PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	A cross-sectional study of national patient groups in Canada to examine their disclosure of relationships with pharmaceutical companies
AUTHORS	Lexchin, Joel; Batt, Sharon; Goldberg, Devorah; Shnier, Adrienne

VERSION 1 – REVIEW

REVIEWER	Ball, Douglas Independent consultant
REVIEW RETURNED	10-Oct-2021

GENERAL COMMENTS	A generally clear and well-written paper with clear explanation of the methods. The analysis of the data from the websites could be made a little more informative in some parts. The Discussion assumes that readers will accept that absolute transparency is necessary and will understand why – I feel that a few sentences saying why certain measures are necessary could provide more insight for those who don't see things in black and white (yet) – e.g. does it matter whether donor logos are shown on websites or that there are hyperlinks to the donor website? Similarly, suggestions of minimum standards could provide a discussion starting point rather than just pointing out that there are no agreed standards. [Page numbers from 10 onwards are not shown clearly, but they have been assumed to follow sequentially and to be n-1 where 'n' is the page number of the generated pdf file as given in the top right or left corner of each page (or m-2 where 'm' is the overall page number of the generated pdf file).] *Detailed comments* Abstract – amend final sentence to be clear that these were publicly available policies. P5 L49 – "When groups had a conflict with the company…" it is not clear what is meant by this. What sort of conflict? Rephrase to be clearer. P6 L3 – "The actions by groups described above highlight the need to systematically investigate how patient groups report financial information on their publicly available websites" – I would say that there is a need to investigate how they report the financial information. Their website is one way to do this (not the only and not necessarily the best). Rephrase to lead into reason for study of why websites.

	P6 L26 – perhaps be clear that the investigation of COI policies was also limited to whether these were posted on the website (it is not clear to me from the methods whether a policy submitted in response to the e-mail request would have been included if not also on the website). P7 L13 – pity that non-national groups were excluded. Would be interesting to know if there are differences (national vs. local/province/territory) and how pronounced they are (and compared using the same methodology at the same time). Maybe the something to study further especially since lobbying does not necessarily take place at national level – add a section of further research needs in Discussion. Perhaps also explain in Introduction why the focus only on national groups (optional). P12 L3 – "brand-name companies" – please be more explicit by what is meant by this. 'Generic companies' (whatever those are) also produce brand-name products and vice-versa. P15 L12 – consider reiterating that it is not that 26 groups had policies, but that 26 that had them publicly available on the website and/or made them available (e.g. reword the way presented that it is 'X% of groups had policies publicly available that ….' or similar). Also consider providing some analysis as % of policies containing certain elements rather than the % of the total number of groups that have that element publicly available. (Optional but strongly recommended; I find the presentation of the data a little misleading by always dealing with the policies as a % of all groups when there is no data available for some (a substantial portion) of them. The text needs to be clear as to exactly what is being shown and the Discussion should also touch on/highlight this.) P15 L15 – mention how many were BMC members. P18 L3 – Again I would like the text to be clear that this is based on what was publicly available, not to be so definitive that these are the only groups that had these policies/regulated these individual aspects. P20 L38 – I would expect mention of the fact that this does not mean that ONLY 54.6% receive donations – that others could do so and make no mention of this on their website. This sort of observation and rider should not just be left to the paragraph on limitations. P20 L58 – Review how written (37 out of 97) P21 L47ff – good to have the comparisons with other studies but what do the comparisons mean? That there is no need for change because they are similar to international practice? Should pressure be directed at international patient organisations or bodies to implement standards rather than expect national groups to do so? Provide some insight derived from the comparisons. P21 L49 – a long and unwieldy sentence. Rewrite. P22 L3 – I suggest adding some words to make clear that the Australian (and following) data is/are from a separate studies (also later – just stating the sentences of data from each study comes across as disjointed and potentially confusing). Some idea of the

	year of the studies would be useful in case there is any change with time and/or to give some idea of the time period over which the different data points come from (optional). P22 L60 – in Limitations, also address the response rate in request for policies. P24 - Also in Discussion, there could be some comment to provide some direction to POs as to what information they should provide with regard to funding/donation – all of this (Table 1), or just a subset (the minimum expected), are Pharma logos of donors to be frowned upon, etc. and also to state explicitly why. Academics and activists may know/think what is best and why but this is not necessarily the case of the POs themselves – and should it be different for national vs local groups, etc. Can we make this more useful for POs by providing policy guidance as to what is 'good practice'? (optional) Table 1 • Amend caption to be clear that these are reported publicly on the group websites. • Need to know/show the total number (n) for the table. • Rather than just a single row, it could be interesting to see some sort of cross-tabulation if possible – are the 42 showing total revenue the same as those showing total value of donations, etc. or are some of them complementary? i.e. same no. of rows and columns with same headers and show numbers/% that have both. It would still miss those that have multiple but not sure how best to capture that other than maybe a larger table as supplementary material – or maybe also a table (or just text) with the number/% of sites showing all (or 80%) of the data elements (to be defined – could do this just for website info or also include or do separately with policies, etc.). At the moment it is not possible to know if there are some websites that provide no information whatsoever, whether the 'transparent' patient organization (POs)/sites are also those that display Pharma logos, etc. Please give some thought to this to make Table 1 more informative. Table 2 • Amend caption to be clear that these are reported publicly on the group website. • Much as for Table 1 – total n, and consider cross-tabulating some information/data. Table 3 • Amend caption to be clear that these are policies that were publicly available on websites or on request. • More info here than in Tables 1 and 2 • While the n of 26 is obvious, perhaps mention in the caption that this data is only from those that had or provided policy documents (optional). • % in Total row as well as n. Table 4 • Amend caption to be clear that these are policies that were publicly available on websites or on request. • Total n (and should this be to the total no. of groups or total no. of policies? Maybe state both here using caption and table)

	• Donor allowed to access membership data or membership lists – address in Discussion about data privacy (Canadian perspective and wider implications).

REVIEWER	Mulinari, Shai Lunds Universitet, Sociology
REVIEW RETURNED	12-Oct-2021

GENERAL COMMENTS	Thank you for the opportunity to review the manuscript by Lexchin et al. This study analyses Canadian patient organizations' online disclosures and their policies, found online, regarding their relations with corporate funders, especially pharmaceutical companies. The study develops a novel and structured analytic approach to these issues, and presents and interpret the results in an understandable and relevant fashion. I do however have a few comments/questions for the authors: 1. There could be more clarity throughout that the analysis is based solely on recipients' - not donors' - disclosures and policies. I would suggest even highlighting this in the title, i.e., say you are looking at PO disclosures on their websites; the current title is ambiguous in this regard. 2. You could also mention somewhere that donors also disclose payments, although my understanding is that the industry in Canada lags behind compared to Europe and Australia. This is important, for example, on p.9 line 14-19 because the literature that you cite does not include a number of recent studies of industry (donor) disclosures. 3. I feel there is sometimes a problematic back-and-forth in the text between talking about POs disclosures and policies that are available online to assuming that these are all disclosures and policies that exists. I think this is particularly problematic for assessment of PO polices, because these may be written for internal use rather than external display. That is, POs may have disclosures and especially policies that are not posted online (which of course could be criticized from the perspective of transparency). Indeed, the authors acknowledge that some POs may be bound by the BMC Code (p.9) but that this Code was never found on POs' websites. However, the assumption that, therefore, the BMC Code was not applicable to the PO could be unwarranted. Similarly, the authors say they did not consider polices that were only available on request, which already suggest they are not considering all polices. 4. This problem becomes clear in the Discussion on p. 22, line 10-43 which clearly implies that the analyzed polices are all that existed (by the way, the fact that some POs have no product endorsements on-line may have other explanations than explicit or implicit polices regarding this, for example, no industry funding, the nature of the disease and its treatment, the professionalization of the PO etc.). 5. The same point applies to the Conclusion, p. 25, line 5-8. 6. Also related to the previous points, I was wondering (a) how many of the POs subscribe to the BMC Code and (b) why you did not subject it to the same analysis as the policies found online. With respect to policy recommendation, you might, depending on what you find, suggest that the BMC Code or something similar should, e.g., be re-written, strengthened, adopted by more or all POs, be better implemented, always posted online etc. 7. The previous points also apply to PO funding disclosures, although it could be argued that it is less of a problem because

	disclosures are mainly for external audiences. Still, some studies have used other sources of PO disclosures than POs own websites, see Ozieranski et al. (2020). BMJ Open, 10(9), e037351. 8. One of the innovations of the study is the structured tool for scoring PO polices. I think the novelty of the scoring tool could be foregrounded much more (perhaps even in abstract). For example, the authors should discuss if and how this tool could be applied in other countries or context. As part of this publication, they should make their tool directly and freely accessible to others. This would be similar to, for example, the use of scoring tools to track and compare industry trial data disclosure polices and COI polices at medical schools in different countries. 9. I found the variation across studied PO polices quite remarkable and probably the most interesting finding (especially Table 4). However, the authors do not analyze or discuss this variation further, for example connecting it to any literature on variation in POs practices, e.g., Parker et al (2021) BMJ Open: e045140. As a reader one wants to know much more about the possible causes and consequences of this variation. 10. In the Conclusion, the authors suggest that more transparency and better polices could somehow ensure that POs can act as truly independent voices. I think this is a quite idealistic position, and I know the authors have made convincing arguments against this idealistic position elsewhere. First, it is not clear what true independence would mean. Second, and most importantly, true independence, however we define it, may not be possible even if one would abolish industry funding because of the broader power relations and dependencies in the health sector that go beyond the particularities of industry funding and COI. 11. I was confused about the relationship between the values in Table 3 and Table 4. For example, in Table 3, 11 POs are said to have polices on “Composition and authority of Board” but in Table 4 there are only three POs scored. Could you please clarify this. 12. Page 6. Line 50-52. “conflict with the company” could be misunderstood. Also, it’s difficult to judge the information in this sentence without knowing the distribution of opinions among POs without COIs. 13. Page 12-13. Line 48-6. This implies POs consistently disclose their funders (or that they all have corporate funding), but this is most likely not the case. As an alternative you could show proportions only for those 53 that disclose pharma funding (possibly compared to those that do not, while noting that this does not guarantee that they no industry funding). 14. There is a typo on p.21, line 59. The parenthesis should include “37”. 15. As a Limitation I think one could mention that it is difficult to know what time-spans POs consider as relevant when disclosing funding, and the on-and-off relations that some POs might have with some companies. In other words, some POs may disclose corporate funding in the current fiscal year; others may include only the previous year, and some include more years. Some may have steady corporate income from the same sources; other may only have a one or a few occasional donations.

REVIEWER	Colombo, Cinzia Ist Ric Farmacol Mario Negri, Public Health
REVIEW RETURNED	13-Oct-2021

GENERAL COMMENTS	The article by Lexchin et al deals with an important issue, which is the relationship of patient groups with pharmaceutical industries, in the setting of drug regulation. The study provides data, which are necessarily partial, that draw a picture useful also for those patients groups that are interested in increasing their transparency and improving their policies on sponsors. Acknowledging the importance of the topic, I think the article needs major revisions. The study objective reported in the manuscript should be more strictly tied to the focus of the study, i.e the transparency of Canadian patient groups in the context of drug access, coverage and review. Regarding the abstract, the objective should be tied to the Canadian patient groups active in the field of drug access and reimbursement. I would not define the collection of information and policies analysis as Interventions, considering the observational design of the study. I would consider this sections as “Methods” or “Data sources/measurement”. Primary and secondary outcome measures should be more clearly defined: which are the primary outcome measures? Which are the secondary (if any)? Which kind of information have been considered as outcome measures? The conclusion should consider the limitations of the study. The study design is appropriate but, as the inclusion criteria refer to patient groups that provided suggestions or comments to institutional entities dealing with drug regulation, the research question should be reframed to refer to this setting in order to be consistent with the methods and results reported in the manuscript. The methods would need to be better detailed. Some information are missing on the tool used for data extraction and on data extraction itself. The literature search carried out is only mentioned, no information is given on the main changes made according to the pilot test; the search on the websites is only mentioned, it is not reported how it was conducted, for example which are the main websites’ sections considered? Data extraction by the authors should be reported more clearly (how many websites have been compared by the authors? There were high discrepancies in data extraction?) The outcomes are not reported in the manuscript. The results address the research objective only partially. As reported above, the research question should refer to the setting of drug regulation in order to be consistent with the methods and results reported in the manuscript. The authors should clarify the reporting of some results: - Information on broad characteristics of patient groups included (for ex. disease of interest, number of members) could be useful for the reader. -In Table 1 the total n. of patient groups (97) should be reported. The layout of Table 1 is not clear: how does the first column (total

	annual revenue n. 42) refer to the other columns (donation in general; pharmaceutical company donations…)? - Table 2: I would use ”pharmaceutical industry employment history reported” and not “disclosed” if the information is missing on the actual employment of board members or staff by pharmaceutical industry. - Table 4. The table reports two kind of information: the presence of the policy and how it is addressed (“yes” or “no”). This makes reading the table not so easy. I would suggest to present the information on separate rows with related headings. -Patient groups not responding to the email should be described, and the response rate should be addressed in the discussion. In the discussion, as the topic covered is important and interesting, I would suggest to discuss more broadly the role of patient groups in drug access and regulation, referring to the literature available, putting this discussion in a broader picture of the role and conflict of interests of patient groups, and how they can handle the issues around this. In the supplementary reporting the STROBE checklist is missing. This study provides important insights in the debate on patient groups transparency and I think it should be considered for publication, after careful revision.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Douglas Ball, Independent consultant

Disclosure of relationships between Canadian patient groups and pharmaceutical companies: an observational study

A generally clear and well-written paper with clear explanation of the methods. The analysis of the data from the websites could be made a little more informative in some parts. The Discussion assumes that readers will accept that absolute transparency is necessary and will understand why.

The Introduction touches on the importance of transparency: “Transparency in reporting is a first step to enabling all affected parties (patient group members, the medical community, governments, policy makers, funders and the public) to assess the independence of groups from these funding sources and the objectivity of the information that they provide.” The Conclusion further elaborates on this point: “Patient groups have an important role to play in the health care system as a voice for their membership. However, they need to act, and be seen to act, as independent voices for patients. Whether this is possible while engaged in relationships with the pharmaceutical industry is a question of active debate; we agree with analysts who would have patient groups decrease, and ultimately end, their dependence on industry funding.”

– I feel that a few sentences saying why certain measures are necessary could provide more insight for those who don’t see things in black and white (yet) – e.g. does it matter whether donor logos are shown on websites or that there are hyperlinks to the donor website?

In the Discussion we now point out that the use of logos has ambiguous meaning (transparency vs. promotional); in the Conclusion, we cite the ongoing debate about whether groups should accept industry funding at all and highlight transparency as an ethical requirement of good governance that applies to non-profits

Similarly, suggestions of minimum standards could provide a discussion starting point rather than just pointing out that there are no agreed standards.

In the Conclusion, as a first step towards the goal of improving transparency standards, we recommend that patient groups convene a series of national and regional workshops, similar to one recently held in Australia, to develop independent guidance for groups looking for assistance in enacting sponsorship policies.

[Page numbers from 10 onwards are not shown clearly, but they have been assumed to follow sequentially and to be n-1 where 'n' is the page number of the generated pdf file as given in the top right or left corner of each page (or m-2 where 'm' is the overall page number of the generated pdf file).]

We are not sure why this problem happened and will examine the page numbering in the manuscript before submitting our revisions.

Detailed comments

Abstract – amend final sentence to be clear that these were publicly available policies.

We have added the phrase "publicly available" before "policies".

P5 L49 – "When groups had a conflict with the company…" it is not clear what is meant by this. What sort of conflict? Rephrase to be clearer.

We are referring to a financial conflict and have added "financial" before "conflict".

P6 L3 – "The actions by groups described above highlight the need to systematically investigate how patient groups report financial information on their publicly available websites" – I would say that there is a need to investigate how they report the financial information. Their website is one way to do this (not the only and not necessarily the best). Rephrase to lead into reason for study of why websites.

We now note that public websites were chosen because they are the most accessible source of information and are the method most patient groups use to make their financial accounts available to the public.

P6 L26 – perhaps be clear that the investigation of COI policies was also limited to whether these were posted on the website (it is not clear to me from the methods whether a policy submitted in response to the e-mail request would have been included if not also on the website).

We have made it clear that any information that we requested from patient groups had to be available on their websites and that we were contacting them to be sure that our website search did not miss anything relevant.

P7 L13 – pity that non-national groups were excluded. Would be interesting to know if there are differences (national vs. local/province/territory) and how pronounced they are (and compared using

the same methodology at the same time). Maybe the something to study further especially since lobbying does not necessarily take place at national level – add a section of further research needs in Discussion. Perhaps also explain in Introduction why the focus only on national groups (optional).

In the Methods we have added the following: “The decision to only include groups that were nationally based was made because of the limited resources available to our team. Including local groups would potentially have significantly increased the volume of work.” While it would be interesting to see if local groups differ from national groups in their transparency, we don’t see that as a priority for further research and have not added a recommendation for undertaking this research in the Discussion.

P12 L3 – “brand-name companies” – please be more explicit by what is meant by this. ‘Generic companies’ (whatever those are) also produce brand-name products and vice-versa.

We have deleted “brand-name” and now just refer to “pharmaceutical companies”.

P15 L12 – consider reiterating that it is not that 26 groups had policies, but that 26 that had them publicly available on the website and/or made them available (e.g. reword the way presented that it is ‘X% of groups had policies publicly available that ….’ or similar). Also consider providing some analysis as % of policies containing certain elements rather than the % of the total number of groups that have that element publicly available. (Optional but strongly recommended; I find the presentation of the data a little misleading by always dealing with the policies as a % of all groups when there is no data available for some (a substantial portion) of them. The text needs to be clear as to exactly what is being shown and the Discussion should also touch on/highlight this.)

In the subsection of the Results, we now say “Twenty-six (26.8%) groups had publicly available policies on their websites that dealt with relations with pharmaceutical companies (Table 3). (In discussing the contents of those policies we refer to the percent of groups with policies and not the percent of all groups.)” and in the rest of that section we express the results as a percent of the groups with policies. Finally, in the Limitations section we note that “Some groups may have had policies on relevant topics, but those policies were not publicly available and would not have been included.”

P15 L15 – mention how many were BMC members.

Nine of the 20 members of BMC that were part of our sample had policies and we present this information at the start of the subsection on Patient group policies.

P18 L3 – Again I would like the text to be clear that this is based on what was publicly available, not to be so definitive that these are the only groups that had these policies/regulated these individual aspects.

The relevant sentence now reads “Table 4 provides details about how many of the 26 groups with policies regulated individual aspects of each of the 7 topics referred to above.”

P20 L38 – I would expect mention of the fact that this does not mean that ONLY 54.6% receive donations – that others could do so and make no mention of this on their website. This sort of observation and rider should not just be left to the paragraph on limitations.

We have replaced “indicating” with “publicly declaring on their websites”. We do not have any information about what percent of the other groups may have received donations from companies and do not make that public on their websites.

P20 L58 – Review how written (37 out of 97)

We have made the correction.

P21 L47ff – good to have the comparisons with other studies but what do the comparisons mean? That there is no need for change because they are similar to international practice? Should pressure be directed at international patient organisations or bodies to implement standards rather than expect national groups to do so? Provide some insight derived from the comparisons.

After the paragraphs presenting the results of surveys in other countries we have added the following: "The similarities among the results from multiple jurisdictions and spanning the period from 2003 to 2021 speaks to a number of issues. First, it indicates how pervasive the relationships between patient groups and the pharmaceutical industry are. Second, it demonstrates that the lack of patient groups' policies governing this relationship is widespread and that patient groups wherever they are located do not see this absence as a problem. Finally, the persistence of the results shows that there has not been any substantial movement to challenge the status quo."

P21 L49 – a long and unwieldy sentence. Rewrite.

The sentence now reads "Ball and colleagues studied patient organizations in Australia, Canada, South Africa, the United Kingdom and the United States (US). Corporate donations were acknowledged in only 7 out of 37 annual reports and none of the groups gave enough information to show the proportion of their funding coming from pharmaceutical companies,7 our results found even fewer groups gave enough information (1 out of 97 groups)."

P22 L3 – I suggest adding some words to make clear that the Australian (and following) data is/are from a separate studies (also later – just stating the sentences of data from each study comes across as disjointed and potentially confusing). Some idea of the year of the studies would be useful in case there is any change with time and/or to give some idea of the time period over which the different data points come from (optional).

The sentence referring to the Australian study now begins with "In another study…"

Rather than giving the dates of each individual paper (and some are systematic reviews with multiple studies), we give the date range (2003-2021) and note that there have not been any substantial changes in the results.

P22 L60 – in Limitations, also address the response rate in request for policies.

The Limitations now says "Only 37 of the 97 groups that we contacted by email responded and out of those, only 8 sent us publicly available policies."

P24 - Also in Discussion, there could be some comment to provide some direction to POs as to what information they should provide with regard to funding/donation – all of this (Table 1), or just a subset (the minimum expected), are Pharma logos of donors to be frowned upon, etc. and also to state explicitly why. Academics and activists may know/think what is best and why but this is not necessarily the case of the POs themselves – and should it be different for national vs local groups, etc. Can we make this more useful for POs by providing policy guidance as to what is 'good practice'? (optional)

We agree with the reviewer that for policies to be effective, they should be developed by the groups themselves, with assistance from academics and activists if requested. Therefore, as we stated

above, in the Conclusion, as a first step towards this goal, we recommend that patient groups convene a series of national and regional workshops, similar to one recently held in Australia, to develop independent guidance for groups looking for assistance in enacting sponsorship policies. At the same time, transparency is a basic standard of responsible governance and should not be left entirely to the organisations. Our conclusion now makes a distinction between the need for independence for all actors shaping health policy (ideally, no funding from the pharmaceutical industry, while we recognize that alternative sources are limited for many groups) and the need for fiscal transparency as a basic value of ethics in the non-profit sector.

Table 1

- Amend caption to be clear that these are reported publicly on the group websites.

The title of the table now reads “Number of 97 patient groups (percent) reporting in formation about revenue and donations on their websites”

- Need to know/show the total number (n) for the table.

The number 97 is now included in the title of the table.

- Rather than just a single row, it could be interesting to see some sort of cross-tabulation if possible – are the 42 showing total revenue the same as those showing total value of donations, etc. or are some of them complementary? i.e. same no. of rows and columns with same headers and show numbers/% that have both. It would still miss those that have multiple but not sure how best to capture that other than maybe a larger table as supplementary material – or maybe also a table (or just text) with the number/% of sites showing all (or 80%) of the data elements (to be defined – could do this just for website info or also include or do separately with policies, etc.). At the moment it is not possible to know if there are some websites that provide no information whatsoever, whether the ‘transparent’ patient organization (POs)/sites are also those that display Pharma logos, etc. Please give some thought to this to make Table 1 more informative.

We thank the reviewer for this suggestion and in response have created Supplementary File 6 and have included some information based on the file in the text. In the process of creating the file we discovered some minor computational errors that we have corrected.

Table 2

- Amend caption to be clear that these are reported publicly on the group website.
- Much as for Table 1 – total n, and consider cross-tabulating some information/data.

The title of Table 2 now reads “Number of patient groups (percent) reporting employment information about board members and staff on their websites”.

We have created Supplementary File 7 and refer to it in the text.

Table 3

- Amend caption to be clear that these are policies that were publicly available on websites or on request.
- More info here than in Tables 1 and 2
- While the n of 26 is obvious, perhaps mention in the caption that this data is only from those that had or provided policy documents (optional).
- % in Total row as well as n.

The title of Table 3 now reads “Topics related to relationships with pharmaceutical companies covered by 26 patient group policies reported on websites”

Percent in the Total row have been added.

Table 4

- Amend caption to be clear that these are policies that were publicly available on websites or on request.
- Total n (and should this be to the total no. of groups or total no. of policies? Maybe state both here using caption and table)
- Donor allowed to access membership data or membership lists – address in Discussion about data privacy (Canadian perspective and wider implications).

The title of Table 4 now reads “Topics of relationships with pharmaceutical companies covered by policies on websites of 26 patient groups”.

While we agree that it is worrisome that some patient groups allow donors to access their membership lists, we feel that the ethical implications are outside the scope of our paper.

Reviewer: 2
Dr. Shai Mulinari, Lunds Universitet

Comments to the Author:
Thank you for the opportunity to review the manuscript by Lexchin et al. This study analyses Canadian patient organizations’ online disclosures and their policies, found online, regarding their relations with corporate funders, especially pharmaceutical companies. The study develops a novel and structured analytic approach to these issues, and presents and interpret the results in an understandable and relevant fashion. I do however have a few comments/questions for the authors:

1. There could be more clarity throughout that the analysis is based solely on recipients’ - not donors’ - disclosures and policies. I would suggest even highlighting this in the title, i.e., say you are looking at PO disclosures on their websites; the current title is ambiguous in this regard.

In line with the comment from the editor and reviewer 2, the title has been changed to read “A cross-sectional study of national patient groups in Canada to examine their disclosure of relationships with pharmaceutical companies”.

In the Introduction we make it clear that we are investigating how patient groups report their relationships.

2. You could also mention somewhere that donors also disclose payments, although my understanding is that the industry in Canada lags behind compared to Europe and Australia. This is important, for example, on p.9 line 14-19 because the literature that you cite does not include a number of recent studies of industry (donor) disclosures.

Thank you for this suggestion. We have added references in the Introduction to research using donor disclosures and interviews with patient group members, as well as a reference to the lack of transparency laws in Canada.

3. I feel there is sometimes a problematic back-and-forth in the text between talking about POs disclosures and policies that are available online to assuming that these are all disclosures and policies that exists. I think this is particularly problematic for assessment of PO polices, because these

may be written for internal use rather than external display. That is, POs may have disclosures and especially policies that are not posted online (which of course could be criticized from the perspective of transparency). Indeed, the authors acknowledge that some POs may be bound by the BMC Code (p.9) but that this Code was never found on POs' websites. However, the assumption that, therefore, the BMC Code was not applicable to the PO could be unwarranted. Similarly, the authors say they did not consider polices that were only available on request, which already suggest they are not considering all polices.

We agree that there might be information or policies that are internal or that require contacting patient groups to access. However, we also strongly feel that patient groups should be as transparent as possible about their relationships with pharmaceutical companies and that means placing information about these relationships in the most easily accessible place, i.e., their websites, so that people who are interested in learning about these relationships can retrieve the information with the least amount of effort. We have tried to make this point clear in the Introduction.

4. This problem becomes clear in the Discussion on p. 22, line 10-43 which clearly implies that the analyzed polices are all that existed (by the way, the fact that some POs have no product endorsements on-line may have other explanations than explicit or implicit polices regarding this, for example, no industry funding, the nature of the disease and its treatment, the professionalization of the PO etc.).

We have changed the Discussion to make it clear that we are talking about publicly available policies. We have added a bullet to the Strengths and Limitations noting that our methodology does not allow us to distinguish between lack of transparency about industry funding and no industry funding.

5. The same point applies to the Conclusion, p. 25, line 5-8.

We have changed the Conclusion to make it clear that we are talking about publicly available policies.

6. Also related to the previous points, I was wondering (a) how many of the POs subscribe to the BMC Code and (b) why you did not subject it to the same analysis as the policies found online. With respect to policy recommendation, you might, depending on what you find, suggest that the BMC Code or something similar should, e.g., be re-written, strengthened, adopted by more or all POs, be better implemented, always posted online etc.

We treated the BMC policy the same as the policies of all the other patient groups and looked for the presence or absence of the same information. As we note in the Methods, if BMC member groups mention the policy on their websites we considered that the policy applied to that group. Based on our analysis we feel that the BMC policy could be strengthened but that applies to the policies of most of the other groups that we examined and we do not feel that BMC should be singled out. Further, as we point out in our reply to reviewer 1, we think that it should be the patient groups themselves that develop policies, with reference to standards of transparent governance, which is not our specific expertise.

7. The previous points also apply to PO funding disclosures, although it could be argued that it is less of a problem because disclosures are mainly for external audiences. Still, some studies have used other sources of PO disclosures than POs own websites, see Ozieranski et al. (2020). BMJ Open, 10(9), e037351.

The Methods subsection "Contacting patient groups" currently says only limited information about patient groups' financing is available through Revenue Canada filings. In the Conclusion we

emphasize the point that in Canada there is no requirement for patient groups to disclose the source of their donations or the amount that they receive from individual donors.

8. One of the innovations of the study is the structured tool for scoring PO polices. I think the novelty of the scoring tool could be foregrounded much more (perhaps even in abstract). For example, the authors should discuss if and how this tool could be applied in other countries or context. As part of this publication, they should make their tool directly and freely accessible to others. This would be similar to, for example, the use of scoring tools to track and compare industry trial data disclosure polices and COI polices at medical schools in different countries.

Thank you for this expression of interest. The Methods section describes the development of our data extraction tool and the two parts of the tool itself, as it appears in Redcap, are shown in Supplementary Files 3 and 4. We have highlighted the development of the novel tool as one of the study's strengths. We would welcome having other researchers adapt it for use in other countries and would be willing to discuss our experience in developing and using it with them.

9. I found the variation across studied PO polices quite remarkable and probably the most interesting finding (especially Table 4). However, the authors do not analyze or discuss this variation further, for example connecting it to any literature on variation in POs practices, e.g., Parker et al (2021) BMJ Open: e045140. As a reader one wants to know much more about the possible causes and consequences of this variation.

We agree that an exploration of the reasons for the differences in policies of patient groups would be an extremely valuable contribution to the study of these groups. Parker et al conducted a qualitative study and were able to examine the reasons for some of the differences. Our study was quantitative and while it allowed us to acquire a large amount of information it was not designed nor able to look into the motivation of groups.

10. In the Conclusion, the authors suggest that more transparency and better polices could somehow ensure that POs can act as truly independent voices. I think this is a quite idealistic position, and I know the authors have made convincing arguments against this idealistic position elsewhere. First, it is not clear what true independence would mean. Second, and most importantly, true independence, however we define it, may not be possible even if one would abolish industry funding because of the broader power relations and dependencies in the health sector that go beyond the particularities of industry funding and COI.

We agree that patient groups will always be exposed to pressure from multiple sources and that complete independence may not be possible. However, we also believe that even with that caveat there is considerable room for improvement. The type of philosophic discussion that the reviewer is calling for is definitely necessary but is not the focus of our study which was structured to examine the current situation. We have, however, added more nuance to our Conclusion about the complexities of independence and our view that transparency is a value in its own right.

11. I was confused about the relationship between the values in Table 3 and Table 4. For example, in Table 3, 11 POs are said to have polices on "Composition and authority of Board" but in Table 4 there are only three POs scored. Could you please clarify this.

In order to clarify the difference in numbers after the sentence "Table 4 provides details about how many of the 26 groups with policies regulated individual aspects of each of the 7 topics referred to above" we added the following sentence "For example, "Composition and authority of board" asked whether the policy covered 5 different aspects of the relationship but in Table 4 we only present numbers for 2 of these aspects."

12. Page 6. Line 50-52. “conflict with the company” could be misunderstood. Also, it’s difficult to judge the information in this sentence without knowing the distribution of opinions among POs without COIs.

We have inserted “financial” before “conflict”. We have added information about the views of patient groups with conflicts with other companies and with no conflicts. We have also changed the wording in the next paragraph to make it clear that our examples do not prove that conflicts influence the actions that patient groups take.

13. Page 12-13. Line 48-6. This implies POs consistently disclose their funders (or that they all have corporate funding), but this is most likely not the case. As an alternative you could show proportions only for those 53 that disclose pharma funding (possibly compared to those that do not, while noting that this does not guarantee that they no industry funding).

We have tried to clarify this point. After the sentence “Fifty-three (54.6%) of 97 groups reported donations from pharmaceutical companies.” we added the following sentence: “The remainder may have received donations or not reported them or did not receive any donations.”

14. There is a typo on p.21, line 59. The parenthesis should include “37”.

We have corrected this problem.

15. As a Limitation I think one could mention that it is difficult to know what time-spans POs consider as relevant when disclosing funding, and the on-and-off relations that some POs might have with some companies. In other words, some POs may disclose corporate funding in the current fiscal year; others may include only the previous year, and some include more years. Some may have steady corporate income from the same sources; other may only have a one or a few occasional donations.

We have added this as a limitation.

Reviewer: 3
Dr. Cinzia Colombo, Ist Ric Farmacol Mario Negri

Comments to the Author:
The article by Lexchin et al deals with an important issue, which is the relationship of patient groups with pharmaceutical industries, in the setting of drug regulation.
The study provides data, which are necessarily partial, that draw a picture useful also for those patients groups that are interested in increasing their transparency and improving their policies on sponsors.
Acknowledging the importance of the topic, I think the article needs major revisions.
The study objective reported in the manuscript should be more strictly tied to the focus of the study, i.e the transparency of Canadian patient groups in the context of drug access, coverage and review.

The objectives of our study were two-fold: 1) to examine the information that patient groups report on their websites that is relevant to their relationships with pharmaceutical companies; 2) to determine if patient groups have policies about their relationships with pharmaceutical companies and, where policies exist, to analyze their content. While our goal was not to examine the effects of these policies on the groups’ recommendations on drug coverage, the Reviewer is correct that the groups included were all registered to comment on drug coverage and this was not adequately highlighted. Their eligibility to participate in drug reviews is central to their obligation to make their relationships with

pharmaceutical companies transparent. We have reworded sentences in the Introduction, the Methods, and the Conclusion to underline this fact.

Regarding the abstract, the objective should be tied to the Canadian patient groups active in the field of drug access and reimbursement.

The patient groups that we selected for our study are ones that are active in the field of drug access and reimbursement, but the role of patient groups in these areas were not the focus of our study.

I would not define the collection of information and policies analysis as Interventions, considering the observational design of the study. I would consider this sections as “Methods” or “Data sources/measurement”.

The format required by BMJ Open for the Structured Summary does not use “Methods” or “Data sources/measurement”. If the editors would like us to use one of these terms instead of “Interventions” we would be happy to do so.

Primary and secondary outcome measures should be more clearly defined: which are the primary outcome measures? Which are the secondary (if any)? Which kind of information have been considered as outcome measures?

The cross-sectional nature of our study does not require primary and secondary measures. We have reworded the “Primary and secondary outcome measures” section of the Structured Summary.

The conclusion should consider the limitations of the study.

We have included a Limitations section.

The study design is appropriate but, as the inclusion criteria refer to patient groups that provided suggestions or comments to institutional entities dealing with drug regulation, the research question should be reframed to refer to this setting in order to be consistent with the methods and results reported in the manuscript.

The material in the Introduction about how patient groups interact with agencies concerned with the funding of prescription drugs was included to show the involvement of patient groups in various topics concerning prescription drugs and the possible influence of their relationships with pharmaceutical companies. It was meant as background information to underscore the importance of investigating these relationships.

The methods would need to be better detailed. Some information are missing on the tool used for data extraction and on data extraction itself. The literature search carried out is only mentioned, no information is given on the main changes made according to the pilot test; the search on the websites is only mentioned, it is not reported how it was conducted, for example which are the main websites’ sections considered?

The data extraction tool went through multiple iterations and detailing the various changes would require an extremely large amount of space. We feel that it is more important to report about the information that we have acquired through use of our tool.

It is not possible to describe which sections of patient groups’ websites were searched since the placement of the relevant information is not consistent from website to website. In some cases, the

information was present on the home page and in other cases we searched all the pages of the website and did not find any relevant information.

Data extraction by the authors should be reported more clearly (how many websites have been compared by the authors? There were high discrepancies in data extraction?)

The Methods section describes how data was extracted: “All four authors independently extracted information from the websites of 23-24 different patient groups and each author did a secondary review of 5 additional websites. Groups of two authors compared their evaluations for these 5 to ensure uniform extraction and then compared information in extraction forms for 1 out of every 5 of the remaining groups. Differences were resolved by consensus and if consensus could not be reached a third author made the final decision.”
The outcomes are not reported in the manuscript.

We respectfully disagree with the reviewer. We believe that the outcomes we described in the Structured Summary are thoroughly reported in the Results.

The results address the research objective only partially. As reported above, the research question should refer to the setting of drug regulation in order to be consistent with the methods and results reported in the manuscript.

We did not set out to study the role of patient groups in drug regulation; therefore, our results discuss only the findings with respect to transparency. We have, however, added material that refers to the setting of drug regulation to the Conclusion and deleted mention of policy-related activities that are not specific to drug evaluation. Additions were made to the introductory paragraph of the Conclusion which now reads:

“In the past few decades, patient groups in Canada have evolved rapidly to play a consequential policy role in the Common Drug Review, pan-Canadian Oncology Drug Review, Quebec’s Institut national d’excellence en santé et en services sociaux, and other provincial and territorial drug programs that decide which drugs will be included on drug formularies…However, groups with funding from the very companies whose drugs are under review may be influenced by their industry sponsors unconsciously, through a complex process of corrupted knowledge systems, or through a transactional system of asset exchange.”

The authors should clarify the reporting of some results:
- Information on broad characteristics of patient groups included (for ex. disease of interest, number of members) could be useful for the reader.

Information about the number of members of the patient groups is not publicly available. Supplementary File 5 provides the names of the patient groups included, which usually indicates the disease of interest, however we did not specifically investigate this area. If we were trying to link donations by companies making particular drugs with particular patient groups, then it would have been important to examine what diseases each group focused on.

-In Table 1 the total n. of patient groups (97) should be reported. The layout of Table 1 is not clear: how does the first column (total annual revenue n. 42) refer to the other columns (donation in general; pharmaceutical company donations…)?

The total number of patient groups is now mentioned in the title of the table: “Number of 97 patient groups (percent) reporting information about revenue and donations on their websites”. Supplementary Table 5 shows the data for individual patient groups.

- Table 2: I would use “pharmaceutical industry employment history reported” and not “disclosed” if the information is missing on the actual employment of board members or staff by pharmaceutical industry.

The change in wording has been made.

- Table 4. The table reports two kinds of information: the presence of the policy and how it is addressed (“yes” or “no”). This makes reading the table not so easy. I would suggest to present the information on separate rows with related headings.

The table has been restructured.

-Patient groups not responding to the email should be described, and the response rate should be addressed in the discussion.

We are not sure what the reviewer means by “described”. We have not named the patient groups that did not respond to the email because groups were promised anonymity in their responses and in the data analysis.
We now mention the response rate in the Limitations section.

In the discussion, as the topic covered is important and interesting, I would suggest to discuss more broadly the role of patient groups in drug access and regulation, referring to the literature available, putting this discussion in a broader picture of the role and conflict of interests of patient groups, and how they can handle the issues around this.

We have provided context about the role of patient groups in drug access and regulation in Canada with numerous references to literature on the same topic in other countries. The focus of our article, however, was the publicly available disclosures of Canadian groups’ relationships with pharmaceutical companies on their websites. We feel a broader discussion of the role these groups play in drug access and regulation and how they handle conflicts of interest is a topic for another paper.

In the supplementary reporting the STROBE checklist is missing.

The STROBE checklist has been added.

This study provides important insights in the debate on patient groups transparency and I think it should be considered for publication, after careful revision.

We thank the reviewer for her support.

VERSION 2 – REVIEW

REVIEWER	Ball, Douglas Independent consultant
REVIEW RETURNED	31-Dec-2021

GENERAL COMMENTS	I am satisfied with the author responses and amendments

REVIEWER	Mulinari, Shai Lunds Universitet, Sociology
REVIEW RETURNED	17-Dec-2021

GENERAL COMMENTS	Thank you for addressing my comments and concerns.