

FACT SHEET 1: SCIENTIFIC ISSUES AND FSD TRIALS

**Instead of just repeating the past,
there can be improvement**

ISSUE #1. PLACEBO

- Everyone knows sexuopharmaceutical trials produce high placebo rates. Bradford's (2013) analysis of placebo issues in FSD clinical trials should be read by every stakeholder.ⁱ She highlights
 - placebo problems with diaries and other self-monitoring measures;
 - the likely lack of blinding in drug vs. placebo comparisons;
 - the influence of the trial requirement to engage in sexual activity;
 - the ways the placebo response takes advantage of “the rituals of seeking treatment, receiving validation, creating a shared understanding of a problem, [and] naming and framing the problem in the privileged language of medicine.”

ISSUE #2. INCLUSION CRITERIA

- The DSM-5's new, more stringent diagnostic criteria for FSI/AD must be applied rigorously: reduced excitement or pleasure in 75-100% of encounters, minimum duration of 6 months, clinically significant distress.ⁱⁱ
- Subjects with medical and psychosocial issues must be included to reflect the real world. Non-industry sponsored studies showed efficacy of sildenafil with spinal cord injured women, but the manufacturer was only interested in the large market of physically healthy women.ⁱⁱⁱ
- Partner experience should be assessed, not for corroboration, but to include how the partner feels about the woman taking a drug in order to have desire for sex with him (or her). This should be assessed over time, not just once. Taking a drug interferes with the fundamental interpersonal meaning of desire, and it involves more than one person.

ISSUE #3. CLINICAL ENDPOINTS

- The multiplication of PRO sexual dysfunction questionnaires with endless bickering about reliability and validity is a scandal and a testimony to the sacrifice of scientific collaboration to competitive marketing in this field.^{iv} Ditch the questionnaires and work towards varied endpoints for subgroups.

ISSUE #4: COMPARATIVE EFFICACY

- Despite Pharma's claims, there are many available effective interventions for women's sexual problems including counseling, sexuality education and relationship work. Use of an inert substance for comparison in drug trials is a wasted opportunity for useful research. New mixed methods research^v allows comparison of qualitative with quantitative data and offers a valuable opportunity to gain information on nonmedical treatment interventions.

ISSUE #5 DATA TRANSPARENCY

- There are many calls to change the accountability standards for clinical trials. The UK-based campaign, *ALL TRIALS REGISTERED AND REPORTED*, has become the international flagbearer for this movement.^{vi} All sexuopharmaceutical trials should be registered and data publicly available. This will help address the problem that adverse reactions as reported in clinical trials are incomplete and flawed.^{vii}

ISSUE #6: POST-APPROVAL MARKETING MORATORIUM

- Risks and harms of a new drug emerge fully only after market entry.^{viii}
- The marketing track record of sexual dysfunction drugs is littered with known and suspected violations (e.g., FDA warning and notice of violations to Robert Whitehead, current CEO of Sprout, about Testopel in 2010^{ix}), reinforcing fears about future marketing in this field.
- The best approach to protect the public would be a two-year moratorium on any direct-to-consumer marketing of an approved FSD drug, including “disease awareness” campaigns, celebrity testimonial campaigns, etc. The AMA called for such a moratorium in 2006.^x

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ⁱ Bradford, A (2013) Listening to placebo in clinical trials for female sexual dysfunction. *J Sex Med*, 10: 451-459.

ⁱⁱ DSM-5 Diagnostic criteria for 302.72, “Female sexual interest/arousal disorder.”

ⁱⁱⁱ Sipski, M.L., et al (2000) Sildenafil effects on sexual and cardiovascular responses in women with spinal cord injuries. *Urology* 55: 812-815.

^{iv} E.g., Forbes, MK, Baillie, AJ and Schniering, CA (2014) Critical flaws in the Female Sexual Dysfunction Index and the International Index of Erectile Dysfunction. *J Sex Research*, 57: 485-491 (and commentary, and reply to commentary)

^v Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011.

^{vi} <http://www.alltrials.net/>

^{vii} Healy, D, Mangin, D, Antonuccio, D (2013) Data based medicine and clinical judgement. *Int'l J Risk and Safety in Medicine*, 25: 111-121.

^{viii} Corrigan, OP (2002) A Risky business: the detection of adverse drug reactions in clinical trials and post-marketing exercises. *Social Science and Medicine*, 55:497-507.

^{ix}

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/ucm259232.htm>

^x <http://www.pharmwatch.org/ads/ama.shtml>