Umgang mit Interessenkonflikten bei Studien und Publikationen

Chr. Herrmann-Lingen
Göttingen

Finanzielle Interessen

- Professorengehalt mit leistungs- und erfolgsabhängigen Bestandteilen
- Evaluationsbasierte LOM-Zuweisungen
- Vortragshonorare Heel, Servier, Novartis
- Advisory Board Pfizer
- Tantiemen Hospital Anxiety and Depression Scale (Verlag Hogrefe-Huber)
- Honorare / Tantiemen für firmenunabhängige Fortbildungsbeiträge und Publikationen

AWMF

Cochrane Library

Cochrane Database of Systematic Reviews

Industry sponsorship and research outcome (Review)

Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L

Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: MR000033.

DOI: 10.1002/14651858.MR000033.pub3.

DECLARATIONS OF INTEREST

Andreas Lundh, Joel Lexchin and Lisa Bero are authors of the some of the previous reviews and included studies.

In 2015 to 2016, Joel Lexchin received payment from non-profit entities for being a consultant on two projects, one looking at indications-based prescribing and a second looking at which drugs should be provided free of charge by general practitioners. He received payment from a for-profit company for being on a panel that discussed expanding drug coverage in Canada. He is on the Foundation Board of Health Action International.

In 2014, Barbara Mintzes was retained as an expert witness by the law firm representing the plaintiffs in a Canadian class action on hormone replacement therapy and breast cancer, and in 2015 to 2016 in an application for a Canadian class action on cardiovascular risks of testosterone supplements. She was a member of the Health Action International - Europe Association Board from 2012 to 2015.

The review authors have no other relevant interests.

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Systemat. Review Industrieförderung und Studienergebnisse

Lundh A et al., Cochrane Database of Systematic Reviews 2017: MR000033.

	N Reviews	N Studien	RR	CI
Studien mit vs. ohne Industrieförderung				
Anteil Studien mit pos. Ergebnis	25	2923	**1,29**	1,19-1,51
- Hohes risk of bias	25	2107	**1,20**	1,11-1,30
- Niedriges risk of bias	5	816	**1,46**	1,25-1,71
Anteil Studien mit pos. Folgerungen	29	4583	**1,34**	1,19-1,51
Anteil Ergebnisse u. Folgerungen konkordant	6	751	**0,83**	0,70-0,90
Studien zu Präparat des Sponsors vs. Konkurrenzpräparat				
Anteil Studien mit pos. Folgerungen eig. Präparat	3	154	**5,92**	2,80-12,54

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JAMA

New Issue | MAY 2, 2017; VOLUME 317, NUMBER 17

IN THIS ISSUE OF JAMA

Highlights

VIEWPOINT

Conflict of Interest: Why Does It Matter?

Harvey V. Fineberg, MD, PhD

Payments to Physicians: Does the Amount of Money Make a Difference?

Bernard Lo, MD; Deborah Grady, MD, MPH

Why There Are No "Potential" Conflicts of Interest

Matthew S. McCoy, PhD; Ezekiel J. Emanuel, MD, PhD

Addressing Bias and Conflict of Interest Among Biomedical Researchers

Lisa Bero, PhD

Conflict of Interest and the Integrity of the Medical Profession

Allen S. Lichter, MD

Conflict of Interest and the Integrity of the Medical Profession

Allen S. Lichter, MD

Strategies for Addressing a Broader Definition of Conflicts of Interest

Ross E. McKinney Jr, MD; Heather H. Pierce, JD, MPH

Role of Leaders in Fostering Meaningful Collaborations Between Academic Medical Centers and Industry While Also Managing Individual and Institutional Conflicts of Interest

Philip A. Pizzo, MD; Thomas J. Lawley, MD; Arthur H. Rubenstein, MBBCH

Conflict of Interest Among Medical School Faculty: Achieving a Coherent and Objective Approach

Jeffrey S. Flier, MD

Teaching Medical Students About Conflicts of Interest

Diane B. Wayne, MD; Marianne Green, MD; Eric G. Neilson, MD

Funding, Institutional Conflicts of Interest, and Schools of Public Health: Realities and Solutions

Sandro Galea, MD, DrPH; Richard Saitz, MD, MPH

Conflicts of Interest and Professional Medical Associations: Progress and Remaining Challenges

Steven E. Nissen, MD

...

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RESEARCH

BMJ 2017;356:i6770 | doi: 10.1136/bmj.i6770

OPEN ACCESS

Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study

Rosa Ahn,[1] Alexandra Woodbridge,[2] Ann Abraham,[2] Susan Saba,[3] Deborah Korenstein,[4] Erin Madden,[2] W John Boscardin,[2,5] Salomeh Keyhani[2,5]

Funding: This project was not directly supported by any research funds. SK is funded by grants from the National Institutes of Health (RO1 HL116522-01A1, RO1 HL114563-01A1) and Veterans Affairs Health Services Research and Development Service (1IP1HX001994). DK's work on this paper was supported by a Cancer Center Support Grant from the National Cancer Institute to Memorial Sloan Kettering Cancer Center (award number P30 CA008748).

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organization for the submitted work, other than that described above; no financial relationships with any organizations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: Not needed.

Data sharing: Dataset available from corresponding author on request.

Transparency: The lead author (the manuscript's guarantor) 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 any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Conclusions

"Financial ties of principal investigators are prevalent and are independently associated with positive clinical trial results. Given the importance of industry and academic collaboration in advancing the development of new treatments, more thought needs to be given to the roles that investigators, policy makers, and journal editors can play in ensuring the credibility of the evidence base."

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BMJ 2017;356:i6770 | doi: 10.1136/bmj.i6770

OPEN ACCESS

Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study

Rosa Ahn,[1] Alexandra Woodbridge,[2] Ann Abraham,[2] Susan Saba,[3] Deborah Korenstein,[4] Erin Madden,[2] W John Boscardin,[2,5] Salomeh Keyhani[2,5]

Table 3 | Association between financial ties and primary study outcome after adjustment for industry funding

	No (%)			Odds ratio (95% CI)	
	Positive study	Negative study	Total No	Unadjusted	Adjusted
Self reported financial ties			**60%**		
Yes	92 (79)	25 (21)	117	2.84 (1.5 to 5.3)*	2.94 (1.4 to 6.1)
No	48 (62)	30 (38)	78	–	–
Industry funding			**69%**		
Yes	98 (73)	36 (27)	134	1.65 (0.87 to 3.1)†	0.93 (0.43 to 2.0)
No	38 (62)	23 (38)	61	–	–
Total financial ties			**68%**		
Yes	103 (78)	29 (22)	132	3.23 (1.7 to 6.1)*	3.57 (1.65 to 7.7)
No	33 (52)	30 (48)	63	–	–
Industry funding					
Yes	98 (73)	36 (27)	134	1.65 (0.87 to 3.1)†	0.83 (0.37 to 1.8)
No	38 (62)	23 (38)	61	–	–

*Unadjusted association between financial ties and study outcome.
†Unadjusted association between industry funding and study outcome.

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Medscape Mittwoch, 17. Mai 2017

Schmerzhafte diabetische Neuropathie: Review berücksichtigt unpublizierte Therapiestudien – und stellt Ranking auf den Kopf

Inge Brinkmann

INTERESSENKONFLIKTE | 2. Mai 2017

Reporting Bias ändert die „Rangfolge“ unter den Medikamenten

So empfiehlt beispielsweise die American Academy of Neurology (AAN) in ihren aktuellen Leitlinien in erster Linie Pregabalin bei schmerzhafter diabetischer Neuropathie (Level A, starke Evidenz); Duloxetin wird dagegen nur mit moderater Evidenz (Level B) empfohlen. Dass sich nun im aktuellen Review die Rangfolge zu Ungunsten von Pregabalin umkehre, sei vor allem auf die Einbeziehung bislang unveröffentlichter Untersuchungen zurückzuführen,

Auch Reviews und Guidelines müssen hinterfragt werden

… „Die vorliegende Übersichtsarbeit zeigt eindrücklich, dass auch die Ergebnisse von Reviews und die Empfehlungen in Guidelines von Ärzten regelmäßig hinterfragt werden sollten.“

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AAN Summary of Evidence-based Guideline for CLINICIANS

TREATMENT OF PAINFUL DIABETIC NEUROPATHY

Anticonvulsants	
Strong evidence	If clinically appropriate, pregabalin should be offered for the treatment of PDN (**Level A**[†]).

Table: Summary of Recommendations

	Recommended Drug and Dose	Not Recommended
Level A	Pregabalin, 300–600 mg/day	
Level B	Gabapentin, 900–3600 mg/day Sodium valproate, 500–1200 mg/day Venlafaxine, 75–225 mg/day Duloxetine, 60–120 mg/day Amitriptyline, 25–100 mg/day Dextromethorphan, 400 mg/day Morphine sulphate, titrated to 120 mg/day Tramadol, 210 mg/day Oxycodone, mean 37 mg/day, max 120 mg/day Capsaicin, 0.075% qid Isosorbide dinitrate spray Electrical stimulation, percutaneous nerve stimulation x 3–4 weeks	Oxcarbazepine Lamotrigine Lacosamide Clonidine Pentoxifylline Mexiletine Magnetic field treatment Low-intensity laser therapy Reiki therapy

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SPECIAL ARTICLE

Evidence-based guideline: Treatment of painful diabetic neuropathy

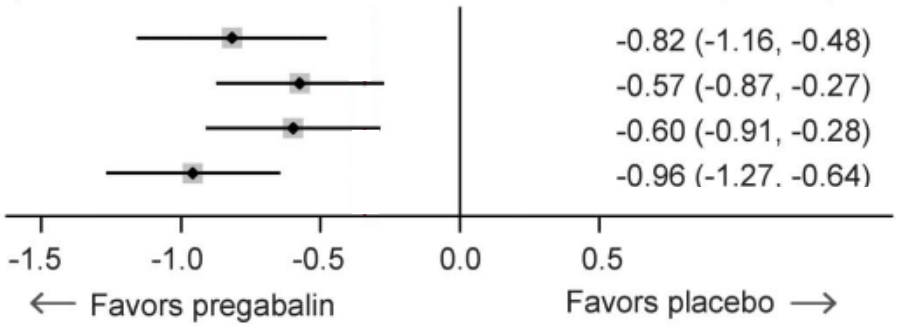
Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation

Brill V et al., Neurology 2011;76:1758–1765

*"**Based on consistent Class I evidence**, pregabalin is established as effective in lessening the pain of PDN."*

Figure 1 Meta-analysis of calculated standardized mean differences (SMD) for studies comparing pregabalin with placebo for pain outcome

Study	Source	Scale	Follow-up (Weeks)	Sample size (Number)	SMD (95% CI)
Ref 17*	Published	NPS	8	146	-0.82 (-1.16, -0.48)
Ref 18*	Published	NPS	5	337	-0.57 (-0.87, -0.27)
Ref 19*	Published	NPS	6	246	-0.60 (-0.91, -0.28)
Ref 20*	Published	NPS	12	338	-0.96 (-1.27. -0.64)



Waldfogel JM et al., Neurology 2017;88:1–10.

Pain 110 (2004) 628–638

PAIN

www.elsevier.com/locate/pain

Pregabalin for the treatment of painful diabetic peripheral neuropathy: a double-blind, placebo-controlled trial☆

Julio Rosenstock[a,*], Michael Tuchman[b], Linda LaMoreaux[c], Uma Sharma[c]

[a]*Dallas Diabetes & Endo Research Center, 7777 Forest Lane, C618, Dallas, TX 75230, USA*
[b]*Palm Beach Neurological Center, Palm Beach Gardens, FL, USA*
[c]*Pfizer Global Research and Development, Ann Arbor, MI, USA*

Sponsor benannt;
kein Interessenkonflikt erwähnt / diskutiert

CME

Pregabalin relieves symptoms of painful diabetic neuropathy

A randomized controlled trial

H. Lesser, MD, PhD; U. Sharma, PhD; L. LaMoreaux, MPH; and R.M. Poole, MD, FACP

NEUROLOGY 2004;63:2104–2110

From the University of Rochester School of Medicine & Dentistry (Dr. Lesser), Rochester, NY; Pfizer Global Research and Development (Drs. Sharma and LaMoreaux), Ann Arbor, MI; and Pfizer Global Research and Development (Dr. Poole), New London, CT.

Sponsored by Pfizer Global Research and Development.

Drs. Sharma, LaMoreaux, and Poole own stock in Pfizer Global Research and Development. Dr. Poole owns stock in excess of $10,000.

Kein Kommentar zur möglichen Relevanz der Interessenkonflikte

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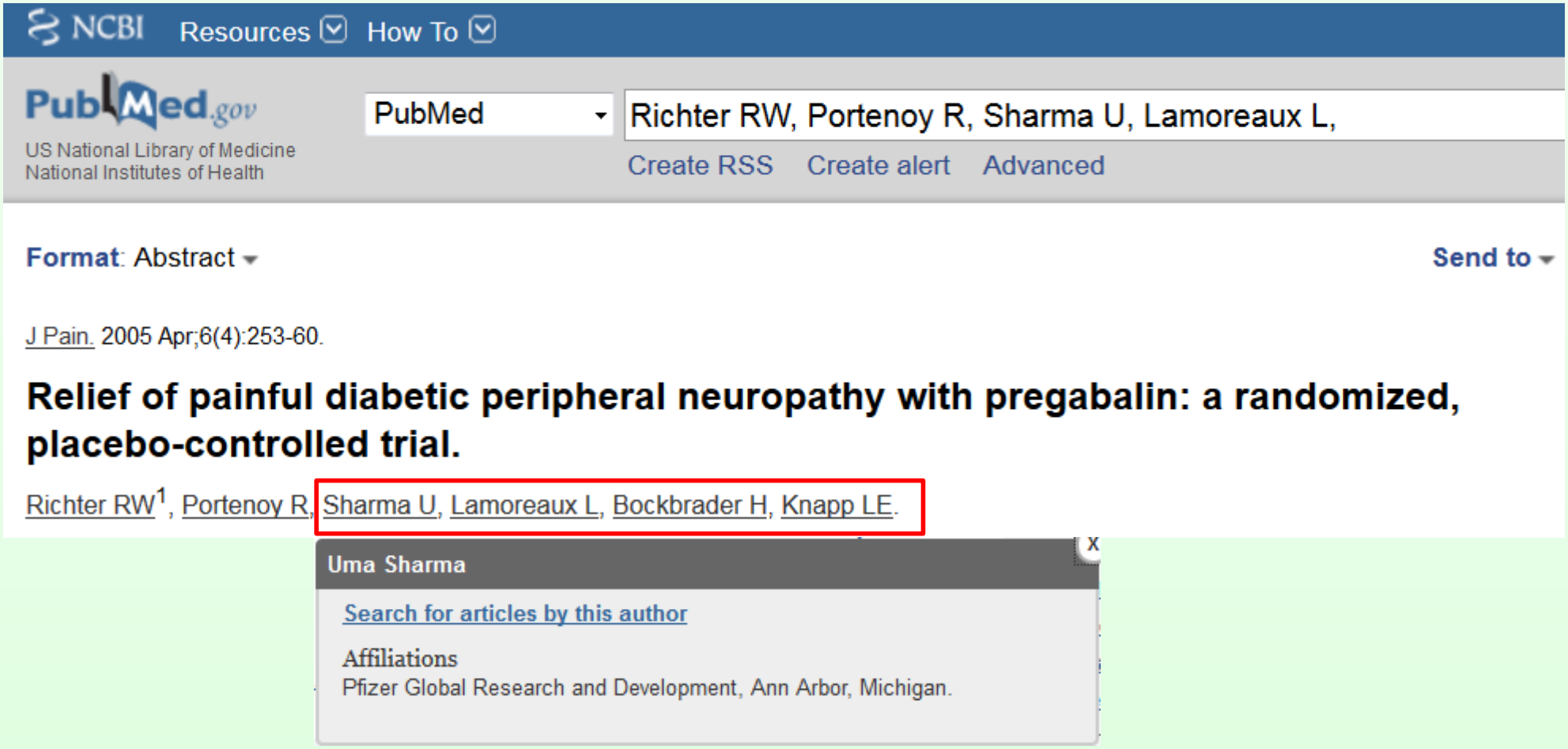

Kommentar zum Interessenkonflikt?

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Pain 115 (2005) 254–263

PAIN

www.elsevier.com/locate/pain

Efficacy of pregabalin in neuropathic pain evaluated in a 12-week, randomised, double-blind, multicentre, placebo-controlled trial of flexible- and fixed-dose regimens

Rainer Freynhagen[a,*], Krzysztof Strojek[b], Teresa Griesing[c], Ed Whalen[c], Michael Balkenohl[d]

[a]*Klinik für Anaesthesiologie, Universitätsklinikum Düsseldorf, Moorenstr. 5, 40225 Düsseldorf, Germany*
[b]*Department of Internal Diseases, Diabetology and Nephrology, Zabrze, Poland*
[c]*Pfizer, Inc., New York, USA*
[d]*Pfizer Global Pharmaceuticals, Freiburg, Germany*

Kein Kommentar zur möglichen Relevanz der Interessenkonflikte

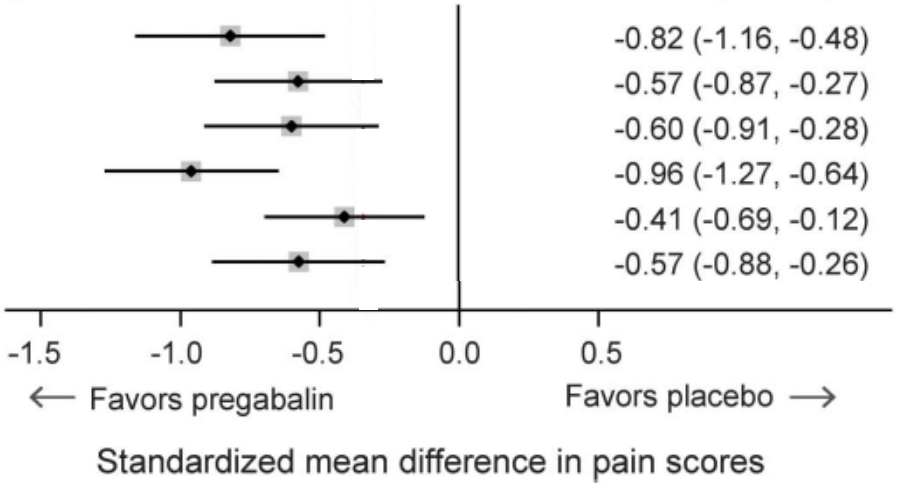
NVL Neuropathie bei Diabetes im Erwachsenenalter, 1. Auflage, 2011, Version 5

Zusammenfassung der Evidenz: Die Wirksamkeit einer Pregabalintherapie bei schmerzhafter diabetischer Polyneuropathie konnte sowohl metaanalytisch als auch in qualitativ guten Studien großer Fallzahl gezeigt werden [227; 253]. = MA Wong et al. 2007, Cochrane review Moore et al. 2009*

Empfehlungen/Statements	Empfehlungsgrad
6-18 Pregabalin sollte zur Behandlung einer schmerzhaften diabetischen Polyneuropathie eingesetzt werden.	⇑

Figure 1 Meta-analysis of calculated standardized mean differences (SMD) for studies comparing pregabalin with placebo for pain outcome

Study	Source	Scale	Follow-up (Weeks)	Sample size (Number)	SMD (95% CI)
Ref 17*	Published	NPS	8	146	-0.82 (-1.16, -0.48)
Ref 18*	Published	NPS	5	337	-0.57 (-0.87, -0.27)
Ref 19*	Published	NPS	6	246	-0.60 (-0.91, -0.28)
Ref 20*	Published	NPS	12	338	-0.96 (-1.27, -0.64)
Ref 21*	Published	NPS	12	395	-0.41 (-0.69, -0.12)
Ref 22	Both	NRS	12	167	-0.57 (-0.88, -0.26)



Waldfogel JM et al., Neurology 2017;88:1–10.

**zusätzlich ausgewertet: NCT00143156; n=456; Sponsor: Pfizer;*
kein Studienleiter genannt; n.s. für Pregabalin 300 mg und 600mg / die; ***unpubliziert***
Interessenkonflikt??!

Available online at www.sciencedirect.com
ScienceDirect
European Journal of Pain 12 (2008) 203–213
www.EuropeanJournalPain.com

Pregabalin for relief of neuropathic pain associated with diabetic neuropathy: A randomized, double-blind study

Thomas Tölle [a,*], Rainer Freynhagen [b], Mark Versavel [c], Uwe Trostmann [d], James P. Young Jr. [e]

[a] *Neurologic Clinic, Technical University of Münich, Germany*
[b] *Universitätsklinikum Düsseldorf, Klinik für Anaesthesiologie, Moorenstr. 5, 40225 Düsseldorf, Germany*
[c] *Pfizer Global R&D, Eastern Point Road 8260/1522, Groton, CT 06340, USA*
[d] *Muehlenweg 14, D-79232 March, Germany*
[e] *Pfizer Global R & D, 2800 Plymouth Road, Ann Arbor, MI 48105 USA*

Declaration of interests

This study was funded by Pfizer Inc. Drs Tölle and Freynhagen have received research support and have been reimbursed for travel related expenses to clinical meetings by Pfizer. Dr Versavel and Mr Young are employees of Pfizer, and Dr Trostmann was an employee of Pfizer when the trial was conducted and during the development of this paper.

Keine Diskussion der Interessen**konflikte**

AWMF

BMC Neurology

BioMed Central

Research article

Open Access

Efficacy and safety of pregabalin 600 mg/d for treating painful diabetic peripheral neuropathy: A double-blind placebo-controlled trial

Joseph C Arezzo*[1], Julio Rosenstock[2], Linda LaMoreaux[3] and Lynne Pauer[3]

Address: [1]Albert Einstein College of Medicine, New York, NY, USA, [2]Dallas Diabetes and Endocrine Center, Dallas, TX, USA and [3]Pfizer Global Research & Development, Ann Arbor, MI, USA

Competing interests

Joseph C. Arezzo, PhD, served as a consultant for Pfizer, Inc. and received research support from Pfizer, Inc. Julio Rosenstock, MD, served as consultant for Pfizer, Inc. and received research support from Pfizer, Inc for other research not reported in this article. Linda LaMoreaux, MPH was a full-time employee of Pfizer, Inc. during the conduct of the study, and Lynne Pauer, MS is a full-time employee of Pfizer, Inc. Pregabalin is marketed by Pfizer Inc under the brand name Lyrica®.

Keine Diskussion der Interessenkonflikte

AWMF

Annals of Internal Medicine | Review

Pharmacologic Interventions for Painful Diabetic Neuropathy

An Umbrella Systematic Review and Comparative Effectiveness Network Meta-analysis

Marcio L. Griebeler, MD; Oscar L. Morey-Vargas, MD; Juan P. Brito, MD; Apostolos Tsapas, MD, PhD; Zhen Wang, PhD; Barbara G. Carranza Leon, MD; Olivia J. Phung, PharmD; Victor M. Montori, MD; and M. Hassan Murad, MD, MPH

Ann Intern Med. 2014;161:639-649. doi:10.7326/M14-0511

*"…pregabalin was **inferior** to venlafaxine (SMD, 0.99 [CrI, 0.02 to 1.96]) and duloxetine (SMD, 0.79 [CrI, 0.20 to 1.38])."*

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VIEWS & REVIEWS

Pharmacotherapy for diabetic peripheral neuropathy pain and quality of life

A systematic review

Waldvogel JM et al., Neurology 2017;88:1–10

*"For reducing neuropathy-related pain, the serotonin-norepinephrine reuptake inhibitors **duloxetine and venlafaxine (moderate SOE***), the anticonvulsants **pregabalin** and oxcarbazepine (**low SOE**), the drug classes tricyclic antidepressants (low SOE) and atypical opioids (low SOE), and botulinum toxin (low SOE) were more effective than placebo. We could not draw conclusions about quality of life due to incomplete reporting. "*

**SOE=strength of evidence*

?

DISCLOSURE

J.M. Waldfogel reports no disclosures. S.A. Nesbit serves as a consultant for Trilogy Wellness, LLC. S.M. Dy, R. Sharma, A. Zhang, L.M. Wilson, W.L. Bennett, H.-C. Yeh, Y. Chelladurai, D. Feldman, and K.A. Robinson report no disclosures. Go to Neurology.org for full disclosures.

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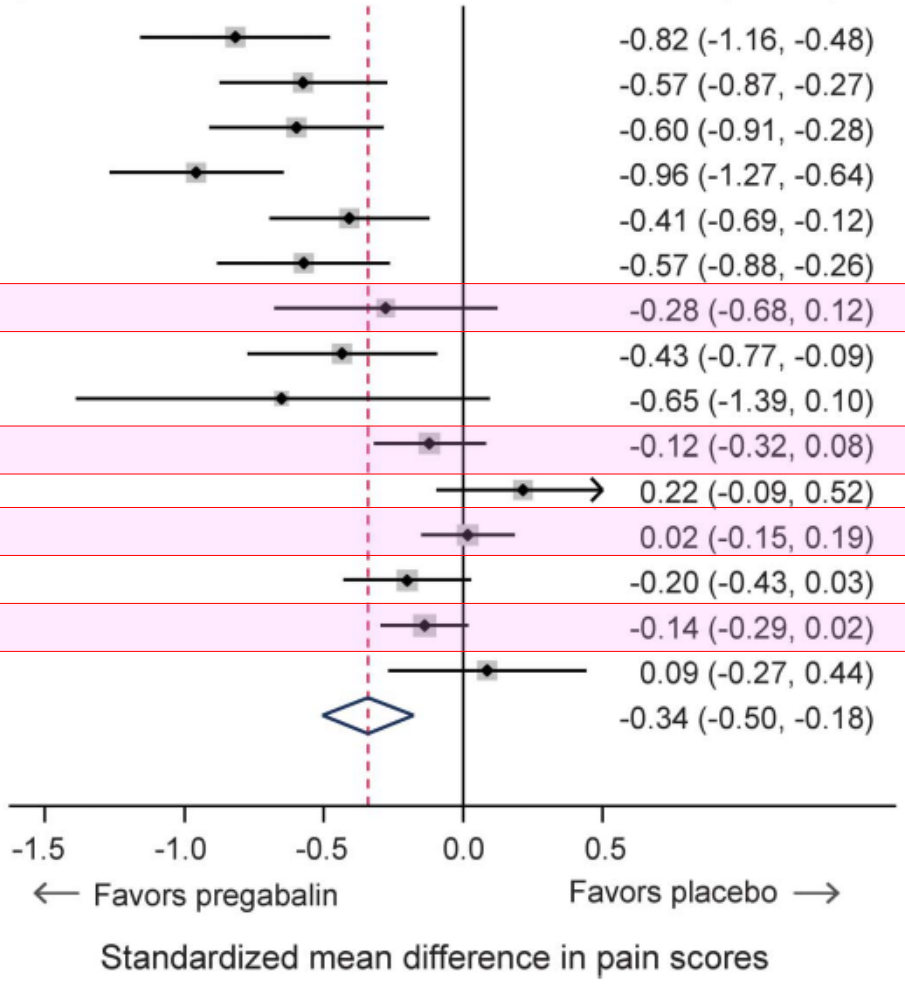
Figure 1 Meta-analysis of calculated standardized mean differences (SMD) for studies comparing pregabalin with placebo for pain outcome

Study	Sponsor	Source	Scale	Follow-up (Weeks)	Sample size (Number)	SMD (95% CI)
Ref 17*	Pfizer	Published	NPS	8	146	-0.82 (-1.16, -0.48)
Ref 18*	Pfizer	Published	NPS	5	337	-0.57 (-0.87, -0.27)
Ref 19*	Pfizer	Published	NPS	6	246	-0.60 (-0.91, -0.28)
Ref 20*	Pfizer	Published	NPS	12	338	-0.96 (-1.27, -0.64)
Ref 21*	Pfizer	Published	NPS	12	395	-0.41 (-0.69, -0.12)
Ref 22	Pfizer	Both	NRS	12	167	-0.57 (-0.88, -0.26)
NCT00785577	Eli Lilly	CT.gov	NRS	5	273	-0.28 (-0.68, 0.12)
Ref 23*	Pfizer	Both	NRS	13	314	-0.43 (-0.77, -0.09)
Ref 24	Pfizer	Both	VAS	4	40	-0.65 (-1.39, 0.10)
NCT01474772	Pfizer	CT.gov	NRS	6	217	-0.12 (-0.32, 0.08)
Ref 14	GSK	Both	NPS	16	186	0.22 (-0.09, 0.52)
NCT01455415	Pfizer	CT.gov	NRS	6	306	0.02 (-0.15, 0.19)
Ref 25	Pfizer	Both	NRS	13	294	-0.20 (-0.43, 0.03)
NCT01332149	Pfizer	CT.gov	NRS	9	626	-0.14 (-0.29, 0.02)
Ref 26	AbbVie	Both	NRS	6	132	0.09 (-0.27, 0.44)
Overall (I^2 = 80.8%, p = 0.000)						-0.34 (-0.50, -0.18)



Waldfogel JM et al., Neurology 2017;88:1–10.

**: Studien aus Griebeler-Metaanalyse*

NCT00143156; n=456; fehlt mangels publizierter Daten
laut Moore et al. 2009 n.s. für Pregabalin 300 mg und 600mg / die;

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Research Paper

PAIN

PAIN 156 (2015) 2013–2020

A randomized double-blind, placebo-, and active-controlled study of T-type calcium channel blocker ABT-639 in patients with diabetic peripheral neuropathic pain

Dan Ziegler[a,*], W. Rachel Duan[b], Guohua An[b], James W. Thomas[b], Wolfram Nothaft[b]

Conflict of interest statement

The authors have no conflicts of interest to declare.

W. R. Duan and J. W. Thomas are full-time employees of AbbVie Inc and hold AbbVie stock or stock options. W. Nothaft and G. An are former employees of Abbott and hold Abbott stock or stock options. W. Nothaft is now employed by Shire, Lexington, MA. G. An is now employed at the Division of Pharmaceutics and Translational Therapeutics, College of Pharmacy, University of Iowa, Iowa City, IA. D. Ziegler received honoraria for consulting activities from Eli Lilly, Pfizer, Wörwag, Meda, Glenmark, Daiichi-Sankyo, Roche, Takeda, and Astellas; for speaking activities from Eli Lilly, Pfizer, Meda, Wörwag, Takeda, Berlin-Chemie, Eisai, Shire, and Menarini; and research support from NeuroMetrix and AbbVie.

This study was funded by AbbVie Inc, North Chicago, IL. AbbVie was involved in the study design. D. Ziegler, W. R. Duan, G. An, J. W. Thomas, and W. Nothaft were responsible for collecting and interpreting data. All authors were involved in the writing process and critically reviewed the manuscript and approved the final version for submission. All authors accept responsibility for the accuracy of the data and its analysis.

Acknowledgements

The authors wish to thank Kelly Cameron, PhD, of The JB Ashtin Group, Inc., who provided medical writing support in the development of this manuscript, and this support was funded by AbbVie Inc.

PLOS ONE | DOI:10.1371/journal.pone.0162198 September 8, 2016

RESEARCH ARTICLE

Relationship between Research Outcomes and Risk of Bias, Study Sponsorship, and Author Financial Conflicts of Interest in Reviews of the Effects of Artificially Sweetened Beverages on Weight Outcomes: A Systematic Review of Reviews

Funding: The authors received no specific funding for this work.

Competing Interests: The authors have declared that no competing interests exist.

Daniele Mandrioli[1,2]*, Cristin E Kearns[3,4], Lisa A. Bero[5]

Conclusions

Review sponsorship and authors' financial conflicts of interest introduced bias affecting the outcomes of reviews of artificially sweetened beverage effects on weight that could not be explained by other sources of bias.

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thebmj

EDITORIALS

BMJ 2017;356:j176 doi: 10.1136/bmj.j176 (Published 2017 January 17)

Page 1 of 2

The ties that bind

Authors' financial ties may be a source of bias in trials and must be disclosed in full

Andreas Lundh *postdoc*[1], Lisa Bero *professor*[2]

"Bei der Bewertung der Validität jedweder klinischen Studie müssen die Bedeutung finanzieller Verbindungen und der Studienfinanzierung sowie die jeweiligen Rollen von Sponsoren und Autoren geprüft werden"

Empfehlungen:

- *Besserer Zugang zu Studienberichten und unabhängige Reanalysen*
- *Bereitstellung der Originaldaten*
- *Beteiligung an industriefinanzierten Studien nur unter dieser Bedingung*
- *Ablehnung von Manuskripten, deren Daten nicht bereitgestellt werden*
- *Sanktionierung von Autoren, die ihre finanziellen Verbindungen nicht darlegen*
- *Transparenz der Rolle von Firmen bei Design, Durchführung und Publikation von Forschung*
- *Zurückhaltende Interpretation von Studien mit Industrie-Finanzierung oder finanziellen*

offengelegt sind

Competing interests: …AL has previously published research and taught at courses in relation to conflicts of interest and industry sponsored trials and is a **member of the Danish organisation Physicians without Sponsor that seeks to promote independence from commercial influence in clinical work, research, and education**. LB has published extensively on the topic of conflicts of interest and research.

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2016

- Vertrauen in Wissenschaft und Publikationen hängt u.a. vom Umgang mit Interessenkonflikten bei Planung, Implementierung, Niederschrift, Begutachtung und Publikation von Forschung ab
- Wahrgenommene Interessenkonflikte sind so bedeutsam wie tatsächliche
- Autoren sollten keine Verträge mit Sponsoren eingehen, die ihren Zugriff auf sämtliche Studiendaten, ihre Freiheit bei der Analyse und Interpretation der Daten sowie bei der Abfassung und Publikation in einem Medium und zu einem Zeitpunkt ihrer Wahl einschränken

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2016

- Alle Beteiligten am peer review und Publikationsprozess, also neben Autoren auch peer reviewer, Herausgeber und Mitglieder von Editorial Boards müssen ihre Interessenkonflikte im Review- und Publikationsprozess berücksichtigen und alle potenziell relevanten Interessenkonflikte deklarieren
- **Reviewer** sollten bei Übernahme eines Reviews nach Interesenkonflikten befragt werden.
- Sie müssen den Herausgebern jeden potenziell relevanten Interessenkonflikt melden und bei potenzieller Befangenheit auf die Begutachtung bestimmter Manuskripte verzichten
- Sie dürfen Kenntnisse aus begutachteten Manuskripten vor deren Publikation nicht für eigene Interessen nutzen.

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ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals

Updated December 2016

- **Herausgeber** sollten keine abschließenden Entscheidungen über solche Manuskripte treffen, bezüglich derer bei ihnen ein Interessenkonflikt vorliegt
- Weitere **Mitglieder von Herausgeberteams** müssen den Herausgebern ihre finanziellen Interessen oder andere einschlägige Konflikte beschreiben und ggfs. sich bei Befangenheit im Entscheidungsprozess enthalten
- **Mitarbeiter** dürfen Informationen aus dem Arbeitskontext nicht für eigenen Gewinn nutzen
- **Herausgeber** sollten regelmäßige COI-Erklärungen der Mitarbeiter publizieren

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SAVE

ICMJE Form for Disclosure of Potential Conflicts of Interest

Instructions

The purpose of this form is to provide readers of your manuscript with information about your other interests that could influence how they receive and understand your work. The form is designed to be completed electronically and stored electronically. It contains programming that allows appropriate data display. Each author should submit a separate form and is responsible for the accuracy and completeness of the submitted information. The form is in six parts.

Section 2. The Work Under Consideration for Publication

Did you or your institution **at any time** receive payment or services from a third party (government, commercial, private foundation, etc.) for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.)?

Are there any relevant conflicts of interest? ☑ Yes ☐ No

If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" button to add a row. Excess rows can be removed by pressing the "X" button.

Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other?	Comments	
	☐	☐	☐	☐		X
	☐	☐	☐	☐		X
	☐	☐	☐	☐		X

ADD

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Updated December 2016

Bei der Publikation sollten folgende Angaben gemacht werden:

- Interessenkonflikte der Autoren, z.B. gemäß ICMJE-Formular
- Fördergeber der Arbeit mit Namen
- Erläuterungen zu ihrer eventuellen Rolle beim Studiendesign, Datenerhebung, -auswertung und –interpretation, Abfassung des Manuskripts, Entscheidung zur Einreichung **oder** Feststellung dass sie jeweils hierbei keinen Einfluss hatten
- Erklärung, ob sowie in welcher Art und welchem Umfang die Autoren Zugang zu den Daten hatten bzw. weiterhin haben
- Bei kommerziell durch eine Firma mit einschlägigem Interesse geförderten Studien verbindliche Erklärung der Autoren, z.B.

"I had full access to all of the data in this study and I take complete responsibility for the integrity of the data and the accuracy of the data analysis."

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Ergänzende Vorschläge

- Jeder Studie sollte ein gemäß klinischer Beobachtung und systematischer Literaturrecherche ungedeckter medizinischer Bedarf zugrunde liegen.
- Sie ist vor Beginn öffentlich zu registrieren
- Bei der Auswahl geeigneter Endpunkte ist auf deren Patientenrelevanz zu achten.
- Die Datenauswertung sollte mindestens bei industriefinanzierten Studien durch unabhängige Biometriker erfolgen
- Erwünschte **und unerwünschte** Ergebnisse müssen zeitnah nach Abschluss jeder Studie publiziert und bei der Interpretation der Ergebnisse ausgewogen berücksichtigt werden.
- Anonymisierte Originaldaten sollten anderen Forschergruppen für unabhängige Reanalysen zur Verfügung gestellt werden

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Ergänzende Vorschläge

- Interessenkonflikte sollten auch bzgl. der Finanzierung von Fachpublikationen (Zeitschriften, Tagungsbände etc.) transparent gemacht werden
- Sie sollten von den Nutzern von Publikationen bei der Interpretation und Synthese der Ergebnisse, insbes. auch im Rahmen von systematischen Reviews und Leitlinien, als potenzielles Bias berücksichtigt werden (vgl. AMSTAR-Checkliste, *Shea BJ et al.* BMC Med Res Methodol. **2007** Feb 15;7:10.)
- Anreizsysteme für Wissenschaftler, die anstelle wissenschaftlicher Qualität die Einwerbung industrieller Drittmittel oder rein quantitativ bewertete Publikationen honorieren, erzeugen sekundäre Interessen, die zu Interessenkonflikten führen können und sollten in Zukunft aufgegeben werden.

VIEWPOINT

Defending Biomedical Science in an Era of Threatened Funding

Ioannidis JPA

JAMA Published online May 1, 2017 E1

"With reduced research budgets, funding may become an even more inappropriately influential driver of careers. ***Investigators are already valued largely in proportion to the amount of funding they bring to their institutions. This creates a perverse incentive.*** *The biomedical research community needs to provide incentives for good science, not expensive science. …*

Institutions should not respect and reward scientists in proportion to the funding they receive. *Getting funding is already a privilege and a reward on its own, and it carries an obligation to make the best of it with high-quality work."*

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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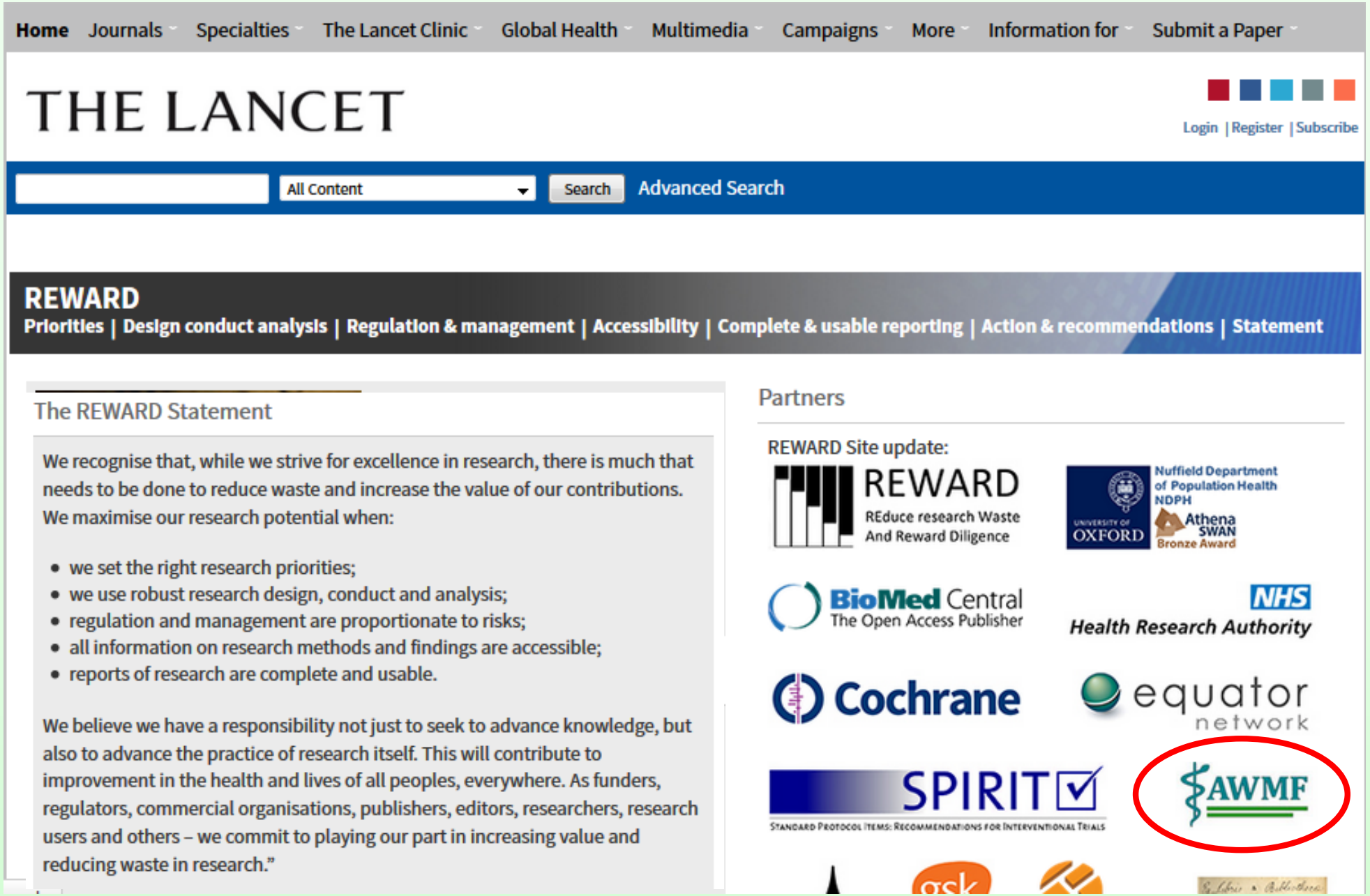
EDITORIAL

Conflict of Interest and Medical Journals

Phil Fontanarosa, MD, MBA; Howard Bauchner, MD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The REWARD Statement
We recognise that, while we strive for excellence in research, there is much that needs to be done to reduce waste and increase the value of our contributions. We maximise our research potential when:
• we set the right research priorities;
• we use robust research design, conduct and analysis;
• regulation and management are proportionate to risks;
• all information on research methods and findings are accessible;
• reports of research are complete and usable.
We believe we have a responsibility not just to seek to advance knowledge, but also to advance the practice of research itself. This will contribute to improvement in the health and lives of all peoples, everywhere. As funders, regulators, commercial organisations, publishers, editors, researchers, research users and others – we commit to playing our part in increasing value and reducing waste in research."
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University of Oxford
Athena SWAN Bronze Award
BioMed Central
The Open Access Publisher
NHS
Health Research Authority
Cochrane
equator network
SPIRIT
Standard Protocol Items: Recommendations for Interventional Trials
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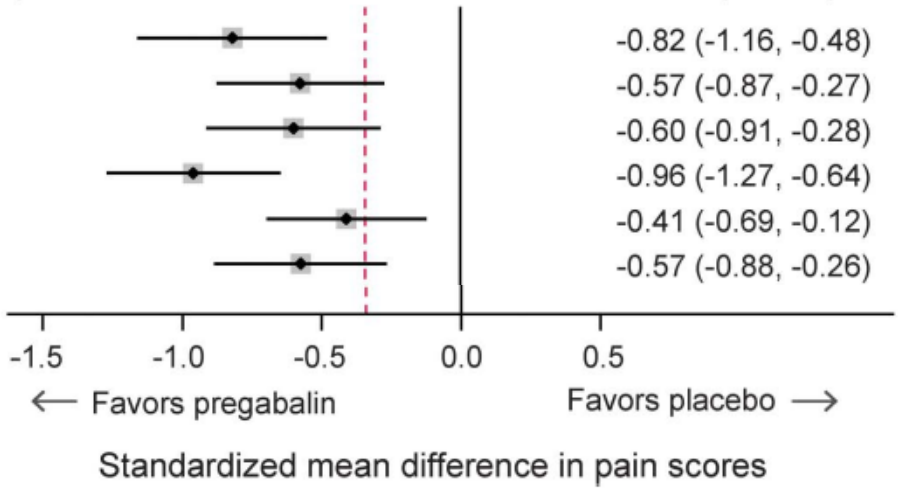
Zusammenfassung der Evidenz: Die Wirksamkeit einer Pregabalintherapie bei schmerzhafter diabetischer Polyneuropathie konnte sowohl metaanalytisch als auch in qualitativ guten Studien großer Fallzahl gezeigt werden [227; 253]. = MA Wong et al. 2007, Cochrane review Moore et al. 2009*

Empfehlungen/Statements	Empfehlungs-grad
6-18 Pregabalin sollte zur Behandlung einer schmerzhaften diabetischen Polyneuropathie eingesetzt werden.	⇑

NVL Neuropathie bei Diabetes im Erwachsenenalter. 1. Auflage, 2011, Version 5

Figure 1 Meta-analysis of calculated standardized mean differences (SMD) for studies comparing pregabalin with placebo for pain outcome

Study	Sponsor	Source	Scale	Follow-up (Weeks)	Sample size (Number)	SMD (95% CI)
Ref 17*	Pfizer	Published	NPS	8	146	-0.82 (-1.16, -0.48)
Ref 18*	Pfizer	Published	NPS	5	337	-0.57 (-0.87, -0.27)
Ref 19*	Pfizer	Published	NPS	6	246	-0.60 (-0.91, -0.28)
Ref 20*	Pfizer	Published	NPS	12	338	-0.96 (-1.27, -0.64)
Ref 21*	Pfizer	Published	NPS	12	395	-0.41 (-0.69, -0.12)
Ref 22	Pfizer	Both	NRS	12	167	-0.57 (-0.88, -0.26)



Waldfogel JM et al., Neurology 2017;88:1–10.

**zusätzlich ausgewertet: NCT00143156; n=456; Sponsor: Pfizer; unpubliziert*
n.s. für Pregabalin 300 mg und 600mg / die

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SPECIAL ARTICLE

AMERICAN ACADEMY OF NEUROLOGY.

Evidence-based guideline: Treatment of painful diabetic neuropathy

Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation

Brill V et al., Neurology 2011;76:1758–1765

"Conclusions. Based on consistent Class I evidence, pregabalin is established as effective in lessening the pain of PDN."

Figure 1 Meta-analysis of calculated standardized mean differences (SMD) for studies comparing pregabalin with placebo for pain outcome

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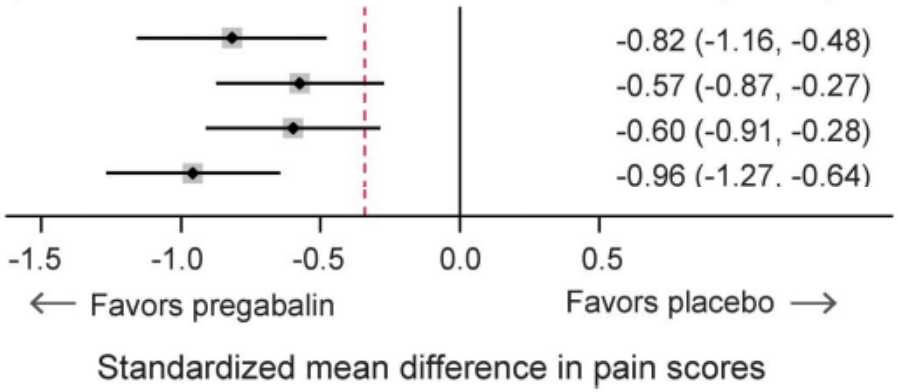

Waldfogel JM et al., Neurology 2017;88:1–10.

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Outcomes	Illustrative comparative risks* (95% CI)		Risk ratio (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Non-industry sponsored studies	Industry sponsored studies			
Number of studies with favorable efficacy results	502 per 1000	638 per 1000 (588 to 688)	1.27 (1.17 to 1.37)	25 papers including 2923 studies	⊕⊕⊕◯ MODERATE
Number of studies with favorable harms results	474 per 1000	649 per 1000 (303 to 1388)	1.37 (0.64 to 2.93)	4 papers including 826 studies	⊕◯◯◯ VERY LOW
Number of studies with favorable conclusions	644 per 1000	863 per 1000 (766 to 972)	1.34 (1.19 to 1.51)	29 papers including 4583 studies	⊕⊕◯◯ LOW

Lundh A et al., Cochrane Database of Systematic Reviews 2017: MR000033.

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Comparison 7. Subgroup analysis

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of studies with favorable efficacy results, stratified by risk of bias	25	2923	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.17, 1.37]
1.1 High risk of bias	20	2107	Risk Ratio (M-H, Random, 95% CI)	1.20 [1.11, 1.30]
1.2 Low risk of bias	5	816	Risk Ratio (M-H, Random, 95% CI)	1.46 [1.25, 1.71]

Comparison 3. Conclusions: industry sponsored versus non-industry sponsored studies

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of studies with favorable conclusions	29	4583	Risk Ratio (M-H, Random, 95% CI)	1.34 [1.19, 1.51]

Lundh A et al., Cochrane Database of Systematic Reviews 2017: MR000033.

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thebmj

EDITORIALS

BMJ 2017;356:j176 doi: 10.1136/bmj.j176 (Published 2017 January 17)

Page 1 of 2

The ties that bind

Authors' financial ties may be a source of bias in trials and must be disclosed in full

Andreas Lundh *postdoc*[1], Lisa Bero *professor*[2]

"When appraising the validity of any clinical trial, the influence of financial ties and study funding must be assessed together with the respective roles of funder and authors.

… Increasing access to clinical study reports and independent reanalyses of trials may assist in this effort.[12] Trial authors should share their data and participate in industry funded trials only if data are made publicly available. Reliable data on financial ties of authors should also be publicly available. Journals could help by

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Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: AL has previously published research and taught at courses in relation to conflicts of interest and industry sponsored trials and is a **member of the Danish organisation Physicians without Sponsor that seeks to promote independence from commercial influence in clinical work, research, and education**. LB has published extensively on the topic of conflicts of interest and research.

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VIEWPOINT

Addressing Bias and Conflict of Interest Among Biomedical Researchers

Lisa Bero, PhD
Charles Perkins Centre, Faculty of Pharmacy, University of Sydney, Sydney, Australia.

JAMA May 2, 2017 Volume 317, Number 17 1723

"Recent attention on so-called nonfinancial interests has led to long lists of disclosures that produce an information overload and distract from the multiple biases associated with financial conflicts of interest. Nonfinancial interests encompass many different types of interests, including personal beliefs or experience, academiccompetition,andtheoretical approach.[7]
Treating nonfinancial interests in the same way as conflicts of interest ignores the reality that research is not value free and is conducted in a social context.[7]
Thus, the nonfinancial interests of researchers should and do affect their research. …
The research community should also strive for research that is enriched by the diversity and varied interests of researchers. Attempting to identify and eliminate the interests that make scientists who they are serves as a distraction to prevent the research community, professionals, and policy makers from dealing with bias related to financial conflicts of interest.

Conflict of Interest Disclosures: The author has completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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VIEWPOINT

Conflict of Interest
Why Does It Matter?

Harvey V. Fineberg, MD, PhD
Gordon and Betty Moore Foundation, Palo Alto, California.

JAMA May 2, 2017 Volume 317, Number 17 1717

"Preservation of trust is the essential purpose of policies about conflict of interest.

… the confidence of others in physician judgment is of paramount importance. When trust in physician judgment is impaired, the role of physicians is diminished.

Physicians should make informed, disinterested judgments. To be disinterested means being free of personal advantage. The type of advantage that is typically of concern in most situations involving physicians is financial.

When referring to conflict of interest, the term generally means a financial interest that relates to the issue at hand. …

a conflict of interest exists when a reasonable person would interpret the financial circumstances pertaining to a situation as potentially sufficient to influence the judgment of the physician in question."

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Comparison 6. Concordance between study results and conclusions: industry sponsored versus non-industry sponsored studies

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of studies with concordant study results and conclusions	6	751	Risk Ratio (M-H, Random, 95% CI)	0.83 [0.70, 0.98]

Comparison 4. Conclusions: Industry sponsorship by test treatment company versus sponsorship by comparator treatment company

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of studies with favorable test treatment conclusions	3	154	Risk Ratio (M-H, Random, 95% CI)	5.92 [2.80, 12.54]

Lundh A et al., Cochrane Database of Systematic Reviews 2017: MR000033.

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