

# The Global Alliance of Publication Professionals

Providing a timely and credible response to influential stories about medical publication professionals  
2012-2018

## The life and times of GAPP MedComms Networking brunch club July 4, 2018

Jackie Marchington, PhD, CM PP

Director of Global Operations, Caudex – a McCann Health company

Former member of GAPP, 2014–2018

# Disclosures

- GAPP
  - All emeritus and retired members provided their time freely
  - ISMPP supported the website from 2012–2107
- Jackie Marchington
  - Employee of Caudex, Oxford, a McCann Health company
  - Member of ISMPP
  - Co-chair, ISMPP Advocacy and Outreach Committee
- Original cartoons ©HamiltonHouse (Cindy Hamilton)



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# BG (before GPP...)

A brief history lesson



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# Issues raised in the literature

PAPER

## Impact of covert duplicate publication on meta-analysis: a case study

BMJ 1997; 315 doi: 10.1136/bmj.315.7109.635 (Published 13 September 1997)  
Cite this as: BMJ 1997;315:635

MARKETING

## Spin doctors soft pedal data on antihypertensives

BMJ 2003; 326 doi: 10.1136/bmj.326.7381.170 (Published 18 January 2003)  
Cite this as: BMJ 2003;326:170.1

NEWS

## Journal "should have revealed scientist's connection to company"

BMJ 2002; 324 doi: 10.1136/bmj.324.7329.70 (Published 12 January 2002)  
Cite this as: BMJ 2002;324:70.1

NEWS

## Firm tried to block report on failure of AIDS vaccine

BMJ 2000; 321 doi: 10.1136/bmj.321.7270.1173 (Published 11 November 2000)  
Cite this as: BMJ 2000;321:1173.1

Science 11 June 2004:  
Vol. 304 no. 5677 pp. 1576-1577  
DOI: 10.1126/science.304.5677.1576

NEWS OF THE WEEK

ANTIDEPRESSANTS AND CHILDREN

**Buried Data** Can Be Hazardous to a Company's Health

PAPER

## Evidence b(i)ased medicine—selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications

BMJ 2003; 326 doi: 10.1136/bmj.326.7400.1171 (Published 29 May 2003)  
Cite this as: BMJ 2003;326:1171



# And then the press...

## Painkiller firm 'hid heart risk'

The Guardian, 2 Nov 2004  
David Teather in New York

The reputation of the drug industry took another heavy blow yesterday with a report suggesting that Merck had fought for years to cover up evidence linking its painkiller Vioxx to heart attacks and strokes.

... The reputation of the drug industry took another heavy blow yesterday with a report suggesting that Merck had fought for years to cover up evidence linking its painkiller Vioxx to heart attacks and strokes. The Wall Street Journal cited...

## Drug giant 'ignored Vioxx heart risk'

The Guardian, 5 Nov 2004  
Sarah Boseley Health editor

The multinational drug company Merck knew four years ago that its blockbuster painkiller Vioxx was causing thousands of heart attacks and deaths, but kept it on the market until five weeks ago, scientists said last night.

... Drug giant 'ignored Vioxx heart risk' ... The multinational drug company Merck knew four years ago that its blockbuster painkiller Vioxx was causing thousands of heart attacks and deaths, but kept it on the market until five weeks ago, scientists said last night. Dampening evidence...

## Glaxo faces drug fraud lawsuit

The Guardian, 3 Jun 2004

David Teather in New York and Sarah Boseley

Firm accused of keeping back negative trial results.

.... The civil lawsuit, filed by the combative and popular New York State attorney general Eliot Spitzer, claims that the company suppressed the results of at least four different studies that showed the drug, called Paxil in the US and Seroxat in the UK, at best...

## Spitzer Sues a Drug Maker, Saying It Hid Negative Data

By GARDINER HARRIS  
Published: June 03, 2004

In a novel claim testing the way that the \$400 billion worldwide pharmaceutical industry is regulated, the New York State attorney general, Eliot Spitzer, sued the British-based drug giant GlaxoSmithKline yesterday, accusing the company of fraud in concealing negative information about its antidepressant medicine Paxil.

## At medical journals, paid writers play big role

Tuesday, December 13, 2005

By Anna Wilde Mathews, The Wall Street Journal



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# It was not without substance...

January 12, 2005

Lila E. Nachtigall, MD  
Department of Obstetrics and Gynecology  
New York University School of Medicine  
251 E. 33rd St.  
New York, NY 10016

Dear Dr. Nachtigall,

On behalf of Wyeth-Ayerst Laboratories, DesignWrite has been asked to assist you with the development of a manuscript concerning breast cancer and sex hormone-binding globulin. Jeff Solomon recently contacted you concerning this matter.

I have sent you a copy of the manuscript, which you should be receiving by FedEx in the next few days. I would very much like to discuss this project with you in greater detail, and will contact your secretary to confirm receipt of the manuscript and to set up a convenient time to speak. If you prefer, please feel free to contact me at 609-924-1116 or via email at [dwrite!knittle@attmail.com](mailto:dwrite!knittle@attmail.com).

Thank you for your cooperation. I look forward to talking with you.

Sincerely,



# It was not without substance...

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Thank you for your cooperation. I look forward to talking with you.

Sincerely,

Adolescent depression - is there a role for SSRIs?						
Proposed authors: Birmaher B, Wagner KD	SS	Manuscript submitted to client for review	02/04/00	SK		<input type="checkbox"/>
Proposed journal: J Child Adolesc Psychopharmacol						



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# And it never...

Soc Stud Sci. 2009 Apr;39(2):171-98.

## Ghosts in the machine: publication planning in the medical sciences.

Sismondo S.

Department of Philosophy, Queen's University, Kingston, Canada. sismondo@queensu.ca

PERSPECTIVE ⓘ

OPEN ACCESS

## Being the Ghost in the Machine: A Medical Ghostwriter's Personal View

Article

Metrics

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Linda Logdberg\*

Biologist, Fernbank Science Center, Atlanta, Georgia, United States of America

To add a note, highlight some text. [Hide notes](#)

OPEN ACCESS Freely available online

PLoS MEDICINE

Policy Forum

## The Haunting of Medical Journals: How Ghostwriting Sold "HRT"

Adriane J. Fugh-Berman\*

Department of Physiology and Biophysics, Georgetown University Medical Center, Washington, DC, United States of America

Science

## Scientists credited on ghostwritten articles 'should be charged with fraud'

guardian.co.uk, 2 Aug 2011

Ian Sample, science correspondent

Legal experts call for severe sanctions against scientists who 'ghost author' papers written by drugs companies ... to ghostwriting and guest authorship were released following a request in court by PLoS Medicine and the New York Times. The papers revealed that Wyeth, a pharmaceutical company, had used ghostwriters to prepare ... emphasised the benefits

Science

## How drug companies' PR tactics skew the presentation of medical research

guardian.co.uk, 20 May 2011

Elliot Ross

Elliot Ross reveals the secret 'army of hidden scribes' paid by the drug companies to influence doctors

... by the International Committee of Journal Editors (ICMJE), Crown's approach, typical among pharmaceutical companies, does not constitute ghostwriting. What publication planners understand by the term is precise but it is also quite distinct from Comment is free

## Medical ghostwriters who build a brand

The Guardian, 18 Sep 2010

Science

## British doctor faces action over claims of 'ghost writing' for US drug company

The Guardian, 18 Sep 2009

Sarah Boseley, health editor

Doctors agreeing to be named as ghost-authors on pharmaceutical research, new evidence suggests

.... Doctors have been agreeing to be named as authors on studies written by employees of the pharmaceutical industry, giving greater credibility to medical research, according to new evidence. The Guardian has learned that one of Britain's leading bone...

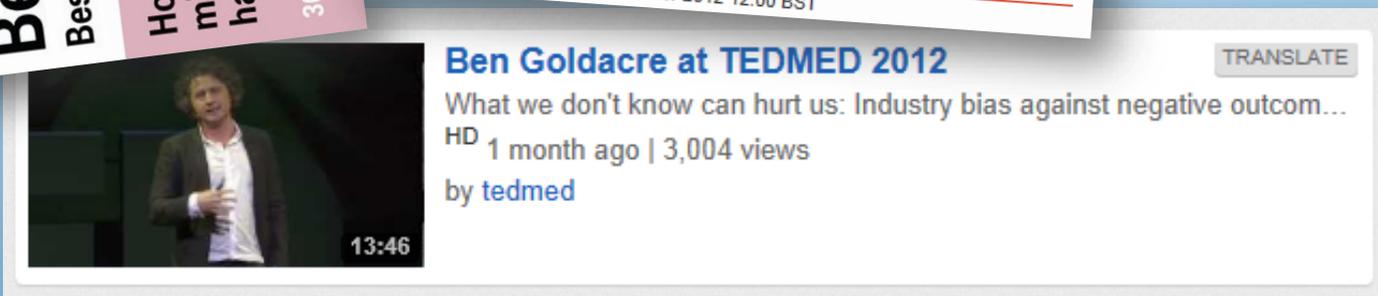
against this, just traditions, good faith, and leaky

of medical ghostwriting. Attributed authorial erent, and more cynical. A commercial medical drug company to produce papers that can be rolled



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...ever...





...goes away...

# Bad Pharma™

## Ben Goldacre

Bestselling author of Bad Science

How drug companies mislead doctors and harm patients

364 pages



the guardian

News | Sport | Comment | Culture | Business | Money

Business > Pharmaceuticals industry

### The drugs don't work: a modern medical scandal

The doctors prescribing the drugs don't know they d they're meant to. Nor do their patients. The manufac full well, but they're not telling.



the guardian | TheObserver

News | Sport | Comment | Culture | Busine

News > Science > Drugs

### Ben Goldacre: you ask the

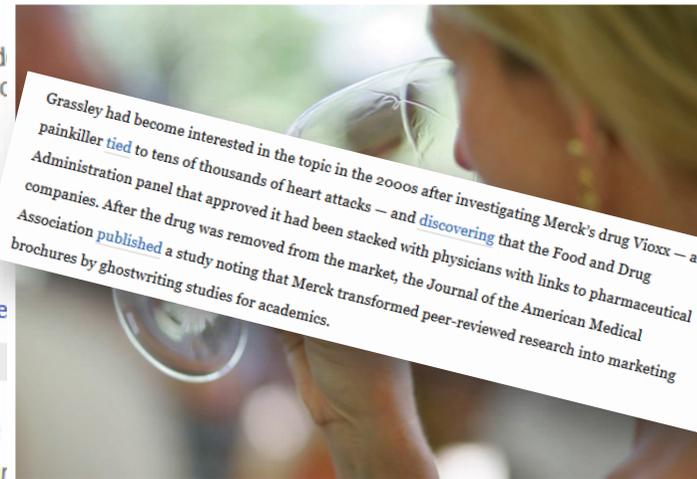
Do you want to quiz the author of Bad Phar industry? Here's your chance

The Observer, Saturday 22 September 2012 12.00 BST

Outlook • Perspective

### How a flood of corporate funding can distort NIH research

The agency doesn't police its conflicts of interest well enough.



Grassley had become interested in the topic in the 2000s after investigating Merck's drug Vioxx — a painkiller tied to tens of thousands of heart attacks — and discovering that the Food and Drug Administration panel that approved it had been stacked with physicians with links to pharmaceutical companies. After the drug was removed from the market, the Journal of the American Medical Association published a study noting that Merck transformed peer-reviewed research into marketing brochures by ghostwriting studies for academics.

The National Institutes of Health ended a study that searched for alcohol's benefits but not its drawbacks, citing ethical problems. (AP Photo/Eric Risberg, File)



By Paul D. Thacker June 22 Follow @macthacker

Paul D. Thacker is a freelance writer and former staffer with the Senate Finance Committee who led federal investigations into corruption in science and medicine.

### Ben Goldacre at TEDMED 2012

TRANSLATE

What we don't know can hurt us: Industry bias against negative outcom...

HD 1 month ago | 3,004 views

by tedmed

# Industry responses

## From within

- Original GPP developed between 1998–2003
  - 1st revision (GPP2) 2009
  - 2nd revision (GPP3) 2013
- #GPP4 being thought about...
- Global Publication Survey
- MPIP

## From without

- ICMJE
- Corporate Integrity Agreements
- Sunshine Act



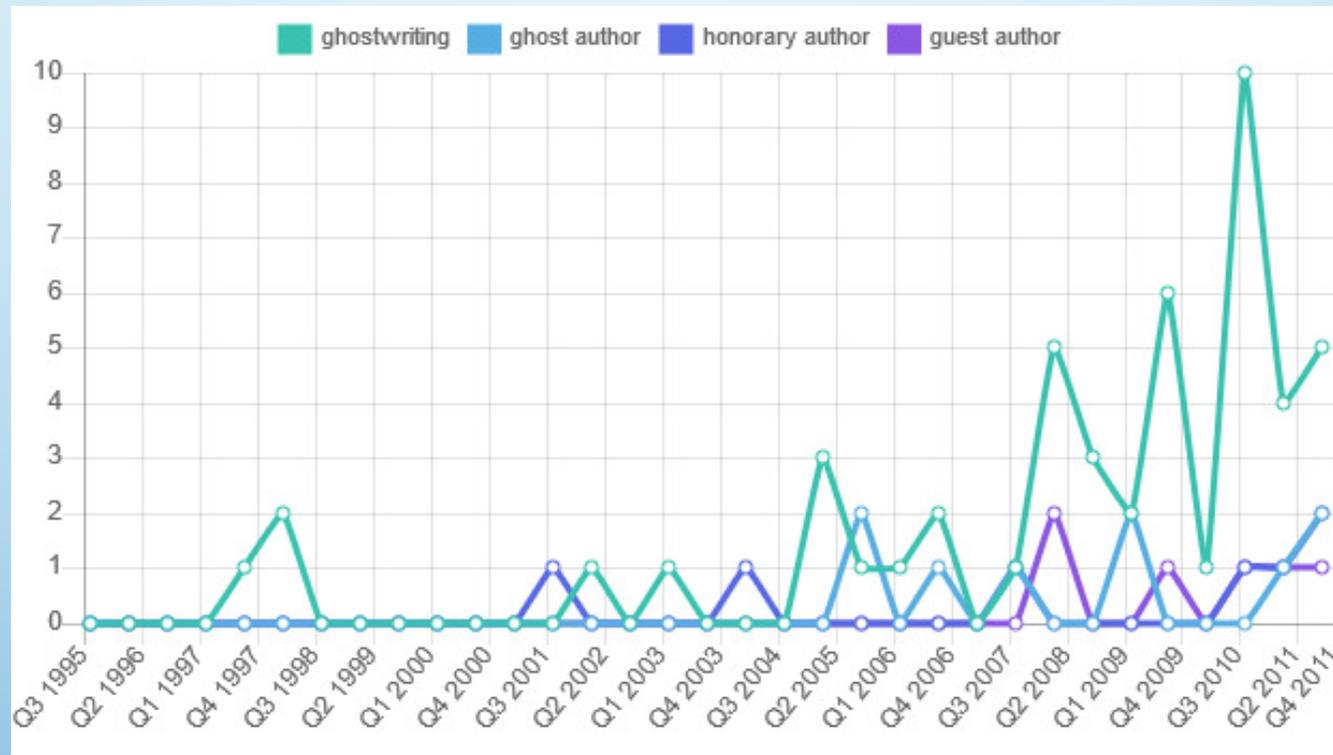
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# The birth of GAPP

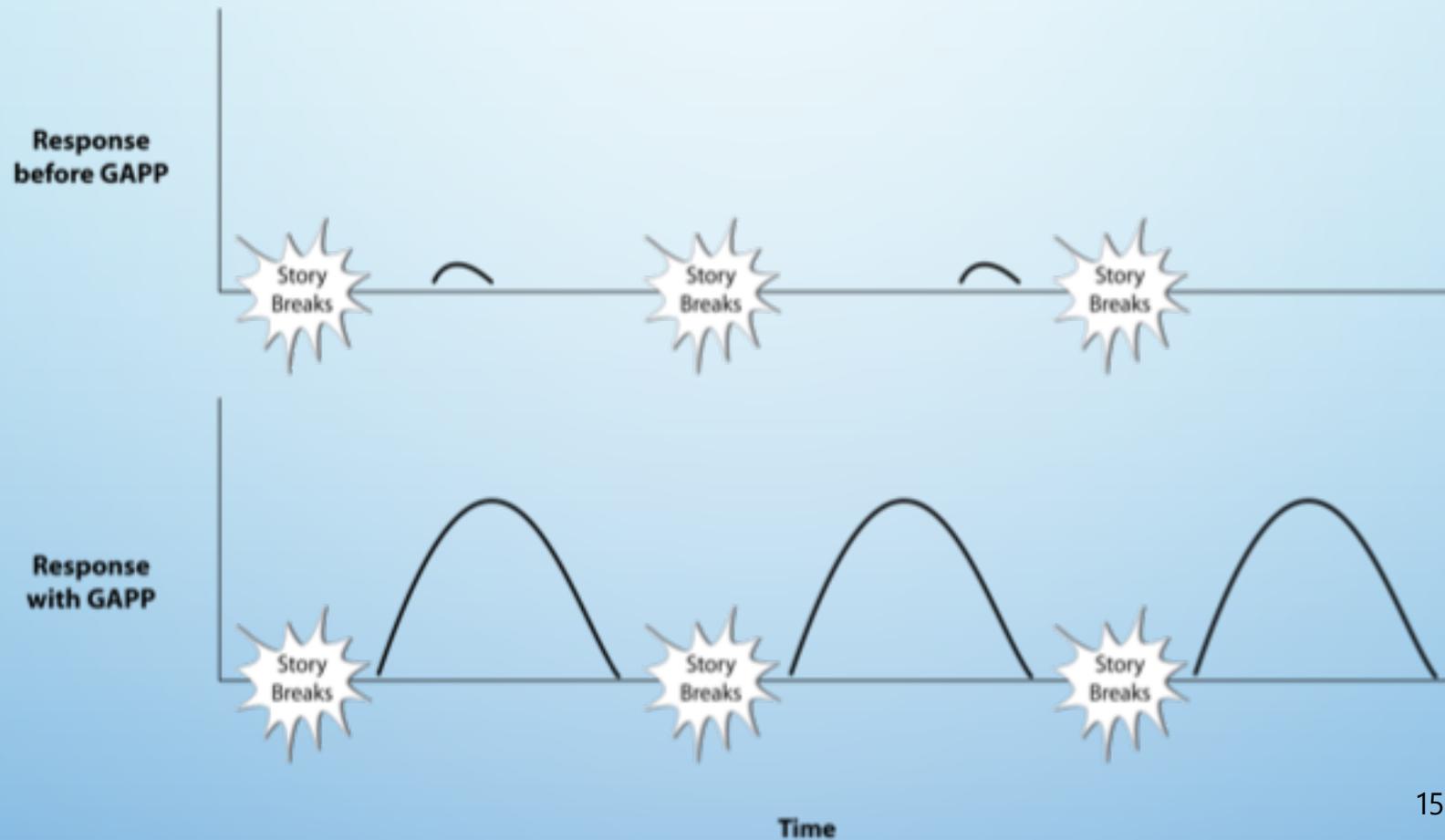
## Why were we needed?

- Around 2010–2012, articles being published about industry sponsored research assumed ghostwriting was common, things were as they were 10 years previously
- Conflating ghostwriting with professional medical writing support
- Suggesting spin and selective reporting were the norm

# Medline publications to end 2011



- Responses were isolated and slow



# How could we (collectively) do it better?

- GAPP was founded to:
  - provide a timely and credible response to influential stories about medical publication professionals
  - be a “go to” group for those needing timely input from international leaders of medical publication professionals



## The team

- 5-people
- Respected members of, but not representing, professional organizations
- Passionate advocates
- 10 weeks leading, else review/approver role
- Find own appropriately qualified successor on exit



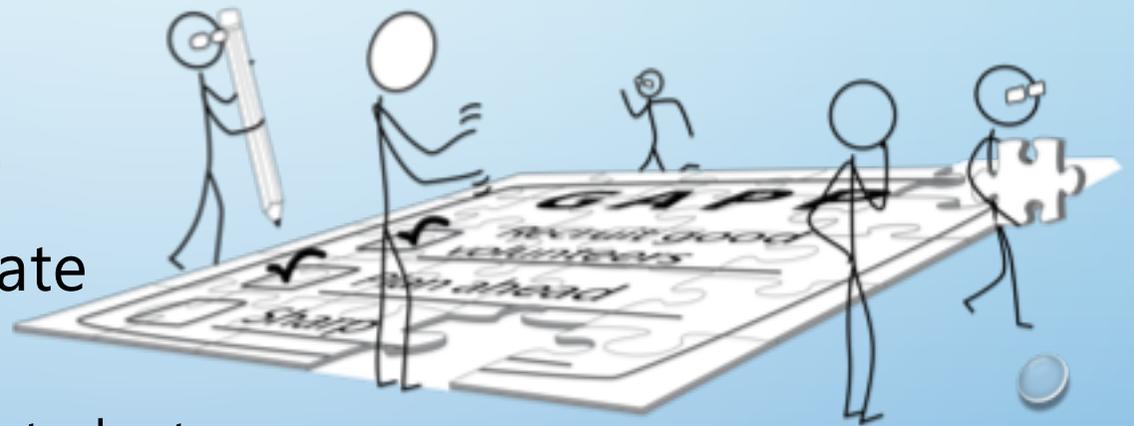
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# Alert process

- Referrals
  - [contact@gappteam.org](mailto:contact@gappteam.org); website form
- Surveillance
- Fortune
- Anticipation

# Characteristics of a trigger article

- On remit
  - Ghostwriting/publication professionals/industry practices
- Decent reach
  - Mainstream journal
  - High profile author(s)
- Opportunity to educate
  - Pubs professionals
  - Researchers/authors/students



# Characteristics of a GAPP response

- Respectful
- Cite third party guidance (ICMJE, WAME, CSE)
- Cite sources correctly/correct misinterpretation
- Refute anecdote with evidence
  - GPS
  - Ghostwriting prevalence
  - CMPP
  - Current practice vs historical
- Highlight current guidance and current behaviour





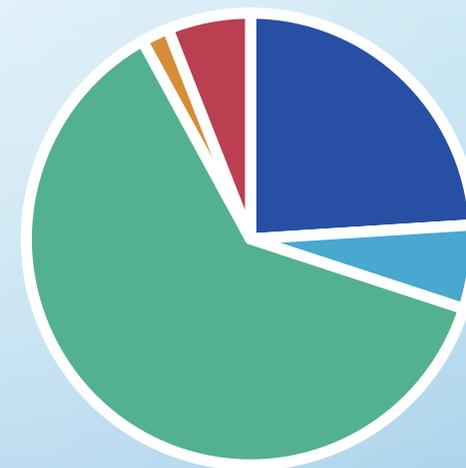
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# GAPP in action

~50 responses

- Some ignored
- 1 attempt to get us banned from PLoS
- PubMed Commons – useful while it lasted

Response types



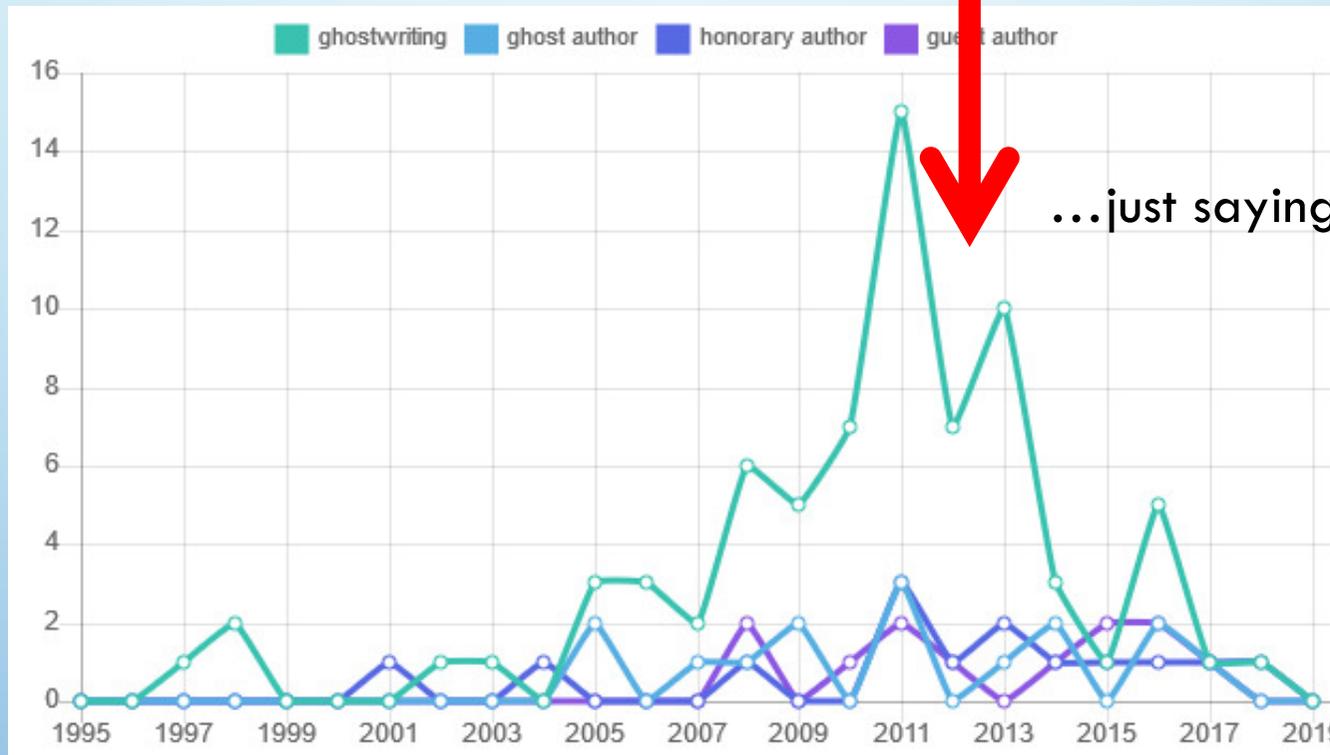
■ Blogs/online comments ■ News outlets  
■ Academic journals ■ Government  
■ PubMed Commons

# Proactive articles

- Woolley KL, Gertel A, Hamilton C, Jacobs A, Snyder G. Poor compliance with reporting research results - we know it's a problem ... how do we fix it? *Curr Med Res Opin.* 2012. doi:10.1185/03007995.2012.739152.
- Woolley KL, Gertel A, Hamilton CW, Jacobs A, Snyder GP. Time to finger point or fix? An invitation to join ongoing efforts to promote ethical authorship and other good publication practices (July/August). *Ann Pharmacother.* 2013;47(7-8):1084–7. doi:10.1345/aph.1S178.
- Gertel A, Hamilton C, Jacobs A, et al. The Global Alliance of Publication Professionals: update on a small group with a big mission. *AMWA J.* 2013; 28(1):42-4, 47.
- Hamilton CW, Gertel A, Jacobs A, Marchington J, Weaver S, Woolley K. Mythbusting medical writing: goodbye ghosts, hello help. *Account Res.* 2016;23(3):178–94. doi:10.1080/08989621.2015.1088788.

# Did it work?

Correlation does not equal causation, but  
GAPP started here



...just saying...

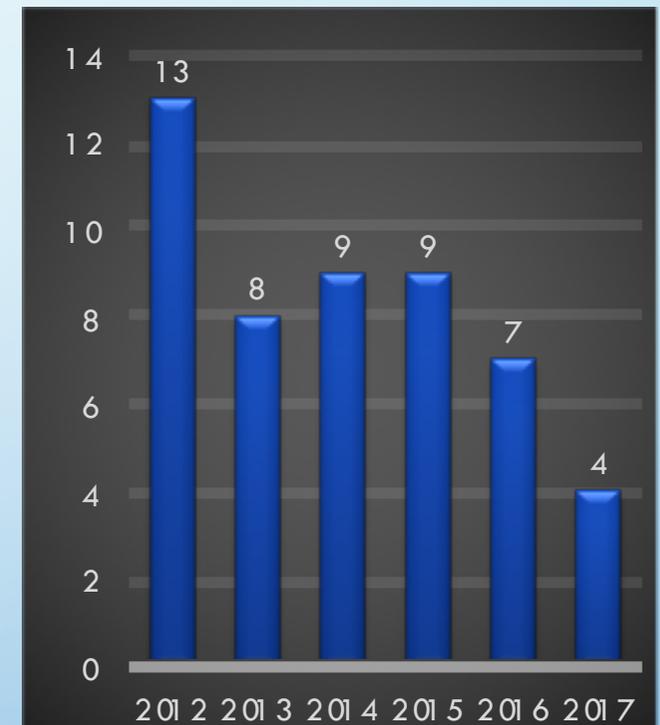


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Time to go?

## Responses: 2012–2018

- The volume of articles about industry sponsored medical publications has decreased
- Misinformed or poorly researched articles are still being published, but they have been focussing less and less on professional medical writing
- The conversation about industry funded research has been moving toward data disclosure and clinical trial transparency for some time
- We responded to only 4 articles in 2017



# The Matheson Event

- In 2016, GAPP responded to a series of articles by Alastair Matheson about how industry manipulated ICMJE criteria for authorship
- The third one, in the BMJ, drew independent responses from GAPP and ISMPP, and, eventually, a joint final response from all organizations
- Organizations had evolved to be able to work together on a timely response

# So long!

- As of 2 May, 2018, the Global Alliance of Publication Professionals stepped down
- After 6 years and ~50 responses, we felt that GAPP had served its purpose and the professional organizations have evolved to a point that we could hand back responsibility for rebuttals and responses to AMWA, EMWA and ISMPP





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# Don't sit back –



- We will continue to maintain the website and the [contact@gappteam.org](mailto:contact@gappteam.org) inbox
- Thank you for your support and assistance over the years



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2012-2018

<http://gappteam.org>  
[contact@gappteam.org](mailto:contact@gappteam.org)

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Jackie.Marchington@caudex.com