

Drug to treat hypoactive sexual desire disorder in women of 'very limited use'

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An independent analysis of the medical trials which formed the final basis of approval by the US Food and Drug Administration (FDA) strongly suggests the drug bremelanotide has very limited effectiveness

as a treatment for hypoactive sexual desire disorder (HSDD) in women, and that trial participants preferred a placebo.

The analysis, published today in the peer-reviewed [*Journal of Sex Research*](#), also highlights issues with the validity of HSDD as a diagnosis. The condition was removed from the American Diagnostic and Statistical Manual of Mental Disorders (DSM-5) in 2013.

Professor Glen Spielmans, of Metropolitan State University, USA, examined data from bremelanotide's FDA New Drug Application, the clinicaltrials.gov protocol entries for the two 24-week Phase III [trials](#), and the journal article ([Kingsberg et al.](#), published in *Obstetrics and Gynecology*) that reported both trials. He also conducted a meta-analysis of efficacy and dropout data appearing in the FDA application and compared these outcomes to those reported in the journal paper.

Spielmans, a Professor in Psychology, found that 42.1% of trial participants given bremelanotide did not complete the study compared to 20.48% of participants given the placebo, with dropout rates due to adverse events much higher for those on bremelanotide. Among participants who reached the end of the trials' acute phase, 87.22% on the placebo wanted to continue treatment in the open-label phase that followed, compared to 69.97% on bremelanotide.

However, the Kingsberg article did not report that adverse event-induced discontinuation was substantially higher for bremelanotide or that participants preferred taking placebo, measured by the combination of both completing a clinical trial and choosing to participate in the follow-up open-label study.

A number of other problems with the article were found including incomplete data reporting, changed efficacy outcomes and conflicts of interest, with four of the authors working for either the company that

conducted the trials (Palatin Technologies) or the company which was licensed to market bremelanotide in North America (AMAG Pharmaceuticals) before the license was transferred back to Palatin.

Professor Spielmans said: "My findings strongly suggest that bremelanotide has very limited treatment efficacy, that the protocol-specified outcomes of bremelanotide are mostly unreported in the main journal article reporting the clinical trial outcomes, and that trial participants would rather take a placebo than bremelanotide."

However, focusing solely on problems with the [clinical trials](#) runs the risk of unintentionally reifying the validity of HSDD, he warned. "The lack of specifying symptom duration, questionable validity for the lack of sexual fantasies as a diagnostic criterion, difficulty in disentangling individual sexual problems from relational problems, and the failure to consider cultural influence—including the pressure on women to satisfy the sexual desires of their male partners—in the experience of sexuality all render HSDD as a problematic entity," Professor Spielmans added.

More information: Glen I. Spielmans, Re-Analyzing Phase III Bremelanotide Trials for "Hypoactive Sexual Desire Disorder" in Women, *The Journal of Sex Research* (2021). [DOI: 10.1080/00224499.2021.1885601](#)

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