

A New View of Women's Sexual Problems

for FDA Advisory Committee Hearing on Intrinsic, December 2, 2004

Concerns about New Hormone Treatments for Women

Problem 1: There is no easy affordable way to measure testosterone.

There is no easy way to measure testosterone levels, so a woman being prescribed Intrinsic by her doctor won't know her own level and how it is affected by the treatment. She and the doctor will just have to go by external signs and symptoms. Testosterone levels vary throughout the day and the menstrual cycle and "data are insufficient to determine what constitutes a low value." (Shifren, 2004, p.S20) *Intrinsic should not be approved until there is an available, affordable assay for testosterone, so women will know if their levels are really abnormal and so they will be able to monitor any changes induced by the testosterone patch.*

Problem 2: The relationship between testosterone and sexuality in women is complicated and although there are dozens of scientific studies, there are no simple conclusions.

Research studies where expensive testosterone measurement is used (research labs differ from clinical labs where patient blood samples are usually sent), show lots of variation among women in amount of testosterone and in reports of sexual desire and behavior, and the two factors don't necessarily go together. This is true in both pre-menopausal and post-menopausal women. (Bancroft, 2003)

It seems that testosterone may be important for some women and not others, in terms of sexuality. This makes sense, because women vary a great deal in their behavioral, motivational, and experiential response to other hormones.

After menopause, many women report a rise in their sexual enjoyment despite the presumed drop in testosterone. This seems to be because the fear of pregnancy is gone and many of the problems associated with menstruation are relieved. [ref?]

Problem 3: Even if some studies show that testosterone in the short term can increase sexual interest or response in some women, long-term safety data for testosterone therapy are lacking and we must have long-term safety information before long-term use can be recommended. (Davis, et al, 2004, p. 83)

Why are we so concerned about long-term safety?

Long-term results with testosterone may show a rise in cancer or stroke or cardiovascular disease or lung blood clots, as occurred in women taking long-term HRT (estrogen and progestin “hormone replacement therapy”). The medical advice since 2003 is only to take HRT short-term for relief of symptoms. Before these long-term results appeared in 2002 women and doctors were misled into thinking that HRT was safe by researchers who did not have long-term evidence. *This betrayal must not be repeated with testosterone.*

In the present trials, Intrinsa was always tested with HRT. Thus an FDA approval of the testosterone patch would almost certainly require that women also be on estrogen. *This literally means that women will be required to take long-term estrogen in contradiction to the current medical recommendations.*

The goal of testosterone therapy in some women is to induce masculinization, as in female-to-male transsexuals. There is a lot of useful information about testosterone on transsexual websites, e.g., <http://web.mit.edu/hudson/www/ttherapybasics.html>. *While Procter and Gamble’s testosterone patch has a smaller amount of testosterone than is typically used by transsexuals, patients are still warned about possible masculinizing effects.*

Problem 4: Hormones get into the water supply because discarded patches still contain a lot of unused hormone.

See “Pharmaceuticals in our water” on <http://www.whp-apsf.ca>

References

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- Davis SR, Guay, AT, Shifren, JA & Mazer, NA (2004) Endocrine aspects of female sexual dysfunction. *Journal of Sexual Medicine*, 1: 82-86.
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