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Strategies and Solutions for Publication Planning and Execution Excellence:

in-depth report from The International Publication Planning Association's 5th Annual Meeting

held in San Francisco, CA, 25–26 June 2007

by Elizabeth Wager

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ThePharmYard product code kwp016 ISBN 978-1-905676-15-6

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Strategies and Solutions for Publication Planning and Execution Excellence
First published September 2007 by NetworkPharma Ltd
89 Oxford Road, Oxford OX2 9PD, UK
Tel: +44 (0) 1865 865943
Web: www.networkpharma.com email: support@networkpharma.com

A CIP catalogue record for this title is available from the British Library.

ISBN: 978-1-905676-17-0

Managing Director: Peter Llewellyn; Editor: Chris Ross; Production/editorial: Gill Gummer; Typesetting and artwork: Blenheim Colour

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Strategies and Solutions for Publication Planning and Execution Excellence:

in-depth report from The International Publication Planning Association's 5th Annual Meeting

by Elizabeth Wager

Executive summary

The reputation of the global pharmaceutical industry is currently suffering, and there is public mistrust of drug companies' publication practices. The industry can only eradicate this problem through increased transparency, honesty and openness in its publications. Clearly, the provision of unbiased information to medical decision makers is essential, not only for the sake of the industry's image, but, more importantly, for the good of public health.

In an environment of rapidly changing rules and regulations, pharmaceutical companies must develop their own robust publication policies that reflect the latest guidelines. Crucially, they must also develop compliance programmes to ensure that all those working on publications not only understand company policy, but actively implement it.

This *Conference Insights* review provides an in-depth review of the 5th Annual Meeting of The International Publication Planning Association held in San Francisco, CA, 25–26 June 2007. It details the major challenges facing publications professionals, including the need for disclosure, transparency and compliance. It offers guidance on how to develop and implement company policy, looks at the involvement of marketing in the publication process, the growth of open-access publishing and how agencies and drug companies can develop effective partnerships.

Contents

Strategies and Solutions for Publication Planning and Execution Excellence – Programme

Organised by The International Publication Planning Association, San Francisco, CA, 25–26 June 2007

Co-Chairs:
Dan Donovan, *Founder and President, Envision Pharma*

Jodie M Sherman Gillon, *Associate Director, Publications Management Team, Pfizer Inc.*

Day one

Legal and Regulatory Update on Publication Planning and Dissemination
James H Smith, *Associate Chief Counsel, Office of General Counsel – US Food and Drug Administration*

Ioana Petrou, *Chief, Major Crimes, Criminal Health Care Fraud Coordinator, US Attorney's Office, NDCA*

Alan Minsk, *Partner and Leader, Food and Drug Practice Group, Arnall Golden Gregory LLP*

An Editor's Perspective: The Outlook for the Convergence of Journal Requirements
Trish Groves, *Deputy Editor and Sr. Research Editor, British Medical Journal*

Academia and Industry: Strategies for Positive Collaboration
Thomas P Stossel, *American Cancer Society Clinical Research Professor, Harvard Medical School; Co-Director, Hematology Division, Brigham & Women's Hospital*

Point–Counterpoint: Is There a Role for Marketing? What About Payment for Publication?
Jodie M Sherman Gillon, *Associate Director, Publications Management Team, Pfizer Inc.*

Jessica Colon, *Associate Director Clinical Communications, Global Clinical Development & Medical Affairs, Novartis Pharmaceuticals Corporation*

†Peter Banks

It is with regret that we announce that Peter Banks died on 21 July 2007, after battling cancer for several months.

With a 25-year career in publishing and as a key advocate of healthcare information, Mr Banks will be greatly missed.

Day two

Industry Panel: Developing and Maintaining a Company Wide Publication Policy
Elizabeth Crane, *Assistant Director, Publications, TAP Pharmaceutical Products Inc.*

Jessica Colon, *Associate Director Clinical Communications, Global Clinical Development & Medical Affairs, Novartis Pharmaceuticals Corporation*

Michael Petrarca, *Director of Medical Writing, Amgen Inc.*

Fostering Effective Publication Planning Team Dynamics
Lynda C McDermott, *President, EquiPro International Ltd*

Clearly Identifying Authors in the World of Guest and Ghost Authorship
Neil W Matheson, *CEO, Axis Healthcare Communications, LLC*

Discussion Tables
Moderator: Kevin G. Doty, *Director Client Development, Complete Healthcare Communications, Inc.*

Survival in the Wake of Cost Cutting and Global Sourcing Initiatives
Dan Donovan, *Founder and President, Envision Pharma*

Joseph Haldey, *Senior Associate Director-Medical Publications Department, Medical Affairs, Boehringer Ingelheim Pharmaceuticals, Inc.*

Varying Perspectives: The Latest on Open Access Publishing vs. the Traditional Journal Model
Barbara Cohen, *Senior Editor, PLoS Medicine*

Peter Banks†, *Founder, Banks Publishing*

An Industry Roundtable on Results Disclosure
Moderator: Art Gertel, *Vice President of Clinical Services, Regulatory, and Medical Writing, Beardsworth*

Panellists: Ida Sim, *Associate Professor of Medicine, University of California San Francisco, Past Project Coordinator, International Clinical Trials Registry Platform, World Health Organization*

Emma Veitch, *Publications Manager, PLoS Clinical Trials*

Pamela A Rose, *Director, Clinical Trial Information Registries, TAP Pharmaceutical Products Inc.*

Career Management: The Outlook for Publication Planning Professionals (and other information your manager preferred you didn't know)
Michelle Poloni, *Project Manager, Pharmaceutical and Biotechnology, Management Recruiters of Vancouver, LLC*

TIPPA

The International Publication Planning Association

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The International Publication Planning Association (TIPPA) is an industry-run association. Our mission is to foster excellence in medical publications and communications within the biopharmaceutical industry by providing a foundation from which industry can stand together to organize thoughts, present recommendations and ethical guidance.

In addition TIPPA provides practical strategies for developing, implementing and executing an effective publication and communication plan as a critical component of the clinical biopharmaceutical development process. Our aim is to help biopharmaceutical communication executives and their agencies produce ethical and targeted publications and clinical data throughout the product lifecycle.

Benefits of Membership

TIPPA brings together professional from pharmaceutical companies, medical journals, academia and medical communication agencies to tackle the challenges of publication planning. There is no fee for membership and some of the benefits include:

- An annual meeting that offers fresh insight on the most pressing issues facing publication planning professionals and networking time to exchange ideas with your peers.
- Regional events that provide additional educational resources and net working opportunities during the months between the annual meeting.
- Online web meetings that provide the latest information and guidance from industry experts on pressing industry topics.
- A mailing list that provides members with an online resource for idea sharing and networking

As a member of TIPPA, you will join a network of peers from the pharmaceutical industry including:

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Introduction

The world of medical publishing is complicated and fast-moving. It involves complex relationships between journal editors, academic investigators and publication professionals working in or for pharmaceutical companies. The 5th Annual Meeting of The International Publication Planning Association (TIPPA) highlighted the need for companies to keep abreast of the latest rules and regulations and to develop guidelines and policies to improve the publication planning process. Such improvements may, in turn, help repair the image of the sector, and restore public trust in industry-sponsored publications which has been damaged recently.

A wide range of issues was addressed. Transparency, disclosure and compliance emerged as keywords. The need to develop and maintain robust company policies that reflect changing publications requirements was also noted. In addition, the meeting looked at authorship guidelines, the latest developments in results disclosure, and the impact of cost-cutting and globalisation on publication planning.

The publication planning process requires cooperation from a diverse group of people and input from a number of different sources. Coordinating such teams and drawing together such information to create transparent, unbiased and educational documents for publication is a major challenge. Likewise, creating, maintaining and enforcing effective company policies can be challenging.

The 5th TIPPA meeting provided a valuable information exchange for stakeholders across the industry, offering practical guidance for all those seeking publication planning and execution excellence.

Elizabeth Wager
September 2007

About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice For Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a First Class zoology degree from Oxford in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services.

She is a member of: the *BMJ*'s Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of the Committee on Publication Ethics, the editorial board of *European Science Editing* (the journal of the European Association of Science Editors) and the World Health Organization Scientific Advisory Group on trial registration.

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Strategies and Solutions for Publication Planning and Execution Excellence:

in-depth report from The International Publication Planning Association's 5th Annual Meeting

The 5th Annual Meeting of The International Publication Planning Association (TIPPA) took place in San Francisco, CA, 25–26 June 2007, one day after the city's annual 'Pride' march. Suitably inspired, Co-Chair Dan Donovan (Envision Pharma) opened the meeting by sharing his vision of a 'Publication Planning Pride Parade'. He suggested this might involve pharma industry professionals walking hand in hand with journal editors, academics and regulators – but probably wearing slightly more subdued costumes than those seen in the previous day's extravaganza! He then settled down to the serious business, presenting a series of case studies that illustrated some of the problems facing publication professionals.

In one case, an article had received two favourable reviews, but the third reviewer raised concerns about an acknowledgement to a professional writer for editorial assistance. Despite the fact that the writer and the funding source were clearly identified in the manuscript, the editor felt this represented 'ghost writing' and therefore queried the independence of the paper. In another case, a journal copy-editor removed the acknowledgement to a medical writer from a paper. In this case, the authors contacted the editor-in-chief who agreed that this should not have occurred and gave assurances that this would not happen again.

More worryingly, a writer from a communications agency contacted a publisher to ask whether a journal might consider publishing a series of clinical trials in a single issue. The publisher said he didn't know the answer and suggested that the writer should contact the editor. The ensuing contact provoked a very negative reaction: the editor not only commented that he could not believe a writer would have the nerve to call the editor and ask that type of question but also complained about the writer to the company that had sponsored the trial.

These examples illustrate the prejudice held against publication professionals by some reviewers and editors. However, Donovan reminded listeners that the industry sometimes contributes to its negative image. For example, an agency sent a manuscript to an author who recognised several lines lifted directly from another publication. The author contacted the sponsoring company and alerted them to this plagiarism. Donovan kicked off the conference by calling on participants to think, discuss, challenge and take action.

Legal issues

The first session of the meeting covered legal and regulatory issues affecting publication planning and dissemination. The panel comprised Alan Minsk (Arnall Golden Gregory LLP), James Smith (US Food and Drug Administration [FDA]) and Ioana Petrou (US Attorney's Office, NDCA). (The participants emphasised that they were speaking in a personal capacity, not necessarily representing the official views of their organisations.)

According to Minsk, hundreds of pharmaceutical companies are being investigated under false claims legislation in the USA. The 17 cases resolved to date have resulted in almost $4 billion being returned to government funds. This has led to the establishment of specialised healthcare fraud offices. The companies under investigation include both major players and smaller organisations. Minsk commented that, whereas large companies have received much of the media attention over settlements, nobody was exempt from investigation. The most common areas for concern are off-label promotion, false claims and kickbacks.

Smith explained that the FDA Modernization Act had ceased to be in force since September 2006. The FDA continues to use its provisions as guidelines, but companies no longer need to submit items for approval before use (as was the case previously).

Petrou underlined that the small size of a company does not exempt it from criminal prosecution. If off-label promotion is proved, this can be considered either a felony or a misdemeanour, depending on whether there was an intention to deceive. If a company is found to have disseminated false or misleading information, this can result in prosecution under various laws, not just the FDA regulations relating to pharmaceutical companies. She noted that press coverage of such activity had resulted in several cases being investigated.

Promotional material may be considered false or misleading if claims are made without sufficient scientific support – for example, if they are based on a post-

hoc analysis or on insufficiently powered secondary endpoints. Just because something is published in a peer-reviewed journal does not mean that it may be distributed or used for promotion.

Everyone acting on behalf of a drug company is held to the same standards, including communication companies and freelance writers. However, the sponsor company will be held responsible if their agent fails to conform to company policies.

Anti-kickback legislation makes it an offence for companies to offer incentives or rewards for prescribing their products. This means that investigators should be paid only the 'fair market value' for any work undertaken. It is not illegal to pay investigators for work on publications, but excessive payments (e.g. paying an author who makes little or no contribution to a paper developed by a professional writer) could be considered a kickback.

The panel concluded with their 'take-home' messages from the session:

- Disclosure and transparency are the keywords: companies should not attempt to hide their involvement in the production of scientific publications.
- Internal compliance programmes are vital: if problems come to light because of good internal processes, the company is less likely to be prosecuted since the authorities encourage monitoring and auditing.
- All companies need written policies to ensure that everybody involved in preparing publications understands them; but training is not enough, compliance monitoring is also essential.

Disclosure and transparency are the keywords in the production of scientific publications

An editor's perspective

The second session of the meeting provided a journal editor's perspective from Trish Groves, Deputy Editor of the *BMJ*. She believes that drug companies want to publish the results of their trials in peer-reviewed journals because this provides them with a 'stamp of approval'. By publishing in an independent journal (rather than simply posting results on a corporate website), the findings are associated with the journal's 'brand' and reputation. It is also an effective way of reaching doctors. However, journal instructions can be hard to find, and many journals fail to provide enough information. She therefore encouraged publication planners to contact journals if they have questions.

Journals, she said, take a tough stance on misconduct, but this should not be misconstrued as being 'anti-industry', since they are equally tough on everybody. Most of the recent cases of major research fraud have been perpetrated by academics or individual investigators, not by companies. But there have also been cases when drug companies have behaved badly, and this has led to justified criticism of some practices.

The *BMJ* has therefore developed a 'transparency policy', which aims to set out relevant guidance in one place, rather than scattered throughout the journal's instructions to contributors. The *BMJ* is happy to receive articles that have been prepared by professional writers since the editors "know to their cost that many scientists can't write!" The *BMJ* was also one of the first journals to endorse the Good Publication Practice (GPP) guidelines for pharma companies, and expects people to follow them.

The BMJ was one of the first journals to endorse the Good Publication Practice guidelines for pharma companies and expects people to follow them

There is a trend for editors to demand increasing transparency about clinical trials and the origins of publications. For example, the next version of the CONSORT (Consolidated Standards of Reporting Trials) statement will require information about changes from the protocol, and the *BMJ* now asks authors to name the person who had the original idea for an editorial or review article.

Some journals have gone further than others. For example, the *BMJ*'s transparency policy is more comprehensive than information provided by other journals, but it has no intention of following the example of the *Journal of the American Medical Association*, which requires that industry-sponsored trials be re-analysed by an independent statistician. In fact, the *BMJ* published a criticism of this policy from one of their senior statistical advisors.[1]

Transparency does not only apply to authors and sponsors. The *BMJ* requires its editors to disclose any competing interests and they are not permitted to have direct financial ties with healthcare companies. However, the *BMJ* does not currently publish a breakdown of its income (e.g. how much money it makes from advertising or reprints) but, in theory, this would be possible.

The drug industry undoubtedly has a tarnished reputation among some people, but Groves believes that increased transparency, more honesty and openness in reporting trials could help to give it a better name.

Next, Thomas Stossel (Harvard Medical School and the Brigham & Women's Hospital) provided his perspective on relations between academia and industry. He

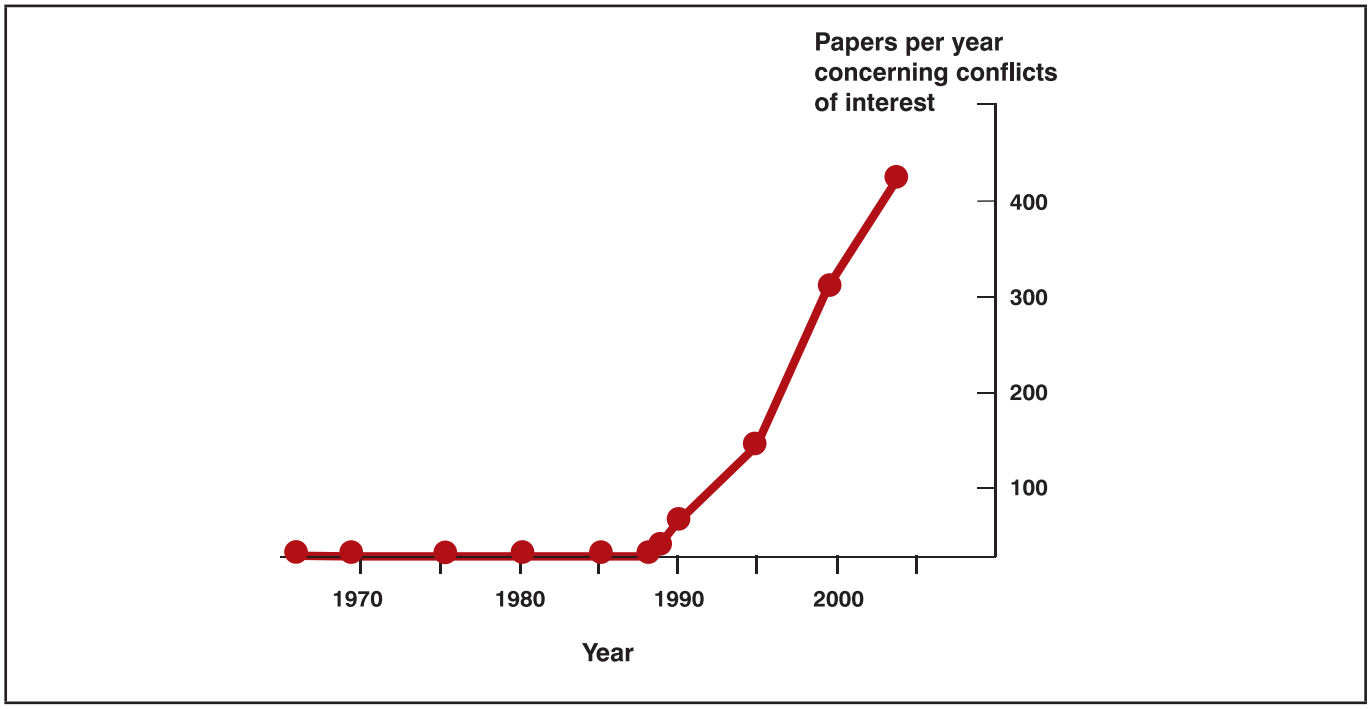

Fig. 1. The number of publications on conflicts of interest published since the 1970s. Reproduced with permission from Thomas Stossel (Harvard Medical School and the Brigham & Women's Hospital).

characterised the view of many of his colleagues that he should tell an audience of "low-life, scum-sucking ghost writers" what they should be doing! But, instead, he believes that the interests of commerce and medicine are largely in harmony.

Clinicians, said Stossel, should remember that many medical advances, such as the 50% decrease in deaths from heart attacks and strokes achieved over the past few decades, can be attributed to new medicines. Many of these advances have come about through collaboration between industry and academia. Such partnerships are clearly productive and should be encouraged. The development of the biotech industry is one example of such a beneficial partnership.

Less than 15% of US medical research is funded by the National Institutes of Health (NIH), and there is no prospect that public funding will ever catch up with private funding. So, Stossel believes, members of the tax-paying public who benefit from pharmaceutical advances are getting a very good deal. Yet academics and editors seem obsessed with conflicts of interests and the number of publications on this topic has soared since the 1990s (Figure 1). The premise of many academics appears to be that companies are "fundamentally evil", yet few of these observers understand how difficult it is to develop new drugs and how good many companies are.

Stossel believes that this preoccupation with competing interests has resulted in an "orgy of disclosure" that is disproportionate to the problems it was designed to curb. Investigators and authors spend increasing amounts of time completing forms for funders, regulators and journals, and this adds to the bureaucracy, and therefore the cost, of research. One consequence of increased compliance requirements has been a decline in support for Continuing Medical Education activities by drug companies, while Draconian rules forbidding conflicts of interest have meant that the NIH has had difficulty recruiting suitably qualified consultants.

Stossel said that editors seem to believe that the incidence of scientific misconduct is increasing, but there is no evidence for this. However, the impression is reinforced by lay press coverage, since scandals are inherently more newsworthy than the slow pace of real technological advance. By focusing on misconduct, Stossel believes that journal editors are simply seeking to enhance their reputations and their power. Criticising bad practice allows them to adopt an attitude of moral superiority – something noted over 200 years ago by Edward Gibbon, who described such behaviour as the "trappings of virtue as an institute of ambition".

The industry should start to fight back – too often, companies have "hunkered down" and taken a "defeatist attitude"

Editors, Stossel said, also appear to ignore the huge biases that may occur in academic research and the fact that many journals are, themselves, multi-million dollar businesses. But the practice of criticising "big, bad pharma" has evolved into an ideology and "when ideology wins, facts don't matter".

Stossel's solution is reasonable disclosure, but not taken to the current extremes. Medical students

should be taught about drug discovery to get a better understanding of the industry and the challenges it faces. At the same time, people within the industry should start to fight back – too often, he said, companies have "hunkered down" and taken a "defeatist attitude".

Finally, Stossel showed slides taken in Zambia where he has established a programme of research into sickle cell anaemia. If the industry critics could only go to Zambia they might understand that rather than "big business being bad for health" it is the lack of business that kills people.

The role of marketing in developing publications

The final session of the day began with a debate on whether marketing departments should be involved in publications. The speakers, Jessica Colon (Novartis Pharmaceuticals Corporation) and Jodie Sherman Gillon (Pfizer Inc.), had previously been colleagues at Novartis, when Jessica was a brand manager in the marketing department and Jodie was a publications coordinator.

The conclusions of a trial report must be based on what the trial findings support, not on the key messages the company wishes to promote

The speakers noted that there are no guidelines on the role of marketing in developing publications, so each company needs to work out its own policy. However, despite there being nothing to state that marketing should *not* be involved with publications, this was a common source of criticism of the industry. So what are the pros and cons of involving the marketing department in publication teams?

Clearly, marketeers can add value to publications through their knowledge of the market. Good marketing requires an understanding of the audience, which, in turn, helps to keep publications focused and relevant to their readers. Too much emphasis on science, they felt, can sometimes mean that patient focus is lost from publications. However, the aim of a publication reporting a trial is to tell the story of the science and relate what actually happened, and marketing needs should not be allowed to influence this. The conclusions of a trial report must be based on what the trial findings support, not on the key messages the company wishes to promote. Scientists and professional writers should therefore be responsible for preparing papers and marketing colleagues should not be allowed to "wordsmith" drafts. So, while the marketing department needs to be involved with planning, they should not carry out detailed work on individual manuscripts.

The industry needs to improve its image, and one of the ways of doing this may be to limit or avoid marketing involvement in publications since this appears to create a negative perception among editors and academics, even if this is not well-founded.

Concluding the session, the panellists suggested they would welcome some guidelines on the role of marketing in publications, noting that "people in pharma want to do the right thing."

Payments for authors

The two speakers then considered whether it was appropriate to pay investigators for publications. Once again, there are no specific guidelines on this; however, as noted before, unreasonable payments could violate US anti-kickback laws. Payments may also raise concerns about off-label promotion.

Many companies feel that authorship is a reward in itself, since it brings visibility to investigators and enhances their resumés, so payment is seldom required.

Developing a company publication policy

Day two began with a panel discussion on developing and maintaining company publication policies. The panel comprised Elizabeth Crane (TAP Pharmaceutical Products Inc.), Jessica Colon (Novartis Pharmaceuticals Corporation) and Michael Petrarca (Amgen Inc.).

TAP is a medium-sized company with a small publication team that only recently felt the need to formalise its publication policy. The main impetus for this was the new requirements on trial registration and results disclosure.

Creating a publication policy enables a company to establish and promote its corporate ethics and values. Many guidelines are available, so anybody creating a new policy should learn from these. To prevent staff from feeling intimidated by new policies, it is important to communicate the need for them and explain why these issues affect their work. It is also important to include all stakeholders and reach relevant people in all parts of the company.

Creating a publication policy enables a company to establish and promote its corporate ethics and values

When TAP developed its policy it decided the first priority was authorship and the second was the company approval process for publications. The policy is based on the GPP and the International Committee of Medical Journal Editors (ICMJE) authorship guidelines (Table 1).

Authorship credit should be based on:

1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) drafting the article or revising it critically for important intellectual content; and
3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- 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 purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Table 1. ICMJE authorship criteria.

Writers are encouraged to contact authors "before pen is put to paper".

Publication groups need to strike a balance between being too large and unwieldy and being too small and excluding key functions. During the development of its policy, TAP ensured wide consultation and worked with partners in other divisions who needed to be aware of the policy (e.g. those involved in developing templates for investigator agreements and any other documents that mention publication policies). According to Crane, they built consensus by "talking, and talking a lot…". Once the policy had been agreed, it was incorporated into the R&D training programme, ensuring awareness for all teams.

At Novartis, the publication policy has been updated every 6–9 months over the past 5 years, reflecting the rate of change in guidelines and policies. Colon said that since Novartis is a global company, it needs a policy that can both be implemented internationally and take account of local requirements. One of the goals of the most recent update was to streamline the approval process, reducing publication teams that sometimes involved 25 people down to a more manageable size of around 12 members. With the larger teams it had become almost impossible to schedule meetings and members were becoming overloaded.

Novartis' authorship guidelines, like those at TAP, are based on the ICMJE criteria (Table 1). These guidelines are distributed to all authors and are enforced strictly. If investigators fail to contribute to the development of a manuscript they can be removed from the list of authors and "demoted" to the acknowledgements. Sometimes just the threat of this action has been enough to ensure that a reluctant author becomes fully engaged.

Colon noted that there are several advantages to having a written company policy:

- it should ensure that company practice complies with regulations
- it protects authors
- it helps establish working relationships with agencies.

At Novartis, a small team takes responsibility for keeping abreast of external policies and guidelines to ensure the company policy is updated when needed.

Petrarca commented that it was reassuring to hear that other companies were facing the same issues. He said there is no magic in creating a policy, it is just a case of putting it down on paper and then communicating it. But one problem can be rapid staff turnover, which means that it is essential to keep training new people. In the most recent update of the Amgen policy, communication and training plans for both internal and external stakeholders have been added.

Once again, the Amgen authorship policy is based on the ICMJE guidelines (Table 1) and authors who are not actively involved may be removed from the list. Amgen also has a standard timetable for review, with specific turnaround times for reviewing abstracts, posters and papers. In addition to final medical, statistical and legal review, Amgen requires written approval of the final version from all authors. This has slightly lengthened the final approval time, but most people accept that this step is important for transparency. Based on the GPP guidelines, the key policy is to "engage authors early". Ideally, they hold a "kick-off meeting" at which roles and responsibilities are agreed.

At Amgen, there are now online courses that all publications staff are required to take. The publications team has also created a 'publication policy portal' – an internal website that aims to be a one-stop shop for publication development and includes useful tools, templates and links to publication resources.

Training external investigators has increased authors' awareness and understanding of industry guidelines and best practices, and helped to manage their expectations. The policy also establishes consistent practices in all parts of the company, which is helpful.

Following this panel discussion, there was further debate about working with co-marketing partners and the need to align company policies. TAP has worked with both Abbott and Takeda, and although it shared its policies with these companies, it did not feel the need to develop a unified policy for all three. Experience at

Amgen suggests that working with a marketing partner can increase the time needed for approval since two companies are involved. Another participant, who had worked for a Japanese company in the USA, noted that there can be cultural differences across global companies and that these also need to be taken into account when developing policies.

The panel was asked for its views on whether approvals should be sought in parallel (from several departments at once) or in series (i.e. one after the other). Many companies now use web-based systems that allow reviewers to see other people's comments. TAP occasionally uses real-time web conferencing, which allows a group of people to work on a document remotely. This works best for small groups of authors, short publications (e.g. abstracts and posters) or for finalising a short section of a longer document. At Novartis, face-to-face meetings and teleconferences are considered helpful for copy review. Dan Donovan, chairing the debate, warned that sequential review tended to slow things up and was potentially troublesome.

Leading publication teams

Discussing the need for publication teams to work together and for publication coordinators or writers to coordinate this process led neatly onto the next speaker, Lynda McDermott (EquiPro International Ltd). Having worked with over 1000 teams in over 30 countries, McDermott concluded that "publication planning is one of the most challenging and complex team-building tasks in the world!" Publications, she said, need a lot of consensus decision making from a large group of internal staff plus external authors, agency staff, etc. Coordinating the efforts of people who don't work for you makes leadership of such groups particularly difficult, since the leader has responsibility for the output but no authority over the team members. McDermott set out three key techniques for creating effective publication planning teams, urging participants to:

- seek out similarities
- ask whether the group is really working like a team
- have the power of courage.

Most publication teams include considerable diversity of expertise, goals, personal objectives and work styles. Global teams may also bring the complexity of different cultures. But the secret of success, according to McDermott, is to focus on what the group has in common rather than what makes its members distinct. One method of doing this is to ask team members to relate their experiences of positive team work and to analyse what makes a good team. She related a case study of a team from Pfizer, which included members from the USA, China, India, Korea, Malaysia, the Philippines and Australia, who all needed to work together to licence a product in an Asian country. Despite their different backgrounds, the team was able to identify similarities in their best experiences of team work, and these formed the values for the team.

Another important role for team leaders is to ask 'Do we have a team?' It is important to distinguish a working group, in which there are no shared performance goals or mutual accountability, from a true team in which members are mutually accountable to achieve results collaboratively. McDermott said that world-class teams develop a high level of engagement and commitment among all members, which also brings satisfaction. If a team identifies with a common calling it can sustain commitment even in tough circumstances. In fact, McDermott gave an example of a strong publication team that continued to function well and produce publications even after its product had been dropped from development.

Lastly, she said, team leaders need to demonstrate "the power of courage" to face the crises, major and minor, that confront us all. In Chinese, the symbol for crisis combines the signs for danger and opportunity. Effective leaders need to bridge the differences between danger and opportunity, and have the courage to take risks such as confronting poor communication within a team and facing conflicts.

Following the presentation, participants discussed the difficulties of sustaining commitment and techniques for team meetings. The discussion concluded that personal style profiles can provide helpful insights into the ways different individuals work. Surveying team members can be a useful method to obtain this, without resorting to techniques that people may consider 'gimmicky'. Developing a formal operating agreement, setting out how the team will communicate, and establishing clear roles and responsibilities can be productive. Scenario planning may also be helpful – for example, getting agreement on what will happen if team rules are broken and members do not fulfil their agreed roles. If team members do not understand others' motivations and personal objectives it can be helpful to identify these. One way of doing this could be to ask the question 'What do you hear when you make decisions?' Different members of a publication team might respond by saying 'I don't want to hear that the company is on the front page of the *Wall Street Journal* because of a scandal', 'I don't want to hear from the FDA' or 'I want our key marketing message to reach doctors'. Voicing these feelings may help team members understand the different perspectives of the group.

For established teams, it is often helpful to use diagnostics to check whether it is still functioning as a team and to identify areas where it could do better. Once again, a survey may be helpful, followed by a meeting to discuss the feedback.

	Full name	Title	Published/ updated	Source
GPP	Good Publication Practice	Guidelines for pharmaceutical companies	2003	www.gpp-guidelines.org
PhRMA	Pharmaceutical Research and Manufacturers of America	Principles on communication of clinical trial results	2002	www.phrma.org
EMWA	European Medical Writers Association	Role of medical writers in developing peer-reviewed publications	2005	www.emwa.org
ICMJE	International Committee of Medical Journal Editors	Uniform requirements for submission of manuscripts to biomedical journals	2003	www.icmje.org
WAME	World Association of Medical Editors	Policy statements: ghost writing/ authorship	2005/2007	www.wame.org
CSE	Council of Science Editors	Policy statement: promoting integrity of scientific journals	2006	www.councilscienceeditors.org

Table 2. Authorship guidelines.

Problems with authorship

The meeting next turned its attention to the problems of authorship with a presentation from Neil Matheson (Axis Healthcare Communications, LLC). He showed newspaper headlines which focused on the fact that, when commercial companies are involved in clinical research and publications, money changes hands. Yet the real issue, he believes, is not the commercial transaction but the fact that authorship forms part of the integrity of the scientific literature.

Authorship terminology has sometimes been a cause for confusion and miscommunication. Terms such as author, contributor and gift author can be used in different ways. There is sometimes confusion between a ghost author and a ghost writer. Matheson said that standardisation across the industry would be helpful and might reduce this confusion.

Many guidelines on authorship exist (Table 2). The best known are those from the ICMJE, which state that authors should be able to take public responsibility for the contents of a publication (Table 1). The Council of Science Editors set up an authorship task force which identified the different roles that might, jointly, constitute authorship. The World Association of Medical Editors provides helpful definitions of ghost authors and ghost writers. The guidelines from the European Medical Writers Association (EMWA) provide the most detail about when medical writers qualify as authors. The EMWA guidelines suggest that writers of primary research papers rarely qualify as authors according to the ICMJE criteria; however, they may qualify for authorship if they develop review articles.

Company publication policies should address authorship and provide clear guidance about how it should be determined. Matheson advised that it is best to address authorship (and to communicate company policy) as early as possible in the research process (e.g. in the investigator's contract). Policies should cover:

- access to protocols and data
- the company review and approval process
- disclosure of competing interests
- compliance issues.

Moreover, when freelance writers or agencies are involved, the policy should set out how this will be managed. Working with co-marketing companies can increase the complexity of the process and it is therefore vital to establish clear roles and responsibilities.

Company publication policies should address authorship and provide clear guidance about how it should be determined

Although, according to ICMJE criteria, many investigators could qualify as authors if they are involved in developing the manuscript, it is necessary to identify a smaller group to form a publication committee or advisory board. The criteria used to determine who will take part in this group, and therefore be listed as an author, need to be clearly communicated. The GPP guidelines state that, whatever the criteria used to determine authorship, they should be applied equally to external and internal team members.

After Matheson's presentation, participants discussed the difficulties of working with authors with limited knowledge of English. One participant asked whether it was ever acceptable for a medical writer to prepare the first draft of a paper for such an author. Matheson

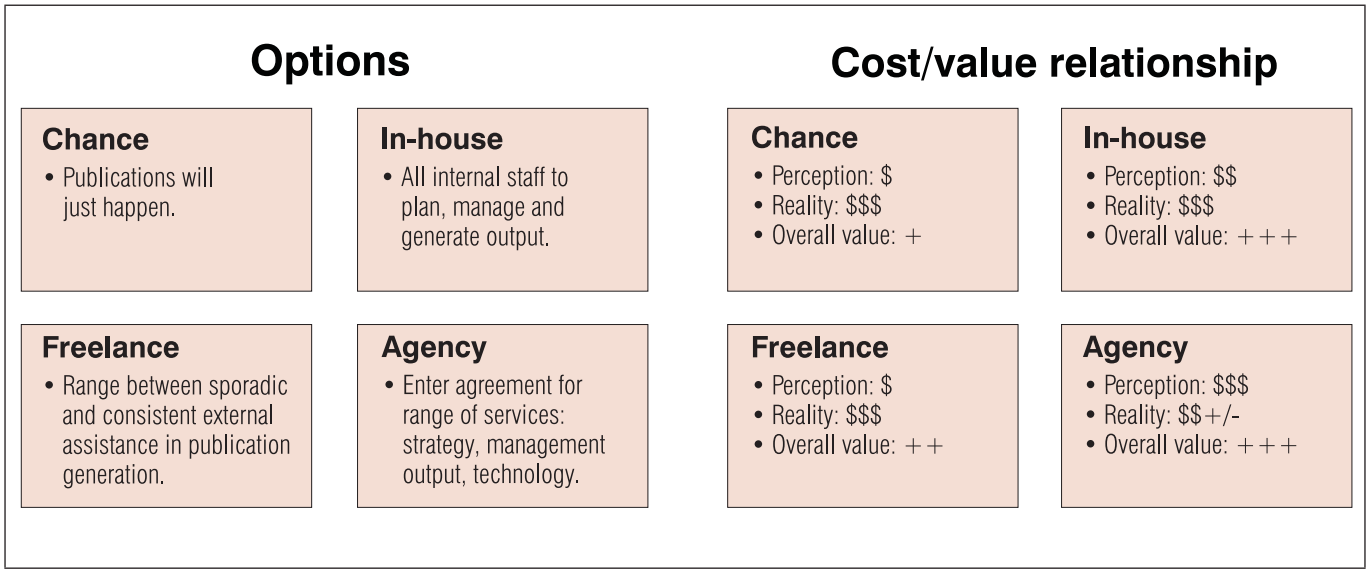

Fig. 2. The four strategies companies use to handle publications and their respective cost/value relationship. Reproduced with permission from Dan Donovan (Envision Pharma).

advised that it was better to involve the author early in the process and identify their personal goals and the publication key messages before preparing a draft. In some cases it might be necessary to discuss outlines and drafts with the help of an interpreter. An alternative suggestion was to encourage the foreign author to prepare a first draft in their own language, which would then be translated, or to prepare a draft on the understanding that a professional writer would put it into standard English. In these situations, writers need to avoid any implication that the company has prepared a final manuscript and is expecting investigators to sign up to it, or of putting words in the mouths of the named authors.

Effects of cost-cutting and global sourcing

The meeting then focused on the effects of cost-cutting and global sourcing initiatives. Introducing the session, Jodie Sherman Gillon remarked that her publication teams spent so much time dealing with finances that she sometimes joked that they needed MBAs instead of MDs and PhDs.

Dan Donovan (giving a presentation developed jointly with Joseph Haldey [Boehringer Ingelheim Pharmaceuticals, Inc.]) described the changes that have affected the industry, in particular the increasing focus on cost containment, procurement policies and outsourcing. Companies are under increasing pressure to produce publications to meet regulatory requirements and to ensure the success of their products, but while the number of publications has grown, budgets have been cut.

Companies may adopt one of four strategies to handle publications (Figure 2). One option is to have no policy and simply let publications develop by chance. Whereas this may appear to be the cheapest option it may, in fact, be the most expensive since it will fail to deliver a good return on investment and many opportunities will be missed. The next option for many smaller companies is to engage freelance writers to work on publications, but this approach tends not to produce strategic solutions. Good freelancers are also in great demand, so work for one company will have to be fitted around other commitments, meaning that the writer may not be able to deliver to the desired timelines or may be unavailable when you need them.

The third strategy is for companies to develop their publications in-house – an option taken by only a few organisations. The major drawback is that this approach reduces flexibility. Organisations may be reluctant to hire sufficient full-time employees owing to 'hidden costs' such as overheads and benefits. However, if companies do follow this model, it has the advantage that in-house writers and planners can develop expertise in company products and procedures, and the company may benefit from direct relationships with authors.

Most companies therefore take the fourth option: working with an agency. This has the advantage of flexibility (providing staff when they are needed) and, if you pick the right agency, should ensure the benefits of working with a professional, experienced partner. A good agency will be able to advise the customer about the latest guidelines and journal requirements, and bring publication planning expertise to the group. Some authors also prefer working with an agency rather than liaising directly with the sponsor. Despite these benefits, Donovan said that the agency option is often perceived as expensive, and some companies are unwilling to relinquish control over their publication strategies to an external company.

Several big pharma companies are now consolidating the agencies with which they work. In order to do this they establish a Master Service Agreement (MSA) and

negotiate a price. Some companies ask agencies to commit to stable pricing for a certain period, whereas for large-scale contracts, some companies demand volume discounts.

One difficulty in comparing agencies is the lack of consistent definitions for activities and the need for procurement staff to understand what communication agencies do. Job titles are not used consistently throughout the industry and therefore may not clearly reflect an individual's role or qualifications. Furthermore, procurement forms designed for other functions such as advertising agencies are sometimes used, making it difficult for the agency to provide the correct information to the potential customer.

Looking to the future, Donovan believes that agency consolidation will continue and that there will be an increase in incentive-based payment methods (e.g. higher proportions of the fee will be paid on submission and less on initiation than is generally now the case). He does not, however, believe that the system of retainers increasingly being used for advertising agencies will spread to communications companies. In summary, Donovan said that the key consideration when hiring an agency is one of cost versus value. It is important for companies to look beyond the immediate outlay and to measure value first and cost second, otherwise they may learn, to their cost, that "cheap is expensive!"

The latest on open-access publishing

Publication planners, of course, need to keep abreast of changes in the world of medical journals. One such development is the emerging tension between open-access and traditional models of journal financing. This became the subject of a thought-provoking session.

Barbara Cohen (PLoS Medicine) began by describing the open-access movement, noting that scholarly publishing involves many stakeholders, including researchers, publishers, funders and consumers. Systemic change, not just change in one or two constituencies, is needed if open access is to take hold. Cohen described how PLoS (Public Library of Science) has evolved from an advocacy organisation into a journal publisher in order to demonstrate that open access can work and that open-access journals can compete with the top tier of 'traditional' journals.

There is sometimes confusion about the term open access. Cohen says it is important to remember that open access is not the same as free access. For a journal to be classified as 'open access' it must not only make its contents freely available, but also permit authors to retain copyright, and commit to archiving all material in an independent repository (e.g. PubMed Central). PLoS uses the Creative Commons licence which ensures that, although the author's work can be republished without permission, the author must be credited and the source properly cited.

When choosing a journal, publication planners should consider the benefits of open access, which include:

- papers being available to prescribing doctors and consumers as well as researchers in institutions
- the author (or company) retains copyright and can therefore distribute reprints without having to purchase them from the publisher
- the prospect of rapid publication.

Even with online journals, it still costs money to publish peer-reviewed articles. PLoS uses author payments to fund its activities but always waives these in cases of hardship. Ideally, the research funder should pay for publication, since it has an interest in maximising its investment. There has been a major change in the attitude of sponsors, and many are now prepared to make funds available to pay for publication. Some legislative initiatives have also supported the open-access model. These initiatives suggest that systemic change is starting to happen. One goal of the open-access movement is to speed up scientific discovery and maximise the efficiency of research investment by ensuring free access to all relevant information for all institutions. However, Cohen believes that a critical mass of journals switching to the open-access model is needed before it will be possible to determine whether this is actually happening.

For a journal to be classified as 'open access' it must not only make its contents freely available, but also permit authors to retain copyright, and commit to archiving all material in an independent repository

Peter Banks (Banks Publishing) does not believe that open access will deliver accelerated science, seeing the process as a more gradual evolution than the dramatic revolution predicted by some open-access advocates. He noted that so-called 'traditional publishing' does not exist any more, since there are now many models of scholarly publishing and many journals now make papers available within 3–12 months of publication.

Although the number of open-access journals is growing, the increase has predominantly been in small local journals rather than in well-known international ones. Banks believes that relying on author payments is not a viable business model. He believes that, rather than lack of access to all published research being a major limitation for researchers, the real limitation is insufficient funding. The NIH budget has been flat since 2003. Banks concluded that, while the goals of the open-access

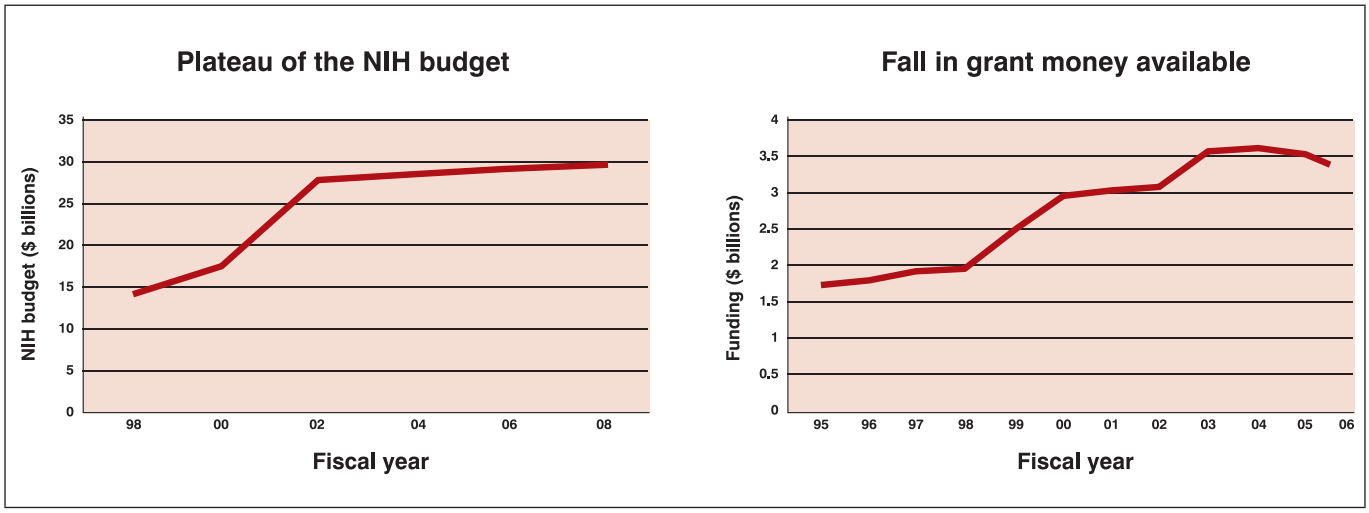

Fig. 3. The real barriers to scientific progress. Reproduced with permission from Peter Banks (Banks Publishing).

movement are honourable, what is really needed to accelerate medical research is better funding (Figure 3).

Groves then returned to provide a brief account of the *BMJ*'s experience in open access. It was, she said, one of the first journals to adopt this model, although it does not levy page charges. Although all original research articles remain freely available, since January 2006 other parts of the journal are available only to subscribers. She commented that if she were a drug company she would want to publish findings in an open-access journal. Publishing in an open-access journal also makes your research results available to a wide audience: BMJ.com gets 1.2 million hits per month and 80% of these are on research articles.

Developments in results disclosure

The final panel discussion was on new developments in results disclosure, moderated by Art Gertel (Beardsworth). Pamela Rose (TAP Pharmaceutical Products Inc.) provided a detailed summary of the current laws and guidelines surrounding trial registration and results disclosure. In the USA, currently the only law relating to results disclosure has been passed in the state of Maine[2]. This requires that results of hypothesis-testing studies be posted within 1 year of study completion for all marketed products, or on licensing for earlier studies. The Maine law stipulates that results summaries should follow the format adopted for the synopses of clinical trial reports submitted to regulatory authorities (known as ICH-E3 from the International Conference on Harmonization). This format is already used by several drug companies for posting trial results on their corporate websites. A recent statement from the ICMJE stated that posting brief abstracts (of under 500 words) would not jeopardise full publication in ICMJE member journals. However, many ICH-E3 synopses required by the State of Maine legislation are considerably longer than 500 words, so this state requirement may affect the ability to publish findings in ICMJE journals.

Rose believes it is best to view registration and disclosure as a continuous process rather than a single step, to ensure consistency. Trial design details must be registered (according to the ICMJE) before the first patient is enrolled. This information will need to be updated if new centres are added to the study, if investigator contact details change or if the protocol is amended. At TAP, a weekly update to ClinicalTrials.gov is performed. Then, when the study is completed, and the drug is marketed, the ICH-E3 synopsis must be posted (according to the State of Maine legislation) within 1 year, and citations from all peer-reviewed publications by any investigator are also added to ClinicalTrials.gov.

Trial registration (but not results disclosure) is now mandatory in Israel, Italy, South Africa and Taiwan

Although Maine is currently the only state to have made results disclosure mandatory, federal legislation is being considered. Three bills are currently being presented to the US Senate (the Enzi–Kennedy, Dodd–Grassley and Kennedy 'Megadufa' bills) and one (the Waxman–Markey bill) is being discussed by the House of Representatives. Since the FDA budget is determined by the Prescription Drug User Fee (PDUFA) legislation, which expires at the end of September 2007, some new legislation will need to be passed before this date.

In addition, eight states are considering their own legislation, with California, New York, New Jersey and Minnesota being closest to passing laws on results disclosure. Internationally, trial registration (but not results disclosure) is now mandatory in Israel, Italy, South Africa and Taiwan, and similar legislation has been proposed in France.

Having received this helpful update of the legislative framework, the meeting heard an editor's view of results disclosure and trial registration. Emma Veitch (PLoS Clinical Trials) believes that editors are mostly concerned with preventing publication bias since there is evidence that up to 50% of studies never get published. There is also evidence of selective reporting of trial outcomes. In each case, trials or individual outcomes favourable to the sponsor, or yielding statistically significant findings, are more likely to be published than negative ones. The result is that the published literature is skewed and treatment risk:benefit ratios may be biased. Registration of protocol details when a study starts should minimise non-publication and will enable reviewers and editors to detect selective publication and therefore prevent it.

The reputation of the pharmaceutical industry has suffered recently and there is public distrust about clinical trials reporting. Trial registration with full results disclosure may not only benefit patient care but also help to restore public faith in science. However, several important questions remain:

- What results should be reported?
- How much detail is required?
- What is the best format?
- Should postings be peer-reviewed?

A newly emerging trend is for post-publication review and evaluation in addition to traditional pre-publication peer review. PLoS has recently launched PLoS One, an electronic journal that will publish results of properly conducted trials regardless of their outcome. The protocol must be submitted with the report and is reviewed alongside it to check that the trial has been responsibly reported. The CONSORT statement is used to provide a template for reporting randomised trials. Submissions are reviewed by independent experts before publication, but may then be annotated and evaluated by readers after publication.

Ida Sim (University of California San Francisco) believes that results disclosure is an ethical imperative, since patients expect trial results to contribute to medical knowledge. This position is set out in the Declaration of Helsinki and has also been reiterated by the World Health Organization (WHO). Sim described the various state and congressional proposals as a "patchwork of initiatives". For example, one of the bills being considered by the House of Representatives requires both a summary for patients and a more technical one aimed at researchers; ClinicalTrials.gov is currently considering both the ICH-E3 and the proposed CONSORT for Abstracts formats but has not yet decided which to adopt. Sim believes that results reporting should be linked to trial registration.

Ultimately, it should be possible to develop machine-readable formats, enabling computers to perform data mining and improving the power of meta-analyses.

The current formats of journal articles cannot be read effectively by computers, but trial banks would enable data from different studies to be compared more efficiently and would improve the synthesis of medical information.

Sim concluded by advising that, since the public may be sceptical about material on corporate websites, companies need to post results on neutral, independent sites. One model would be to deposit numerical data in a trial bank and then for journals to publish peer-reviewed articles providing clinical interpretation and discussion of the findings. The position of the WHO is clear: clinical trials are primarily for the public good and therefore the results of all trials should be made public.

The position of the WHO is clear: clinical trials are primarily for the public good and therefore the results of all trials should be made public

Conclusions

The variety of speakers and topics at the 5th TIPPA meeting demonstrated the complex and fast-moving nature of scientific publications. Professionals need to keep abreast of pending legislation, new requirements from journals and technological advances. Company policies need to reflect the latest guidelines, and all staff need regular training. Organisations such as TIPPA provide a valuable opportunity for networking, learning from other companies and keeping up to date.

Themes emerging from this year's meeting included transparency and compliance. In her closing remarks, Sherman Gillon encouraged participants to stand up for the industry. We may not be ready (quite yet) to march through the streets of San Francisco, but publication professionals should take pride in what we do and dispel prejudice by explaining what we do and demonstrating the value that medical writers and publication planners can bring to the process. The 5th TIPPA Annual Meeting certainly provided food for thought, plus practical guidance, for all those seeking publication planning and execution excellence.

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Medical Writers and Peer-Reviewed Journals: Understanding the Rules and Responsibilities

A KeywordPharma **Expert Review** by **Elizabeth Wager** Published June 2007

ThePharmYard product code kwp016 ISBN 978-1-905676-15-6

Liz Wager explains the concerns about the role of medical writers in developing peer-reviewed publications and helps writers and communications companies keep abreast of recent guidelines and new journal policies.

Executive Summary

Medical writers perform an invaluable role in the dissemination of scientific information, in particular the publication of clinical trial results. However, their work has not always been acknowledged. The pharmaceutical industry has endured much criticism of how it reports clinical trials. High-profile abuses of publication ethics from within the industry have fuelled suspicions of the sector and, by association, damaged the reputations of responsible writers and communications companies. This has led to escalating calls for greater transparency in the relationships between journals, medical writers and pharmaceutical sponsors. Many journals have responded by establishing and enforcing stricter guidelines on the publication of clinical trials.

Editors and readers have responded to concerns about conflicts of interest in publications by demanding greater information on individuals involved in developing publications. Policies of disclosing individuals' contributions to publications have increased awareness of the roles of company employees previously hidden from public view and brought about wider acknowledgement of the work of medical writers.

This Expert Review, *Medical Writers and Peer-Reviewed Journals: Understanding the Rules and Responsibilities*, looks at the complexities of reporting clinical trials and the important role played by medical writers. It outlines guidelines affecting medical writers that are being adopted by many journals and medical editor associations. It calls on journals and sponsor companies to work together to embrace transparency and to agree best practice in the publication of clinical trials.

Contents

About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice for Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a First Class zoology degree from Oxford in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services.

She is a member of: the *BMJ*'s Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of the Committee on Publication Ethics, the editorial board of *European Science Editing* (the journal of the European Association of Science Editors) and the World Health Organization Scientific Advisory Group on trial registration.

She can be contacted at: liz@sideview.demon.co.uk or via www.lizwager.com

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