

REMARKS TO THE FDA ADVISORY COMMITTEE HEARING ON
“INTRINSA” – DECEMBER 2, 2004

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My name is Leonore Tiefer.

As a psychologist with over 30 years of teaching, research, awards and publications in sexuality, I see today as a perilous moment in the history of women’s sexuality.

A few random credentials – which I offer because this is the first women’s sexuality drug that the FDA has ever reviewed, and there is no Sexuality Drug Committee. There may be one someday, but at the moment, input may be useful from someone who has spent decades immersed in issues of sexual nomenclature, measurement, motivation, behavior, and biology.

Here are my concerns.

I have handouts with documentation on each of these points since I can only give the briefest input in 180 seconds.

The Intrinsic trials are inadequate to assess the risks of extended steroid hormone treatment. I hope we don’t have to go through another hormone scandal to learn this again. That’s point one.

Point two is that assessing sexual experience is subtle and complex and -- arbitrary. Experts in sexology agree that there are numerous ways to define and measure desire and satisfaction. The methods chosen in every study must be closely examined for what they leave out as well as what they include.

Point three. These Intrinsica trials excluded women with medical problems, relationship problems, mood or self-esteem problems,-- it's no wonder it took 52 trial sites to find a meager 1095 subjects. But how representative are these carefully selected subjects of the millions P&G is hoping to interest in its new medicine?

Which brings me to point four. Intrinsica is not a glass of Chardonnay, and yet we have already seen that it may well be promoted with a giggle and a wink as "the female Viagra." Not so - this is a steroid hormone women must continuously take for weeks before getting an effect. Yet P&G's promotional materials encourage the attitude that millions of women are walking around under-androgenized in danger of imminent sexual withering away. It's a revival of menopause as a deficiency disease -- only this time it's testosterone, not estrogen that rides to the rescue.

So here are my recommendations

First, postpone the application until there are longer studies on more appropriate populations

Second, if women with low desire are testosterone deficient, we must have an affordable assay to measure that deficiency and there is none now.

Third, good sex research should always have a qualitative component

And finally, the FDA's DDMAC needs to carefully monitor the P&G materials for bias and boundary violations.

I am representing a large group of experts who couldn't be here today.