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DIVISION OF SEXUAL MEDICINE
Department of Psychiatry

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June 13, 2000

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
USA

Dear Sirs:

**Re: Draft Guidelines for the Design of Clinical Trials for FSD
(Female Sexual Dysfunction)**

I was pleased to learn that the FDA will accept comments on the draft guidelines for 60 days subsequent to their issuing on May 22nd, 2000 as I fear the proposed outcome measures are not reflective of women's sexual experience.

Primary end points for clinical trials should include numbers of "satisfactory" sexual events and where appropriate, rewarding increase in sexual thoughts and sexual interest. The word "success" implies performance with some specific goal – this concept of "goal" does not fit with our understanding of healthy female sexual function. (See Tiefer L. Historical scientific clinical and feminist criticisms of "the human sexual response cycle". Annual Review of Sex Research 1991;2:1-23; Regan P., Berscheid E. Belief about the state, goals and objects of sexual desire. Sex and Marital Therapy 1996;22:110-120.)

The huge focus in the currently proposed guidelines on the achievement of orgasm by various routes is inappropriate. Women's enjoyment, satisfaction and freedom from pain (physical or emotional) is not particularly dependent on orgasm. The experience of orgasm for women is a *potential* component of their sexual experience. Orgasms may be single, multiple, prolonged (status orgasmus) or entirely absent and yet, the experience completely rewarding. Orgasm may be present but the experience still be unrewarding or painful, or both. If the woman's self-identified sexual problem is lack of orgasmic release of arousal, then it would be reasonable to have attainment of orgasmic release as an outcome measure, but this is just one subset of FSD.

Alternative end points, for your consideration, include (depending on which FSD subtype is in question:-

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Alternatively, end points could be comparative, e.g.,

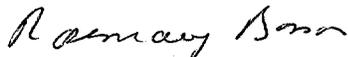
- Increased sexual satisfaction
- Increased pleasant sexual genital sensation
- Increased intensity of mental sexual excitement
- Increased intensity of orgasm
- Increased well-being post orgasm or post arousal

For desire concerns:-

- Increased sexual thoughts
- Increased interest in sexual matters
- Increased responsiveness to sexual stimuli (including the partner)

I strongly advocate consideration of this type of "end point". Clearly, it is not as neat and simplistic as counting orgasms but far more relevant and more accurately reflecting women's healthy sexual response. This way any role of pharmacological agents in the treatment of women's sexual dysfunction will become clear.

Sincerely,



Rosemary Basson, MB, BS, MRCP

Clinical Associate Professor

Departments of Psychiatry and Obstetrics & Gynecology

c.c. Dr. Lenora Tiefer

Lana Pauls, Project Manager, Reproductive Urology Division, FDA

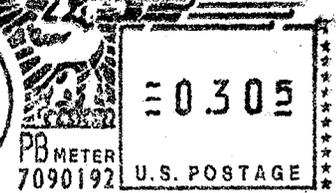
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