

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Physicians' attitudes towards disclosure of payments from pharmaceutical companies in a nation-wide voluntary transparency database: a cross-sectional survey
AUTHORS	Stoll, Marlene; Hubenschmid, Lara; Koch, Cora; Lieb, Klaus; Egloff, Boris

VERSION 1 – REVIEW

REVIEWER	Checketts, Jake Oklahoma State University Medical Center
REVIEW RETURNED	08-Sep-2021

GENERAL COMMENTS	<p>Intro: The introduction section in my opinion is too long, it is almost 3 and a half pages. Please consolidate this to 5-700 words max.</p> <p>Methods: The methods are overall well conducted, however why only use 2015 and 2016 data? Why was 2017 data not used if you were conducting in 2018? Furthermore, you stopped sending out questionnaires in February of 2019. This means that the physicians were questioned up to 4 years following the disclosure year which to me presents an issue of bias into their own response. Additionally, it has almost been 3 years since you sent the last questionnaire to now and would be closer to 3 years by the time this paper would potentially be in print meaning that from the very get go this paper's data (which was already reporting on happenings to physicans 3-4 years prior, is 3 years dated.</p> <p>I am concerned that the data is not up to date, and does not cover enough years to be generalizable even though 2017 data may have been available when you started the study, and was almost certainly available when you were sending out surveys still in 2019.</p> <p>Results: Well detailed, no changes</p> <p>Discussion: Well written, no changes</p> <p>Overall I think the study was well thought out, but very slow to develop and submit for publication meaning the data may be dated and seems to exclude relevant years of data. Other than shortening the introduction, I do not know that my comments could be addressed in a timely by the study group so I will not suggest they do so.</p>
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REVIEWER	McDonald, Patrick J. Univ British Columbia, Neurosurgery
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GENERAL COMMENTS

The authors present the results of a survey of German physicians attitudes towards voluntary disclosure of payments from pharmaceutical companies in 2015 and 2016 after implementation of a national requirement for pharmaceutical company disclosure of payments to physicians.

The topic of financial conflicts of interest in medicine has become of great interest to physicians, the public and industry since the implementation of the Physician Payment Sunshine Act and the Open Payments Database in the United States in 2013. The publication of this data in the German press has led to significant interest among all stakeholders.

The authors are to be commended for attempting to investigate patterns of disclosure among German physicians. I have number of suggestions for the manuscript that I have outlined below, some general and some more specific:

1. In order for disclosure to occur under the regulation, physicians must agree to have their information disclosed. This is a significant limitation of the regulation, and hence any conclusions that can be made from whatever data is made publicly available. Although the authors do mention this, I feel it merits more discussion, perhaps in a paragraph or two regarding the genesis of the regulation in Germany. Also, is the regulation part of a specific national statute ie is it a legislated regulation, or simply an administrative or edict of the executive branch of government.
2. Line 24- consider changing the word salience to awareness
3. Page 6- the second paragraph is quite speculative and makes a number of assumptions about potential motivations for agreeing or not agreeing to disclosure. I think this paragraph would be better placed and modified after the results section as potential motivations for what the study results show.
4. In the Methods section, page 7- 28,230 physicians disclosed a financial interaction- what is the denominator for this ie. what percentage of German physicians agreed to disclosure.
5. Although excluding payments of <1000 Euro is reasonable, presumably because this is considered a small sum, please provide justification or reasons why this threshold was used. In addition, is there a range, median and mean number for payments made to German physicians or a breakdown by specialty? If so, please provide.
6. Is the disclosure entirely from pharmaceutical companies or are device manufacturer payments also included? If not, this is also a significant limitation of the disclosure regulation and should be described as such.
7. Page 8- Procedure and Sample Size- how were the 150 participants selected and how was in ensured that this was a representative sample of German HCPs?
8. Page 8- main outcomes- How is pleasantness of interaction defined?
9. For the qualitative data, how was this derived? Was it simple free text written onto the survey- if so please indicate.
10. Page 10- Analysis- paragraph 2 indicates that qualitative content analysis was undertaken. Please provide a reference outlining content analysis methodology for the benefit of readers not familiar with its use.

	<p>11. Page 10 Results- provide an explanation for why 2 surveys were excluded.</p> <p>12. Page 13- Further exploratory investigations- please define what is meant by a more nuanced disclosure of payments.</p> <p>13. Page 14, table 3- Please define undifferentiated.</p> <p>14. Page 15- what is meant by "dark figure" of undisclosed information.</p>
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REVIEWER	Henry, David Bond University, CREBP
REVIEW RETURNED	22-Sep-2021

GENERAL COMMENTS	<p>This paper seems to build on study previously published in BMJ Open. Although that paper is referenced the fact that it appears to work with the same sample of physicians and possibly the same data collection instruments is not made clear in the current report. The relationship between the current study and the previous work needs to be transparent.</p> <p>Secondly, the paper appears to have used stratified sampling based on the level of payments and whether these were greater or less in 2015 or 2016. This leads to some quite complex analyses that are difficult to follow. In addition, the question of whether patterns of disclosure in the first year of the transparency directive predict disclosure in the second year seems be central to the analyses and is framed as hypotheses. But I don't think such analyses will reveal a general truth about factors that influence willingness to disclose over the longer term. It would be better to concentrate on the descriptive data.</p> <p>The study methods appear to have been described previously and seem sound. The response rate was low – but that's expected in this situation. The sample is heavily male dominated. Some of the themes that are explored seem simplistic – for instance asking respondents to agree or disagree with 'transparency' in 2020 is motherhood. The great majority of course will agree.</p> <p>The general conclusions of the study seem OK although rather focused on the hypothesis testing rather than general conclusions based on their descriptive data.</p> <p>The introduction to the paper is very long and much of it should be in a more detailed discussion of their general findings, how they compare with published work (there is quite a lot in the literature) and whether disclosure is likely to be important including a recently published systematic review https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/415848 .</p>
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REVIEWER	Simmering, Jacob The University of Iowa College of Pharmacy
REVIEW RETURNED	23-Sep-2021

GENERAL COMMENTS	Stoll et al presenting an interesting analysis of the decision by German physicians to disclose payments by drug makers following the passage of a voluntary disclosure law. They find:
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	<p>1. Providers that disclosed in 2015 but not in 2016 often reported deciding not to disclose following negative feedback in 2015.</p> <p>2. Providers that disclosed in 2016 but not in 2015 chiefly did so because they were not contacted in 2015.</p> <p>3. Most providers reported no or little reaction from the public, from colleagues, or the private environment following disclosure</p> <p>4. Perhaps because of #3, regression models of the decision to disclose found no effect of pleasantness of reactions, norms, or attitudes.</p> <p>Major Comments</p> <ul style="list-style-type: none"> - Drop the Group 4 and Group 5 discussion that are not included in this paper. Consider folding Groups 4 and 5 into Group 3 - it is unclear why they are treated separately for this analysis. - Drop the R2 discussion. This is a measure of the models predictive accuracy; however, in this analysis, you are only concerned about inference. A low R2 does not inform us at all about the model's inferential results. A model with low predictive power can still provide valid statistical inference. - Is this study powered? An n=30 seems limited, albeit a rule of thumb. Merging groups 4 and 5 into Group 3 should improve power. - Why was alpha of 0.01 selected? <p>Minor comments:</p> <ul style="list-style-type: none"> - page 12 - stick with clearer language than "no more" and "not yet." Either stay with the group labels or be explicit - "those who reported in 2016 but not in 2015." - Given that providers are not consulting the database and it does not appear to be changing patient/provider attitudes (because they aren't consulting it), what is the value of the disclosures?
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Jake Checketts, Oklahoma State University Medical Center

Comments to the Author:

R1.1: Intro: The introduction section in my opinion is too long, it is almost 3 and a half pages. Please consolidate this to 5-700 words max.

#R1.1: Thank you for pointing this out. We revised the introduction section, and we believe it is now much clearer to read and with more focus. Since we were encouraged at the same time to include more literature, to involve background information about the German transparency regulation and to incorporate the connection to our first study more, our introduction now is 991 words long. We were concerned that further abridgement would result in the loss of important information about the concepts of the study and thus weaken the understanding of the study approach.

R1.2: Methods: The methods are overall well conducted, however why only use 2015 and 2016 data? Why was 2017 data not used if you were conducting in 2018? Furthermore, you stopped sending out questionnaires in February of 2019. This means that the physicians were questioned up to 4 years following the disclosure year which to me presents an issue of bias into their own response.

Additionally, it has almost been 3 years since you sent the last questionnaire to now and would be

closer to 3 years by the time this paper would potentially be in print meaning that from the very get go this paper's data (which was already reporting on happenings to physicians 3-4 years prior, is 3 years dated.

I am concerned that the data is not up to date, and does not cover enough years to be generalizable even though 2017 data may have been available when you started the study, and was almost certainly available when you were sending out surveys still in 2019.

#R1.2: Your concerns are legitimate. We can give you more explanation on the current data, which will hopefully show you that these points do not compromise the validity of our findings. Your first question is: Why are only 2015 and 2016 data used? We only used this data and not of the following years, since the "Euros for Doctors" database, in which all disclosed payments per person are collected, was not continued afterwards. We added this information in the section Introduction/Germany's transparency regulation, p.6, l.46: "The database started in 2016, but it was discontinued after only two years, making the investigation of long-term changes of disclosing rates difficult.[26]". Data from 2017 on are only found on each of the 54 pharmaceutical companies' websites, in various formats that are in parts not searchable, which means that one cannot search for one specific physician and see how much money they have received from how many pharmaceutical companies. Further, the act of disclosing itself took place in the following year of when the payment had been received, which means that physicians decided to disclose payments from 2015 in the year 2016, and payments from 2016 in the year 2017. In 2017, having observed the current situation with the second disclosure round, we started to plan this study, and it took a little under a year until we were able to start the survey, in which we asked physicians about the experiences of the last year and that year before. As the study was one part of the dissertation project of Marlene Stoll, it afterwards took some time to submit the study results for publication.

We believe that the questions we asked in this study and the observations we made are of high interest for the discussion of transparency regulations, since not much has changed in this specific field (see for example this recent study by Mulinari et al. (2021):

<https://doi.org/10.1016/j.healthpol.2021.04.015>). Most of European transparency regulations are still only voluntary, and – as in the German example – have not been improved but rather stagnated or databases even became less accessible.

Results: Well detailed, no changes

Discussion: Well written, no changes

R1.3: Overall I think the study was well thought out, but very slow to develop and submit for publication meaning the data may be dated and seems to exclude relevant years of data. Other than shortening the introduction, I do not know that my comments could be addressed in a timely by the study group so I will not suggest they do so.

#R1.3: We thank you for giving us your honest opinion. We hope we could explain our decisions for the study approach and show you that we did not exclude relevant years but analyse those years of data that were available. We hope that we were able to show that the questions asked in this study and the observations we made are of high relevance for the current discussion of transparency regulations.

Reviewer: 2

Dr. Patrick J. McDonald, Univ British Columbia

Comments to the Author:

The authors present the results of a survey of German physicians attitudes towards voluntary

disclosure of payments from pharmaceutical companies in 2015 and 2016 after implementation of a national requirement for pharmaceutical company disclosure of payments to physicians.

The topic of financial conflicts of interest in medicine has become of great interest to physicians, the public and industry since the implementation of the Physician Payment Sunshine Act and the Open Payments Database in the United States in 2013. The publication of this data in the German press has led to significant interest among all stakeholders.

The authors are to be commended for attempting to investigate patterns of disclosure among German physicians. I have number of suggestions for the manuscript that I have outlined below, some general and some more specific:

R2.1: In order for disclosure to occur under the regulation, physicians must agree to have their information disclosed. This is a significant limitation of the regulation, and hence any conclusions that can be made from whatever data is made publicly available. Although the authors do mention this, I feel it merits more discussion, perhaps in a paragraph or two regarding the genesis of the regulation in Germany. Also, is the regulation part of a specific national statute ie is it a legislated regulation, or simply an administrative or edict of the executive branch of government.

#R2.1: Thank you for this suggestion. We have now added a corresponding section to the introduction, in which more background information on the regulation is given, see p. 6, l.32 ff.: Introduction/Germany's transparency regulation.

R2.2: Line 24- consider changing the word salience to awareness

#R2.2: We changed the word salience to awareness, p.5, l.57: "However, at least in the United States, public awareness of the Open Payments website was low".

R2.3: Page 6- the second paragraph is quite speculative and makes a number of assumptions about potential motivations for agreeing or not agreeing to disclosure. I think this paragraph would be better placed and modified after the results section as potential motivations for what the study results show.

#R2.3: We revised this section so that is now less speculative (p.6. l. 11 ff.), and based the assumptions on the concepts of norms. We hope it is now much clearer.

R2.4: In the Methods section, page 7- 28,230 physicians disclosed a financial interaction- what is the denominator for this ie. what percentage of German physicians agreed to disclosure.

#R2.4: We added the numbers on p.6, l. 55: "An analysis of the 2015 and 2016 data of this database by our group [13] showed that about 28% and 24% of all HCPs who had received payments agreed to disclose payments in 2015 and 2016, respectively."

R2.5: Although excluding payments of <1000 Euro is reasonable, presumably because this is considered a small sum, please provide justification or reasons why this threshold was used. In addition, is there a range, median and mean number for payments made to German physicians or a breakdown by specialty? If so, please provide.

#R2.5: We are happy to provide more information on the background of our approach by adding more links between the current study and our previous study of the German voluntary database. In the section Methods/Sample, it is now clarified that, p.7, l.38: "To enhance the probability that we survey HCPs who receive payments annually, we excluded HCPs who disclosed an annual payment sum < 1,000 €. This was based on the observation that the median disclosed annual payments of HCPs who disclosed in both years was 899€ in 2015, compared to the median disclosed sum of HCPs who disclosed only once, which was 452€.[13]"

R2.6: Is the disclosure entirely from pharmaceutical companies or are device manufacturer payments also included? If not, this is also a significant limitation of the disclosure regulation and should be described as such.

#R2.6: The disclosure is entirely from pharmaceutical companies. The newly added paragraph in the section Introduction/Germany's transparency regulation, p.6, l.32 ff. now makes this clearer.

R2.7: Page 8- Procedure and Sample Size- how were the 150 participants selected and how was it ensured that this was a representative sample of German HCPs?

#R2.7: We are happy to clarify. The selection of participants is described in the section Methods/Sample, p.7, l.31ff. The sample was not planned to be representative. We had only made sure to include physicians who disclosed only in the first year, but not in the second as well as physicians who disclosed only in the second year, but not in the first and physicians who disclosed in both years.

R2.8: Page 8- main outcomes- How is pleasantness of interaction defined?

#R2.8: We asked the participants for their subjective perception of the reactions they had received, and they were able to answer on a scale from "very unpleasant" to "very pleasant" – the original German item was "sehr unangenehm"/"sehr angenehm". We did not define the expression for the participants as we were interested in their subjective interpretation of the situation. The wording of the main outcomes is shown in Table 1, p.9.

R.2.9: For the qualitative data, how was this derived? Was it simple free text written onto the survey- if so please indicate.

#R2.9: We added a statement explaining the derivation of the qualitative data in the section Methods/Questionnaire, p.8, l.30: "Responses were given by ticking boxes or writing text onto the questionnaire."

R2.10: Page 10- Analysis- paragraph 2 indicates that qualitative content analysis was undertaken. Please provide a reference outlining content analysis methodology for the benefit of readers not familiar with its use.

#R2.10: Thank you for this suggestion. We added a reference on qualitative content analysis (<https://www.ssoar.info/ssoar/handle/document/39517>), p.10, l.23.

R2.11: Page 10 Results- provide an explanation for why 2 surveys were excluded.

#R2.11: We added a statement in the section Results/Sample, p.10, l.53 : "Two questionnaires needed to be excluded: one was missing a page and could not be allocated to a group; another contained a note that the participant was not a medical doctor but a biologist."

R2.12: Page 13- Further exploratory investigations- please define what is meant by a more nuanced disclosure of payments.

#R2.12: We are happy to clarify that this is based on the critic of the undifferentiated way of disclosing information, for example by not mentioning the designated use of the money. We added a statement in the section Introduction/Germany's transparency regulation, p.6, l.49 ff. to clarify: "They criticised the undifferentiated way of disclosing (e.g., the designated use of the money was not disclosed), and

the large number of HCPs who did not disclose information.”

R.2.13: Page 14, table 3- Please define undifferentiated.

#R2.13: Please see above (#R2.12). We hope that more context in the introduction section provides readers with enough information to get a feeling for what is meant by “undifferentiated”.

R2.14: Page 15- what is meant by "dark figure" of undisclosed information.

#R2.14 We added an explaining statement in the introduction section, p.6, l.52 (“the large number of HCPs who did not disclose information.[18,27]”) and revised the wording in the section Results/Further exploratory investigations, p.15, l.10, to “unknown cases of undisclosed information”.

Reviewer: 3

Prof. David Henry, Bond University

Comments to the Author:

R3.1: This paper seems to build on study previously published in BMJ Open. Although that paper is referenced the fact that it appears to work with the same sample of physicians and possibly the same data collection instruments is not made clear in the current report. The relationship between the current study and the previous work needs to be transparent.

#R3.1: Thank you for this suggestion. We have added links to the previous work in the section Introduction/Germany’s transparency regulation, p.6, l.32ff. (“An analysis of the 2015 and 2016 data of this database by our group [13] showed that about 28% and 24% of all HCPs who had received payments agreed to disclose payments in 2015 and 2016, respectively. Of all disclosing HCPs, 26% disclosed payments in both years, whereas 44% disclosed only in 2015, and 29% only in 2016. The total number of disclosing HCPs decreased by 21%.”) and in the METHODS/Sample section (“To enhance the probability that we survey HCPs who receive payments annually, we excluded HCPs who disclosed an annual payment sum < 1,000 €. This was based on the observation that the median disclosed annual payments of HCPs who disclosed in both years was 899€ in 2015, compared to the median disclosed sum of HCPs who disclosed only once, which was 452€.[13]”)

R3.2: Secondly, the paper appears to have used stratified sampling based on the level of payments and whether these were greater or less in 2015 or 2016. This leads to some quite complex analyses that are difficult to follow. In addition, the question of whether patterns of disclosure in the first year of the transparency directive predict disclosure in the second year seems to be central to the analyses and is framed as hypotheses. But I don’t think such analyses will reveal a general truth about factors that influence willingness to disclose over the longer term. It would be better to concentrate on the descriptive data.

#R3.2: We understand this point and tried to revise the manuscript in direction of the descriptive data. However, as our approach is preregistered and hypothesis testing was main part of the study plan, we did not want to exclude these analyses completely.

R3.3: The study methods appear to have been described previously and seem sound. The response rate was low – but that’s expected in this situation. The sample is heavily male dominated. Some of the themes that are explored seem simplistic – for instance asking respondents to agree or disagree

with 'transparency' in 2020 is motherhood. The great majority of course will agree. The general conclusions of the study seem OK although rather focused on the hypothesis testing rather than general conclusions based on their descriptive data.

#R3.3: Thank you for these insights. We revised the sections Discussion/Meaning of the study, p.16, l.42ff. ("Physicians in our sample reported to be concerned about reputational damage and public exposure. Those who did not disclose payments had various reasons. Mandatory transparency could approach these issues: Firstly, if disclosure is mandatory, it will no longer feel "unfair" that some disclose information and some hide this information....") and in the conclusion, p.17, l.36ff. ("We found no significant predictors for future disclosure behaviour and no statistically significant difference in the reactions to disclosures between the first year and the second year of the database. The exploratory results of this study show preliminary evidence that although German HCPs experienced only few reactions by patients, colleagues or in private, they are concerned that disclosing payments in a public database will result in reputational damage. Considering public opinion and media exposure was the most frequent reason for non-disclosure in this subsample.").

R3.4 The introduction to the paper is very long and much of it should be in a more detailed discussion of their general findings, how they compare with published work (there is quite a lot in the literature) and whether disclosure is likely to be important including a recently published systematic review <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/415848> .

#R3.4 Based on your suggestions, we shortened the introduction and added literature in the introduction as well as in the discussion section. The review in our view best fit in the introduction section, to complement the argumentation of physicians' fear of patients' trust (p. 5, l.55: "Public awareness thus appears to be a relevant element of transparency regulations.[16] Research has shown that patients would like their physicians to disclose financial COI, since they were concerned about biased clinical judgement.[19,20] However, at least in the United States, public awareness of the Open Payments website was low, as shown by citizen surveys in 2014 and 2015 ...")

Reviewer: 4

Dr. Jacob Simmering, The University of Iowa College of Pharmacy

Comments to the Author:

Stoll et al presenting an interesting analysis of the decision by German physicians to disclose payments by drug makers following the passage of a voluntary disclosure law. They find:

1. Providers that disclosed in 2015 but not in 2016 often reported deciding not to disclose following negative feedback in 2015.
2. Providers that disclosed in 2016 but not in 2015 chiefly did so because they were not contacted in 2015.
3. Most providers reported no or little reaction from the public, from colleagues, or the private environment following disclosure
4. Perhaps because of #3, regression models of the decision to disclose found no effect of pleasantness of reactions, norms, or attitudes.

Major Comments

R4.1: Drop the Group 4 and Group 5 discussion that are not included in this paper. Consider folding Groups 4 and 5 into Group 3 - it is unclear why they are treated separately for this analysis.

#R4.1: This is a sensible suggestion. We dropped this detail and only speak of groups 1-3 now.

R4.2: Drop the R2 discussion. This is a measure of the models predictive accuracy; however, in this analysis, you are only concerned about inference. A low R2 does not inform us at all about the model's inferential results. A model with low predictive power can still provide valid statistical inference.

#R4.2: Thank you for pointing that out. We dropped the discussion.

R4.3: Is this study powered? An n=30 seems limited, albeit a rule of thumb. Merging groups 4 and 5 into Group 3 should improve power.

#R4.3: The study has not been powered a priori, as we had not found any comparable studies from which we could have estimated effect sizes, which is why we relied on basic rule of thumbs and decided for a conservative level of significance.

R4.4: Why was alpha of 0.01 selected?

#R4.4: We selected alpha = .01 since it is a conservative testing level. We are aware of the replication crisis in psychology and knew that our study approach is not established, therefore we wanted to diminish the probability of false-positive results.

Minor comments:

R4.5: page 12 - stick with clearer language than "no more" and "not yet." Either stay with the group labels or be explicit - "those who reported in 2016 but not in 2015."

#R4.5: Thank you for this helpful feedback, we revised the passage and stayed with the group labels (p.12, l.8ff.).

R5.5: Given that providers are not consulting the database and it does not appear to be changing patient/provider attitudes (because they aren't consulting it), what is the value of the disclosures?

#R5.5: We are happy to clarify. In our opinion, disclosure is only valuable if it is regulated mandatorily. Our results refer to the voluntary nature of the regulation. Nevertheless, transparency is not seen as a sufficient measure to manage COI. Other measures need to build upon the disclosed information. We added this discussion in the section Discussion/Meaning of the study, p.17, l.8ff.: "For the management of financial COI in medicine, transparency is by now seen as a necessary, but not sufficient, measure.[7,10,36] Managing the influence of COI involves further higher action, e.g. people with relevant COI being excluded from guideline development groups.[1,36] Voluntary transparency regulations do not serve this aim. They may fuel discussion and raise awareness for the interaction of pharmaceutical companies with HCPs, however this may backfire if information is not contextualized, and the regulation is not driven forward."

Reviewer: 1

Competing interests of Reviewer: None

Reviewer: 2

Competing interests of Reviewer: None

Reviewer: 3

Competing interests of Reviewer: N/A

Reviewer: 4

Competing interests of Reviewer: None

VERSION 2 – REVIEW

REVIEWER	McDonald, Patrick J. Univ British Columbia, Neurosurgery
REVIEW RETURNED	03-Jan-2022

GENERAL COMMENTS	<p>The authors have addressed most of the concerns I outlined in my initial review. I believe that the manuscript could be further improved however but further outlining the limitations of the database in general, mainly that it is entirely voluntary. The fact that half of physicians chose to not disclose in 2016 is very intriguing and speaks to the problem with a voluntary disclosure. In addition, I think a paragraph or more in the limitations outlining the fact that actual payments, both the amount and number of physicians receiving, may be grossly underestimated given the nature of the database.</p> <p>In general, the manuscript has been improved but it is still often difficult to follow.</p>
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REVIEWER	Simmering, Jacob The University of Iowa College of Pharmacy
REVIEW RETURNED	16-Dec-2021

GENERAL COMMENTS	All of my comments and concerns have been addressed by the authors.
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VERSION 2 – AUTHOR RESPONSE

Reviewer 2: The authors have addressed most of the concerns I outlined in my initial review. I believe that the manuscript could be further improved however but further outlining the limitations of the database in general, mainly that it is entirely voluntary. The fact that half of physicians chose to not disclose in 2016 is very intriguing and speaks to the problem with a voluntary disclosure. In addition, I think a paragraph or more in the limitations outlining the fact that actual payments, both the amount and number of physicians receiving, may be grossly underestimated given the nature of the database.

In general, the manuscript has been improved but it is still often difficult to follow.

#R2: Thank you for this suggestion. We share your opinion that the limitations of the database should be emphasised even more. We added a paragraph in the discussion section and added another reference to our first study where we analysed the voluntary database and where a detailed discussion on this issue can be found, p.17 l. 16-24: "Voluntary transparency regulations do not serve this aim, but may paint a distorted picture of the actual situation. The voluntary database investigated in this study is a good example: Only 24% of HCPs decided to disclose information about pharmaceutical payments in 2016, [13] which means that the publicly visible amount of payments and

number of HCPs who receive payments very probably greatly underestimates the actual amount of payments and the actual number of HCPs. Voluntary transparency regulations may fuel discussion and raise awareness for the interaction of pharmaceutical companies with HCPs, however this may backfire if information is not contextualized, and the regulation is not driven forward.”

VERSION 3 – REVIEW

REVIEWER	McDonald, Patrick J. Univ British Columbia, Neurosurgery
REVIEW RETURNED	27-Feb-2022
GENERAL COMMENTS	The revisions have improved the paper.