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Food & Drug Administration Amendments Act of 2007

Implications for Public Planning Professionals and for Bio-Medical Publication

Larry Hirsch, MD
President, ISMPP
January 17, 2008

Outline

- ISMPP – What, Who, and Why
- A Brief History:
  - Public Trust (or loss of it…) & COI
    - –Authorship, Access, Accountability
  - FDAAA – Registration and Disclosure
- Today's Program

ISMPP International Society for Medical Publication Professionals

ISMPP

- Non-profit society [501(c)6] in state of NJ
- Founded ~ 3 years ago
- Membership > 600 and growing
  - Pharma, biotech, device industry
  - Medical communication companies (agencies)
  - Medical writers
  - Editors & Publishers
  - Academics

ISMPP International Society for Medical Publication Professionals

ISMPP

- **ISMPP's Mission is to:**
- **Support medical publication professionals through education and advocacy**
- **Promote integrity and excellence in medical publishing through author- and contributor transparency, and open exchange of data**
- **Be at the forefront of information-sharing and debate of medical publication issues for the benefit of its members and the medical publication community, at large**
  - **Annual Meeting, Conferences**
  - **ISMPP U "webinars"**
  - **Debate – proactive & reactive**

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ISMPP

- ISMPP's Vision is to be the recognized and respected authority for the pharmaceutical, biotech, and device industries' medical publication profession
  - Code of Ethics (www.ismpp.org)
  - Credentialing / Certification
  - ISMPP journal
  - Standards and Best Practices

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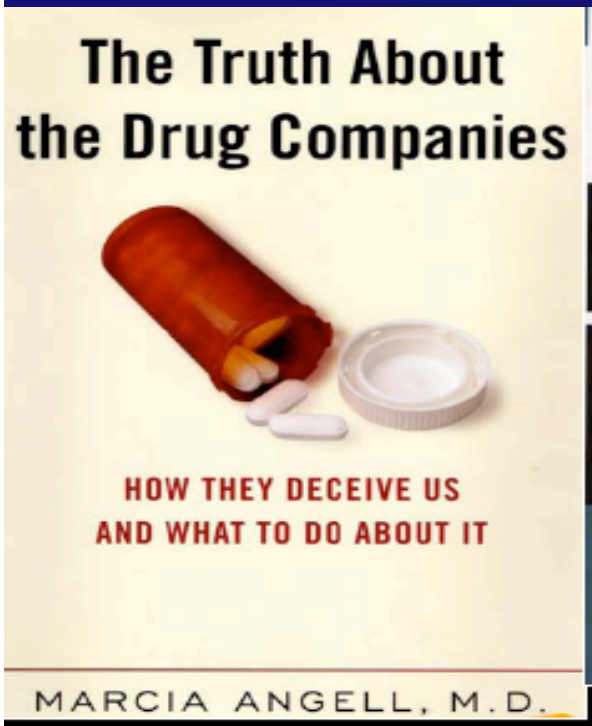
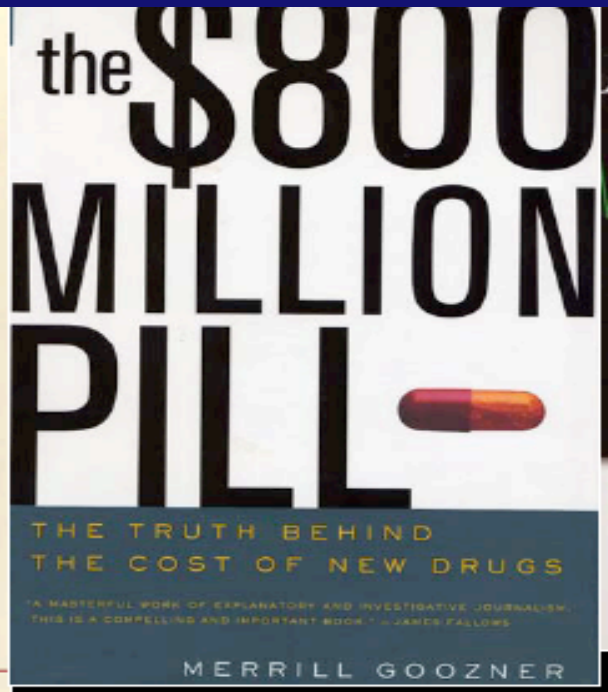
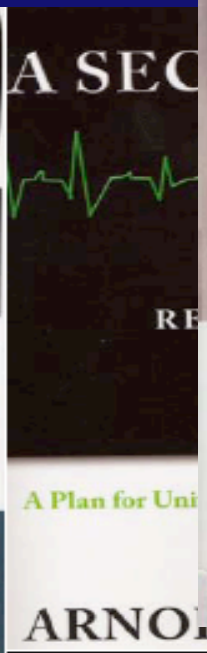
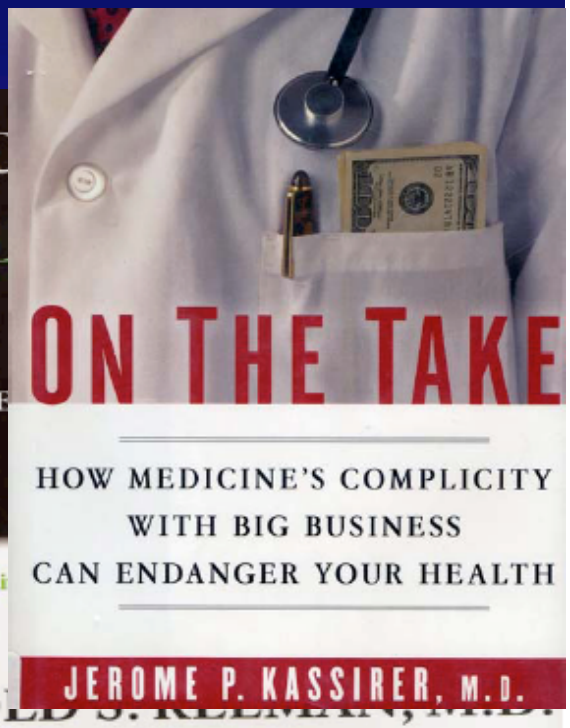
Today's Environment (1)

- Public opinion polls place the pharmaceutical industry at the same level of trust as oil & tobacco companies and gun manufacturers
- Widely publicized books…









COI – History (1)

- Today, JAMA requires "independent" statistical analysis [only] of manuscripts sponsored and analyzed by industry
- Disclosure requirements (COI) are often "over the top"
- How did this happen? A brief history:
  - Rothman – *JAMA* 1993: "Scientific McCarthyism"
  - 1990s-2001: Several egregious incidents
  - ICMJE 2001: "Sponsorship, Authorship & Accountability"
  - 2002: Implementation of FDAMA Sect. 113: CT.gov
  - 2004: Reports of non-publication of paroxetine trials in adolescents with depression, Vioxx

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COI – History (2)

- ICMJE 2004: Mandatory clinical trial registration
  - –2005: All "clinically directive" trials
  - –2005: P*h*RMA _ www.clinicalstudyresults.org
    - 2006: State of Maine legislation
- ICMJE 2007: Rules changed – ALL human trials need to be registered; posting results > 500-word structured abstract in a public registry…"may [be] considered prior publication."

- 2007 FDAAA and Title VIII

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Today's Conference

- Amy Muhlberg, PhD, office of Senator Enzi
- Terry Toigo, RPh, Director FDA Office of Special Health Issues
- Scott Lassman, Esq., former Counsel at PhRMA
- Donald Lindberg, MD, Director, Nat'l Library of Medicine

LUNCH

- Frank Rockhold, PhD, SVP Biomedical Data Sciences, GSK
- Kenneth Jamerson, MD, Prof. of Medicine, U. Michigan
- Trish Groves, MBBS, MRCPsych Deputy Editor, *BMJ*
- Alan Goldhammer, PhD, Assoc. VP Regulatory Affairs, P*h*RMA

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Closing Thought

- Chinese Curse: May you live in interesting times

- “Like it or not, we live in interesting times”

Robert F. Kennedy, Cape Town SA June 7, 1966

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Back-Ups

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ISMPP & Advocacy

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COMMENTARY

International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer

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Key words: Contributorship – ISMPP – Medical writers – Publication

ABSTRACT

The International Society for Medical Publication Professionals (ISMPP) is an independent, nonprofit professional association with members from the pharmaceutical, medical device, and biotechnology industries; publication planning and medical communications companies; academia; and medical journal staffs, including editors and publishers. ISMPP's mission is to support the educational needs of medical publication professionals by providing a forum to facilitate awareness and development of best practices in publication planning and implementation, and fostering consensus policies related to medical publishing.

This position statement reflects our concern about the current climate of mistrust regarding the use of professional medical writers in the preparation of manuscripts. We acknowledge the skills and training of medical writing professionals and support their role in working with research teams to develop clear and concise manuscripts in a timely fashion. Further, we support complete and transparent disclosure of the role of the medical writer and the source of funding for the writing initiative in order to build awareness of, and trust in, the appropriate use of medical writing professionals. ISMPP endorses use of the contributorship model, which offers detailed information on the roles of all who participated in planning, conducting, developing, and publishing medical research. Further, we propose that this model be integrated into the standard operating procedures of the diverse organizations that comprise our membership because the responsibility for authorship disclosure is shared by sponsors, authors, study investigators, and medical writers. Finally, we commend the many organizations that have worked to increase recognition and understanding of the legitimate role of the medical writer, and are eager to work in concert with them to ensure the rigorous maintenance of all ethical standards for reporting the results of medical research.

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The "Debate"

OPEN ACCESS Freely available online

PLoS MEDICINE

Essay

Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?

Sergio Sismondo

"What is the purpose of publications?... [The] purpose of data is to support, directly or indirectly, the marketing of our product." [1]

From Ghost Writing to Ghost Management

There are many reports of medical journal articles being researched and written by or on behalf of pharmaceutical companies, and then published under the name of academics who had played little role earlier in the research and writing process [2–14]. In extreme cases, drug companies pay for trials by contract research organizations (CROs), analyze the data in-house, have professionals write manuscripts, ask academics to serve as authors of those manuscripts, and pay communication companies to shepherd them through publication

agents control or shape multiple steps in the research, analysis, writing, and publication of articles. Such articles are "ghostly" because signs of their actual production are largely invisible—academic authors whose names appear at the tops of ghost-managed articles give corporate research a veneer of independence and credibility. They are "managed" because those companies shape the eventual message conveyed by the article or by a suite of articles. As discussed below, a substantial percentage of medical journal articles (in addition to meeting presentations and other forms of publication, which are not the focus here) are ghost managed, allowing the pharmaceutical industry considerable influence on medical research, and making that research a vehicle for marketing.

Ghost writing and honorary

exerts influence at multiple stages of research, writing, and publication, it will shape the resulting article. In turn, bias affects medical opinion and practice, and ultimately, patients.

How Common Is Ghost Management?

Because ghost management is hidden, we cannot tell how common it is from published exposés. Current practices in the medical sciences legitimately allow people to serve as authors on the basis of narrow contributions. Therefore many near-honorary authors find little reason to feel uncomfortable with their roles. Fully honorary authors may not see enough of the process of the production of their articles to know that they are ghost managed. Finally, it is not in the interests of writers, authors, or sponsors and their agents

ISMPP & Debating "Issues"

Sismondo:

"Ghost writing and honorary authorship are not in and of themselves scientific problems….. Some honorary authors are senior professors and chairs of departments, who are added to articles because of local academic politics rather than at the request of drug companies…"

ISMPP Response:

We wish to correct the misperceptions of ISMPP resulting from the commentary by Dr. Sismondo…. Manipulation of peer-reviewed publication with pharmaceutical-controlled ghost-writing, guest authoring, etc… are problems of industry-funded research, he argues, but [he] apparently accepts and excuses questionable authorship practices common within academic…research…. We contend honorary or guest authorship violates basic tenets of authorship promulgated by ICMJE.

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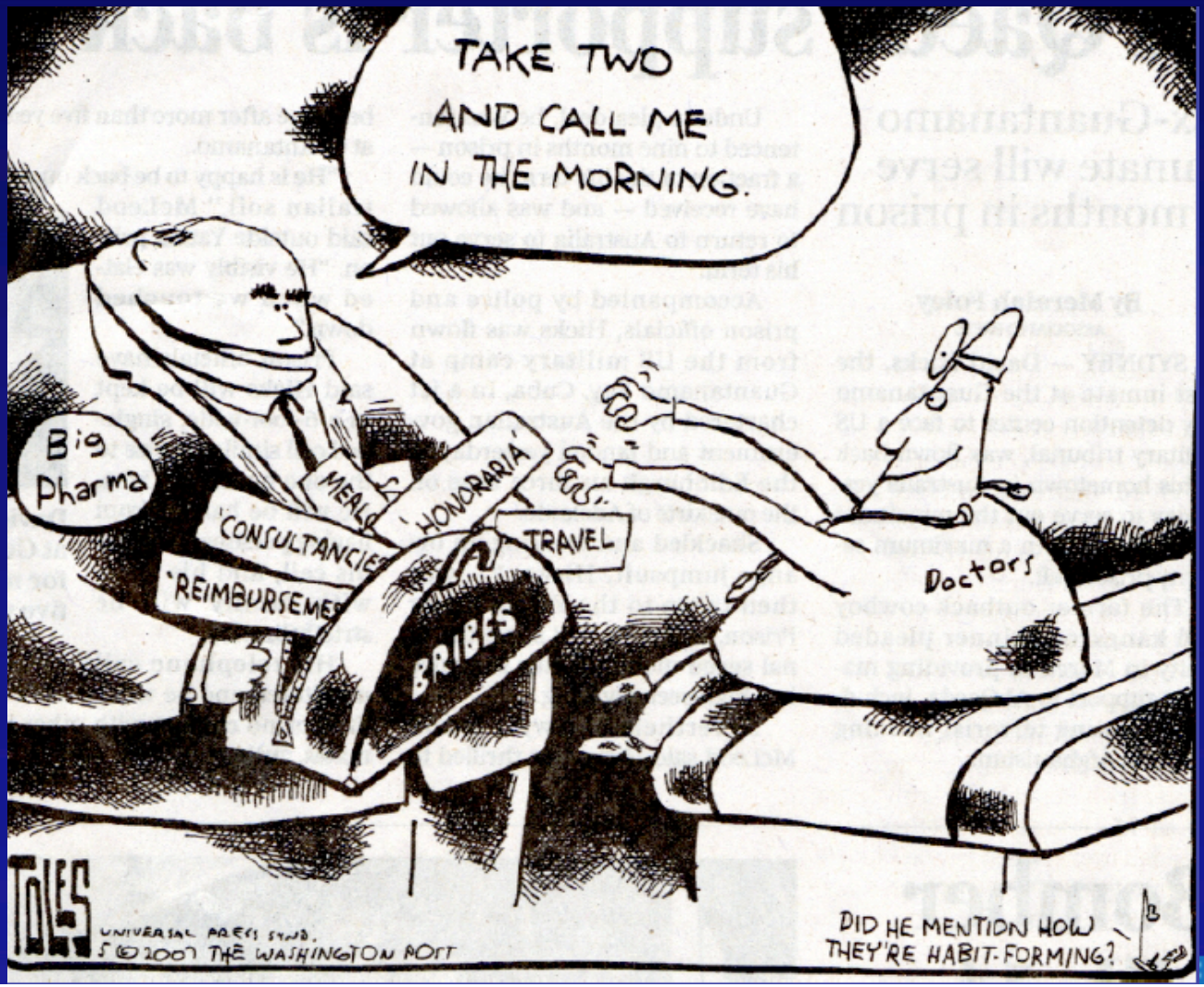
Today's Environment (2)

- …amplified by the media



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Conflict of Interest…

Annals of Internal Medicine 146: 450, 2007 | ACADEMIA AND CLINIC

Reproducible Research: Moving toward Research the Public Can Really Trust

Christine Laine, MD, MPH; Steven N. Goodman, MD, PhD, MHS; Michael E. Griswold, PhD; and Harold C. Sox, MD

"Cases of scientific misconduct have surfaced with alarming frequency."

- ***Science*** **publication of fabricated Korean stem cell papers**
- ***Lancet*** **retraction of oral cancer paper with fabricated data**
- ***Annals of Internal Medicine*** **retraction of paper with fabricated data (Poehlman case).**
- ***New England J Med*** **"statement of concern" over omission of important adverse outcome data (VIGOR Vioxx trial).**
- ***JAMA*** **reinforcement of disclosure policies following disclosure failures.**

[JAMA's] View

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

The Influence of Money on Medical Science

Catherine D. DeAngelis, MD, MPH

WHILE ON VACATION RECENTLY, I HAD THE OPportunity to contemplate the sometimes unethical influence of money on medical science, a very serious issue, which has become more evident over the past year or so. It seemed ironic that this wonderful time of contemplation was aided by the soothing, normal flow of the Delaware River in Pennsylvania, which just a week before had deluged roaring destructive flood waters well beyond its normal banks. Such is the nature of Nature, which very much mimics the pattern of my thoughts over the past few weeks as I experienced what happened as a result of trying to address a serious problem.

There can be no doubt that editors of peer-reviewed medical journals must always place the interest of patients above all else. Every published article eventually can and should affect patient care. Therefore, all articles that we publish must be ethically sound, valid, reliable, and credible (ie, reflect larities involving for-profit companies, such as the refusal to provide all study data to the study team,[2] reporting only 6 months of data in a trial designed to have 12 months of data as the primary outcome[3]; incomplete reporting of serious adverse events[4,5]; and concealing clinical trial data showing harm.[6]

For-profit companies also can exert inappropriate influence in research via control of study data and statistical analysis, ghostwriting, managing all or most aspects of manuscript preparation, and dictating to investigators the journals to which they should submit their manuscripts. For example, I have been told that in response to *JAMA*'s policy requiring an independent statistical analysis by an academician for industry-sponsored studies in which the only statistician who analyzed the data is employed by the study sponsor,[7,8] some companies are insisting that the researchers not submit those studies to *JAMA*. That tactic risks not only the perception that the company may have something to hide, but the reputation of any researcher willing to accede to such a company demand. Since the announcement of our policy

International Society for Medical Publication Professionals

COI Realpolitik

- The incidence of scientific misconduct has not changed over the last 2-3 decades, despite the great rise in funding by for-profit companies
- The worst cases of misconduct – fraud and fabrication of data – have all come from studies by investigators funded by government (NIH or NSF) and foundation sources
- "Where's the beef?"

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Balance?

The NEW ENGLAND JOURNAL of MEDICINE

SOUNDING BOARD

Regulating Academic–Industrial Research Relationships — Solving Problems or Stifling Progress?

Thomas P. Stossel, M.D.

Biomedical research takes place in university health centers, in government laboratories, and in the laboratories of pharmaceutical and medical-device companies, but only industry translates the research into products. Until the 1970s, academic researchers rarely worked on applied technologies, although they conducted clinical trials for companies and industry exploited academic basic research. Then, the revolution in molecular genetics that enabled investigators to produce large quantities of rare molecules with medicinal properties brought these groups closer together. Academic researchers joined venture capitalists in founding the biotechnology industry, leading to immense benefits — for example, the hepatitis B vaccine.[1] The participation of prominent scientists in the first biotechnology companies instantly reversed the perception that academicians' involvement in business activities was unsavory or evidence of intellectual bankruptcy. Nor were financially bankrupt university researchers receiving research support and profiting personally from their discoveries, although the value to society of the products far exceeded any individual's accrual version of increasingly stringent regulations imposed by many universities on researchers working with private industry. Had these rules been in force in the 1970s and 1980s, they would have prevented the scientists who were founding the biotechnology industry from making their breakthrough contributions. The stark contrast between the benefits of academic–industrial research relationships and the severity of the efforts on the part of the NIH and some universities to ban or control these relationships warrants examination.

THE EVOLUTION OF REGULATIONS

Despite misgivings expressed by some academic leaders,[4] few problems marred the interactions between academe and industry during the first, unregulated decade of the development of biotechnology. In 1988, newspaper reports alleging misconduct during corporate-sponsored research undertaken at a Harvard-affiliated hospital provoked Harvard Medical School to regulate academic–industrial research relationships. The measures adopted for-

NEJM
Sept 8, 2005

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FDAAA

- Paradigm shift
- Implications not just for publication planning; for all parties involved in clinical research
  - Need for Rulemaking, education
  - Many changes from bills passed by House & Senate!
  - Multiple conferences – CBI, TIPPA, law firms, ISMPP
- Law preempts any state legislation
- Does not call for registering Phase 1/feasibility studies
- Exceeds ICMJE policies _ results disclosure by 1 year p LPO
  - Substantial penalties for non-compliance
  - Some key provisions from prior bills gone

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