

A New View of Women's Sexual Problems

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

<p>Problems with P&G's Marketing Plans for Intrinsa</p>
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Problem 1: P&G expects Intrinsa to be a “billion dollar brand”

Problem 2: Intrinsa will be marketed to doctors for primarily off-label use

Problem 3: P&G will promote a public education campaign that will medicalize menopause, overemphasize the prevalence of low sex desire, overemphasize the role of testosterone in sex desire, and underemphasize the role of nonmedical factors in sex life

“There's a large unmet need,” says P&G spokeswoman Mary Johnson, noting that P&G received priority review status from the FDA. P&G recently conducted a survey on female health, which found that of 30 million women who are naturally menopausal, 3 million are distressed by their lack of sexual desire.” Business week, Oct 28, 2004.

What P&G doesn't say is that sexological research shows that many women who report distress over sexual desire acknowledge that the problems arise from relationship, stress, or other nonmedical causes, and that some women don't feel sexual distress but rather are concerned that their partners want to have sex more than they do.

“We think the market is worth billions of dollars,” says Steve Simes, of BioSante Simes, maker of LibiGel, a testosterone drug competitor, in a recent press release.

P&G's annual report (www.pg.com) focuses on “building billion dollar brands” (p. 6), bragging that their osteoporosis drug, Actonel, “became a billion dollar brand faster than any other brand in P&G history” (p. 4) and reporting company restructuring to favor health care products because of higher-margin” (p. 7).

The likely off-label marketing of Intrinsa is indicated by the titles and content of three recent Continuing Medical Education Courses that emphasized uses of Intrinsa well beyond surgical menopause. Disclaimers indicated that the courses might include off-label ...:

- “Renewing Sexual Desire: Understanding HSDD in postmenopausal women” in New York on November 20, 2004, emphasized the role of testosterone in natural menopause as well as numerous off-label indications (e.g., “diminished well-being”)
- “Restoring Sexual desire: The safety and efficacy of testosterone in menopausal women,” an online course posted October 7, 2004, <http://www.medscape.com/viewprogram/3138>
- “New Horizons in Female Sexual Dysfunction: A focus on HSDD in postmenopausal women,” videoteleconference, October, 2004.
- P&G’s 24 page *Reporter’s Guide to Testosterone and its Role in Women’s Health* never refers to testosterone as a steroid hormone, but indicates its uses for bone health, muscle health, cognition, well-being. Complexities in the measurement of these problems or non-drug interventions are absent. http://www.pgpharma.com/guide_testosterone.pdf
- P&G’s “Virtual Press kit” contains a “Fact sheet: Low sexual desire” that similarly oversimplifies the known facts about testosterone’s role in sexual desire, measurement problems with low desire, causes of low desire, and the relationship between low desire and distress. The picture given is biased towards medical causes and treatments. <http://www.pgpharma.com/patch.pdf>

CONCLUSION

P&G is actively promoting the medicalization of sexual desire and of menopause in order to obtain the largest market for their testosterone product. Promoting Intrinsa in this way will result in massive off-label use involving millions of women.

Prescription drugs like the steroid hormone patch Intrinsa are serious medicine. The promotion of this as the “female Viagra” is an attempt to trivialize an important new era in women’s sexual medicine.

RECOMMENDATIONS

There needs to be prospective monitoring of P&G’s “educational” campaigns to professionals and the public. The so-called “disease awareness” or “help-seeking” communications to the public about Intrinsa must have better balance than the ones cited above so as not to overstate the known facts about testosterone or the condition of HSDD. Continuing full disclosure in CME courses will allow professionals to accept new product information with the appropriate degree of scientific skepticism.