

Fix for low sex drive puts reporters in a bad patch

Stories about the testosterone patch are a case study in misleading media coverage

As the debate over the safety of new anti-arthritis drugs rolls around the world, the gap between marketing messages and scientific truths becomes clearer by the day. The estimated toll of heart attacks associated with Merck's rofecoxib (Vioxx) mounts; questions about other COX 2 inhibitors arise; and the drug companies and regulators are rightly being criticised and investigated. Now is a good time for rigorous scrutiny of the media's role in initially boosting this new class of anti-arthritis drugs: the record will show that many reporters seemed simply to reproduce the marketing hype in their stories.

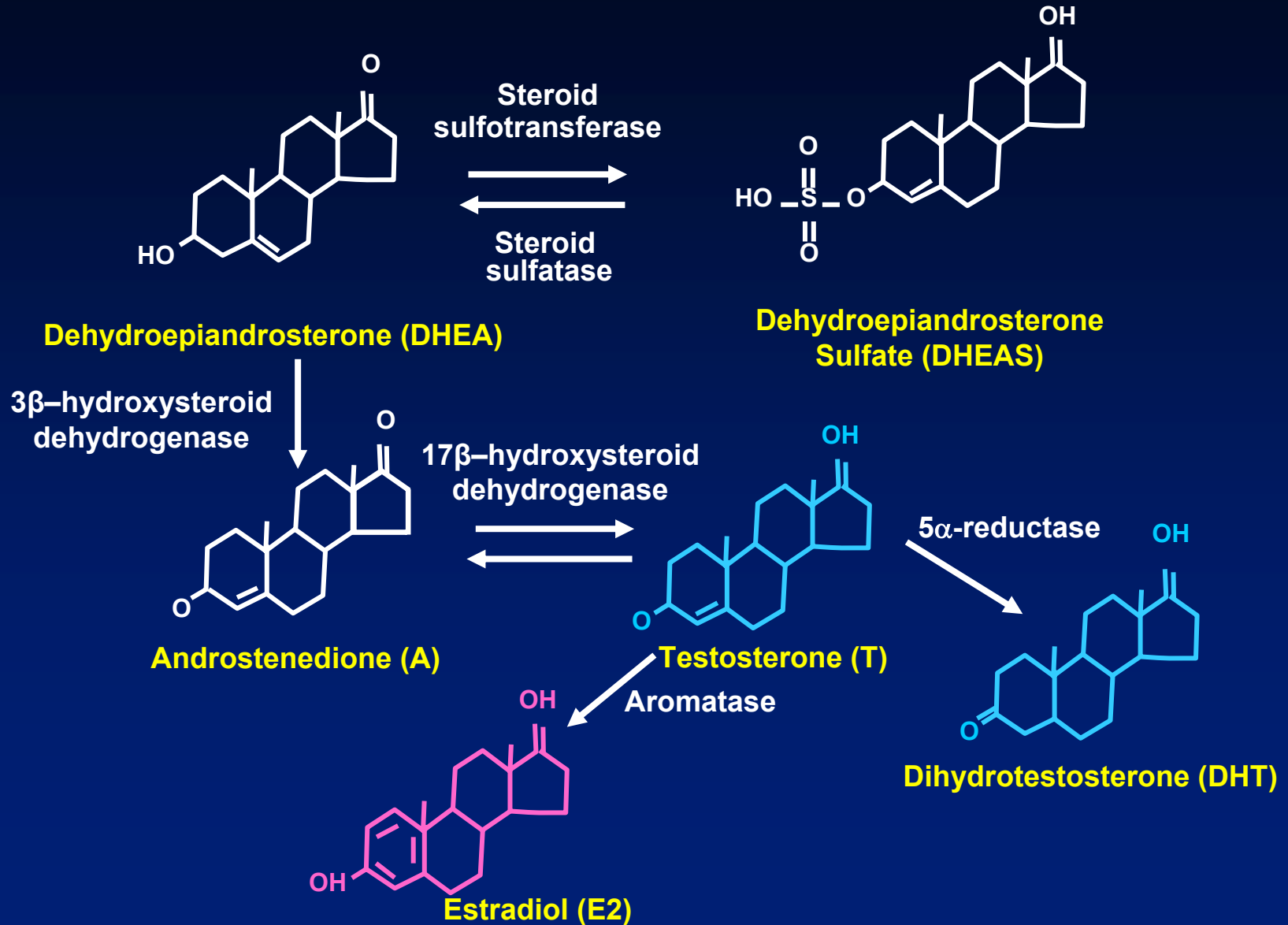
Yet even while this debacle continues, another case study in misleading media coverage around the world is fast emerging: many of the articles about the experimental testosterone patch for women look more like marketing fiction than rigorous journalism. In their search for sexy stories some media outlets are exaggerating the benefits of the patch, inflating the potential pool of patients, playing down well established harms, and ignoring important conflicts of interest. None of the key clinical trials of Procter & Gamble's testosterone patch has been published in peer reviewed journals, yet for a year or more excited media reports have sung the praises of the latest panacea for women's "low sex drive." Next week, despite a virtual worldwide absence of independent public scrutiny of the scientific data, a panel of advisers to the US Food and Drug Administration will decide whether or not to recommend this drug's approval.

BMJ 2004;329:1294 (27 November), doi:10.1136/bmj.329.7477.1294

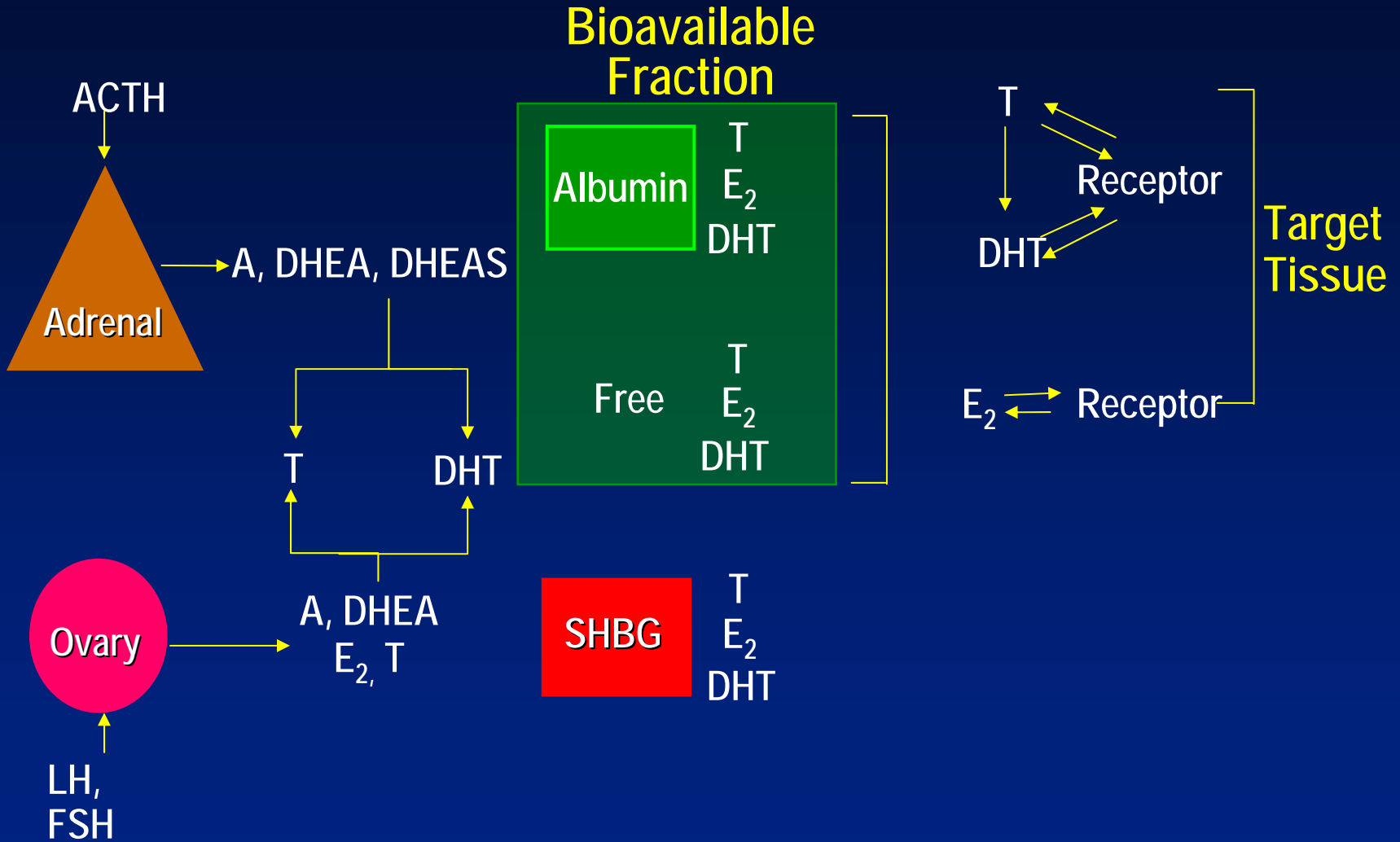
Androgens

- Steroid hormones made in gonads and adrenal glands from cholesterol
- Structurally very similar so need to purify for accurate measurement
- Normal precursors of estrogens
- Men and women produce testosterone; levels 10 to 40-fold higher in men.
- Testosterone and DHEA have been used to treat androgen deficiency in women

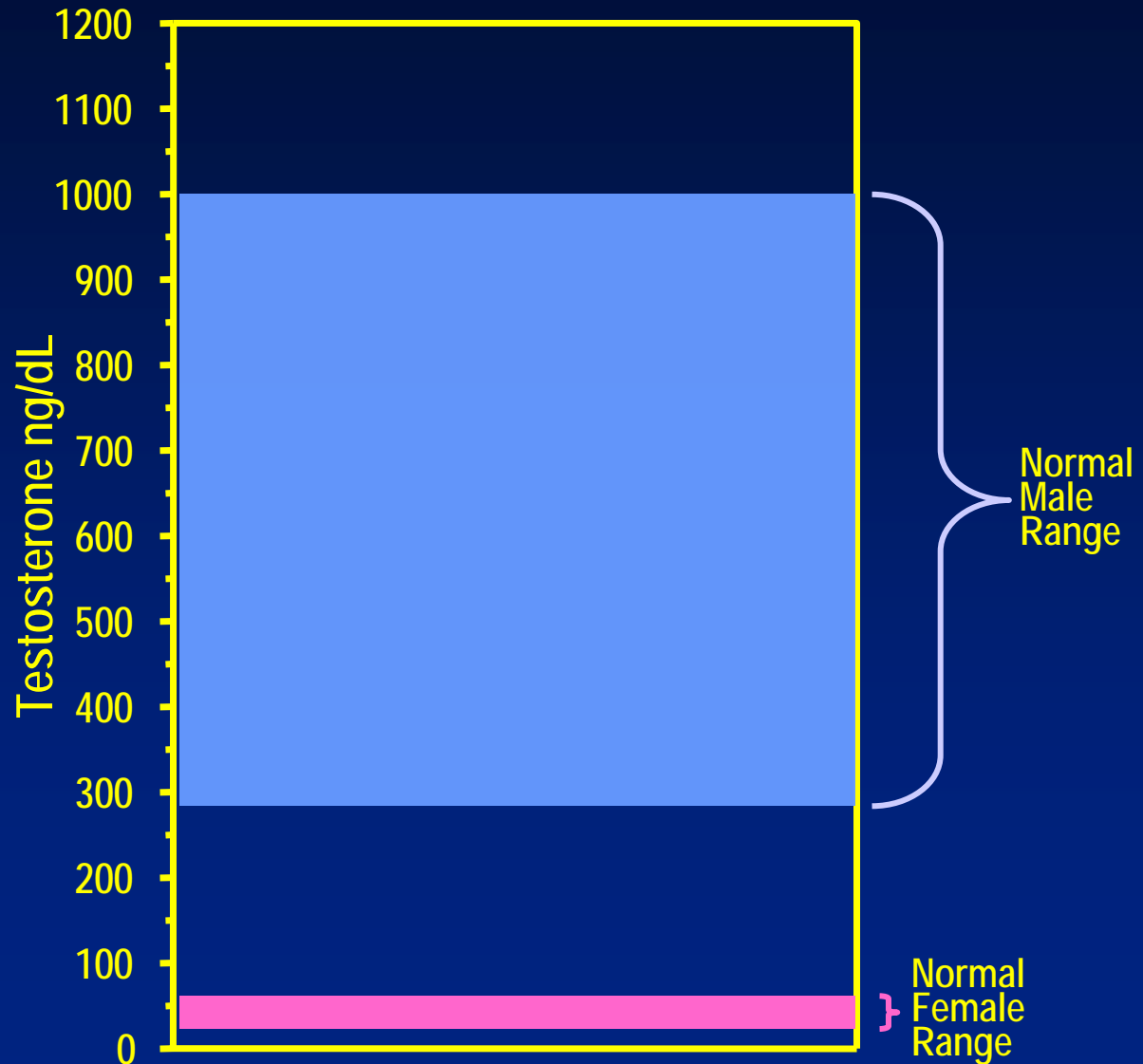
Hormone Production



Hormone Action



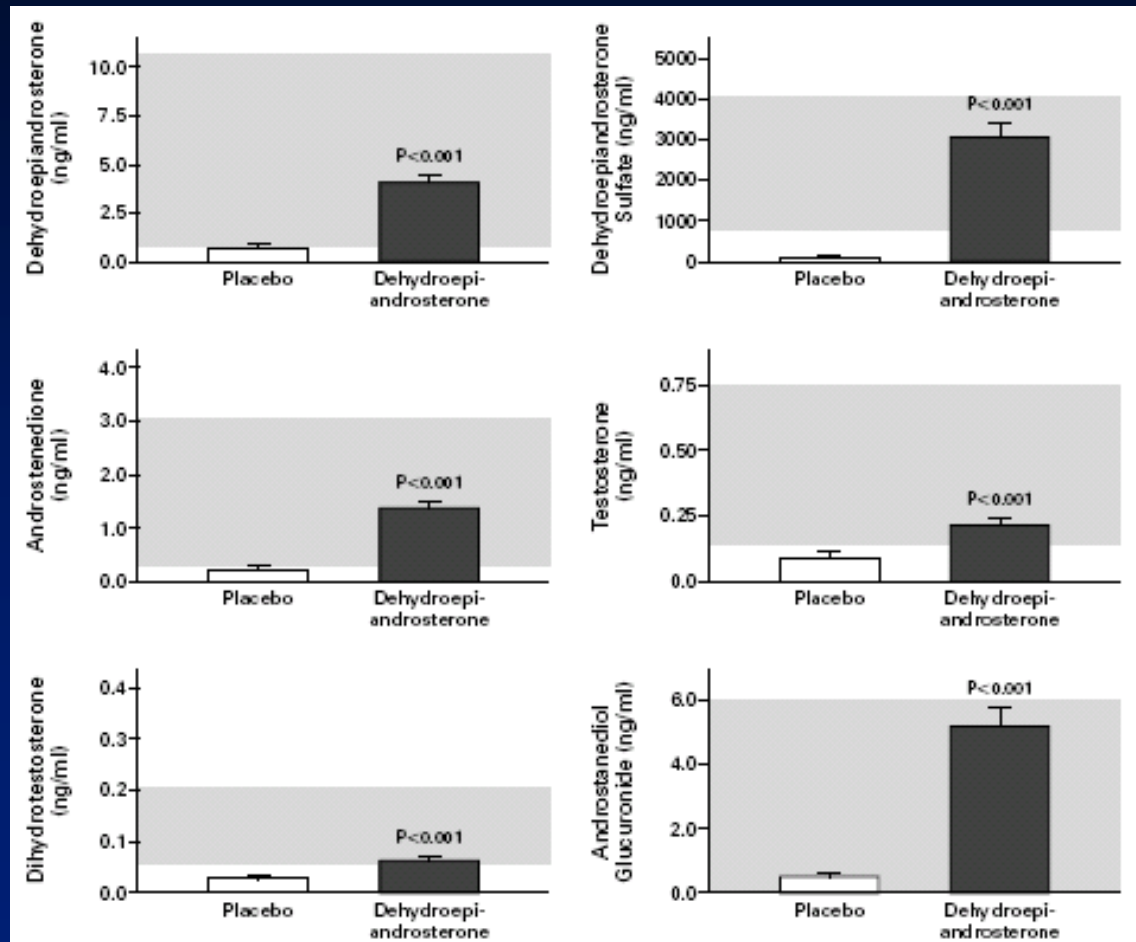
Testosterone Levels Men & Women



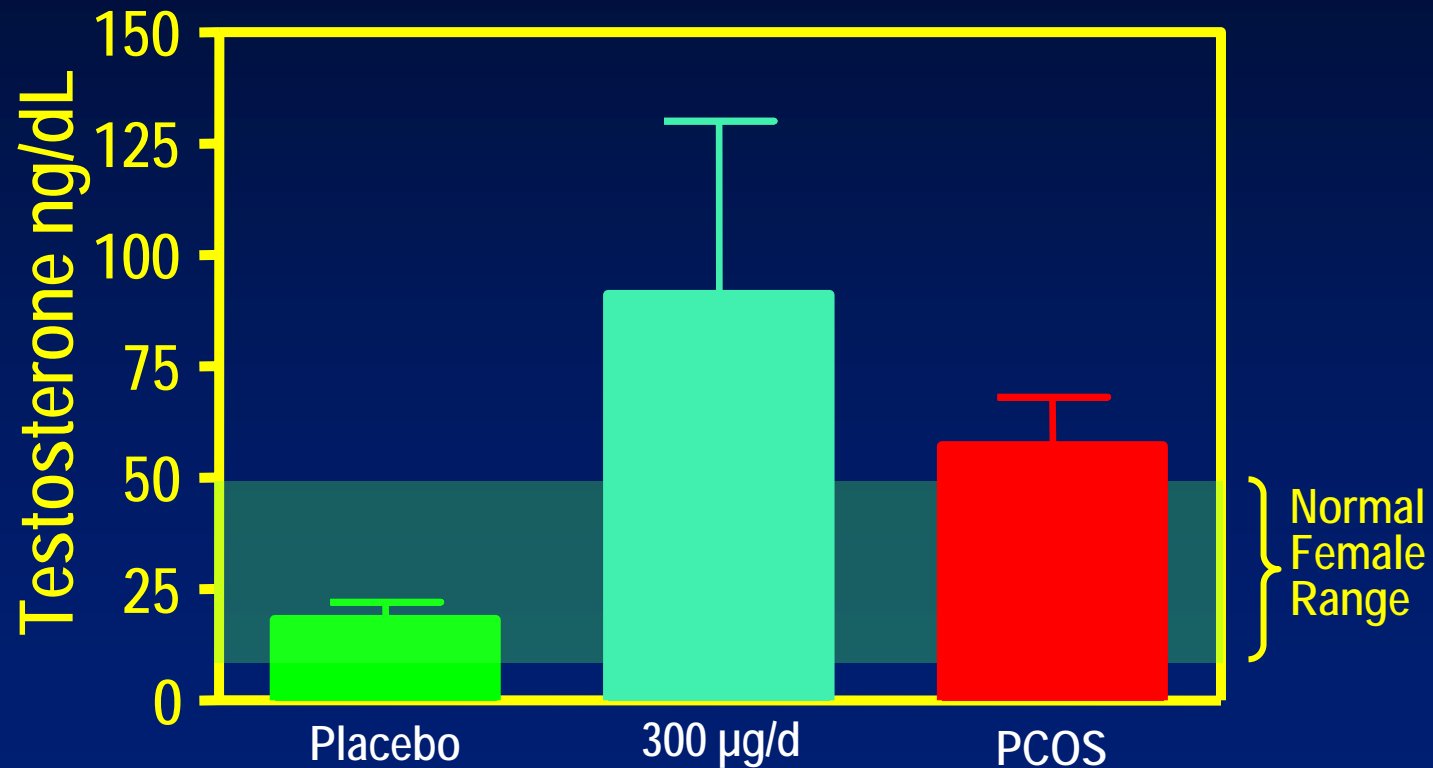
DHEA Administration

Women with Adrenal Insufficiency

19/24 Androgenic Symptoms in 4 mons

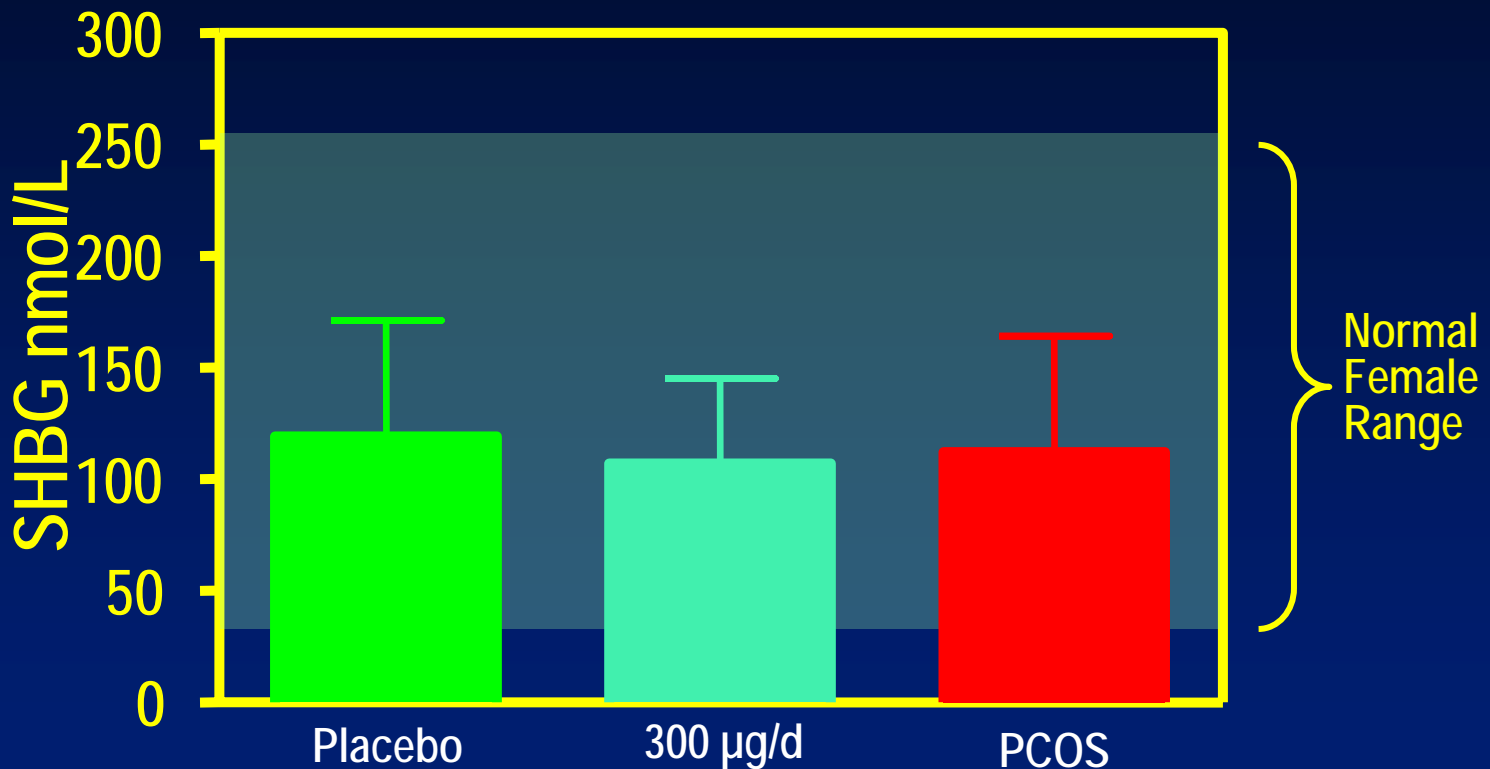


Testosterone Levels 24 Weeks



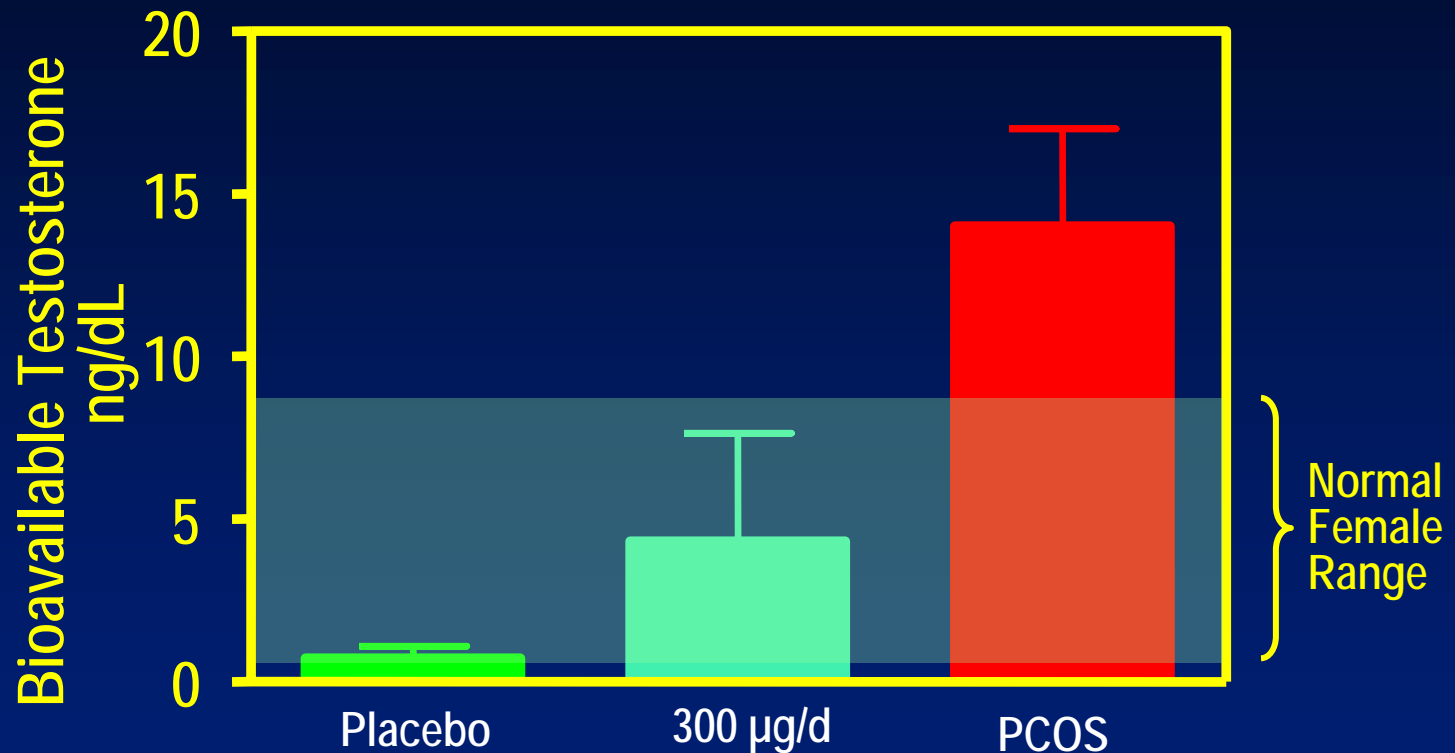
Data from Braunstein et al *Arch Int Med* 165:1582, 2005 , Dunaif et al *J Clin Endocrinol Metab* 65:499-507, 1987 & Legro et al *Am J Med* 111:607-613, 2001

SHBG Levels 24 Weeks



Data from Braunstein et al *Arch Int Med* 165:1582, 2005 , Dunaif et al *J Clin Endocrinol Metab* 65:499-507, 1987 & Legro et al *Am J Med* 111:607-613, 2001

Bioavailable Testosterone Levels 24 Weeks



Data from Braunstein et al *Arch Int Med* 165:1582, 2005 , Dunaif et al *J Clin Endocrinol Metab* 65:499-507, 1987 & Legro et al *Am J Med* 111:607-613, 2001

What are the long-term effects of testosterone levels in the range produced by the patch?

Women with polycystic ovary syndrome (PCOS) have elevated testosterone levels in this range.

Androgen Excess -PCOS

Hirsutism, Acne, Alopecia



Other Disorders in Women with Androgen Excess - PCOS

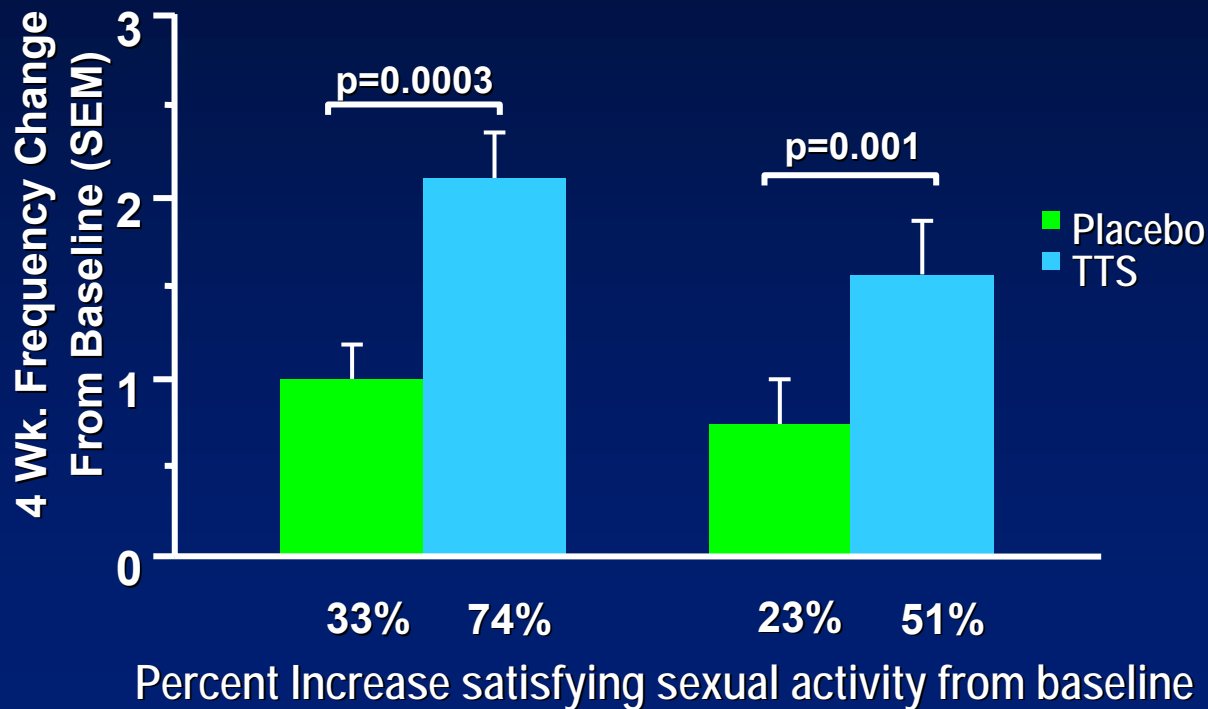
- Insulin resistance – Glucose Intolerance
- Obesity, particularly abdominal
- Elevated LDL Levels
- Increased Triglyceride and Low HDL Levels
- Increased Risk for Endometrial Cancer

**It may takes years for
testosterone effects to
develop.**

Male puberty is a good example.

Does the benefit justify the risk?

About one episode satisfying sexual activity increase in 4 weeks.



Simon, *JCEM* 2005; 90:5226
Buster, *Obstet Gynecol* 2005; 105:944

Implications of FDA approval

Limited indicated patient population but what about off-label use?

What's In the Future?

Selective androgen receptor modulators
"SARMs"; centrally active drugs ?

Intimacy-Based Model of Female Sexual Response Cycle

