PEER REVIEW HISTORY

This paper was submitted to a another journal from BMJ but declined for publication following peer review. The authors addressed the reviewers' comments and submitted the revised paper to BMJ Open. The paper was subsequently accepted for publication at BMJ Open.

(This paper received three reviews from its previous journal but only two reviewers agreed to published their review.)

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effect of the Public Disclosure of Industry Payments Information on Patients: Results from a Population-Based Natural Experiment
AUTHORS	Kanter, Genevieve; Carpenter, Daniel; Lehmann, Lisa; Mello, Michelle M

VERSION 1 – REVIEW

REVIEWER	Paolo Vercellini Department of Clinical Sciences and Community Health and Department of Obstetrics and Gynaecology, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milan, Italy
REVIEW RETURNED	29-May-2018

GENERAL COMMENTS	Kanter and co-workers conducted an interrupted time series study to assess the effect of the Open Payments programme, created by the US Physician Payments Sunshine Act, on (i) patients' awareness of industry payments as an issue; (ii) patients' awareness that industry payments information was publicly available; (iii) knowledge of whether own physician had received industry payments. To this aim, to US population-based surveys were conducted, before the public release of Open Payments information and again two years later. According to the results of this study, the Open Payments programme did not impact on the proportion of responders who were aware of the issue of industry payments and on the proportion of those who knew whether their physician had received industry payments. The proportion who knew that payment information was publicly available increased significantly, but the magnitude of the effect was small. The study question is interesting, the design appears appropriate, the conduction and data analysis adequate. The study limitations are correctly addressed in the Discussion section. The manuscript is well written and clear. I have only a minor comment regarding this manuscript and some general considerations regarding the overall consequences of the Open Payments programme on the transfer of money from industry to physicians.

	Result section, page 10, lines 35-40. In most US states the proportion of responders aware that industry payments information was publicly available increased between 2014 and 2016 (+3.3%), whereas it decreased in those states that had already made industry payments information publicly available before 2014 (-6.7%). The authors provide a possible explanation for this unexpected variation (lines 40-45). However, can the authors exclude that this finding might reflect a difference in the characteristics of individuals who completed the first survey and those who completed the second survey specifically in Massachusetts, Minnesota, and Vermont? More in general, the authors state that "the rationales underlying this disclosure requirement [Open Payments] were that patients, in making health care decisions, would be better informed of the potential influence of industry ties on their physicians, and payment transparency could deter physicians from accepting payments that patients might view as suspect" (page 5, lines 25-35). The findings of this study add further evidence demonstrating that, unfortunately, those goals have not been fully achieved. In particular, in the opinion of this reviewer, focusing the attention on the end-prescriber, means dealing with the last link in the chain, paying little attention to the origin of the problem. Scientific information is crucial to increase sales of drugs and devices. The way scientific information is generated, selected, published, disseminated among physicians, and conveyed to patients is precisely the process that industry may be tempted to influence. In fact, without scientific information in favour of specific drugs and devices, industry could not modify prescribing patterns to a great extent. Thus, the most important financial investment of industry is by far on the academic world, not on the multitude of individual physicians. Academicians could accept to conduct trials expressly designed to systematically favour the experimental drug. The reports of these trials may appear in prestigious journals that would gain from selling advertisement and reprints. The publication of these results could influence the drafting of guidelines issued by scientific societies, especially when members of the panel of experts received industry funds. Annual conferences, which are indispensable for the financial survival of many professional organisations, could be supported by drug and device manufacturers, provided sponsored symposia including selected key opinion leaders are strategically positioned within the scientific programme. In addition, a large proportion of CME activities worldwide is still supported by industry. Industry may focus not only on investigators tempted to facilitate their career and increase their visibility, but also on patient associations, generally considered by citizens as honest and reliable sources of information. Awareness campaigns can be organized by façade committees behind which industries operate. Influenced scientific information seems the cornerstone of the entire issue, and no distortion of evidence would ever be possible without the active role of academia. Finally, the flow of money seems to have taken different routes with respect to the past years, and several intermediators (e.g.,

	professional congress organisers, professional medical organisations) today “clean up” industry money thus reducing the effectiveness of the Open Payments program. In fact, direct payments from industry to physicians are now reduced compared with the pre-Open Payments era, but this does not constitute a definite demonstration of the efficacy of the programme. In the opinion of this reviewer, to limit the impact of industry on medicine, much more emphasis should be put on the flow of money toward medical journals; COI of editors, members of the editorial boards, and members of the panels of experts drafting guidelines; and industry support to scientific societies, conferences, and CME activities. Only in case the authors share the above thoughts, they might consider including a sentence on the fact that focusing the attention on individual prescribers does not appear to have been a major success, and that this may not be the most effective strategy.

REVIEWER	Jonathan Mendel University of Dundee, Scotland I've been involved in some writing and campaigning relating to COIs (and their disclosure) in the UK
REVIEW RETURNED	29-Jun-2018

GENERAL COMMENTS	This is an interesting, well-written paper which addresses important questions. I'm happy to recommend publication, subject to relatively minor revisions. The comments below focus on what I think should be improved; however, this should not take away from the fact that I think this paper offers a worthwhile contribution to the literature. In terms of substantive changes: - The paper could offer a slightly more detailed account of the objectives of - and policy context around - the Sunshine Act. This doesn't need to be lengthy, but another paragraph or so drawing on some more of the work on the Act would be helpful. Additionally, it's worth noting the limitations of EFPIA, compared to the Sunshine Act. - While none of this seems ethically problematic, there should be at least a brief mention of ethical approval. - Interesting recommendations on how to improve public awareness. However, I'd encourage the authors to draw more on previous research on public/patient engagement. The suggested options for increasing awareness seem fairly centralised - and this literature might also open up other options to consider. One minor tweak: P10: could “claimed to know” be replaced by a more neutral phrasing like 'said they know'? I would be willing to review the manuscript again if needed, but as these are fairly minor revisions I don't think imagine that will be necessary. The authors are welcome to contact me if they have any queries.

VERSION 1 – AUTHOR RESPONSE

Thank you for the very helpful and encouraging comments. We were able to incorporate almost all of the suggestions, and the paper is much improved.

Below is a detailed response to the comments:

Result section, page 10, lines 35-40. In most US states the proportion of responders aware that industry payments information was publicly available increased between 2014 and 2016 (+3.3%), whereas it decreased in those states that had already made industry payments information publicly available before 2014 (-6.7%). The authors provide a possible explanation for this unexpected variation (lines 40-45). However, can the authors exclude that this finding might reflect a difference in the characteristics of individuals who completed the first survey and those who completed the second survey specifically in Massachusetts, Minnesota, and Vermont?

Thank for raising this possibility as an alternative explanation. In response to your suggestion, we analyzed differences in non-response rates, by respondent characteristic (e.g. gender, income), between respondents in Sunshine states and those in non-Sunshine states. We did not find any statistically significant differences (according to the Bonferroni correction standard) in observed demographic or health characteristics. We have added a full paragraph (top of p. 13) to discuss the possibility that you mentioned.

The findings of this study add further evidence demonstrating that, unfortunately, those goals have not been fully achieved. In particular, in the opinion of this reviewer, focusing the attention on the end-prescriber, means dealing with the last link in the chain, paying little attention to the origin of the problem… In the opinion of this reviewer, to limit the impact of industry on medicine, much more emphasis should be put on the flow of money toward medical journals; COI of editors, members of the editorial boards, and members of the panels of experts drafting guidelines; and industry support to scientific societies, conferences, and CME activities.

Only in case the authors share the above thoughts, they might consider including a sentence on the fact that focusing the attention on individual prescribers does not appear to have been a major success, and that this may not be the most effective strategy.

Thank you for your raising this point. We are sympathetic with this position. We have a second paper that focuses on the Sunshine Act and its effect on prescribers, and a discussion of the points you mention would be particularly suited for that manuscript's focus. For now, because of this particular manuscript's focus on the Act's effect on consumers, we have decided to narrow our policy discussion on policy implications within the consumer realm.

The paper could offer a slightly more detailed account of the objectives of - and policy context around - the Sunshine Act. This doesn't need to be lengthy, but another paragraph or so drawing on some more of the work on the Act would be helpful.

There is a surprising dearth of documentation related to the policy justification for the Sunshine Act aside from what is discussed in the regulation itself, which we discuss in the first paragraph of the Introduction. Although we had little additional information to add in terms of the policy context, we thought—in light of your comment—that it might be useful to add a discussion of other empirical work on the Sunshine Act and what that work reflects about the scope, scale, and effects of industry payments in the US. This discussion may be found on p. 6. We have also added a new citation to a relevant publication that has come to our attention.

Additionally, it's worth noting the limitations of EFPIA, compared to the Sunshine Act.

We have added a section (p. 15) discussing some differences between EFPIA and the Sunshine Act and one implication of these differences.

While none of this seems ethically problematic, there should be at least a brief mention of ethical approval.

We have added a statement mentioning the human subjects research letter of determination issued by the institutional IRB (p. 9).

Interesting recommendations on how to improve public awareness. However, I'd encourage the authors to draw more on previous research on public/patient engagement. The suggested options for increasing awareness seem fairly centralised - and this literature might also open up other options to consider.

Thank you for this suggestion. We have reviewed some of the patient engagement literature and have added a recommendation that draws from the readings (p. 14).

P10: could "claimed to know" be replaced by a more neutral phrasing like 'said they know'?

Yes, thank you – this is a better phrasing, and we have made this change in the text (p. 11).

VERSION 2 – REVIEW

REVIEWER	Paolo Vercellini Università degli Studi, Milano, Italy and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Italy
REVIEW RETURNED	26-Oct-2018

GENERAL COMMENTS	The authors have adequately addressed the comments raised, and the text is well-written and clear. This reviewer is now satisfied with the manuscript as it is now and congratulates for a very interesting and hopefully useful study.