

A New View of Women's Sexual Problems

Prepared for FDA Advisory Committee Hearing on
Intrinsa, December 2, 2004

Problems with the Intrinsa Clinical Trials

Problem 1: The sample is too narrow and too small

- The population used in the trials was restricted to women with surgical removal of both their ovaries and their uterus who were also taking estrogen (or estrogen and progesterone) and who were distressed about their loss of desire and who had no other problems and who were willing to use an experimental testosterone patch.
 - There were only 1095 such women in the trials
 - The population of women with surgical menopause is a relatively small group and we cannot generalize to other groups
 - Many women in this group are seriously ill (what were the health reasons for their surgery?)
 - This is NOT the group where P&G will focus its marketing (as evidenced by recent Continuing Medical Education courses for doctors and by advertising plans discussed in business news)
 - The public needs to see Intrinsa safety and efficacy data on women bothered by low sex desire going through natural menopause.
 - The public needs to see Intrinsa safety and efficacy data on women bothered by low desire not taking estrogen and/or progesterone.
 - The public needs to see Intrinsa safety and efficacy data on women bothered by low desire using oral contraceptives.

Problem 2: Too many women were excluded

- The population used in the trials only included women
 - With a regular heterosexual partner in a satisfactory committed relationship,
 - With NO psychological problems,
 - With NO relationship problems,
 - With NO health problems
 - Taking NO other medications

- This is NOT the real world
- Where are the trials on real women in the real world who will be the targets of P&G's marketing?
- If P&G markets Intrinsa widely (e.g., in women's magazines, in health magazines, through TV ads), women will take a drug which has been tested for safety and efficacy in only a tiny selected group – they will be participating in a giant hormone experiment.

Problem 3: The outcome measures are flawed

- The primary outcome measure of effectiveness for Intrinsa in these clinical trials is a "Sexual Activity Log" which has
 - never been published
 - never had independent scientific examination
- It appears that this "Sexual Activity Log" is a subjective recording of "satisfactory sexual events" including intercourse, oral sex, or masturbation.
 - The public needs detailed information about the exact measures used in order to know whether the benefits of using the patch outweigh the health risks involved in using a hormone treatment for months and years
 - The emphasis on frequency of sexual activity as a main outcome measure is controversial
- Using the "Sexual Activity Log," the number of "satisfying sexual events" between the testosterone patch and the PLACEBO patch is statistically significant, but not much real change (e.g. only one additional event per month).
 - The public needs research showing why women benefitted from the placebo patch.