HOSTS AND GUESTS IN THE HAUNTED HOUSE

AT THE FIRST CONFERENCE OF PUBLICATION PLANNERS I ATTENDED, THERE was a debate about whether authors on articles should be allowed to see the data reported in those articles. Yes, a debate, with people arguing on both sides! The conference organizers had decided to create a panel that would help foster a discussion about publishing ethics. The panel included Dr Aubrey Blumsohn, a medical researcher who had become a whistle-blower, and the discussion ended up focusing on the issue of author access to data.

How did things get to this point?

MEDICAL JOURNALS OPEN THE DOOR

Where are medical journals in the process of ghost-managing articles? Surely, for their own credibility, the journals are doing what they can to keep ghosts out of the process?

Almost every conference for publication planners invites a few medical journal editors to sit on a panel, and occasionally invites a representative from a publisher of journals. At these meetings, the editors don’t show any hostility toward publication planners. On the contrary, they claim to value the work done by planners and the manuscripts they provide. Dr Eaton, editor of a very highly regarded journal, insists, ‘We love publishing pharma papers – if they’re good.’

These editors have extensive dealings with planners, though usually through author intermediaries. Dr Edge, editor of a general medical journal, starts his presentation with a sales job. ‘The journal has a circulation of 87,000, plus
reaching millions through the web. … We have an impact factor of 13.25, which places us fifth among all medical journals.

Other editors make very similar statements. At a different publication planning meeting, editor Dr Eklund promotes his highly specialized journal:

Some statistics. We got more publications [sic] than any other journal in the respiratory field, we get about 3,400 new submissions each year. … It’s hard to tell about circulation today because a lot of things is electronic so it was easy when it was just a print version. When it wasn’t a print version we had the highest circulation of any respiratory, sleep or critical care journal in the world. … The impact factor … is one way that you can get some idea of the quality of what’s published in the journal and the 43 journals that are listed in the ISI with the impact factor we were third last year we still don’t know what the results are for this year. … When you now look at something called the eigenvalue, which takes into account the self-citations of those journals that self-cite themselves a lot, when you adjust for that we are very close to being number one.

And here again is Dr Eaton, shortly afterwards:

To say a little about [journal name]: It’s a flagship journal in [the field]. Our closest competitors, well there is another one with a fairly high impact factor but not with nearly the circulation we have. … We have a circulation about 24,000 and we were also one of the top 100 journals named by the special library association last year. And our impact factor is over 8 and that is very good.

There are obvious reasons why editors would want to tout their journals’ statistics at publication planning conferences, and why they would jockey for position with their competitors and encourage submissions of pharma articles. Some of those articles report on well-funded clinical trials. Given that clinical trials are the most valued sources of medical information, we shouldn’t be surprised when editor Edge announces that his journal is interested in attracting companies’ clinical trial reports, and has instituted a new streaming system to allow
his team to make quick decisions on whether to fast-track clinical trial articles. Articles reporting on clinical trials are likely to be highly read and cited, and of the most highly cited clinical trial articles published recently, the majority are funded by the pharmaceutical industry.¹

A portion of these high levels of citation may stem from an interesting version of self-citation, characteristic of ghost-managed work.² A publication plan that involves fifty or a hundred articles provides many potential entries in its reference list. Later articles will almost certainly cite earlier ones, and all articles can cite ones from earlier publication plans. Describing an episode in her work as a medical writer, Marilynn Larkin writes:

> I agreed to do two reviews for a supplement to appear under the names of respected ‘authors’. I was given an outline, references, and a list of drug-company approved phrases. I was asked to sign an agreement stating that I would not disclose anything about the project. I was pressured to rework my drafts to position the product more favourably.³

Presumably, the list of references Larkin was given was just as drug-company-approved as was the list of phrases – medical writers and publication planners describe the literature review as a key step in the development of an article. It would be curious if reference lists were not skewed toward the company’s previous articles, because those articles support the company’s commercial interests and because those would be the articles or references to hand.

But the reasons why journals welcome ghost-managed submissions go beyond high numbers of citations. Some journals allow companies to sponsor supplements on special topics, at prices that help to subsidize the journal as a whole. Individual articles can become a significant source of revenue for journals, because sales representatives take reprints to physicians’ offices to back up their claims, and reprints can be distributed at conferences and in other ways. As I mentioned in Chapter 2, Merck bought 900,000 copies of an article reporting a large trial of Vioxx.⁴ That number is an extreme outlier. However, when I asked the New England Journal of Medicine to quote a price on an order of 10,000 reprints of an eight-page article in black and white, they responded
within hours (US$15,974 at the time). Clearly this kind of business represents a conflict of interest, but it’s one that journals willingly accept.\(^5\)

The editors at publication planning conferences make remarkably uniform statements. They want to protect scientific integrity, and their approach is to insist on performing clinical trials well, reporting those trials honestly, and following rules for writing and disclosing support. Theirs is a formal view of scientific publishing that doesn’t distinguish between pharma-sponsored trials and other trials. As long as companies follow the ‘rules’ of science and of medical publishing, they are valued contributors.

When talking at planning conferences, many journal editors give a basic course in trial design and reporting – far too basic, considering that most of the audience members are experts in medical publications. Dr East, a senior editor at one of the very best known of all medical journals, gives a very simple overview of issues of integrity in publishing, in the context of providing a history of the journal’s conflict of interest policy. Dr Ellis, an associate editor of a major journal, but here wearing her hat as a member of the Council of Science Editors, emphasizes procedural matters to do with disclosure and authorship. In a long presentation, Dr Eaton does the same, emphasizing the steps that she and some of her colleagues have taken to improve full disclosure of funding and assistance. Dr Edge advises, ‘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’ – Edge clearly recognizes the monetary value of articles to drug companies.

If medical journals are hosts in the haunted house of pharmaceutical research, they are inviting the ghosts to the table, recognizing that they have valuable offerings. All that journals ask is that the ghosts follow rules of good conduct, so that they don’t create too many disruptions.

**Publishers See Eye to Eye**

If journals are willing to work with the industry, publishers are even more so. Mr Porter, the head of a publication planning firm, complains about mixed messages:
“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.” Porter wishes that journals could iron out this difference, but 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 saw in the last chapter, publication planners handle this relationship to their satisfaction; perhaps they hope that journals can, too.

Mr Edwards, who is at this publication planning conference representing a publishing company that owns many journals, explains that if the journal ‘clearly has affiliations with the industry then you may get a more lenient ride’. But independent journals – such as ones run by medical associations – 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, Edwards aligned the publishing industry with the pharmaceutical industry, against the scientific editors who generally sit between the two.

In his talk, Edwards also stands up for editors; the diverse members of his panel were asked to list complaints, and he performs well, chiding his audience and eliciting laughter. Edwards is a young and articulate British executive, exuding London cool while talking to a somewhat more homespun, mostly US-based audience. 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 Edwards’s barrage, there is no doubt that he is on the side of the industry. He wants the 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.

In a promotional moment, Edwards mentions a new journal, an online, open-access, peer-reviewed journal, financed by payments from sponsors, that 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 is a medical version of the dead letters office, where unwanted results go so as not to be read.

Publishers are willing to think much bigger than individual articles. The publishing giant Elsevier produced an entire line of made-to-order medical journals in order to place articles marketing drugs. The planning firm Excerpta Medica, at that time an arm of Elsevier, brokered the deals and provided the imprint for the journals; these included The Australasian Journal of Bone and Joint Medicine (AJBJM), produced to market two of Merck’s drugs. Presumably, the articles placed in AJBJM were chosen for their commercially valuable messages. They were probably written with those messages in mind. The studies on which they are based were probably designed to maximize the chance of Merck-friendly results. Some of those studies may even have been performed only for their public relations value. This isn’t an isolated event: Wiley, known best for publishing in the sciences, advertises on its website that it can produce
‘custom books and journals’ for the healthcare industry. A bespoke journal can offer pharma companies an extremely efficient marketing vehicle.

LAYING DOWN THE RULES: WHO CAN BE AN AUTHOR?

Medical journals try to govern their relationship with pharma mostly by making authors responsible for the content of articles. In effect, that means trying to restrict authorship to those people who can be accountable.

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. For the ICMJE, authors have to claim all of the following:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Versions of the first three requirements have long been in place. The ICMJE added the fourth in 2013, in direct response to concerns about ghostwriters and guest authors, though also about misconduct more generally.

The ICMJE definition tends to restrict authorship. The only people who qualify will have been involved in multiple stages of the research and writing of the article. The ICMJE recognizes fewer and more important authors, which probably reflects medicine’s cultural preferences for how to assign credit. Restricting authorship poses some problems when it comes to large-scale medical research, however.

Clinical research is increasingly decentralized and complex, with teams distributing tasks widely. A large clinical trial, for example, may involve more than a
hundred doctors who recruit and deal with subjects in sites around the globe. It may involve experts in statistics, pharmacology, multiple medical specializations and other fields. Even in fully independent research, the authors don’t necessarily write the articles, because the task of mere writing may be left to more junior colleagues. So, there may be nobody who meets the criteria for authorship of articles stemming from a significant project. The ICMJE definition is an attempt to enforce traditional ideas of authorship, tying credit to intellectual and moral responsibility, but often there simply are no authors in any traditional sense.\(^9\)

In response to some of these problems, though, some medical editors have tried to move in a very different direction. In the 1990s, there was a serious proposal to replace the notion of ‘author’ with that of ‘contributor’, whose precise contributions would be listed in something like film credits.\(^10\) Rather than restricting authorship to a few, the proposal expands contributorship to many. This idea hasn’t been taken up, though a few medical journals, such as Neurology, have defined authorship in an expansive way, requiring that everybody who makes substantial contributions to a manuscript be listed as an author.

Medical journals have difficulties addressing ghost-managed science. First, as I’ve already noted, the journals are conflicted because they want pharma’s manuscripts, which they find valuable. Second, at the practical level, ghost management is by definition hidden. Efforts to ban it have to start by exposing it, perhaps by designing and implementing procedures that trace histories of manuscripts – all difficult tasks.\(^11\)

While most editors speaking at publication planning meetings explicitly condemned ghostwriting, there was also some recognition of the medical writers’ role in improving manuscripts. Here is Dr Ellis: ‘We appreciate [professional writers] 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.

The burden, then, is placed on academic authors who, by implication, sometimes fail at one or more junctures. True, sometimes the authors are egregiously at fault: one editor, in a private conversation, told me that a major difficulty he was dealing with would have been prevented had the lead author even *read* the manuscript he had submitted.

Ideally, the journals want to apply their rules evenly. Editor Dr Eaton, whom I quoted above as saying that she loves publishing pharma papers, repeated the statement several months later: ‘[W]e really love to publish really nice clinical trials, we like that, we really want to. We just want to make sure that everything is as transparent as possible, full disclosure: we want to know who did it, who did what.’ Similarly, Ellis is keen to keep the playing field even for pharma: ‘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, it can be a private foundation, it can be a university, or it can be a pharma company.’

Despite her comments expressing her love of pharma papers, Eaton was the most critical of all the editors I heard, and she was even more critical when I interviewed her. She was also somewhat resigned. Until economic structures of medicine and medical research change, she thought, pharma will have a major presence in medical journals. To a publication planners’ meeting at which she spoke she brought some clear cases of fraud, and she was quick to emphasize that they were recent – she was ready for the common industry response that ethical lapses were a thing of the past! In addition, Eaton recounted her own and her fellow editors’ efforts to try to improve authorship criteria, to try to enforce them, and to try to establish full disclosure of the industry’s involvement in publications – efforts such as the added ICMJE criterion. This last criterion, that authors agree ‘to be accountable for all aspects of the work’, is supposed to convince authors not to sign on if they haven’t seen enough of the study and the data, to try to ensure that the people agreeing to be authors will have had access to the data. But this depends on the honour system, which is almost impossible to enforce.
CONJURING AUTHORS

The most prominent ethical concerns voiced in publication planners’ conferences involve authorship. Publication planners have difficulties dealing with 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 a few company employees could meet authorship criteria, though it’s more likely that no single person would, given the ICMJE’s traditionalist concept of authorship. For example, publication planners and pharma companies do not give writers the authority to approve final manuscripts, so they fail to reach author status. Research as managed by planners is therefore hard to fit into the ICMJE’s criteria. Worse, it directly opposes the ethical stance implicit in those criteria.

Most authors on ghost-managed articles play limited roles. A flowchart drawn by a publication planner working in a major drug company puts decisions about authorship at the fourth step in the preparation of an article, after company employees have presented and discussed the data and its implications, established ‘tactical plans’ and identified the target journal. However, planners want much or all of the important work behind an article to appear to have been done by its authors – or more precisely by key opinion leaders (KOLs) who happen to be authors.

As explained by Mr Edwards, a KOL is a well-known specialist, highly regarded by peers, who ‘can influence other physicians’ and who has experience with the product. In this way, a KOL is defined by being able to act as a mediator between companies and physicians. In practice, the term is only applied to people who are already enmeshed in relationships with pharmaceutical companies, not to fully independent specialists. KOLs are essential to the credibility of the manuscript, and so to the whole project of publication planning.

KOLs may have multiple reasons for agreeing to serve as authors on pharma manuscripts. On the basis of very little work, they add articles to their CVs, and those articles are likely to be more prominent and better cited than average. Although pharma companies don’t pay for authorship, they often ask authors to give generously-paid presentations of, or related to, the research. (Payment
to a KOL author contravenes guidelines of good publication practice, and a lawyer at one publication planning conference strongly cautioned against it, because it might be seen as a kickback, and as part of an attempt to manipulate prescribers.) Finally, it can be flattering to be considered an expert, and the manuscripts themselves may even contain more flattery, as this short excerpt from a legal deposition of a publication planner, discussing a ghost-managed review article, shows:

Q. All right. So before Dr M. Brincat [the eventual author] saw the outline, Designwrite [the publication planning firm involved] had done the medical research, the literature research, to determine whether there was sufficient scientific evidence to support a scientific platform for this article. An outline was drafted and then [Designwrite] approached Brincat and Brincat agreed to be an author; is that correct?

A. That is correct, because it mostly cited Dr Brincat’s research.

Planners often portray KOL authors as lazy and greedy. According to 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. Authors even try to violate ethical practices, for example by trying to remove acknowledgement of medical writers.

Planners would like authors to make some contribution to manuscripts, for the sake of legitimacy, and to gesture toward good publication practice guidelines. However, authors need to be coaxed and coached. When an audience member asked, probably tongue-in-cheek, about deadbeat authors, planner Ms Pace recommended very specific questions as a way of eliciting a contribution:

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?’
Pace 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 planners complain about deadbeat authors, they create the conditions for those deadbeats. According to Mr Palmer’s estimate, 50% of companies show only the penultimate manuscript to authors, to solicit their input. It’s likely that authors have little to add to a well-crafted penultimate manuscript. Having nothing to add is especially likely if authors are given tight deadlines. They may see abstracts for conferences only after they have been submitted (and accepted) for meetings, and receive manuscripts only days before the planners’ deadlines for journal submission. The orderly and efficient rollout of presentations and articles means that authors are likely to contribute little, and are a potential source of disorder.

Publication planners bristle at the term ‘ghostwriter’, and are quick to assert that medical writers are not ghostwriters.

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. (Mr Porter, the head of a large [220-person] publication planning firm)

Increasingly, to forestall potential criticism, medical writers are acknowledged on the final articles, credited with providing ‘writing assistance’. To try to limit accusations of ghostwriting, publication planning associations have adopted codes of ethics. Although most planners think that this is a step in the right direction, not everybody is happy with the attention to ethical codes. At one conference, Dr Klein, a professor of medicine, opened his remarks by saying, ‘My message to you is … stop with the integrity crap, OK, and let’s fight back.'
So I’m never coming back here if we have any more trust and integrity trust-athon events again. What’s wrong with integrity? It gets in the way of profitable interactions between physicians and industry.

Codes of ethics often serve to promote a kind of quasi-transparency. Here, for example, is a typical detailed acknowledgement section from a recent article, the first five authors on which are university faculty and the last three employees of the pharma company GSK:

The authors thank all study participants and their families, all clinical study site personnel who contributed to the conduct of this trial, and the following coordinators/contributors: Dominique Descamps, Karin Schulze, and Pam Kalodimos. The authors also thank Monique Dodet for her precious input during the revision of the manuscript and Benedicte Brasseur for the management of the HPV serology testing. Authors would like to thank Business & Decision Life Sciences platform for writing, editorial assistance, and manuscript coordination, on behalf of GSK. Jonathan Ghesquière coordinated manuscript development and editorial support. The authors would also like to thank Sasi Taneja (GSK, India) and Carole Nadin (Fleetwith Ltd on behalf of GSK) for providing medical writing support.15

Descamps, Kalodimos, Dodet and Brasseur all work for GSK, in different offices around the world; Schulze works for the Swiss MECC Solutions for Life Sciences and Ghesquière for the Belgian CRO Business & Decision Life Sciences. Quasi-transparency here means that we don’t know how much or how little input the academic authors had on the research and writing behind this article; but we do know that many people working directly or indirectly for GSK made substantial contributions.

The concept of ghostwriting often presumes the violation of old-fashioned norms of authorship. In the prototypical case, a single author’s writing would be done by a single ghostwriter. However, medical writing is part of a larger process of the corporate production of knowledge. A vice-president of a large pharma company, addressing publication planners, reminded his audience: ‘I
am going to have my chance to say one final word to you, and that is, please remember [that] in the industry we work in a system which is like conveyor belt. Everybody has a section to do.' Articles are produced by teams, perhaps no one member of which meets requirements for authorship. In this largely unseen process, pharma companies initiate and fund the planning, research, analysis, writing and placing of articles, 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 do. Authors are there to give a sheen of legitimacy and independence to articles.

SHOULD AUTHORS HAVE ACCESS TO THE DATA?

Let’s return to Dr Aubrey Blumsohn and the debate about access to data. Blumsohn, originally from South Africa but long ago relocated to the UK, is a bone metabolism expert with a broad smile, a slightly scruffy beard and an intense commitment to scientific ideals. The company Procter & Gamble (P&G) had asked Blumsohn’s research unit to do new tests on some old samples, to determine whether, though trial evidence had suggested that its osteoporosis drug was less effective than competing drugs, the drugs might be equally effective in practice. The samples were blinded, so Blumsohn had no way of knowing which were from subjects on the drug at issue, or for how long those subjects had been on that drug.\textsuperscript{16} He submitted his results to the company, and was shortly afterwards, along with his immediate superior, made an author on several conference presentations and three journal articles. The articles were put together by a writer, Mary, who had been hired by the company. Mary was introduced to Blumsohn and his superior, Dr Richard Eastell, in an email:

Mary is based in New York and is very familiar with both the risedronate data and our key messages, in addition to being well clued up on competitor and general osteoporosis publications.\textsuperscript{17}

Incidentally, the same email included information on other articles:
Mary and I have just finished writing a publication with [another researcher] (Richard you will be contacted as you're a co-author!) and Mary was involved at the very beginning and wrote from scratch.

Perhaps this was included to reassure the recipients that they wouldn’t have to do much work on the publications.

Blumsohn, though, focused on the data, which looked odd: ‘A key conclusion of all three papers was that there was [a] plateau at a commercially convenient point in the response relationship for the drug – a matter of practical clinical relevance.’ When he asked to see the unblinded data, he was stonewalled:

They claimed that ‘we don’t need to ask an independent person to analyse the data just to make a few people happy’.18

The ‘independent person’ being referred to was Blumsohn, the primary researcher on the work and the intended first author on articles stemming from it. One article was published before his suspicions hardened. On the next article, he refused to sign the medical journal’s author declaration forms; he would have had to attest that he had had full access to the data and took responsibility for the results. The result is that two more articles were not published. Meanwhile, P&G continued to deny him access to the data.

Unfortunately, Blumsohn lost his job for speaking publicly about his conflict with P&G and for accusing his immediate boss of fraud on behalf of the company. When he eventually saw the data, Blumsohn’s suspicions were vindicated, as it turned out that the company had misleadingly focused on the most supportive portion of his results, truncating the analysis where it showed the drug to be ineffective.

Dr McGrath, a medical director at a pharma company (not P&G), was given the unenviable task of presenting the ‘industry perspective’ on the case. He worked for a direct competitor to P&G, but he nonetheless defended the company’s position. Reading stiffly and religiously from the bullet points on his slides, McGrath drew this contrast:
In an ideal world, the data from the research studies would be available freely to everyone, and everyone would have the time and ability to analyse and write up the results accurately and effectively. No one would have a bias or an agenda, and everyone would agree on the results.

But in the real world almost everyone has an agenda, sometimes hidden. And not everyone is skilled at analysing or reporting the results of studies. Differences in interpretation can and do occur, and there are grey areas around such important things as authorship decisions, access to data, and accountability. We all enjoy scientific controversy from an intellectual standpoint. In particular, journals, academic authors and lay press benefit greatly. … Anything that’s newsworthy is considered a win by these participants, especially because it not only attracts attention but an opportunity for additional publications in the future.

Departing from his slides but still speaking carefully, McGrath then reminded the audience of how complicated the analysis of data is, and how individuals might misinterpret it:

I’m aware of cases where amateurs have tried to analyse databases and failed to match up IDs, for example, when they are merging variables from different places and you end up with complete garbage. You wouldn’t be able to identify that if you weren’t already familiar with the database. It puts the sponsor in a position where they have to go back and verify any analysis that is done outside, which is time-consuming and can result in disputes that are very very hard to resolve.

Finally, in a lovely piece of sceptical argumentation, McGrath pointed out that it’s never clear what the data are. Are they the paper records of individual research subjects? Are they the computerized version of those records? Are they the spreadsheets? Or are they the cleaned and analysed spreadsheets? There is no one set of objects that must be ‘the data’. Therefore, the request for investigators to have access to data is incoherent. 19

At the time of this debate, the US lobbying group PhRMA had a clear
policy that applied to its member companies, and McGrath drew attention to it: ‘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.’ Revisions to that code published in 2009 state that ‘[i]nvestigators who are authors of study-related manuscripts will be given all study data needed to support the publication.’ However, the companies themselves can decide what data are – whether they are handwritten patient records, electronic versions of those records, already-analysed reports, or statistics based on them – and what access authors need to support the publication.

**CONCLUSIONS**

Medical researchers have normalized their relations to the industry to the extent that most prominent experts have substantial ties to it. Publication planning takes this process several steps further. The *visible* experts who serve as the prominent authors on 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 their actual expertise. In the commercialized science I’ve been describing, 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.

So, in the ghost management of articles, what are authors? They are shown well-crafted manuscripts that have been reviewed by many scientists, writers, and marketers. They are given only limited access to the data. They are asked for their views on very specific points. They are given short deadlines. For these and other reasons, authors on industry manuscripts are largely sidelined from the process of analysing, writing and publishing research. In these circumstances, authors are unlikely to make major contributions to the analysis or writing of an article.

In the ghost management of medical research, authors are valued for their authority and to obscure the work of others. 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.

Just as medical research in general has normalized ties to the pharmaceutical industry, so has medical publishing. Journal editors can address an audience of 400 or more 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 these 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, selling without appearing to sell.

Almost everybody systematically connected with publication planning wants to work with formal rules of conduct. As sub-contractors, publication planners would like to reduce uncertainty, 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 doesn’t automatically become a scandal. When planners invoke ethics, it is as a defensible code within which work can go on, not as a substantive goal. Meanwhile, editors express the hope that a combination of authorship guidelines, standardized procedures for the performance and analysis of clinical trials, and standard formats for journal articles will control problems of bias; this is even though publication planning generally runs directly opposed to the goals behind those guidelines and standards. Regulatory agencies look to rules to govern the use of medical journal articles because there is an intrinsic conflict of interest in this arena, and these agencies are either not powerful enough to eliminate it or don’t care to; the conflict of interest can only be managed.

Everybody recognizes that there is plenty of interpretive flexibility in any of the rules guiding good scientific publication or marketing conduct. That may not matter – indeed, it may be attractive to some of the parties – because the rules are largely designed to insulate institutions and people from charges of unethical behaviour, rather than achieve objectively valuable science or ethical behaviour. Rules to govern good publication practices may enable trust by
creating a kind of formal objectivity, but the primary purpose of the rules is to enable plausible deniability.

When pharma companies, publication planners and others are confronted by cases of apparent ghostwriting, one of their standard refrains is to insist that ghostwriting is a thing of the past. For example, when one pharma company was contacted in 2010 for a news story about ghostwritten articles from the early 2000s, it declared that it had instituted policies that require authors to be involved throughout their writing. For the same news story, Dr Thomas Stossel of Harvard University, who frequently writes and presents pro-industry commentaries, claimed: “This behaviour has happened, but arguably not often, and probably not recently.”

After I published my first article on publication planning in 2007, the then-President of ISMPP penned a response, saying that my overall claims were out-of-date. He suggested that if I attended an ISMPP meeting I would have a completely different perspective. He did not know that I had taken him up in advance, and that what I took from the meeting, including some of the information I report here, perfectly confirmed what I had written earlier.

My research associates and I attended publication planning meetings spanning 2007 and 2017. In terms of how publication planners present their activities, I didn’t see any substantial difference during that time in terms of the practices being discussed. Yes, later presenters emphasized new codes of ethics, guidelines and operating procedures, but the core of their work has not changed over the course of this decade.

Even though standards are changing, the central conflict has never gone away. Companies want to maintain as much control as possible over the shape and content of publications, so that they can best market products. They also want the names of independent authors at the tops of those publications, to increase their credibility, again so that they can best market products. Industry control, however, is incompatible with independent authorship.