

# The Dangers of Polarization in Publications

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## INTRODUCTION

As the profession of publications planning has risen in importance in pharmaceutical and biotechnology companies, some of the good, the bad, and the ugly practices and perceptions around the development and production of publications also have emerged. Some of these practices and perceptions include:

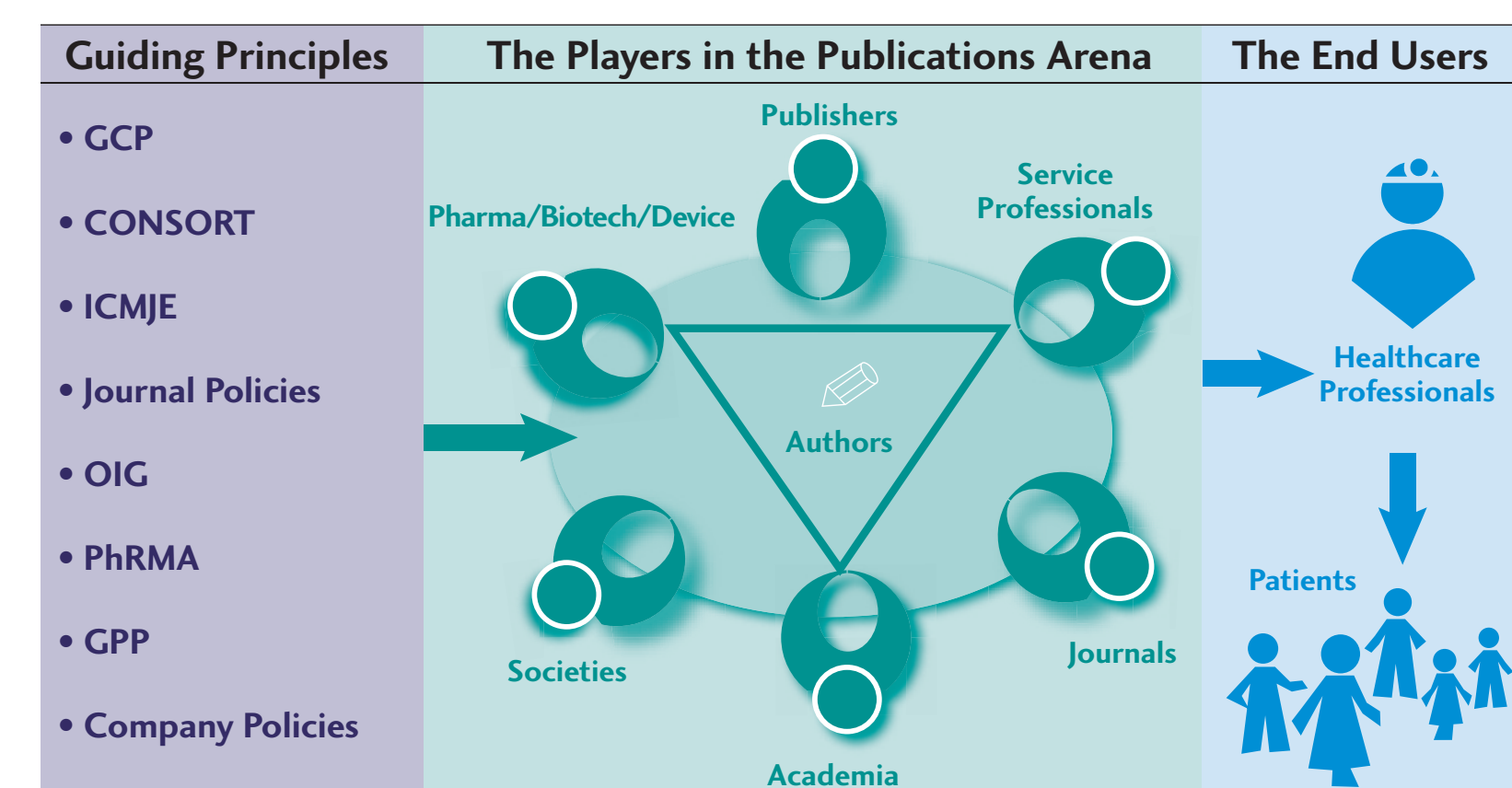
- Publication of negative results
- Conflict of interest
- Complete disclosure
- The value of industry-sponsored trials
- Ghostwriting

Unfortunately, we have entered into an era in which the key stakeholders: industry, academia, government, medical publishers, and patients alike are increasingly at odds in their opinions about these and other publications-related issues. More distressing perhaps is that the positions taken by the interested parties to advance solutions to the perceived flaws with the publishing system are, in themselves, biased. Furthermore, interested parties are becoming more and more extreme in their positions. These positions often are characterized by intolerance, extreme cynicism, and mistrust. They can involve a profound misunderstanding and simplistic characterization of someone else's positions or intentions, castigating the good for the misguided actions of the few. The characterizations that are relayed in the lay press offer black and white positions, breeding an "us-against-them" attitude and a "my-way-or-the-highway" approach to the exchange of ideas. In so doing, we are seeing these groups isolating themselves and digging their heels in around their own single-minded opinions, rather than coming to the table, trying to understand the positions of all of the players involved, and coming up with a solution that respects the position of the various groups and responds to the issues at hand.

## UNDERSTANDING THE STAKEHOLDERS IN THE MEDICAL PUBLICATIONS ARENA

There are a number of interested parties in the publications planning arena. While so much energy is spent today on identifying differences and portraying potential conflicts, little attention is paid to some of the similarities that these groups have in common. All participants:

- have an interest in the generation of fair balanced medical publications
- realize that the impact of that which they publish has a direct effect on how medicine is practiced
- realize that the impact of that which they publish has a direct impact on the lives of patients
- support specific guidelines (a sample of which is shown in the graphic) that dictate what they should be doing as far as generating medical publications



GCP, Good Clinical Practice; CONSORT, Consolidated Standards of Reporting Trials; ICMJE, International Committee of Medical Journal Editors; OIG, Office of Inspector General; PhRMA, Pharmaceutical Research and Manufacturers of America; GPP, Good Publication Practice.

## WHERE POLARIZATION TAKES ROOT

Extreme opinions create a publications environment that can be characterized as hostile. Polarization is fostered when different stakeholders take accusatory positions.

Some of these positions are debated in the medical literature:

*...the use of clinical trials primarily for marketing, in our view, makes a mockery of clinical investigation and is a misuse of a powerful tool.*  
- N Engl J Med editorial – September 13, 2001

**Alternate viewpoint:** the dissemination of articles published in respectable, peer-reviewed journals supported by pharmaceutical companies should be encouraged in the interest of sharing the insights of the published work quickly and across a broad audience that might not otherwise be reached.

*Manuscripts that are ghostwritten by industry employees or hired writers or that have other undisclosed important contributions should not be submitted to JAMA.*

- JAMA – July 6, 2005

**Alternate viewpoint:** because industry sponsors so much research and contributes a vast amount of knowledge and experience to the database of medical literature, we support a policy of clear identification of contributorship.

*Universities and academic health centers should prohibit contracts that allow sponsors to draft, edit, or suppress articles, or that allow sponsors to keep data from authors; they should even prohibit sponsors from facilitating publication.*

- PLoS Medicine – September 2007

**Alternate viewpoint:** sponsor companies offer a deep resource of talent and insight into clinical trial development and the dissemination of information. We believe it is in the best interest of society and suffering patients that academicians and researchers do what they do best:

- better understand the many diseases that plague the world today
- test therapeutic options to treat those diseases

*It is of greater benefit for these experts to spend their talents researching, rather than writing.*

Other examples that purport an inflammatory tone have been seen in the lay press:

*Increasingly, journal editors say, they struggle with evidence that the industry-backed studies they publish may not always tell the whole story—and are often crafted to serve as part of sophisticated marketing campaigns.*  
- WSJ Dec 9, 2005

**Alternate viewpoint:** study design, including methodology, endpoints, comparators, etc, are plainly available and if not made clear in the manuscript should be queried. Further, authors, whether industry or academic based, must take responsibility for accurate representation of data. Once concerns are satisfied, journal editors recognize the power of dissemination that the pharmaceutical companies represent and appreciate their contribution to the broad distribution of the work published in their journals.

*Dr Dodgson says she was given an instruction sheet directing her to emphasize the "main message of the study..." The instructions noted that some patients on large doses didn't seem to do well with the once-weekly administration but warned that this point has not been discussed with marketing and is not definitive!*  
- WSJ Dec 13, 2005

**Alternate viewpoints:**

1. As a fundamental premise of good writing practice we support structured writing for clear communication of trial results. That communication starts with a theme/message and the remainder of the paper seeks to support that theme.
2. If Dr Dodgson is considering authoring this manuscript she should be eminently more concerned about ensuring that the data is definitive and less concerned about a discussion with marketing.

And some publishers have taken polarizing positions:

*Articles must be written exclusively by the authors; they may not be prepared by outside parties or be written by an individual with less than full status as an author. Articles may not be reviewed for acceptance by manufacturers or other commercial entities.*

- Proceedings of the American Thoracic Society

<http://www.thoracic.org/sections/publications/about-the-journals/pats/instructions-for-contributors.html>

**Alternate viewpoint:** Avoid submission to journals with draconian policy that espouses single-minded thinking.

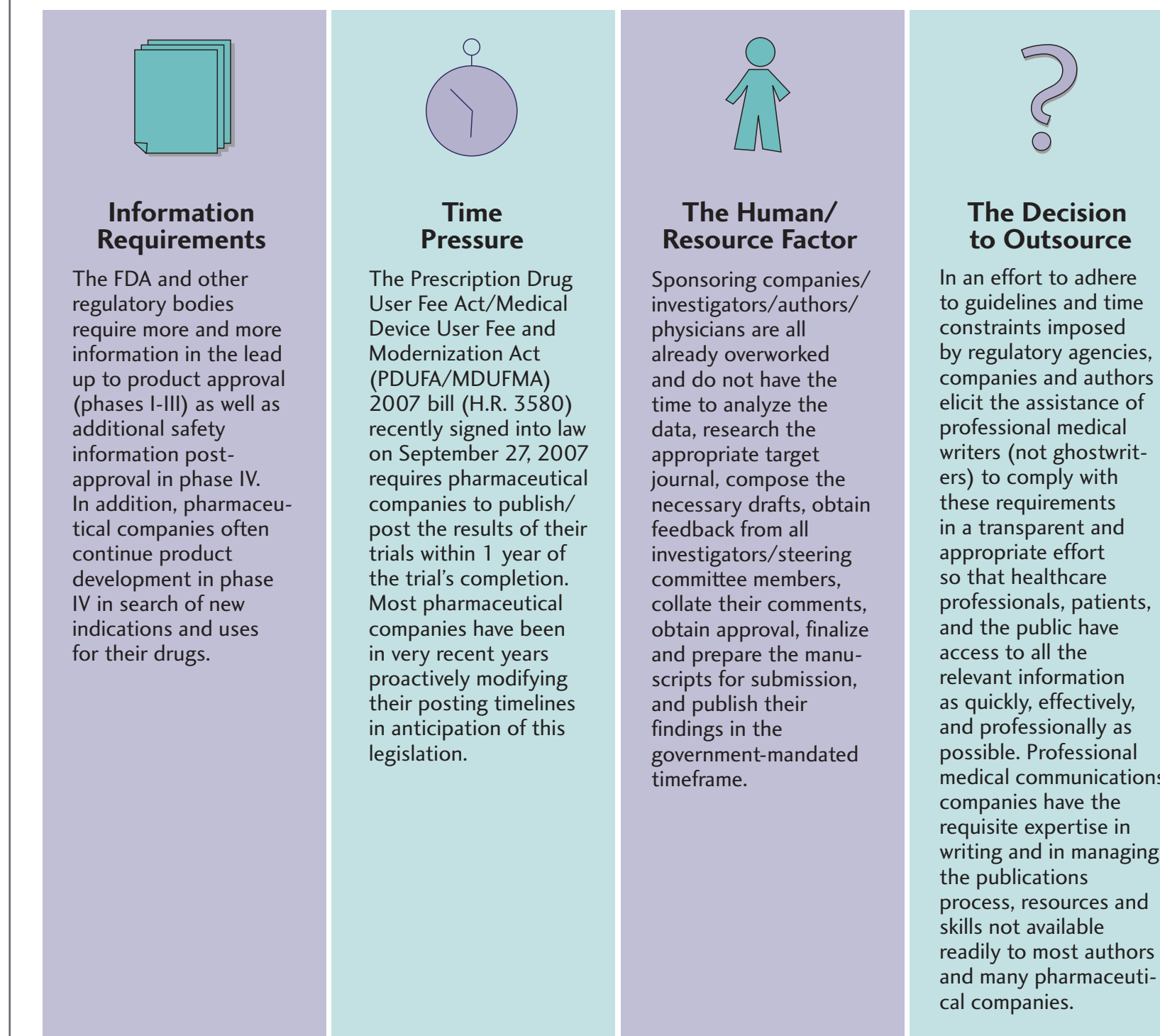
Now required by JAMA guidelines as revised in July, 2004:

Data analyses for industry-sponsored studies are to be conducted by a statistician at an academic center.

**Alternate viewpoint:** Industry-based statisticians have been educated at the very same universities as academic-based statisticians and have chosen a different career path, but often have more experience in different environments that shape/augment their critical thinking ability. Further, they often have access to more resources for discussion and therefore more options to challenge their findings. Industry statisticians therefore are at least as capable as academic-based statisticians.

## THE ROLE OF THE SERVICE INDUSTRY

Understanding the genesis and role of the service industry is important to beginning to bring the publications professions together. A basic principle of business is that where there is a need, businesses tend to grow. The same is true of professional medical writing. Not too long ago, professional medical writing and its management was a small cottage industry with most writers being independent of both academia and the pharmaceutical industry. As the need for that skill set grew so did the number of companies offering those services. This growth has been fueled by:



Thus, a thriving business environment was created and the ever-increasing need for accurate and rapid dissemination of medical information serves to further stimulate the growth of this industry.

## SAFEGUARDS ALREADY EXIST

Understanding the need for fair, unbalanced portrayal of data generated out of clinical trials, many of the concerned stakeholders have developed guidelines and instituted processes to help ensure medical data is presented in an appropriate manner. Some of those guidelines and practices are noted here.

- Good Publication Practice (GPP) guidelines: The aim of these guidelines is to ensure that clinical trials sponsored by pharmaceutical companies are published in a responsible and ethical manner.
- Ensuring authorship criteria are clearly understood and communicated
- International Committee of Medical Journal Editors (ICMJE) triple criteria
- Provision of disclosure information is almost universally required, allowing the reader to assess, in context, the published information and the different contributions made by the authors
- The peer-review process will capture and address questionable statements or presentation of results (it is not a perfect system, but it is quite effective)
- Journal editors are increasingly sensitive to the potential for overstating results or misrepresentation of data and know when to question
- Qualified professional medical writers challenge results and how results are presented
- Pharmaceutical companies and authors appreciate the candor on the part of the professional medical writers with whom they work

Finally, it is important to acknowledge that the target audience for most publications is physicians. Physicians are among the most highly educated professionals in our society. They can question and dismiss anything they find dubious.

## FROM A BROADER PERSPECTIVE

Considering that all of the interested stakeholders in medical publications have a similar final objective—to improve patient well being—perhaps it is in the best interest of society and suffering patients alike, that academicians and researchers do what they do best: continue to focus on better understanding the many diseases that plague the world today and continue to test therapeutic options to treat those diseases. For all concerned, it is perhaps more beneficial that these experts spend their talents researching, rather than writing.

## SEEKING SOLUTIONS

In an effort to bridge the divide and to eliminate an environment characterized by mistrust and misperceptions, concerned stakeholders need to seek cooperation and forward-thinking solutions. Consideration should be given to establishing a Medical Publishing Co-operative that includes:

- Pharmaceutical industry publications specialists
- Publishers
- Editors
- Academic institution-based author(s)
- Industry-based author(s)
- Service professionals
- American Medical Writers Association (AMWA)/ The International Publication Planning Association (TIPPA)/ International Society for Medical Publication Professionals (ISMPP) representatives
- ICMJE representative(s)
- Legislative representative(s)
- National Institutes of Health (NIH) representative(s)

The co-op will create a process for all stakeholders that:

- Provides an open forum to air concerns
- Provides an open forum for discussion of issues
- Facilitates all parties to come to agreement
- Commits to communicating the results of discussions via publications in the medical and lay presses

## CONCLUSION

If we are going to find a way to ensure medical publishing is a trustworthy source of credible information upon which informed decisions can be made, it is critical that all stakeholders take responsibility and seek to come together to find reasonable solutions.

Ralph Waldo Emerson said,

*If you meet a sectary, or a hostile partisan, never recognize the dividing lines; but meet on what common ground remains, – if only that the sun shines, and the rain rains for both; the area will widen very fast, and ere you know it the boundary mountains, on which the eye had fastened, have melted into air.*

It is only through open discussion that we will be able to agree upon practical solutions that balance medical need, resource management, and fiduciary responsibility.