# Financial conflicts of interest in psychiatry

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*The issue of conflicts of interest has brought clinical medicine to an unprecedented crisis of credibility. The situation of psychiatry does not appear to be different from other areas of medicine. The problems caused by the increasing financial ties between the pharmaceutical industry and researchers and clinicians can be addressed only by a complex effort encompassing both the establishment of lines of support of independent researchers who are free of substantial conflicts of interest and better disclosure policies and conduct regulations as to financial ties. Such effort requires a bold shift from current, largely inadequate strategies. In the long run it may entail, however, substantial advantages to patients, clinicians, researchers, the health industry and the civil society at large. Psychiatry, in view of its humanistic and social roots, may lead this effort.*

**Key words:** Conflicts of interest, disclosure, psychotropic drugs, practice guidelines, psychiatry

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The proliferating connections between physicians and the pharmaceutical industry have brought the credibility of clinical medicine to an unprecedented crisis (1). The public seems to be increasingly skeptical of clinical medicine, since corporate actions that have placed profit over public health have become regular news in the media (2). Medical journals have been defined by a former editor as "an extension of the marketing arm of pharmaceutical companies" (3). The dangers of medicine's complicity with big business have been disclosed to the lay public in several books (4-7). In one of these books, John Abramson admirably unveils how propaganda has substituted research evidence in the medical field (7).

More and more voices from academic medicine are questioning the relationship between the pharmaceutical industry and the physicians (8). Conflicts of interest have thus become a major issue of concern in medicine, including psychiatry, and are getting more and more important for medical journals (9). They undermine the credibility of papers which are submitted, their review process, and even the editorial decisions about acceptance or rejection.

The notion of conflict of interest is widely used but may entail different meanings. Margolis (10) 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 conflicts of interest.

I will describe some of the insights that research on conflicts of interest has generated in medicine and psychiatry, and some strategies which may counteract this phenomenon.

## CONFLICTS OF INTEREST IN MEDICINE

In the past decade there has been a considerable amount of research, mostly in the US, on the issue of conflicts of interest in medicine. This research has yielded important insights into the dimensions and importance of the phenomenon. Special attention will be given to the psychiatric field.

**Table 1** Main sources of conflicts of interest in medicine

| Being a clinician/researcher and: |
|---|
| - an employee of a private firm |
| - a stockholder |
| - a member of a company board of directors |
| - a regular consultant of a private firm |
| - an occasional consultant of a private firm |
| - an official speaker of a private firm |
| - an occasional speaker of a private firm |
| - getting refunds from a private firm |
| - recipient of honoraria |
| - a clinical investigator in a sponsored trial |
| - recipient of research support from a private firm |
| - owing 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 et al (11) 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 (11) took a very conservative stand as to what constitutes a financial conflict of interest: owing 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. These results, however, were systematically downplayed by the scientific community, as exemplified by the

response of *Nature* to them (11).

The same group of researchers addressed the issue of the financial ties with the pharmaceutical industry of the 170 DSM-IV panel members. Ninty-five (56%) had one or more associations with companies (12). The percentage reached 100% among members of the panels on mood disorders and schizophrenia and was above 80% among members of the panels on anxiety and eating disorders (12).

It has been reported (8) that one of ten US physicians is currently engaged in a formal consultancy with investment industry. We should expect this proportion to be much higher in clinical research, including psychiatry, even though there may be differences from one field to another.

**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 (13)). Such disclosure often takes place in the media, instead of coming from the authors or scientific community. For instance, Zalewski (14) illustrates an impressive list of examples where the problem of conflict of interest was associated with important scientific and clinical issues. At times, conflicts of interest may undermine the credibility of scientific data, such as in the scandal over a study on a heart attack medication (tissue plasminogen activator, TPA) published in the *JAMA*, when a reporter from *Newsday* revealed that at least 13 researchers were long-term stockholders of the company manufacturing the drug.

Such scandals have also involved psychiatric researchers (4). A very 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 (15). It is worth mentioning that this scandal was not triggered by an investigative reporter, but by a member of the society which was linked to the journal.

It must be noted that, while disclosure has become standard practice in North American meetings and journals, it has not achieved wide currency in Europe.

**Scientific societies may be beholden to the drug industry**

Glassman et al (16) 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 conflicts 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. In an accompanying editorial, Lexchin (17) reported on the growing concern about the relationship between the World Health Organization (WHO) and the pharmaceutical industry. The WHO issued a set of guidelines for the diagnosis and management of essential hypertension in conjunction with the International Society of Hypertension. A letter signed by close to 900 physicians and scientists pointed out that the guidelines ignored ground rules of clinical assessment and placed an excessive weight on trials funded by the pharmaceutical companies. This casts serious doubts on the WHO, which has been accepting temporary substitutes of personnel from the pharmaceutical industry. As has been pointed out concerning the diagnosis of depression and the use of antidepressant drugs, the game is clear: to get as close as possible to universal consumption of a drug, either by stretching its indications (e.g., to include demoralization) or by encouraging its preventive use (18). 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.

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

Choudhry et al (19) 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 (19).

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

A review (20) 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. Wilkes (21) commented on the consequences of the interactions: "Physicians take gifts form drug companies and then spend patients' money to help make the same pharmaceutical industry the most profitable in the world. They recruit 'research' subjects without advising them of the personal financial gain that accrues to them.… All these behaviors are directly opposed to what patients and society expect from us in return for the privileges that have been bestowed". And, as the subtitle of the editorial indicates, when trust goes, so does the healing power of physicians.

### 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 (22-25). Industry sponsorship also results in restrictions on publication and data sharing (23) and in selective reporting (26). Perlis et al (25) examined funding sources and authors' financial conflicts of interest in clinical trials published in four leading American journals concerned with psychiatry. Sixty percent were funded by 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 (26) 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 (27). This casts serious doubts on the representativeness of the drug trials which are included in meta-analyses (28). Further, even systematic reviews require careful critical appraisal (29,30). Conflicts of interest may affect this appraisal. Evidence-based medicine may thus be a deceptive instrument of propaganda.

Heres at al (31) analyzed the sources of bias which may limit the validity of head-to-head comparison studies of second-generation antipsychotics, such as equivalent dosages, study entry criteria, statistical analysis, reporting of results and wording of findings.

### Often researchers do not own their data

Mello et al (32) explored the legal agreements that exist between industry sponsors and academic investigators. In 80% of institutions the sponsor may own the data and in 50% the sponsor may write up the results for publication. There have been many instances in the media about the struggles between clinical researchers and pharmaceutical companies as to the publication and analysis of data (14). In most of the instances investigators have been quite alone in their battles. In sponsored scientific presentations at meetings, it is a quite common practice that the slides of speakers are reviewed and approved by the sponsor.

### Independent investigators are a threat to special interest groups

There have been growing concerns about the independence of academic psychiatry (33). We are often led to believe that virtually all clinical investigators should have some ties with the pharmaceutical industry, even though this is not true (8). We are also led to believe that the advertising section of a major medical journal has nothing to do with the editorial section. There is evidence to call such view in question (34). Apparently, it is also possible to buy editorials (35).

When the percentage of investigators with conflicts of interest reaches 100% (as in DSM panels), this means that there is systematic exclusion of independent investigators. They may represent a threat to special interest groups, self-selecting academic oligarchies who are the gatekeepers of corporate interest in scientific information (36). Several examples are available to indicate the degree of retaliation that may be provided to outliers (36).

## WHAT CAN WE DO?

So far, the problem of conflicts of interest in medicine has been conceptualized in naïve terms. The scenario is pictured as the corporate industry (bad guys) exerting more and more pressure on physicians (helpless victims), with the medical journals (good guys) attempting to protect both the physicians and their patients. The inadequacy of this scenario is reflected by the pathetic outcomes of the efforts to limit the phenomenon. For instance, the *JAMA* rules for reporting industry-sponsored studies require that at least one author, who should not be a firm employee, takes full responsibility for the integrity of the data and that an independent biostatistician should perform or confirm data analysis (37). Does an academic researcher loaded with conflict of interest provide more trust than a firm employee? I believe the contrary is true. Similarly, registration of trials and tougher standard for disclosure are certainly welcome (38), but comprehensive disclosure could not restore public trust as wished.

A crucial problem lies in the lack of a definition of substantial conflict of interest. Are eating a pizza at a drug-sponsored lunch and being a regular consultant to a firm the same thing? Table 2 outlines some tentative criteria which are based on Krimsky et al's work (11). The first two situations shown in the Table 2 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. The latter two situations depicted in the Table 2 indicate major financial sources of bias.

Another issue is that the problem of conflicts 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 poli-

**Table 2** Criteria for the presence of substantial conflict of interest of a researcher

| The researcher meets at least one of the following: |
|---|
| - Being an employee of a private firm |
| - Being a regular consultant or in the board of directors of a firm |
| - Being a stockholder of a firm related to the field of research |
| - Owing a patent directly related to the published work |

cy makers and physicians on the safety and efficacy of treatments, on the hazard of chemicals and on the safety of technology (4). Do we believe that researchers who opted for not having any form of conflict of interest and, by doing this, gave up financial gains, are of special value? Or do we believe that their opinion is in no way different from that of researchers with substantial conflicts of interest and that they are simply a pathetic remnant of the past century? Is the pharmaceutical industry interested in researchers who may cooperate with marketing, as most of the academic physicians who are involved with them now do, or are they interested in independent and critical minds? Not surprisingly, innovative and groundbreaking development of new drugs by the pharmaceutical industry has been extremely disappointing in the past few years (5).

Yet, the experts who are free of conflicts 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.

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 should endorse the steps which are outlined in Table 3. If a grant agency committee, or a medical journal, or a scientific meeting committee does not include 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 (39). Such influence may be particularly strong if the editor is vulnerable because of his/her conflict of interest.

Information overload is the key vehicle of pharmaceutical propaganda (40). 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 issue of conflicts of interest (40).

Only in this context, interventions aimed to getting a better control of conflicts 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 conflicts 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.

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 (41). Scientific organizations may also request disengagement from corporations that abuse public trust (e.g., false advertising, regulatory fines) and do not allow publication of scientific results (42). Individual members of a society can also decline participation in specific meetings or society events (43), 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 this 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 is also important. The American College of Cardiology Foundation and the American Heart Associ-

**Table 3** Lines of support to independent researchers who are free of substantial conflicts of interest

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

**Table 4** Steps to addressing financial conflicts of interest in medical research

- Disclosure should become the rule in all scientific meetings and journals
- Each scientific organization should have a conflict of interest advisory committee
- Individual members of societies and readers of medical journals should express their dissent from presentations and articles biased by conflict of interest
- Specific policies for integrity in science by professional societies, universities, granting agencies, pharmaceutical companies
- Independent review bodies (within each field) for examining the issues concerning conflicts of interest
- Educational plans for recognizing conflicts of interest

ation's report on professionalism and ethics (44) may inspire psychiatric associations to take similar steps.

The creation of independent review bodies (within each field) for examining the issues concerning conflicts of interest would be another important step. Such bodies might provide peer support to struggling authors or editors, well beyond the generic, if not ridiculous, encouragement to register unpublished research (45). Further, these bodies may become an important reference to consumers' associations, which so far have not fully realized the importance of addressing the issue of conflicts of interest. A notable exception is represented by the brave battle of a British consumers' association for the recognition of withdrawal reactions following use of benzodiazepines (46) and second-generation antidepressants (47). We should realize that public research money is often invested for the benefit of special interest groups instead of addressing key public health issues.

Finally, professional training programs (e.g., medical school, residency training, etc.) should teach individuals to recognize conflict of interest situations (41) and increase awareness of biased interpretations of research results (28).

## CONCLUSIONS

The problem of conflicts 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 aim 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 (36). By choosing the latter course, they should be aware that they will also be defending their own intellectual freedom (48). Psychiatry, in view of its humanistic and social roots, may lead this effort.


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# Conflicting interests and doing right

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Although Giovanni Fava's title is "Financial conflicts of interest in psychiatry", the definition he gives is a more general one, which I like: "conflicts of interest… are characterized by individual occupying dual roles which should not be performed simultaneously". And he asks which roles these are. In answer, he focuses exclusively upon all those that academics may play for pharmaceutical companies. He could have added roles with a voluntary organization, a charity, a law firm, a department of government, an investment company or any other formally constituted body with interests in the field of psychiatry. But it is part of the current Zeitgeist that pharmaceutical companies are particularly demonized (1).

Is there a current problem? Unfortunately, I must accept that there is. Do some individuals in academia abuse their position in exchange for fees from companies, for example, by putting their names on articles they have scarcely read, let alone written? I am sure some do and it is wrong. Is the influence of industry on medical prescribing excessive? Yes. At present we have far more spent on continuing medical education by companies than by anyone else. But that also represents a failure of healthcare systems funded by governments. Are some roles incompatible one with another? Obviously so: one cannot personally buy and sell shares in a specific company and claim not to have an interest in its success; advising regulatory bodies is an activity that largely precludes working with industry. But the majority of research academics do not, or certainly need not occupy roles that are incompatible with involvement with industry, and many that are most critical of such contact may have problems of an analogous kind, that they do not have to declare.

To understand why I say this, let us explore a more general definition of conflict of interest – in other words the positions, allegiances or interests that shape the people we are and the decisions that we reach. Some of the most compromising allegiances may be less quantifiable than the fees received from a pharmaceutical company.

Such issues provide part of the reason this debate seems to have become so vitriolic in psychiatry. I believe it taps into a more profound disagreement about the status of drug treatment per se, for what we still call in English "mental disorder". I do not know Giovanni Fava personally, but, from reading his published papers, I would not be surprised if he believes, as I know many social psychiatrists do, that drugs ultimately do not work, or anyway do not work very well, and that psychotherapy or social interventions are superior, or anyway preferable. This is often associated in my experience with a high-minded view that social factors cause or exacerbate mental illness and that ultimate solutions lie in a better society, rather than better medicines. My own position is more or less the opposite of this: I see medicines as holding a primary role for significantly improving the chances that an individual patient may recover from severe psychiatric disorder. I accept the value of pragmatic psychotherapies, but, while drug-placebo differences seem to be magnified by illness severity, psychotherapies tend to look less effective as illness severity increases. Finally, I am pessimistic about social solutions to personal problems. If I have asthma, I want an inhaler: I can complain about the air quality later.

There is a more explicitly political argument, which is also close to the surface in the current controversy. Is the making of money on the back of drug development and sales somehow immoral? It is part of a more general political critique of capitalism, whereof Winston Churchill once remarked: "The inherent vice of capitalism is the unequal sharing of blessings; the inherent virtue of socialism is the equal sharing of miseries". Those of us who want to see an improvement in the efficacy, tolerability and use of medicines are bound to accept the capitalism of pharmaceutical companies. Innovation may start in academia, but it can only be delivered by companies. Along with that come marketing, consultancy, and hype, and the countervailing forces of government regulation, attention seeking whistle blowers, newspaper-puffed scandals, etc. It is untidy, but it is how a free society works. In my opinion, my patients have benefited directly and significantly from the new medicines licensed in the last 20 years. And there is no doubt, either, that the first generation drugs were a major breakthrough at the beginning of the psychopharmacological era. They were also no doubt a major source of profit to the companies that made them. However, drug companies are for the most part public companies. In other words, we may all benefit through the employment they create, the taxes they pay and the pension funds that invest in them. Further, they spend much more on medical research than any other sector of the economy.

Can we improve the current state of affairs? I agree with Giovanni Fava that the USA is ahead of Europe in relation to policies of disclosure, and that transparency is a minimum essential safeguard. Journal editors need to be vigilant, and learned societies need to decide what the ethos of their meetings is to be and get the balance right: the atmosphere in some is embarrassingly commercial. But to seek to sterilize academic activity from the pharmaceutical industry is to deny a key link between academic innovation and actual delivery of a product to the consumer. There has to be a relationship if we want any more new compounds. And it is a real further concern that, if we protest too much, psychiatry may come to seem not worth the bother.

Finally, while I applaud Giovanni Fava's focus on individual responsibility, I am not convinced that a narrow obsession with what he refers to as un-

necessary risks offers clinical research any kind of intellectual freedom at all. Intellectual freedom comes from a training that instils independence of mind, a sceptical approach to evidence and a taste for the truth. These are classical virtues. I see nothing that should prevent their display in one's relationship with pharmaceutical companies.

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# One flew over the conflict of interest nest

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Giovanni Fava has given us an excellent analysis of the development of crisis about commercial conflicts of interest in psychiatry. But there are some grounds to think the entire subject is something of a red herring, or that Fava's position is itself industry-friendly.

If we view the issues from the frame of the past 400 years, and consider where science has come from, then it is clear that a key triumph of the new branch of knowledge lay not just in any of the so often celebrated breakthroughs in physics, chemistry or biology, but rather in the fact that society had found a means to move knowledge forward that overcame the issue of conflicting interests. If they adhered to the scientific method, then the fact that scientists might be Catholic, Protestant, Hindu, Muslim, Jew or atheist was irrelevant.

Aside from these powerful social prejudices, several studies of the scientific process suggest that individual scientists are all but insane. Many of our most famous scientists can be seen to have pursued their goals obsessively and with a conviction that must have appeared to many contemporaries as close to delusional.

But the scientific method, which involved a new emphasis on observable and replicable data, has provided us with a way to overcome both social prejudice and individual idiosyncrasy (1). The success of science lies in the fact of its being a communal and empirical process rather than a process whose success depends on the motives of individual practitioners. It is against this background that *Nature* and other journals cited by Giovanni Fava have been slow to respond to the new proposals for statements of conflicts of interest. Why would scientists in general expect relatively small amounts of money given to a few individuals to undo a system that has tamed far more powerful inner demons than this?

Reframed in this way, the fact that there is an undoubted crisis at present suggests that focussing on conflicting interests as the origin of this crisis may be mistaken. Another option is that the apparent studies and related reviews that are at the centre of this crisis are in fact not scientific – they are a cuckoo's egg in the nest of science. And indeed a key feature of the clinical trial reports and review articles that Fava makes reference to is that they do not conform to the central tenet of science which is to engage with issues that are replicable and/or to make the data publicly available.

The current problem for any aspect of medical science involving therapeutics with agents that are on patent is that a significant proportion of trials now remain unpublished and those that are published are often ghostwritten and bear an ambiguous relationship with the underlying data (2). Company postings of trials on the internet do little to mitigate this problem. The difficulties are best symbolised by the case of the pediatric trials of selective serotonin reuptake inhibitors, where we have the greatest known divide in medicine between the raw data on an issue on the one side and the published accounts purporting to represent those data on the other. The data can now be seen to indicate that the drugs do not convincingly work and are hazardous, but prior to the release of the data the scientific literature universally portrayed these agents as safe and effective (3). This divide, it is important to note, only came to light as a result of the efforts of journalists and lawyers. It came to light not because they chased the question of conflicting interests but because it seemed obvious to lay people that the data did not add up. To our shame, no clinician or scientist had a hand in questioning the validity of the "science". What lessons can be drawn from this situation?

If companies want to market their product under the banner of science, they can be required to conform to the norms of science. This will require journal editors and academic meeting organizers to refuse publication to articles or presentations on data not freely accessible. Taking a stand like this will challenge the conflicts of journal editors and meeting organizers, but this rather than conflict of interest declarations from individual academic authors or speakers is much more likely to have teeth.

Ghost writers are in fact much more likely to insert conflict of interest declarations into articles or lecture slides

in a manner that conforms to journal or meeting protocols than are academics. If I were employed in a company marketing department I would much prefer to have the field think that all that is wrong is that a few corrupt academics fail to declare competing interests than to have the field think that company practices that restrict access to data while still claiming the moral high ground of science are the real source of the problem.

### Disclosure

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# Psychiatry: from interest in conflicts to conflicts of interest


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There was a time when psychiatry was largely influenced by the view that most mental conditions were the result of unsolved inner conflicts. That was a time when the availability of effective drugs for psychiatric disorders was extremely limited, and access to mental health care was also restricted to the very wealthy or to very sick patients, who would be confined in institutions for the mentally ill for long periods of time, and kept apart from society. The emergence of psychopharmacology rapidly changed this panorama, but it has carried novel challenges, not only for clinical practice, education and research, but also for doctor-patient relationships. These changes go in parallel with those of modern societies, increasing the distance between developed and struggling countries, and raise further ethical concerns. This is why I believe that the debate on conflicts of interest, particularly for the financial ones, is difficult to separate from ideology/politics, and this is why I think that we should take a global approach to it. Hence, as Giovanni Fava rightly points out, clinical medicine and psychiatry are suffering from an unprecedented crisis of credibility, and this has more to do, in my opinion, with increased awareness about this issue rather than with decreased ethical standards or malpractice. Our society is increasingly aware of potential conflicts of interest and this is good for transparency, although one of my arguments will be that some conflicts are more visible than others and, to be fair, our responsibility as clinicians, educators or researchers is to disclose all of them, regardless of their nature. At the end of the day, having a potential conflict of interest is not the same as being necessarily biased or corrupt. Psychiatry has taught that avoiding conflicts is not generally the right way to solve them.

The increasing skepticism about drug development, clinical trials, and publications goes in parallel with the popular view on pharmaceutical industry, which is far from unbiased. It has been reported that people see pharmaceutical companies as business corporations with low ethical standards such as the arms industry. The paradox is that never in history there were as many regulations, constraints and supervision of drug development, approval, and marketing strategies as nowadays. Hence, this climate comes up from mistakes made by several agents in this drama: the pharmaceutical industry, of course, but also opinion leaders, medical journals, regulatory bodies, politicians, and even clinicians. The raise of evidence-based medicine may also be partly responsible, because evidence is only available for questions receiving funding, and most of the funding comes from companies expecting refunds from their investments. Some of us believe that this would be fair as far as strict regulations and public funding are able to counteract against the risk of relying almost exclusively on company-sponsored evidence-based medicine. Otherwise, evidence-base may become evidence-bias.

Bias may come from two main sources: biases in trial design, and biases in results dissemination. Trial design biases are easier to counteract: for instance, regulatory bodies as the Food and Drug Administration (FDA) in the United States or the European Agency for the Evaluation of Medicinal Products (EMEA) in Europe have set their own trial design guidelines for marketing approval (1,2). This strategy

has been successful to avoid marketing of potentially ineffective or unsafe drugs via sophisticated designs or statistical analyses. However, those trials have characteristically high internal validity but poor external validity (3), providing little information about the use and effectiveness of a given drug in clinical practice. Non-regulatory trials, on the other hand, may be more generalizable, but are commonly biased in favour of the novel (expensive) drug. Examples of trial design biases include false non-inferiority designs, enriched designs, underpowered comparator samples, unfair comparator doses, inclusion of patients who are non-responsive to the comparator, unfair rescue medication rules, and "creative" outcome measures favouring the drug of choice. Biases in results dissemination are more difficult to ascertain. The most well-known one is publication bias: positive trials are published while the negative ones remain forever as "data on file", or at most they are presented at a small meeting as a poster or shown at a website in a very concise format. Conversely, positive trials are re-analysed, subanalysed, and repeatedly published and presented at scientific meetings. Publishing negative trials and making that information available to society is not only the responsibility of pharmaceutical companies, but also of researchers and opinion leaders, particularly those who sit on companies' advisory boards and have access to privileged information. Confidentiality rules apply to matters that may have to do with competitive research, but if the companies do not put their negative data in the public domain within a reasonable time period, the rights of the patients who voluntarily participated in those trials are being broken. Other sources of bias not as evident as selective publication include unbalanced presentations, which are especially common at but not exclusive of standalone meetings or satellite symposia: exclusion of the comparator arm in placebo-controlled trials, emphasis on certain (favourable) secondary measures, minimization of adverse events, and many more; again, not only the industry but also academics and speakers should avoid this kind of pseudoscience, and ideally clinicians should be able to identify and criticize those who promote it. Unfortunately, in most countries the only source of continuing medical education (CME) is the pharmaceutical industry, so, even when there are no biases as those mentioned so far, the focus of the meetings is rarely free of indirect or direct financial interest. Here, national governments and scientific societies also have their responsibility. In Europe, CME credits are not well implemented and this carries higher risk of unbalanced meeting programmes and poor attendance to scientific sessions. Finally, the issue of treatment guidelines deserves further discussion: while recusal of experts with potential conflicts of interest would leave them practically orphan of any expertise, the fact is that the evidence-bias discussed above, which has more to do with the dearth of independently sponsored trials than with the potential interests of the advisors, makes them often more supportive to newly marketed drugs than to cheap, old compounds (4,5), such as lithium, which has been decreasingly prescribed in many countries despite the evidence that it is effective and may have unique antisuicidal properties (6,7). Boyd and Bero (8) have recently reviewed the management of conflicts of interest in guidelines development and they recommend a standard policy requiring all financial ties to be made public in advance.

Everything that we discussed so far suggests that something should be done to increase the integrity and credibility of pharmaceutical companies, journals, meetings, authors, and presenters. Fava is right when he says that disclosure is simply the minimal requirement for scientific credibility. Systematic feedback is another advisable practice: I think that every scientific meeting should provide feedback forms including a specific score for scientific balance for every presentation. Scientific societies and editorial boards should have a conflicts of interest advisory committee to discuss the feedback provided by meeting attendees and readers (9). I do not think, though, that we should make the mistake of considering potential conflicts of interest as something necessarily bad. Having a potential conflict of interest does not mean at all that whatever that person says or writes is biased; excluding highly respected academics from editorial boards or meetings just because they have a potential conflict of interest would lead to the total fall of clinical research, with enormous impact on the number and quality of new drugs becoming available for the treatment of most conditions, including mental disorders. Consistently, most research subjects and patients understand and accept conflicts of interest (10) and some of them actually encourage them as far as they may carry benefit for the people (11). The best experts in certain conditions have generally multiple potential conflicts of interest, but at the end of the day what makes them attractive for patients, clinicians, trainees, governments and pharmaceutical companies is their credibility, and credibility is hard to achieve and easy to lose. At the end of the day, conflicts of interest are not always a bad thing: they correlate with interaction between public and private health care providers, and some of us believe that the best health care system is neither purely public nor purely private, but every effort should be made to ensure that the interest of a few does not go over the interest of society, the integrity of clinical research, and the progress of medicine.

Some potential sources of conflicts of interest do not seem to be as popular or scandalous as the ones that come up from the marketing of pharmaceutical companies, even though they may be an important source of bias in education and clinical practice. First of all, not all conflicts of interest are of financial nature; in fact, a very oppositional attitude towards the pharmaceutical business may carry political or professional benefits; others have actually made a lot of money with books reporting "drug compa-

nies malpractice". Finally, some financial conflicts of interest that are rarely disclosed are the ones belonging to the public health care sponsors: the government, the local authorities, and the hospital managers, whose interest is generally to avoid spending money on the most expensive drugs. In several countries, physicians get supplementary income if they are able to save money from the pharmaceutical expense; in certain hospitals, expensive drugs are not provided even though they have an approved indication; and in the editorial arena, some government-sponsored publications show a bias against new expensive drugs which is only comparable to the bias of company advertisements in favour of their drug.

In conclusion, I would agree with Fava that medicine and psychiatry's credibility is in crisis. But, at the end of the day, I do not think that there is such thing as somebody free of conflicts of interest. Conflicts are dimensional, not dichotomous, and they may have ideologic, financial, social, or academic nature, but they always carry the risk of biasing the information. Moreover, readers and clinicians are not just clueless, passive receptors of information, and there is plenty of examples of highly promoted drugs that were not successful at all once prescribers noticed that they would not solve their patients' problems. But we need to hear their voice in this regard. To increase the credibility of psychiatry, I would improve the tools to get actual and honest feedback from meeting attendees and journal readers, I would implement a true and effective CME credits policy, I would encourage governments and scientific societies to promote independent clinical trials, and I would request all journals in Medline and scientific meetings to include a full disclosure of financial and non-financial potential conflicts of interest at the beginning of every presentation or article. Credibility, as mental health, is not a matter of absence of conflicts, but a matter of overcoming them.


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# On the propriety of collaborations between academicians and the pharmaceutical industry: an alternate viewpoint


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Giovanni Fava convincingly summarizes the many reasons why the relationships between the for-profit industries and academicians – as well as physicians more generally – are very serious matters and may adversely affect both society's confidence in the medical profession and the integrity of the evidence base that helps to guide selection of treatments. As my own experiences are those of an academician who does several different kinds of work with the pharmaceutical industry, I will generally limit my comments to this area.

After decades of denial and minimization, there are now sufficient data

on the impact of unmanaged conflicts of interest to justify the conclusion that speaking for, advising/consulting, and doing research with pharmaceutical industry can influence opinion leaders' evaluations of the industry's products. Most often the nature of this effect is a positive bias, which can result in overvaluation of a treatment's strengths and underappreciation of that therapy's limitations. The net result of such bias could be overly favorable presentations at scientific meetings and/or insufficiently critical interpretation of results or conclusions in manuscripts, which ultimately could result in greater use of that treatment and higher profits for the manufacturer.

Fava has correctly pointed to a number of notorious cases involving purportedly unreported conflicts of interest that have been an embarrassment to the broader academic community, with several recent cases specifically involving psychiatry. Although the initial public presentations of these "scandals" often did not fairly reflect the facts of the cases, there is the growing public perception that all collaborations between academicians and the pharmaceutical industry are unseemly and, at best, suspect. For these reasons and more, academicians must examine their relations with the pharmaceutical industry with much greater scrutiny than ever before, and think much more carefully about the potential for conflicts of interest and strategies to manage such conflicts.

Before turning to our more specific areas of agreement and disagreement, it is important to clarify that the pharmaceutical industry is a heavily regulated business, which does produce medications that can save lives and reduce human suffering; few of our currently used psychiatric medications have been developed by alternate (i.e., governmental, academic, or not-for-profit) agencies. When practicing within accepted ethical guidelines, it is not inherently a conflict of interest for an academician to earn income from working with a drug company. Such financial relationships do have the *potential* to cause conflicts of interest, however, and as such they must either be avoided (as suggested by Fava) or properly managed (the approach that I recommend)

One factor that complicates debates such as this is that "accepted ethical guidelines" for managing potential conflicts of interest are continually changing. Thus, when the standards of today are applied to work completed a decade ago, it should be no surprise that a large proportion of academicians appear to fall short of the standard. And, no doubt, the same will be true when the standards of 2017 are applied to work performed today.

I fully agree with Fava that effective management of the potential for conflicts of interest represents one of the major challenges facing academic medicine in the 21st century. Moreover, I feel strongly that we must come to terms with these issues in order for collaborations between academicians and industry to continue, which I believe offers the best opportunities for development of improved therapeutics. As I have written about previously (1,2), however, the pharmaceutical industry is not a monolithic evil and, despite being in business to earn profits for stockholders, all of the companies and the vast majority of people who work in the pharmaceutical business want to develop – and sell – new and improved products that really do help humanity. And, although it is true that new (patent-protected) medications are too expensive for many people and a large proportion of publicly funded health care agencies, it is also true that – without first introducing these new drugs "on patent" – there would be no newer generation generic medications after patents expire.

As is often the case in polemical papers, Fava focuses on the negative side of this issue and does not give proper credit to the legitimate contributions of the pharmaceutical industry to improved public health and the potential benefits that can result from academic-industry collaborations (e.g., improved research designs, research on pharmacogenomics, development of biomarkers, etc.), if the potential for conflicts of interest is properly managed. Although I share Fava's disdain for the practice of selective publication (i.e., suppression of "negative" studies), I do not think that it is fair to describe as pathetic the industry's efforts to create study registries and to make all data from all relevant trials available for meta-analysis. Nor do I view the potential benefits of longer-term antidepressants for patients with highly recurrent forms of depression to be "propaganda".

Giovanni Fava also largely fails to deal with the potentially deleterious effects that noncontractual or uncompensated conflicting interests can have on "scientific" matters, such as those related to different schools of thought, sociopolitical positions, interpersonal rivalries, or even spiritual, religious, or quasi-religious beliefs, which are virtually never acknowledged and also have shown to have potential negative effects on both professional relations and the design, interpretation, presentation, and publication of research results. As one example, it should be recognized that academicians who strongly believe that the pharmaceutical industry conducts shoddy research often provide negatively biased evaluations of industry-sponsored studies.

With respect to management of potential conflicts of interest, who in 2007 can argue against full disclosure and transparency? To take such an untenable position would reflect both ignorance of the data and insensitivity to the issues involving public trust. In fact, in order to avoid even the appearance of trying to conceal ties with industry, I (along with most colleagues that I know who do work with the pharmaceutical industry) have begun to report all financial relationships in all manuscripts, regardless of relevance of the paper to the pharmaceutical industry.

I also agree with Fava that expert consensus panels should include individuals (clinicians, researchers, and patients and their family members) with no industry ties, although I disagree with the notion that individuals with such ties should be systematically excluded. Parenthetically, the fact that 100% of the DSM-IV panelists for mood disorders and schizophrenia had some industry relationships reflects the ubiquity of these relationships in the

1990s, not the systematic exclusion of those without such ties.

As one of the so-called gatekeepers at the industry sponsored symposia at the American Psychiatric Association's annual meetings, I can report that there is no pressure whatsoever to pick faculty from a select "oligarchy" of colleagues who work with industry (we are, in fact, strongly encouraged to recruit a very diverse faculty for these presentations). Our other continuing medical education (CME) talks are independently reviewed to ensure a lack of commercial bias and, unless the talk is explicitly promotional (i.e., clearly labeled as such), the rules are clear: industry representatives must keep their hands off the material. Although I am not immune to commercial bias, I am fairly certain that I have a greater risk of unrecognized bias when presenting work that I have performed and findings that are consistent with my clinical beliefs. Consistent with this view, although it is true that industry sponsorship does have an effect on study outcome (e.g., 3,4), it is also true that – in work not sponsored by the pharmaceutical industry – much larger effects have been associated with an investigator's allegiance to particular models of psychotherapy (5).

With respect to advising and consulting, I cannot see how the public health could be benefited by mandates that prevent the pharmaceutical industry from utilizing the input of experts. At one point, Fava wonders out loud: wouldn't the pharmaceutical industry want to hear the opinion of someone – like himself – with an unbiased opinion? I am sure that they would and often do. But, given Fava's stated position, wouldn't he have to decline the invitation or, if he accepted it, wouldn't he no longer qualify as an unbiased advisor?

I likewise disagree with the merits of prioritizing governmental research funding for investigators with no industry ties. Could a system that arbitrarily excludes some of the best and brightest scientists actually result in better science? In this case, the remedy may be much worse than the malady.

I admire the stand taken by Fava, as well as his disciplined adherence to a personal code of conduct that eschews industry support. There are legitimate differences of opinion here and I would not be surprised if our disagreements herein might be mirrored by similar differences in sociopolitical world views. I am glad that there is such a diversity of opinion on this matter and remain optimistic that the dialogue between those who are and are not interested in working with industry will lead to better ways of managing the very real potential for conflicts of interest and ultimately will result in better treatments for our patients.

### Disclosure

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# Staying true to mission


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I am probably not the only reader who responded with defensiveness and irritation to the strident tone of Giovanni Fava's commentary. Nevertheless, when my higher cortical functions returned, I found myself in substantial agreement with his concerns. We face a wave of public mistrust that has not yet crested. In truth, ethical breeches have occurred. The integrity of psychiatry and all of medicine requires that we take bold, earnest, prompt steps to remedy this.

I approach this issue as a physician and psychiatrist, a university professor and department head, an editor, and a teacher. As my declaration of interest statement will reveal, I have also consulted to many pharmaceutical manufacturers. I chair the work group revising the American Psychiatric Association's guidelines for the treatment of major depressive disorder. Thus, all aspects of this multifaceted issue come alive within my own consciousness.

To make informed decisions, one must be able to gather sufficient data to inform those decisions. This applies to clinical choices made by patients and clinicians. If an author, scientist, speaker, or guideline writer has an agenda other than to inform and educate, as

Giovanni Fava notes, a serious ethical breech is likely.

In a world of infinite resources, it would be comparatively easy to heal this lesion. All scientists and scholars could have access to neutral resources, i.e., funding without "strings". When asked to render opinions on matters of public health importance, this untainted brain trust could opine from a position of objective altruism.

In today's real world, however, with constrained resources and imperfect systems of oversight, we need iterative steps to earn the public's trust. Immediate solutions are transparency and proportionality. Journals, including the one I edit, are broadening the definitions for interests that must be declared by authors and reviewers. Journals are entertaining consequences for failures to disclose. Universities may be informed of ethical breeches, and journals will be reluctant to accept future submissions from offenders. At the very least, this growing transparency will allow consumers (including medical and lay readers) to make more informed decisions based on the source of information and potential biases.

Proportionality is another important component. Because the pool of expertise is limited in most areas of medicine, including psychiatry, the government, professional organizations, and private industry turn to the same pool of experts to serve as consultants. Many of us function in this manner and provide input in multiple settings. In screening members to serve on its work groups on practice guidelines, the American Psychiatric Association establishes *de minimis* standards in which the proportion of a scholar's income is examined to assess magnitude of possible influence. Thus, a small proportion of a professor's income that comes from consulting to multiple sources is less likely to have a major hold on that scholar's opinion than if 50% of one's income comes from a single source. To pick up one of Giovanni Fava's examples, a pizza is less likely to influence opinion than a mansion on the Riviera.

The same issue of proportionality holds true of organizations. The American College of Neuropsychopharmacology has recently elected to "tighten its belt" by spending less on its annual meetings, thereby reducing its dependence on industry funding. This is a conscious and value-based decision to diminish both the perception and the actuality of industry influence.

As physicians and scientists, our esteem in society is based on the public's trust. That trust is eroding, and we must take immediate and serious steps to earn it back.

**Disclosure**

The author has been a consultant for Eli Lilly, Pfizer, Best Practice, Astra Zeneca, Wyeth, Cyberonics, Novartis and Forest. He owns stock options in Vela Pharmaceuticals. He is editor of the *Journal of Clinical Psychiatry*.

# Conflicting views on conflicts of interest in medicine

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I would like to divide my commentary on Giovanni Fava's paper into two parts. Firstly, I will discuss style and tone and secondly content.

As scientists – and Fava, I am sure, fits this category – we should be guided by the principle *sine ira et studio*. At least the former is not adhered to in Fava's remarks. I understand that he has a strong opinion regarding the issue of conflicts of interest, but I feel that a more balanced and less affectively charged manuscript would have helped his cause more. Merely repeating accusations and unfounded insinuations, which have been unfairly generalized to the whole field in the past, will only jeopardize a rational discussion of the problem. Consequently, those of us, and I trust we are many, who believe that the field needs to actively tackle the issue, will be taken aback and disengage from discussing the matter. As I firmly believe that we need this discussion, from both the perspectives of scientific ethics and integrity and of the distorted public view of it, I find the style and tone of Fava's comments regrettable.

The 1850 edition of the Webster Dictionary defines conflict of interest as "a conflict between private interests and official responsibilities of a person in a position of trust" (I believe this was cited by Ira Glick at the 2006 Meeting of the American College of Neuropsychopharmacology). This nicely outlines the point that I would like to make in the following, namely that the issue goes way beyond financial interests, although most of the public discussion, especially in the lay media, has focused on these. All of us face conflicts of interest regularly in our professional lives. For instance, we may see a manuscript sent to us for review in a more favourable light if it approvingly cites our own work. When writing up scientific papers, we may be more eager to report data which support our hypotheses than those who do not. As journal editors, we could be more willing to accept a manuscript which is likely to drive up the impact factor of the journal. As conference organisers, we may put more emphasis on topics which suit our own interests. As librarians, given the choice to spend the rest of the library budget on a book on the same topic written by a friend or by a stranger, we may favour our friend's

book. As clinicians, deciding among drugs of similar efficacy and safety profile, we may recommend the one that the company representative has just left a package of, and so on.

These few examples dealing with various aspects of a clinician/scientist's job represent an incomplete list of everyday challenges to our work ethics. Many of them are much more subtle than financial conflicts of interest, but yet of at least comparable relevance. In addition, monitoring these types of conflicts is considerably more difficult than the tracking of financial relationships, which may be one of the reasons why the latter have become much more the focus of the debate.

The field is charged with a challenge that, I believe, must be targeted from within the scientific community. While declarations of financial conflicts of interests on publications, during scientific meeting, etc. help to enhance transparency, all the other potential conflicts call for additional measures. I am convinced that the concept of peer review, if taken really seriously, can be the strongest force in this struggle. Peer review can function as a continuous self-monitoring instrument. We have to revive the skill of reading between the lines of manuscripts we are reviewing and point out potential conflicts of interests to editors, who need to make such remarks part of their decision process. Journal editors should explicitly ask their reviewers to look at manuscripts under this aspect, just as they require to judge the ethical standards of studies under review. (As a bynote, open access publishing and open peer review will not make the task easier). Similar rules should apply to the grant review process and to program committees of scientific meetings. Conflicts of interest have to be identified in such settings and individuals affected by them must be excused from the decision process.

Some international societies have already established committees to provide guidance regarding these matters. Again, the scope must go beyond the relationships between scientists and the pharmaceutical industry. Clearly, such rules should not be buried in the minutes of the relevant committees, but actively communicated to the field and the public. Societies should not only set up rules but also suggest means to oversee compliance with these standards. Let us not leave this important business to self-appointed watchdogs, but assume a leading role ourselves, as a strong responsibility of and for our field.

At the 2006 meeting of the American College of Neuropsychopharmacology, David Braff stated that "conflict of interest is the entry of wrongdoing not wrongdoing in itself", and I would submit that we all need to be sitting near the entryway to make sure that nobody harms the field by crossing the line.

### Disclosure

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# 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

The authors are solely responsible for the content of this commentary, which should not be considered as an official position of Eli Lilly and Company.

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# A counter proposal to manage financial conflicts of interest in academic psychiatry


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As stated by Giovanni Fava, the issue of financial conflicts of interest in medicine, and in psychiatry in particular, has strained the credibility of academic researchers in the eyes of the public as well as fellow physicians. Fava documents legitimate criticisms leveled against the pharmaceutical industry. He suggests that part of the solution is to establish a system to support a group of experts who are free of financial conflicts of interest and who can act as arbiters of truth and can evaluate available evidence with a dispassionate and objective eye. These groups can then produce conflict-free reviews and advise other groups (governments, hospitals, other physicians) who make financial and policy deci-

sions about risks and benefits of psychiatric treatments.

Fava's proposals have substantial merit. It would be ideal to have some system to support objective physician researchers who could provide the services outlined. And his call for training in recognizing the effects of conflicts of interest and potential bias is reasonable. But, ultimately, the solution outlined may not serve the public as well as he suggests. In some ways, the problem of conflicts of interest brings up the business of medicine and the pharmaceutical industry. Is the capitalistic system that focuses on profit good or bad for patients? Is the pharmaceutical industry focus on marketing – and the explicit or implicit cooperation of experts in marketing – the actual culprit as opposed to academicians' financial conflicts of interest? If experts are to have relationships with industry, what type of relationship between expert clinical researchers and pharmaceutical companies would serve patients best? Can drug development be improved with the input of experts or would drug development be better served by excluding those experts in order to manage financial conflicts of interest? I will make the case that a mutually beneficial relationship between experts and industry, with clear ethical rules, can help patients, and that excluding experts from this process may impede drug development. I will also argue that non-financial conflicts of interest are just as important as financial ones and these, too, need to be understood and managed.

I write this commentary as one who has evolved from rejecting any industry influence on practice (I rejected the offer of a free stethoscope from Eli Lilly during medical school) to someone who has collaborated with the pharmaceutical industry whenever I felt that it would eventually benefit patients. I believe that my relationships with industry are mutually beneficial and I value my relationships with the companies that produce the medications that help my patients. I also believe that, without the capitalistic for-profit motive of the pharmaceutical industry, we would not have any innovative treatments. Few, if any, treatments have arisen from government alone or from non-industry sources.

At their best, pharmaceutical companies want to make a profit by helping patients and want to help patients while making a profit so that they can afford to make new treatments and repeat the cycle. At their worst, pharmaceutical companies market medication through direct and physician advertising and continuing medical education (CME) symposia that act as hidden (or not so hidden) marketing. I worry that we have abrogated our responsibility for our ongoing post-graduate education and, instead, we have deferred to industry to fund it. This type of pseudo-education is justly criticized by Fava. I fear that there is a dearth of independently funded CME or at least CME that, if funded by industry, includes a firewall that separates it from marketing. One such CME with a firewall has been launched by the Massachusetts General Hospital Psychiatry Academy (www.mghcme.org). Within the site, interested readers can find the integrity policy and statement, view some of the content, and make a decision about the effectiveness of the firewall. Several pharmaceutical companies fund the Academy, but none have any input into content or speakers. But, relevant to this commentary, is it a conflict of interest for me to include the Academy website? While I teach for the Academy, I get no additional revenue from writing about it here. Nor will I get invited to give more talks for the Academy because it is listed here. The results of any study or any review that I publish have no bearing on my invitation to teach.

Would drug development be helped by excluding some experts from participating in industry-academic relationships and, in effect, serve as industry watchdogs? I think not. Industry needs the perspective of those physicians who best know the disorders of interest. Which relationships constitute an acceptable conflict of interest and which are unacceptable? Giovanni Fava outlines a reasonable set of criteria to define sources of financial conflict of interest, but it is less clear which of these will lead academics to be unacceptably biased such that they will minimize risks and magnify benefits of drugs. A more challenging question is "What would constitute an ethically acceptable, mutually beneficial relationship between academics and industry?". I propose that such a relationship be guided by ethical behavior that ultimately helps patients and avoids any harm.

I am not so sure that developing panels of independent researchers/academics that are completely free of relationships with industry will solve the problems so well outlined by Giovanni Fava. His solution may veer to the other side by assembling a group that has a negative bias against industry and innovation – without any way to disclose, manage, or check this. His proposal to have professional training programs and the recognition of conflicts of interest can, however, be practical and should be implemented. Such training in critical thinking about any evidence and the detection of any bias, no matter its source, should be an integral part of any training program.

Finally, non-financial conflicts of interest can also contaminate research and produce unacceptable biases. These non-financial conflicts of interest include advancing one's career, academic promotion, achieving success, attracting non-industry funding, pride, status, power, fame, prestige, recognition, and a desire to avoid impeding the progress of research (through membership in institutional review boards) (1-3). Foster warns us that "we are expected to have a dominant commitment to serving others, rather than to personal gain" (2). Yet, he also outlines the varieties of activities that can lead physicians astray, since their most human of motivations will still respond to reward and he acknowledges that the "tension between altruism and self-interest is unavoidable". Korn further warns: "Those who propose new remedies to deal with financial conflicts of interest in aca-

demic biomedical research should take care that in their zeal to recreate an idealized state of virtue in which financial conflicts of interest no longer exist, they do not interdict a developmental pathway of immense social benefit" (3).

That a group of experts free of financial conflicts of interest would be free of non-financial conflicts of interest is probably unrealistic. That academic researchers can strive to achieve the highest levels of ethical behavior in their dealings with industry and attempt to minimize bias may be equally unrealistic, but should be the goal. Perhaps the solution to the problem of conflicts of interest is somewhere in the middle between Fava's stance and the one I have outlined here: partial support of experts from impartial financial sources and peer oversight of activities which have even the appearance of bias due to conflict of interest.

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# What is the impact of financial conflicts of interest on the development of psychiatry?


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In recent years the relationship between drug companies and psychiatry has received an increasing attention from physicians, scientists and the media. Some authors support the notion that this relationship is having a negative influence on clinical practice and medical education, threatening the objective and independent development of mental sciences. According to this position, psychiatrists should avoid or minimize the interaction with pharmaceutical companies (1,2). On the other hand, some professional leaders have suggested that a substantive relationship between doctors and the drug industry is necessary and beneficial, and that any commercial influence mediated via this relationship does not harm significantly the future of psychiatry (3,4).

In the last couple of years, serious doubts have been raised about the reliability of drug trials. In a study by Perlis et al (5) on 162 randomized, double-blind, placebo-controlled trials, those involving potential conflicts of interest were 4.9 times more likely to report positive results; this association was significant only in the subset of pharmaceutical industry-funded studies. Concerns have been also expressed about the promotional tactics used by the industry to display the results of these studies. The medical research community has tried to address the problem by proposing measures like the introduction of a clinical trial registry. However, several studies have shown that these measures are insufficient and a more radical reform of the clinical trials regulation is needed.

Conflicts of interest have also been reported in the elaboration of clinical guidelines and the definition of diagnostic entities and classifications. It has been reported that a substantial percentage of the DSM-IV panel members had a financial tie with the pharmaceutical industry (6). With regard to clinical guidelines, a recent comparison of meta-analyses concluded that "industry supported reviews of drugs should be read with caution as they were less transparent, had few reservations about methodological limitations of the included trials, and had more favorable conclusions than the corresponding Cochrane reviews" (7). An important scientific journal has recently introduced the concept of "corporate-sponsored disease", suggesting that pharmaceutical companies, with the collaboration of physicians, are increasing the number of prescriptions of certain psychotropic agents by mongering diseases (8).

According to some sources, at least 10% of the physicians in Europe and the US have close relationships to pharmaceutical companies (9). In Latin America this percentage may be even higher. In the last decade, international pharmaceutical companies have created close links to local private research managing organizations in order to run multicenter drug trials with local investigators. In most of the cases the institutions sponsoring these trials are the owners of the data.

In Chile, the main medical scientific societies have proposed formal guidelines for a better control of conflicts of interest (10). However, the limited awareness of the problem and the marketing strategies designed by the industry do not help in this attempt,

and the practice of disclosure has not achieved wide currency. A worldwide collaboration between international organizations like the WPA and the World Health Organization with their national or local counterparts is strongly recommended in this area.

As Helmchen pointed out (11), one of the premises of a psychiatric intervention is the trust of the patient in his therapist, in his knowledge and scientific background. Our patients cannot lose this confidence. Otherwise, the role of psychiatry, as we know it, is going to disappear. An international effort of the psychiatric community to redefine its relationship with the pharmaceutical industry is urgently needed.

Drug companies can be of considerable benefit for the development of our profession, but only if we learn to manage this collaboration without commitments and dependencies, considering our ethical foundations and respecting the interest of our patients over any other form of interest.

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