# Selling Sickness 2013
# People Before Profits

**Washington, D. C., February 22, 2013**

**Panel: Corruption**

# The End of Medical Ghostwriting?

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# Abstract

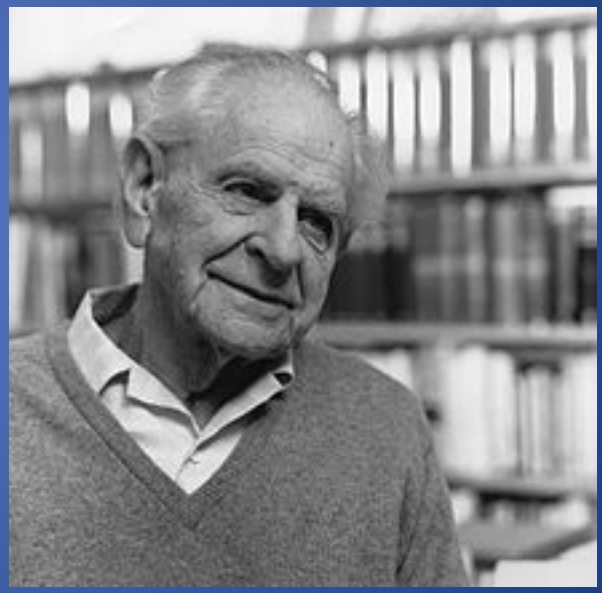
While academic researchers have sought to expose the harmful effects of medical ghostwriting for well over fifteen years, industry representatives and their attorneys have sought to conceal this lucrative business. Industry now offers to address the problem of erosion of confidence in the reporting of industry-sponsored clinical trials with new policies of transparency and disclosure, yet there are many reasons why clinicians should continue to view the medical literature with a healthy dose of skepticism. A radical solution is required that severs the relationship between the industry and the journals.

# Disclosure

- I have been a research consultant for the law firm of Baum Hedlund Aristei & Goldman, Los Angeles, California since 2003 and a member of Healthy Skepticism since 2010.
- No sponsor company has done the research, writing or contributed any of the key ideas for this presentation.

# Sir Karl Popper

- Philosopher of Science, Karl Popper, in his *The Poverty of Historicism* (1936) imagined circumstances in which **industry would suppress and control speech and writing in their favor** and therefore corrupt the integrity of science.
- This is realized today in academic medicine with the problem of ghostwriting.
- Popper would certainly see the pharmaceutical industry as an enemy of the open society.



# The Credibility Gap

- Any scientific experiment, according to Popper, that does not risk falsification is pseudoscience.
- Design, conduct and reporting of industry- sponsored clinical trials are manipulated in favor of the study drug.
- Studies of drug trials funded by the pharmaceutical industry have overwhelming positive outcomes.* When they do fail, *in spite of manipulation*, the companies hide the results.

*E.g. "Pharmaceutical industry sponsorship and research outcome and quality: systematic review" Lexchin et al. *BMJ 2003; 326 doi*

# The Credibility Gap

- A master class in psychopharmacology offering CME credit held annually at Harvard University demonstrates Popper's point. One faculty member, an "internationally renowned psychiatrist" is advertised as "author of over 900 scientific articles and book chapters, co-editor, *Textbook of Psychopharmacology*" in 2012.
- In 2013, the number jumped to 975.
- At least 3 of the faculty have been at the focus of major ghostwriting scandals.

# The Credibility Gap

COMMENTARY

MAYO CLINIC

## Ten Recommendations for Closing the Credibility Gap in Reporting Industry-Sponsored Clinical Research: A Joint Journal and Pharmaceutical Industry Perspective

Bernadette A. Mansi, BA; Juli Clark, PharmD; Frank S. David, MD, PhD; Thomas M. Gesell, PharmD; Susan Glasser, PhD; John Gonzalez, PhD; Daniel G. Haller, MD; Christine Laine, MD, MPH; Charles L. Miller, MA; LaVerne A. Mooney, DrPH; and Maja Zecevic, PhD, MPH

From GlaxoSmithKline, King of Prussia, PA (B.A.M., C.L.M.); Amgen, Thousand Oaks, CA (J.C.); Leavink Swann Consulting, LLC, Boston, MA (F.S.D.); Novartis Pharmaceuticals Corporation, East Hanover, NJ (T.M.G.); International Society for Medical Publication Professionals, Briarcliff Manor, NY (T.M.G.); Johnson & Johnson Pharmaceutical Research & Development, LLC, Raritan, NJ (S.G.); AstraZeneca, Macclesfield, United Kingdom (J.G.); *Journal of Clinical Oncology*, Alexandria, VA (D.G.H.); *Annals of Internal Medicine*, Philadelphia, PA (C.L.); Pfizer Medical, New York, NY (L.A.M.); and *The Lancet*, Elsevier, New York, NY (M.Z.). Dr Gesell is currently with United BioSource–Envision Group, Franklin Lakes, NJ. Dr Haller is currently with *Gastrointestinal Cancer Research*, Melville, NY.

The credibility of industry-sponsored clinical research has suffered in recent years, undercut by reports of selective or biased disclosure of research results, ghostwriting and guest authorship, and inaccurate or incomplete reporting of potential conflicts of interest.[1,2] In response, many pharmaceutical companies have integrated best practices and recommendations from groups such as the International Committee of Medical Journal Editors (ICMJE), the Good Publication Practice guidelines, the Committee on Publication Ethics, the EQUATOR (Enhancing the QUAlity and Transparency Of health Resources) Network, and the Medical Publishing Insights and Practices (MPIP) initiative into their internal policies and standard operating procedures.[3-10] However, a credibility gap remains: some observers, including some journal editors and academic reviewers, maintain a persistent negative view of industry-sponsored studies.[11] Given industry's pivotal role in the development of new therapies, further improvements in research conduct and disclosure are needed across the industry-investigator-editor enterprise to restore confidence in industry-sponsored biomedical research.

In 2008, the MPIP was founded by members of the pharmaceutical industry and the International Society for Medical Publication Professionals to elevate trust, transparency, and integrity in publishing industry–sponsored studies through education and creation of a discussion forum among industry research sponsors and biomedical journals.[12,13] In 2010, the MPIP convened a roundtable of 23 journal editors and industry representatives (see the "Acknowledgments" section for a list of MPIP participants) to characterize the persistent and perceived credibility gap in industry-sponsored research and identify approaches to resolve it. Attendees agreed that there have been important improvements in the conduct and reporting of industry-sponsored studies during the past 5 years, but several opportunities remain for additional improvement. Attendees reached consensus on a top 10 list of recommendations (Table), intended to serve as a call to action for all stakeholders—authors, journal editors, research sponsors, and others—to enhance the quality and transparency of industry-sponsored clinical research reporting. Although framed in the context of industry sponsorship, many of these recommendations would enhance the credibility of clinical research publications in general, regardless of the funding source.

### Recommendation 1: Ensure Clinical Studies and Publications Address Clinically Important Questions

Many perceive a mismatch between the research hypotheses of some industry-sponsored studies and the needs of the public and practicing clinicians to improve patient health. The best way to elevate the credibility of industry-sponsored clinical research is to ensure that such research is designed to answer important clinical and scientific questions while respecting regulatory requirements that may influence certain aspects of study design. Credibility is compromised when clinical research is intended for marketing purposes rather than advancing scientific and medical knowledge. Sponsors could enhance transparency and credibility by better explaining to journals,[3-9] the biomedical community, and the public the decision-making process underlying the research endeavor. For example, sponsors could be more transparent in describing how external input and involvement from the academic community were obtained to inform study design (eg, by acknowledging participants in protocol development, advisory boards, and other roles).



Mayo Clin Proc. ■ May 2012;87(5):424-429 ■ doi:10.1016/j.mayocp.2012.02.009 

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# Credibility Gap

- Tactic by industry to **neutralize criticism** by creating the appearance to take the high moral ground--own the criticism, offer what appear to be reasonable solutions and then… business as usual.
- The approach taken by Mansi *et al.* is interesting for introducing a new term -- "the industry-investigator-editor enterprise."
- The very concept betrays a disturbing sense of entitlement, namely ownership of the medical journals. *

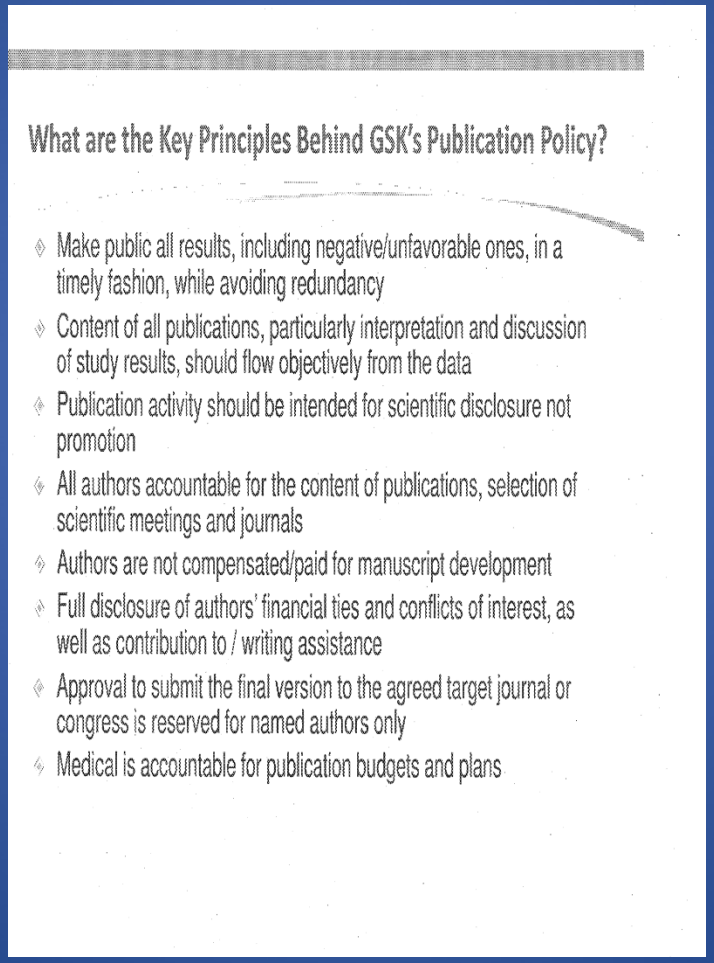
- *McHenry, L. and Jureidini, J. "On the Proposed Changes to the Credibility Gap in Industry-Supported Biomedical Research: A Critical Evaluation," *Ethical Human Psychology & Psychiatry*, 14/3, 2012.

# Credibility Gap

- If followed, the ten recommendations would eliminate some of the worst practices that have fatally undermined the biomedical literature over recent decades.
- An admission for that past practice, authored as it is by some of the very individuals whose companies created, maintained and implemented ghostwriting strategies.
- But describing the problem as a “credibility gap” seriously underestimates a state of affairs that has had lethal consequences.

# GSK's New Commitment

# GSK's New Commitment



**What are the Key Principles Behind GSK's Publication Policy?**

- Make public all results, including negative/unfavorable ones, in a timely fashion, while avoiding redundancy
- Content of all publications, particularly interpretation and discussion of study results, should flow objectively from the data
- Publication activity should be intended for scientific disclosure not promotion
- All authors accountable for the content of publications, selection of scientific meetings and journals
- Authors are not compensated/paid for manuscript development
- Full disclosure of authors' financial ties and conflicts of interest, as well as contribution to / writing assistance
- Approval to submit the final version to the agreed target journal or congress is reserved for named authors only
- Medical is accountable for publication budgets and plans

# GSK's New Commitment

Window dressing on a Crack House?

# Reasons for Continued Skepticism

- First, for over ten years, the industry already has had in place internal operating policies and published guidelines that expressly prohibited ghostwriting, misrepresentation of data and off-label promotion by sales representatives, but these have had little effect on the actual practices of pharmaceutical marketing in the period that generated the greatest volume of ghostwritten publications

# Reasons for Continued Skepticism

- Second, ghostwriters working covertly within the industry have come forward to expose how they work effectively within ICMJE guidelines and still manage to conceal their input and the origin of the manuscript.*

*Matheson, A. (2011). "How industry uses the ICMJE guidelines to manipulate authorship—And how they should be revised." *PLoS Medicine,* 8: e1001072. doi:10.1371/journal.pmed.1001072.

# Reasons for continued Skepticism

- Third, there remains the problem of the thousands of ghost-managed and/or ghostwritten articles, reviews and letters to the editor that seriously misrepresent the science and remain unretracted in the medical
- If the industry were serious about restoring credibility, correcting the present and past scientific record would be the best place to demonstrate a commitment.

# A Radical Solution

- In the age of the internet, there is no longer any legitimate scientific or academic purpose to publishing industry-sponsored studies in medical journals.
- Journals should therefore decline to publish any paper reporting data from a company-sponsored trial.
- Companies can simply post their protocols on-line, and then, when the results of their studies become available, publish the data in full on their websites.
- Third parties, perhaps commissioned by journals, can then offer rigorous, critical evaluation of the methodology and trial results.

# A Radical Solution

- No longer will there be a need for key opinion leaders to lend their names and academic affiliations to ghostwritten papers.
- No longer will there be rewards for medical communication companies to plant marketing messages and spin data from the final summary reports in the journals.
- No longer will anyone take seriously an academic's *curriculum vitae* that list over 900 publications.

# A Radical Solution

- The idea of an independent basis for judging therapeutic claims of pharmaceuticals is nothing new. It was the focus of *JAMA* editor, George H. Simmons, famous complaint in 1907 about "debauching our medical journals" and his reform campaign designed to keep in check a commercialism that threatened to undermine the scientific basis of medicine.*

- What is new is that the goal is much more achievable with the global communication of the world-wide-web.

- *Simmons, G., *JAMA,* 1907, p. 1645; Marks, H. M. *The progress of experiment: Science and therapeutic reform in the United States, 1900-1990.* 1997, p. 24.