

Original Paper

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Medication labels from the perspective of Brazilian health professionals: difficulties, level of satisfaction, and proposed improvements

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Submitted: 08-11-2022 Accepted: 22-11-2022

Peer review: blind reviewer and Eugenie Desirée Néri

Abstract

Objective: To evaluate health professionals' perceptions of medication error situations associated with labeling. **Methods:** Cross-sectional study of 1056 nurse technicians, nurses, and pharmacists interviewed in 10 Brazilian capital cities. We assessed participants' perceptions of difficulty in differentiating or seeing information on labels, likelihood of a medication error to occur, and frequency of medication errors, including: 1) look-alike vials or labels; 2) two packages of the same medicine but of different doses; 3) ampoule labels; 4) blister pack labels; and 5) labels printed on secondary packages. **Results:** Most participants reported it difficult or very difficult to differentiate between look-alike vials (82.4%) and between different doses of the same medicine (82.5%). Identifying important information on ampoules, blister packs, and secondary packages was considered difficult or very difficult by 89.9%, 64.4%, and 48.9% of participants, respectively. Approximately half of the participants reported that an error was most likely to occur in situations involving difficulty in seeing the information on an ampoule, look-alike labels, and packages of the same medicine but of different doses. **Conclusion:** Difficulty in at least one of the situations involving the identification or differentiation of medication labels is common among health professionals, leading to a greater likelihood of medication errors.

Keywords: medication labels, labeling, perception, medication use, readability, health personnel.

Rótulos de medicamentos na perspectiva dos profissionais de saúde brasileiros: dificuldades, nível de satisfação e melhorias propostas.

Resumo

Objetivo: Avaliar as percepções de profissionais da saúde sobre situações de erros de medicação associado a rotulagem. **Métodos:** Estudo transversal com 1.056 técnicos de enfermagem, enfermeiros e farmacêuticos entrevistados em 10 capitais brasileiras. Avaliamos a percepção dos participantes sobre a dificuldade em diferenciar ou ver as informações nos rótulos, a probabilidade de ocorrer um erro de medicação e a frequência de erros de medicação, incluindo: 1) frascos ou rótulos semelhantes; 2) duas embalagens do mesmo medicamento, mas com doses diferentes; 3) rótulos de ampolas; 4) rótulos das embalagens blister; e 5) etiquetas impressas nas embalagens secundárias. **Resultados:** A maioria dos participantes relatou ser difícil ou muito difícil diferenciar entre frascos idênticos (82,4%) e entre diferentes doses do mesmo medicamento (82,5%). A identificação de informações importantes sobre ampolas, blisters e embalagens secundárias foi considerada difícil ou muito difícil por 89,9%, 64,4% e 48,9% dos participantes, respectivamente. Aproximadamente metade dos participantes relatou que um erro era mais provável de ocorrer em situações envolvendo dificuldade em ver as informações em uma ampola, rótulos semelhantes e embalagens do mesmo medicamento, mas com doses diferentes. **Conclusão:** A dificuldade em pelo menos uma das situações que envolvem a identificação ou diferenciação dos rótulos dos medicamentos é comum entre os profissionais de saúde, levando a uma maior probabilidade de erros de medicação.

Palavras-chave: rótulos de medicamentos, rotulagem, percepção, uso de medicamentos, legibilidade, profissional da saúde.



Introduction

Concerns about patient safety have grown in recent years, becoming a central issue in several public policy actions around the world¹. The topic has gained relevance after the release of the Institute of Medicine “To Err is Human” report, indicating the occurrence of approximately 100 000 deaths per year attributable to errors in hospital care in the United States². Since then, patient safety has been considered one of the 6 domains of health care quality³.

Studies conducted in England, Canada, Portugal, Sweden, and Brazil⁴⁻⁹ have also reported a high incidence of adverse events resulting from medication errors. On average, 10% of inpatients experience some type of adverse event, of which 50% are preventable¹⁰. In this context, the World Health Organization (WHO) chose in 2017 “Medication Without Harm” as the theme of the third Global Patient Safety Challenge, an initiative to reduce severe, avoidable medication-related harm by 50% globally over 5 years. The Challenge aims to address the weaknesses in health systems that lead to medication errors and harm resulting from errors¹. One of the planned actions focuses on improving packaging and labeling, by engaging with regulatory agencies and international actors¹.

In Brazil, there is a national regulatory standard for medication labels that establishes the rules for appropriate identification, storage, and tracking of medications¹¹. However, this standard has several deficiencies, many of which have been identified by medication users in a previous study¹².

Errors can occur at different stages of the medication process, especially when multiple health professionals are involved in patient care¹³. Factors related to packaging and labeling, such as small font size and style, font color without contrasting background, and look-alike labeling, are estimated to account for approximately 33% of all medication errors². Health professionals report that look-alike labels are potential causes of errors and recognize that improving the packaging and labeling of drug products would contribute to reducing the possibility of errors¹⁴. However, research on the benefits of improved labeling has been piecemeal, often involving specific medications¹⁵. In this setting, characterizing situations of potential medication errors associated with labeling from the perspective of health professionals is essential to guiding actions aimed at ensuring patient safety.

The present study aimed to evaluate health professionals’ perceptions of medication error situations associated with labeling. A secondary objective was to evaluate the level of satisfaction of health professionals with current labels and assess their opinions about possible label improvements in order to prevent medication errors.

Methods

We conducted a cross-sectional study in 10 Brazilian capital cities (2 capital cities in each of the 5 macro regions of Brazil) between August 12 and September 22, 2017. The target population consisted of pharmacists, nurses, and nurse technicians aged 18 years or older who were actually engaged in the activities of a pharmacist, nurse, and nurse technician at their workplaces. Participants were selected by convenience sampling based on their willingness to participate in the study. Capital cities and workplaces were also selected by convenience sampling for logistic/cost reasons. An

equal number of participants was recruited from each city. All health professionals were contacted at their workplaces because of ease of access rather than for reasons related to type, size, or characteristics of the hospital, health care unit, or pharmacy. Approximately 250 professionals were expected to be interviewed in each professional category. Data were collected by trained interviewers, in face-to-face interviews, using a tablet computer.

The data collection instrument included questions on sociodemographic data, professional experience, health professionals’ perceptions of situations where handling labels may lead to medication errors and likelihood of an error to occur, level of satisfaction with medication labels currently available in Brazil, and health professionals’ opinions about possible label improvements.

The following situations where handling labels may lead to medication errors were presented to participants: 1) difficulty in differentiating between look-alike vials or labels; 2) difficulty in differentiating 2 packages of the same medicine but of different doses; 3) viewing (seeing) the information on an ampoule; 4) viewing (seeing) the information on a blister pack; and 5) viewing (seeing) the information on secondary package. For each situation, participants were shown a picture of the package in question and instructed to use this picture as an example to help them recall similar situations that they may have experienced in their day-to-day practice. Participants’ perception of difficulty in seeing important information in the 5 presented situations was assessed using a 3-point adjectival scale (very difficult, difficult, not difficult). The 5 situations presented to all health professionals, with instructions, pictures, questions, and response options, are available as supplementary material (Supplementary File 1).

An analysis of the difficulty in differentiating or seeing information on the labels of ampoules, packages, and blister packs according to sociodemographic and professional characteristics was performed by categorizing ‘very difficult’ and ‘difficult’ responses as ‘reported difficulty’ and ‘not difficult’ responses as ‘reported no difficulty’.

Participants’ perception of the likelihood of an error to occur in each of the 5 situations was assessed by asking the following question: “In your opinion, on a scale of 1 (least likely) to 5 (most likely), how likely is an error involving [situation 1 or 2 or 3 or 4 or 5] to occur?”

Participants’ perception of the frequency of medication errors occurring in each of the 5 situations was assessed by asking the following question: “In your professional experience, error situations involving [situation 1 or 2 or 3 or 4 or 5] are: common/uncommon/ rare.”

Participants’ satisfaction with medication labels available in Brazil was assessed by asking the following questions: “Overall, how satisfied are you with ampoule labels/blister pack labels/labels printed on secondary package? [] very satisfied, [] satisfied, [] not very satisfied, [] not at all satisfied.”

Finally, we assessed health professionals’ opinions about possible label improvements based on internationally accepted guidelines^{11, 13, 16-20}. For look-alike labels, participants were asked: “In your opinion, how much would the following measures contribute to the prevention of errors due to look-alike labels? 1) Using colored caps on vials; 2) Increasing the font size of the name; 3) Highlighting the name with colors.” The response options to each item were: [] contribute a lot, [] contribute, [] not contribute. Similarly, the following measures were proposed for: different doses of the



same medicine (displaying the doses in different colors; using labels of different colors for each dose); difficulty in seeing the information on an ampoule (writing the text horizontally rather than vertically; using labels with a white background rather than labels printed directly on the ampoule); difficulty in seeing the information on a blister pack (blister packs with a white or colored background; blister packs with the drug information repeated on each blister pocket); secondary package (increasing the font size; using colors to highlight some information).

The questionnaire was tested in a pilot study for adequacy of the questions and content with 25 pharmacists, nurses, and nurse technicians in 2 hospitals in southern Brazil. The data collected from the interviews were analyzed using IBM SPSS Statistics for Windows, version 18.0, and expressed as absolute and relative frequencies, with prevalence ratios and 95% confidence intervals estimated by Pearson's Chi-Squared test.

Ethics approval

The study was approved by the research ethics committee of the Hospital Moinhos de Vento, Porto Alegre, Brazil (approval number 1.885.498). Written informed consent was obtained from all participants.

Results

A total of 1056 health professionals were interviewed. Demographic and work-related characteristics of participants are shown in Table 1. Most participants were women (78.3%), aged 30 to 39 years (40.2%), had up to 5 years of professional experience (34.2%), worked in hospitals (64.0%), and were involved in activities of dispensing medications (68.0%).

Table 2 shows health professionals' perceptions of difficulty in differentiating between look-alike vials, between different doses of the same medicine and in seeing information on ampoules, blister packs, and secondary packages. Most participants reported it difficult or very difficult to differentiate between look-alike vials (82.4%) and between different doses of the same medicine (82.5%). As for identifying important information on ampoules, blister packs, and secondary packages, participants reported more difficulty in reading information on ampoules (89.9%) and less difficulty in reading information on secondary packages (48.9%).

Figure 1 shows health professionals' opinions about the likelihood of a medication error associated with labeling to occur. Approximately half of the participants rated as 5 (most likely) the likelihood of a medication error to occur when handling look-alike labels (49.9%) or different doses of the same medicine (48.7%).

Likewise, more than half of the participants reported that an error was most likely to occur when handling ampoules due to difficulty in reading the information (54.8%), followed by 26.1% for blister packs and only 15.1% for secondary packages.

Table 1. Demographic and work-related characteristics of health professionals interviewed (n=1056).

Variables	n	%
Sex		
Male	229	21.7
Female	827	78.3
Age group		
19 to 29 years	231	21.9
30 to 39 years	424	40.2
40 to 49 years	253	24.0
50 to 68 years	146	13.9
Professional category		
Nurse technician	258	24.4
Nurse	262	24.8
Hospital pharmacist	277	26.2
Community pharmacist	259	24.5
Years of experience		
Up to 5 years	359	34.2
6 to 10 years	272	25.9
11 to 20 years	273	26.0
21 to 44 years	147	14.0
Workplace		
Hospital/Emergency department	723	68.5
Primary health care unit	72	6.8
Community pharmacy	261	24.7
Activities involving medicines*		
Dispensing	718	68.0
Preparation	560	53.0
Administration	630	59.7
Inventory control/stockroom	678	64.2

*Total exceeds 100%, because health professionals can be involved in more than one activity with medicines.

The results of the analysis of the difficulty in differentiating or seeing information on the labels of ampoules, packages, and blister packs according to sociodemographic and professional characteristics are shown in Supplementary File 2. Based on these results, older people reported more difficulty in reading information on ampoules, packages, and blister packs. Women, nurses/pharmacists, and those working in hospitals reported more difficulty in differentiating between look-alike vials and between different doses of the same medicine. The differences, although statistically significant, were small in terms of magnitude of association.

Table 2. Health professionals' perceptions of difficulty in differentiating or seeing information on medication labels (n=1056).

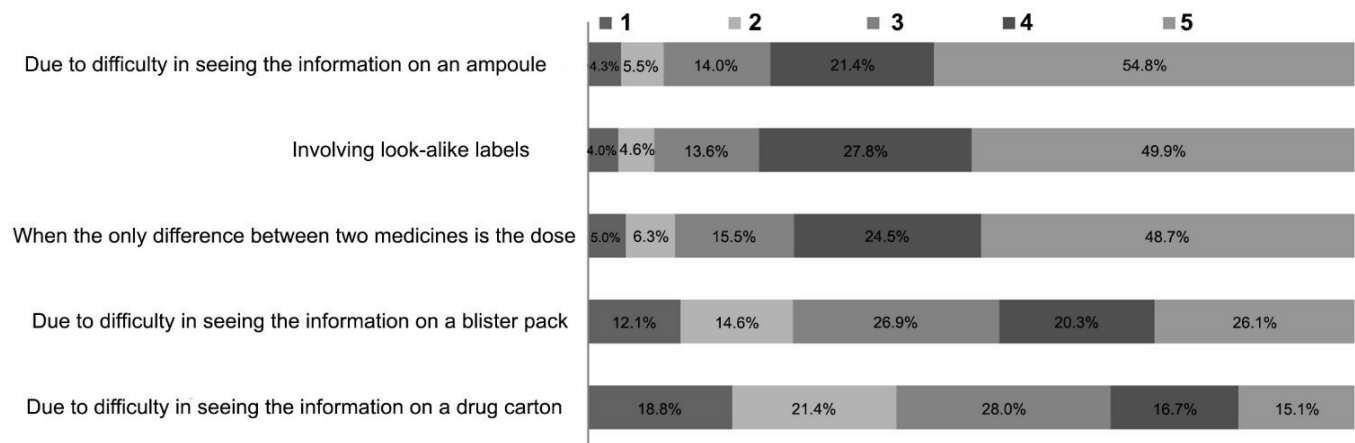
Variables	Very difficult		Difficult		Not difficult	
	%	95%CI	%	95%CI	%	95%CI
Differentiating between look-alike vials	35.5	32.7-38.4	46.9	43.9-49.9	17.6	15.5-20.1
Differentiating 2 packages of the same medicine but of different doses	43.6	40.6-46.6	38.9	36.0-41.9	17.5	15.4-19.9
Seeing the information on an ampoule	58.4	55.4-61.4	31.5	28.7-34.4	10.1	08.4-12.1
Seeing the information on a blister pack	22.8	20.3-25.4	41.6	38.6-44.6	35.6	32.8-38.6
Seeing the information on secondary package	13.0	11.1-15.1	35.9	33.0-38.8	51.1	48.1-54.2

CI, confidence interval.



Figure 1. Health professionals' opinions about the likelihood of a medication error to occur (n=1056).

**In your opinion, on a scale of 1 to 5, how likely is an error to occur?
(Consider 1 the least likely and 5 the most likely)**



Most participants reported that medication errors involving ampoules are more common (51.9%), followed by errors involving different doses of the same medicine (47.1%) and look-alike labels (43.0%) (Table 3).

As for the level of satisfaction with medication labels, only 14.5% of participants were satisfied or very satisfied with ampoule labels. The level of satisfaction with blister packs and secondary packages was higher (39.0% and 54.1%, respectively) (Table 4).

Supplementary File 3 shows health professionals' opinions about possible label improvements. Most participants responded that using colors to differentiate between look-alike vials, between different doses of the same medicine and to highlight information on secondary package would contribute to reducing errors. More than 90% of participants reported that using labels with a white background on ampoules would contribute to preventing errors attributable to difficulty in seeing the information.

Discussion

The present study revealed an impressive number of health professionals reporting difficulty in reading and differentiating between labels. One in every 2 health professionals interviewed reported difficulty in at least 1 of the 5 situations involving the identification or differentiation of medication labels. Also, 1 in every 2 health professionals reported that a medication error was most likely to occur due to difficulty in seeing the information on an ampoule, look-alike labels, and packages of the same medicine but of different doses. These findings show that, from the perspective of nurse technicians, nurses, and pharmacists, medication labels are not currently meeting the basic labeling regulatory requirements, which state that labels should be easy to read and understand by health professionals handling the medications, aiming at prompt identification and avoiding medication mix-ups²⁰.

Table 3. Health professionals' perceptions of the frequency of medication errors associated with labeling (n=1056).

Variables	Common		Uncommon		Rare	
	%	95%CI	%	95%CI	%	95%CI
Look-alike labels	43.0	40.0-46.0	41.1	38.1-44.1	16.0	13.9-18.3
Different doses of the same medicine	47.1	44.1-50.2	38.5	35.6-41.5	14.3	12.4-16.6
Ampoules	51.9	48.8-55.0	33.7	30.8-36.7	14.4	12.3-16.7
Blister packs	29.2	26.5-32.0	44.4	41.4-47.4	26.4	23.8-29.2
Secondary packages	21.2	18.8-23.8	46.1	43.1-49.2	32.7	29.9-35.6

CI, confidence interval.

Table 4. Health professionals' satisfaction with medication labels (n=1056).

Variables	Very satisfied		Satisfied		Not very satisfied		Not at all satisfied	
	%	95%CI	%	95%CI	%	95%CI	%	95%CI
Ampoule labels	1.2	0.7-2.1	13.3	11.3-15.4	63.2	60.2-66.0	21.3	20.0-25.0
Blister pack labels	1.8	1.1-2.8	37.2	34.3-40.2	52.3	49.2-55.3	8.7	7.1-10.6
Labels printed on secondary package	3.0	2.1-4.3	51.1	48.1-54.1	41.6	38.6-44.6	4.3	3.2-5.7

CI, confidence interval.



For approximately half of the health professionals interviewed, look-alike labels have the greatest likelihood of leading to error. This high perception of risk suggests that health professionals can recognize the difficulties, and such perception to some extent reflects their previous experiences with this type of error. Greater difficulty was reported in identifying information on ampoule labels. In addition to restrictions on the amount of information and font size on this type of package, text printed on glass or on a clear label increases the degree of difficulty¹⁸. Also, health professionals perceived a greater likelihood of an error to occur and were dissatisfied with the use of ampoules, especially compared with the use of blister packs and secondary packages. Despite the problems inherent in ampoule labels, the perception of risk and dissatisfaction with this type of label may have been influenced by the error tolerance threshold in handling and administering intravenous/intramuscular injections, which we believe is lower than that accepted in orally administered medications.

There are several reports in the literature of concentration or medication mix-ups resulting from confusion between look-alike labels²¹⁻²⁵. Look-alike confusion has been recognized and reported in several studies as one of the main causes of medication error²¹⁻²³. Nevertheless, it is a common practice of drug manufacturers to use the same layout of label across all their product lines. Using the same type style, font size and color, color scheme, package size, and layout of information hinders the proper differentiation between products²⁶. Lack of contrast between the product concentration and the background, in turn, hinders the differentiation between medications that have more than one type of concentration²⁷.

Mix-up of high-alert medications, from the same or different manufacturers, is particularly worrisome, because these incidents are more likely to cause serious harm to the patient, such as death.²⁶ In a survey of Canadian anesthesiologists, most participants (61.7%) reported at least one medication error, and almost half of them (46.8%) cited the misidentification of the ampoule or vial as a factor contributing to error²⁸. In another study, anesthesiologists from 3 South African hospitals attributed the error to ampoule misidentification in 36.9% of cases; of these, 64.4% were due to look-alike ampoules²⁹. In an Australian incident monitoring review, 187 (20.8%) of 896 reports of medication error were due to selection of the wrong ampoule³⁰.

The high level of dissatisfaction with ampoule, blister pack, and secondary package labeling observed in the present study demonstrates a clear need for improvements in the design of medication labels. This study also captured health professionals' perceptions of potential improvements. More than 90% of participants reported that using labels with a white background on ampoules would contribute to preventing errors attributable to difficulty in seeing the information. Other changes included the use of colors to differentiate between look-alike vials, between different doses of the same medicine and to highlight information on secondary package.

These findings are consistent with the recommendations provided in guidelines from Canada, European Union, and Australia^{13, 16, 17, 26} and in a systematic review of the literature.³¹ Use of color differentiation has been recommended in designing safe labels, especially for look-alike packages from the same manufacturer^{18, 26}. In addition, there is evidence that the use of color to highlight key information, such as medication name and concentration, helps to identify information faster and more accurately^{32, 33}. A systematic review evaluating different strategies to minimize medication errors due to look-alike labels identified 2 studies in

which the correct reading score was higher and reading time was shorter for ampoules with a white label than for those with text directly printed on glass or on a clear label³¹. Contrast between the text and the background should be provided by contrasting color combinations, as they improve the legibility and decrease the likelihood of reading errors³⁴. In addition to contrasting background, other factors should be considered in order to improve the legibility of ampoules, such as vial size, font size, and orientation of text on the label^{18, 34}.

In Brazil, labels are developed by pharmaceutical industries and must meet the minimum requirements established by federal legislation¹¹. The Brazilian Health Regulatory Agency (ANVISA), linked to the Brazilian Ministry of Health, establishes the rules for drug registration, including label/package format and content, and is responsible for approving the label of pharmaceutical products before marketing. According to a previous study of medication users¹², several aspects are not adequately provided in current Brazilian legislation, such as font size and the use of graphic elements and color, especially to emphasize critical information such as concentration and expiration date. The evaluation of users' acceptance and understanding of labels is part of the regulatory process for packaging in several developed countries, such as Canada, Australia, and European Union^{13, 16, 20}, but this step is not included in Brazilian legislation. Also, the use of Tall Man letters to reduce potential errors associated with look-alike medications is not regulated in Brazil, despite evidence showing their effectiveness^{35, 36}. Altogether, these findings indicate the need for improvements in current legislation.

Guidelines and sanitary standards that guide labeling design will be more effective if they take into account the perceptions and opinions of the health professionals who handle the medications. This is the first study to evaluate the perceptions of a comprehensive sample of health professionals working at different health facilities in 10 Brazilian capital cities. In addition, research on medication labeling problems from the perspective of health professionals is scarce, especially in developing countries such as Brazil. The main results are consistent with those obtained through a household survey conducted by our study group involving 6255 medication users, where more than half of the participants reported it difficult or very difficult to read (50.8%) and/or understand (52.0%) medication labels¹². Likewise, the results of a qualitative study, with data collected through semi-structured interviews with 30 health professionals and 8 focus groups with medication users, showed that the main difficulties reported by the respondents were look-alike labeling, difficulty in locating information on the labels, and difficulty in viewing information on the labels (Barroso *et al.* 2019, unpublished data).

This study has some limitations. A non-validated questionnaire was used; nevertheless, it was previously tested with 25 health professionals and adjusted to the needs identified by them. Because a convenience sample was used, the results are not generalizable to all Brazilian health professionals, although the sample consisted of health professionals working at different workplaces in 10 Brazilian capital cities. Despite the large sample size, the study was conducted in a single country. However, the literature on this topic is scarce, especially with regard to international studies, as countries around the world appear to share the same labeling issues. Of note, medication labeling legislation in Brazil is similar to that in countries of the European Union and Australia, resulting in labels with similar characteristics and limitations as those of other settings.



Conclusion

By characterizing the needs of health professionals handling medications, the results of the present study may assist policy makers in developing standards and guidelines, as well as drug manufacturers in designing clearer and safer labels. We recommend that drug manufacturers include the participation of health professionals in the design and testing of medication labels, extending their interests beyond business settings to include strategies aimed at reducing medication errors.

Supplementary File 1. Five situations presented to health professionals to evaluate their perception of difficulty in seeing important information.

Supplementary File 2. Analysis of the difficulty in differentiating or seeing information on the labels of ampoules, packages, and blister packs according to sociodemographic and professional characteristics.

Supplementary File 3. Health professionals' opinions about possible label improvements that may contribute to the prevention of medication errors (n=1056)

Funding

This work is based on research supported by Hospital Moinhos de Vento and the Program of Support for the Institutional Development of the Unified Health System (PROADI-SUS) (Website: <http://portalms.saude.gov.br/aco-es-e-programas/proadi-sus>). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Collaborators

Conception and design: CGMP, MF, ESP

Analysis and interpretation: CGMP, ESP, TSDP, GW

Data collection: CGMP, ESP

Writing the article: CGMP, TSDP, ESP

Critical revision of the article: MF, LRS, AFDVC, GW

Final approval of the article: CGMP, TSDP, ESP, LRS, AFDVC, GW

Statistical analysis: TSDP

Overall responsibility: ESP

All authors have read and approved the final version of the article.

Conflict of interest statement

All authors declare that they have no conflicts of interest

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