Publication Planning 101: A Report

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ABSTRACT

Publication planning is the sub-industry to the pharmaceutical industry that does the organizational and practical work of shaping pharmaceutical companies' data and turning it into medical journal articles. Its main purpose is to create and communicate scientific information to support the marketing of products. This report is based mostly on information presented at the 2007 annual meeting of the International Society of Medical Planning Professionals, including a workshop entitled "Publication Planning 101/201", attended by one of us. We provide some analysis of the role of publication planning in medical publishing, and its implications for the structuring of medical knowledge.

INTRODUCTION

Because of their valued status, in the past two decades pharmaceutical companies have increasingly and systematically used primary and secondary publications on clinical research to affect the opinions and prescribing habits of physicians. The marketing departments of pharmaceutical companies increasingly treat clinical research as a carefully developed and deployed asset. What follows is an account of a pervasive but largely unknown drug research practice called "publication planning". The primary purpose of publication planning is to create and communicate scientific information to support the marketing of products (1, 2, 3, 4, 5). Our report is based on information presented at the 2007 annual meeting of the International Society of Medical Planning Professionals (ISMPP) attended by one of us (Sismondo), including a workshop entitled "Publication Planning 101/201"; in addition we draw on planning agencies' self-presentation on websites and on secondary sources. We provide an analysis of the role of publication planning in medical publishing, and its implications for the structuring of medical knowledge. Unless otherwise noted, all quotes in this report are by speakers at the 2007 ISMPP meeting; to guard their identities, speakers are labeled with fictitious initials.

Organizing Publication

Pharmaceutical company research and its presentation in journals and conferences has increasingly become governed by extensive publication plans. Most sponsored clinical trial research is handled by Contract Research Organizations (CROs), the data they produce is typically analyzed by pharmaceutical company statisticians, articles are written by medical writers, and the process through to submission is typically supervised by publication planners. Many publication planners work for independent agencies hired on a contract basis, though pharmaceutical companies employ a substantial number directly.

Planners are almost always involved in the design and composition of industry-sponsored articles, and they are sometimes involved in designing the studies that lead to those articles. So while the bare publication plan is a document that, says conference presenter and publication planner MH, "outlines the recommended medical communications and their timings," the activity of publication planning is broader. According to planners, their work can and should start even before the research does.

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They prefer to be involved in all aspects of the process, including: research design, the formulation of key messages intended to guide research, the tailoring and distribution of articles to particular audiences and journals, and the selection of potential authors for those articles.

The best publication plans specify in detail how the production of presentations and journal articles is to be accomplished, drawing on information on 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. Tactical recommendations are developed for specific submissions, dates of submission are laid out, and dates of publication are then projected. A plan may also describe other communication opportunities, such as symposia and roundtables, journal supplements, advisory board meetings, monographs, slide programs, formulary kits, and more. One gets the impression of a world without uncertainty, of articles written and published on schedule. According to CI, "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."

Depending on the circumstances, the publication planning team might be formed upon proof of concept, two years before the expected launch of the product, at the start of Phase III trials, or when the company begins making expenditures on commercial plans. The publication planning team should be put in place early, says planner FD, "before too much data has gone unpublished." Being present for the designing of research projects is especially important if there is "need to create (a) market" or need to create an "understanding of unmet need".

Although it is now a common business practice, and although there are instances of marketing campaigns that look like publication plans that go back to the 1950s, such as Merck Sharp & Dohme's campaign for chlorothiazide (Diuril) (6), publication planning as a systematic activity is relatively new. According to HK, a senior member of the field and the CEO of a medium-sized agency, its origins can be traced back to research planning done by Pfizer on amlodipine (Norvasc) in 1984. But the rise of publication planning did not occur until the mid-1990s, and may be connected to other big changes in the global pharmaceutical economy that were taking place at the time. The 1990s saw an enormous increase in global sales of pharmaceuticals, at an average rate of over 10% per year (7). This was largely the result of an increasing number of blockbuster drugs and consistent high sales growth in the U.S. (despite the widespread perception of decreasing levels of innovation). Perhaps related, it was a period that saw a large number of mergers and acquisitions in the industry (8). There was also a change in the structure of research: industry funding for academic research was increasingly shifted to private CROs (9). The simultaneous rise of the publication planning and CRO industries is almost certainly not coincidental, since CRO research can be exploited for marketing purposes more easily than academic research. Some CROs even own publication planning agencies. For example, Quintiles, which advertises itself as the world's largest CRO, owns Innovex, a company that "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" (10).

Marketing

Publication planning presents itself as being in the service of developing and disseminating scientific knowledge: "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 planner NF. Planners understand that they are in a sensitive position. On a number of occasions ISMPP conference audience members were reminded to watch what was written down or entered into databases, because if publicized, some of their work could be construed as ethically questionable or illegal. Seminar leader MH suggested that planners talk about "communication points" rather than "messages," because critics see the latter as driven by marketers. CZ says "we need to look very carefully at those messages. And if there is some words in there that could imply marketing intent, we need to avoid them."

Yet, planners recognize that their work has marketing value. Tongue in cheek, industry consultant RS asks the audience at the ISMPP meeting: "By the way, is anything you do ever used in a promotional context? Oh yeah!" On its website, Watermeadow Medical says that "We'll ensure your products and markets are thoroughly prepared, supported by persuasive and professional communications." Their services include "developing all types of manuscripts, such as primary manuscripts, secondary manuscripts, review articles, letters, editorials and proceedings supplements, as well as abstracts and posters"(11). Envision Pharma's site says that "data generated from clinical trials programs are the most powerful marketing tools available to a pharmaceutical company"(12). Conference presenter MH says that publication plans should identify "target audiences," should lay out key "scientific & clinical communication points," should do "competitor publication & gap analyses," and need to outline "top-line tactics" and "critical timing." The number of articles produced by a publication planning team should peak at about the time that the product launches, for maximum commercial value, ensuring that medical professionals are familiarized with the product at a commercially optimal time. NF, who had earlier stressed the difference between publication planning and PR, asked, "How are we going to create publications that have the right message, and a memorable message, for prescribers?"

Promotion through publication can take various forms. Publisher RB complains to an audience of planners about the pressures on journal space caused by an effective technique – the saturation of journals with information on a particular drug: "You don't help when you take your research and you do your primary publication and then you follow it with 20, 30, 40 secondary analyses." Although RB is exaggerating for effect, his point is corroborated minutes later by a planner: "There are more publication ideas coming from my medical team than we can handle even if we had 15 agencies and 20 people focused solely on publication for this one area. That's one of the bigger challenges, cause it adds more analyses. And now I need more statisticians, I need more investigators, I need more authors. I need more writers." Her developing point is that planners need to winnow ideas for articles early, for sake of efficiency.

Indeed, the publication plans that have become visible involve significant numbers of articles, 85 in the case of a campaign for sertraline, and perhaps 96 in the case of rofecoxib (1) (13). These and similar numbers suggest that 40% of important journal reports and a significant percentage of meeting presentations on clinical trials of new drugs are “ghost managed” through to publication – controlled or shaped by pharmaceutical companies or their agents at multiple steps of research, analysis, writing, and publication (3).

Consultant RS discusses other promotional techniques, such as the strategic use of articles that are not directly about drugs: "The newest thing right now is disease states. … You all know what I'm talking about, where you don't mention the name of the drug but you talk about the disease." She goes on to discuss the promotion of off-label use, and warns of the dangers of regulators seeing publication plans: “If they looked at a publication strategy that, I don't know, had, 'We're going to put out 80 papers this year on one drug, all off-label. 50 of those will be review articles where we'll pay someone to write about off-label use….'" A regulator who saw that would have to act forcefully, as, for example, the FDA has acted in some other cases of off-label promotionn (14).

Ultimately, then, agencies make innovative use of medical journal articles to generate sales revenue for their clients. And as with other marketing initiatives, they want to be able to measure and demonstrate their success at achieving this goal. Two presentations during the ISMPP meeting addressed the difficult problem of how to measure the return on investment (ROI) of publication planning. In one of these, BJ, an efficiency expert talking on metrics argued that the "scientific objective" of increasing awareness directly produces the "commercial objective" of improved ROI. A second presentation on ROI suggested that off-label use was a good measure of the effects of journal articles, because in principle it is unaffected by the actions of sales reps and other vectors for marketing.

Though planners understand that their work has marketing value and is funded because of that value, 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, would 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 — though it does typically retain that one place, because "they're probably paying the bill." LB, a journal editor speaking at ISMPP, corroborated the antagonism between marketing and science, exhorting the audience to prevent marketers from writing manuscripts. She can tell, she said, when articles are written in the marketing department; they are peppered with certain adjectives and adverbs that a scientist wouldn't write. Such articles are typically rejected.

For planners, scientific standards are doubly important. First, meeting these standards constitutes part of what is considered ethical behavior. Concern with ethics is important, both for itself, and for sake of appearances. Thus ISMPP has recently adopted a “Code of Ethics” (15); in terms of the concerns of those outside the industry, this later document essentially repeats an earlier “Good Publication Practice Guidelines” (16) accepted by the organization. Second, publication planners can only successfully publish if their work displays high standards. They claim to have very high acceptance rates; for example, an "acceptance rate on first submission of 94% for abstracts and 78% for manuscripts (17). The three editors of major medical journals speaking at the ISMPP meeting appeared to recognize this, as they appeared to be actively promoting their journals and soliciting manuscripts.

It is only by stifling the marketing department's efforts to hype the product that publication planners can effectively market to scientific audiences. Yet, publication plans exist to serve the marketers, and therefore the planners have to convince the marketers that their more subtle approach is the right one: to "sell without selling" is a sales and marketing ideal, as the most persuasive rhetoric is successful in part because it is not marked as rhetoric (18).

Authors and Ghosts

Authorship is a major issue for publication planners and was a major issue at the ISMPP meeting. Publication planners have difficulties dealing with the International Committee of Medical Journal Editors (ICMJE) criteria for authorship, which stipulates that an individual author must make a substantial contribution, and be closely involved in and responsible for ensuring the accuracy of research (19). Industry publications are produced not by individuals, but by coordinated teams including company statisticians, company and agency researchers, medical writers, and sometimes independent researchers. Though some of these people might meet some of the authorship criteria, it is unlikely that any single individual, and rarely any of the independent researchers, will meet all of them.

Because of the commercial importance of having the right sort of author, publication planners regularly find “key opinion leaders” (KOLs) to serve as the nominal authors of manuscripts. A KOL is a well-known medical specialist, highly regarded by peers, who serves as a mediator between pharmaceutical companies and physicians, has experience with the product, and in the words of publisher RB, "can influence other physicians". This allows planners to make it seem as if articles were written by respected independent researchers, instead of by coordinated corporate teams. It increases the perceived credibility of an article and also functions to hide features of the research process: even though they usually contribute more than the nominal authors, company statisticians and researchers, reviewers from an array of departments, medical writers, and definitely the publication planners themselves, are only rarely acknowledged in journal publications (20, 21), and mention of the corporate sponsorship of articles is omitted from many meeting abstracts (22).

Although they are recognized as crucial, KOL authors are portrayed as lazy and greedy. As depicted by planners, they typically make few contributions to the manuscripts they author, are slow to respond, and miss deadlines. But even to partially legitimize their status authors need to contribute something to manuscripts, and publication planners have developed techniques for managing these contributions, partly in reaction to the (for the industry) ill-suited ICMJE criteria and an awareness. 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."

Though the planners complain about deadbeat authors, they create the conditions for those deadbeats. In general, KOL authors are not likely to have seen the data. Industry representative RQ argues that authors should not be given access to the data, because they may lack the knowledge needed to interpret it properly, and they may have their own agendas. "As the owners of the study database, the sponsors will decide who will have access to the database. … PhRMA companies commit to making a summary of the results available to the investigators." 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, especially if they are given tight deadlines. In the extreme case the author's complete non-contribution is interpreted as a kind of contribution – agreement with and endorsement of the manuscript. Therefore, it seems that planners typically view the author as just another member of the team whose job is to perform his/her function in order to serve of the interests of the planning team, and ultimately, the interests of the corporate sponsor.

Medical Journals and the Value of Manuscripts

Mentioned above is that editors of three very highly respected medical journals addressed the conference, and a representative of a publishing company; in addition, another editor spoke, representing an association of journal editors. The publisher and one of the editors took their opportunity at the podium to promote their journals, soliciting manuscripts from the audience; the others merely mentioned their journals frequently. None of the editors were critical of publication planning, and one thanked planners for producing better manuscripts than academics do on their own: "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." All the editors framed misconduct as either an abstract problem or a problem for authors, not the pharmaceutical industry and its agents. For example, editor LB says: "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 ….."

These editors appear to be well aware that many manuscripts are funneled to them via publication planners. One of the publication planning document that has come to light makes it clear that planners, not authors, are the journals' primary contacts on many manuscripts (1). In addition, journal editors recognize that the publications have a market value. 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 the period of time before you can start enjoying the acclaim and the revenue that comes with successful publication in a big journal."

Industry articles also make money for the journals, through advertising and reprint fees. Publisher RB explicitly recognizes the connection between articles and advertisements, saying "If you have special requirements, like you need an ad or a logo, … tell us." Richard Smith, former editor of the BMJ, claims that Merck bought 900,000 reprints of one paper reporting a large trial, which would have brought the journal in question (NEJM) a very substantial amount of money (23). Those reprints would have been distributed to physicians and other prescribers, to buttress sales pitches with scientific evidence. Finally, the journals simply want industry articles, because they tend to be better cited than non-industry articles (1).

Clearly, although some editors have taken strong stances against the pharmaceutical industry's research and publication practices, they are too dependent on the industry for material and revenue to refuse industry manuscripts. In this and other regards, medical journals have conflicted interests

(24). Moreover, there are direct financial connections between some journals and publication planners. Some planning agencies are owned by major publishers (3), and as has been seen, in extreme cases planning agencies create entire journals in order to market products: Elsevier's planning agency Excerpta Medica created *The Australasian Journal of Bone and Joint Medicine* and other journals for Merck and other pharmaceutical companies (25).

CONCLUSION

Ghost-managed research is not neutral or disinterested. Designing, analyzing, and writing up results from clinical trials all involve extensive decision-making. In addition to making their own contributions, publication planners organize and facilitate their teams' work, communicate closely with medical writers, ensure that all documents produced are consistent with the plan and reconcile divergent demands and suggestions. The work of the planner is creative mediation: planners use the insights of many people who come into contact with data and drafts in order to develop manuscripts that will both communicate influential messages to physicians and fare well in peer-review.

Yet, in order to better perform its promotional role, ghost-managed research presents itself as neutral and disinterested. Many physicians are all too familiar with the fact that pharmaceutical sales representatives often rely on laudatory peer-reviewed publications in their sales pitches. Publications are invaluable tools for sales reps who want to influence the prescribing habits of physicians. In a survey conducted by PhRMA, 53% of physicians identified themselves as relying a 'great deal' on the information provided by peer-reviewed journals when making prescriptions, whereas only 11% identified themselves as relying on (other) information provided by pharmaceutical sales reps (26). Though we may question its accuracy and applicability, this statistic suggests something that publication planners already seem to know: peer-reviewed publications can be more valuable as marketing tools than other tools a sales representative has access to. Thus, it is no wonder that sales reps are often the people who provide physicians with sponsored research; indeed, presentations at the ISMPP meeting made clear that planned publications are designed to be used as tools for sales reps. Because of the invisibility of its planned production, and its more trusted scientific standing, physicians may be more likely to be influenced by this research than by marketing brochures.

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