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Undisclosed financial conflicts of interest in DSM-5-TR: cross sectional analysis

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ABSTRACT OBJECTIVE

To assess the extent and types of financial ties to industry of panel and task force members of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, text revision (DSM-5-TR), published in 2022.

DESIGN

Cross sectional analysis.

SETTING

Open Payments database, USA.

PARTICIPANTS

92 physicians based in the US who served as members of either a panel (n=86) or task force (n=6) on the DSM-5-TR with information recorded in the Centers for Medicare and Medicaid Services Open Payments database during 2016-19. This period was chosen to include the year that development of the DSM-5-TR began and the three years preceding, a time consistent with previous research on conflicts of interest and consistent with the American Psychiatric Association's disclosure requirements for the fifth revision (DSM-5) of the manual.

MAIN OUTCOME MEASURES

Type and amount of compensation the panel and task force members of DSM-5-TR received during 2016-19.

RESULTS

After duplicate names had been removed, 168 individuals were identified who served as either panel or task force members of the DSM-5-TR. 92 met the

inclusion criteria of being a physician who was based in the US and therefore could be included in Open Payments. Of these 92 individuals, 55 (60%) received payments from industry. Collectively, these panel members received a total of \$14.2m (£11.2m; €13m). One third (33.3%) of the task force members had payments reported in Open Payments.

CONCLUSIONS

Conflicts of interest among panel members of DSM-5-TR were prevalent. Because of the enormous influence of diagnostic and treatment guidelines, the standards for participation on a guideline development panel should be high. A rebuttable presumption should exist for the *Diagnostic and Statistical Manual of Mental Disorders* to prohibit conflicts of interest among its panel and task force members. When no independent individuals with the requisite expertise are available, individuals with associations to industry could consult to the panels, but they should not have decision making authority on revisions or the inclusion of new disorders.

Introduction

Relationships between academia and industry have come under increased scrutiny because of the potential to undermine the integrity of medical research. Financial conflicts of interest that result from these relationships can lead to implicit bias, compromise the research process, and erode public trust.¹⁻⁶ The *Diagnostic and Statistical Manual of Mental Disorders* published by the American Psychiatric Association standardizes symptom criteria and codifies psychiatric disorders. This manual plays a central role in the approval of new psychiatric drugs and the extension of patent exclusivity, and it can influence payers and mental health professionals who seek third party reimbursements. Indeed, the manual has been referred to as the "bible" of psychiatric disorders, and industry influence over the development of this diagnostic guideline can have a profound effect on public health (eg, by broadening diagnostic categories and influencing what drugs will be prescribed and covered by insurance). It is thus critical that authors of this psychiatric taxonomy should be free of industry ties.

Previous research into the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition, text revision (DSM-IV-TR) and the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition (DSM-5) showed that financial ties to industry were common among panel and task force members, despite the implementation of a disclosure policy for DSM-5.^{7,8} In this study we examined the extent and type of conflicts of interest of panel and task force members of the recently published text revision of DSM-5, the

WHAT IS ALREADY KNOWN ON THIS TOPIC

Financial conflicts of interest can erode public trust in evidence based medicine
Previous research showed that industry ties were common among contributors to the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition, text revision (DSM-IV-TR) and the fifth edition (DSM-5)

Before the development of DSM-5, the American Psychiatric Association made a commitment to improve its management of financial conflicts of interest
Until the development of the Open Payments database, it was not possible to determine the amount of monies received by authors of diagnostic and clinical practice guidelines

WHAT THIS STUDY ADDS

Of the 92 panel and task force members who met inclusion criteria, 55 (60%) received payments from industry

Collectively these panel members received >\$14m

There should be a rebuttable presumption of prohibiting financial conflicts of interest among the panel and task force members of the *Diagnostic and Statistical Manual of Mental Disorders*

Diagnostic and Statistical Manual of Mental Disorders, fifth edition, text revision (DSM-5-TR).⁹

Methods

Procedures

Since 2013, under the Physician Payments Sunshine Act, all US drug and device manufacturers are required to disclose payments given to physicians and teaching hospitals.¹⁰ The Centers for Medicare and Medicaid Services developed a publicly accessible database, Open Payments, that identifies monies given by pharmaceutical and device companies to individual physicians and institutions.¹⁰ The data from Open Payments has been used to assess the ways in which financial conflicts of interest may influence physician behavior. For example, this database has been used to determine physicians' likelihood to prescribe certain drugs and how that may have been influenced by compensation from the pharmaceutical industry.^{11 12} For the present study, we searched Open Payments by manually entering each physician's name in the database¹⁰ to determine the type and amount of compensation that panel and task force members of

DSM-5-TR received during 2016-19, including general, research or associated research, and ownership or investment payments. This time period was chosen to include the year that development of the DSM-5-TR began (2019) and the three years preceding, a time consistent with previous research on conflicts of interest and consistent with the American Psychiatric Association's disclosure requirements for DSM-5.¹³ The names may be found between the copyright and the preface sections of the electronic version of DSM-5-TR.⁹ The American Psychiatric Association does not provide detailed information about the responsibilities of panel and task force members, but the task force historically has had decision making authority.^{7 8} To ensure that the physicians listed in Open Payments were the correct panel or task force members, we confirmed their identity using the middle initials, geographic locations, and medical specialties listed in Open Payments.¹⁰ For individuals who could not be identified solely from Open Payments data, we confirmed identity through a general search of LinkedIn. Individuals without an entry in Open Payments were coded as receiving no remuneration. Also, given that Open Payments is a dynamic database (eg, although rare, individuals may rebut a payment, and amounts can change slightly), we selected the 2 March 2023 as a cut-off date for no further consideration of information. Although it would be informative to see if an association existed between type and amount of industry payment and suggested revisions, this was not possible. The American Psychiatric Association does not publicly disclose minutes of the meetings of the *Diagnostic and Statistical Manual of Mental Disorders*, nor does it provide descriptive summaries of proposed changes and reasons for inclusion or exclusion of the proposed changes.

Patient and public involvement

No patients or members of the public were directly involved in this research. Although there was no direct patient and public involvement (owing to the fact that this study did not involve human participants/patients), speaking with people with lived experience informed the focus of the current study as well as previous ones.

Results

After the removal of duplicates during screening, 168 physicians were identified who served on the task force and the 20 panels for the disorders included in the DSM-5-TR (in the text revision edition, panel members are now referred to as review groups). Of those 168 physicians, 92 (86 panel members and six task force members) met the inclusion criteria of being a US based physician with industry payments tracked in Open Payments (fig 1). Fifty five physicians (59.8%) had financial ties to industry. Thus, nearly 60% of the task force and panel members who met the inclusion criteria had one or more of the 10 types of payments listed in Open Payments. The most common type of payment was for food and beverages (90.9% total

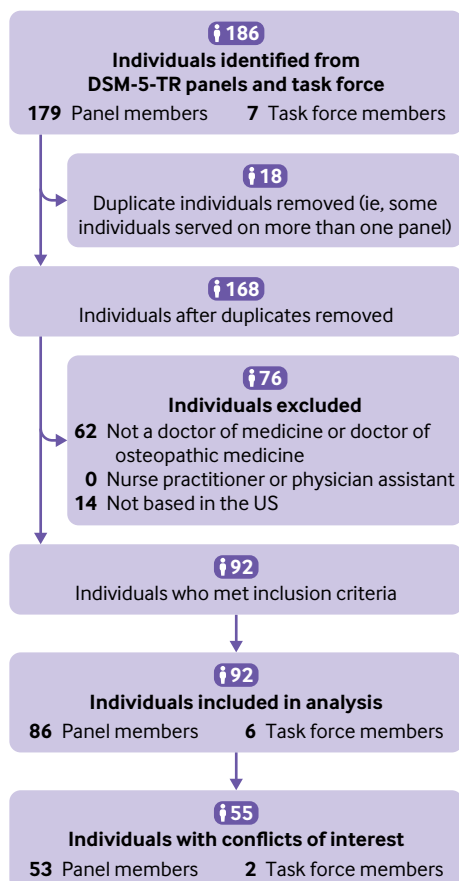


Fig 1 | Flowchart of individuals identified from *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, text revision (DSM-5-TR) panel and task force members. Individuals were screened based on physician status (doctor of medicine or doctor of osteopathic medicine) and being a resident in the US. Individuals with nurse practitioner or physician assistant credentials were not included in the analysis because these individuals were not included in the OP database during the study period

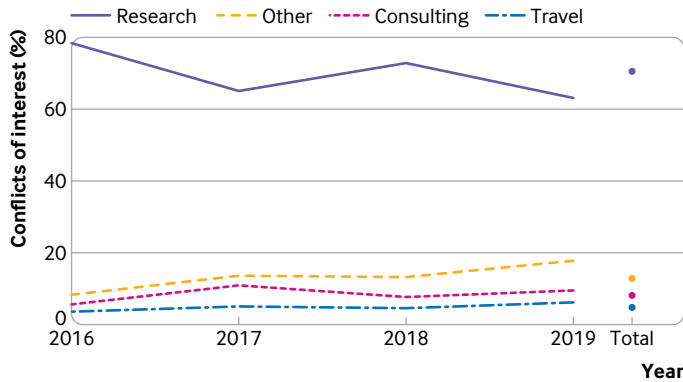


Fig 2 | Annual proportion of compensations for the four highest categories in Open Payments database that were made to panel and task force members of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, text revision (DSM-5-TR). Proportions are also given for the sum across all four years. The research payments category was combined to include both associated research funding and research payments, as listed in the US Centers for Medicare and Medicaid Service's Open Payments

amount \$89 506.7 (£70 473.6; €81 473.2) followed by travel (69.1, total \$684 622.2) and consulting (69.1%, total \$1 178 603.4). Nineteen panel members (34.6, total \$1 833 960.1) received "Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program" (see supplemental figure 1). The largest proportion of remuneration was in the research category (71%), followed by "other payments" (13%), consulting (8%), and travel (5%). The largest increase in proportion of payments was found for the "other payments" category, at 9.5 from 2016 to 2019 (fig 2). The per cent of panel members with industry support was similar between DSM-5-TR and DSM-5 (fig 3). Three quarters ($\geq 75\%$) of the members of five panels (and 100% on one panel) had received payments from industry. The total payments received by these panel and task force members was >\$14.2m (range \$13.8-\$2.7m per physician) (fig 4).

Task force members

Only two of the six task force members had any payments reported in Open Payments, totaling \$196.0 and \$792.6 for 2016-19.

Discussion

In this study, we found that almost 60% of panel and task force members of the *Diagnostic and Statistical Manual of Mental Disorders* had financial ties to industry, which is consistent with previous research on the financial conflicts of interest of authors of DSM-IV and DSM-5 (fig 3, also see supplemental figure 2).^{7,8} Collectively these panel and task force members received a total of >\$14.2m. The most common types of payment were for food and beverages, followed by travel and consulting. More than one third received "Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program" (see supplemental figure 1).

The impact of financial conflicts of interest on the medical literature, including randomized clinical trials, meta-analyses, and clinical diagnostic and practice guidelines, has been well documented for more than two decades.¹⁴⁻¹⁷ Indeed, researchers have consistently shown that conflicts of interest lead to subtle but impactful pro-industry thinking and conclusions.¹⁸ For example, it was recently reported that when meta-analyses of antidepressants included an author who was an employee of the manufacturer of the assessed drug, the meta-analysis was 22 times "less likely to have negative statements about the drug than other meta-analyses."¹⁹ Similarly, when access to the full unpublished dataset was provided to researchers who conducted a reanalysis of SmithKline Beecham's Study 329—an influential study concluding that paroxetine was safe and effective in adolescents—they found an increase in harms for paroxetine that was not reported in the published literature.²⁰

It should be emphasized that the problem is not unique to psychiatry or to the US. Guidelines from the National Heart Lung and Blood Institute recommending lipid screening of about 40% of the children in the US have been called "evidence of a broken process" because of extensive ties between the expert panel and the pharmaceutical industry.²¹ In France, the French Health Authority withdrew two guidelines following charges that chairpersons of both working groups had major financial conflicts of interest.²²

Although the problem of conflicts of interest is not unique to psychiatry, as one psychiatrist noted "[T]he increasing influence of the pharmaceutical industry on psychiatric research and practice is leading to an intellectual and clinical crisis."²³ That is why before the development of the DSM-5, the American Psychiatric Association stated that the organization had the goal of developing a "transparent process of development for the DSM [*Diagnostic and Statistical Manual of Mental Disorders*], and . . . an unbiased, evidence-based DSM, free from any conflicts of interest."⁸ Although for the latest edition of the manual,⁹ the American Psychiatric Association did not publicly disclose ties to industry, we found that the task force for DSM-5-TR had fewer conflicts of interest (69% v 33% with commercial ties, respectively), which is a small step in the right direction. However, the fact that almost 60% of the 92 panel and task force members who met inclusion criteria had ties to industry and that collectively they received >\$14m during 2016-19 is cause for concern. Indeed, the amount of money received from pharmaceutical companies by individuals with decision making authority over the revision process raises questions about the editorial independence of this diagnostic manual. Our study was not designed (nor could it be) to determine if these financial ties affected decision making. However, a wealth of research documents the ways in which academic-industry relationships lead to pro-industry conclusions,²⁴ non-evidence based prescription practices,²⁵ and untrustworthy guideline recommendations.^{26,27}

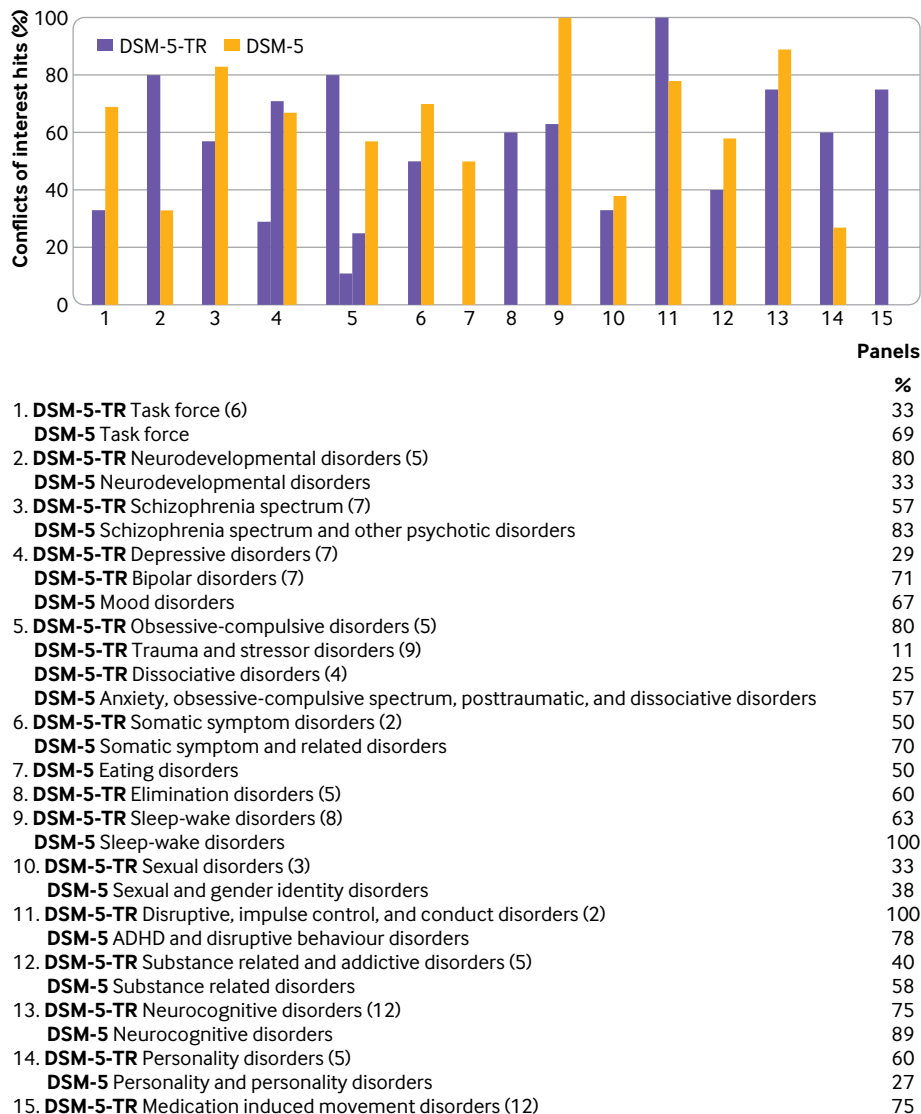


Fig 3 | Comparison of financial conflicts of interest among panel and task force members of the *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition (DSM-5) and DSM fifth edition, text revision (DSM-5-TR). The total number of authors for each DSM-5-TR panel who met inclusion criteria are indicated in parentheses. Panels for which no authors had reported conflicts of interest were excluded from this figure (ie, from DSM-5-TR, anxiety disorders, feeding and eating disorders, gender dysphoria, paraphilic disorders, and disorders in childhood and adolescence)

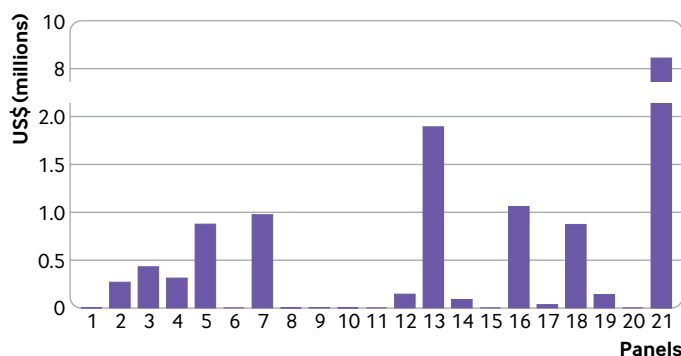
Comparison with other studies

Congruent with our previous studies,⁷⁸ we found that panel members of the *Diagnostic and Statistical Manual of Mental Disorders* who received the most remuneration from drug companies were those working in diagnostic areas where drug interventions are often the standard treatment, such as depressive disorders, neurocognitive disorders, and drug induced movement disorders (fig 4). Notably, more than one third of the panel members received “compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program.” (see supplemental figure 1) This category captures what the pharmaceutical industry refers to as key opinion leaders—“physicians who influence their peers’ medical practice, including but not limited to prescribing behavior.”²⁸ Being on a speakers bureau or being a key opinion leader is widely

recognized as an egregious financial conflict of interest because the role of the key opinion leader is essentially a marketing one; the talks given are usually presented at educational events sponsored by industry.²⁹ As one author pointed out, key opinion leaders are hired by industry because, as the terms suggests, they can lead (or change) opinions.³⁰ Moreover, key opinion leaders are influential not only because they are often affiliated with prestigious universities, but also because industry provides them with wide ranging and influential platforms and speaking engagements.³¹

Policy implications

The greatest proportion of compensation (by category of payment) was research funding or research payments ($\geq 70\%$ across all years) (see fig 2). Research funding was excluded from the American Psychiatric Association’s disclosure policy for DSM-5, and some



1. Task force (\$988.7)
2. Neurodevelopmental disorders (\$268 423.2)
3. Schizophrenia spectrum (\$429 791.0)
4. Bipolar disorders (\$311 751.0)
5. Depressive disorders (\$875 373.9)
6. Anxiety disorders (\$0.0)
7. Obsessive-compulsive disorders (\$973 851.1)
8. Trauma and stressor disorders (\$122.1)
9. Dissociative disorders (\$3363.9)
10. Somatic symptom disorders (\$13.8)
11. Feeding and eating disorders (\$0.0)
12. Elimination disorders (\$143 770.0)
13. Sleep-wake disorders (\$1 892 430.9)
14. Sexual disorders (\$88 195.1)
15. Gender dysphoria (\$ 0.0)
16. Disruptive, impulse control, and conduct disorders (\$1 059 910.3)
17. Substance related and addictive disorders (\$34 285.7)
18. Neurocognitive disorders (\$872 277.4)
19. Personality disorders (\$139 661.2)
20. Paraphilic disorders (\$0.0)
21. Medication induced movement disorders (\$8 443 468.4)

Fig 4 | Total compensation for each *Diagnostic and Statistical Manual of Mental Disorders*, fifth edition, text revision (DSM-5-TR) panel and task force members during 2016-19

individuals might believe that such compensation does not influence behavior. Nonetheless, evidence is lacking to suggest that simply because money comes in the form of a research grant it does not create an obligation to reciprocate or invoke an implicit bias. Similarly, although some panel members received <\$1000 in remuneration, relatively minor gifts do affect physician behavior and prescribing practices; empirical research shows that even small gifts can have a substantial impact on behavior.³²⁻³⁴

Additionally, it is important to emphasize that the problem of overdiagnosis is not limited to the inclusion of new disorders in the *Diagnostic and Statistical Manual of Mental Disorders*. Even seemingly small changes to the manual (eg, to symptomatology of previously included disorders) can have a substantial impact on increasing the number of people who would receive a diagnosis and increasing the number of people prescribed drugs. For example, many researchers and clinicians, including the former chair of the DSM-IV, pointed out that the seemingly small changes to the criteria for attention deficit/hyperactivity disorder (ADHD) in the 2013 edition of the DSM-5 would likely result in a considerable increase in the diagnosis of ADHD and an increase in the prescriptions of stimulants (eg, the DSM-5 made the change that symptoms could appear before age 12 years rather than age 7 years; that symptoms need only to “impact”

behavior rather than cause impairment). Interestingly, authors of a recent systematic scoping review of more than 300 studies in children and adolescents found “convincing evidence that ADHD is overdiagnosed in children and adolescents.”³⁵

Finally, panel members also have the authority to eliminate disorders—not just add new ones—and make changes that would help prevent overdiagnosis. In other words, if the developers of the next edition of the *Diagnostic and Statistical Manual of Mental Disorders* were all free of ties to industry and were a genuinely multidisciplinary group (which would be congruent with the Institute of Medicine’s 2011 recommendation for developing trustworthy clinical guidelines), the manual may be less likely to lead to overdiagnosis and overtreatment.

Strengths and limitations of this study

A major strength of this study is that it provides novel data about the appreciable conflicts of interest in the DSM-5-TR and extends past research on this topic.^{7 8} The present study, however, only used information provided by Open Payments, which does not include payments to physicians based outside the US. Although mandatory disclosure of payments for US pharmaceutical and medical device companies that make products covered by Medicare and Medicaid is required, until recently the database did not include payments to non-physicians. (Under the 2021 SUPPORT ACT, Open Payments expanded its database to include non-physician prescribers such as nurse practitioners and physician assistants).¹³ Of the 168 total panel members (after duplicates were removed), 92 met the inclusion criteria, and thus it is possible that the 76 individuals who did not meet the inclusion criteria were free of commercial ties. Additionally, as other researchers have noted, the amounts listed in the database can change slightly, and although there is a validation process, it can be cumbersome and there “remain ways in which [the data] may be imprecise or inaccurate.”³⁶

Conclusion

To ensure unbiased, evidence based mental health practice, it is important to prohibit industry influence in the *Diagnostic and Statistical Manual of Mental Disorders*. The extent of conflicts of interest among these panel and task force members reveals how important it is to examine the systemic and institutional practices that allow for these conflicts and that reinforce them as normative.^{7 8} Professionalism and the belief in scientific objectivity cannot protect against implicit bias because, as the social psychological literature shows, individuals are unable to assess how conflicts of interest influence decision making.³⁷ Moreover, disclosure may not only make conflicts of interest normative, but may have the iatrogenic effect of worsening bias as empirical research shows.^{38 39}

Also, as previously noted, the American Psychiatric Association does not publicly disclose minutes of the meetings of the *Diagnostic and Statistical Manual*

of *Mental Disorders*, nor does it provide descriptive summaries of proposed changes and reasons for inclusion or exclusion of the proposed changes. As one prominent psychiatric researcher noted, the revision process for the DSM-5 “suffered from lack of an adequate public record of the rationale for changes, thus shortchanging future scholarship . . . DSM-5 was a missed opportunity to increase the conceptual validity of psychiatric diagnosis by aggressively addressing false-positive issues.”⁴⁰ We believe that the DSM-5-TR also represents this missed opportunity, and we call upon the American Psychiatric Association to ensure greater rigor in, and transparency of, the process for revising the manual. Doing so will help mitigate overdiagnosis and overtreatment.

More than a decade ago, the year before the DSM-5 was published, we made the following recommendations: Individuals who have participated on pharmaceutical companies’ speakers bureaus should be prohibited from being panel members of the *Diagnostic and Statistical Manual of Mental Disorders*, and there should be a rebuttable presumption of prohibiting conflicts of interest among such panel members. When no independent individuals with the requisite expertise are available, individuals with associations to industry could consult to the panels, but they would not have decision making authority on revisions or inclusion of new disorders.⁷ Given our present findings, these recommendations are even more pressing 10 years later. As researchers, clinicians, policy makers, and leaders in evidence-based medicine have argued,⁴¹ guideline writers should be free of financial relationships with industry, especially those writers who are responsible for such an influential manual on psychiatric taxonomy.

We would like to thank and dedicate this paper to Shelly Krimsky, PhD, who was a mentor to LC and who coauthored many papers with her, including those addressing financial conflicts of interest in previous editions of the *Diagnostic and Statistical Manual of Mental Disorders*. Dr Krimsky began working on this project before his death in April 2022. He was a pioneer in quantitative bioethics research and a long term collaborator, and he served as an inspiration to all of the authors of this paper and countless others around the world.

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Contributors: LC conceptualized the paper, along with BP, and LC developed the first draft of the paper and reviewed and contributed to all subsequent drafts. LD, BP, and NE developed all the figures and BP contributed to all sections of the paper. LD, GD, SD, NE, FH, and AD searched the Open Payments database for all *Diagnostic and Statistical Manual of Mental Disorders* panel members, identified and recorded all conflicts of interest information, conducted literature searches, and participated in writing various drafts. All authors contributed to the manuscript revision and read and approved the submitted version. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: BJP reports contributing to an osteoarthritis research team supported by Pfizer and Eli Lilly (2019-21) and reports receiving grants from the Pennsylvania Academic Clinical Research Center, outside the submitted work; no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Not required. The Geisinger institutional review board determined that this study was not research on human subjects (2022-0814).

Data sharing: The raw data used in this study is publicly available at <https://openpaymentsdata.cms.gov>.

The manuscript’s guarantors (LC and BP) affirm that the manuscript is an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants and related patient and public communities: All the information in this study is publicly available. We plan to disseminate the results of this by writing a companion article (point/counterpoint), for which we will invite someone in a leadership position in the American Psychiatric Association to respond to our paper. We will also present our results at medical grand rounds and disseminate the main results through social media platforms.

Provenance and peer review: Not commissioned; externally peer reviewed.

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Supplemental information: Additional figures 1 and 2 and tables 1 and 2