

The biomedical standardization of premenstrual syndrome

Loes Knaapen, George Weisz

Department of Social Studies of Medicine, McGill University, 3647 Peel Street, Montreal, Quebec H3A 1X1, Canada

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Abstract

This essay traces the history of premenstrual syndrome (PMS) in French, British, and American medical literature from 1950 to 2004. Aetiological theories, treatments and diagnostic criteria have varied over time and place, reflecting local conditions and changing notions of objectivity and evidence. During the 1970s researchers in each nation utilised different research strategies to overcome variation and contradictory results characteristic of PMS research. Since the 1980s, attempts have been made to standardise research internationally through prospective daily rating questionnaires that diagnose and measure PMS. Amidst controversy, a psychiatric reformulation of the syndrome was included in the Diagnostic and Statistical Manual of Mental Disorders (DSM). While the diagnostic criteria for this psychiatric category, now called premenstrual dysphoric disorder (PMDD), are widely accepted for research purposes, efforts to transfer them to medical practice have been less successful. PMDD remains a contested disease construct.

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1. Introduction

Premenstrual syndrome (PMS) and its psychiatric derivative, premenstrual dysphoric disorder (PMDD), are contested medical categories. They have emerged and been criticized within a complex network of institutions and public arenas. One of the most sophisticated sociological analysts of a central event in their development (Figert, 1995, 1996) has identified three intersecting arenas in which groups struggled to impose their own definitions of these conditions: a professional arena in which health occupations competed with one another; a wider social arena in which the women's movement competed against medical experts; and a scientific arena in which research efforts and controversies took place. This analytic

division has heuristic value in pointing out the complex social contexts in which PMS/PMDD has developed; but by placing them all on the same plane it ignores the extent to which the question of the validity of PMS research has been important to the other domains. As Figert's own account shows, debates among professionals or between professionals and women's health activists all revolve to one degree or another around the adequacy of the science surrounding these conditions. The science has influenced public debate which has in turn affected research. For these reasons this paper centres on the science of PMS/PMDD.

This focus has a number of advantages. First, it allows us to analyze virtually all positions taken in the debate without taking sides. It transforms the argument that

E-mail addresses: loes.knaapen@gmail.com (L. Knaapen), george.weisz@mcgill.ca (G. Weisz).

PMS/PMDD is an ideological or cultural construct that stigmatizes, divides and/or controls women from a widespread theoretical presupposition of sociological research into one of the historical forces that have shaped the scientific evolution of these conditions. Second, this perspective allows us to fill a glaring lacuna in the literature—the actual role of science in constructing PMS/PMDD. Richardson (1995) provides a useful, but incomplete account. Stolberg (2000) rightly points to the role of the new science of endocrinology in making possible the emergence of premenstrual pathology, but his analysis ends where ours begins: with the establishment of specific menstrual troubles as a distinct premenstrual syndrome. To the extent that there is discussion (usually brief) in other accounts, the existence of disagreements and variations in medical definitions are utilized to confirm the view that PMS is not a ‘real’ scientific category but a cultural/ideological construct (Johnson, 1987; Rodin, 1992; Richardson, 1995) or a social problem (Rittenhouse, 1991). As if true medical science deals only with biology/pathology and is free of the influence of culture. This leads to a third benefit of the position we adopt; like other recent work in Science and Technology Studies, it breaks down the artificial division between science and other social domains, acknowledging the many external influences on PMS research without reducing the latter to ‘mere’ ideological and social interests (Latour, 2005). Demonstrating the socially constructed nature of a disease category does not make it invalid, unreal, or unscientific *per se*. Most scientific practices in biomedicine when viewed close up are characterized by variation, disagreement and multiple definitions of key concepts, even in relatively stable, somatic conditions like atherosclerosis (Mol, 2002). This does not of course mean that there is no such thing as ‘bad’ science. But what constitutes good and bad science is not given; it varies according to actors, times and places. Our approach allows us to analyze how workers in the field have approached the challenges of scientific rigour and how others have evaluated these efforts.

The final advantage of our approach is that it provides an alternative frame for key events in the history of PMS/PMDD. When it is not presented as a medical conspiracy against women, the story of PMS whether viewed through the lens of Figert’s three arenas or the far more ubiquitous ‘medicalization’ model (Chananie, 2005; Pugliesi, 1992; Riessman, 1983) is usually framed as a power struggle among various kinds of medical specialists and health professionals jostling for territory, pharmaceutical companies seeking profits and influencing consumers through advertising, women in search of medical validation for their suffering or fighting against what they perceive as the power of experts. All this is certainly correct and accounts for much that has occurred as our own account will show. But we would also argue that an essential ingredient has been missing in these accounts: the extent to which major developments in the history of PMS/PMDD have resulted from efforts (whether judged

successful or not) to conform to evolving scientific standards.

In the essay that follows we show how PMS/PMDD were constructed as biomedical objects utilizing a variety of techniques, strategies and resources; these reflected efforts to respond to the evolving evidentiary requirements of biomedical science by making research practices increasingly rigorous even as the influence of interest groups intensified. A fluid and protean condition was continually constructed, reconstructed, stabilised and standardised. While most of the more recent and detailed work on the subject (Rittenhouse, 1991; Caplan, 1995; Figert, 1996) focuses on the debates of the 1980s and 1990s, when PMDD was introduced amid much controversy into the American psychiatric classification system, the Diagnostic and Statistical Manual of Mental Disorders (DSM), we examine a longer time frame that goes from the 1930s to the present. Our approach moreover is comparative, examining systematically, in addition to work in American journals, published research in two other countries: the UK and France. British work was at the leading edge of PMS studies until powerful American institutions like the American Psychiatric Association and National Institutes of Mental Health became concerned with the condition in 1980s. French work in contrast has been scant and, until recently without international influence, but exemplifies alternative ways in which PMS is conceptualized and studied within biomedical science. Finally, although biomedical PMS research is our primary focus, we attempt to view the effects of this research on medical practice on the basis of the fragmentary evidence that is currently available. For this purpose we look at, among other things, products of biomedical research that have only appeared since the 1990s: systematic reviews and practice guidelines.

The argument advanced in this paper proceeds as follows. After briefly examining some characteristics of the scientific literature, we follow PMS from its origins through the 1960s. During this period, the small domain of PMS research was divided along national lines largely because of the isolation of national research communities; similarities resulted from adherence to common research styles. We go on to describe how in the 1970s the norms governing such scientific research evolved as randomized clinical trials came to dominate therapeutic evaluation. Although work on PMS was initially welcomed by women’s health activists who believed that female problems had long been ignored by the medical establishment, increasing numbers of activists, along with some feminist psychologists, psychiatrists, and scholars in other disciplines, came to oppose the central premises of PMS research. Such opposition was reinforced by serious scientific weaknesses that were widely acknowledged within the PMS research community; the chief of these were 1) the inability to find a physiological marker and 2) the difficulty of settling on a stable definition that could make comparable research possible. The first problem was never really solved although it has never been abandoned. The second, however, was more or less over-

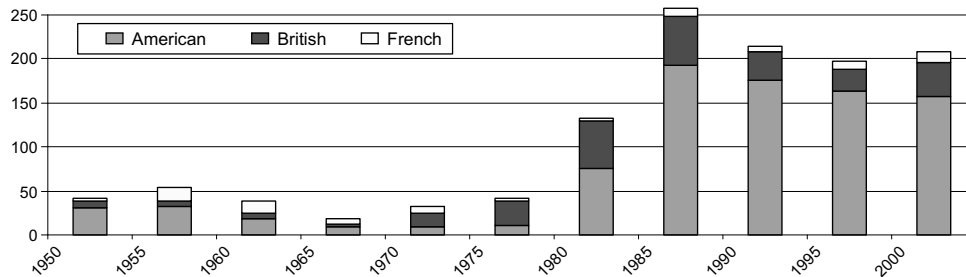


Fig. 1. Number of articles per five year period on PMS/PMDD.

come for many though by no means all researchers through measurement techniques modelled on psychological questionnaires.

We then go on to explore how in the 1980s PMS became a highly public issue in the English-speaking world after it burst onto the legal stage. Research intensified and became more international in scope, even as American influence increased. The development of a more rigorously defined and predominantly psychiatric entity, PMDD, was at least in part the consequence of the widely recognized imperative for a more stable definition of the condition that could promote comparability in research. PMDD has in fact succeeded in becoming a mainstay of PMS research, at least in North America; it has not however fully penetrated the clinical domain, as we show in the final section where we examine clinical practice. While some national differences remain, the chief disagreements are now between different specialties and disciplinary groups that construct this and other disease categories in distinctive and often competing ways. The continuing debate about the status of PMS/PMDD is now to a large extent an American phenomenon.

2. Our sources

PubMed is a selective data base that ignores many potential sources. Nonetheless, it suffices for a preliminary overview of a research domain. A PubMed search of the literature on PMS between 1950 and 2004 produced 1602 articles on PMS¹ in the English-language literature. In comparison, a search for ‘menopause’ and related terms (‘menopausal’ and ‘climacteric’) in the title yielded 6267 English-language titles, suggesting that PMS constitutes a relatively small research domain. (The discrepancy is significantly greater if we include foreign-language articles.) To alleviate the problem of under representation of non-English language biomedical research in PubMed we also searched several European databases and utilised bibliographies to come up with a total of 92 French articles. Although the number of articles on PMS in French journals is small, the proportion of French articles on this subject is

comparable to the proportion of articles in that language in the scientific literature at large, about 5% (May, 1997).

Fig. 1 describes the growth of publications in the field since the 1950s, distinguishing between journals published in each country. Table 1 lists the fifteen journals covered by PubMed that have published the greatest number of articles on this subject. These comprise nearly one third of all articles located. Several characteristics of this data are worth pointing out.

1. Publication on this condition took place on a relatively small scale until the late 1970s. In subsequent years it intensified considerably for reasons to be discussed below.
2. Although journals of general medicine published frequently on PMS before the 1970s, thereafter specialist journals came to dominate the scene. Only in the UK did such general publications as *The Lancet* and *BMJ* continue to publish a significant number of articles in this field.
3. While journals of obstetrics/gynaecology have played a significant role in PMS publication since the 1950s, journals of psychiatry published relatively little until the 1970s when they became very active, first in Britain and then the US. The same is true of publications in the field of psychology. (PubMed includes major journals of psychology but to obtain a fuller view of the psychological literature in the analysis that follows we also searched PsychINFO.)
4. A significant category of journals describe themselves as ‘psychosomatic’. They publish papers on a variety of conditions focusing on the relationship between mind and body. Some have a more psychological orientation (*Journal of Psychosomatic Research*) while others are more physiologically oriented (*Psychoneuroendocrinology*). But all are interdisciplinary to some degree and draw on international groups of authors. Several are published by European associations and have been categorized above as international even though they are published in the UK.
5. In all other cases we have listed one of the three countries in which journals are edited and published. While

¹ Search terms in the title: premenstrual, pre-menstrual, PMS, PMT (premenstrual tension), LLPDD (late luteal phase dysphoric disorder) and PMDD (premenstrual dysphoric disorder).

Table 1
Major journals publishing on PMS/PMDD

Journal Title	Total	Origin of publication	1950s	1960s	1970s	1980s	1990s	2000–2004
Obstetrics and gynecology	45	USA	4	3	1	16	14	7
Journal of clinical psychiatry	44	USA	–	–	0	15	16	14
Journal of reproductive medicine	44	USA	0	0	1	27	11	5
Journal of psychosomatic research	41	International	0	1	4	15	20	1
Lancet	38	UK	1	3	8	17	7	2
American journal of psychiatry	38	USA	2	0	0	19	13	4
British Medical Journal	36	UK	5	1	8	16	4	2
Psychoneuroendocrinology	32	International	–	–	2	5	16	10
Psychosomatic medicine	27	USA	0	1	2	6	12	6
Journal of psychosomatic obstetrics and gynaecology	27	International	–	–	–	0	16	11
British journal of obstetrics and gynaecology	25	UK	1	0	4	9	7	4
Acta psychiatrica Scandinavica	25	Scandinavia	–	1	2	11	10	1
Acta obstetrica et gynecologica Scandinavica	24	Scandinavia	1	1	4	9	7	2
Clinical obstetrics and gynecology	23	USA	0	0	0	16	16	14

journals published in the UK played an important role in PMS research until the 1980s, American journals have since become the dominant locus of publication for work in this field. French journals in contrast have published relatively little in this area. The actual significance of place of publication can vary significantly. Among PMS articles in all French publications, three leading American journals, four leading British journals,² we found that in the first case 98% of first authors had a French address, in the second 83% resided in the US, while in the third only 52% of authors resided in the UK making British journals uniquely oriented internationally. Nonetheless systematic differences among national sets of journals have been noted.

With these points in mind we now turn to a qualitative analysis of the content of this PMS literature.³

3. 1950s–1960: nationally isolated research

Although medical writing on premenstrual problems has a long history (Stolberg, 2000), the modern history of PMS is ordinarily thought to have begun during the interwar years with the publication of two articles, one by German psychoanalyst Karen Horney (1931) and another more influential one by American gynaecologist Robert Frank (1931). By the 1950s the quantity of research on PMS in all three countries remained small. Although there were, as we shall see, important differences of emphasis in the different national journals, research everywhere displayed a number of common features.

First, in all three countries during the 1950s and 1960s, the clinical characteristics of premenstrual syndrome or tension were thought to be clear to the observing doctor. The lack of standardised means of diagnosis was not a matter of concern since diagnostic judgments represented the

domain and art of the clinician. Symptoms were frequently not spelled out in publications because they were thought to be so familiar (Herschberg & Creff, 1955; Behrman & Buxton, 1961).

Second, when symptoms were described, emphasis in all three countries was on somatic complaints, particularly bloating of the breasts and abdomen, as well as headaches, nausea, or diarrhoea. Emotional symptoms like irritability, depression or anxiety were noted but were rarely the centre of research attention. In all three countries the cause of PMS was usually thought to lie in a hormonal imbalance, not surprising in view of the recently developed understanding of the role sex hormones in the female menstrual cycle. Initial theories of oestrogen excess became widely invalidated by the end of the 1950s, and were replaced by different somatic or hormonal theories.

Third, research in all three countries shared a certain style: clinical testing, usually with very small populations and only rarely including control groups, ordinarily with the goal of testing a medication whose success confirmed the aetiological hypothesis. In a few studies this was supplemented by physiological measures and analyses of temperature, blood-sugar levels, and, rarely, endometrial biopsies.

Despite these common characteristics, a different aetiological mechanism and treatment recommendation became a point of reference for researchers within each set of national periodicals. In the USA the major point of reference was that fluid retention (the result of hormones) was the immediate cause of premenstrual problems. This seems to have developed from Frank's original description of premenstrual tension in 1931. Frank recommended expelling the excess hormones through urine and faeces with the help of various diuretic substances. In American medical journals in the 1950s diuretic treatment continued to be recommended even after the theory of excess oestrogen had been

² US: *American Journal of Obstetrics and Gynecology*, *American Journal of Psychiatry*, *Journal of the American Medical Association (JAMA)*; UK: *British Journal of Obstetrics and Gynaecology (BJOG)*, *British Journal of Psychiatry*, *British Medical Journal (BMJ)* and *The Lancet*.

³ Because of the size of the literature sample, it is impossible to provide all references to a specific point without making the paper impossibly long. Our references therefore are frequently exemplary.

rejected. Its apparent effectiveness supported the notion that it was the water retention itself that produced symptoms (Bickers, 1952; Behrman & Buxton, 1961). This old treatment and its new rationale were frequently challenged (Lamb et al., 1953; Morton, 1950); nonetheless, even its opponents agreed in the early 1970s that this remained the ‘generally accepted theory of etiology and treatment’ (Reeves et al., 1971).

In Britain, it was the work of the British physician Katharina Dalton that shaped the early aetiology and treatment rationale. Starting in the 1950s, she cast PMS as a deficiency of progesterone that could be resolved by hormone replacement therapy using natural progesterone (Greene & Dalton, 1953). During her career Dalton published in important medical journals such as *The Lancet* and *BMJ*, treated women in special premenstrual syndrome clinics, and published popular books on premenstrual syndrome (e.g. Dalton, 1964, 1977). Her ideas were also propagated through self-help and women’s health books; in several countries, women’s groups demanding more public and scientific attention to women’s health issues considered Dalton an exemplary figure and medical concern with PMS a positive development. She is certainly the single figure most closely associated with PMS (Editorial, 1981; Knaapen, 2003). Her success in popularizing the condition was due to formidable polemical abilities but was also a sign of the times. The decades after the Second World War gave rise to what has been termed a pharmaceutical ‘revolution’. A huge number of new products came on the market: antibiotics, psychotropics, hormones, steroids, anti-hypertensives, to name but a few (Tomes, 2005). These profoundly transformed the practices of the pharmaceutical industry and of health-care professionals, while modifying the attitudes and expectations of consumers. It is in this context that Dalton made progesterone a popular remedy for PMS.

Although progesterone therapy became established as a common treatment for PMS in the UK, Dalton’s views were not widely accepted by British researchers. Some early critics of Dalton’s hypothesis had emphasised that the psychological symptoms of PMS responded to muscle-relaxing drugs or tranquilizers (Swyer, 1955; Appleby, 1960; Coppen & Kessel, 1963). Overall, Dalton’s theories did not inspire much research in the UK until the 1970s. By then laboratory studies sought but did not find the proposed ‘progesterone deficiency’ and small placebo trials had increasingly questioned the efficacy of progesterone therapy.

French researchers in this period initially believed that an excess of oestrogen was the source of premenstrual problems and considered water retention important in the symptomatology of PMS (Lambusier, 1961). They did not however base these views on Frank’s article of 1931, but on the 1936 work of French endocrinologist, Gilbert-Dreyfus who called it ‘*syndrome hyperfolliculinique*’ (SHF) (Gilbert-Dreyfus et al., 1936). Gilbert-Dreyfus recommended testosterone treatment, and French researchers

found the American emphasis on diuretic therapy to be simplistic, as it did not address the underlying hormonal cause (Herschberg & Creff, 1955). The aetiology of SHF and treatment with testosterone became strongly linked, but after 1950 this approach was challenged in France. New hormone assay techniques failed to find any consistent abnormality in oestrogen levels (Sendrail et al., 1953), and the effects of testosterone treatment were unacceptable to many patients. A. Netter, the best known gynaecologist and endocrinologist of this era in France, proposed as an alternative model a *relative* oestrogen excess due to progesterone deficiency (Netter et al., 1951; Netter, 1960). As a variety of synthetic progestins became available and the prices decreased tenfold (Norris, 1987), both the term SHF and its associated testosterone treatment became obsolete by 1960.

The idea that luteal (progesterone) deficiency was the cause of PMS was at this time also being proposed by Dalton in Britain; although not the accepted view in the US, it had been mentioned by several early American researchers (Israel, 1938; Morton, 1950). But although these aetiological theories appear similar, the recommended treatments differed from one country to the next. In the USA diuretics were the common treatment. In France, Netter proposed small doses of progestins rather than natural progesterone in high doses, as Dalton and others advocated, on the grounds that the latter would worsen symptoms (Netter, 1960). Despite similarities, few direct influences seem to have been at play; before 1980 only three French articles on PMS refer to Dalton’s work.

PMS research in all three countries during the 1950s and most of the 60s was not concerned with establishing a rigorous clinical definition of the condition based on a biological marker. On the contrary, what counted was having an aetiology/treatment principle that was self-validating. A causal mechanism (based on knowledge of physiology and/or clinical experience) suggested a logical treatment, and successful treatment (as judged by clinical case studies) confirmed the validity of the aetiological explanation. PMS shared this research style with many if not most domains of medical science during the 1950s. By the late 1960s, however, research styles were changing radically making it difficult to defend either part of the PMS aetiology/treatment rationale and raising new evidentiary demands.

4. 1970s: diverging research programs

PMS research during the 1950s and 1960s had a national focus, but was based on similar principles in all three countries. Starting in the 1970s it was increasingly perceived as problematic in part due to unresolved problems and in part because research styles were changing dramatically. Researchers in each country utilised different strategies to resolve the difficulties raised by negative and contradictory research results.

The French case was fairly unique. From 1965 to 1985 there was a sharp drop in original French literature on

PMS. Despite the breakdown of similar theories elsewhere, the luteal deficiency model persisted in France. This was due in some measure to the relatively slow change in research styles in France and in large part to the influence of Netter's successor, Mauvais-Jarvis, who together with his group at the Necker Hospital published substantial amounts during the 1970s and 1980s on the more general topics of luteal deficiency and progestin therapy (Löwy & Weisz, 2005). One member of the group, B. de Lignière, used mastodynia (breast pain) as a way to understand PMS more generally (Rayr, 1984, p. 17). For the most part, however, PMS was not a French preoccupation and the little research produced was centred on the broader somatic model of luteal deficiency.

In contrast, there was a gradual increase starting in the early 1970s in numbers of articles published in British journals, as innovations in medical techniques were introduced and more extensive laboratory studies including hormonal assays and biochemical profiling became the norm. It continued to be impossible to validate Dalton's claims for the luteal deficiency hypothesis and, as randomized clinical trials became more widespread during the 1970s, progesterone therapy was—with isolated exceptions—shown to be about as successful as placebo (Sampson, 1979; O'Brien et al., 1980). The predominant approach in British publications was to search for other chemical or physical imbalances whose excess or insufficiency might be cured by medication. The chemical complexity of the menstrual cycle provided a range of substances and mechanisms to be tested including prolactin (Benedek-Jaszman & Hearn-Sturtevant, 1976), prostaglandin metabolites (Wood & Jakubowicz, 1980), thyroid hypofunction (Sutherland & Stewart, 1965), and many others. However the only effective way of dealing with the wide variety of symptoms involved was suppressing cyclical ovarian activity with the attendant serious side effects. The notion that psychological factors played an important role in PMS was supported by high rates of improvement using placebos and some reports of good results using anxiolytics or lithium (e.g. Clare, 1979).

In American publications, one finds much the same effort to discover underlying physiological mechanisms and the rational therapies these suggested. However, here another issue gained increasing attention as well. Articles expressed profound concern about great variation in symptomatology and reported prevalence of PMS, attributed to the lack of a standardised and rigorous diagnosis of the condition. Up to 300 different somatic, psychological and behavioural symptoms, each varying considerably in severity, had been associated with the condition. Many symptoms were very common and could be associated with PMS if they occurred only during the premenstrual phase of the cycle. Estimates of incidence therefore varied from

5% to 95% of menstruating women. As a prerequisite for the proper scientific study of PMS, it was argued, the kind, number and severity of symptoms constituting the syndrome needed to be established. As research had not found a conventional somatic marker for identifying PMS, it was proposed from the 1960s to provide a quantifiable standard of symptom measurement using the kinds of standardised questionnaires that had been pioneered by psychologists to measure subjective states. The first and by far the most important of these was the *Menstrual Distress Questionnaire (MDQ)* designed by American psychologist Rudolf Moos to measure (pre)menstrual symptoms (Moos, 1968). The product of this questionnaire—a quantified report of forty-seven symptoms associated with specific phases of the menstrual cycle—made PMS more 'objective' and was taken as proof of the existence of an underlying hormonal disorder. It also increased possibilities for comparability among studies. The *MDQ* clearly filled a gaping research hole. It was taken up in the next decades by many researchers as a way of determining who suffered from PMS.⁴

But the introduction of the *MDQ* and other psychometric instruments also provoked criticism from feminist psychologists studying the menstrual cycle. Among these were members of the 35th Division (Psychology of Women) of the American Psychological Association, and members of the Society for Menstrual Cycle Research founded in 1977 'to promote interdisciplinary woman-centred research on the menstrual cycle' (Society for Menstrual Cycle Research website) and whose annual meetings have over the years generated extensive interdisciplinary research on PMS (Taylor, 2006). Their work was part of a wider literature studying the psychological aspects of biological processes such as menstruation. But as feminists and psychologists, they criticised much of the gynaecological research for assuming that women's psyche and behaviour were in important ways determined by their hormones (Sommer, 1972), and the psychoanalytic and psychodynamic literature which for frequently portraying women as neurotic, and their menstrual/somatic symptoms as psychogenic in origin (Golub, 1976). Many of the studies in psychosomatic journals combined both assumptions, portraying PMS as both hormonally determined and neurotic in origin (Ivey & Bardwick, 1968; Patkai et al., 1974). The most influential feminist psychological studies rejected both these approaches and emphasised the importance of *social* and *cultural* factors in women's health and illness. The reporting of menstrual cycle symptoms, they argued, depended on ways of measuring and reporting as well as on learned expectations and stereotypes about premenstrual suffering; consequently retrospective self-rating of symptoms led frequently to overestimations (Parlee, 1974). More symptoms were also reported if the subject

⁴ Moos's (1968) article is likely the most cited article in the history of PMS research, cited 430 times as of 20 March 2006. In comparison the founding article written by Robert Frank in 1931 has been cited 389 times (based on *ISI web of science citation index*).

believed herself to be in the premenstrual phase, even if this did not correspond with reality, which was itself frequently gauged inaccurately by researchers (Ruble, 1977; Brooks et al., 1977). They pointed to societal roles which discouraged expression of irritability and anger which could only surface under the guise of a medical condition (Ruble & Brooks-Gunn, 1979). Finally, they pointed out the many statistical problems of validity and reliability associated with PMS as a diagnostic category arrived at through self-reports of ill-selected populations (Parlee, 1973, 1974). Some concluded that little evidence existed in support of a medical condition linked to a woman's hormonal cycle (e.g. Parlee, 1973, 1974).

This psychological and feminist writing had effect in the biomedical sphere in raising questions about PMS measurement and research. An article in the prestigious journal *Science* (Ruble, 1977) and a number of other articles were widely cited.⁵ By the end of the 1970s, this literature had successfully introduced serious doubts about the view that premenstrual symptoms had only hormonal causes and had increased awareness of the impact of research methodologies, culture, and expectations of both scientists and research subjects in shaping the condition. The methodological debates of the 1970s in the psychosomatic and psychological literature on the MDQ set the stage for the public and scientific controversy that followed in the 1980s and beyond. They introduced two powerful and contradictory discourses about PMS: one in favour of greater standardization and the other advocating demedicalization.

By the early 1980s, some PMS researchers in all three countries wondered about the lack of real progress in their field. French researchers did not see the condition as particularly problematical and published relatively little on it. In the UK and USA, PMS received increasing attention but research was characterised by negative findings and disagreement. An editorial in *The Lancet* concluded that 'the foundations of the premenstrual syndrome remain as fragile as they were fifty years ago' (Editorial, 1981). American journals echoed such sentiments but tended to be more optimistic about the future, believing that the most recent efforts at standardisation would soon bear fruit (Blume, 1983).

5. 1980s and beyond; establishing PMDD

As disagreement about the best methodological approach to menstrual cycle research continued, the vari-

ety of perspectives on and interested parties in PMS increased. Things came to a head in the early 1980s when a public controversy erupted. In 1980 and 1981 three women in the UK successfully pleaded diminished responsibility or mitigation due to premenstrual syndrome in crimes of manslaughter, arson and assault (Dalton, 1980). (Katharina Dalton served as an expert witness in two trials.) Sentences were reduced on condition that the women receive progesterone treatment. These trials received wide attention in the popular press and transformed PMS from a medical problem of individual women into a legal, moral and social problem (Rittenhouse, 1991). One of the effects of the British criminal trials and subsequent media attention was that American women in unprecedented numbers sought help from doctors (Gonzalez, 1981). Popular groups like PMS Action were founded to promote recognition and treatment of PMS by medical professionals. Private PMS clinics began to appear in the USA, modelled after those in the UK, and progesterone therapy was enthusiastically adopted, much to the chagrin of many gynaecologists who viewed its use as 'unscientific' and 'commercial', not to mention unlicensed (Gonzalez, 1981; Blume, 1983). With the increased public interest, research on the subject in the UK and USA accelerated as well. PMS attracted increased interest from scholars in such disciplines as sociology, anthropology, law and philosophy (Riessman, 1983; Laws, 1983; Ginsburg & Carter, 1987; Martin, 1987). Articles on the subject appeared increasingly in the major journals of psychology. Furthermore, researchers on PMS (with the help of computers) increasingly took note of foreign research. Fifty percent of citations in articles on PMS in French medical journals and almost 30% in American journals during the 1980s referred to British publications.⁶

The controversy ensuing from the court trials publicly exposed the lack of agreement in PMS research. The involvement of different disciplines, the increasingly international character of PMS research and the heightened public scrutiny made the elimination of variation and the introduction of standards a pressing imperative. Disagreements about diagnosis and methodology also had serious consequences for the many researchers now seeking funding: 'one investigator related that a grant proposal he had recently submitted had been rejected with the comment: "You want to study something that does not exist with methods that are inadequate"' (Blume, 1983, p. 2866). Terminology was quickly harmonised;

⁵ Parlee (1973) was cited 136 times (as of 20 March 2006), Parlee (1974), 141 times, and Ruble (1977), 177 times (based on *ISI web of science citation index*).

⁶ In our sample of journals described in n. 2, the proportion of citations referring to non-American journals in PMS articles in American journals rose from 18% in the period from the 1950s through the 1970s, to 44% during the 1980s when British journals were frequently cited. Since then foreign citations have declined to about 20%. In French publications, citations to articles in non-French journals rose from 40% of all references from the 1950s through the 1970s, to 86% in the 1980s (largely British) and to 92% after 2000 (predominantly to American journals). In British journals, references to foreign periodicals (mainly American) slightly outnumbered references to British periodicals 52% to 48% from the 1950s until the 1980s. After 1990, the proportion of citations to non-British journals increased to more than 80%. PMS articles in both France and the US have relied largely on citations to American publications in recent years. British publications in contrast continue to have a very strong international orientation with 30% of all citations referring to publications appearing in neither the US nor UK.

‘Premenstrual Tension’ which had been the most common term in the USA was replaced by ‘premenstrual syndrome’ or PMS, utilised in Britain and France.

American psychiatrists played an especially important role in redefining this condition in order to make research on it more fundable. PMS was a tiny part of the wider program to shift psychiatry from a psychodynamic orientation to one focussing on discrete disease entities defined by observable symptoms. Several important groups encouraged this shift. Third party payers required clear diagnoses to rationalize payment procedures; pharmaceutical companies needed specific diagnostic categories around which to develop and sell their products; researchers needed clear diagnoses to justify applications to funding agencies insisting increasingly on standardized diagnostic categories that would render results comparable and reproducible. The American Psychiatric Association responded to these pressures by publishing in 1980 DSM-III (Wilson, 1993; Healy, 1997). This turned out to be the first step in an ongoing process with immeasurable consequences for psychiatry and an almost immediate impact on PMS research.

In 1983, the National Institute of Mental Health (NIMH) in the USA held a workshop to standardise diagnostic criteria for the condition: it concluded that two months of daily symptom rating showing a 30% increase in symptom intensity during the premenstrual phase were required for diagnosis (Blume, 1983). Despite continued criticisms from some psychologists, the use of daily self-reports became a prerequisite of PMS research. However, only limited standardisation was achieved; as many as sixty-five different psychometric instruments were used in clinical trials in the following years, resulting in urgent calls for ‘a single best instrument’ (Budeiri et al., 1994).

The diagnostic criteria of the NIMH represented the first of several steps taken by American psychiatrists in the 1980s to create a more stable PMS diagnosis. In 1985 the first reference to a premenstrual mood disorder label appeared in MEDLINE (Taylor, 2006). That same year a committee was established to develop a diagnostic category for premenstrual syndrome to be included in the DSM-III-R (Figert, 1996). This led to renewed public controversy, as PMS was one of three especially contentious new diagnoses that provoked critical discussion.⁷ The stakes were high because the DSM is regarded as the basic reference book for mental health professionals, can determine insurance reimbursement, is often used in legal disputes, and plays a role in determining what research receives funding. We will not recount these developments in detail since others have already done so (Rittenhouse, 1991; Caplan, 1995; Figert, 1996), except to say that the issue proved highly contentious. In addition to contributing to the medicalization of what some considered normal physiological events and/or the results of psycho-social

conditions faced by women, the new diagnostic category seemed to stigmatise many women as mentally ill.

The heated debates about the categorisation of PMS resulted in a compromise. A new psychiatric entity called Late Luteal Phase Dysphoric Disorder (LLPDD) was included in the research appendix of the DSM-III-R, as a ‘preliminary diagnosis requiring further study’. The DSM-IV published in 1994 included in the appendix a slightly revised version of the condition, now called premenstrual dysphoric disorder (PMDD), also mentioned in the main text as an example of a ‘depressive disorder not further specified’.

LLPDD/PMDD and its placement in the appendix can be plausibly seen as a tentative first step toward creating a new formally recognized psychiatric diagnostic category. But it can also be viewed (and in fact was thus justified) as way of satisfying medical researchers requiring a more precise and standardized entity to study, with the aim of facilitating and attracting funds for more rigorous research. The compromise effectively splits the condition into, on the one hand, PMDD, a distinct predominantly psychiatric category affecting small numbers of women that can more easily be subject to research and, on the other hand, PMS, a diffuse set of symptoms that leads far greater numbers of women to seek medical help in clinical practice. Regarded as such, the creation of this new category had significant effects. Although full comparability remained elusive ‘because of a lack of consensus in study criteria and design... studies differ in their interpretation of DSM-IV criteria, and definitions of clinically significant premenstrual symptoms are not comparable’ (Steiner et al., 2003, p. 204), PMDD validated by prospective rating questionnaires has become the ‘gold standard’ for clinical trials. Studies that use other criteria are still published, especially in British publications, but are often discounted in meta-analyses and guidelines at least in the USA. Through the use of this standardised diagnostic entity in clinical trials (frequently industry sponsored), some substances have been understood to show efficacy or lack thereof. Older cycle suppressants like GnRH analogues have had their efficacy confirmed (Wyatt et al., 2004). Above all, a specific type of antidepressant (selective serotonin re-uptake inhibitors or SSRIs) has been shown in by-now numerous trials to be more effective than placebos in relieving the premenstrual symptoms that are currently studied. Calcium also had efficacy confirmed for some of the common premenstrual symptoms (Thys-Jacobs et al., 1989) and a number of other substances provide specific symptomatic relief (Halbreich, 2005). Most recently, oral contraceptives containing a progestin, drospirenone, have shown positive results (Kroll & Rapkin, 2006). However one of the things that this research has not been very concerned with is the determination of a cause or mechanism of PMDD. The relative success of SSRIs—they are said

⁷ The others were masochistic personality disorder and paraphilic rapism. See Caplan (1995).

to work in about 60% of cases (Halbreich, 2005)—has led some authors to suggest that serotonin levels are somehow involved. This, like the many other hypotheses that have been and continue to be advanced, remains unproven.

Just as psychological research in the 1970s facilitated the ‘psychiatrisation’ of PMS, the appearance of PMDD has opened more space for psychologists (and other therapists) who have published extensively on this subject since the 1980s. Many of the subjects they deal with are totally congruent with and have helped advance biomedical research on PMS/PMDD: measurement of symptoms (e.g. Schnurr, 1989); relationship of personality characteristics or stress to symptom intensity (e.g. Dinning and Guptill, 1992); effects of PMS on cognitive or physical performances (e.g. Collins, 1991); effects of PMS on job, marriage and life in general (as well as the effect of these factors on symptoms) (e.g. Mello-Goldner & Jackson, 1999); relationship of PMS to other mood disorders (e.g. Hartlage & Gehlert, 2001). Other psychological publications emphasise a variety of non pharmaceutical treatments ranging from cognitive therapy and peer group treatment to relaxation techniques (e.g. Hunter, 2003; Taylor, 1999). These too are congruent with dominant approaches in the biomedical literature although their results have not appeared fully convincing according to the criteria of evidence-based medicine. In American medical journals of various sorts, research on premenstrual problems has increasingly focused on psychological rather than somatic symptoms.⁸

There continues to be an important current within the psychological literature that raises serious methodological questions about the way that PMDD in particular is diagnosed through self-reporting of symptoms (e.g. Klebanov & Jemmott, 1992). While some researchers previously opposed to PMDD have more or less adjusted to new realities and now seek to introduce strategies to mitigate difficulties (Gallant & Hamilton, 1988; Hamilton & Gallant, 1990) a certain number have repeatedly rejected PMDD as a disease construct that subjugates women and medicalizes their problems (Chrisler & Levy, 1990; Caplan, 1995; Chrisler & Caplan, 2002; Ussher, 2003). For some scholars, the existence of this condition is a result of psychiatric attempts to dominate and shape the behaviour of women along ideological lines (Caplan et al., 1992). For others it results from the skewed priorities of biomedical research (Parlee, 1994). In either case, this critical approach to PMDD research is nearly invisible in the biomedical literature.

The publication of PMDD research has in recent years occurred mainly in the US. The focus in British journals has been on producing review articles and meta-analyses of the results of American research. Research that is pub-

lished in these British journals often uses the term PMS, without even mentioning PMDD. French researchers, despite their traditional attachment to somatic symptoms like breast pain and enthusiasm for progestin therapy, have to some degree accepted the new American orientations on psychological symptoms and antidepressant treatment. Confronted with ‘Anglo-Saxon’ research with a psychological focus and trial data questioning the effects of progesterone and progestins, many French researchers have postulated two kinds of PMS: one ‘congestive’ and the other ‘psychoneurological’ (Quereux & Bory, 1997; Dendoune, 2000). In this way, the French emphasis on luteal deficiency and progestin treatment continues to be justified for the treatment of the congestive version of PMS (breast symptoms, bloating), while international research results are explained as bearing on the ‘psychoneurological’ (anxiety, irritability, depression) premenstrual syndrome (Lignières, 1986, p. 29). Postulating the co-existence of multiple premenstrual syndromes provides a useful way to maintain distinct disciplinary and international preferences in treatment and research methodology and aetiological theories. However, since the year 2000 writing by psychiatrists has come to dominate the tiny French-language PMS literature, recapitulating rather closely American research on PMDD.⁹ Nonetheless, the status of PMDD as a *clinical* entity is hardly uncontested in any of these countries.

6. PMDD: moving towards official clinical diagnosis?

The position of PMDD as a clinical diagnosis is currently ambiguous in the DSM-IV, but it does have an official diagnostic code that can be used for diagnosis and insurance reimbursement. In 1998 a meeting of experts funded by the Eli Lilly Company was convened in order to decide whether PMDD was a distinct clinical entity. Although not unanimously accepted by those present, the positive response was presented to regulatory agencies (Endicott et al., 1999). With remarkable speed the Medicines Control Agency in the UK recognised in 1999 the existence of PMDD and approved fluoxetine (Prozac manufactured by Lilly) as a treatment for it; both the US Food and Drug Administration and the European regulatory agency followed suit (Endicott, 2000; Wyatt et al., 2002; Moynihan, 2004). With its patent for Prozac soon expiring, Lilly repackaged fluoxetine as ‘Sarafem’ specifically aimed at PMDD, and marketed it heavily in the USA (Greenslit, 2002). In spite of a campaign by women’s health activists and researchers to rescind authorisation of the drug, the FDA has gone on to approve a number of other antidepressants for this condition. In 2003 PMDD was added

⁸ An analysis of the three major American journals mentioned in n. 2 representing various specialties found that until the 1970s, somatic symptoms were discussed 2.5 times more frequently than emotional symptoms in articles on PMS. During the 1980s the two categories were roughly equal and today emotional symptoms are discussed about twice as often.

⁹ Since 2000, of the references cited in French articles on PMS about 8% refer to articles in French journals while 58% refer to American and 17% to British journals. The terms ‘troubles dysphoriques prémenstruels’ and ‘dysphorie prémenstruelle’ are frequently used and DSM-IV criteria often cited.

to the new version of ICD-9-CM, the diagnostic coding system used in the United States. But it was added as an inclusion term to code 625.4 (premenstrual tension syndrome), without any specific diagnostic criteria and thus appears not as a distinct disease but as a condition closely related to PMS (Witt, 2003).

The status of PMDD is even more problematic in Europe. In 2003 the European license for fluoxetine to treat PMDD was recalled by the European Committee for Proprietary Medicinal Products on the grounds that 'PMDD is not a well-established disease entity across Europe' as it is not listed in the International Classification of Diseases currently in use in Europe (ICD-10), and only as a research diagnosis in the DSM-IV. 'There was considerable concern that women with less severe premenstrual symptoms might erroneously receive a diagnosis of PMDD resulting in widespread inappropriate short and long term use of fluoxetine', wrote the committee (Moynihan, 2004).

We are only beginning to get an idea of the number of women diagnosed with PMDD or PMS. These data do not suggest that diagnoses are increasing. In a detailed British study by Wyatt et al. (2002) the number of PMS diagnoses by GPs in West Midlands Region fell very sharply from 1533 in 1993 to only 441 in 1998; diagnoses as a percentage of the total female population fell from 0.92 to 0.42. There is no mention of PMDD in this study. In France the diagnosis of PMS by GPs is even rarer, although this reflects the special role that gynaecologists play as primary-care specialists. Nonetheless it seems significant that diagnosis of PMS among a small sample of French general practitioners declined from a little under 0.7% of female patients in 1994 to under 0.1% in 2005 (the proportion of consultations rather than patients is 0.03%) (Observatoire de Médecine Générale, n.d.). Although some North American studies report very high prevalence rates, 4.6–8.1% for PMDD and 13–31% for severe PMS (Steiner et al., 2003), these are based on retrospective self-reported symptoms from women attending a clinic for other health reasons. Data on actual diagnosis from office-based physicians (excluding hospitals) produced by IMS, an international organization collecting health data, suggest North American figures that are similar to those in Europe. During the past five years, the proportion of women consulting physicians diagnosed with PMS (which since 2003 includes PMDD) has been below 0.1% in the USA and well below 0.1% in Canada (IMS, National Disease & Therapeutic Index; IMS Health Canada, Canadian Disease and Therapeutic Index).

In sum, despite reports of possible high rates of PMS/PMDD, the numbers of women seeking medical help for these conditions and receiving an official diagnosis is small and may even be declining. Wyatt et al. (2002) attribute the sharp British decline of the 1990s in PMS diagnosis to the popularity of alternative forms of treatment, leading fewer women to consult doctors for these problems. The study by Hylan et al. (1999) indicates that about half the women reporting severe PMS symptoms do not seek professional

help because they think 'nothing would help', symptoms are considered not severe enough or 'natural', or because they simply prefer to self-treat. Another possible explanation may be that the uncertainty and controversy surrounding PMDD have led to more stringent criteria for the diagnosis of PMS.

7. Recommended treatments: guidelines and meta-reviews

There has been little consensus about how to treat premenstrual symptoms. But increasingly, professional organisations and scientific articles make treatment recommendations on a collective scale in the form of clinical guidelines, meta-reviews and expert articles. In the USA at least two psychiatric guidelines on depression have discussed PMDD, a consequence of its place in the DSM-IV, although PMDD need not include any symptoms of depression. In both, the first line treatment recommendation is fluoxetine and secondarily another SSRI (Brigham and Women's Hospital, n.d., p. 9; Altshuler et al., 2001). Altshuler et al. (2001) also recommend psychotherapy and life style modifications, either in addition to SSRIs or alone, for mild symptoms. Non-psychopharmacological medications like progesterone or diuretics are not mentioned in these guidelines.

In non-psychiatric American guidelines the status of PMDD is not so clear. The American College of Obstetricians and Gynecologists' (ACOG) guideline of 2000 uses the traditional term premenstrual syndrome and never mentions PMDD. It ends with a comment about the worrisome gap between PMS research and clinical gynaecological practice: it is difficult to establish evidence-based guidelines because 'many recent PMS studies have properly included only women with the full-blown syndrome, including mood-related symptoms whereas many women seek care from their practitioners for a less severe condition, with primarily somatic symptoms'. Four years later, an ACOG expert article directly tackled the relation between PMS and PMDD (Johnson, 2004). In this account, PMDD is most definitely not primarily a mood disorder while PMS is a physical one, as DSM-IV-R suggests. It is rather the severe form of PMS 'a small subset of women at the extreme end of the PMS severity spectrum' which is in no way 'etiologically distinct'. Although this is the only guideline article explicitly challenging PMDD as a distinct entity, this attitude seems to underlie most non-psychiatric guidelines which either ignore the term PMDD (referring exclusively to PMS), combine the two categories as 'PMS/PMDD' or specify that PMDD is a 'severe form of PMS'. Jean Endicott (2000) admits, despite all her efforts to establish PMDD as a distinct clinical entity, that the vast majority of practitioners view PMDD as merely the most severe form of PMS. The place of PMDD as part of code 625.4 (premenstrual tension syndrome) in the ICD-9-CM reflects and reinforces this view.

The treatment recommendations in guidelines developed by/for gynaecologists and primary care practitioners

recommend a wide range of treatments and are not solely ordered according to the 'level of evidence'. They weigh the overall and usually unquantifiable benefits of a healthy lifestyle against the risks, side-effects and costs of treatments that have been shown to be effective in clinical trials; one thus starts with supportive therapy, complex carbohydrate diet, aerobic exercise, and nutritional supplements; if that fails treatment moves to SSRIs, then to an anxiolytic and finally ovulation suppression. In addition, specific treatments can be recommended according to the most severe symptom of the individual patient (bromocriptine for breast swelling, analgesics for headache, SSRIs for depression) (Bhatia & Bhatia, 2002; Dickerson et al., 2003; Evidence-based recommendations for managing the premenstrual syndrome, 2000; ACOG Committee on Practice Bulletins, 2000; Johnson, 2004).

So far as we have been able to determine, American psychologists who have produced relatively few formal collective guidelines (e.g. American Psychological Association, 2005) have not fashioned specific guidelines on PMS/PMDD. There is however one explicitly feminist set of guidelines prepared by the Association of Women's Health, Obstetric, and Neonatal Nurses (2003). It covers all pain and discomfort (including those of mood) during the entire menstrual cycle and (in its summary version at least) singles out premenstrual problems only once: 'Antidepressant medication may be considered for women with severe premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PMDD)'. This guideline mentions a large variety of therapies; behavioral, dietary, environmental, as well as prescription medications including NSAIDs like Ibuprofen and Vioxx and oral contraceptives. Although it includes an unusually large range of therapies that 'may be recommended', the products under consideration are not what distinguish this guideline from the psychiatric and gynecological guidelines. It is the process of decision-making about evaluation and treatment, which must be collaborative at all times. This guideline summarizes all the available treatments without recommending or prioritizing one over another. It is the woman's choice, goals and expectations that are to guide the health professional in recommending an 'individualized treatment plan' to be set up 'through mutual goal-setting'.

In France the gap between research and practice seems particularly wide and neither guidelines nor systematic reviews have been produced to bridge this gap. Several review essays and expert articles have been published and these seem to be the chief means of guiding French practitioners in their choice of PMS treatment. These articles set out extremely diverse recommendations. The most recent ones are similar to those found in American psychiatric articles and recommend SSRIs as the first line of treatment (Guedj, 1997; Bianchi-Demicheli et al., 2003). But others emphasise somatic symptoms like breast pain and abdominal swelling and suggest only hormones as treatment (Guillerd et al., 1995; Fourcade, 2005). Yet other reviews distinguish among multiple premenstrual syndromes and

suggest various treatments for each (Quereux & Bory, 1997; Dendoune, 2000). These conflicting recommendations are not clearly divided along specialty lines.

In Britain a single group of researchers in Exeter has produced several meta-analyses of randomised clinical trials that have tested many common treatments for PMS. These conclude that Vitamin B6 effectively diminishes premenstrual symptoms (Wyatt et al., 1999) as do SSRIs (Dimmock et al., 2000), while progesterone or progestins do not (Wyatt et al., 2001). They suggest limited usefulness of GnRH antagonists because of costs and side effect (Wyatt et al., 2004).

8. Treatment and prescription data

This British research group also conducted a study of actual treatments prescribed for PMS in general practice between 1993 and 1998 (Wyatt et al., 2002). This study showed that SSRIs are increasingly prescribed in the UK, but otherwise practice in the UK was not congruent with the meta-review recommendations. Progesterone was the most popular treatment for PMS in the UK and elsewhere in the 1980s (Lyon & Lyon, 1984; Alexander et al., 1986), and despite negative recommendations in guidelines and systematic reviews its use did not decrease significantly in the UK; between 1993 and 1998 it dropped from 44% to 42% of drugs prescribed for PMS by British GPs and remained the most prescribed substance (Wyatt et al., 2002). Vitamin B6 has a positive meta-analyses recommendation and has been a very popular treatment in the UK (Corney & Stanton, 1991); nevertheless its use suddenly declined from 22% of prescriptions for PMS in 1993 to only 11% in 1998, after the UK Department of Health made an effort to limit its sales because of concerns about neurotoxic effects at very high doses (Wyatt et al., 2002). Prescriptions for SSRIs however increased dramatically during this period from an insignificant 2% to 16% of all prescriptions, making them the second most frequently prescribed substances for PMS in the West Midlands in 1998 (ibid.).

It is likely that in the years since then, British physicians have increasingly prescribed anti-depressants for PMS as a result of the practice guidelines and meta-reviews discussed in the previous section. This has certainly been the case in the USA. According to IMS data, in the latter country anti-depressants, overwhelming SSRIs, account from about one-half to over two-thirds of all written prescriptions annually for PMS, with hormones (including birth control pills) and analgesics lagging far behind (IMS, National Disease & Therapeutic Index). In Canada, SSRI written prescriptions, while not quite so high and extremely variable from year to year, also constitute the largest category of drugs treatments for this condition (IMS Health Canada, Canadian Disease and Therapeutic Index). It remains to be seen whether such high levels of psychotropic drugs are also now characteristic of European countries.

All this data makes it clear that the vast majority of women do *not* visit physicians for PMS symptoms; those who do are likely to be prescribed a psychotropic drug. Guidelines thus do seem to be having an effect on prescription patterns, at least in North America, although we do not know how many women actually take these medications or for how long. We know even less about what women who do not see physicians (the vast majority) do about PMS symptoms. Hylan et al. (1999) found in an international telephone survey asking about retrospective symptoms and treatments that of the 75–80% of women reporting premenstrual symptoms without visiting a medical professional, many self-medicated: the most common non-prescription medications were anti-inflammatory or analgesic agents. These data, if accurate, confirm the claim made by ACOG that many women suffer from physical symptoms of pain (breast, headache, backache), and not predominantly from psychological problems, as often claimed in the (psychiatric) literature. If that is the case, data about the increased prescription of psychotropic drugs suggests a major discrepancy between symptoms and drugs prescribed that may account for the fact that the vast majority of women are dealing with PMS without the help of physicians.

Overall, it is fairly clear that the appearance of PMDD in the DSM and the medical literature has not established a distinct new psychiatric entity managed by psychiatrists. Its inclusion in the DSM has not fully standardised diagnosis and drug use in daily practice but has rather standardised recruitment for and execution of clinical trials, at least in North America. We can however be certain that the prescription of psychoactive drugs for premenstrual symptoms has become more common. A psychiatric diagnosis that few utilise in practice (PMDD) thus has as its main function to test drugs (often psychoactive) which are then prescribed for premenstrual problems predominantly by GPs in Canada (IMS Health Canada, Canadian Disease and Therapeutic Index) and gynaecologists in the USA (IMS, National Disease & Therapeutic Index). On the whole, however, it seems that women are dealing with premenstrual problems without turning for help to the medical profession or to prescription drugs.

9. Conclusion

The history of PMS research, although by no means typical of biomedical science, has much in common with the history of other domains of biomedical research and reflects a broad range of influences. One sees distinct national traditions of research reflecting the relative isolation of research communities before the 1970s. Apparent as well are changing research styles. During the 1950s and 1960s PMS research was based on efforts to establish a biologically sound aetiology/therapy rationale. From the 1970s there was continuous effort to develop standard measurement instruments and clear diagnostic categories that would allow for comparability of test results, espe-

cially in randomised clinical trials. The emergence of an American feminist critique of PMS that occurred in the 1970s was part of a far wider social movement contesting medical expertise. In recent years, pressure to translate research results into practice has led to the production of practice guidelines and systematic reviews. Each of these developments has embodied changing norms of scientific rigour and ‘objectivity’ a notion whose evolution is only beginning to receive serious attention (Daston, 1992; Daston & Galison, 1992). Consequently, the major problems of PMS research in the 1950s (finding a relationship between cause and cure) have not been resolved; rather they were *replaced* during the 1970s and 1980s by another challenge—imposing standardisation and comparability. Today, standardisation has become synonymous with objectivity in this field (e.g. Wittchen et al., 2002).

This kind of standardisation that now characterizes American PMS/PMDD research—negotiated conventions that establish definitions, classifications, and numerical markers as well as determining their meanings—is increasingly widespread in western biomedicine and can be characterised as a new form of ‘regulatory objectivity’ (Cambrosio et al., 2006). Such efforts at standardisation claim usefulness rather than truth for these collectively agreed-upon, often quantifiable categories; PMDD was initially and explicitly acknowledged as such a category necessary for research comparability. In the course of time, however such standards may slide from this conventional status to the status of ‘truth’, as has occurred in the case of PMDD, viewed by some as an objective condition that is ‘true to nature’. This shift occurs because it reflects the interests of the pharmaceutical industry, the needs of insurers and regulators for clear diagnostic categories, as well as the experiences of significant numbers of women and physicians; it is promoted by the EBM movement which now exerts considerable pressure to quickly transfer to clinical practice research results and standardised categories that become reified as ‘diagnoses’. Nonetheless, if current diagnostic criteria measuring symptoms allow PMS research to participate in what has become the central epistemological demand of current biomedicine, large-scale randomised clinical trials showing a statistical benefit for one treatment or another, they do not translate easily into the complex and heterogeneous world of PMS/PMDD practice, which remains surrounded by uncertainty and unpredictability.

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