

Long list of conflicts of interest in industry-funded drug trials are counterproductive and opaque for readers

Sophie Leducq, Richard Barlow, Arabella Baker, Mikolaj Swiderski, Hywel

Williams

▶ To cite this version:

Sophie Leducq, Richard Barlow, Arabella Baker, Mikolaj Swiderski, Hywel Williams. Long list of conflicts of interest in industry-funded drug trials are counterproductive and opaque for readers. Journal of Clinical Epidemiology, 2024, pp.111491. 10.1016/j.jclinepi.2024.111491. hal-04668789

HAL Id: hal-04668789 https://hal.science/hal-04668789v1

Submitted on 7 Aug 2024

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers. L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés. 1 Article Type: Letter to the Editor

2 Title: Long list of conflicts of interest in industry-funded drug trials are counterproductive3 and opaque for readers

4 Authors and affiliations

Sophie LEDUCQ, MD, PhD (0000-0002-4860-6365), Centre of Evidence Based
Dermatology, School of Medicine, University of Nottingham, Nottingham, United Kingdom,
Department of Dermatology, CHRU Tours, University of Tours, University of Nantes,
INSERM 1246-SPHERE, Tours, France

9 Richard BARLOW, trainee in dermatology, Birmingham Children's Hospital, Birmingham,

10 United Kingdom

11 Arabella BAKER, PhD (0000-0003-0101-4693), Centre of Evidence Based Dermatology,

12 School of Medicine, University of Nottingham, Nottingham, United Kingdom

13 Mikolaj SWIDERSKI, MSc, MRes (0000-0001-5462-6170), Centre of Evidence Based

14 Dermatology, School of Medicine, University of Nottingham, Nottingham, United Kingdom

15 Hywel C. WILLIAMS, DSc (0000-0002-5646-3093), Centre of Evidence Based

16 Dermatology, School of Medicine, University of Nottingham, Nottingham, United Kingdom

17

18 Corresponding to: Prof Hywel C. Williams, Centre of Evidence Based Dermatology, Faculty
19 of Medicine & Health Sciences, Applied Health Research Building, University Park,
20 Nottingham, NG7 2RD, United Kingdom; Email: <u>Hywel.Williams@nottingham.ac.uk</u>; Tel:
21 +44 (0) 115 84 68631

- 23 Manuscript word count: 499
- 24 **References:** 5
- **Figure:** 1

- **1 Table:** 1
- 2 Keywords: conflict of interest, statement, funding, industry, randomized controlled trial,
- 3 atopic dermatitis, observational study

1 MANUSCRIPT

2

1. Introduction

Conflict of interest (COI) has been widely accepted as a mandatory item of reporting.[1] The optimal method for declaring COI remains unclear and varies from brief statements to extensive lists.[2,3] We hypothesise that exhaustive lists, encompassing all financial relationships with drug companies spanning many years (whether related to the study drug or not) are counterproductive and opaque. The objective was to determine whether the use of lengthy lists of COIs creates difficulties for readers in identifying the most relevant COIs in dermatological industry-funded randomised controlled trials (RCTs) of drug treatments.

10 **2.** Methods

A recruited panel of typical dermatology journal readers (UK dermatology clinicians and researchers) completed an online cross-sectional survey about COIs in a purposive sample of four RCTs published in leading journals. Each paper had a long list of COIs, covering more than a third of a page, on the topic of a commercial drug for a single skin condition. The primary outcome was the percentage of readers correctly identifying the company that developed the drug with authors who had a direct conflict with that company for the four papers included, assessed independently by three authors who acted as a reference standard.

18 **3. Results**

A total of 23 readers completed the survey (response rate 44%). Six (26%) were exclusively clinicians and 17 (73.9%) were research active (**Table**). No readers correctly identified direct COIs of authors to the experimental drugs (**Figure**). All 23 readers correctly identified the companies producing these drugs. Median time per paper taken to try and identify the authors with direct COI was 6 minutes [4-8]. Readers reported a median score of 3 [2-4] for confidence in their COI conclusions, indicating moderate confidence (6-point Likert scale; 1: no confidence to 6: complete confidence). Scores obtained by readers with an exclusive clinical activity were lower than the scores obtained by researchers. Free comments
 highlighted challenges in discerning relevant COIs.

4. Discussion

Identifying authors with relevant COIs from long lists of COIs is counterproductive. 4 5 According to our readers' comments and previous literature, [4] several modifiable factors 6 could have contributed to challenges in accurately identifying relevant COIs, such as dense 7 paragraphs, small font, initialled names rather than full names, information split across 8 different pages and declaration of COIs in an appendix. In some senses, such COIs have 9 become the exhaustive "small print" for terms and conditions that few people read on many websites. There is a need for transparency to avoid analysis bias and facilitate interpretation 10 11 of COIs.[5] We suggest that a clear and simple statement should indicate which authors have a direct financial conflict with the product. We advocate for more reader-friendly and clear 12 13 COI disclosures, which could be facilitated using an "ACE" framework denoting the Author(s) who received financial support from Company X (...a subsidiary of Company Y) who 14 15 developed/manufactured the Experimental treatment drug [name of drug] in this study. Others 16 have suggested a similar approach.[4] The standard full ICMJE COI statement could remain at the end of the article for those who need the detail. 17

1 ABBREVIATIONS

- 2 COI: Conflict of Interest
- 3 RCT: Randomised Controlled Trial

4 ACKNOWLEDGEMENTS

We thank patient contributors, Mrs Amanda Roberts and Mr Tim Burton, for their helpful 5 6 comments on the manuscript, Dr Sonia Gran for her helpful comments on the protocol and 7 questionnaire, Dr Laura Howells for her helpful comments on the questionnaire, Dr Carron 8 Layfield for her help for disseminating the questionnaire and Maggie McPhee for her 9 technical help. We acknowledge Dr Rachel Abbott, Dr Louise Clarke, Dr Stuart N. Cohen, Dr 10 Jane Harvey, Dr Rubeta Matin, Mrs Rheanne Leatherland, Prof Nick Levell, Dr Bayanne Olabi, Prof Charlotte Proby, Mr Corey Simpson, Dr Hannah Wainman and anonymous 11 12 participants who kindly answered the questionnaire.

13 FUNDING

No funding has been received for this study. Dr Sophie Leducq received a grant from the *Fonds de Dotation* of the French Society of Dermatology (on an educational grant funded by
Amgen, unrelated to the submitted work) and *Collège des Enseignants en Dermatologie de France* for her one-year fellowship at the Centre of Evidence Based Dermatology.

18 COMPETING INTERESTS

19 The authors declare no competing interest.

20 ETHICS APPROVAL

21 Not applicable

22 TRANSPARENCY DECLARATION

23 The lead author affirms that this manuscript is an honest, accurate, and transparent account of

the study being reported; that no important aspects of the study have been omitted; and that

1 any discrepancies from the study as planned (and, if relevant, registered) have been

2 explained.

3 DATA SHARING

4 Data supporting the study findings will be available from the corresponding author on

5 reasonable request.

6 **REGISTRATION**

- 7 This prospective observational study was registered on the 22^{nd} of December 2022 at the
- 8 Centre of Evidence Based Dermatology registration portal. The protocol can be accessed at
- 9 https://www.nottingham.ac.uk/research/groups/cebd/documents/protocol-coi.pdf.

REFERENCES

2	1.	International Committee of Medical Journal Editors. Author Responsibilities
3		Conflicts of Interest. Recommendations for the Conduct, Reporting, Editing, a
4		Publication of Scholarly Work in Medical Journa
5		https://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-
6		responsibilitiesconflicts-of-interest.html [accessed 26th February 2024]
7	2.	Bauchner H, Fontanarosa PB, Flanagin A. Conflicts of interests, authors, and journal
8		new challenges for a persistent problem. JAMA 2018; 320:2315-2318.
9		https://doi.org/10.1001/jama.2018.17593
10	3.	Grundy Q, Dunn AG, Bero L. Improving researchers' conflict of interest declaration
11		BMJ 2020;368:m422. <u>https://doi.org/10.1136/bmj.m422</u>
12	4.	Agrawal D, Haque W. Transparent disclosure of conflicts of interest. JAMA 201
13		321:1728. https://doi.org/10.1001/jama.2019
14	5.	Boutron I, Page MJ, Higgins JPT, Altman DG, Lundh A, Hróbjartsson A. Chapter
15		Considering bias and conflicts of interest among the included studies. In: Higgins JF
16		Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochra
17		Handbook for Systematic Reviews of Interventions version 6.0 (updated July 201
18		Cochrane, 2019.

1 **TABLE.** General readers' characteristics

2

Characteristics	N = 23	
Gender, <i>n</i> (%)		
Female	14 (60.9)	
Male	9 (39.1)	
Age (years)	34 [31-44.5]	
Number of scientific articles read by month	5 [4.0-10.0]	
Professional role, n (%)		
Clinician	6 (26.1)	
Researcher	7 (30.4)	
Both clinician and researcher	10 (43.5)	
Work setting for clinicians, <i>n</i> (%)*		
Public practice (NHS)**	16 (100)	
Private practice**	2 (12.5)	
Number of years within dermatology specialty (1 st year of	7 [3.0-15.25]	
residency)*		

3 Data are expressed as median [IQR] or number (%)

4 *Not applicable for 7 readers with an exclusive research activity

5 **A reader can have multiple activities

- **FIGURE.** Outcomes stratified by paper and readers' characteristics
- 2 Primary outcome (percentage of readers who correctly both identified the company that
- *developed the drug and whether any (and which) of the authors have a direct conflict with*
- *that company for the 4 papers included) stratified by paper and readers' characteristics*
- 5 (created with flourish.studio: <u>https://flourish.studio</u>).

1 Supplemental file

- 2 Appendix 1. Methods
- 3 Appendix 2. Search strategy in Medline (equation research used in the GREAT database)
- 4 Appendix 3. Characteristics of included studies and extracted data