

FDA Committee Says No to Testosterone Patch

By Amy Allina

In December 2004, the Food and Drug Administration's (FDA) Reproductive Health Drugs Advisory Committee voted unanimously against approval of a testosterone patch to treat low sex desire in women. Committee members explained their opposition, citing concerns about the safety of long-term use of the patch and use by groups that have not been adequately studied. Procter & Gamble (P&G), which asked the FDA to consider the new product (proposed name 'Intrinsa') had conducted research in women who had had their ovaries removed, were taking estrogen, and were experiencing a problematic lack of sexual desire. A few weeks after the Committee met, P&G withdrew the application for Intrinsa's approval. A spokeswoman told reporters that the company plans to work with the FDA on a revised approach and to file a new application for Intrinsa later.

NWHN OPPOSED INTRINSA

At the Advisory Committee meeting, the NWHN and other organizations urged the Committee not to approve the drug. While recognizing that women who are troubled by a lack of desire for sex have a real problem that needs attention, NWHN opposed Intrinsa because numerous questions remain about the safety of women's testosterone use. Many of the concerns the NWHN raised were cited in the Committee's discussion.

Research indicates that Intrinsa could benefit the narrow group of women in whom it has been studied: women whose ovaries have been removed and/or who take estrogen. The need in this group is real, and the chance to provide help is hard to pass up. As women's health advocates, however, NWHN cannot consider this product in a vacuum, and neither should the FDA.

Intrinsa is intended for long-term use; women who might benefit from the testosterone patch need to know about

its long-term effects on their health. In the wake of the Women's Health Initiative showing health risks associated with long-term use of hormone therapy, it is both appropriate and necessary to exercise special caution about the safety of long-term hormone use. The limited knowledge available about testosterone's effects on women raises concerns about its effect on both breast cancer and heart disease and highlights the need for long-term safety data.

It would be naive and irresponsible to expect that Intrinsa will *only* be promoted and prescribed to women exactly like those studied in the trials. Viagra use quickly spread beyond the initial tar-

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get group. It is extremely likely that advertising and other promotional efforts will blur descriptions of appropriate users in order to expand the market for Intrinsa. A cursory scan of health websites and publications on sexual health issues shows that broader groups of women are already being advised to use testosterone for sexual problems.

Yet, the drug's effects have only been studied among women whose ovaries have been removed and/or who take estrogen. Testosterone use by women in their reproductive years raises a whole new set of questions about the drug's safety, and we have yet to generate reliable answers to these questions. For example, testosterone use is contraindicated during pregnancy; might women who use Intrinsa during a pregnancy find that their future fertility is affected?

**RESEARCH THAT LOOKS
BEYOND MEDICAL SOLUTIONS**
Despite opposing Intrinsa, NWHN is committed to increasing awareness

of women's options for addressing sexual problems and improving sexual health. For many women who experience problems with sexual activity and/or dissatisfaction, there is no physiological cause and drugs are unlikely to help. Sexual problems may be caused by relationship issues, work fatigue, economic anxieties, or past experiences of sexual violence, to name just a few possibilities. To help women who have the courage to confront their sexual dissatisfaction, NWHN believes it is necessary to look beyond medical solutions.

Just as Viagra galvanized public conversations about men's sexuality, Intrinsa and other products for women may create opportunities for both genders to discuss women's sexual lives and the need for sexual health research. Sexuality holds a central place in individuals' lives: it affects physical and mental health, relationships, and families. Thus, it is critically important that the government fund research that explores social, relational, economic and other issues involved in problems with sexual activity and satisfaction.

Public funding is essential because the research conducted by drug companies focuses on developing profitable drug products. It is unlikely to explore the broader sexual health questions required to truly understand these issues. In recent years, unfortunately, Congress has attacked funding for sexual health research, which has had a chilling effect on the field (see 'The Politicization of Science,' *The Women's Health Activist*, Jan/Feb, 2005). The NWHN hopes the Committee's unanimous vote is a positive sign of impending change in this attitude. *

NWHN was joined in opposing Intrinsa by a other women's health advocacy organizations. Statements from these groups, and background on 'Female Sexual Dysfunction', are available at <http://www.fsd-alert.org/intrinsa.html>.

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