Ghosts in the Machine: Publication Planning in the Medical Sciences

Sergio Sismondo

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ABSTRACT Publication of pharmaceutical company-sponsored research in medical journals, and its presentation at conferences and meetings, is mostly governed by 'publication plans' that extract the maximum amount of scientific and commercial value out of data and analyses through carefully constructed and placed papers. Clinical research is typically performed by contract research organizations, analyzed by company statisticians, written up by independent medical writers, approved and edited by academic researchers who then serve as authors, and the whole process organized and shepherded through to journal publication by publication planners. This paper reports on a conference of an international association of publication planners. It describes and analyzes their work in an ecological framework that relates it to marketing departments of pharmaceutical companies, medical journals and publishers, academic authors, and potential audiences. The medical research described here forms a new kind of corporate science, designed to look like traditional academic work, but performed largely to market products.

Keywords corporate science, drugs, ghostwriting, ghost management, marketing, medical journals, pharmaceutical industry, publication planning

Ghosts in the Machine:

Publication Planning in the Medical Sciences

Sergio Sismondo

Pharmaceutical companies perform and sponsor significant amounts of medical research and analysis, especially clinical trials, but also meta-analyses, reviews, epidemiology, laboratory science, and health economics research. Although these companies have long recognized the value of scientific journal papers that report their research (Rasmussen, 2005), in the past two decades they have increased efforts to systematically treat research as a resource that needs to be carefully developed and deployed to affect the opinions of researchers and practitioners. This has brought clinical research into the 'marketing era' (Applbaum, 2004).

Publication of pharmaceutical company-sponsored research in medical journals, and its presentation at conferences and meetings, is now governed by 'publication plans'. These plans extract more scientific and commercial value out of data and analyses, sometimes by designing studies with that value in mind, and always by carefully constructing papers that establish consistent

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profiles for drugs. Most sponsored clinical trial research is handled by contract research organizations (CROs), the data they produce is typically analyzed by pharmaceutical company statisticians, papers are written by medical writers, and the whole process is guided and shepherded through to publication by planners and planning teams. The situation is similar, though simpler, for industry-funded review papers, commentaries, and letters to the editor; for these, research is typically carried out within the pharmaceutical company or the publication planning firm.

To gain the most commercial value from research, the papers publicizing it are written under the names of independent medical researchers – often 'key opinion leaders' (KOLs) – though company authors may also be recognized in the list of authors. The work of company statisticians and researchers, reviewers from an array of departments, medical writers, and certainly the publication planners themselves, is only rarely acknowledged in journal publications (Gøtzsche et al., 2007; Moffatt & Elliott, 2007). Even sponsorship, the company funding of the trial, is omitted from many meeting abstracts (Finucane & Boult, 2004). For this reason we might see publication planning as the 'ghost management' of medical research and publication (Sismondo, 2007). This ghost management is a major activity, with more than 50 firms, some of them claiming to have hundreds of employees, advertising publication planning services on the Internet (list available from the author). Though the activities are largely invisible, there is evidence that up to 40% of important journal reports of clinical trials of new drugs (and, more anecdotally, perhaps a higher percentage of meeting presentations on clinical trials) are ghost-managed through to publication (Sismondo, 2007).

Because it is unseen, some of the best demonstrations of the existence and effects of ghost management have arisen as a result of legal action. Court proceedings showed that Parke-Davis hired a medical communications firm to write, and paid physicians to author, a number of scientific papers on gabapentin (Neurontin) in an attempt to promote off-label uses of the drug (Steinman et al., 2006). A legal action gave psychiatrist David Healy access to a document listing 85 papers on the drug sertraline (Zoloft or Lustral), many of them written by medical writers and then authored by academics, being handled by a public relations firm, Current Medical Directions, for Pfizer (Healy & Cattell, 2003). Court proceedings showed that in 1996 Wyeth hired the medical communication firm Excerpta Medica to prepare ten manuscripts on its diet drug dexfenfluramine (Redux) for medical journals. Excerpta wrote the manuscripts and located authors, paying them between US$1000 and US$1500 for their editing work (Elliott, 2004). Most of those manuscripts never saw print, because the drug was withdrawn from the market. As a result of lawsuits, it was claimed that Merck may have under-reported deaths on rofecoxib (Vioxx) in its 'Advantage' trial. In a widely quoted statement, first author Dr Jeffrey Lisse said,

> Merck designed the trial, paid for the trial, ran the trial … . Merck came to me after the study was completed and said, 'We want your help to work on the paper.' The initial paper was written at Merck, and then it was sent to me for editing. (Berenson, 2005)

Lawsuits about rofecoxib also led to a more systematic study identifying 96 published papers (24 on clinical trials and 72 review papers) on which Merck had worked prior to their publication, and which were later published mostly under the names of academic first authors (Ross et al., 2008). The company Scientific Therapeutics Information wrote a number of papers for Merck, and one document lists eight review papers for which they had intended authors and journals, and estimated delivery dates of first or second drafts. Interestingly, ghost-managed review papers were likely to be single-authored by academics who were especially likely not to declare financial support for the work (Ross et al., 2008).

What follows is a slightly less direct but broader view of publication planning. It reports on a meeting, the third annual meeting of the International Society of Medical Planning Professionals (ISMPP). I had three goals in attending the meeting. First, I was continuing an earlier project of documenting the activity of publication planning, which is largely invisible and yet is an important part of pharmaceutical companies' interventions into the medical science literature. In the bulk of this paper, I use the meeting to describe and provide some analysis of publication planning, in an ecological context that relates it to marketing departments of pharmaceutical companies, medical journals and publishers, academic authors and potential audiences. Second, I wanted to learn about general insights that publication planners, as experts on this topic, have on the production of scientific knowledge. As I describe below, I was only partially successful in achieving this goal. Third, I was interested to learn about publication planners' understanding of ethics, a central theme of this meeting: new pressures by regulatory agencies and critics of the pharmaceutical industry prompted the creation of ISMPP, an organization that has focused much of its attention on ethics and good publication practices – for example, participants at the meeting were asked to comment on a draft code of ethics, and on a proposal for establishing accreditation of publication planners. I do not explore the third theme directly in this paper.

Because it was a public meeting, it is difficult and artificial to fully ensure the anonymity of speakers. Nonetheless, I refer to them by initials, not their own. I am taking the views of most of these speakers as representative of publication planners more generally, and I do not want to highlight their identities. I maintain that naming convention even when the speakers are invited outsiders. I did not attempt to interview any of the participants, because I felt that the hidden nature of their work would make it difficult for both me and potential interview subjects to represent ourselves honestly; when I attended the ISMPP meeting I presented myself as a researcher in STS, interested in the management of knowledge, but I avoided lengthy conversations about my specific interest.

Publication Planning 101/201: An Insider History of the Field

> Media. That's a funny word to use in a scholarly conference like this. But publications are your media. (MH, publication planner)

ISMPP is one of two similar organizations, the other being The International Publication Planning Association (TIPPA), which also holds annual meetings, even involving some common speakers. Approximately 400 people attended the ISMPP meeting, held in a hotel in Philadelphia, adjacent to GlaxoSmithKline's US headquarters. Almost all attendees were publication planners, of whom approximately two-thirds worked for independent 'agencies' and one-third directly for pharmaceutical companies. The non-planners were mostly invited speakers, including journal editors, ethicists, and consultants to the industry. Slightly more women than men attended, and the median age of participants was approximately 40 years; this is a new field, and has few senior figures. Attire was roughly what I would have expected in a group of medical writers and scientists working for industry: a range from business suits to business casual, but mostly of the ordinary and slightly rumpled variety. Eighty per cent or more of the attendees were American, and most of them had not traveled far, since the US pharmaceutical industry is concentrated between North Carolina and Massachusetts. The UK, one of the centers of publication planning, was well represented among speakers, though not so much among participants more generally.

The meeting was two days long, and was preceded by a day of workshops: I registered in Publication Planning 101/201, which provided 'an interactive and instructive introduction to the world of strategic publication planning', for those either new to it, working as support to planning or working in connected areas. Most of the 30 women and 13 men taking the course were new publication planners, though there was also a handful of others, including medical writers, publishing company employees and more experienced publication planners. Day-long seminars were held simultaneously in adjacent rooms: 'Publication Planning 301, Developing a Strategic Publication Plan'; 'The Life of a Manuscript: From Initial Concept to Publication (and Beyond)'; and 'Statistics for the Non-statistician, and Publishing Pharmacoeconomics and Outcomes Research'.

The program for Publication Planning 101/201 began with a history of the field given by HK, a senior member of the field and the chief executive officer (CEO) of a medium-sized agency. Undoubtedly artificially, HK pinpoints to 1984 the origins of publication planning, when three employees of Pfizer realized that the company had extensive data on the drug amlodipine (Norvasc, a calcium antagonist), and wondered where they should publish it. To do this rationally, they had to gather information about all of the trials to which Pfizer had access, as well as information on other publications, and then sort it all and decide how to publish it in credible journals for non-overlapping global audiences. The company had to greatly increase communication within itself to achieve this. Even by 1988, publication planning was not well established within Pfizer; HK quoted an internal memo saying 'Please … return details of any new trials, new plans for publication of existing trials, or missing details.' HK made it clear that this sounds quaint today, because of close tracking of all trials from their conception onward, and top-down guidance of their publication. 'Today, if you go to a meeting, you know pretty much what is going to be presented.'

The amlodipine campaign was deemed a great success, increasing interest in calcium antagonists generally, and making amlodipine a very highly cited and prescribed drug by 1989.

The bare publication plan is a dynamic document that 'outlines the recommended medical communications and their timings'. However, the activity of publication planning is broader, and includes the work to implement the plan, to produce the deliverables. Publication planning can and should start even before the research does, contributing to research design, mapping out key messages, and identifying papers for different audiences and journals, and potential authors on those papers. The focus is communication, and the research is created with communication in view. Once the research is available, publication planners hire writers on those papers, deal with potential authors and various interests within the pharmaceutical companies, and shepherd the papers through journals' submission and revision procedures. Publication planning as a whole is typically done by heterogeneous teams, and increasingly those teams include one or more professional planners who understand and guide the process of turning data into papers and presentations. Most of these planners work for dedicated agencies, though pharmaceutical companies employ a substantial number of them directly (Medical News Today, 2005).

According to HK, the field can take credit for some improvements in medical publishing. It helped to give non-Anglophone researchers more presence in medical journals. It also helped pharmaceutical companies meet AIDS activists' demand that trial data be published more quickly: between 1987 and 1995, the time between the end of a trial and publication was reduced from more than 2 years to a matter of months. This was partly achieved through a new emphasis on meetings, abstracts, and posters as publication venues; these became much more important than journals in the mid 1990s, with journal publication following wide dissemination of results at meetings. In the late 1990s, medical journals recaptured some of their claim to being newsworthy by taking advantage of electronic movement of texts to shorten review and editing times, and by publishing electronic copies in addition to paper ones. 'People [at journals] had to get used to the fact that things had to get done more quickly.'

A further milestone was a shift in how drug company share prices were evaluated. Starting around the year 2000, stock markets began focusing less on performance and profit, and more on pipeline. 'Blockbuster' drugs, usually defined as drugs with sales in excess of one billion dollars annually, made up the largest share of drug companies' revenue and profits, and therefore protection of those from competition and the timelines of new potential blockbusters in development meant much more than anything else one might evaluate. The news for publication planners was that their work had immediate market value, and there was more reason than ever to get positive news in print quickly.

The period HK describes was one of enormous change in the industry more generally, and some of that change may be connected to the rise of publication planning. Global sales of pharmaceuticals increased enormously, at an average rate of more than 10% per year (World Health

Organization, 2004). This was largely the result of an increasing number of blockbuster drugs, and consistent high sales growth in the USA. Perhaps related, it was a period that saw a large number of mergers and acquisitions in the industry. There was also a change in the structure of research in the industry, as industry funding moved from supporting academic research to purchasing research from CROs; in 1990, for example, 70% of pharmaceutical industry research funding went to universities and teaching hospitals, whereas in 2000, 70% went to CROs (Mirowski & Van Horn, 2005). As Mirowski and Van Horn argue, the movement from academic-led studies to CRO-led studies changed the structure of data ownership and expectations around publication. Thus, the simultaneous rise of the publication planning and CRO industries is almost certainly not coincidental. Some publication planning firms are even owned by CROs, allowing these pairings to fully guide research from inception to communication. Innovex, for example, is part of Quintiles, which advertises itself as the world's largest CRO. Innovex 'provides comprehensive product commercialization at all stages of the product development life cycle: from Phase II, through national and international product launches to ongoing support, extending into generating noise about established products' (Innovex, 2007).

Order

> This is what utopia looks like from an industry perspective. We have agreement and alignment on a plan, not even just a publication, a full plan, investigators on board, agencies lined up, everybody ready to play and we're going to get this done in a timely way, in an orderly fashion, and things work like clockwork. (CI, a planner working within a pharmaceutical company)

Utopia, then, is a publication plan implemented without hitches. The plan sets out an orderly performance of research and rolling out of presentations and publications; appendices give the relevant data for each of the meetings and journals to which abstracts and papers will be submitted – the audiences they reach, their impact factors, their rejection rates, and publication lead times (for example, Complete Healthcare Communication, 2006). Tactical recommendations are for specific submissions, based on strategic considerations, parceling out data for different target audiences, time and resource considerations, and the sequence in which one wants the data to roll out. Dates of submission are laid out, and dates of publication quickly follow. A plan may also describe other communication opportunities, such as symposia and round-tables, journal supplements, advisory board meetings, monographs, slide programs, formulary kits, and more. Though the publication plan should be a dynamic document, changeable if circumstances change, one gets the impression of a world without uncertainty, of papers written and published on schedule. And planners take pride in their efficiency: according to one presenter, Glaxo-Wellcome conducted a survey of sponsored publications and compared them with investigator-led publications and publications developed by people in the company's clinical

research department. Those developed by a planning team were submitted and published much more rapidly.

The publication planning team should be put in place early, says seminar leader FD, 'before too much data has gone unpublished'. Although planners focus on publications, they would ideally want to be present when the research is designed. This is especially important if there is 'need to create [a] market' or to create an 'understanding of unmet need'. Critics characterize such creative activities as 'disease mongering' or 'selling sickness' (Moynihan & Cassels, 2005; Moynihan & Henry, 2006). Publication planning probably plays important roles in such 'disease mongering': Healy (2004) connects the dramatic expansion of clinical depression to publication planning campaigns; Jennifer Fishman (2004) describes what amounted to a campaign to establish female sexual dysfunction as a disease, with academics as mediators between the pharmaceutical industry and physicians and regulators.

The publication planning team might be formed upon proof of concept, or two years before the expected launch of the product, or at the start of Phase III trials (trials to establish efficacy and safety before the drug is approved), or when the company begins making expenditures on commercial plans. The planning team rationalizes expenditures by integrating the company's research, scientific communication and marketing communication strategies. It also manages knowledge flow: planner MS advises that papers from Phase I (pilot trials typically on healthy subjects) should be written early, so that papers from Phase II (small clinical trials to guide Phase III trials) can refer to them; MH says that, for maximum effect, the number of papers should peak at about the time that the product launches. The right knowledge flow should lead to increased presence in the medical understanding and the commercial market.

We can see the type of order desired and created by publication planning in discussions of the Ingelfinger Rule. Put in effect in 1969 at the *New England Journal of Medicine* by editor Franz Ingelfinger, the rule does not allow the publication of results that have appeared previously (with exceptions made for scientific meetings). It was quickly and widely adopted by other medical journals, having the effect of making them newsworthy. As editor SG says, 'If it isn't news, we don't want it.' At the meeting, nothing received more scrutiny than the conflict between journals' application of the Ingelfinger rule and new regulatory pressures to post data from clinical trials.

There is considerable pressure on pharmaceutical companies to make all of their clinical trial data available quickly. For example, in 2005 the state of Maine passed a law regarding the posting of data: if companies wish to sell their products in Maine, they need to comply with its regulations (Maine, 2005). In response to the general pressure, the Pharmaceutical Research and Manufacturers of America (PhRMA) set up guidelines for posting data. Companies interpret these guidelines differently, and some apply more strict standards – to appear as good corporate citizens some companies have adopted rigid internal protocols that are difficult for publication planners to challenge, even when those protocols put their work, and the companies' interests, in jeopardy.

Meanwhile, journals are inconsistent: some see prior posting as amounting to prior publication, some do not, and others make judgments on a case-by-case basis. The situation is further complicated by the fact that many studies are presented at meetings prior to being published, and journals might see the combination of meeting presentation and posting of trial data in a different light than either separately. For publication planners, this situation is infuriating. One study of journals, done by three junior planners, identified a wide variety of interpretations of the Ingelfinger rule; another planner identified a range of posting standards among pharmaceutical companies.

The PhRMA guidelines explicitly state that posting is not intended to conflict with publication in reputable journals, and so journal publication should take precedence. The Maine regulations allow for up to two 6-month delays in posting to allow for analysis; the timelines with which publication planners normally work should allow for both publication and posting. Thus, posting of data might seem relatively easy to deal with. It is important, though, because it is a new irritant with the potential to create disorder. Planners are trying to create an orderly world, with each paper appearing as scheduled in the chosen journal. By and large, they are successful, at least if we judge by the way they present their accomplishments, but also by the evidence we have of their activities (for example, Healy & Cattell, 2003). In the light of tightly woven plans and high success rates, nothing creates more difficulty for that order than capricious or inflexible journal editors, who have the power to set work back by months. After telling of a conversation with a journal editor, one audience member said, 'It sounds like there's no clear answer on this, and that each journal can treat it differently.' Posting rules, whether they are PhRMA's or internal company protocols, give journal editors a new way of behaving unpredictably.

Marketing

> Historically, Phase IV studies were primarily conducted to support a product's commercialization; now they are increasingly conducted to maximize it. (Glass & Dalton, 2006)

On its standard self-presentation, publication planning should be, though isn't always, independent of marketing. It should be in the service of scientific knowledge about results: 'We really do like to stress that the publication planning company is not an advertising agency, is not a PR [public relations] agency, even though it might look like one', says NF. Planners understand that they are in a sensitive position. Revelations of ghost-written medical journal papers have caused scandals, and have resulted in coverage in prominent newspapers (Barnett, 2003; Berenson, 2005; Mathews, 2005). On a number of occasions conference audience members were reminded to watch what was written down or entered into databases, because their documents and databases could become public through lawsuits or otherwise. Seminar leader MH suggested, for example, that planners talk about 'communication points' rather

than 'messages', because critics see the latter as driven by marketers. The *Wall Street Journal*, in particular, with its readership in the world of finance, was mentioned fearfully several times over the course of the conference: planners wanted the results of their work to be reported in its pages, but not their work itself, especially when associated with any one drug company. MH says, 'A publication plan might be made public, might appear on the front page of the *Wall Street Journal*. So you don't want to make it appear that you don't have authors. This is verboten today.' The references to this one newspaper suggest that planners' central concern about exposure is about its consequences for business, not about exposure of unethical behavior per se.

In their interactions with each other and with the pharmaceutical industry, planners recognize that their work has marketing value. The websites of publication planning firms promote their work on that basis. Watermeadow Medical says that its 'mission is to ensure that your messages reach and energize your target customers', including through 'hardcore scientific writing' (Watermeadow Medical, 2007). Envision Pharma's site says that 'data generated from clinical trials programs are the most powerful marketing tools available to a pharmaceutical company' (Envision Pharma, 2006). 'Adis Communications works in partnership with clients to position their products at the right place, at the right time through: Hundreds of well-respected, and high-impact factor journals … ' (Adis Communications, 2006).

New publication planners are told to pay attention to marketing. In the 101/201 course, NF explained that a publication plan begins with a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis, which 'paints a complete picture of the market situation for a new product'. In addition, MH says that publication plans should identify 'target audiences', lay out key 'scientific and clinical communication points', perform 'competitor publication and gap analyses', and outline 'top-line tactics' and 'critical timing'. Clearly, these analyses are parts of the apparatus of interested intervention, not disinterested diffusion of results. Similarly, after an exercise in the 101/201 seminar NF asked, 'How are we going to create publications that have the right message, and a memorable message, for prescribers?' Alastair Matheson (2008) describes the messages as 'narratives' that establish consistent profiles for drugs – though these can be different for different national or specialist audiences (Lakoff, 2004).

Ultimately, publication planning needs to generate revenue by providing information that increases sales. It is difficult to measure return on investment (ROI) directly, says NF, because publications typically go hand-in-hand with many other activities that affect markets and sales, as well as constantly changing markets. Nonetheless, two presentations during the meeting addressed how to measure the ROI of publication planning. BJ, an efficiency expert talking about metrics, argued that the 'scientific objective' of increasing awareness directly produces the 'commercial objective' of improved ROI. Thus, BJ suggested measuring multiple surrogates for ROI, such as the number of papers per message: the team would create the list of key messages for dissemination, and then chart the number of times that each of those messages is represented in a document. Another

presentation, by two junior planners, RT and HJ, in a very large medical information and publication planning firm, discussed a more direct study of ROI for publications, which examined prescriptions of a particular hormone replacement therapy (HRT) by cardiologists before and after a group of published reports on the HRT for hypertension, as well as patient use of that HRT for the same condition. After three major publications in *Circulation*, *Menopause*, and *Hypertension*, all showing that not only did the HRT reduce the symptoms of menopause but also reduced hypertension, there was a significant increase in prescriptions by cardiologists, though not by gynecologists. There were several advantages of this particular focus, including the fact that hypertension is an off-label (unapproved) indication for HRTs: consequently, unless it was acting illegally the sales force should not have been a complicating factor. Indeed, a questioner from the audience asked if the speakers were doing inappropriate off-label promotion, an accusation forcefully denied.

Though they appear inconsistent, the planners presenting at ISMPP are not merely being duplicitous when they distance themselves from marketers. They understand that their work has marketing value and is supported because of that value, but they see a clear distinction between what they do and what marketing departments do. Marketers, as planners portray them, would consistently ride roughshod over scientific standards, and in particular be relatively unconcerned with what the scientific data can support. To be compliant with 'good publication practice', says MH, a publication plan is a basis for dissemination of scientific and clinical data, and is 'not a marketing communications plan'. The marketing department, NF said, is considered lucky to have one place on a publication team – it does typically retain that one place, because 'they're probably paying the bill'. A journal editor, LB, corroborated the antagonism between marketing and science, exhorting the audience to prevent marketers from writing manuscripts. She can tell, she said, when papers are written in the marketing department; they are peppered with certain adjectives and adverbs that a scientist wouldn't write. Such papers are typically rejected. Publication planning negotiates between marketing and science, implies FD. Without it, 'bottlenecks will inevitably occur' and 'vast delays are likely', but also 'marketing may drive the process' and 'the resulting publications might be "cherry picked"'. Especially in the context of scrutiny around publication of results, cherry-picking is a worry (Turner et al., 2008).

Thus, publication planners see part of their job as constraining the influence of pharmaceutical marketers. Yet, publication plans exist to serve the marketers, and therefore the planners have to convince the marketers that their more subtle approach, with its limited range of tools, is the right one. This is a version of a common tension occurring when the most persuasive rhetoric is not marked as an explicit attempt to persuade. Of course, to 'sell without selling' is a sales and marketing ideal, too (Oldani, 2004). Nonetheless, publication planning does its work almost entirely through scientific meetings and journals, without any direct contact with physicians.

Scientific standards are doubly important. First, as was apparent throughout the conference, meeting them constitutes part of what is considered ethical behavior, and so underpins the entire business and the distinction between doing publication planning and public relations. After planners persuade their sponsors that their work will provide a good ROI, they want to obey ethical guidelines in the hands-on work they do, and to adopt high scientific standards for the writing of each paper. Second, publication planners can only succeed if their work displays high standards, so that their papers will be published to best advantage. Medical journals have high rejection rates, from as high as 94% in the case of journals such as the *Journal of the American Medical Association* (JAMA) and the *British Medical Journal* (BMJ) (McCook, 2006). Meanwhile, publication planners claim to have very high acceptance rates; for example, an 'acceptance rate on first submission of 94% for abstracts and 78% for manuscripts' (Gardiner-Caldwell Group, 2007). It is only by stifling the marketing department's efforts to hype the product that publication planners can do effective marketing to scientific audiences. At least some of the time, marketing is best done if it is invisible.

Journals

> We spend a lot of time trying to re-educate our journal editors. … We're saying you have to change your instructions for authors. You have to reflect the changing mood of the times. And yet we still get journal editors who say 'This journal frowns on ghostwriting' or something similar. 'This journal will not accept papers that have writing support.' And actually what we're trying to say to them is, 'Fine, you may have that view but what you're actually doing is driving it underground. It's far better to be transparent and get this out into the open.' (RB, publisher)

Invited to address the meeting were representatives of three of the ten best-regarded medical journals, one publisher of numerous medical journals, and one leading journal editors' organization; a few other publishers and journals had booths in the foyer. Publishers and editors represent very different interests, and are represented as having very different attitudes toward publication planners. BC, the head of a publication planning firm, says, 'From publishers we often get quite a strong sell, engagement and willingness to work with. And from editors we often get very much a hands-off and keep your distance.' Though BC wishes that journals could iron out this difference, he understands its origins:

> We understand and recognize that tension. To me it actually mirrors very closely the relationship between medical and marketing within the pharmaceutical industry … . And it's about the relationship between commercial needs and the integrity of the science.

As we've seen, publication planners manage this relationship to their satisfaction; perhaps they hope that journals can find a similar resolution.

Several publication planning firms are divisions of major publishing houses. For example, Carus Clinical Communications 'offers clients a unique combination of world class innovation and experience supported by the unmatched depth and breadth of Elsevier's worldwide medical publication resources' (Carus Clinical Communications, 2007). Thomson Scientific Connexions, owned by the publisher Thomson, will develop 'a publications strategy and recommendations for coordinated and targeted data dissemination through medical meetings, journal papers, and other communication vehicles to educate clinicians and build a foundation for clinical acceptance' (Thomson Scientific Connexions, 2006). The connections may improve planners' access to their publishers' journals, and may improve access to KOLs.

The director of medical publishing for a very large publishing company, RB, made two presentations, first to the 101/201 seminar ('Medical Journals for Dummies'), and then to the general meeting the following day. For RB, journals provide registration of ideas, vehicles for dissemination, an archive of results, and certification: 'the air of impartiality that you wouldn't be able to get if you publish elsewhere'. If the journal 'clearly has affiliations with the industry then you may get a more lenient ride than a society journal'. But society journals tend to have higher circulation, prestige, and impact factors, and their editors tend to have more independence, which 'impacts their attitudes to the industry'. Here, and at a number of other points, RB clearly aligns the publishing industry with the pharmaceutical industry, against scientific editors.

In a promotional moment, RB mentions a new journal, an online, open access, peer-reviewed journal, financed by author payments ($2600 per paper), and which will publish negative or inconclusive data; its main criterion is that the study be well performed. 'This is a service to the pharmaceutical industry. You may have large quantities of data … . This is peer-review *light*.' The journal appears to be intended as a medical version of the dead letters office, where unwanted results go so as not to be read.

When RB addresses the ISMPP meeting as a whole, he does so in a session entitled 'Publishing Research: Please Don't Make My Job Any Harder'. Once again, he aligns publishers with planners and the pharmaceutical industry, but he also stands up for editors; all of the panelists were asked to list complaints, and RB performs well, chiding his audience, and eliciting laughter in so doing. In this presentation, he emphasizes that most editors are hard-working volunteers, and that they need to be treated well.

> Stan at [major medical journal] had an industry author submit a couple of papers a few years ago now, to the journal. The journal put them out for peer review and the answer was, yeah, OK, it's in need of minor revisions but essentially it's publishable. So the comments went back to the author. No response. Never. Same author submitted a paper a month ago, and Stan said, 'So what's going on, then? What happened to those other papers we bothered to peer-review and sent back to you?' 'Oh those, yeah, well the company's downgraded the efforts on that product so we didn't bother continuing with the publication of those articles.' Well again, think. It's not exactly going to put you in a very good light when you want to

> continue to publish in that journal if you're taking all of that expertise in peer-review and just throwing it down the toilet.

Yet throughout RB's barrage, there is no doubt that he is on the side of the pharmaceutical industry and its publication experts. He wants their business:

> If you have a deadline, it's a really good idea to tell us about it, and tell us nice and early. If you have special requirements, like you need an ad or a logo, you need information about prescribing, information whatever it might be, again, tell us. Don't leave it until one day before we go to press before you start dropping this stuff on us.

Despite the claimed differences between publishers and editors, when journal editors (including ex-editors and associate editors) speak, there is no apparent hostility toward publication planners. On the contrary, they claim to value the work done by planners, and the manuscripts they provide: industry manuscripts are well written, and include important papers. These editors have extensive dealings with planners, who are often their primary contacts on submissions. Editor-in-Chief SG starts his presentation with a sales job: his is a general journal, 'with a circulation of 87,000, plus reaching millions through the web … . We have an impact factor of 13.25, which places us 5th among all medical journals.' He goes on to say that the journal is interested in attracting clinical trials, and has instituted a new 'trial-track' in which editors make quick decisions whether to fast-track clinical trial papers.

There are obvious reasons why journals would want to encourage submissions of industry-sponsored papers. Some of these papers report on well-funded, well-constructed clinical trials. Given that clinical trials are the most valued sources of medical data, these papers are likely to be highly regarded and cited, even without publication planners working to cite their own papers – of the most highly cited recent papers reporting clinical trials, the majority are funded by the pharmaceutical industry (Patsopoulos et al., 2006). Some medical journals allow companies to sponsor supplements on special topics at rates that help to subsidize the journal as a whole. In addition, the papers may represent a significant source of revenue for journals. As described below, pharmaceutical companies use their sponsored papers to sell their products. Representatives take reprints of these papers to physicians' offices to back up their claims, and reprints can be distributed at conferences and in other ways. Richard Smith, former editor of the BMJ, claims that Merck bought 900,000 copies of an paper reporting a large trial of Vioxx (Smith, 2006). Though that number is an outlier, the NEJM can quickly quote a price on an order of 10,000 reprints of an eight-page paper in black and white ($15,974, quote emailed to author). Clearly this represents a conflict of interest on the part of the journals, but it is one that they accept (Lexchin & Light, 2006).

Although they spoke individually, and for the most part did not hear each others' presentations, the editors presented remarkably similar positions. They were concerned to safeguard scientific integrity, and their approach was to insist on performing clinical trials well, reporting them

honestly and in an unbiased fashion, and following rules for writing and disclosing support. Theirs was a transactional view of scientific publishing that does not distinguish between pharmaceutical company-sponsored trials and other trials. As long as they follow the 'rules' of science and of medical publishing, pharmaceutical companies are valued contributors to their journals. Editor SG says,

> The way to get an article published easily, which is what our goal is and yours, is to avoid practices that are going to slow things up and slow the period of time before you can start enjoying the acclaim and the revenue that comes with successful publication in a big journal.

MD, a former editor of another very well regarded journal, emphasizes issues of trial design, as does SG. Each gives a very basic course in trial design and reporting, far too basic considering that most of the audience members have participated in producing many papers reporting clinical trials. LB, an associate editor, but wearing her hat as member of the Council of Science Editors, emphasizes procedural matters of disclosure and authorship; ME, a senior editor at one of the very best known of all medical journals, similarly gives a very simple overview of issues of integrity in publishing, in the context of a discussion of a history of the journal's conflict of interest policy.

There are different sets of criteria for authorship of medical papers, but the most important is that of the International Committee of Medical Journal Editors (ICMJE), adopted by most journals. According to these criteria,

> 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 paper 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. (International Committee of Medical Journal Editors, 2005)

These criteria are an attempt to enforce traditional notions of authorship, tying credit to intellectual responsibility, which begets moral responsibility (Biagioli 2003), this contrasts with some notions of authorship in large collaborations in particle physics, that assign authorship to all members of a laboratory (Galison, 2003). While some editors explicitly condemned ghostwriting, there was also appreciation of medical writers, who improve manuscripts. LB says, 'We appreciate it as editors because we have to read a lot of papers and we can tell which ones have had expert writers participate in their development.' She goes on to describe what *authors* need to do to make sure that medical writers don't become ghostwriters:

> An academic researcher needs to insist on early active involvement in the research project. They should decline any offers to sign off on already-written manuscripts, particularly in review articles. They should insist that the article reflects their own interpretation of the evidence. They have to be adamant about full disclosure … .

Thus the burden is placed on academic authors who, by implication, sometimes fail at one or more of these junctures.

While there was some attention to fraud, these and other speakers focused on fraud perpetrated by independent scientists: the recent Hwang, Poehlman, and Sudbo cases (Couzin et al., 2006; Couzin & Schriber, 2006; Sox & Rennie, 2006) were all mentioned at least three times over the course of the conference, and described once by editor ME. This is roughly consistent with the approach of the British journal editors' organization, the Committee on Publication Ethics (COPE, 2008). With one large exception – a single case given a whole session – probable cases of pharmaceutical industry fraud were ignored, and even flatly denied by a physician, SU, speaking as an ethicist. Similarly, the editors placed a certain amount of emphasis on the fact that medical publishing's rules are applied evenly. Editor LB says,

> All these comments about authors and sponsors apply regardless of the affiliation of the author or the sponsors. So the sponsor can be the NIH [National Institutes of Health], it can be a private foundation, it can be a university, or it can be a pharma company, whoever's sponsoring the research and whoever's doing the research.

The journal editors thus treated the audience as full and legitimate participants in, and valued contributors to, medical research and publishing. As do medical journal editors as a whole, these editors respond to industry-sponsored manuscripts by welcoming them, even catering to them, but describing a set of rules of conduct and reporting intended to safeguard scientific integrity and authorial function. Although they are aware that the science involves careful interpretive work and depends heavily on expertise, they treat it as formulaic and try to make it more so. Although some editors and editors' organizations have taken strong stances against the pharmaceutical industry's research and publication practices, they probably feel too dependent on the industry for material and revenue to refuse industry manuscripts.

Authors

> Now we often hear this term 'ghostwriting'. … My point is that we use this term sometimes indiscriminately, without understanding necessarily how it will be picked up by those other channels, particularly journalists and the media … . In fact ghostwriting and medical writing could not be more different. And that is the heart of my concern. So my plea is the very careful use of this term, since it has negative connotations, which really damage all of us involved in the process. (BC, the head of a large [220-person] publication planning firm)

A KOL is a well-known specialist, highly regarded by peers, who, in the words of publisher RB, 'can influence other physicians', and who has experience with the product. Thus the KOL is defined by being able to act as a

mediator between companies and physicians. In practice, the term is only applied to specialists who are already enmeshed in relationships with pharmaceutical companies, not to fully independent specialists who merely have the potential to mediate.

Authorship problems represented a major ethical concern voiced in the workshop and conference. Publication planners have difficulties dealing with ICMJE criteria for authorship because their position involves coordinating work by people who they (typically) do not want to become authors, such as company statisticians, company and agency researchers, and medical writers. Perhaps some of these would meet criteria, or perhaps no single person will, as the ICMJE cleaves to a concept of authorship that may not apply to cases of corporate production of manuscripts. Research as managed by publication planners is hard to fit into the ICMJE's framework, and in some sense it directly opposes the implicit ethical stance adopted by those criteria.

Meanwhile, planners want academic authors – or rather KOLs – to appear to have done much or all of the important work behind a paper. Especially since their work is driven by deadlines, these KOLs often do not meet ICMJE criteria. The KOLs are valuable to the credibility of the manuscript and therefore essential to the whole project of publication planning. In addition, relations with them can be severely damaged if their names are removed from manuscripts late in the process. Therefore, it is good if planners can work to create authors out of KOLs.

Although they are recognized as crucial, KOL authors are often portrayed as lazy and greedy. As depicted by planners, they typically make few substantial contributions to the manuscripts they author, are slow to respond, and miss deadlines. They expect prominence in authorship order, and sometimes demand money for their contribution. (Payment to a KOL author contravenes guidelines of good publication practice, and a lawyer speaking at the meeting strongly cautioned against it, because it might be seen as a kickback, and as part of an attempt to manipulate prescribers.) Authors even try to violate ethical practices, for example by trying to remove acknowledgement of medical writers.

To satisfy good publication practice guidelines, authors need to contribute to manuscripts. Publication planners have techniques for managing this process. When an audience member asks, probably tongue-in-cheek, about deadbeat authors, CZ says:

> You can actually guide them to where you want feedback. So don't just say, 'Here's a first draft, and can I have your comment.' Say, 'Here's a first draft, and I've tried to figure out the methodology, to fit within the word requirement. However, I feel, could you pay some attention to this, and have I picked up the right point?' The thing I want to say in this particular discussion is really to push the author to have to make a response, to have to have some input. And if they come back again, then you say 'We'd really like your input on how we pick up this point in the discussion.' And even if at the end of all of that he comes back with little comment, then obviously you've done an absolutely fabulous job and there is nothing to add, and at least you've documented the fact that we have asked every single point at which we wanted feedback.

This planner tries to create authors in the ICMJE sense (though adopting a broad interpretation of the criteria), by giving KOLs very specific writing responsibilities. In the extreme case the author's complete non-contribution becomes a kind of contribution, agreement with and endorsement of the manuscript.

While the planners complain about deadbeat authors, they create the conditions for those deadbeats. According to speaker BJ's estimate, 50% of companies show only the penultimate manuscript to authors, to solicit their input. Although BJ's point is about efficiency – it is expensive and time-consuming if authors insist on large changes to manuscripts at that point – it is likely that authors will have little to add to a well-crafted penultimate manuscript. That is especially likely if they are given tight deadlines. Researcher BB, a whistle-blower and the only speaker critical of publication planning, remarks that part of the problem he faced was that he received abstracts only after they were submitted (and accepted) for meetings, and authors receive manuscripts only days before the planners' deadlines for journal submission. The orderly and efficient rollout of presentations and papers means that authors are likely to contribute little.

We can speculate on the meaning of BC's distinction between ghostwriting and medical writing, quoted at the top of this section. The concept of ghostwriting presumes old-fashioned norms of authorship, which are then violated; in the prototypical case a single author's writing is done by a single ghostwriter. However, medical writing is part of a larger process of the corporate production of knowledge, of which authors are only one link, a weak but important link. Papers are produced by teams, perhaps no single member of which meets requirements for authorship. In this largely unseen process, pharmaceutical companies initiate and fund the planning, research, analysis, writing, and the placing of papers, and typically maintain control of data throughout. In the corporate production of knowledge, medical writers perform their functions, just as planners, company scientists and statisticians … and authors do.

Physicians and Sales Representatives

> Folks, they're dying for your work, by the way. Field reps are dying every day for more of your work. You know that, right? Because that's what doctors are going to see. (RS, consultant)

Publications address many audiences, and these sometimes create conflicting pressures. Presentations and papers in key meetings and journals may reach the general public via press releases (Ham et al., 2008). They reach researchers who influence clinicians, and also some clinicians directly. They may also be distributed to clinicians by sales representatives. Of these routes, the last is most important and most regulated.

At the ground level, pharmaceutical sales representatives use reprints of publications for promotional purposes. In the USA, the only national jurisdiction specifically discussed during the meeting, promotion is regulated by the Division of Drug Marketing, Advertising and Communication

(DDMAC), part of the Food and Drug Administration (FDA). If a paper is going to be used for promotion, it cannot contain anything that might be seen as a recommendation for off-label use. It also has to be balanced, and not contain false or misleading information, a point made in the ethics portion of the 101/201 workshop. So if the paper is to be used for promotion, planners involve the pharmaceutical company's legal and regulatory departments, getting them to read the penultimate draft.

There is some ambiguity about this situation. Of interest to the community has been a challenge to the FDA's understanding of the scope of promotional activity. The Washington Legal Foundation (WLF), an organization defending 'business civil liberties', has argued that distribution of reprints of peer-reviewed scientific papers should be considered as part of a scientific 'safe harbor' as long as the reprints are not accompanied by additional promotional messages (Washington Legal Foundation, 2007). This challenge would allow sales representatives to distribute scientific papers on off-label use, and thus ease the constraints on planners. Since the ISMPP meeting, the FDA has proposed making all peer-reviewed papers part of the scientific safe harbor for sales representatives, more than capitulating to the WLF challenge (Food and Drug Administration, 2008).

RS, a consultant to the pharmaceutical industry and an expert on regulatory issues, identifies the difficulty of actually complying with even the WLF's understanding of this safe harbor:

> Those of you who've been a sales rep know how difficult that would be. First reprint I've gotten now in three years, and I've got it gripped, I've got it in my hand. … So now I'm now in an office and I've got this reprint and I think 'Hi doc, good to see you today. By the way, and one more thing, here's this reprint. Goodbye.' What do you think the doctor's likely to say? … 'What's this about?'

However, she also points out that there are only 20 to 25 regulators working in DDMAC, who have billions of dollars worth of promotional activity to monitor, so the chances of being caught are small. Talking about representatives distributing papers, RS says:

> Some of your companies … are distributing some of your reprints through the sales force even though they may not be totally consistent with label. I am not here to say that that is illegal, wrong, and you shouldn't be doing it. Whatever your company has determined to do in today's world, I am sure that they have determined it through great thought and care and have made the right decision, whatever that may be. So please, as they think about it, what they are thinking about is balancing that balancing act between not promoting off-label and trying to come up with a scientific exchange reason to be able to hand out the reprint without selling from it. It's the normal way.

Luckily for the companies, there are many vectors for the dissemination of reprints. There are the sales representatives or 'drug reps' (Oldani, 2004), earlier called 'detail men' (Greene, 2004). But large companies also employ 'field medical directors', 'field medical information scientists', and 'medical

information managers', all of whom provide physicians with information without engaging in promotion, says ethics seminar leader FJ: the field medical director is to the sales representative as the publication planner is to the marketer. Unlike sales representatives, field medical directors have advanced degrees in relevant sciences, and do not have prescription quotas they are expected to meet. Communications between these professionals and physicians are deemed to fall under the scientific 'safe harbor', as long as they do not involve promotion. However, FJ complains, materials that field medical directors distribute are also tightly regulated, and must be submitted to DDMAC 60 days prior to dissemination, which creates more constraints on getting the publications to physicians.

Given these different routes to physicians, with their different regulatory contexts, publication planners have to understand the purposes of manuscripts before they are written. Again, this places their work in the context of broad communication strategies.

Creating Knowledge through Mediation

> I'm on a publication planning team right now on a limited budget. We had a publication plan with 20 publications for early 2007. We just got cut and now we can do perhaps five. The clinical trials director gave his five priorities, the director of marketing had a different five, and the director of medical research had yet another five. So we had to have a meeting to hash it all out. (FD, publication planner)

Publication planners are both outsiders and insiders to the clinical research world. They are outsiders because they are not physicians or statisticians, who would normally be thought to contribute most to clinical research, and do not play a visible role in knowledge production. They are insiders because they often have detailed knowledge about clinical research, pharmacology, and medicine – in conversations I had with planners, they appeared fluent in the areas in which they were currently working. More importantly, they contribute to an enormous amount of research: a typical active planner is involved with many more research publications than are most medical researchers. In Collins and Evans' (2002) terminology, planners have demonstrated 'contributory expertise', though they would not normally be seen as legitimate bearers of it.

I had hoped that the meeting would reveal some general insights about clinical knowledge. That is, I had hoped that planners would have analyses of medical knowledge, stemming from their need to create it efficiently. I was disappointed, whether because their analyses weren't revealed during the meeting, because I did not recognize analyses as such, or because they didn't have any. Nonetheless, the meeting strongly suggested explanations for the effectiveness of knowledge-creation driven by the pharmaceutical industry.

Clinical research and publication is unusual in that acceptable methods have been very precisely spelled out, and these have been widely accepted. The randomized, controlled trial (RCT) is a recent development,

with Austin Bradford Hill's 1946 trial of streptomycin for the treatment of tuberculosis often being considered the first modern RCT. Since then, advocacy by statisticians and medical reformers has led to the RCT becoming the 'gold standard' of clinical research for both researchers and physicians – a standard considered far more valuable for clinical purposes than observational or laboratory studies (Marks, 1997; Timmermans & Berg, 2003). Reports of clinical trials are relatively formulaic and constrained, as journals demand tightly structured papers, and increasingly demand structured abstracts. Though there are many choices behind any paper reporting a clinical trial, there are fewer choices about the format or language they employ.

It may appear, then, that at least for clinical trials the work of planners and writers is relatively mechanical, or that their main job is to balance sponsors' with editors' demands, to tread a fine line between marketing and science. This would account for my not seeing any of planners' analyses of knowledge creation: if the work is mechanical, then there would be little to analyze. However, there is abundant evidence that designing, analyzing, and writing-up results from clinical trials involves extensive decision-making. Planners also handle other kinds of research and manuscripts. And planners do not represent their own work as mechanical. Speaking without apparent humor, BC tries to present agency concerns to those working in pharmaceutical companies:

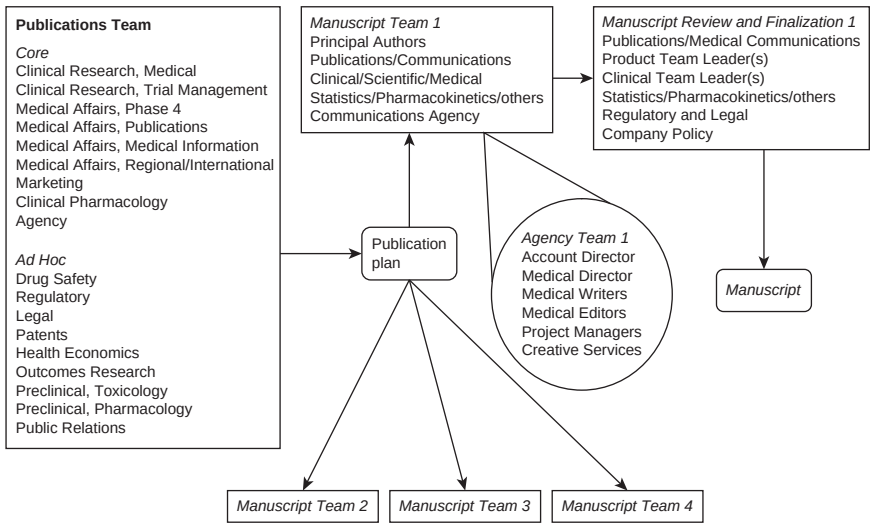
> My plea here is to think again about attempting to commoditize something [publication planning and medical writing] that is actually a highly tailored service, a professional skill. I believe that commoditization undermines the value of medical writing. You're not buying widgets.

Despite appearances, one cannot buy manuscripts by the gross – by the dozen perhaps, but even then they are individually crafted.

Manuscripts and their forerunners are in the hands of many skilled contributors and reviewers. In addition to making their own contributions, planners facilitate their teams' work, keeping in contact with medical writers, making sure that all documents produced are consistent with the plan, managing information, and reconciling divergent demands and suggestions. The work of the planner is creative mediation, using the insights of the many people who come into contact with data and drafts to develop manuscripts that will fare better in peer review, and will have an impact. This is the mediation familiar to anybody who has chaired a committee charged with producing a complex document, not quite the broader and theoretically exciting mediation central to actor network theory (Callon, 1986; Latour, 1987).

Pharmaceutical companies, like all large companies, are complicated organizations. From the outside we might be tempted to see them as consistently organized around producing their usual huge profits. However, they are split into divisions that develop their own proximate goals, often conflicting with the company's overall goal and the goals of other divisions. The clinical trials department may be trying to increase the number of trials it performs, and to thereby increase its budget and importance. That

FIGURE 1
Publications and manuscripts teams



department may be permeated with values other than strict market values, including imported scientific values that emphasize rigor and caution. Thus, says FD, 'publications reflect the work of several functions and matter to several functions'. For this reason publication planning is done by stratified teams, as represented in Fig. 1, my consolidation of several different discussions.

Manuscripts run a gauntlet, being subject to scrutiny by many actors with differing goals and requirements. The overall publication planning team, says FD, 'ensures buy-in from all stakeholders', because those stakeholders have input into the process and result. The multiplication of contributors multiplies the knowledge. Pharmaceutical company planner CI says:

> Involving folks early works. The sooner you involve them before you have data available the easier it is. Much, much easier. You go from having one manuscript to having eight from a pivotal program. Which is phenomenal. And it's not data-mining, it's just things that are relevant to the clinical practice in that area.

Of course, many actors may give the manuscript only a cursory review, and may have little or no positive input into it. MH notes, 'All the people on the [manuscript development] team have input. But if 3 or 4 can get together and work things out' it will be a lot more efficient. Similarly, BJ, the efficiency expert, claims that the internal review process is the most time-consuming part of producing a final manuscript, and should be consolidated.

The wide contributions to pharmaceutical research may appear to be merely a feature of a developing new mode of biomedical science. Cambrosio et al. (2006) describe the development of styles of knowledge

production that depend heavily on distributed work to create data and evidence. That distributed work may take any one of a number of shapes, such as multi-center trials, mass reporting of data for epidemiological studies, meta-analyses, or clinical practice guidelines. All of these forms depend on, first, evidence collected by many different people and/or institutions, and second, regulation of the ways in which that evidence is managed and marshaled. Ghost-managed research and publication typically builds on that base, but is distinctive by being controlled from above by a relatively unified set of actors with narrow interests, by being oriented toward marketing, and in the fact that many of its contributors are constitutively hidden. Ghost-managed research and publication thus might be seen to undermine the regulatory objectivity that the new mode of biomedical science produces (Cambrosio et al., 2006).

Planners (and their medical writers) themselves have considerable expertise, often knowing something about their subject matter, having the experience of working on a much larger number of manuscripts than do most researchers, and consequently understanding the world of medical publishing very well. In addition, they sit in the middle of a number of other experts who are all interested in producing high-quality publications, and who are contributing to them, albeit in different and possibly contradictory ways. The careful rhetorical work in papers on clinical trials, like that which goes into major papers in any field, is done by a distributed network, and one that has access to substantial resources. In the context of regimented demands from journals, and a suppression of individualized voices, science by committee may be ideal: analyses and papers effectively go through review before being submitted to journals.

Discussion

> We call it a sales force, but our sales force doesn't sell. It transmits knowledge. (Hank McKinnell, Pfizer CEO; quoted in Petersen [2008: 321])

Commercialized science has been of wide interest in STS in recent years, in a variety of different contexts. In particular, analysts have explored the ways in which connections to industry are shaping academic cultures and the scientific knowledge they produce (for example, Slaughter et al., 2002; Kleinman, 2003; Metlay, 2006). The pharmaceutical industry's adventures in medical research are probably the most prominent and largest connections between industry and the academy. Medical researchers appear to have normalized their relations to the pharmaceutical industry to the extent that most prominent experts have substantial ties to the industry: it is commonly believed that one can find either expertise or disinterested science, but both together only with difficulty.

Publication planning takes this process several steps further. The *visible* experts who serve as the prominent authors of ghost-managed research stand in front of a number of other people who have likely done the bulk of the intellectual and organizational work to produce the published knowledge.

Visible experts are needed for their authority and independence, not for the contents of their expertise. In the commercialized science I describe here, published research is valued for its marketing potential. Ghost-managed research does not merely shape academic cultures and the knowledge they produce, but makes them unnecessary except to provide authority.

The ghost management of medical research has thus rehabilitated the connection of authors to authority: academic authors are valued almost entirely for their authority. The more hidden contributors to the research, analysis, and written material are entirely capable of producing texts on their own, but without KOLs their work has much less value.

Interestingly, just as medical research in general has normalized ties to the pharmaceutical industry, so has medical publishing – as well as, in different ways, regulatory agencies (for example, Daemmrich, 2004; Abraham, 2007; McGoey, 2007). Thus, journal editors can address an audience of 400 publication planners, warn them against ghostwriting and the inappropriate manipulation of data, and then solicit their business. At the same time, the planners are keenly attentive to scientific norms, because it is only by meeting those norms that they can distinguish themselves from marketers, and in so doing achieve their marketing goals. Theirs is the job of persuading without appearing to persuade.

Implicit in many of the exposés of ghostwriting in the medical science and popular literature is an assumption that ghostwritten science is formally inferior. Given the very high acceptance rates of ghost-managed papers, that assumption is questionable in general – though it may be right about important cases (Psaty & Kronmal, 2008). Pharmaceutical company research, analysis, and writing results in knowledge. It is not different from other medical research, analysis, and writing in the fact that companies and their agents make choices in the running of clinical trials, in interpretations of data and established medical science, and in the messages they convey in papers and presentations. This point is straightforwardly suggested by STS's longstanding commitment to symmetry (Bloor, 1976). It is justified by the results of canonical studies that have shown how science is choice-laden (for example, Knorr Cetina, 1981; Pickering, 1984; Collins, 1991). Thus, the work of pharmaceutical companies to produce research and place it prominently in medical journals is not merely a corporate use of the patina of science. It is science, though it is science done in a new, corporate mode.

Pharmaceutical company research, analysis, and writing *is,* though, different from other medical research, analysis, and writing in being driven by a very important and well-defined set of commercial interests. Despite the scrutiny the notion of interests has received in STS (for example, Woolgar, 1981; Latour, 1988; Ylikoski, 2004), it is well established that such material interests will typically shape the knowledge that they drive (for example, MacKenzie, 1978; Shapin, 1979; Mercer, 2002). There is scope for STS to analyze and challenge ordinary notions of conflict of interest, both in terms of treating it symmetrically and understanding it causally. Nonetheless, we can reasonably treat material interests in this arena as establishing something akin to pervasive conflicts of interest. That is, many

people might object to commercial interests importantly shaping medical research, seeing those interests as importantly illegitimate in this context. Conflicts of interest here cannot be easily addressed by formal rules to enforce scientific standards. The interpretive flexibility of those formal rules means that people following them can still shape the knowledge that they produce to reflect their material interests. In addition (this is not a problem raised by insights from STS), so much of the research and writing process takes place outside of public view that it might be extremely difficult to identify and assign blame for violations of rules. Objectionable conflicts of interest should be addressed by eliminating them, by keeping, for example, pharmaceutical research, writing, and publication isolated from unacceptable interests.

Everybody systematically connected with publication planning wants established formal rules of conduct. As sub-contractors, publication planners would like to reduce uncertainty, so that they can plan ahead and so that they can produce exactly the papers that will satisfy all of the different parties with whom they interact. Both publication planners and pharmaceutical companies want formal rules to guide and cover their work, to legitimize it so that its exposure does not amount to scandal. Although there was not room to demonstrate the point here, when planners invoke ethics they prefer to treat it as a defensible code within which work can go on, not as a substantive goal. Editors explicitly express the hope that a combination of authorship guidelines, standardized procedures for the performance and analysis of clinical trials, and standard formats for journal papers will control for problems of bias, even though (as they sometimes recognize) publication planning generally runs directly against the goals behind those guidelines and standards. The FDA and other regulatory agencies look to rules to govern the use of medical journal papers because there is an intrinsic conflict of interest in this arena, and these agencies are either not powerful enough to eliminate it or do not care to do so; the conflict of interest can only be managed. Undoubtedly, all of these parties recognize that there is considerable interpretive flexibility in any of the rules guiding good scientific, publication, or marketing conduct that they might create. That may not matter – indeed, it may be attractive to some of the parties – as these rules of conduct serve largely as devices to insulate institutions and people from charges of unethical behavior, rather than devices to achieve objective scientific results or ethical behavior. Rules to govern good publication practice may enable trust, as rules to create formal objectivity (Daston & Galison, 1992; Porter, 1995), but for those trying to put them in place the primary purpose of the rules is to enable deniability. Actors can more easily avoid responsibility for the consequences of their actions when they can make cases that they are following rules, even if they steer very close to the edges of those rules, or pass beyond, the edges of normal acceptable behavior.

In the ghost management of medical research by pharmaceutical companies, we have a novel model of science. This is corporate science, done by many hidden workers, performed for marketing purposes, and drawing

its authority from traditional academic science. The high commercial stakes mean that all of the parties connected with this new science can find reasons or be induced to participate, support, and steadily normalize it. It is likely here to stay for a while.

Notes

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Sergio Sismondo is Associate Professor of Philosophy at Queen's University, Canada, with a cross-appointment in Sociology. He is a generalist in STS, and the author of *An Introduction to Science and Technology Studies* (Blackwell, 2004). His current work concerns the political economy of pharmaceutical knowledge, focusing on industry sponsorship of clinical trials. This work began with his chance editing of a special issue on pharmaceutical research and marketing in this journal (vol. 34(2), 2004). He has also explored mathematical models and computer simulations, and issues at the intersection of STS philosophy of science. See <www.sismondo.ca> for further details.

Address: Department of Philosophy, Queen's University, Kingston, Canada K7L 3N6. Email: sismondo@queensu.ca