Medical writing support of industry-sponsored research: how bright (or not) is the future?

Karen Woolley,
ISMPP Director and Chair, Asia–Pacific Advisory Committee,
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Professor, University of Queensland and
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THINGS CAN ONLY GET BETTER
- OH REALLY?

“THE PESSIMIST COMPLAINS ABOUT THE WIND;
THE OPTIMIST EXPECTS IT TO CHANGE;
THE REALIST ADJUSTS THE SAILS.”
WILLIAM A. WARD

Photo credit: Robert Gardner
HOW IS THIS GOING TO WORK?
GETTING TO KNOW YOU…

- When I think about the future of publication professionals, my thoughts are probably:
  1. Pessimistic
  2. Optimistic
  3. Realistic
When I think about the future of publication professionals, my thoughts are probably:

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GETTING TO KNOW YOU…

• I work in:
  1. A pharmaceutical / biotech / device company
  2. A service provider company
  3. A publishing / journal editor role
  4. Academic research
  5. Other
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GETTING TO KNOW YOU…

• My main activity is:
  1. Medical writing
  2. Publication planning
  3. Client relations
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GETTING TO KNOW YOU...

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GETTING TO KNOW THE OTHER EXPERTS

**Futurist:** Elizabeth Wager
Freelance Publications Consultant, Sideview
Futurist: Russell Traynor
Business Development and Marketing Lead, UBC-Envision
GETTING TO KNOW THE OTHER EXPERTS

Futurist: Gary Evoniuk, Director, Scientific Communications, GlaxoSmithKline
GETTING TO KNOW THE OTHER EXPERTS

**Futurist:** Wim Weber
Clinical Editor (Europe) BMJ, BMJ Publishing Group
GETTING TO KNOW THE OTHER EXPERTS

Futurist: Leighton Chipperfield
Head of Publishing, Society for General Microbiology
In the next 3-5 years, journal editors will increasingly recognise the value and ethics of professional medical writers:

1. You’re kidding me right? Not a chance
2. I hope so…but doubt it
3. I hope so…but doubt it, unless we have strong evidence to validate such claims
4. Sure – that’s started to happen already
Topic 1 Your predictions?

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In the next 3-5 years, the best way to reduce ghostwriting will be:

1. To take legal action against ghostwriters and the authors and sponsors who work with them
2. For sponsors and authors to work only with writers who are CMPP-qualified or able to pass a test on ethical publication practices before being hired
3. For journals to require that any manuscript with writing support includes a supplementary “audit trail” file documenting compliance with ethical publication practices
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Topic 1 Your predictions?

In the next 3-5 years, the best way to reduce ghostwriting will be to:

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The professional medical writer has been, and will be, a necessary help to busy physicians in preparing papers and other literary material.

Instead of being condemned for mistakes in the past, the writer is to be encouraged, and authors are well-advised in acknowledging assistance rendered by her (or him).”

Frank Place, New York Academy of Medicine Bull Med Lib Assoc, 2013
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Topic 1: Professional medical writers are NOT ghostwriters – seeking a vision for the future

Presenter: Liz Wager
Why does this matter to publication professionals?

• If all forms of writing assistance (acknowledged or not) get labelled as ‘ghostwriting’, there’s a risk that it will all be viewed as unacceptable and people may try to ban it.

• We need to clarify the legitimate contributions made by writers.
My “top 3” concerns about this issue are:

1. Continuing problems with terminology (which can affect guidelines, e.g. institutional ones)
2. Journals that redefine ICMJE (eg *Neurology*)
3. Misunderstanding of what medical writers contribute
‘False fixes’

- Concerns about ghostwriting are about disclosure and conflicts of interest
- ‘Solutions’ requiring ghostwriters to be experts in a topic are unhelpful – that’s the role of the other authors!
  - **Blood**: involvement for primary research articles acceptable only if the writer has “appropriate expertise and background to provide substantive input to the background research or writing .. the article”
  - **CMRO editorial (GATE guidelines)**: “Expertise: does the professional writer have sufficient knowledge in the relevant specific field?”
- We need to promote professionalism (and qualifications) but ensure clarity about writers’ role
Future scenario…
if it gets worse:

• Increasing numbers of academics / investigators will refuse to work with medical writers

• There may be reluctance to disclose writers' involvement

• Medical writers may not be properly acknowledged and may BECOME ghost writers!
Future scenario...

if it gets better, we will:

• Work together with institutions and editors to develop clear authorship guidelines acceptable to all medical publications (for different types of publication?)

• Communicate the benefits that professional writers can bring (knowledge of guidelines, preventing non-publication due to lack of investigator interest, communication skills, etc.)

• Establish guidelines for the roles and involvement of other authors (preventing guest authorship)
Who needs to act now?

- Institutions / academics / researchers
- Medical writers (ISMPP)
- Journal editors (not just ICMJE!)
If I could do just one thing to help, it would be:

• Work with institutions to define detailed authorship criteria for different types of research and different types of publication

• OR (radical plan!) abandon authorship altogether, switch to contributorship and force institutions to find a different way of measuring researchers’ output
In the next 3-5 years, public disclosure of fees paid to healthcare professionals for medical writing support will:

1. Still be under debate
2. Not be required
3. Be required – and help dispel concerns about the relationships between sponsors, writers, and authors
4. Be required – and do little to dispel concerns about the relationships between sponsors, writers, and authors
5. Result in allegations of price fixing
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Topic 2: Declaring physician payments – shining a light on potential scenarios

Presenter: Russ Traynor
Why does this matter to publication professionals?

• Sunshine Act and other global legislation requires reporting of payments, or transfers of value to HCPs/physicians

• As publication professionals we will need to understand what needs to be reported and how this should be done, so we can facilitate this, and also advise clients/colleagues/agencies and authors on the requirements
My “top 3” concerns about this issue are:

1. If medical writing support is reportable, how we can work out the transfer of value in a fair and meaningful way.

2. Will authors turn down help if reportable, leading to publication delay, hence delay in important clinical information reaching practising HCPs.

3. The end of professional publication support, and therefore all the good work we do in ensuring accurate data reaches clinicians in a timely manner.
How did we get here?

• Large honoraria payments for…
  • Advisory board input?
  • Guest authorship?
  • Nothing substantial?

• Sins of the father…?
  • The past defines us, but should it be allowed to hold us back?
  • Publication professionals and Tour de France cyclists are in the same boat!
Future scenario...
if it gets worse, it will:

- Mean the end to medical writing support
- Large delays to data being published
- Kill our profession
Future scenario…
if it gets better, it will:

• Have absolutely zero impact

• Afraid no positives here, it is negative or neutral!
Who needs to act now?

- Not much we can do to action, we’ve input our views, responded as we can and we wait and see in terms of US Sunshine
- For other countries, they will likely see what US says, and then we may need to lobby again.
If I could do just one thing to help, it would be:

• Prepare and be ready to report…

• …or in the words of Cher:
  “If I could turn back time!”
• In the next 3-5 years, publication plans will be accepted as a transparent and efficient way to ensure results are disclosed in a complete, accurate, and timely manner:

1. Strongly disagree
2. Disagree
3. Neutral
4. Agree
5. Strongly agree
Topic 3 Your predictions?

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In the next 3-5 years, associations representing publication professionals (eg, ISMPP, AMWA, EMWA) will work together on specific advocacy projects to provide a stronger, more unified, and international voice for our profession.

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1. Strongly disagree
2. Disagree
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4. Agree
5. Strongly agree
“If patients knew that most results from clinical research were not shared as completely or as quickly as they should be, how many patients would volunteer for research studies?

If patients knew this problem was worse for government-funded research than pharmaceutical industry-funded research, how many would want their tax dollars allocated to government-funded research?”

Global Alliance of Publication Professionals (GAPP)
Curr Med Res Opin 2012
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Topic 3: Publication planning – advocacy and raising ethical benchmarks in 2013 and beyond

Presenter: Gary Evoniuk
Why does this matter to publication professionals?

- The credibility of the profession is at stake
- Too many people do not understand the positive contribution that publication professionals can make to quality and transparency
- Too many “authors” have been spoiled by past practices
- Too many publication professionals have not pushed back on #1 & 2
"I am sorry, but we cannot publish your paper on X. There seems to be a lot of good information in the paper. I have no problem with most properly disclosed conflicts, but have to draw a line with writing and editing "assistance" that was funded by the company who sponsored the study being summarized. Please understand that I am not questioning the veracity of the material you submitted. But as we set about strengthening JournalName, we must also be mindful of our own credibility."

Journal editor, in response to a manuscript submission that contained the following disclosure:

“The authors acknowledge X for assistance with writing this manuscript and Y for editorial assistance. These contributions were funded by GlaxoSmithKline.”
My “top 3” concerns about this issue are:

1. Definition of “authorship” and how it needs to be implemented in real life
2. Completeness of disclosure
3. Timeliness of disclosure
How did we get here?

The past:
- "Strategy"
- Messaging
- Key Opinion Leaders

The present:
- Transparency
- Scientific conclusions
- Authors
Future scenario…
if it gets worse, it will:

• Lead to additional onerous process requirements that distract from the real work

• Result in a failure of society to trust our science and how we communicate it
Future scenario...
if it gets better, it will:

• Improve the credibility and role of the publication professional
• Enable us to get on with the real work
• Enable physicians to have the information needed to provide the right medicine to the right patient at the right time
Who needs to act now?

• Publication professionals need to communicate about, and advocate for their proper role

• Journal editors need to cooperate more and compete less, especially in providing clear guidance regarding authorship

• Authors need to act responsibly and credibly
If I could do just one thing to help, it would be:

- Encourage all sponsors (not just industry) to report all their study findings promptly, completely and transparently
TOPIC 3: Q & A
PUBLICATION PLANS / ADVOCACY / ETHICS

Photo credit: Freedigitalphoto.net
EXPERTS’ PREDICTIONS – RE-VISIT AT ISMPP EU 2016...
NEXT 3 YEARS...
PESSIMISTIC, OPTIMISTIC, REALISTIC?

<table>
<thead>
<tr>
<th>Positive effect</th>
<th>Negative effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification will gain traction; some journals will only consider papers with writing support when writers are certified publication professionals</td>
<td>More complex publication landscape (decline of traditional journals); if you don’t keep up you will be left behind</td>
</tr>
<tr>
<td>Enhanced transparency of involvement of publication professionals in published articles</td>
<td>Political grandstanding on ghost authorship as it relates to publication professionals</td>
</tr>
<tr>
<td>Continuing concern about nonpublication and selective publication will lead to recognition of the important role of publication professionals</td>
<td>Over-reliance on authorship (vs contributorship) of peer-reviewed articles by academic institutions means writers will continue to be viewed with concern (vs serving a legitimate function)</td>
</tr>
<tr>
<td>Increased open-access journals and IT facilitated creativity will enhance effective communication of data</td>
<td>HCP reluctance to work with pub prof (old stories drive perceptions) exacerbates low, slow, and poor quality communication of data, and, ultimately, adversely affects patient care</td>
</tr>
<tr>
<td>IT increasingly cuts out the middle man (HCP); more self-mgt creates new opps for pub prof</td>
<td>Economic crisis fall out continues, cutting budgets for health care, health care companies, pub prof</td>
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2013 European meeting of ISMPP: doing the right thing and doing things right