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Not in the Mood but Want to Be? New Studies Bring Women Hope

CLEVELAND, Ohio (December 4, 2013)—For women, passing midlife can deal a blow to their sex drive. But two new studies just published online in *Menopause*, the journal of The North American Menopause Society, offer hope to women who want to get their sexual mojo back.

No testosterone treatment for women has yet passed muster with the FDA. An important step toward developing a successful and safe treatment for women after natural or surgical menopause is to find out how much testosterone is really needed to bring desire back. One of these studies looked for that, as well as how much it took to produce other testosterone-related effects, such as increases in lean body mass, in women who had undergone hysterectomy. The other study tested a nonhormonal therapy, flibanserin, which did not meet FDA approval before but has since been resubmitted to the agency.

When FDA first reviewed flibanserin for this purpose in 2010, the agency did not think it made a difference that was meaningfully different from placebo. This new study in women who had very low desire and were distressed about it showed some statistically significant differences. The women who took flibanserin (100 mg/day at bedtime) had increases in the number of satisfying sexual encounters (SSEs) and in a standard score of desire that were statistically better than placebo. Thirty percent of the women experienced side effects, including dizziness, sleepiness, nausea, and headache, but only 8% stopped taking the drug because of them.

The testosterone study included women ages 21 to 60 who had undergone hysterectomy. They all had testosterone levels that were lower than the average for healthy young women. Because the ovary continues to secrete male hormones after menopause, there is usually little decrease in testosterone levels for women who go through menopause naturally, but in women who undergo any type of hysterectomy, testosterone levels drop substantially. Women who also have one or both ovaries removed, even if they take estrogen, have worse sexual function than women who still have one or both ovaries. All the women took estrogen and then also got injections of placebo or of different doses of testosterone enanthate for six months.

Only the women who got the highest dose—25-mg weekly—had statistically significant improvements in their libido and other measures of sexual function as well as in lean body mass and muscle strength. That dose raised testosterone levels to about 210 ng/dL, which is nearly five to six times higher than a healthy, normal level. So simply raising low testosterone levels to what's normal won't improve sexual function and these other measures, concluded the investigators. But is it a dangerous level?

The investigators saw no serious adverse effects. Total and LDL cholesterol, triglycerides, and fasting glucose didn't change significantly in the women who got testosterone. Levels of HDL, the "good cholesterol," did decrease, but not in a statistically significant way. Nevertheless, cautioned the authors, the cardiovascular and metabolic risks need to be investigated in long-term trials.

"Keeping hormone levels within the normal range for your gender and age is the safest approach. Hormones affect many systems in the body, and it takes a large and long-term study to identify side effects. One recent well-designed study in men reported that mortality was greater among older men taking testosterone. More is not necessarily better when it comes to hormones," says The North American Menopause Society Executive Director Margery Gass, MD.

The flibanserin study, "Efficacy and safety of flibanserin in postmenopausal women with hypoactive sexual desire disorder: results of the SNOWDROP trial," was funded by Boehringer Ingelheim, its first manufacturer. Sprout Pharmaceuticals Inc has acquired flibanserin and has resubmitted a new drug application to FDA. The testosterone study, "Testosterone dose-response relationships in hysterectomized women with or without oophorectomy: effects on sexual function, body composition, muscle performance and physical function in a randomized trial," was funded by grants from the National Institute of Child Health and Human Development and by the Boston Claude D. Pepper Older Americans Independence Center. Both articles will be published in the June 2014 print edition of *Menopause*.

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Founded in 1989, The North American Menopause Society (NAMS) is North America's leading nonprofit organization dedicated to promoting the health and quality of life of all women during midlife and beyond through an understanding of menopause and healthy aging. Its multidisciplinary membership of 2,000 leaders in the field—including clinical and basic science experts from medicine, nursing, sociology, psychology, nutrition, anthropology, epidemiology, pharmacy, and education—makes NAMS uniquely qualified to serve as the definitive resource for health professionals and the public for accurate, unbiased information about menopause and healthy aging. To learn more about NAMS, visit www.menopause.org.