

Menopause or “Hormone Deficiency Disease”? How Disease Mongering Inflated Breast Cancer Rates and Harmed Healthy Women

Amy Allina

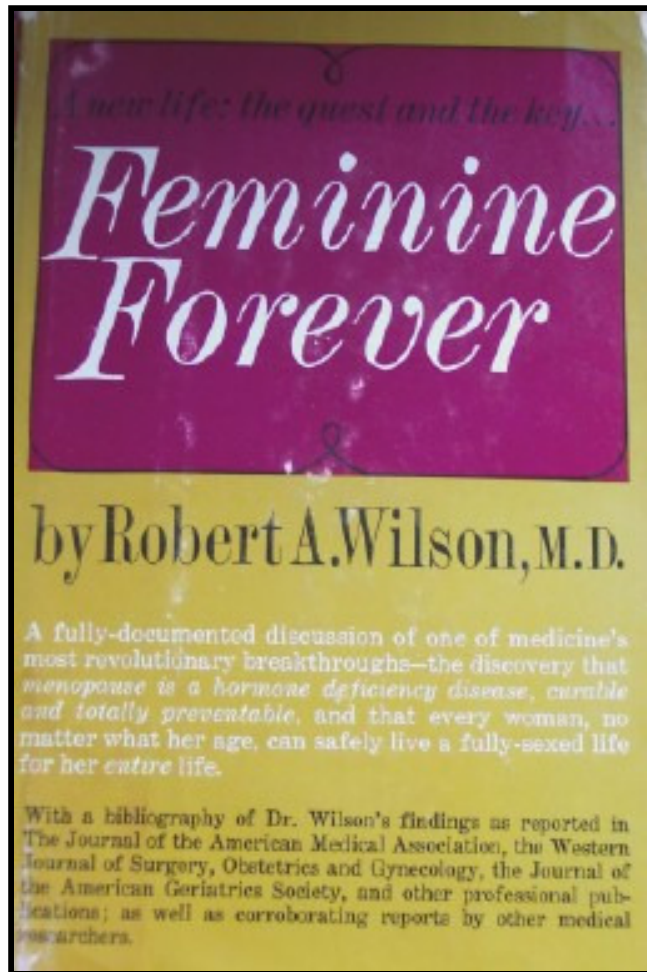
February 22, 2013



**NATIONAL
WOMEN'S
HEALTH
NETWORK**



Feminine Forever, 1966



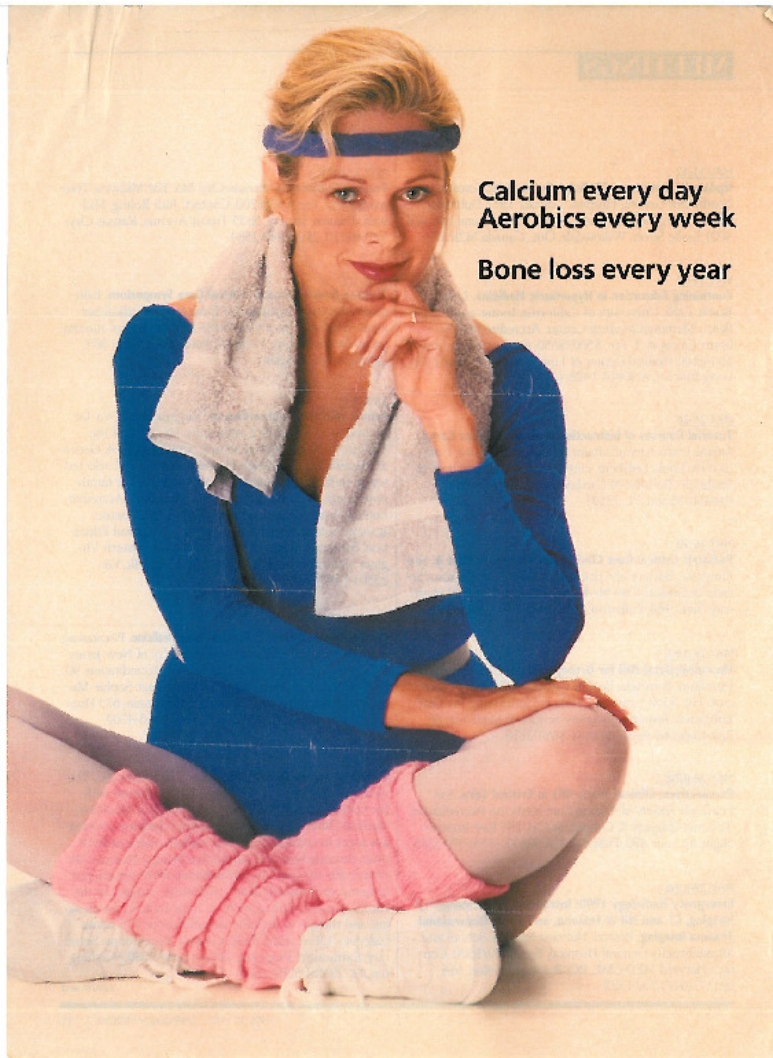
“A man remains male as long as he lives. [...] How different is the fate of woman. [...] At the very moment when she is most able and eager to enjoy her achievements, her femininity – the very basis of her selfhood – crumbles in ruin. But now, at last, medicine offers a practical escape from this fateful dilemma.”

Not a “change,” a catastrophe

“There we were – my husband at the peak of his career – busy, successful...but no time for me. With that and all my other problems, I’d lie awake night after night, more depressed every day. This wasn’t a ‘change,’ it was a catastrophe.”

— JAMA ad, 1976

From anxiety to aerobics...



**Calcium every day
Aerobics every week
Bone loss every year**

She needs PREMARIN to help prevent further bone loss

Calcium¹ and exercise are not enough to prevent postmenopausal osteoporosis, since estrogen deficiency is the primary cause.² PREMARIN is the only brand of estrogen indicated to prevent further bone loss and in a recently published study has been shown to reduce the risk of hip fractures by as much as 68%.³

Early PREMARIN therapy offers the best protection

The most significant rate of bone loss occurs in early menopause. PREMARIN can help maintain bone mass, preventing the progression of osteoporosis and its consequences.

Protection continues as long as estrogen therapy continues

Clinical studies show that within three years of menopause when therapy is withdrawn, bone loss begins again.⁴

PREMARIN[®]
(conjugated estrogens tablets)

**Proven benefits
for menopause and beyond**

See important information on adjacent page.

Spreading the gospel

HORMONE REPLACEMENT THERAPY

AFTER MENOPAUSE



- **REDUCES RISK:**
DEATH
HEART DISEASE
- **DOES NOT INCREASE RISK:**
CANCER
CLOTS
STROKE

FOX
HD

7:56am TODAY 70°

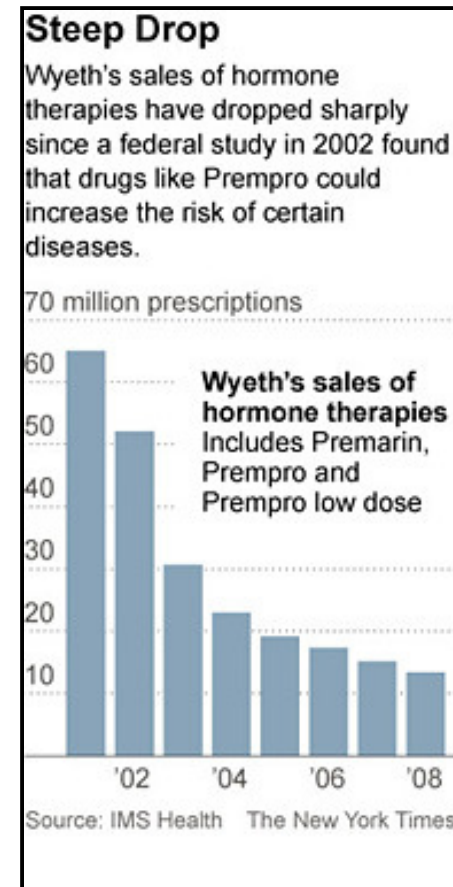
VIEW THE LIONS-BEARS GAME SUNDAY MORNING AT 10AM ON FOX KICKOFF SUNDAY. FOX N

Women's Health Initiative results

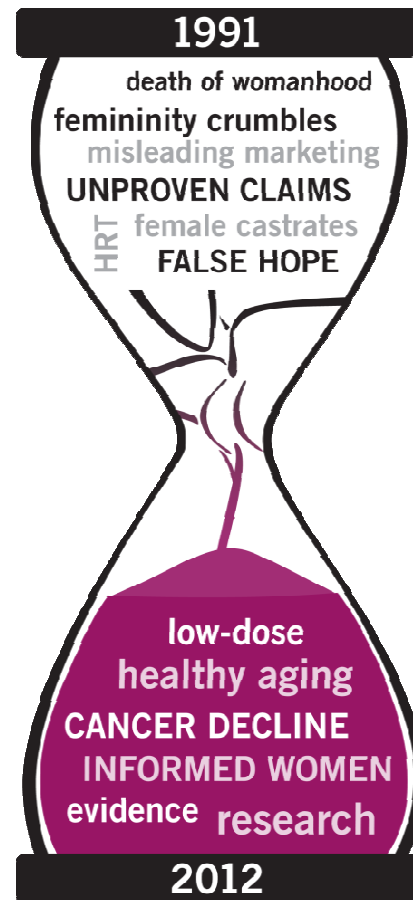
Harm caused by HT:

- Breast cancer
- Blood clot
- Stroke

And the consequent
drop in HT prescriptions



What else dropped? Breast cancer rates



Window of opportunity theory



More information about the WHI



<http://nwhn.org/get-facts>

Learning from the mistakes

- Stronger protections from misleading promotion of unproven and unsafe drugs, including better regulation of drug ads
- Increased investment in research to develop safer alternatives to treat hot flashes
- Inclusion of more women in heart disease prevention research
- An end to drug company funding for medical education

**Life Saving Diet Products:
Is the FDA Being Taken in by a
Corporate Smoke & Mirrors Job?**

Kate Ryan, MPA
National Women's Health
Network
February 22, 2013

Ad for the Lap-Band



Ad for Xenical



Health Impact of Obesity

- Rising rates of overweight and obesity in the U.S.
 - 64% of adult women are overweight or obese
 - 78% of African-America women are overweight or obese
- Rise in associated health conditions
 - Diabetes
 - Hypertension
 - Heart Disease

Rush for Manufactured Solutions

- In 2010, Xenical (orlistat) only weight loss drug on the market
 - = Blockbuster potential for new products
- Increase in weight loss products seeking FDA approval
 - Qsymia (phentermine/topiramate)
 - Belviq (lorcaserin)
 - Contrave (naltrexone/bupropion)
 - Lap-Band

Overview of New Drugs & Devices

- Qsymia, Belviq & Contrave
 - Marginally effective
 - Serious safety concerns
 - Poor long-term data
- Lap-Band
 - Effective for weight loss
 - almost 1/2 had to have their bands removed
 - nearly 60% of people had at least one reoperation

Weight Loss or Obesity Drugs?

- Products are intended to help those who are obese achieve a healthy weight, not for general weight loss
 - Should improve obesity-related health conditions
 - Should be safe for intended long-term use
 - Ads should set realistic expectations
- NOT weight loss products... products to treat obesity

What Counts as Effective?

- Current efficacy standard = based on 5% weight loss
- Women want to know that an obesity drug will improve their health, not just reduce the number on the scale
 - FDA should require drug-specific data demonstrating health benefit

Does Effective = Thin or Healthy?



How Safe is Safe?

- Safety standard = benefits outweigh risks
- Previous obesity drugs have caused serious cardiovascular harm, but no requirement to study specific safety endpoints pre-approval
 - FDA should require trials designed to assess specific safety endpoints, such as cardiovascular effects

How Long Will It Last?

- Long-term standard = 1 year clinical trial
- Obesity products are intended for chronic use and indicated for weight loss maintenance but are not assessed for long-term safety or efficacy
 - FDA should require 3 years of pre-market safety and efficacy data

Need Better Regulation of Ads



Conclusion

- Current FDA standards for obesity products are too low
- National Women's Health Network is advocating for:
 - Comprehensive efficacy standards
 - Pre-market safety standards
 - Long-term safety and efficacy standards

Thank you!

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Phentermine/Topiramate

- Met both efficacy standards
 - Treatment group lost 10.6% of their weight
 - Control groups lost 1.7% of their weight
 - 70% of treatment group lost 5% of their weight
 - 20% of control group lost 5% of their weight

Phentermine/Topiramate

- Serious safety concerns:
 - Cardiovascular
 - Birth defects
 - Psychiatric
 - Neurocognitive
- 2 year trials – cherry picked 2nd year sites
- Approved by the FDA

Lorcaserin

- Only met the 2nd efficacy standard
 - Only 3% difference in mean weight loss
 - 47% of treatment group lost 5% of their weight
 - 23% of control group lost 5% of their weight

Lorcaserin

- Serious safety concerns:
 - Valvular heart disease
 - Breast cancer
- 2 year trials
- Approved by the FDA

Naltrexone/Bupropion

- Only met the 2nd efficacy standard
 - The highest dose only achieved 4.8% difference in mean weight loss
 - 48% of treatment group lost 5% of their weight
 - 16.4% of control group lost 5% of their weight
 - 44.5% of treatment group lost 5% of their weight
 - 18.9% of control group lost 5% of their weight

Naltrexone/Bupropion

- Serious safety concerns:
 - Increased risk of hypertension
 - Seizures
 - Suicidality/psychiatric side effects
- 1 year trials = no data on WL maintenance
- Not approved by the FDA

Laparoscopic Adjustable Gastric Banding

- LAGB already approved
 - BMI>40
 - BMI>35 with an obesity-related health condition
- Manufacturer applied for an expansion
 - BMI>35
 - BMI>30 with an obesity-related health condition

Laparoscopic Adjustable Gastric Banding

- Effective for short-term weight loss
 - Average WL was 18.3% at 1 year
- BUT approval based on short-term studies
 - At most 3 years of data
- FDA approved partial expansion
 - BMI>40
 - BMI>30 with an obesity-related health condition

Laparoscopic Adjustable Gastric Banding

- Long-term data
 - almost 1/3 experienced band erosion;
 - almost 1/2 had to have their bands removed;
 - nearly 60% of people had at least one reoperation;
 - no beneficial effect on high blood pressure and diabetes