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An Operational Proposal for Addressing Conflict of Interest in the Psychiatric Field

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ABSTRACT

The issue of conflict of interest has brought clinical medicine to an unprecedented crisis of credibility. Corporate actions that have placed profit over public health have become regular news in the media. The public seems to be increasingly sceptical of the integrity of medical practice, including psychiatry. Clinicians are more and more disoriented because of the discrepancy between the campaigns to shape a favourable climate of opinion for new drugs and the disappointing results in practice. Attempts to control conflict of interests by simple disclosure have yielded very limited results.

A radical proposal for addressing the issue of conflict of interest in psychiatry and regaining credibility is advanced. It is based on the definition of "substantial" conflict of interest: being an employee of a private company; being a regular consultant or in the board of directors of a company; being a stockholder of a company related to the field of research; owning a patent directly related to the published work. Occasional consultancies, grants for performing investigations, or receiving honoraria or refunds in specific occasions would not be a source of substantial conflict of interest.

Psychiatric investigators who hold positions in scientific societies, medical journals (editorship), groups for guidelines and clinical matters, should be devoid of substantial conflict of interest. Disclosure is no longer sufficient for the independence of the psychiatric field.

Key Words: conflict of interest, ethics, disclosure, practice guidelines, psychiatry

The issue of conflict of interest has brought the credibility of psychiatry to an unprecedented crisis (Anonymous, 2008). The public seems to be increasingly skeptical of psychiatry, since corporate actions that have placed profit over public health have become regular news in the media (Anonymous, 2008; Fava, 2007). The dangers of psychiatry's complicity with big business

have been disclosed to the lay public in the media with a regular pace in the past two years. Conflict of interest undermines the credibility of papers which are submitted, their review process, and even the editorial decisions about acceptance or rejection (Jureidini & McHenry, 2009)

The reaction of the psychiatric establishment (scientific societies, academic centers, educational activities, journals) has been generally slow and inadequate. A typical example is provided by the American Psychiatric Association which has failed to endorse adequate changes in its highly criticized policies. A notable exception has been the World Psychiatric Association which has hosted an operational proposal (Fava, 2007) in a forum in its journal, with several discussants, such as David Healy (2007), Michael Thase (2007) and Paul and Tohen (2007), and whose current president has regarded conflict of interest as a major challenge (Maj, 2008).

The notion of conflict of interest is widely used but may entail different meanings. Margolis (1979) distinguishes between conflicting interests and conflicts of interest. The former occur in any situation where competing considerations are presumed to be legitimate. Conflicts of interest, on the other hand, are characterized by individual occupying dual roles which should not be performed simultaneously. Because of the potential for abuse, performing both roles at the same time is considered to be inappropriate. Which roles? For instance, being a researcher and holding a financial interest in an area related to the research one is involved in. Table 1 lists the main sources of conflict of interest.

I will describe some of the insights that research on conflict of interest has generated in medicine and psychiatry, and some strategies which may counteract this phenomenon (Fava, 2007; Fava, 2008).

Conflict of Interest In Psychiatry

Important insights have been gained in the past decade as to the importance of financial conflicts of interest in medicine. These findings may apply to the psychiatric field.

TABLE 1: MAIN SOURCES OF CONFLICT OF INTEREST IN PSYCHIATRY

Being a clinician/researcher and:

- an employee of a private company
- a stockholder
- a member of a company board of directors
- a regular consultant of a private company
- an occasional consultant of a private company
- an official speaker of a private company
- an occasional speaker of a private company
- getting refunds from a private company
- recipient of honoraria
- a clinical investigator in a sponsored trial
- recipient of research support from a private company
- owning a patent

Prevalence is very high

The first idea of the prevalence of situations of conflict of interest in scientific research came from a landmark study which appeared in the 1990s. Krimsky, Rothenberg, Stott & Kyle (1998) analyzed 789 articles written by authors from Massachusetts universities publishing in leading scientific journals in 1992. In one out of three cases, at least one author had a vested interest in research. Krimsky et al (1998) took a very conservative stand as to what constitutes a financial conflict of interest: owning a patent directly related to the published work; being a major stockholder or executive in a company with commercial interests tied to the research, or serving on the board of directors of such a company. The percentage of cases of conflict of interest would have greatly increased if consultancies and honoraria had been taken into account. The study clearly showed the extent of corporate presence in scientific publishing.

The same group of researchers addressed the issue of the financial ties with the pharmaceutical industry of the 170 DSM-IV panel members. 95 (56%) had one or more associations with companies (Cosgrove, Krimsky, Vijayaghavan & Schneider, 2006). The percentage reached 100% of the members of the panels on mood disorders and schizophrenia and was above 80% in anxiety and eating disorders.

Disclosure is seldom performed

Disclosure has emerged as a first and essential step for dealing with conflict of interest contamination in science. But, despite journals' policies, it is seldom performed (in less than 1% of medical articles according to a study by Krimsky (2001)).

Such disclosure often takes place in the media, instead of coming from the authors or scientific community. Such scandals have also involved psychiatric researchers. A recent one about an article on vagus nerve stimulation has led to the resignation of the lead author from the editorship of an important journal (Armstrong, 2006).

Scientific societies may be beholden to the drug industry

Glassman, Hunter, Hayer & Nakamura (1999) investigated whether revenues generated from pharmaceutical advertisements in medical journals create potential conflicts of interest for nonprofit physician organizations that own those journals. They found that financial conflict of interest were substantial, and some prestigious medical organizations, such as those underlying the *JAMA* and the *New England Journal of Medicine*, could be viewed as beholden to the drug industry.

Scientific societies may control medical journals and affect editorial policies and the selection of papers. Further, financial ties may also affect the scientific meetings of those societies. This is something anyone walking in a major society meeting may easily perceive. Not surprisingly, in a study of all exhibit booths of pharmaceutical companies at the 2002 American Psychiatric Association (APA) convention, a total of 16 violations of the APA's own exhibit rules has been found (Lurie, Tram, Wolfe & Goodman, 2005).

Authors of clinical practice guidelines are often linked to the pharmaceutical industry

Choudhry, Stelfox & Detsky (2002) examined authors of clinical practice guidelines endorsed by North American and European societies on common adult diseases. Eighty-seven percent of authors had some form of interaction with the pharmaceutical industry (58% had received financial support to perform research and 38% had served as employees or consultants for a pharmaceutical company). In published versions of the 44 clinical practice guidelines, specific declarations regarding the personal financial interactions of individual authors with the pharmaceutical industry were made in only two cases. Cosgrove, Bursztajn, Krimsky, Anaya & Walker (2009) have examined, by multimodal screening techniques, the degree and type of financial ties to the pharmaceutical industry held by authors of 3 Clinical Practice Guidelines of the American Psychiatric Association. Ninety percent of authors had financial ties to companies that manufacture drugs which are identified in the guidelines as recommended therapies. None of the financial associations were disclosed.

Attending drug sponsored scientific events is associated with an increased prescription of the sponsor's medication

A review (Wazana, 2000) has outlined how attending sponsored continuing medical education (CME) events and accepting funding for travel or lodging for educational symposia were associated with an increased prescription rate of the sponsor's medication. Attending presentations given by pharmaceutical representative speakers was also associated with nonrational prescribing.

Studies sponsored by pharmaceutical companies are more likely to have outcomes favorable to the sponsor

It has been repeatedly reported that studies sponsored by pharmaceutical companies are more likely to have outcomes favorable to the sponsor (Melander, Ahlquist-Rastad & Beermann, 2003). Industry sponsorship also results in restrictions on publication and data sharing and in selective reporting. Perlis, Perlis, Wu, Hwang, Josep & Nierenberg (2005) examined funding sources and authors' financial conflict of interest in clinical trials published in four leading American journals concerned with

psychiatry. Sixty percent were funded from a pharmaceutical industry, and conflict of interest was associated with a greater likelihood of reporting a drug to be superior to placebo. Further, Melander et al (2003) analyzed controlled studies of selective serotonin reuptake inhibitors and found that sponsored studies with favorable results were more often published than negative studies. A very good example of this selective publication is given by the scandal following the finding that a major pharmaceutical company allegedly withheld from the medical community clinical trial findings which indicated that a widely used antidepressant had no beneficial effect in treating adolescents (Kondro, 2004). Jureidini & McHenry (2009) have illustrated how selective reporting, publication bias and poor methodology may lead to unjustified conclusions in prescribing antidepressant drugs in children and adolescents. This casts serious doubts on the representativeness of the drug trials which are included in a meta-analysis. Further, even systematic reviews require careful critical appraisal. Conflict of interest may affect this appraisal. Evidence-based medicine thus may be a deceptive instrument of propaganda.

Ghostwriting has become increasingly common

Ghostwriting is an increasingly common practice which may involve up to 75% of papers concerned with drug trials (Sismondo, 2007). Jureidini & McHenry (2009) have illustrated the implications of this procedure for data presentation and marketing.

An Operational Proposal

A crucial problem lies in the lack of a definition of substantial conflict of interest. Are eating a pizza at a drug-sponsored lunch or being a regular consultant to a firm the same thing? Table 2 outlines some tentative criteria which are based on Krinsky et al's work (1998). The first two situations shown in the Table involve the concept of continuity of a relationship with a private firm. Indeed, occasional consultancies, grants for performing an investigation, or receiving honoraria or refunds in specific occasions would not be a source of substantial conflict of interest. For instance, if a researcher is a regular consultant to a pharmaceutical industry, he/she may be reluctant to endorse positions which may threaten a fixed source of income. A researcher who is involved only with a specific project (e.g., a drug trial) is less likely to be concerned about independent stands. The latter two situations depicted in Table 2 indicate major financial sources of bias.

Another issue is the fact that the problem of conflict of interest has been viewed so far mainly in negative terms: how to limit corporate influence in medical research. There has been little or no emphasis on the fact that the scientific community is draining itself of a reservoir of disinterested experts who can be called upon to advise government policy makers and physicians on the safety and efficacy of treatments, on the hazard of chemicals and on the safety of technology (Krinsky et al., 1998).

Yet, the experts who are free of conflict of interest may find increasing difficulties in obtaining appropriate visibility at meetings and in journals and in getting support for their research. It is not that disinterested experts are extinct: it is that they are marginalized by the gatekeepers of corporate interest within public institutions, scientific societies and medical journals (Fava, 2001).

TABLE 2: CRITERIA FOR THE PRESENCE OF SUBSTANTIAL CONFLICT OF INTEREST OF A RESEARCHER

The researcher meets at least one of the following:

1. Being an employee of a private firm
2. Being a regular consultant or in the board of directors of a firm
3. Being a stockholder of a firm related to the field of research
4. Owning a patent directly related to the published work

As a result, if we believe in the value of independent research and researchers and in the need of preserving and promoting this independence, we must endorse the steps which are outlined in Table 3 (Fava, 2007; Fava, 2008). These steps may appear to be radical and excessive, but are necessary for quickly re-establishing credibility. The idea that the problems which have been exposed in the lay press are only the result of lack of appropriate disclosure by individual researchers runs counter an increasing amount of findings pointing to loss of intellectual freedom by academic researchers and institutions (Fava, 2009). The operational feasibility of setting a threshold for substantial conflict of interest has been demonstrated by Krinsky, Rothemberg, Stott & Kyle (1998).

TABLE 3: LINES OF SUPPORT OF INDEPENDENT RESEARCHERS WHO ARE FREE OF SUBSTANTIAL CONFLICT OF INTEREST

1. Priority for obtaining grants from public agencies supported by taxpayer money
2. Priority for scientific societies and medical journals editorship positions
3. Adequate visibility in scientific societies meetings programs
4. Inclusion only of researchers with no substantial conflict of interest in clinical practice guidelines groups
5. Conflict-free investigations and reviews should be emphasized in training and continuing medical education and should have priority in medical journals.

If a grant agency committee, or a medical journal, or a scientific meeting committee does not include at least some experts with no substantial conflicts of interest, and particularly those who have none, it does not deserve credibility.

For certain positions (e.g. editor-in-chief of a medical journal), the situation should be evaluated on an individual basis. For instance, tie to a single firm, contrary to what is often assumed, allows an easy monitoring of an editor's job (he or she can be excluded from assessing papers dealing with products of that firm), whereas multiple forms of conflict of interest make this control impossible. At times advertising departments appear to influence editorial decisions in journals which advertise drugs or devices (Dyer, 2004). Such influence may be particularly strong if the editor is vulnerable because of his/her conflict of interest.

Information overload may be the key vehicle of selective information (Fava & Guidi, 2007). A psychiatrist may be overwhelmed by scientific articles, often of redundant nature. He or she may become aware of certain articles because of firms pointing to those, or because they appear in very well-known and

distributed journals. Yet this may be very misleading. Conflict-free articles (particularly review papers) and purely subscription-based journals should become the focus of attention of clinicians who have become educated to the issues of conflict of interest (Fava, 2007).

Only in this context, interventions aimed to getting a better control of conflict of interest may become successful (Table 4). While disclosure has become standard practice in North American meetings and journals, it is still poorly practiced in Europe. It should be emphasized that in psychiatry conflict of interest may arise not only when there are ties with the pharmaceutical industry, but also when the researchers, for instance, are involved in private schools for training in psychotherapy. Disclosure is the minimal requirement for scientific credibility. It should have a specific time frame (e.g., 3 years). When an endless list of financial ties is provided, it should be clear that it becomes virtually meaningless, unless the potential implications of such ties are described in a note.

TABLE 4: STEPS TO ADDRESSING FINANCIAL CONFLICT OF INTEREST IN MEDICAL RE-SEARCH

1. Disclosure should become the rule in all scientific meetings and journals
2. Each scientific organization should have a conflict of interest advisory committee
3. Individual members of societies and readers of medical journals should express their dissent from presentations and articles biased by conflict of interest
4. Specific policies for integrity in science by professional societies, universities, granting agencies, pharmaceutical companies
5. Independent review bodies (within each field) for examining the issues concerned with conflict of interest
6. Educational plan for recognizing conflict of interest and the role of treatment ingredients

Each scientific organization should have a conflict of interest advisory committee that represents different segments of the organization and that should be a referral point to individual members identifying possible conflicts of interest (Warner & Gluck, 2003). Scientific organizations may also request disengagement from corporations that abuse public trust (e.g., false advertising, regulatory fines etc.) and do not allow publications of scientific results. Individual members of a society, not unlike the alternative consumer, can also decline participation in specific meetings or society events, or refuse to pay the dues of the society, or write to the journal which was involved in a specific case of conflict of interest (and the letter should be published, whereas it is seldom done with the excuse of lack of space or by not having a dangerous letter section). Members attending a meeting of their association should be able to rate the quality and the influence of the pharmaceutical industry with appropriate evaluation forms and to manifest their dissent (electronic mail is a powerful instrument for it).

The development of specific policies for integrity of agencies and pharmaceutical industries are also important (Brennan, Rothman, Blank, Blumenthal, Chimonas, Cohen, Goldman, Kassirer, Kimbill, Naughton & Smelser, 2006).

Finally, professional training programs (e.g. medical school, residency training, etc.) should teach individuals to recognize conflict of interest situations and increase awareness of biased interpretations of research results and treatment ingredients (Dubovsky & Dubovsky, 2007).

Conclusions

The problem of conflict of interest in psychiatry does not appear to be different from other fields of clinical medicine. It can be addressed only by a complex effort on different levels, which cannot be postponed any longer. In fact, either clinical researchers become salespeople (and the main scope of many scientific meetings today is apparently to sell the participant to the sponsor) or they must set out boldly to protect the community from unnecessary risks (Fava, 2001). The increasing influence of pharmaceutical industry on psychiatric research and practice is lending to an intellectual and clinical crisis (Fava, 2006). A proper and brave handling of the issue of conflict of interest may foster an overdue renewal of the field (Fava, 2009).

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