The making of a disease: female sexual dysfunction

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Is a new disorder being identified to meet unmet needs or to build markets for new medications?

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The corporate sponsored creation of a disease is not a new phenomenon,[1] but the making of female sexual dysfunction is the freshest, clearest example we have. A cohort of researchers with close ties to drug companies are working with colleagues in the pharmaceutical industry to develop and define a new category of human illness at meetings heavily sponsored by companies racing to develop new drugs. The most recent gathering, featured Pfizer as chief sponsor and Pfizer-friendly researchers as chief speakers. The venue? The Pfizer Foundation Hall for Humanism in Medicine at New York University Medical School.

Since the launch of sildenafil (Viagra) in 1998, more than 17 million men have had prescriptions written for it as a treatment for erectile dysfunction, with Pfizer reporting sales in 2001 of $1.5bn.[2] The emerging competitors, Bayer's vardenafil and Lilly-ICOS's tadalafil, are likewise expected to have annual markets in excess of $1bn each.

To build similar markets for drugs among women, companies first require a clearly defined medical diagnosis with measurable characteristics to facilitate credible clinical trails. Over the past six years the pharmaceutical industry has funded, and its representatives have in some cases attended, a series of meetings to come up with just such a definition (table).

Summary points

Researchers with close ties to drug companies are defining and classifying a new medical disorder at company sponsored meetings

The corporate sponsored definitions of "female sexual dysfunction" are being criticised as misleading and potentially dangerous

Commonly cited prevalence estimates, which indicate that 43% of women have "female sexual dysfunction," are described as exaggerated and are being questioned by leading researchers

Controversy surrounds current attempts to medicalise sexual problems and establish "normative data" for a range of physiological measurements of female sexual response

The role of drug companies in the construction of new conditions, disorders, and diseases needs more public scrutiny

Defining the new disorder

In a ground breaking gathering in May 1997, clinicians, researchers, and drug company representatives met for two days at a Cape Cod hotel "to discuss the future direction of clinical trials" in this area, against a backdrop of "widespread lack of agreement about the definition" of female sexual dysfunction.[3]

In response to an email inquiry about the Cape Cod meeting, co-chair Raymond Rosen wrote: "The meeting is completely supported by pharmaceutical companies, and approximately half of the audience will be pharmaceutical representatives. The goal is to foster active and positive collaboration between the two groups. Only investigators who have experience with, or special interest in working collaboratively with the drug industry have been invited." The subsequent publication of the meeting's presentations and discussions acknowledged sponsorship from nine drug companies.[3]

Eighteen months later, in October 1998, the first international consensus development conference on female sexual dysfunction took place in Boston under "closed session" deliberations.[4] Participants for this multidisciplinary meeting were hand picked by a group from the American Foundation for Urologic Disease on the basis of their research or clinical expertise and their positions as "thought leaders." Working with existing classification systems, including the American manual of psychiatric disorders (*Diagnostic and Statistical Manual of Mental Disorders*, 4th edition), participants produced a new definition and classification featuring disorders of desire, arousal, orgasm, and pain, to be used in "medical and mental health settings."[4]

Publication of the proceedings of the consensus conference disclosed support from eight pharmaceutical companies and showed that 18 of the 19 authors of the new definition had financial interests or other relationships with a total of 22 drug companies.[4]

In October 1999 the Boston University School of Medicine hosted a further conference, which was supported by 16 companies. In a response to a question from a speaker at the conference, a show of hands at one session revealed that around half of the participants were connected to the drug industry.[5] In 2000 and 2001, the newly formed Female Sexual Function Forum hosted annual conferences in Boston supported each time by more than 20 companies, with Pfizer as a key sponsor. Interviewed just before Christmas 2002, Pfizer's Urology Group's leader, Dr Michael Sweeney, said the company had played a passive role in sponsoring a series of discussions about the disorder, simply providing unrestricted grants in response to requests from physicians.

On the international stage, female sexual dysfunction was discussed as part of the first international consultation on erectile dysfunction in Paris in 1999, hosted chiefly by urology associations and sponsored heavily by pharmaceutical companies. A second meeting is planned for Paris in June 2003, with one aim being the adoption of an "internationally accepted instrument for assessment of sexual function."[6]

All three Boston meetings (1999-2001) were chaired by Dr Irwin Goldstein, professor of urology and gynaecology at Boston University School of Medicine, who is also a key figure at the international gatherings. Originally trained as an engineer, Goldstein has widened his focus in recent years from male to female sexual dysfunction. A regular speaker at meetings funded by industry and a consultant and lecturer for virtually every pharmaceutical company, he is a passionate advocate for building a new discipline of sexual medicine, because, as he told the recent New York gathering, in this emerging field "there is such joy in treating these people successfully."

Difficulties become dysfunctions become disease

One of the milestones in the making of the new disorder was a *JAMA* article in February 1999 titled "Sexual dysfunction in the United States: prevalence and predictors."[7] The authors, two of whom belatedly disclosed close links to Pfizer,[7] said that for women aged 18-59, the "total prevalence of sexual dysfunction" was 43%, a figure now widely cited in both the scientific and lay media.[8 9]

As an example, in November last year a Californian firm offering "business intelligence" announced that "43% of all women over 18 experience sexual dysfunction . . . Greater public awareness and acceptance of SD [sexual dysfunction] as a common and treatable disease will heavily influence market growth, predominantly for women." In August, a company advertising trials of a new drug for "female sexual arousal disorder" prominently cited the figure in its press release. Dr Sweeney told me that 40% of women have the dysfunction in one form or another, "but not all have the most severe form of the disease."

Serious questions hang over the 43% figure, obtained when University of Chicago sociology professor Ed Laumann and colleagues reanalysed a slice of data from a 1992 survey. About 1500 women were asked to answer yes or no to whether they had experienced any of seven problems, for two months or more, during the previous year, including a lack of desire for sex, anxiety about sexual performance, and difficulties with lubrication. If the women answered yes to just one of the seven questions, they were included in a group characterised as having sexual dysfunction.

Drug company sponsored meetings to define new disorder

Year	Meeting and host	No of company sponsors*
1997	Sexual function assessment in clinical trials—Cape Cod conference	9
1998	International consensus development conference on female sexual dysfunction: definitions and classifications—American Foundation for Urologic Disease, Boston	8
1999	Perspectives in the management of female sexual dysfunction—Boston University School of Medicine	16
2000	Female sexual function forum—Boston University School of Medicine	22
2001	Annual meeting of the female sexual function forum, Boston	22
2002	The new view "female sexual dysfunction": promises, prescriptions, and profits, San Francisco	0
2002	Annual meeting of the International Society for the Study of Women's Sexual Health,[4] Vancouver	15
2003	International consultation on erectile and sexual dysfunctions—to endorse instruments for assessment of sexual function, Paris	Currently seeking sponsors

*A very small minority of sponsors were not drug companies.

The *JAMA* article stated that its data were "not equivalent to clinical diagnosis,"[7] yet this caveat is now regularly overlooked, and leading sex researchers have raised serious concerns about the figure's constant misuse.[10]

One of those concerned is Dr Sandra Leiblum, professor of psychiatry at Robert Wood Johnson Medical School and a clinical psychologist. She believes real dysfunction is much less prevalent than 43%, and that the figure has contributed to an overmedicalisation of women's sexuality, where changes in sexual desire are the norm. "I think there is dissatisfaction and perhaps disinterest among a lot of women, but that doesn't mean they have a disease," she said during an interview at the recent New York educational workshop.

The director of the Kinsey Institute at Indiana University, Dr John Bancroft, believes the term "dysfunction" is highly misleading, and he is one of several researchers critical of the corporate sponsored 1998 definition.[11] He argues that an inhibition of sexual desire is in many situations a healthy and functional response for women faced with stress, tiredness, or threatening patterns of behaviour from their partners.[10] "The danger of portraying sexual difficulties as a dysfunction is that it is likely to encourage doctors to prescribe drugs to change sexual function—when the attention should be paid to other aspects of the woman's life. It's also likely to make women think they have a malfunction when they do not," he said during a telephone interview. In response, Laumann defends his use of the term "dysfunction" but concedes that many women among his 43% are "perfectly normal" and that a lot of their problems "arise out of perfectly reasonable responses of the human organism to challenges and stress."

New York University's clinical associate professor of psychiatry, Dr Leonore Tiefer, contends that the medical model itself is severely limited for dealing with problems of sexuality because of its mind-body split, biological reductionism, focus on diseases rather than people, and reliance on norms.[12] She claims pharmacological research runs the risk of oversimplifying the sexual difficulties of both men and women because it "promotes genital function as the centrepiece of sexuality and ignores everything else"[13]

What is healthy and what is sick?

While the measurement of sexual problems in men has focused almost exclusively on erections, female sexual responses have proved much more difficult to quantify, creating problems for researchers testing pharmacological therapies. In recent years, however, a host of new methods have been identified, and some clinicians now recommend, along with a physical and psychosocial examination, a comprehensive evaluation that can include the measurement of hormonal profiles, vaginal pH, and genital vibratory perception thresholds, as well as the use of ultrasonography to measure clitoral, labial, urethral, vaginal, and uterine blood flow. In 1999, Dr Jennifer Berman, assistant professor of urology at the University of California, Los Angeles, wrote "Normative data are being gathered for comparison to determine what normal physiologic responses are for women in particular age groups."[8]

Studies by Berman, Goldstein, and others have used those physiological measurements to test the effects of

Fluffy bunnies are used as models for “female sexual dysfunction”

sildenafil on women with “female sexual arousal disorder.”[14] In October 2002, Berman presented results from another study of sildenafil, conducted with three authors from Pfizer, at a conference where the company was chief sponsor.[15] Last month she told me: “There is clearly a role for medical therapies but not in isolation from emotional and relationship issues, which are equally if not more important with women.”

On the basis of studies of the genitalia of female New Zealand White rabbits, Goldstein and colleagues have developed animal models of “vaginal engorgement insufficiency and clitoral erectile insufficiency.”[16] Using data from studies comparing the testosterone levels of “normal” women with the levels of his patients, he told the December meeting in New York that women with “female sexual dysfunction” might have a “specific defect in steroid synthesis.”

Goldstein regularly cites the 43% prevalence figure and dismisses suggestions from his colleague Dr Leiblum that it may indicate the prevalence of difficulties rather than real dysfunction: “I love psychologists but they don’t deal with evidence.” Asked during a break in the New York gathering about criticisms that medicine may not be best equipped to deal with sexual problems, Goldstein’s replied: “Who’s best equipped to deal with it? The horticulturists? It’s a form of medicine. I think physicians are most appropriate.” He added that he worked within a “mind-body relationships” framework and a multidisciplinary team that includes psychologists and nurses.

The pharmaceutical industry’s role in helping build the science of this new disorder has been “paramount,” according to Goldstein, and he rejects suggestions that closeness between drug companies and academic researchers may be inappropriate. Asked whether marketing campaigns worth hundreds of millions of dollars may ultimately tend to amplify particular views of sexual difficulties and promote certain therapeutic options over others, he said: “I’m an academic clinical doctor. That’s a question for some philosopher.”

Another view of women’s problems

In contrast to the definition driven by Goldstein and others, Tiefer and colleagues are promoting a women-centred definition of sexual problems: “discontent or dissatisfaction with any emotional, physical, or relational aspect of sexual experience,” with four categories of causes: sociocultural, political, or economic; relationship related; psychological; and medical.[5] “Sex is like dancing,” Tiefer told me during an interview in her Manhattan office, “If you break an ankle while you’re dancing you go to a doctor. But your doctor doesn’t take a dance history and wouldn’t advise you whether your dancing is normal. The medical model is about defining what’s healthy and what’s sick—but sex isn’t like that.”

The potential benefits of this current medicalisation campaign are a more humanised doctor-patient relationship, effective and safe new drugs, and increased public and research attention to the complexity of female sexual problems. The potential risk, in a process so heavily sponsored by drug companies, is that the complex social, personal, and physical causes of sexual difficulties—and the range of solutions to them—will be swept away in the rush to diagnose, label, and prescribe. Perhaps the greatest concern comes from the flip side of inflated estimates of disease prevalence—the ever-narrowing definitions of “normal” which help turn the complaints of the healthy into the conditions of the sick.

These revelations about female sexual dysfunction should spark a more widespread and rigorous investigation into the role of drug companies in defining and promoting new diseases and disorders.

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