Pharmaceutical Companies and Medical Publishers

Working together in a world of increasing regulation

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Disclaimer

The ideas or opinions expressed in this presentation are those of the individuals and do not necessarily reflect those of their employers or other affiliated organisations.
Publication of industry-sponsored research: The stakeholder network
The regulatory environment

- Ethical guidelines
- Legal requirements
- Journal requirements
- Industry guidelines
- Promotional codes
Legal requirements for disclosure of industry sponsorship or payments

- FDAAA and EU legislation
  - Protocol registration
  - Posting of results within 12 months* of study completion
  - Applicable for all* pharmaceutical interventions

- Physicians Payments Sunshine Act
  - Part of the Patient Protection and Affordable care act
  - In effect from 1st Jan 2012
  - Requires manufacturers to publicly disclose all payments and “transfers of value” to physicians

- Corporate integrity agreements (CIA)
  - Imposed by the Office of the Inspector General of the Department of Health and Human Services
  - Usually lasting four to five years
Industry guidelines on publication of industry-sponsored research

- **Pan-company, eg**
  - Joint Position on the Publication of Clinical Trial Results in the Scientific Literature from EFPIA/IFPMA/JPMA/PhRMA
    - “… submitted for publication wherever possible within 12 months and no later than 18 months …” (timeliness)
    - “… should be submitted to journals indexed by online bibliographic databases” (accessibility)

- **Company specific, eg**
  - AstraZeneca
  - GlaxoSmithKline
  - Merck
  - Pfizer
Pfizer’s Publication Policy

- Supports ICMJE guidelines on authorship
- Requires
  - Recognition of medical writers in the publication
    - author (if meet criteria)
    - acknowledgement
  - Medical writers work under the direction of the authors
  - Disclosure of funding source(s)
    - study, writing support, other support
  - Disclosure of potential conflicts of interest

Pfizer marketing colleagues are not involved in preparation, planning or content development of publications
Relationship Between the Journals and Authors is Maintained

- Primary relationship
  - Authors and Journal
- Authors responsible for
  - Content
  - Journal selection
  - Response to peer reviewers
Author input is essential; otherwise they are considered ‘guest authors’

**Rules and Guidelines for Responsible Conduct of Research**

6. “Ghost-writing,” a practice whereby a commercial entity or its contractor writes an article or manuscript and a scientist is listed as an author, is not permissible. Making minor revisions to an article or manuscript that is ghost-written does not justify authorship.

**College of Physicians and Surgeons**

Ghost Authorship and Ghost Writing: Contributions to medical literature made by or through commercial entities should be transparent with respect to authorship and the contribution of authors. P&S Faculty, trainees and students are prohibited from authoring or co-authoring articles written by employees of commercial entities, or their agents, where their name or Columbia title is used without their substantive contribution. If commercial employees are co-authors, they should be acknowledged as such. Any articles or other materials written in conjunction with commercial entities must include full disclosure of the role of each author, as well as other contributions or participation by such commercial entities. P&S Faculty authors who collaborate with commercial entities must maintain editorial independence at all times.
Pfizer’s Commitment to Transparency in Publications

- Publications Management Team
- Processes to facilitate adherence to ICMJE guidelines
  - Author Letter
    - Educate non-Pfizer authors on:
      - ICMJE guidelines
      - Disclosure of writing support/financial support
      - Disclose potential conflict of interest
      - Timely publication of study results
  - Pre-submission quality control checklist (Final Check)
  - Standard disclosure statements
- Training colleagues and publication vendors on ICMJE guidelines and Pfizer policy
Pfizer’s Author Letter — Sent to non-Pfizer Authors

Dear Doctor,

Re: Pfizer policy on authorship

As a potential author to a Pfizer supported publication, I am writing to confirm with you Pfizer’s policy regarding authorship. Pfizer requires retaining the included Acknowledgments.

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of the data;
2. Drafting or revision of the manuscript for important intellectual content, and
3. Approval of the final version to be published.

These criteria apply to all researchers involved in the publication, including Pfizer employees. All contributors, including agencies providing editorial support, who do not meet the criteria for authorship, should be listed in an acknowledgments section.

Authors must acknowledge individuals who provide editorial support and disclose the funding source for this assistance.

Pfizer policy is that all authors in accordance with the relevant journal guidelines, must disclose in the manuscript or that part of the manuscript submission, all relationships that could be viewed as presenting a potential conflict of interest.

For Pfizer sponsored studies (including Global Outcomes Research), the fact that the study was sponsored by Pfizer must be disclosed. Financial compensation cannot be paid by Pfizer to investigators for authorship of manuscripts for primary publications on clinical trials.

Deliverables and timelines for primary publications (clinical trial results)

- These criteria apply to all contributors, including Pfizer employees. All contributors, including agencies providing editorial support, who do not meet the criteria for authorship, should be listed in an acknowledgments section.

- Authors, as determined by the journal to publish in, and their statistical tables, figures and text right to review publications for final content.

- Conflict of Interest

According to ICMJE, a conflict of interest exists when an individual has financial or personal relationships that may appropriately influence (bias) his or her actions. Financial relationships (i.e., employment consultancies, stock ownership,

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1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of the data;
2. Drafting or revision of the manuscript for important intellectual content, and
3. Approval of the final version to be published.

These criteria apply to all researchers involved in the publication, including Pfizer employees. All contributors, including agencies providing editorial support, who do not meet the criteria for authorship, should be listed in an acknowledgments section.
Pfizer Checklist Completed Prior to Submission

Items Checked include:

- Financial support appropriately disclosed
- Consistent with clinicaltrials.gov registration
- Data in manuscript is consistent with study data tables
- Reviewed by biostatistician for statistical interpretation
Pfizer: Some Standard Disclosures

- This study was Sponsored by Pfizer Inc.

- Editorial Support was provided by <name> at <company/affiliation> and was funded by Pfizer Inc.

- <Author Name> is an employee of <Vendor Name>, who were paid consultants to Pfizer in connection with the development of the manuscript.

- <Author Name> received an honorarium from Pfizer in connection with the development of this manuscript or <Author Name> was a paid consultant to Pfizer in connection with the development of this manuscript.
QUESTIONS?
Promotional codes

- Although journal advertising is considered promotional, Publication of industry-sponsored research in literature isn’t.
- Unless activity is deemed ‘disguised promotion’ eg, Breach of ABPI Code Clause 12.1
  - Trajenta case (2012)
  - Multaq case (2011)
  - RoActemara case (2010)
  - Cymbalta/Zyprexa case (2009)
Journal requirements

• Pan-journal
  ◦ ICMJE: “All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided … writing assistance...“

• Journal specific:
  ◦ Neurology: “Professional writers employed by pharmaceutical companies or other academic, governmental, or commercial entities who have drafted or revised the intellectual content of the paper must be included as authors.”
Ethical guidelines

- MPIP authors’ submission toolkit
  - Collaboration between Pharm and ISMPP to promote more effective partnership between sponsors and journals and enhance trust and transparency for industry sponsored publications
- GPP2 –
  - update on GPP 2003
What keeps us awake …

Will my process be considered compliant?
Will my paper be accepted?
In a timely manner?
Will my manuscript be read?
Increasing scrutiny on industry sponsored research
Ethical conduct: Defined by who?

Industry Sponsored Editorial Assistance
February 12, 2012 by sickpopulations

The September 2011 edition of the Quarterly Journal of Medicine contained two review articles which dealt with the use of new oral anticoagulants in patients with atrial fibrillation.

The first was by Prof Richard Hobbs and Isabelle Leach, who works for a reputable sounding organisation called Chameleon Communications. The funding and conflict of interest statements read as follows.

"F.D.R.H. received no funding for this work. Bayer AG and Johnson & Johnson Pharmaceutical Research & Development, LLC, through funding of the professional medical writing services provided by IL. The sponsors were not involved in writing or editing the material. The authors take full responsibility for all content...F.D.R.H. has received occasional speaker fees or sponsorship from a variety of pharmaceutical companies, some with interests in AF including Boehringer Ingelheim, Pfizer, and Bayer. I.L. is an employee of Chameleon Communications International which received funding from the sponsors for her time on this manuscript."

Editorial
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Authorship and the role of medical writers

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In the correspondence section of this month’s journal there is an interesting debate on the role of medical writers in scientific publication. Dr Vallance raises the issue of ‘medical ghostwriting’ and authors’ responsibilities,1 Professors Holz and Meyer2 rightly confirm that they have appropriately acknowledged the contribution of a medical writer to their publication,3 and Gail Flockhart confirms how her company follows current best practice in publishing.4
Manuscript submission and acceptance challenges

- Realistic journal selection – not all articles are destined for JAMA!
- Increasing likelihood of acceptance with appropriate journals
- Navigating the submission ‘admin’ burden
- Dealing optimally with peer-review comments
Timeliness of publication

- Desire to achieve journal publication prior to results postings
- Traditionally print lead-times have been factored into planning, but online first altering dynamics:
  - Epub ahead of print improving speed to print
    - Significantly different for some journals
  - Has planning implications
    - (eg, conference abstracts)
- Impact of rejection on timeliness
Accessibility of article: Considerations

- Database listings (esp, MedLine)
- Open-access options
  - Pay open-access
  - Older content open-access
  - Full open-access journals
- Journal on-line activity
- Article-level metrics
QUESTIONS?
What would help us…

- Compliance
- Acceptance
- Timeliness of disclosure
- Accessibility
What would help us...

1. Ensure individual journals explicitly require writing & editing support to be acknowledged
2. Move towards more obvious acknowledgement of funding / writing support
3. Help us navigate the narrative review article and supplement arena
4. Assist in education of academia on good publication practice
5. Communicate journal options that assist disclosure (eg, BMJ Open)
What would help us...

Acceptance

1. Facilitate pre-submission discussions
2. Work towards standardisation of COI requirements
What would help us...

1. Expedite time to acceptance/rejection
2. Communicate clearly on average print and on-line lead-times
3. Provide rapid-publication options
What would help us...

1. Open-access archives and open-access article options (in addition to open-access journals)
2. Journal’s use of social media
Examples of journal activity
Help us understand the future

- Paper articles
- Pdfs of paper articles
- Supplementary materials (e.g., podcasts and slide presentations)
- What’s next?
- (How) Do we need adapt?
How can we help you?

Coming together is a beginning; keeping together is progress; working together is success.

Henry Ford