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THE *DSM*, BIG PHARMA, AND CLINICAL PRACTICE GUIDELINES:

PROTECTING PATIENT AUTONOMY AND INFORMED CONSENT

LISA COSGROVE

Abstract

The author of this paper discusses why the issue of financial conflicts of interest (FCOI) in psychiatry has important public health implications for women and why FCOI complicate the informed consent process. For example, when psychiatric diagnostic and treatment guidelines are unduly influenced by industry, informed consent becomes a critical issue, because women may be assigned diagnostic labels that are not valid and may also be receiving imbalanced or even inaccurate information about their mental health treatment options. However, mere disclosure of industry relationships is an insufficient solution. Following Ells (2003), the author offers a more robust account of autonomy, inspired by Foucault, to strengthen informed consent practices. In addition to addressing power relations, this Foucauldian account of autonomy emphasizes the relational and dialogical aspect of the physician–patient relationship.

Researchers, investigative journalists, community physicians, ethicists, and policy makers have voiced strong concerns about the integrity of medicine. Specifically, questions have been raised about the ways in which financial conflicts of interest (FCOI) in the biomedical field may be compromising the integrity of the scientific research process and thus compromising patient care by disseminating imbalanced or even inaccurate information (Angell 2004). Indeed, many of us are no longer surprised when we read about settlements made by pharmaceutical companies—some totaling hundreds of millions of dollars—for withholding information on adverse side effects, overstating the efficacy of medications, or for aggressive off-label marketing practices deemed unethical (Berenson 2009; Wilson 2010a). Although no medical subspecialty has been immune to concern over FCOI, the field of psychiatry has been plagued by allegations that industry may be exerting an undue influence on the profession. In 2008, Republican United States Senator Charles Grassley widened his series of hearings and investigations into financial associations between medicine and the pharmaceutical industry by requiring the American Psychiatric Association (APA) to provide “an accounting of industry funding that pharmaceutical companies and/or the foundations established by these companies have including but not limited to grants, donations, and sponsorship for meetings or programs” (Moran 2010, 1).

The scrutiny of potential FCOI is especially timely because the highly influential psychiatric taxonomy that the APA produces and disseminates, the *Diagnostic and Statistical Manual of Mental Disorders (DSM)*, is currently undergoing revision. As Zucker (2010, 220), chair of the *DSM-V* Work Group on Sexual and Gender Identity Disorders, noted, “the *DSM* has had an enormous (international) impact on clinical training, the delivery of clinical care, and programs of research (both basic and applied).” Because the *DSM* affects such wide-ranging domains as jurisprudence, research, and insurance claims, as well as treatment interventions, it is critically important that it not be compromised by industry influence.

Big Pharma and the *DSM*

The *DSM* is often referred to as the “bible” of psychiatric disorders because it is the main instrument that mental health professionals rely upon for diagnosing their clients. Because of its clinical importance, the appearance, let alone the reality, of industry bias can undermine its integrity and weaken public trust. The concern about possible bias was heightened when it was discovered that the

organization that produces the *DSM*—the APA—receives substantial drug industry funding and that the majority of individuals who serve as diagnostic and treatment panel members also have drug industry ties (Cosgrove et al. 2009, 228–32). The fact that 100 percent of the individuals in two *DSM* panels (Schizophrenia and Psychotic Disorders; Mood Disorders), for example, had financial ties with industry (e.g., served on speakers' bureaus, corporate boards, received honoraria) is particularly problematic because psychopharmacology is the standard treatment in these two categories of disorders (Cosgrove et al. 2006, 154–60).

To its credit, the APA has made numerous public statements pledging its commitment to greater transparency and more stringent conflict of interest policies. In preparation for the upcoming *DSM* revision (now scheduled for publication in 2013), the APA instituted a conflict of interest policy for the first time in its more than fifty-five-year history. However, of the twenty-seven task force members who will oversee the development of the *DSM-V*, only eight reported no industry relationships. When 70 percent of the task force members for the *DSM-V* have industry ties (representing a relative increase of more than 20 percent compared to the *DSM-IV*), it is obvious that disclosure alone is not enough of a safeguard for restoring public trust or protecting patients' welfare (Cosgrove, Bursztajn, and Krinsky 2009, 2035–37). Despite increased transparency, financial relationships between *DSM* panel members and the pharmaceutical companies that manufacture psychotropic drugs persist.

Why the connection among the FDA, the *DSM*, and the APA may not be good for women's mental health

According to the information made publicly available by the APA (www.dsm5.org), the proposed revisions to the *DSM-V* continue to be silent on the issue of iatrogenic harm. In fact, many of the revisions seem only to reinforce and expand the primacy of medications in the management of psychiatric disease. As my colleagues and I have noted elsewhere (Gobal, Cosgrove, and Bursztajn forthcoming), a psychiatric taxonomy that touts indications for medications but does not address their associated risks is evidently unbalanced, and raises ethical questions about undue industry influence. In light of the extreme profitability of the psychotropic drug market, the increasing number of people exposed to these drugs, and the burgeoning data regarding the highly problematic and potentially chronic side effects of commonly prescribed psychiatric medications, this omission is cause for concern, especially for women. Research spanning three decades has consistently found that “women are prescribed and take

psychotropic medications more than men” (Romans et al. 2008, 615). For example, antidepressants are increasingly being prescribed for conditions other than depression (Olfson and Marcus 2009, 848–56), many of which are diagnosed solely or predominately in women (e.g., hot flashes, Premenstrual Dysphoric Disorder, and fibromyalgia). Yet even more questions remain about the efficacy and safety of prescribing antidepressants for off-label applications.

In the United States, when the FDA receives an application for approval of a new psychotropic drug, there has to be a legitimate psychiatric disorder for which a new (or safer or more efficacious) medication is needed. The requirement that there must be agreement in the scientific community that a disorder exists before a new medication can be approved is intended to provide a safeguard for the public (e.g., to ensure that individuals are not exposed to medications whose long-term side effects may outweigh short-term benefits; to ensure that newer, more costly drugs are really necessary). Because of the lack of biological markers for psychiatric conditions, an unintended consequence of this requirement is that it opens the door for what some have referred to as “disease mongering” or “widening the boundaries of treatable illness” (Moynihan, Heath, and Henry 2002, 886–91). Seemingly, in an effort to expand markets and generate more revenue, the lack of biological markers in psychiatry sets the stage for “widening the boundaries” of psychiatric disorders by inclusion of diagnoses in the *DSM* that may be invalid. In turn, this allows pharmaceutical companies to apply for FDA approval of psychotropic drugs whose iatrogenic harms may outweigh benefits. Often these drugs are ones that will be prescribed predominately or solely to women.

Two examples will illustrate. In June 2010, the pharmaceutical company Boehringer-Ingelheim submitted an application to the FDA for approval of Flibanserin (a serotonergic drug), for the treatment of “Hypoactive Sexual Desire Disorder.” The *DSM* defines Hypoactive Sexual Desire Disorder as “a deficiency or absence of sexual fantasies and desire for sexual activity” (APA 2000, 539) and gives a prevalence rate of 33 percent for women. (Interestingly, no prevalence rates are given for men.) Supporters of the diagnosis use the *DSM*’s nomenclature to claim it is a legitimate condition.

However, this disorder has been the subject of much controversy because it is based on the assumption that there is a universal, staged, and biologically based sexual response pattern, the human sexual response cycle model (HSRCM). Questions have been raised about the validity and generalizability of the HSRCM as a universal norm (Tiefer 2004; Wood, Koch, and Mansfield 2005, 236–44). The assumption that sexual problems are biologically driven

undermines an appreciation for women's lived experiences and for the gendered power dynamics in which sexual problems are inevitably embedded. For example, the HSRCM, as a universal model, does not address the needs and experiences of women who have been sexually molested or who are currently in abusive relationships. Thus, feminists have criticized the *DSM's* categorization of sexual problems for being reductive, for reinforcing a dichotomous mind-body approach, and for medicalizing women's sexual experiences (Kaschak and Tiefer 2002). Moreover, despite the 33 percent prevalence rate given for women for Hypoactive Sexual Desire Disorder, the *DSM* acknowledges that there are no "normative age- or gender-related data on frequency or degree of sexual desire [and] the diagnosis must rely on clinical judgment . . ." (APA 2000, 539). Clearly, the *DSM's* own acknowledgment of the lack of normative data renders the reliability and validity of Hypoactive Sexual Desire Disorder suspect, even before the other more far-reaching feminist criticisms noted above are considered.

An especially important issue for women in terms of the request for FDA approval of Flibanserin is iatrogenic harm; paradoxically, one of the most well-known side effects of serotonergic agents is sexual dysfunction. Recent reviews suggest that the prevalence of sexual side effects (e.g., loss of libido, difficulty achieving orgasm) can be anywhere from 30 to 70 percent (Clayton et al. 2002, 357–66; Gregorian et al. 2002, 1577–89; Montejo et al. 2001, 10–21). There also is increasing evidence that serotonergic agents have a host of adverse side effects, ranging from increased risk of upper gastrointestinal tract bleeding (Dalton et al. 2003, 59–64; De Abajo and Rodriguez 2008, 795–803) to documented adverse neonatal outcomes in relation to maternal exposure to SSRIs and other newer serotonergic/noradrenergic antidepressants (see Tuccori et al. 2009, 1426–53 for review). In addition, serotonergic drugs have been shown to have deleterious effects on the metabolism and therapeutic efficacy of tamoxifen and other anti-neoplastic agents (Spina, Santoro, and D'Arrigo 2008, 1206–27; Aubert et al. 2009). Progress in the field of pharmacogenomics has led to concerns about the complex relationships among serotonin, serotonergic agents, prolactin, and tamoxifen, and how these interrelationships may affect breast cancer risk in women (Kelly et al. 2010). Because of the lack of evidence that Flibanserin increased sexual desire, and because of concern over side effects, the FDA rejected Boehringer-Ingelheim's application, although "the company was encouraged to continue its research" (Wilson 2010b).

The Flibanserin–Hypoactive Sexual Desire Disorder story is certainly not unique. The search for the "pink Viagra" has been going on for more than a decade

(Tiefer 2004).¹ After years of trying to find the female equivalent of the blockbuster drug Viagra, in 2004 Pfizer decided to stop clinical trials of Viagra in women due to inconclusive results (Wilson 2001). Also in 2004, the FDA rejected Procter & Gamble's testosterone patch Intrinsa (designed for the controversial "Female Sexual Desire Disorder," to boost women's sexual desire) because of concerns over potentially fatal side effects such as increased risk of heart disease.

Similarly, the search for a pharmaceutical "cure" for menstrual distress has a long and interesting history. Shortly before Eli Lilly was about to lose its patent on its blockbuster drug, Prozac, women were inundated—in print ads and in the major women's magazines, on TV and on Web sites—with reports of "expert knowledge." Women were encouraged to diagnose themselves with Premenstrual Dysphonic Disorder ("Think it's PMS? Think again it could be PMDD") and to take advantage of a "new" treatment that had been developed: "Sarafem." Eli Lilly's ad for Sarafem included the following statement: "PMDD affects millions of women . . . but the good news is that your doctor can treat PMDD with a new treatment called Sarafem." What women were not told in these ads is that the psychotropic medication produced by Eli Lilly to treat PMDD was Prozac, which was relabeled as Sarafem and manufactured in pink and lavender pills. Unbeknownst to the vast majority of consumers, fluoxetine hydrochloride is the generic name for both Prozac and Sarafem (Caplan and Cosgrove 2004). The public also was not told that Lilly's patent on Prozac, with sales in 1999 of more than 2.6 billion dollars (Gussin and Raskin 2000), was about to expire just as Lilly was seeking FDA approval for Sarafem.

Also, as will be discussed in more detail below, the design and structure of the *DSM*—what has been referred to as "diagnosis by checklist" (Andreasen 2007, 108–12)—further conflate mental health treatment with psychopharmacology and set the stage for patent-extending possibilities that are not necessarily in the public's best interest. Indeed, in December 2000, the FDA sent a warning letter to Eli Lilly, mandating that Lilly cease using this ad because it did not clearly distinguish premenstrual syndrome (PMS) from PMDD and minimized important risk information (Stockbridge 2000). Interestingly, the European Medicines Evaluation Agency refused to approve serotonergic or other drugs for PMDD because of concerns that "women with less severe pre-menstrual symptoms might erroneously receive a diagnosis of PMDD resulting in widespread inappropriate short- and long-term use of fluoxetine" (Mintzes 2006, 463).

Because Direct to Consumer (DTC) advertising is legal in the United States, it is likely that many women went to their health-care providers asking

for this “new” treatment for PMDD. It is also possible that many of the women who were prescribed Sarafem were not told that they were actually taking Prozac. Certainly, disclosure of the fact that Sarafem was fluoxetine would have helped women make a more informed choice about which treatment options to pursue. However, would disclosing this information, including the adverse side effects of taking fluoxetine hydrochloride, and alternatives to treatment, be enough for the patient to be genuinely “informed” and able to give consent? I will address this question in the following section.

Informed consent, autonomy, and gender normativity

Over the last decade, evidence-based approaches to the management of psychiatric illnesses have incorporated the concept of concordance or shared decision making between clinicians and patients (Penston 2007, 154–59; Appelbaum 1997, 445–46). Thus, the paradigm has shifted from a paternalistic model, where the clinician makes decisions for patients, to a patient-choice model. Collaborative decision making can only be achieved if there is transparency and informed consent. Informed consent, defined by the Nuremberg Code (<http://ohsr.od.nih.gov/guidelines/nuremberg.html>), updated in 2004 by the World Medical Association Declaration of Helsinki (<http://ohsr.od.nih.gov/guidelines/helsinki.html>), and articulated by professional organizations, requires, among other considerations, the ability to assess the risks and benefits of proposed treatments, alternatives to the proposed treatment, and disclosure of important information. However, the standard for disclosure that must be achieved for informed consent remains a controversial issue. As May (2002, 17) pointed out, in a liberal society, the purpose of informed consent is to protect patient autonomy. He describes the three commonly proposed standards of disclosure: the professional practice (What are the customary practices of the profession?), the reasonable patient standard (What would a “reasonable” patient want to know), and the subjective standard (What are the “idiosyncratic values of the individual patient”?). May argues that the professional practice standard is grounded in an incipient paternalism, and the reasonable patient standard is grounded in too vague a concept to be useful for genuine informed consent. He maintains that the subjective standard is most compatible with a “liberal society’s concern to protect *an individual’s right to author his or her own life*” (20, italics added). May emphasizes the critical importance of autonomy, freedom of choice, and the right of the patient “to decide for herself whether to accept or reject [a] proposed treatment” (31).

For example, in May's analysis, the subjective standard for informed consent would be met if (1) a woman diagnosed with PMDD and prescribed Sarafem was informed that the "new" drug to treat PMDD is actually the same medication in Prozac; (2) an attempt was made to develop an appreciation of her "idiosyncratic values" (e.g., would she, for whatever reason, be opposed to taking an antidepressant? Would her life circumstances lead her to be concerned about the possible sexual side effects associated with taking an SSRI?); and (3) she was told about the risks and benefits of the medication and alternatives to fluoxetine. Although the concern about being able to "author one's own life" is certainly compatible with a feminist agenda, from a feminist bioethical perspective, May's analysis does not go far enough. A more complex question must also be asked: Is the liberal conception of autonomy and the right to patient choice based upon an adequate conception of subjectivity—one that addresses the ways in which power dynamics constitute and constrain the subject? I will turn to Foucault to address this question.

Subjectivity, according to Foucault, is partly constituted in and through mechanisms of subjugation—specifically through mechanisms of (self-) regulation (Foucault 1980; Foucault 1996, 298–301). If Foucault is correct, then the concept of "biopower" means that in contemporary society individuals willingly engage in numerous practices of self-surveillance—we are constantly assessing our behavior and our bodies. The biopsychiatric discourse that grounds the medical model is a good example of how biopower operates. For example, although the United States and New Zealand are the only countries that have legalized direct-to-consumer advertising, others allow for "nonbranded" advertising—ads that describe diseases and encourage consumers to see their doctors, but do not name specific drugs (Mintzes 2006, 461–65). Thus, it is possible that there are tens of thousands of women throughout the world asking themselves if they "have" Premenstrual Dysphoric Disorder (PMDD),² and, if corporate interests prevail, there may one day be just as many asking themselves if they "have" Hypoactive Sexual Desire Disorder.³

Indeed, diagnosis by checklist (Andreasen 2007, 108–12) is no longer the domain of mental health professionals—it is a form of self-regulation and surveillance that has become part of our everyday culture. Simplified versions of the criteria for *DSM* disorders are marketed via mass media, the Internet, and DTC. Biopower—the operation of power through self-regulated bodies—is enhanced by the hegemony of the *DSM*'s biomedical discourse, and by the public's increasing acceptance of the view that emotional distress and negative affect are

best understood as symptoms of a disorder rather than as part of the human condition. It is commonplace to open up a magazine, turn on the TV, or go on the Internet and be asked to complete a brief survey to determine if one has a mood, attention-deficit, menstrual, or sexual disorder. However, what may superficially appear as liberating—women taking charge of their mental health, no longer relying solely on the experts but instead participating in their own diagnostic assessments and treatment choices—is perhaps another form of subtle subjugation rather than a straightforward example of autonomy and empowerment (Cosgrove, Pearrow, and Anaya 2008, 457–65).

For example, PMS/PMDD discourse reinforces a rigid and stereotypical model of femininity by forcing women into constant self-surveillance. Insofar as it is impossible to be both “feminine” and irritable (Ussher, Hunter, and Brown 2000, 87–99; Cosgrove and Riddle 2003), labeling one’s emotional distress and negative emotions as PMDD preserves the fantasy and fiction of idealized constructions of femininity. Therefore, in terms of informed consent practices, what is not made transparent is the possibility that instead of engaging in autonomous practices and exercising our freedoms, we are being subjugated by industry-supported conceptions of normative femininity (PMDD) and heteronormativity (Hypoactive Sexual Desire Disorder).

As Ells (2003) astutely noted, the moral basis upon which informed consent is grounded is problematic because it relies on a liberal view of persons as self-determined and unconstrained by disciplinary practices, discourses, and technologies. She writes, “[T]he current liberal view holds persons to be discrete autonomous entities who make moral choices from the perspective of disinterested rational agents in accordance to abstract rules or principles” (218). By problematizing the goal of “autonomous authorization,” Ells extends and deepens May’s position that unique life experiences of the individual must be taken into account for the informed consent process to be meaningful. Because people are “multiply disciplined by various social institutions such as race, class, [and] religion . . . [a] morally acceptable theory of informed choice will need to take this complexity of power relations and the political technology of the body into account” (222). Bluhm (2009, 134–51) makes a similar point in discussing evidence-based medicine; conflating patient autonomy with patient choice actually reinforces the authority of the physician because the patient is positioned passively by being asked to choose from a predetermined list of treatment options.⁴ This positioning undermines the importance of attending to power dynamics when members of oppressed groups are asked to make decisions about their treatment. Thus, a Foucauldian

perspective reveals significant weaknesses in standard notions of informed consent, even ones like the subjective standard that emphasizes the need to appreciate an individual's unique life circumstances and lived experiences.

In addition to utilizing a more robust theory of autonomy, informed consent practices also need to address the prevalence of academic industry collaborations. As the Sarafem and Flibanserin stories suggest, women may be receiving inaccurate or even invalid diagnoses, and may be offered drugs as frontline interventions even though the iatrogenic harms of the drugs outweigh their benefits. There is mounting evidence of attempts by pharmaceutical companies to influence the content of published efficacy and safety studies in high-ranking medical journals through practices such as ghost writing and selective reporting of clinical trials, and there is documented variability in the reporting of harm-related results in publications of randomized clinical trials (Ioannidis 2010, 1737–39; Pitrou et al. 2010, 1751–56). These documented industry practices raise questions about how meaningful the informed consent process can be if practitioners are not privy to accurate and complete data on efficacy and risks.

Conclusions and recommendations

The diagnoses PMDD and Hypoactive Sexual Desire Disorder discussed in this paper are illustrative of the concern that the relationship between pharmaceutical companies and the development of gender-specific psychiatric disorders is one that must be challenged. This is not to suggest a simple solution, for protecting patient autonomy and improving informed consent practices in an industry-dominated climate is an arduous task. Indeed, we must be careful not to reify informed consent as something that can be achieved or guaranteed via disclosure standards and policies; transparency is an insufficient solution. It is not enough to disclose to a woman that the “new” medication her doctor prescribed has actually been on the market for years under a different name, or that a pharmaceutical company funded most of the research on the efficacy and safety of a new medication (although that would be an improvement over current disclosure practices). Genuine informed consent requires, first and foremost, that mental health professionals be trained in a critical approach to psychiatric taxonomy. This could be achieved by teaching clinicians to appreciate the limits of intra-individual models, like the biopsychiatric one, that take an acontextual view of people's problems. Rather than assuming that emotional distress is something that exists “in” a person, clinicians in training need to develop an appreciation for the relational and sociopolitical context in which

distress is manifest. It also is necessary to address FCOI issues within the context of a Foucauldian-inspired conception of autonomy, as outlined by Ells (2003). That is, autonomy must be re-theorized in terms of overt and covert power dynamics that may constitute (and constrain) individuals. Thus, respecting patient autonomy requires the clinician to initiate conversations about the ways in which people can be manipulated by the “social constructions of normalcy, beauty, and health” (Ells 2003, 225).

For example, a woman seeking treatment for PMDD or Hypoactive Sexual Desire Disorder after being exposed to a DTC ad should be made aware of the controversy in the medical community about the validity of these disorders, the concern that DTC is more of a marketing tool than an educational campaign, and the ways in which psychiatric diagnoses can undermine an appreciation of the relational context in which problems arise. Instead of understanding the problems that brought her to seek treatment in terms of a discrete disorder, a conscious effort should be made to recognize and discuss the power relations (individual and institutional, such as FCOI) that influence health-care decisions. Attending to these power dynamics means understanding informed consent as a relational, dialogical process. It is an exercise (Bluhm 2009), not something that can be achieved once and for all by disclosing currently known risks, benefits, alternatives to treatment, and FCOI. Ethical practice is enhanced because informed consent is conceptualized as a partnership and conversation that occurs over time (*ibid.*, 134–51; May 2002) and not as a static event. By taking a reflective and critical approach to contemporary models of psychiatric taxonomy, clinicians will, it is hoped, be more likely to actively engage their patients in ongoing conversations about the meaning of their diagnosis and about the ways in which their treatment choices affect their lives.

Notes

1. The New View Campaign, a grassroots network aimed at challenging “the distorted and oversimplified messages about sexuality that the pharmaceutical industry relies on to sell its new drugs,” has exposed the extensive conflicts of interest in sexual medicine, see <http://www.fsd-alert.org/>.

2. According to the report of the *DSM-V* Mood Disorders Work Group, as of the writing of this paper (6 August 2010), “Sub-work groups are being formed to conduct research in the areas of pre-menstrual dysphoric disorder (PMDD) and seasonal affective disorder (SAD). Advisors to these subgroups will provide evidence concerning the criteria and disposition of these conditions, whether they

should be classified as subtypes or dimensional constructs, and how they relate to the spectrum of bipolar disorders,” see www.dsm5.org.

3. Both the title of and criteria for Hypoactive Sexual Desire Disorder are currently undergoing revision. The new title is “Sexual Interest/Arousal Disorder in Women” (incorporating the *DSM IV-TR* diagnosis “Female Sexual Arousal Disorder”). The rationale for both revised titles “reflect[s] the common empirical finding that desire and (at least the subjective) experience of arousal highly overlap” www.dsm5.org.

4. See also Rawlinson’s 2001 excellent essay on the invisible gendering of the universal and the need for a feminist bioethics and Radden’s 2002 insightful analysis of the challenges associated with applying the autonomy model to psychiatric patients.

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