Conflicts of interest and the credibility of psychiatric research

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The credibility of psychiatric research has been seriously compromised of late, undermined by both real and perceived – and some would argue all-too-pervasive – financial conflicts of interest (COI). Giovanni Fava underscores the seriousness of the problem, which he fully acknowledges is not unique to psychiatry but extends to virtually all fields of medicine. In fact, we believe the problem of financial (and other) COI could well erode the credibility of the entire enterprise of academic medicine, if not properly and promptly addressed. Financial COI are also not limited to pharmaceutical research and can occur wherever (and whenever) profit-seeking companies interact with either the academic-research or clinical care communities. We would also submit that financial COI are not the only COI that threaten the credibility of academic medicine. Indeed, most of the recently publicized and egregious cases of scientific misconduct and outright fraud have for the most part involved other (non-financial) forms of COI among academic investigators (1). Given the complexity and pervasiveness of the problem of COI in medicine, it seems unlikely that they can be completely eliminated, nor is a simple solution likely to be found. With respect to COI in psychiatric research, we offer the following brief commentary.

First, like Fava, we believe that full transparency, including full disclosure of any potential COI, is absolutely essential. We also concur that the problem with "full disclosure" is often defining (and then disclosing) what exactly constitutes a "substantial COI". Our experience suggests that for industry scientists such transparency is relatively straightforward but it is often much more obscure for those working in academia or government. For example, simply listing the existence of consulting relationships with industry for a given academic investigator (e.g., on scientific publications), as is now customary, is insufficient in our opinion to establish whether or not a substantial "financial" COI exists. The criteria listed by Fava for establishing a substantial COI

are a good start, but in our experience "the devil – i.e., the extent of such relationships – is always in the details". As suggested by Freedman et al (2), academia and the pharmaceutical industry need to set their ethical boundaries and standards. We propose that, in order to be embraced by industry and academic scientists worldwide, codes of conduct regarding research collaborations need to be further developed jointly and embraced at national levels by institutions such as the American College of Neuropsychopharmacology and globally by associations such as the WPA.

However, we emphasize that, beyond enhancing efforts to fully disclose and minimize potential COI, attempts to eliminate investigator bias, regardless of the source of funding, and to independently verify results of important studies become paramount. Rothman (3) has proposed that the value of the results should not be tainted by the affiliation or source of funding (nor by any other obvious non-financial COI), but rather assessed on the basis of the methodology employed. We do not argue that industry-funded research, nor publicly-funded research for that matter, is (or will ever be) completely free of bias, but that the solution is not to focus solely on the funding source or potential COI. More importantly, efforts should be directed at assuring that the research methodology employed is sufficiently robust to avoid such bias in the first place. In our extensive experience in conducting research in both industry and academia, we are impressed with the methodology and rigor employed to minimize investigator bias in most industry-sponsored clinical trials. We maintain that, contrary to the views of some, industry actually has a vested financial interest in generating valid, reliable and reproducible data on compounds either in development or on the market. Results from industry studies are thoroughly scrutinized by regulatory agencies around the world. Poor methodology will lead to non-approval of new products or indications with the obvious financial consequences.

We also believe that efforts to allow for independent verification of research results, from academia, industry or government studies, should be enhanced. For industry-sponsored clinical trials, regulatory agencies, such as the Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMEA), receive all relevant data on given compounds, and such data is often independently analyzed by these regulatory agencies prior to review and approval. More recently, companies such as ours (www.lillytrials.com) have created comprehensive clinical trial registries and websites where clinical trial data on all marketed products are routinely posted (www.clinicalstudyresults.org/home) and are readily accessible by the public. We also support, in principle, efforts to verify data prior to publication in peer-reviewed journals, but again would argue that such verification should occur irrespective of the funding source or potential COI.

So, like Fava, we too are concerned that the problem of financial (and other) COI, if not adequately addressed, may completely erode the credibility of psychiatric research and thus undermine the essential trust that patients have in their physicians and in the treatments they prescribe. We believe, however, that productive and meaningful collaborations between industry and academia (as well as with the clinical care/practice community) are not only possible but are absolutely essential for the development of new therapeutics in psychiatry. Better definitions of the nature of such collaborations, including their boundaries, are therefore desperately needed.

Disclaimer

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References

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