on “Premarin” receive treatment that covers every aspect of the menopause, including prompt relief of physical distress.

Is it any wonder physicians say the woman suffering in the meno-

pause deserves “Premarin”? Many a family would agree.

“Premarin,” conjugated estrogens (equine), a complete natural estrogen complex, is available as tablets and liquid, and also in combination with meprobamate or methyltestosterone.

Ayerst Laboratories • New York 16, N. Y. • Montreal, Canada



1998

If your menopausal patients have new questions about menopause...consider the entire body of evidence.

They need the kind of counseling only you can provide.

Brain: In the past 10 years, research has explored questions surrounding the consequences of menopause and cognitive functioning, memory, and Alzheimer's disease.

Eyes: Ongoing research continues to investigate cataracts in post-menopausal women, as well as age-related macular degeneration, the leading cause of blindness in the aging population.

Uncomfortable symptoms:

For over 50 years, it's been known that estrogen loss associated with menopause causes the hot flashes and night sweats that often influence mood and sleep.

Teeth: Epidemiological research continues to explore the association between tooth loss and menopause.

Heart: Since the 1950s, large-scale clinical trials have researched cardiovascular disease in post-menopausal women, looking at cholesterol, heart attacks, and death.

Sexuality: Half a century of study has confirmed that estrogen loss causes vaginal thinning and dryness and increases the frequency of vaginal infections, which can be uncomfortable and interfere with intimacy.

Bone: Decades of research have proven that estrogen loss decreases bone mineral density and increases the risk of fractures from osteoporosis.

Colon: Ongoing epidemiological research continues to explore the risk of colon cancer among women after menopause.



Today, we know more than ever about the consequences of menopause, and the effect it has on the entire body. So-called "selective" or "designer" estrogens may not impact a number of health issues associated with menopause. Counsel your patients about all their health needs at menopause and beyond, because postmenopausal problems aren't always selective.

Medicalization

Osteopenia

Exaggerating the Risks of Osteoporosis

- The risk that a woman will fracture her hip in the next 10 years is:

0.4% at age 50 (1/250)

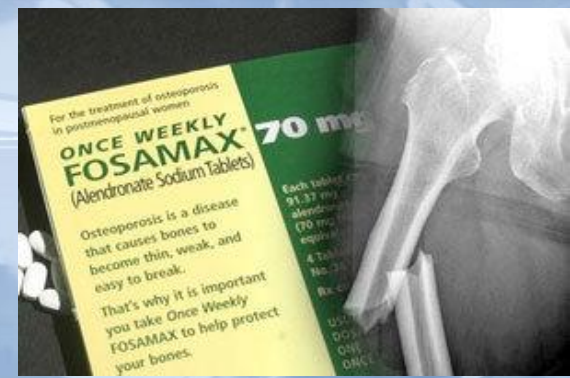
1.5% at age 60 (1/70)

4.7% at age 70 (1/20)

11% at age 80 (1/9)



Osteopenia: Fosamax



- Merck promoted bone densitometry devices for office use
 - bought exclusive rights to one company's technology
 - gave a loan to another company to develop an additional device
 - financed two other firms
- Merck created the Bone Measurement Institute, and financed the National Osteoporosis Foundation

Medicalization

Female Sexual Desire Disorder

Sprout Pharmaceuticals



The Female Sexual Function Index (FSFI)

- “Over the past 4 weeks, how often did you feel sexual desire or interest?”
 - A woman who feels sexual desire for about 50% of her waking hours scores 3.

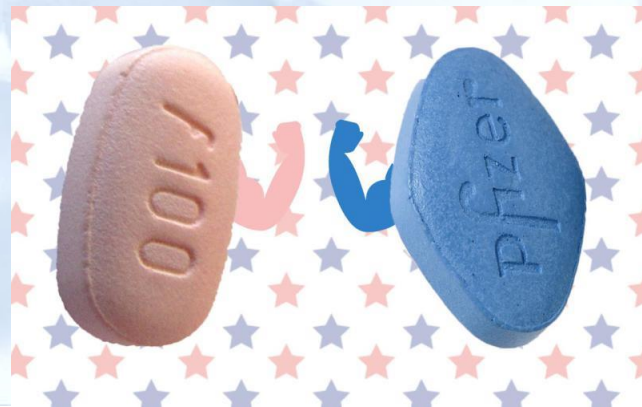


Even the Score



**November
2015**

- Bloomberg Business reports that in the first month on the market, Addyi has sold 227 prescriptions.
 - Only 1% of OBGYNs and primary care physicians have been certified to be prescribers.
- By contrast, in the first month that Viagra was on the market, it sold 500,000 prescriptions.



Women's Health Strategies Work

- PMDD died with patent expiration of Sarafem
- HT use (and breast cancer) has dropped dramatically
- No BMD screening at age 50
- Addyi is failing spectacularly

Lessons Learned

- Takes time to get rid of invented conditions
- Stay vigilant

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For More Information

National Women's Health Network

www.nwhn.org

nwhn@nwhn.org

PharmedOut

www.PharmaedOut.org

Can you take Addyi?

- Are you....
 - ✓ A heterosexual woman?
 - ✓ Pre-menopausal?
 - ✓ Willing to stop drinking alcohol?
 - ✓ Not asian?
 - ✓ Not taking other medications?
 - ✓ Do not have other psychological or medical conditions?
 - ✓ In a long-term monogamous relationship?
 - ✓ Willing to spend \$700 a month for your prescription?
 - ✓ Willing to seek a specially certified doctor and then drive to a specially certified pharmacy?
 - ✓ Willing to sign a waiver that says you will never drink?
 - ✓ Not feeling desire every waking hour of the day?
 - ✓ Being annoyed by your partner to have sex?
 - ✓ Prepared to suddenly and unexpectedly become unconscious?

October 2015: Valeant launches Addyi.



48 hours after the FDA approval of flibanserin, Sprout and the drug were sold to Valeant Pharmaceuticals for \$1 billion.



The Female Sexual Function Index (FSFI)

- The FSFI contains a long list of questions and a scoring system, but no information on interpreting the scores

Domain	Questions	Score Range	Factor	Minimum Score	Maximum Score	Score
Desire	1, 2	1 - 5	0.6	1.2	6.0	
Arousal	3, 4, 5, 6	1 - 5	0.6	1.2	6.0	
Lubrication	7, 8, 9	1 - 5	0.6	1.2	6.0	
Orgasm	10, 11, 12, 13	1 - 5	0.6	1.2	6.0	
Satisfaction	14, 15, 16, 17	0 - 5	0.4	0.0	6.0	
Pain	17, 18, 19	0 - 5	0.4	0.0	6.0	
Full Scale Score Range				2.0	36.0	

Industry may establish or redefine “new” conditions

- Hypoactive Sexual Desire Disorder (HSDD)
- Binge-eating Disorder (BED)
- Gastroesophageal Reflux Disease (GERD)
- Premenstrual Dysphoric Disorder (PMDD)
- Social Anxiety Disorder (SAD)
- Overactive Bladder Syndrome
- Osteopenia
- Pediatric Bipolar Disorder
- Excessive Sleepiness (ES)
- Late-onset hypoandrogenism (Low-T)



Companies often present benefits in relative terms and risks in absolute terms

- Wyeth touted the decreased hip fracture risk in relative terms.
- However, a 34% decrease in hip fracture risk translates into an absolute benefit of 0.05%.
- An absolute increased risk of breast cancer of 8 per 10,000 patients may not sound high.
- But if you present both in absolute terms, the woman using HT who suffers “less than 1 additional diagnosis of breast cancer per 100 women” gains a “benefit” of less than 1 hip fracture per 1000 women.



Doubt is our product

- Even physicians who understood that HERS showed that hormone therapy did not benefit women with heart disease still believed that hormone therapy could benefit healthy women.

