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Tripartite Conflicts of Interest and High Stakes Patent Extensions in the DSM-5

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Conflict of interest · Mental disorders · Clinical trials · Drug therapy · Diagnostic and Statistical Manual of Mental Disorders

Abstract
Background: The revision process for and recent publication of the DSM-5 initiated debates about the widening of diagnostic boundaries. The pharmaceutical industry had a major financial stake in the outcome of these debates. This study examines the three-part relationship among DSM panel members, principal investigators (PIs) of clinical trials for new DSM-5 diagnoses, and drug companies. ***Methods:*** Financial conflicts of interest (FCOI) of DSM panel members responsible for some new diagnoses in the DSM-5 and PIs of clinical trials for related drug treatments were identified. Trials were found by searching ClinicalTrials.gov. Patent and revenue information about these drugs was found using the US Food and Drug Administration's Orange Book and manufacturer Annual Reports. ***Results:*** Thirteen trials met inclusion criteria (testing drugs for some new DSM disorders). Sixty-one percent of the DSM Task Force members and 27% of Work Group members reported FCOI to the trial drug manufacturers. In 5 of the 13 trials (38%), PIs reported ties other than research funding to the drug manufacturer. In 3 of the trials (23%), a PI had financial ties to the drug manufacturer and was also a DSM panel member who had decision-making authority over the revision process. ***Conclusions:*** These findings suggest that increased transparency (e.g., registration on ClinicalTrials.gov) and mandatory disclosure policies (e.g., the American Psychiatric Association's disclosure policy for DSM-5 panel members) alone may not be robust enough strategies to prevent the appearance of bias in both the DSM revision process as well as clinical decisions about appropriate interventions for DSM disorders.

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Previous research documented the financial ties between the panel members for the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) and the drug companies that manufacture the medications used to treat the disorders identified in this manual [1]. To its credit, the American Psychiatric Association (APA) instituted a conflict of interest policy requiring all panel members on the DSM-5 to file financial disclosure statements. This policy resulted in some changes in work group composition; compared to DSM-IV some DSM-5 work groups had fewer individuals with industry ties. Elsewhere we reported [2] that this new APA requirement rendered the DSM's disclosure policy more congruent with

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most leading medical journals and federal policies on financial conflicts of interest (FCOI). DSM panel members were required to list any FCOI for 3 years prior to their appointment on the DSM, and they could not accept more than USD 10,000 from industry (e.g., for consultancies) per year or hold more than USD 50,000 in stock in a pharmaceutical company during their tenure on the DSM [2].

Although APA's increased transparency was an important step forward in restoring public trust, the revision process for (and recent publication of) the DSM-5 ignited debates about the taxonomy of mental illness and the widening of diagnostic boundaries. The fact that the pharmaceutical industry had a major financial stake in the outcome of these debates raised additional concerns. Thus, the issue of trustworthiness in the revision process is a critical one. In 2010, the APA issued an official policy document, approved by the Board of Trustees, in which the APA leadership stated that:

> We affirm our support of the Institute of Medicine report [*Conflict of Interest in Medical Research, Education, and Practice*]. Members involved in clinical practice, education, research, and administration must be diligent and aware in identifying, minimizing, and appropriately managing secondary (personal) interests (financial, contractual, career-centered) that may inhibit, distract, or unduly influence their judgment or behavior in a manner that detracts from or subordinates the primary interest of patients and may be perceived by some as undermining public trust [3].

Clearly, the perception of trustworthiness in relation to FCOI is critical in the medical field, especially in terms of maintaining confidence in professional judgment. Harvard philosopher Dennis Thompson's work in this area has been highly influential (see e.g., the 1993 decision made by *The New England Journal of Medicine* to develop an FCOI policy), and he emphasizes the fact that the conflict is not an indictment of wrongdoing but rather points to a generic risk: 'The point is to minimize or eliminate circumstances that would cause reasonable persons to suspect that professional judgment has been improperly influenced, whether or not it has' [4]. Congruent with both the APA's and Thompson's concern that FCOI may undermine public trust, we investigated how FCOI function in these new diagnostic categories during this period of transparency.

The DSM-5, which was published in May 2013 [5], introduced new or revised diagnoses such as Binge Eating Disorder, Autism Spectrum Disorder, Disruptive Mood Dysregulation Disorder in children, Mild Neurocognitive Disorder, and Premenstrual Dysphoric Disorder. In addition to the newly included diagnoses, one of the most controversial revisions in the DSM-5 is the elimination of the bereavement exclusion from the diagnostic criteria for a Major Depressive Episode. With this change, individuals who are actively grieving a loss may be diagnosed with Major Depressive Disorder (if they present with symptoms of depression 2 weeks after the loss). Some clinicians maintain that this change is a positive one in that now individuals who are actively grieving a loss may receive the diagnosis and treatment that they need. Others have argued that people who are going through the normal process of grieving would now be diagnosed with depression.

Indeed, pharmaceutical companies were already operating clinical trials of drugs that could be used to treat new DSM-5 disorders before the publication of the manual in May 2013. Certainly, these companies have a fiduciary responsibility to serve their shareholders' interests by working to increase their shareholder value. Although questions of potential bias may be raised with any treatment modality, if the heavy emphasis on the use of psychotropic medications to treat new DSM-5 disorders is linked to the financial interests of APA panel members and researchers who test the safety and efficacy of drugs, then the objectivity of scientific findings will be questioned. The purpose behind federal and professional conflict of interest rules is to reduce the probability of bias entering into the decision-making process [see e.g., 6].

In fact, concerns about preventing bias and producing high-quality science led the Institute of Medicine to recommend that only independent experts (i.e., individuals without commercial ties) be involved in clinical guideline decision-making [7]. Questions about the potential for bias when making judgments about the validity of new DSM disorders, and about what interventions should be developed to treat these conditions, are rendered even more salient when drugs being investigated as treatments for them are under patents that have expired or will soon expire. Without patent protection, companies lose considerable profit to generics, providing a strong incentive to find new indications that will effectively grant extended patent protection to a drug. In light of this incentive, it is critical that researchers charged with the responsibility of making decisions about psychiatric diagnosis and treatment do not have FCOIs that could increase the probability or appearance of bias in clinical decision-making. Overdiagnosis in the mental health field can have significant adverse public health consequences because it leads to unnecessary drug treatment [8]. This is the first study that investigates FCOIs with ongoing clinical trials, showing the three-part relationship among DSM panel members, principal investigators (PIs) of clinical trials for new DSM-5 diagnoses, and drug companies.

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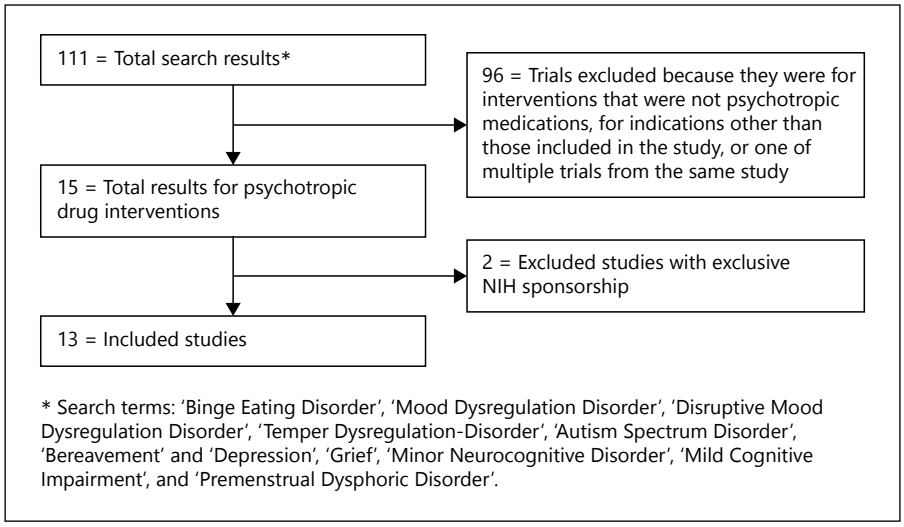

Fig. 1. Results from searching ClinicalTrials.gov.

Methods

We examined the FCOI of DSM panel members responsible for decisions about the inclusion of five new DSM disorders and one major revision (elimination of the bereavement exclusion for Major Depressive Disorder) and the pharmaceutical companies conducting clinical trials for drugs to treat these new disorders. We also examined the FCOI of PIs for the clinical trials of treatments for these newly included disorders, whereby FCOI is defined in this study as financial associations with the manufacturers of trial medications. Congruent with previous research [1, 2, 9–11], financial associations are defined in our study as consultancies, honoraria, speakers bureau membership, expert testimony, research funding, and stock holdings.

The disorders investigated were: Bereavement-Related Depression, Binge Eating Disorder, Disruptive Mood Dysregulation Disorder, Autism Spectrum Disorder, Mild Neurocognitive Disorder, and Premenstrual Dysphoric Disorder. These disorders were selected because of the questions raised regarding their validity [12–15], concerns that these diagnoses lack specificity and will result in unnecessary diagnostic inflation [16], and documented problems with reliability [14, 17].

We searched ClinicalTrials.gov for the six disorders of interest (fig. 1). Because previous research has found that industry-affiliated clinical trials are more vulnerable to bias than government-funded ones [11], we excluded trials that were exclusively funded by one of the National Institutes of Health (NIH). It is possible that receiving NIH or National Institute of Mental Health funding also presents a conflict of interest (financial and/or intellectual), although probably a much subtler one. There are ties between NIH-funded investigators and grant reviewers and possibly DSM panel members. However, these ties are not the focus of our study. Industry sponsorship of the trials was identified by the sponsors and collaborators listed on the trial page. Manufacturers of the drugs and patent status information were identified using the US Food and Drug Administration's (FDA) Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm).

There are two main groups who serve on the DSM and are charged with decision-making authority: Task Force members and Work Groups. Task Force members provide oversight for the entire manual, and Work Group members are teams of individuals who review a specific diagnostic category (e.g., Eating Disorders). Following previous research, we use 'panel members' to refer collectively to both Work Group and Task Force members included in the study. Posted disclosure statements from the DSM-5 website for the included members of the DSM panel were reviewed to identify: (1) financial ties to pharmaceutical companies, and (2) any DSM panel member who was also a PI for one of the clinical trials. Members of the DSM-5 Work Groups that were responsible for the five new disorders and one major revision included in the search (e.g., Eating Disorders Work Group for Binge Eating Disorder) were screened for FCOI using their posted disclosure statements on the DSM-5 website (www.dsm5.org), accessed between March 15, 2013 and March 25, 2013. Because of their importance in clinical decision-making, all DSM-5 Task Force members were also screened for FCOI. Task Force members, who include Work Group chairs, played a critical role in the revision process by shaping the panel through nomination of other Work Group members, contribution to the draft criteria, and review of the final revisions to the draft before its final approval.

Additionally, we conducted Internet searches to determine if PIs of the clinical trials had financial associations to manufacturers of trial drugs. Internet searches were conducted for sources published 3 years prior to the start of the clinical trial, a time period congruent with published research on FCOIs and consistent with the APA's own FCOI policy. Searches included ProPublica, peer-reviewed articles, conferences, participation in continuing medical education events (i.e., courses and/or seminars for health professionals), and self-reporting of any industry ties following interviews with the media. Internet searchers were also conducted for speakers bureau participation of DSM panel members because speakers bureau membership was not an identified FCOI category in the DSM-5 disclosures. Speakers bureau participation was included in our analysis only when there was unambiguous information.

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Table 1. Summary of included trial drugs, patent expiration dates, and 2012 revenue

	Trial indication	Trial drug	Trial sponsors and collaborators	Trial drug company	Compound patent expiration date	Global revenue in 2012 (in millions)
1	Bereavement-related depression	duloxetine hydrochloride (Cymbalta)	Eli Lilly Jefferson Clinic, P.C.	Eli Lilly	December 2013	USD 4,990
2	Complicated grief	citalopram hydrobromide (Celexa)	New York State Psychiatric Institute National Institute of Mental Health	Forest	expired	unavailable[1]
3	Binge eating disorder	armodafinil (Nuvigil)	Cephalon Lindner Center for HOPE University of Cincinnati	Cephalon	June 2024	USD 347
4	Binge eating disorder	duloxetine hydrochloride (Cymbalta)	Eli Lilly University of Cincinnati	Eli Lilly	December 2013	USD 4,990
5	Binge eating disorder	lamotrigine (Lamictal)	GlaxoSmithKline Lindner Center for HOPE University of Cincinnati	Glaxo-SmithKline	expired	USD 937
6	Binge eating disorder	lisdexamfetamine dimesylate (Vyvanse)	Shire	Shire	June 2023	USD 1,030
7	Autism spectrum disorder	arbaclofen (STX209)	Seaside	Seaside	unpatented	Not yet marketed for sale
8	Autism spectrum disorder	methylphenidate (Daytrana)	University of Oklahoma	Noven	September 2018	unavailable[2]
9	Severe mood dysregulation	lisdexamfetamine dimesylate (Vyvanse)	Shire University of California Los Angeles National Institute of Mental Health	Shire	June 2023	USD 1,030
10	Severe mood dysregulation	risperidone (Risperdal)	Federal University of Rio Grande do Sul	Janssen	expired	USD 1,425
11	Premenstrual dysphoric disorder	paroxetine hydrochloride (Paxil)	Hamilton Health Science Corporation	Glaxo-SmithKline	expired	USD 571
12	Mild cognitive impairment	donepezil hydrochloride (Aricept)	North China Pharmaceutical Group Corporation	Eisai	expired	USD 1,480
13	Mild cognitive impairment	galantamine hydrobromide (Razadyne)	Johnson & Johnson	Janssen	expired	unavailable[3]

[1] Revenue for individual drug not found. USD 3,694 million reflects total revenue for all Forest Pharmaceuticals central nervous system drugs. [2] Revenue for individual drug not found. USD 71 million reflects 2009 revenue data from Shire Pharmaceuticals, which held licensing rights until between 2003 August 2010. Total 2012 sales of all products for Noven Pharmaceutical's parent company, Hisamitsu Pharmaceutical Co., were USD 1,707 million. [3] Revenue for individual drug not found. USD 2,874 million reflects total revenue for all Johnson & Johnson neuroscience drugs except for Concerta, Invega, and Invega Sustena.

Results

Thirteen clinical trials met inclusion criteria. These clinical trials were designed to investigate 10 patented drugs and one investigational new drug. Nine of these trials were testing 'blockbuster' drugs with patents that had expired or would expire in the next 2 years. Table 1 provides a summary of trial drugs, their patent status, and their 2012 revenue (obtained from the drug manufacturers' 2012 annual reports). The trial drug manufacturer was one of the sponsors or collaborators for 8 of the 13 trials (62%).

Financial Ties between DSM Panels and Drug Manufacturers

Of the 55 Work Group members, 15 (27%) reported at least one FCOI to a trial drug manufacturer, while 19 of 31 (61%) of the Task Force members similarly reported at least one FCOI to a trial drug manufacturer.

In 3 of the 13 trials (23%), a DSM panel member reported speakers bureau participation (i.e., company X sponsored a clinical trial for a new indication and a panel member responsible for decisions about inclusion of the new disorder served on the speakers bureau of company X).

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Table 2. Summary of FCOI among the included DSM panel members by trial

Trial	New DSM-5 diagnosis	Trial drug manufacturer	Work group	Work group FCOI to any pharmaceutical company	Work group FCOI to trial drug manufacturer	Task force FCOI to any company	Task force FCOI to pharmaceutical trial drug manufacturer
1	Major depressive episode, bereavement exclusion eliminated	Eli Lilly	Mood Disorders	8/12	5/12	20/31	15/31
2	Major depressive episode, bereavement exclusion eliminated	Forest	Mood Disorders	8/12	1/12	20/31	5/31
3	Binge eating disorder	Cephalon	Eating Disorders	6/12	0/12	20/31	2/31
4	Binge eating disorder	Eli Lilly	Eating Disorders	6/12	3/12	20/31	15/31
5	Binge eating disorder	GlaxoSmithKline	Eating Disorders	6/12	3/12	20/31	5/31
6	Binge eating disorder	Shire	Eating Disorders	6/12	1/12	20/31	1/31
7	Autism spectrum disorder	Seaside	Neurodevelopmental Disorders	5/13	2/13	20/31	1/31
8	Autism spectrum disorder	Noven	Neurodevelopmental Disorders	5/13	0/13	20/31	0/31
9	Disruptive mood dysregulation disorder	Shire	Child and Adolescent Disorders	0/10	0/10	20/31	1/31
10	Disruptive mood dysregulation disorder	Janssen	Child and Adolescent Disorders	0/10	0/10	20/31	5/31
11	Premenstrual dysphoric disorder	GlaxoSmithKline	Mood Disorders	8/12	2/12	20/31	5/31
12	Mild neurocognitive disorder	Eisai	Neurocognitive Disorders	7/8	2/8	20/31	1/31
13	Mild neurocognitive disorder	Janssen	Neurocognitive Disorders	7/8	3/8	20/31	5/31

There were three instances in which DSM panel members were also PIs (i.e., an individual was both a DSM panel member responsible for making decisions about including a new disorder and a PI for a trial for a drug to treat the new disorder); each of these 3 panel members reported an FCOI to the trial drug manufacturer (see table 2 for a summary of DSM panel member FCOI data by trial).

Financial Ties between PIs of Clinical Trials and Trial Drug Manufacturers

In 5 (38%) out of 13 trials, at least one of the trial PIs reported an FCOI other than research grant funding to the trial drug manufacturer (i.e., in addition to the pharmaceutical company sponsoring the trial, the PI reported an additional FCOI to the company).

Because some of these 13 clinical trials had more than one PI, and one individual was a PI on multiple trials, there were a total of 41 PIs. Twelve out of the 41 (29%) PIs reported research funding from the trial drug manufacturer and 8 (20%) had ties other than grant funding to the trial drug manufacturer, including 3 PIs that reported participating on the speakers bureau for the company (see table 3 for a summary of the PI FCOI data by trial).

Discussion

In all but 1 trial, FCOIs were found between DSM-5 panel members and the pharmaceutical companies that manufactured the drugs that were being tested for the new DSM disorders. The financial associations of panel members included research grants, consultation, honoraria, speakers bureau participation, and/or stock. Seven out of the 10 patented drugs included in the trials either are currently or have been blockbusters for their manufacturers. (A blockbuster drug is defined as a drug that

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Table 3. Summary of FCOI data among trial PIs by trial

Trial	New DSM-5 diagnosis	Trial drug manufacturer	PI FCOI to any pharmaceutical company	PI research funding to trial drug manufacturer	PI all other FCOI to trial drug manufacturer
1	Major Depressive Episode, bereavement exclusion eliminated	Eli Lilly	0/1	0/1	0/1
2	Major Depressive Episode, bereavement exclusion eliminated	Forest	5/5	3/5	2/5
3	Binge Eating Disorder	Cephalon	1/2	0/2	0/2
4	Binge Eating Disorder	Eli Lilly	1/1	1/1	0/1
5	Binge Eating Disorder	GlaxoSmithKline	1/1	0/1	0/1
6	Binge Eating Disorder	Shire	17/21	4/21	3/21
7	Autism Spectrum Disorder	Seaside	5/8	3/8	1/8
8	Autism Spectrum Disorder	Noven	0/1	0/1	0/1
9	Disruptive Mood Dysregulation Disorder	Shire	1/1	1/1	1/1
10	Disruptive Mood Dysregulation Disorder	Janssen	1/1	0/1	1/1
11	Premenstrual Dysphoric Disorder	GlaxoSmithKline	0/0	0/0	0/0
12	Mild Neurocognitive Disorder	Eisai	0/1	0/1	0/1
13	Mild Neurocognitive Disorder	Janssen	0/0	0/0	0/0

earns over USD 1 billion in revenue in 1 year [see e.g., 18].) Our data show that there are financial ties between some DSM panel members and pharmaceutical companies that have a vested interest in finding a new indication for their drugs. A new indication allows the drug manufacturer to obtain an additional 3 years of exclusivity for that drug. Pharmaceutical companies have used 'exclusivity' as an informal mechanism to effectively extend patent protection for that time period [19]. However, it should be emphasized that trials examining off-label indications conducted after a patent has expired are not necessarily meant to obtain a secondary indication.

The fact that in 3 out of 13 (23%) of the trials the PIs were also DSM panel members raises questions about the potential of such multivested interests for implicit bias when making decisions about inclusion of new DSM disorders and their respective treatments. These questions are pressing in light of the fact that there are no biological markers for the majority of psychiatric disorders; the use of subjective discretion to widen diagnostic boundaries becomes more likely when there are no biological tests to ground clinical decision-making.

For example, Binge Eating Disorder may be diagnosed in individuals who do not have Anorexia or Bulimia Nervosa and who have the following three 'symptoms' one time per week for 3 months: (1) eating more rapidly than normal, (2) eating until uncomfortably full, (3) and eating large amounts of food when not physically hungry [5]. Mild Neurocognitive Disorder may be diagnosed based on 'concerns of the individual, a knowledgeable informant, or the clinician that there has been a modest decline in cognitive function'. These cognitive deficits 'did not interfere with capacity for independence in everyday activities' and the decline may be based on a 'clinical evaluation' (i.e., formal testing is suggested but not required for the diagnosis) [5]. Certainly some individuals consistently overeat and some individuals struggle with age-related cognitive decline. However, both researchers and clinicians have expressed concerns about 'diagnostic inflation' [16] when nonspecific diagnoses such as Binge Eating Disorder and Mild Neurocognitive Disorder are identified as specific mental disorders. In fact, a former president of the APA writing about the revisions to DSM-5 noted that:

> The flexible boundaries of many psychiatric diagnostic categories, in the absence of definitive diagnostic tests, may encourage expansive definitions of affected populations and create opportunities for industry to promote treatments for people who would not previously have been seen as having a disorder [20].

Indeed, our study shows that increased transparency (e.g., registration on ClinicalTrials.gov) and mandatory disclosure policies (such as APA's disclosure policy for DSM-5 panel members) may not be robust enough to prevent the appearance, if not the reality, of bias in both the DSM revision process as well as clinical decisions about appropriate interventions for DSM disorders. In fact, a 2012 comparison between DSM-IV and DSM-5 panel members showed that despite increased transparency, commercial ties remained strong. Although some work groups had decreased the number of individuals with industry ties, overall, 69% of the DSM-5 task force members reported financial ties to industry, representing

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a 21% increase in the proportion of DSM-IV task force members with such ties. Also, three fourths of the work groups continued to have a majority of members with ties to drug firms, and it is noteworthy that, as with the DSM-IV, the most conflicted panels are those for which pharmacological treatment is the first-line intervention [2].

In light of the decrease in government funding of clinical trials over the past two decades, it is not surprising that 29% of the PIs of trials in this study reported research funding from a trial drug manufacturer. However, 20% of all of the PIs in our sample had financial ties other than research funding with the trial drug manufacturer, and 3 were on speakers bureaus for the manufacturers of the drugs they are investigating. Many policy makers, medical journal editors, and bioethicists have raised concerns that the line between marketing and research has become blurred [21, 22] when researchers have ongoing, close, and lucrative ties with industry such as speakers bureau participation.

Our findings suggest that there may be a risk of industry influence on the DSM revision process. Additionally, our findings of FCOI of PIs running the clinical trials suggest that there also may be a risk of industry influence on the clinical decision-making process for identifying interventions to treat these new 'disorders'. Of particular note is the fact that in 3 of the clinical trials, PIs reported that they participated on company speakers bureaus. Such participation may have a biasing effect. Transparency of FCOI and of clinical trial data are important first steps in strengthening public and professional trust in evidence-based medicine. However, the improvements facilitated by transparency are insufficient. Disclosure alone is not a satisfactory response to prevent bias in the revision process for psychiatric diagnostic guidelines or for maintaining integrity of psychotropic drug research.

The present study has several limitations. Our study did not include all of the revised or new DSM-5 diagnoses and thus our findings for the six new or modified disorders should not be overgeneralized. The sample size is small and caution should be exercised when interpreting the data. Also, our metric for assessing independence in clinical decision-making (DSM panel members' and PIs' financial associations with industry) is an indirect measure and thus no conclusion can be drawn about actual bias in decision-making. Moreover, the complexity of the debate over FCOI and the potential for bias is compounded by the fact that trials that are commercially funded often report negative findings. For example, researchers found that half of the studies on the efficacy of antidepressants failed to show an advantage over placebo (and over older tricyclic antidepressants) even though many of these were industry-funded studies [23]. Despite these limitations, our examination of financial ties among DSM panel members, PIs of drug trials, and trial drug manufacturers suggest that the public, clinicians, and policy makers should be concerned about the way in which new diagnoses in the DSM-5 may provide an opportunity for pharmaceutical companies to effectively extend their patents on blockbuster drugs. For example, Eli Lilly is listed on ClinicalTrials.gov as a collaborator for a clinical trial to test the efficacy of one of Lilly's antidepressants (Cymbalta) for 'bereavement-related depression', and Eli Lilly is listed as a sponsor for a clinical trial testing Cymbalta for 'Binge Eating Disorder'. The patent for Cymbalta expires in December 2013. Five of the 12 members of the Mood Disorders Work Group and 3 of the 12 members of the Binge Eating Disorder Work Group have ties to Eli Lilly. If the FDA approves Cymbalta for these new indications, Lilly will benefit by obtaining another 3 years of market exclusivity for this drug. It has been one of Lilly's recent blockbuster drugs: In just the fourth quarter of 2012, Lilly reported revenue of USD 1.42 billion from Cymbalta alone (24% of total revenue for that quarter) [24].

There are also 3 clinical trials for 'Binge Eating Disorder', testing an antidepressant, a 'mood stabilizer', and a psychostimulant as potential treatments for this new condition. (The three trial drugs, Cymbalta, Lamictal, and Nuvigil, made USD 5 billion, USD 937 million, and USD 347 million in revenue in 2012, respectively.) The FDA requires at least 2 trials to obtain authorization to market a drug for a new indication. Although more trials are needed before the FDA would grant authorization, it is important to note that the pharmaceutical companies that manufacture these three drugs would clearly benefit financially if they received such authorization.

A Call for Drug Trials That Are Not Sponsored by For-Profit Entities

Our FCOI findings show the tripartite interrelationship among DSM panel members, PIs of clinical trials for new DSM-5 diagnoses, and drug companies. These findings suggest that FCOI may function subtly, but powerfully, to shift the direction of the research, focusing on interventions that are the most commercially attractive but that do not necessarily represent the best science. Indeed, as was recently noted, when NIH decreased funding of clinical trials for new drugs, 'turning new drug development over to industry, many clinically important clinical trials… were simply not done' [25; see also 26]. Hence, there must be systemic valuing and support of disinter-

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ested experts and their scientific contributions [27], and there is a clear need for drug trials that are not sponsored by and managed by industry. In our opinion, PIs should be prohibited from participating on a speakers bureau for a company whose drug they are testing. Speakers bureau participation is usually prohibited elsewhere (e.g., for faculty in medical schools), as it is widely recognized to constitute a significant FCOI [2]. Pharmaceutical companies refer to individuals who serve on speakers bureaus as 'key opinion leaders' because they are seen as essential to the marketing of drugs.

Finally, as a policy objective, it is critical that the APA recognize that transparency alone is an insufficient response for mitigating implicit bias in diagnostic and treatment decision-making. Specifically, and in keeping with the Institute of Medicine's most recent standards, we recommend that DSM panel members be free of FCOI. In the future, DSM panel members should also be prohibited from serving as PIs of trials for any disorder being considered for inclusion in the DSM.

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