Round up the usual suspects?
Involvement of medical writers and
the pharmaceutical industry in
retracted publications

A/Professor Karen Woolley
ProScribe Medical Communications

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An Original Research Study by ProScribe Medical Communications
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Who are the usual suspects?

“...it is now fairly well known that pharmaceutical companies launder their promotional efforts through medical communication companies that ghostwrite articles and then pay ‘key opinion leaders’...to affix their signatures to the fraudulent articles...”

McHenry L. Ethical Issues in Biomedicine
2008;6:146-156
Where is the evidence?

Retracted Publications

MEDLINE – mistake (error) or misconduct (fabrication, falsification, plagiarism) confirmed by author, author’s legal counsel, department head or journal editor.
Objectives

1. To determine, for the first time, the proportion of retracted publications, especially those retracted for misconduct, that involved declared medical writers or pharmaceutical industry sponsorship.

2. To investigate factors that may be associated with misconduct retractions.
Methods

- **MEDLINE**
- **Retracted publications**
  - 1966 – 2008
  - Limit = human, English
- **Retrieved**
  - Original publication and retraction notice
- **Data extraction**
  - Standardized data collection tool
  - Standardized definitions (Woolley KL et al., JAMA 2006
  Nath S et al., MJA 2006)
- **Independent statistician**
  - Design and analyses (inter-rater reliability, percentages, odds ratios, univariate and multivariate logistic regression)
I'm shocked, shocked to find out who is and who isn't involved in retracted publications!
Why guilty until proven innocent?

Medical writer and pharma: 0.4%
Medical writer: 4.9%, 1.4%
Pharma: 7.8%, 3.8%
Non-pharma: 92.2%, 96.2%

All Retractions: Medical writer and pharma 0.4, Medical writer 4.9, Pharma 7.8, Non-pharma 92.2
Misconduct Retractions: Medical writer 1.4, Pharma 3.8, Non-pharma 96.2

N = 463, n = 213

Why innocent until proven guilty?
Results

- Odds of retraction for misconduct, rather than mistake (control group), were higher if the ‘usual suspects’ were NOT involved

  - 6.23-fold higher (CL 1.81, 21.48) if a declared medical writer was NOT involved
  - 3.74-fold higher (CL 1.66, 8.40) if declared industry sponsorship was NOT involved
Limitations

- Data source retracted publications
  - Time lag
  - Limiters used (English, human)

- Declared vs hidden involvement
  - Ghost writers and ghost sponsors
  - Non-financial conflicts of interest

- Retraction vs bias
Conclusions

- Publications involving declared medical writers or industry sponsorship have rarely had to be retracted, particularly for misconduct.
- Appropriate declarations should continue.
- Evidence challenges potential bias against manuscripts involving declared medical writers and industry sponsorship.
Out of all the medical journals in all the world, they had to publish their fraudulent data in mine!
Disclosures

Contributors (ProScribe employees)
- All met ICMJE authorship criteria; Dr Karen Woolley (guarantor), Dr Mark Woolley, Dr Rebecca Lew, Dr Narelle Bramich, Dr Julie Ely, Dr Serina Stretton, Dr Julie Monk, Dr Janelle Keys

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Conflicts of interest
- All authors are active members of associations for professional medical writers in the Asia-Pacific region, Europe, and North America

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- Profiled in Nature Medicine, 2009
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