EDITORIAL

The pharmaceutical company–healthcare relationship: much ado about something

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Introduction

The relationship between the pharmaceutical companies and the healthcare profession, especially doctors, has always been fraught with conflicts of interest (COI). The publication of the influential *The Diagnostic and Statistical Manual for Mental Disorders, Fifth edition, Text Revision* (DSM-5-TR), by the American Psychiatric Society (APA) raised concerns that the financial relationships between pharma and members responsible for DSM could result in bias. This resulted in calls for stricter enforcement of controls on financial conflict of interest (FCOI) [1,2], which could influence the formulation of diagnostic criteria (resulting in more people being "diagnosable as mentally ill"), creating a larger pool of "patients" who "need" pharmaceutical drugs. Knowingly or unknowingly, they would end up serving the pharmaceutical companies' agenda to sell more drugs and drive up profits [2].

This editorial will discuss this controversy, the impact of FCOI on diagnosis and treatment in psychiatry specifically, and in medicine in general, its relevance in India in the context of the recent Uniform Code of Pharmaceutical Marketing Practices (UCPMP, 2024), and the disclosures about electoral bonds purchased by pharma companies [3,4].

DSM and the FCOI controversy

When DSM III was released in 1980, the use of diagnostic criteria in psychiatry introduced a degree of precision and replicability. Its descriptive details about individual mental health conditions served as a useful source of updated information. Subsequent versions of DSM reflected changes in the understanding of mental illness. When DSM 5 was released in 2013, it generated controversy on issues relating to changes in certain diagnostic categories. There were concerns that financial links existed between DSM members responsible for these changes, investigators of drug trials, and pharma [5], and that despite APA's FCOI disclosure policies, there was a risk of bias. While acknowledging that top researchers are often fielded by pharma, and have the necessary expertise to contribute as DSM panel members, it was suggested that they not be given "decision making" powers on revisions or the inclusion of new disorders. After DSM-5-TR's release in 2022, the financial links between pharma and DSM panel members were flagged once again [2]. Since 2013, as per the Physician Payments Sunshine Act, it is mandatory in the USA for drug and device companies to declare all payments made to physicians and teaching hospitals [2]. This made it possible for pharma payments to DSM-5-TR panel members to be tracked through the freely accessible Medicaid and Medicare database. Nearly 60 percent of 168 physicians associated with DSM-5-TR were found to have financial ties to the pharma industry [2]. The relevant payments amounted to more than US $14 million, ranging upwards from amounts of less than US $1000 [2]. The most common payments were for "food and beverages" and the maximum payment was for "research". Other payment categories included travel, consultations and talks other than continuing education programmes. These findings emphasised the need for public disclosure of the existence of such FCOI [2].

The DSM-5-TR group rebutted these allegations on various grounds, including the methodology used. They stated that when APA's COI Committee or COI review editor felt any recommendation could stem from FCOI, then it was not incorporated into the manual. They also argued that DSM-5-TR is a text revision, not a treatment manual — updating categories with information from new research, but not adding new categories [6].

COI in medicine

Personal, intellectual, financial or commercial COI can affect one's judgement and actions, sometimes even inadvertently. If one cannot avoid the COI, one is expected to "manage" it by transparency [7]. Research experience can endow an expert with special

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insights, even strong opinions, which can be an important contribution when one is part of a group entrusted with creating guidelines. But influencing of opinions could represent a COI if pharma has funded a particular research, say one resulting in the extending of patents by finding new uses for older medication.

There is evidence to suggest that financial "gifts", however they may be packaged, can influence a doctor's prescribing practice. (If one is sceptical about this, one just needs to look at who is approaching the doctor with the gift. It is the marketing division of the pharma company, not an independent altruistic foundation). Despite popular thinking, there is no "dose–response" — no direct link between the "size" of the financial gift and the degree of influence. Even a "small" gift can create a "network of obligation" as doctors are also social beings, affected by the "rules of social reciprocity" [8]. This is why it is critical that doctors become self-reflective and aware of this risk of bias, so that they can actively counteract it themselves, and encourage their academic peers to do so too.

The interaction between a pharmaceutical company and medical academic activity also risks "an influence". Harvard Medical School in its Policy document on COI says the existence of industry–physician relationships is not in itself a conflict [9]. However, it is important to understand the motivations of the people involved, which may not be immediately obvious.

In medicine, recognising COI is important as it can result in bias, which can at times be unintentional (implicit bias). This risks harm if biased advice leads to faulty recommendations. A review of disclosed and undisclosed FCOI in clinical practice guidelines (CPG) suggested that oncology, neurology and gastroenterology had a high prevalence of authors with FCOI [10], but whether it actually had an impact on the practice guidelines has not been studied. Databases tracking pharma company payments to physicians when compared with self-disclosure of FCOI reveals underreporting by authors [10]. Cain et al argued that disclosure is not as protective as one would imagine, as the public may not adequately understand the implications of biased advice. Paradoxically, some authors, after self-disclosure, may feel more "morally licensed" to put forth their biased opinion. Their conclusions were from an experimental model which may not be applicable to CPG settings, but are nevertheless interesting [11]. Despite these risks of underreporting, self-disclosure is an important first step to manage FCOI, but clearly inadequate if that is the only measure.

Classification and diagnosis in psychiatry: Insights into potential FCOI

One difficulty in psychiatry is that classification is based on description of patients' experiences (psychopathology) and behaviour; not on a physical examination, or laboratory/X-ray/MRI findings. Students of psychiatry are trained in mental state examination and to clarify the words patients use, as patients may use terms like "depression" very differently from the way a psychiatrist understands them. Importantly, they understand that guidelines, while useful, remain only a guide and it is "clinical judgement" that is needed to separate a normal response to a distressing circumstance from one that warrants intervention.

The US-based DSM and the World Health Organization's International Classification of Diseases and related health problems (WHO's ICD Classification of Mental and Behavioural Disorders) are two well-respected and accepted classificatory systems used in psychiatry [12]. DSM has always had its fair share of controversies relating to diagnosis, which have always been responded to by integrating newer and evolving understandings as to what an illness is and what it is not. For instance, in 1952, homosexuality was listed as a "disorder". In 1973, it was removed from DSM II, in recognition of the understanding that homosexuality is not a disorder. In 2013, DSM 5 had no category based on sexual orientation.

DSM IV contained a "bereavement exclusion" which stated that depression should not be diagnosed if the depressive symptoms, lasting less than two months, occurred after the death of a loved one. This exclusion was dropped in DSM 5, which was seen by some as "medicalising normality" and serving the agenda of pharma companies, which would make more money if antidepressants were prescribed. DSM-5-TR now categorises "Prolonged grief disorder" as a medical condition, leading again to accusations of seeing something normal as abnormal [13]. While this is a legitimate concern, normalising mental illness is as unacceptable as medicalising normality, especially when there is suicidal risk and dysfunction [14]. As cognitive behaviour therapy would generally be the treatment of choice here rather than antidepressants, pharma would not particularly stand to benefit from this diagnosis.

There are other important implications to changes in DSM-5-TR. The criteria to diagnose autism have been tightened, which is arguably good and prevents overdiagnosis [15]. However, changes to ADHD's (attention deficit hyperactive disorder) criteria from DSM IV to DSM 5 raised concerns as it widened the scope of diagnosis, thereby looking as if this action would greatly benefit pharma. Some experts do feel the change in diagnostic criteria did not have a sound scientific base [16]. The concern was not just about influence from the pharma lobby, but from parents who felt their children had ADHD and needed easier access to medication [17]. Not every child with attentional difficulty has ADHD. Anxious parents are vulnerable to advertising, with FCOI extending even to patient advocacy groups [18].

Does the presence of the pharma–doctor relationship mean there is a bias?

In 1992, Sartorius rightly said, "A classification is a way of seeing the world at a point in time. …scientific progress and experience …will ultimately require their revision and updating" [19]. The impact of changes in DSM-5-TR on medication use probably varies from nil (autism), low (prolonged grief disorder) to high (ADHD). While the authors of DSM-5-TR have published the rationale behind the changes [15], there is a request for access to explanatory documents to better understand the thought process behind these changes [16], including a suggestion that the minutes of DSM meetings be published [20]. If concerns about pharma influence are needless, these documents should put speculation to rest.

DSM-5-TR is truly a mammoth team effort by around 200 experts. One would think that putting a group of eminent doctors together to bring out any consensus document, would usually ensure enough dissent to prevent bias. But as it is often said, it is not only important to do the right thing, but to be seen to do the right thing. The optics is about complying with the principle of transparency over opaqueness, about internal processes on such important matters. While there seems to have been an effort to base decisions on current scientific evidence, an accessible declaration of COI — financial, intellectual or personal — would have been useful for users of DSM-5-TR, not just for the in-house DSM/APA COI committees. This is in any case, standard practice in academic journal publications.

While it is technically correct that DSM-5-TR is not a treatment manual, it does inform treatment, towards which diagnosis is the first step. Allen Frances, the Chair of the DSM IV task force, cautioned about over diagnosis saying, "I despair the diagnostic inflation that results from a too loose diagnostic system, aggressive drug company marketing, careless assessment, and insurance company pressure to rush to judgement……", and that "Diagnostic inflation exists not just in psychiatry, but in every medical and surgical specialty." [21]

Is there a need for this degree of concern about pharma–academic association when even the loudest critics are stopping short of saying that existing FCOI has resulted in actual bias [2]? From a regulatory viewpoint, when looking at the potential impact of this relationship, there is need of a "prophylactic COI policy". Lexchin offers an analogy from environment protection policy, where it is stated that when there is a risk of serious or irreversible damage, one need not wait for scientific certainty to take protective action [22].

A request for even greater transparency needs to be responded to, or one risks allegations of "guild interests" [23], or conspiracy theories. Losing trust would be unfortunate, as when used correctly, psychiatric medication can greatly improve the functioning and quality of life, indeed at times be lifesaving.

Relevance to India

It is ICD-11 that is used in India and not DSM-5-TR, while there has been an effort at synchronisation between the two. To the best of my knowledge, there has been no discussion on COI related to ICD-11 or to clinical practice guidelines brought out in India.

While mental health professionals have been discussing issues around pharma influence in academic journals, FCOI occur in other medical and surgical specialties too [10]. In the US, the specialty which reportedly received the largest payments from the healthcare industry was orthopaedic surgery, and the product associated with the largest payment was surgical devices [24].

In India, it is the pharma–individual doctor relationship that has attracted attention. The Supreme Court of India stepped in two years ago to prevent a pharmaceutical company from claiming tax benefits on gifts to doctors. Justices Bhat and Lalit had pointed out that it was not a taxation issue, but a matter of public importance that a doctor's prescription can be influenced by these gifts, and that "…these freebies are technically not 'free'- as the cost of supplying these freebies is usually factored into the drug, driving prices up..." (In this case, the drug was a multivitamin supplement) [25]. The revised National Medical Council (NMC) Ethics guidelines addressed some aspects of the pharma–doctor relationship although concerns on important aspects like generic drug quality and safety remain [26]. However, even these guidelines have been put on hold [27].

On the issue of FCOI, it is not just the pharma-doctor relationship that is important, but the pharma–hospital relationship as well. The recent Uniform Code for Pharmaceutical Marketing Practices (UCPMP, 2024), while prohibiting gifts in "Relationship with health care professionals", does not discuss COI — financial or otherwise. Its section on free samples/brand reminders allows items like books/diaries up to a value if Rs 1,000/- as well as support of research and continuing medical education (CME) programmes [3]. While the UCPMP's recognition of the need to regulate pharma marketing practices is welcome, it needs to consider multi-stakeholder discussion on revisions to this Act. While the Act states that companies have to keep track of payments to doctors to enable audit, there is a need for an equivalent of the US Sunshine Act in India. FCOI needs to be recognised when there is an interaction with pharma for academic purposes, even with medical colleges or other bodies. Ultimately, there are academic ways, albeit more competitive, to avail money for scientific research through grant application processes; while online CMEs are cost effective. Another route by which pharma influence can percolate into clinical care is

through the use of company-provided software, so doctors would need to be alert to that too [28]. It is difficult to contort the fiduciary nature of a doctor–patient relationship into the business interest of a pharmaceutical company, irrespective of how much we try to rationalise the relationship.

One can ask why health professionals should discuss the ethics of taking a pen offered as a gift from pharma, when India has just published details of crores of rupees paid by pharma companies for electoral bonds. While the bonds issue is a cause for grave concern, it does highlight the importance of transparency [4,29]. We know that big or small financial gifts can manipulate a relationship, and it is the patient who ends up paying the price — both literally and figuratively. In the US, the scandal around Vioxx, used for pain in arthritis, showed how drug safety can be compromised if commercial COI exists between the Food and Drug Administration and pharma [30]. Managing real or perceived COI only by disclosure is ineffective [31]. The Indian Council of Medical Research and the NMC need to set up COI guidelines that go beyond merely stating the need for disclosure for transparency. There is a need for robust systems to manage COI and prevent bias by ensuring audit and independent review processes. This ensures better protection from biased opinion, as well as protecting valid opinions from claims of bias.

The personal qualities of the doctor like humility and modulation of self-interest remain central, as also integrity in clinical work and research [32,33]. A simple yet effective step to prevent harm due to these COI is to ensure awareness amongst healthcare professionals and students. While the risk of influence does exist, it is not inevitable, and doctors still have the choice to put their pen to the prescription, or not.

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