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July 9, 2000

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 00D:1278
Draft Guidance: Female sexual dysfunction:
Clinical Development of Drug Products for Treatment

FROM:

Carol Tavis, Ph.D.
Social psychologist, science writer, lecturer
Author of *The Mismeasure of Woman* and coauthor of *Psychology and Psychology in Perspective*; Fellow of American Psychological Association and American Psychological Society; Member, Board of Directors of the Council for Scientific Clinical Psychology and Psychiatry.

I am writing to express my very serious concerns about the Draft Guidance document for companies planning drug trials to treat the newly-invented "disorder" of "Female sexual dysfunction." My major concerns are (1) the vagueness of the criteria for diagnosing the "disorder"; (2) the population on whom the new drugs will be tested, versus the women who are actually most likely to use them; and (3) the inadequacy of the proposed measurements of "success" of treatment.

1. VAGUENESS OF CRITERIA

The definition of FSD "continues to evolve," says the statement. You bet, because this is the result of a drug treatment in search of a "diagnosis" to warrant it. No one disputes that certain medical conditions, such as diabetes and hormonal deficiencies, and certain medications, can affect a woman's sexual response. But the "recognized components" of FSD under II., Definition of Female Sexual Dysfunction, are neither unique to this new diagnostic label, nor new, nor sufficiently precise. "Decreased sexual desire and arousal"? Given the vagueness and imprecision of the criteria, how then will clinical trials only

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enroll women "who have a valid and reliable diagnosis of FSD"? Where is the evidence that FSD, a vague enough term to begin with, *is* a valid and reliable label for anything?

By way of analogy, suppose that I inform the FDA that I have discovered a new disorder, which I call "Human Work Performance Dysphoria." Its "symptoms" are decreased desire to work hard, reduced excitement at new projects, and irritability at employers for failing to provide better working conditions. I propose that these symptoms are due to glitches in the employees' synapses and suppressed endorphin levels, but fortunately I have a new wonder drug that can help, if the FDA will only let me test and market it.

My manufactured label HWPDP, like FSD, *confounds the symptoms with their alleged cause*. If "FSD" is really a result of some physiological abnormality, *that* is what needs to be identified. I would hope that before the FDA allowed me to market a treatment that allegedly will perk up employees' synapses, it would require me to demonstrate that *there really is a physiological problem in that subset of employees*. Otherwise, the "symptoms" of HWPDP – dissatisfaction, reduced excitement, and irritability – can be caused by far more things than a glitch in brain chemistry. Likewise, the causes of female sexual dissatisfaction and lack of sexual response, which have been long known to sexologists, are far and away more likely to be caused by social and psychological factors than by reduced blood flow to the clitoris.

2. TEST POPULATION VS. VULNERABLE POPULATION

In practice, conferring legitimacy to the label "FSD" and using it to justify medication as the preferred treatment will mean that any woman who is unhappy with her sex life will be able to seek a simplistic solution – a pill. And in this pill-happy, quick-fix culture, countless women whose sexual problems have nothing at all to do with their physiology will be vulnerable. When the placebo effect of the pill wears off, women will then be faced with the same old difficulties.

Drug companies will be allowed to exclude from their trials anyone with "relationship difficulties with a partner." But relationship difficulties often cause sexual problems, and vice versa. It is abundantly clear, as is now evident with the prescription of Viagra, that once there is a medication for "FSD," the candidates most likely to seek it will be those with "relationship difficulties."

In addition, the exclusion criteria in the draft statement also permit the exclusion of women using "concomitant medications that could affect sexual dysfunction" and other medical conditions (such as depression). But these are precisely the women who would be most motivated (or perhaps feel most pressured) to try a new medication for "FSD." Just as trials of Viagra excluded the men most likely to use it – e.g., those with heart conditions, or taking other medications that suppress sexual function – this is a potentially dangerous oversight.

3. MEASUREMENT OF "SUCCESS" OF TREATMENT

Years of research in sexology have provided abundant evidence that female sexuality cannot be reduced to some simple biological process that exists independently of the woman's current relationship, feelings about her body, past experiences, and other psychological and cultural factors. The draft statement's criteria for "effectiveness" are thus as vague and imprecise as for defining "FSD" in the first place: "satisfactory" sexual intercourse and numbers of orgasms. Such measures might seem objective and straightforward, but considerable research suggests that these are not measures that reflect the concerns of many women. Repeatedly, research finds that women's reports of satisfaction, sexual and relational, do *not* correlate with number of acts of intercourse or number of orgasms. Therefore, the outcome measures do not reflect the quality of the woman's sexual experience or of her relationship. The proposed development of "new scales, questionnaires, and other instruments to diagnose FSD" suggests that all of the new measures will be narrowly focused on orgasm and physiological response and omit any efforts to study and measure the many important psychological, cultural, and social factors that affect women's sexual pleasure or unhappiness.

4. CONCLUSIONS

"FSD" as currently described is too broad a category, and too vague, to be used to legitimize research seeking medical treatments for it, whatever "it" is. Sexologists are deeply divided about the utility and legitimacy of this label. Of course, studies can and should be conducted to determine the effects of medical conditions and medications on sexual health, but this can be done without the grandiose justification of a new diagnosis. The Draft Statement as presently written is merely an effort to promote trivial and ultimately meaningless research, research that barely disguises the commercial intentions of promoting lucrative Viagra equivalents for women. I urge you to resist the pressures of the pharmaceutical industry and postpone approval for these clinical trials—until and unless a legitimate consensus process takes place, one that includes other points of view about women's sexual problems and needs. "FSD" as currently constructed is scientifically unsound, with a far greater potential to harm women than help them.

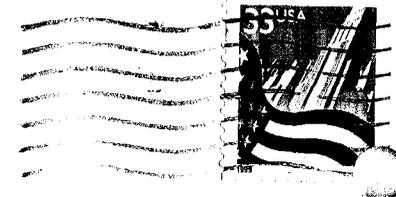
Sincerely,



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