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Abstract

Roughly 40% of the sizeable medical research and literature on recently approved drugs is "ghost managed" by the pharmaceutical industry and its agents. Research is performed and articles are written by companies and their agents, though apparently independent academics serve as authors on the publications. Similarly, the industry hires academic scientists, termed *key opinion leaders*, to serve as its speakers and to deliver its continuing medical education courses. In the ghost management of knowledge, and its dissemination through key opinion leaders, we see the pharmaceutical industry attempting to hide or disguise the interests behind its research and education.

Keywords

medical research, pharmaceutical industry, interests, ghost management, ghostwriting, key opinion leaders, KOLs

1. Introduction

On the basis of the data they produce, as well as publicly available medical research, pharmaceutical companies and their agents produce substantial numbers of scientific manuscripts on major current drugs. They recruit academic researchers to serve as the listed authors of those manuscripts; those authors' contributions typically range from having supplied some of the patients for a clinical trial, to editing the manuscript, to simply signing off on the final draft. The companies submit the manuscripts to medical journals, where they generally get published, contributing to received scientific opinion. Marketing departments of the companies involved often buy thousands of reprints from the journals, so that their sales representatives can present to physicians supposedly independent scientific evidence of the safety and efficacy of the drugs in their portfolios.

Roughly 40% of the sizeable medical research and literature on recently approved drugs is "ghost managed" in the above way by the pharmaceutical industry and its agents (Sismondo, 2007). Ghost-managed work amounts to thousands of articles per year—publication plans for "blockbuster" drugs (ones with annual sales of US$1 billion or more) can involve 80 to100 articles appearing in reputable medical journals over the course of a few years (Sismondo, 2009). Similarly, the industry hires academic scientists, termed *key opinion leaders* or *KOLs*, to serve as its speakers and to deliver its continuing medical education courses. In the ghost management of knowledge, and its dissemination through KOLs, we see the pharmaceutical industry going to great lengths to hide or disguise the interests behind its research and education.

In this article, I provide an overview and examples of pharmaceutical corporations disguising their interests through KOLs and the ghost management of scientific publications. Pharmaceutical companies have the resources to create rigorous science that supports their marketing plans. In so doing they integrate science and marketing, which we might see as an ethically dubious activity, with problematic consequences for the political economy of knowledge. Were the companies to present their research and marketing material without disguises, I argue that material often would be judged in terms of corporate interests. Thus, the KOLs who disguise those interests are valuable to the extent that they can maintain an appearance of independence.

Despite critiques of interests as explanatory, the actors in this system—in particular the companies and their target audiences—treat interests as though they are real and have important effects. These actors thus implicitly reject a formal model of science, under which rigorous science effaces interests, instead recognizing that pharmaceutical companies' choices in the performance and presentation of science will bias that science.

2. Marketing Hormone Therapy

As of this writing, the drug company Wyeth, recently acquired by Pfizer, is facing some 8,000 lawsuits to do with its overpromotion of hormone replacement therapy (HRT); it has lost most of the first handful of cases to be decided. Because of these suits, a number of documents became available for

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public scrutiny on the Internet in 2009 (see Fugh-Berman, 2010). We know, for example, that in the late 1990s and early 2000s, Wyeth turned to the medical education and communication companies (MECCs) DesignWrite, Parthenon Publishing, and Oxford Clinical Communications to work on publication plans and publications for HRT. These agencies created suites of articles and conference presentations that were intended to maintain and expand the market for drugs like Premarin, Prempro, and related products. Over the course of 6 years, DesignWrite produced for Wyeth "over 50 peer-reviewed publications, more than 50 scientific abstracts and posters, journal supplements, internal white papers, slide kits, and symposia" (DesignWrite, 2005).

Hormone *replacement* therapy has been part of a somewhat speculative, though largely successful, attempt to label menopause a condition of deficiency. Reassuring doctors and their patients would turn out to be particularly important commercially, because in 2002 the routine acceptance of HRT for women was shattered. The results of the Women's Health Initiative study indicated that women who used estrogen plus progestin HRT faced an increased risk of breast and ovarian cancer. What is more, while it had been expected that HRT would decrease the risk of cardiovascular disease, the study suggested that risk increased with HRT. After the Women's Health Initiative definitively showed problems with hormone therapies, Wyeth's new publication plan was called "Achieving Clarity, Renewing Confidence" (DesignWrite, 2002). That effort continued previous efforts to establish confidence in the face of cancer worries: On an earlier note about breast cancer risks, a Wyeth employee had written "Dismiss/distract" (Singer & Wilson, 2009).

Here I follow one of these ghostly articles, labeled PC(2) in Wyeth's plan, on a hormone treatment with the feminine inflected brand "Totelle." The first draft of manuscript PC(2) was ready on August 16, 2002. Jean Wright, a member of the Totelle team working for the British MECC and publisher Parthenon Publishing, contacted a group of Wyeth employees. "Please find attached the first draft of PC(2)," she wrote. This manuscript, based on data coming from a clinical trial of Totelle performed for Wyeth, had the unwieldy title "A 2-year comparison of the effects of continuous combined regimens of 1 mg 17β-estradiol and trimegestone with regimens containing estradiol and norethisterone acetate upon endometrial bleeding and safety in postmenopausal women" (Wright, 2002). Just under the title of that draft was written: "Author: to be determined" (TBD, 2002).

Eight months later, the manuscript was still without an author. A March 4, 2003, tracking report on articles and conference submissions to do with Totelle nevertheless showed that Paper PC(2) was making steady progress (DesignWrite, 2003a). At that point, this high-priority manuscript had been revised once by Parthenon in response to December 7 comments by Wyeth employee Daniele Spielmann (revision done on January 3), a second time in response to February 5 comments by Wyeth's Sophie Olivier (revision done on February 28), and had yet to be revised in light of further Wyeth employee Richie Lu's February 28 comments. It was moving toward its final shape.

By April 2, three authors had finally appeared on the tracking report, Wyeth's Daniele Spielmann being the third. A note on the author list read "Need to contact," perhaps suggesting that the first two had not yet been consulted (DesignWrite, 2003b).

The fourth draft was sent to the publication team on March 12, and the fifth on July 2 (DesignWrite, 2003c). By June 6, 2003, the manuscript had clear authors: "Bouchard P, Addo S, Spielmann D, and the Trimegestone 301 Study Group." The first two of these are independent researchers, and the last is the name for a long list of physicians who had provided patients for the Wyeth trial.

But that was not quite the end of the road for manuscript PC(2). An October 27, 2003, report revealed that in July Parthenon updated the manuscript before it was sent out to external authors for their final review. An August 18 note showed that submission had been delayed during Wyeth sign-off process. A note followed on August 29 indicating that "sign-off" was nearly complete, with another on September 22 confirming that it was in the "final stages of sign-off at Wyeth" (DesignWrite, 2003d).

But the authors had changed. They had become "Bouchard P, De Cicco-Nardone F, Spielmann D, Garcea N, and the Trimegestone 301 Study Group." What had happened in the meantime? An email by Spielmann explained: "The 2 Italian authors agree with the paper and replace ADDO woho [sic] went to our competitors" (Spielmann, 2003). In an earlier email Jean Wright of Parthenon wrote: "Please note that S. Addo has been deleted from the author list for PC(2). Daniele was doubtful whether she should be included because she now has connections with Organon," another drug company (Wright, 2003).

In all of this, there is no indication that the external authors made any input. On August 26, 2003, for example, Wright had completed the draft on which Wyeth eventually signed off and mentioned only that she had dealt with queries by yet another Wyeth employee.

Although a 2004 tracking report listed the manuscript as accepted in the journal *Menopause* (DesignWrite, 2004), it actually appeared in the journal *Gynecological Endocrinology*, in the following year—perhaps that had to do with the fact that the latter journal was then published by Parthenon (!). On its publication, article PC(2) took its place in the marketing effort for the new formulation Totelle. Not surprisingly, it found Totelle to be an improvement over earlier hormone treatment.

Authors, it seems, are largely interchangeable. They were all "to be determined" until the publication team thought that the manuscript was nearly ready to be sent out to a journal. At that point, Wyeth appears to have determined who the authors would be, and contacting them was added to its "to do" list. Perhaps there was not much consultation even then.

When Addo established ties with Organon, Wyeth no longer wanted to work with her, and simply replaced her with two other authors. It is not clear that she was ever notified that she had been put on or taken off the author list.

Even before their authors are chosen, drug company articles run a gauntlet of reviews by planners and company scientists and are vetted and revised many times. Those articles have been given much more thorough reviews than medical journals can ever give. Authors have little to add other than their names, and by adding their names they gain prestigious publications, which are the basic measure of worth in academic settings.

3. The Ghost Managers

Elsewhere, I have described in detail the process of the ghost management of pharmaceutical research and publication (e.g., Sismondo, 2009). Here I give only an overview.

"Publication planners," who tend to work for independent agencies (MECCs such as Parthenon and DesignWrite) rather than directly for pharmaceutical companies, guide the development, writing, and editing of drug company manuscripts. More than 50 medical MECCs advertise publication planning on the Internet, competing for Big Pharma contracts. Because medical science is disproportionately written in English, most of the largest publication planning agencies are based in the United States and the United Kingdom, though there are also some in Continental Europe, and probably elsewhere, as well. There are enough publication planners and planning agencies that The International Publication Planning Association was founded in 2003, and a competitor, The International Association for Medical Publication Professionals (ISMPP) was founded in 2005; the latter currently boasts of having over 800 members. The two associations hold conferences, publish reports, and have developed guidelines and codes of behavior.

Planners cannot afford to be too ghostly when they are advertising to their potential clients, mostly drug companies. If they were, they would not attract much business. Watermeadow Medical (2007) boasts on its website 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." Envision Pharma's (2006a) site says, "Data generated from clinical trials programs are the most powerful marketing tools available to a pharmaceutical company." Complete Healthcare Communications, Inc (2006) claims on its banner that it "has honed the systems and skills needed to develop the intellectual heart of pharmaceutical marketing—the publication plan. The result for your product? A continuum of awareness, interest, and prescriber confidence." And "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).

Systematic ghost management is relatively new, emerging as a widespread practice in the 1980s, and growing in size and importance since then. There are known instances of pharmaceutical companies apparently ghostwriting medical science as early as the 1930s (Rasmussen, 2008), and instances of marketing campaigns similar to publication plans in the 1950s (Greene, 2007). For example, Merck Sharp & Dohme's 1958 campaign for Diuril (chlorothiazide) assembled 84 independent clinician-researchers, selected for their influence, and for their ability to geographically represent each of the company's marketing districts. A symposium at the prestigious New York Academy of Sciences launched the drug, followed by a traveling scientific road show that stopped in each of 20 states (Greene, 2007).

Over the past two decades, global sales of drugs have increased at over 10% per year. This period of tremendous growth coincides with the rise of publication planning. It also coincides with a change in the structure of research, as industry funding shifted from supporting academic research to creating research through contract research organizations (CROs; Mirowski & Van Horne, 2005). This changed the structure of data ownership and expectations around publication, because market-driven CROs work for contracts, not publications. So the simultaneous rise of the publication planning and CRO industries is not coincidental. Some publication planning agencies are even owned by CROs, fully guiding research from inception to communication. The planning agency Innovex, for example, is part of the company Quintiles, which advertises itself as the world's largest CRO. Innovex (2009) "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."

Publication planners market drugs through core scientific media. According to Henryk Bohdanowicz (2005), director of the planning agency Lowe Fusion, they gain "product adoption and usage through the systematic, planned dissemination of key messages [using] . . . publications, journal reviews, symposia, workshops, advisory boards, abstracts, educational materials/PR." Science can mesh smoothly with marketing. In his analysis, Bohdanowicz writes that science and marketing are equal partners. Therefore, "Where shall we publish this study?" is paired with "Who are our customers?" and "What can we claim from the results?" is paired with "What are our customers' needs?" These equal partners together simultaneously determine what the science says and how the products can be sold.

Ultimately, pharmaceutical companies demand that publication planners generate revenue by producing and publicizing information that increases sales. And publication planning works. We can see this, for example, in the case of HRT prescription patterns after a group of published articles on HRT

for high blood pressure: Major ghost-managed publications in *Circulation*, *Menopause*, and *Hypertension* all claimed that the treatment not only reduced symptoms of menopause but also reduced blood pressure. After those publications, there was an increase in prescriptions by cardiologists, though not by gynecologists (Ryan & Hayes, 2007). Cardiologists, trying to reduce blood pressure, were responding to the latest scientific information. The publications did their job.

In this case, publications sold drugs for an off-label use, perhaps with the help of sales reps pointing cardiologists to the articles. Talking to the 2007 ISMPP conference, industry consultant Lucy Rose warned 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." (ISMPP, 2007)

A regulator who saw that would have to act forcefully. Rose should know, because she had taken the revolving door between industry and government: She is a former award-winning director of the unit of the FDA that monitored and regulated drug promotion, as well as having been a former sales rep for different drug companies.

It is by stifling marketing departments' tendencies to hype products that publication planners effectively market those products to scientific audiences. "The newest thing right now," says Rose, "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" (ISMPP, 2007). Marketers, as planners see them, would ride roughshod over scientific standards and would not care about what the scientific data can support. Gary McQuarrie, president of Scientific Connexions, says that the marketing department is lucky to have one place on a publication team—it does typically keep that one place, though, because it's "probably paying the bill." But he goes on to ask: "How are we going to create publications that have the right message, and a memorable message, for prescribers?" (ISMPP 2007). Publication planning successfully integrates science and marketing, by infusing scientific arguments with marketing goals.

Scientific standards are doubly important. Meeting them makes up part of what planners consider ethical behavior—how could good science be unethical? This underpins the distinction between doing publication planning and mere public relations. In addition, publication planners can only succeed if their work displays high standards, which means in turn that their articles will be published to best advantage. Medical journals have high rejection rates, as high as 94% in the case of the *Journal of the American Medical Association* and the *British Medical Journal* (McCook, 2006). Meanwhile, planning agencies appear to be very successful, claiming, for example, an "acceptance rate on first submission of 94% for abstracts [to conferences] and 78% for manuscripts [to journals]" (Gardiner-Caldwell Group, 2007). Systematic rejection is presumably for independent academics, not, it seems, for Big Pharma.

How much of the medical science literature is ghost managed? The 85 articles on Zoloft managed by Pfizer between 1998 and 2000 (Healy & Cattell, 2003) and the 96 on Vioxx managed by Merck for the 4-year period when that drug was available in the early 2000s (Ross, Hill, Egilman, & Krumholz, 2009), both amount to 40% of the articles in core clinical journals on those drugs at the time. Forty percent of medical journal articles is enough to allow a company to use apparently independent authors to attract interest in a drug and shape its image.

Ghost management affects both trials performed after a drug has been approved for sale, and before. Considerable numbers of Phase III drug trials—normally called "registration trials" because they are ostensibly performed to gain regulatory approval—are performed with an eye to ghost-managed publications. Hubert Pouleur, vice president for cardiovascular clinical research at Bristol-Myers, complains, already in the 1990s:

> The FDA told us that we don't need all these trials. . . . But there is a difference between getting a drug approved and having it be a commercial success. A new drug will be used only if it is a significant improvement on existing drugs, and to establish that you need trials that aren't required for approval. (quoted in Langreth, 1998)

Companies often run as many as 10 Phase III clinical trials for major drugs. Presumably, they do so for the reasons that Pouleur identifies, to increase commercial success, through ghost-managed publications.

Academics call it "salami slicing" when they generate multiple articles out of a single study, and efficient salami slicing is part of the job for planners. One planner, an employee in a drug company with a new antipsychotic, told the author that she was in charge of a campaign involving more than a 100 manuscripts and conference presentations! Their effectiveness at slicing can be a problem. Jessica Colon, a planner working for drug company Novartis, outlines the challenge of winnowing out the best ideas early in order to maximize production. "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," she explains. "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" (ISMPP, 2007). Colon does not object to multiple publications but wants to make sure that they are cost-effective. They cost money and should produce the right returns on investment.

Good management of projects produces quantity. As samples of Complete Healthcare Communication's (CHC) service, it provides hypothetical lists of abstracts and

presentations to academic conferences, complete with their status, dates of presentation, and so on. Its website lists 10 hypothetical trials and the 32 journal articles that can be generated from them. CHC lists Pfizer, Aventis, Ortho Biotech, Wyeth, Schering-Plough, Shire, and AstraZeneca among its clients. CHC claims to have an acceptance rate of 80%. To allow it to reach this extraordinary rate, CHC has resources far beyond those of most researchers: Not only are all its studies fully supported by large pharmaceutical companies, it boasts a team of 50+ medical writers and editors, 30+ publication planners, and 40+ other staff. It only needs authors (CHC, 2010).

4. What Is an Author?

In a presentation on "the author dilemma," the agency Envision Pharma asks: "Who are they? Why are they authors? What is their role?" (Envision Pharma, 2006b). Presumably, Envision does not ask these questions because of an interest in literary theory.

Many of the authors listed on ghost-managed manuscripts are medical specialists like the people on Wyeth's manuscripts, who have established relationships with the company. They are typically faculty in medical schools, generously called "thought leaders," "key opinion leaders," or more normally "KOLs." Publication planners make KOLs their authors on articles, and their speakers at conferences, workshops, and other events. In so doing, they build reputations, turning people into opinion leaders who are even more "key."

Because medical schools place unrealistic expectations on their researchers, academic KOLs are keen to add to their CVs; it is not unheard of for researchers to list a thousand authored and coauthored scientific publications. Most medical science articles have multiple authors, so researchers are used to making modest contributions to published research. Publication planners further pare down the necessary work. To some KOLs, a free manuscript may feel like another perk of having good relations with a drug company, complementing the dinners, the trips to meetings and conferences, speaking and consulting fees. In some cases, academic authors may not even be fully aware, or may decide not to be aware, that they are freeloading off a drug company.

But are they authors? The International Committee of Medical Journal Editors (ICMJE), adopted by most medical journals, says that authorship credit should rest on, first, "substantial contributions" to an article's conception and design; second, data collection, analysis and interpretation, or drafting or revising the manuscript for important intellectual content; and third, approval of the final version before publication. Authors should meet all of these conditions (ICMJE, 2005).

ICMJE cleaves to a traditional concept of authorship, one that does not apply to the corporate production of manuscripts. Planners coordinate work by company statisticians, company and agency researchers, and medical writers, none of whose names they want on the publication. Perhaps some of these would meet the criteria, or perhaps no single person will.

Planners want KOLs to appear to have done much or all of the important work behind an article, presumably because many readers would be less inclined to give credence to an article that had only pharmaceutical company authors. But, especially since the work of publication planners is driven by marketing goals and deadlines, these KOLs typically cannot meet ICMJE criteria. Half of companies show only the penultimate drafts to authors, to solicit their input (Brown, 2007). They may review the manuscript, and may even make some contributions to it, but almost never make enough contributions to qualify as genuine authors.

Among themselves, planners portray authors as lazy, greedy, and prone to miss deadlines. For the sake of legitimacy, planners would like authors to make some contribution to manuscripts. However, they need to be coaxed and coached. Jessica Colon of Novartis recommends 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?" (ISMPP, 2007)

Colon's authors make minimal contributions, but at least she can point to some.

5. The Key Opinion Leader

Invited to a pharmaceutical industry conference on relationships with key opinion leaders was Dr. Michael Thase, a representative KOL (ExL Pharma, 2010). Thase, who was introduced as having authored over 500 publications and being "one of the brightest stars in neuroscience," was a smiling and confident speaker, comfortable giving his narrative to this audience of mostly pharmaceutical company managers—he gave his talk without PowerPoint, the first time he had done so in years, he said, because a mishap that morning involving his cat and his laptop led him to scramble to assemble notes for the talk and another that he would give later that afternoon.

After explaining how the cat lost his presentation, Thase gave his disclosures in a practiced move. As he explained,

> In the past decade, I have been a consultant to the manufacturer of every compound that has been developed for the treatment of depression or the treatment of bipolar disorder, and some number of other compounds that haven't made it through the multi phases stages of development.

Normally, he said, he presents this as two slides. He added a list of six pharmaceutical companies that had paid him to give talks in the previous 3 years, and another four that have recently funded research projects. He does not believe, he opined, that academics are very often dishonest, but he does recognize that "who you spend time with, where you make money, and so on," can influence what you believe to be true.

Dr. Thase is the quintessential KOL, a nationally recognized expert who is personable and a good public speaker. As one insider defines them, KOLs are well-known specialists who "can influence other physicians." Thase started his connection with the industry in the 1980s, doing dinner speaker programs, later giving promotional talks, serving on various advisory boards, and even once helping run a speaker training program. But there are many different kinds of KOLs, corresponding to the many uses pharmaceutical have for them. Indeed, Thase's path took him through many of the common KOL roles.

Traditionally, KOLs are seen as arrayed in an "influence cascade." In addition to the international and national KOLs, there are also local KOLs, whose main role is to influence physicians in their local areas. Kimberly Elliott, a former pharmaceutical company sales representative, says,

> Key opinion leaders were salespeople for us, and we would routinely measure the return on our investment, by tracking prescriptions before and after their presentations. . . . I would give them all the information that I wanted them to talk about. I would give them the slides. They would go through specific training programs on what to say, what not to say, how to answer to specific questions, so that it would be beneficial to my company. (quoted in Moynihan, 2008)

Those talks could be occasional lectures to which targeted local physicians are invited, scientific presentations at conferences, or in the form of continuing medical education. Pharmaceutical companies train physicians, work with them to make them "product champions," and pay them generously for their lectures (Moynihan, 2008). It should be noted, though, that a number of governments are in the process of regulating payments to physicians, effectively lowering payments to the level of "fair market value," however difficult that is to assess.

Advisory boards and consultancies create different relationships between pharmaceutical companies and KOLs. As their names suggest, advisory boards and consultancies allow companies to benefit from outside expertise. But they also allow companies to pay physicians and to develop relationships with physicians. According to John Mack of Pharma Marketing News, "Pharmaceutical companies view KOL advisory boards as the first and most influential activity in thought leader development" in the context of a plan for a new product (Mack, 2006). "Companies that assemble KOL advisory boards early in the product development phase stand to benefit by forging long-term ties with these experts."

Pharmaceutical companies' commercial or medical affairs units, now legally separated by firewalls to prevent certain flows of information, may want to hire physicians as advisors or consultants. Medical expertise is valuable to developing marketing and R&D plans alike, and medical experts are valuable for marketing directly and also marketing via science. The companies draw on the influence they have, and also put them in better positions to have that influence, effectively turning them into KOLs.

Companies typically offer research support to their more valuable KOLs. Sometimes that comes from companies proposing trials that they want done, offering research roles and expected authorship to their KOLs. Other times, investigators will themselves initiate trials and seek support from companies with which they have established relationships. Pharmaceutical companies support these investigator-initiated trials (IITs) both to further the relationship and to contribute to positive scientific publicity. Mark Schmukler of Sagefrog Marketing, a general marketing firm with expertise in the health sector, claims that the goals of any IIT program are

- Adding to the base of knowledge for a product
- Generating abstracts and publications to be shared with the medical community at congresses or meetings
- Increasing the familiarity of key physicians with the use of a product in specific disease states
- Producing advocates for the use of a product in specific disease states

Moreover, "the IIT process itself, which derives from the Clinical Development Plan, should be timed carefully. For pre-launch trials, results and publications should come forward within 6 months of the anticipated launch" (Schmukler, 2006, p. 15). All of that suggests that while IITs may be "investigator-initiated" in some sense, they are fully expected to fit into the company's marketing plans.

In his talk to pharmaceutical company managers, Michael Thase complained that KOLs do not like to be managed or used. He described how he had served as an expert witness in a court case, and saw, as part of the plaintiff's efforts to discredit him, the "individual management plan" for him by the company being sued: "so-and-so will meet with him on such-and-such a date with this expected result, and then we'll invite him to do this" (ExL Pharma, 2010). Thase's complaint set in motion a handful of comments through the remainder of the 2-day conference. Most of the speakers and audience were or had been involved in medical science liaisons, and as such were or had been in the business of "KOL management," to use their normal term. Yet on the whole they were also committed to an ideal on which scientific experts are independent. Their response to Thase was to find another term. Marc Jensen, a director of medical science liaisons for Bayer, suggested "opinion leader engagement." Linda Harris, a consultant who had formerly worked for Wyeth, suggested that they talk not about managing KOLs but about "managing relationships with KOLs." John Vieira, a senior marketing

director for Daiichi Sankyo, suggested that they think in terms of "managing experiences." Most of these people fell back on the familiar, older term: developing and implementing KOL management systems was a central topic of the conference. And they never suggested that their or their staff's activities needed changing (ExL Pharma, 2010).

Paul Weber, the head of Medical Affairs at PTC Therapeutics, sees KOLs as part of a broad coalition around a drug, a coalition that can also involve advocacy groups, nonprofits, and other companies (ExL Pharma, 2010). Coalitions involve genuine collaboration. And Weber is right in this, because the relationships are not merely unidirectional or unidimensional. The companies want to influence these influence leaders, but they also want to learn from them: consultants and advisory boards help develop R&D plans, and also marketing plans, even while they build good will and long term relationships.

If the coalition metaphor works, then relationships with KOLs extend the company beyond its formal boundaries. This theme was echoed by other commentators on KOLs: Marc Jensen of Bayer argued that building a KOL network is "building an armamentarium of expertise" outside the company. John Vieira of Sankyo Daiichi spoke of KOLs as part of companies' "activation networks" for particular products (ExL Pharma, 2010). On this perhaps Latourian (e.g., Latour, 1987) way of seeing them, KOLs are actors whose interests have been aligned with those of the companies, enabling an extension of action to new domains.

Though there may be efforts to move away from the instrumentalism of "KOL management," influential physicians are enough of a resource that there are firms that provide lists of KOLs for a pharmaceutical company project, design the KOL management plan, integrate that plan with a publication plan, and will even train KOLs in public speaking, so that they will be more effective when they give lectures. There are many dozens of such firms, offering variations on these services, and promising a good return on investment.

Ultimately all this is important because KOLs are key mediators between pharmaceutical companies and physicians. According to Kimberly Elliott, the former star pharmaceutical sales representative, "There are a lot of physicians who don't believe what we as drug representatives say. If we have a KOL stand in front of them and say the same thing, they believe it" (Moynihan, 2008, p.1403).

6. Other Disguises: Seeding Trials, Continuing Medical Education, Patient Advocacy Organizations

There are other ways in which the pharmaceutical industry uses outside actors and science to do its marketing or represent its interests. I mention three prominent ones here, as an indication of the range of practices of disguise in the industry.

Phase IV trials, or "postmarketing trials," are done after approval by regulatory agencies. In 2004, Phase IV trials were 13.2% of pharmaceutical companies' R&D. Seventy three percent of them were paid for by marketing, rather than research, departments; most of the rest were jointly funded (Gagnon, 2009). Marketing departments are involved because a considerable number of Phase IV trials are designed to familiarize physicians with products, to encourage prescriptions, or to allow drug representatives more access to prescribers.

For example, "seeding trials" pay physicians to prescribe specific drugs as part of trials but are aimed at increasing prescriptions. Thus, pharmaceutical companies also support research by nonacademic physicians. Merck's "Advantage" trial of Vioxx, for example, appears to have been a seeding trial. It was designed by Merck's marketing division, which also handled all of the data (Hill, Ross, Egilman, & Krumholz, 2008). According to one internal document, a goal of the trial was to allow physicians to "[g]ain experience with Vioxx prior to and during the critical launch phase." For this reason, the trial aimed to enroll 600 primary care *physicians* rather than a specific number of patients. The prescriptions of those physicians were tracked and compared with a control group of 99 physicians not in the trial. To the extent that data mattered, it was sales data; however, the company presented the trial to physicians as scientific research.

Over the past 40 years, patient groups have become increasingly prominent in medicine, raising awareness, lobbying governments, and even becoming involved in research (e.g., Callon & Rabeharisoa, 2008; Epstein, 1996; Greene, 2007). Through funding and support, pharmaceutical companies can influence their positions and actions, again using apparently independent mediators to represent its interests (Applbaum, 2009; Batt, 2009). The industry may even create some groups out of whole cloth: one individual is currently the chair, president, or spokesperson for six different industry-funded patient advocacy groups in Canada. Although these groups may represent legitimate patient interests, how they represent them is likely to be influenced by funders.

Pharmaceutical companies also have a presence in continuing medical education (CME), required of most physicians in North America in order to maintain their accreditation. More than 60% of all support for CME comes from pharmaceutical and medical device companies (Steinbrook, 2008). The MECCs that organize the courses are legally allowed to provide organization, pay for speakers, help speakers prepare their talks, and provide entertainment for participants. The companies do not control the content of CMEs, but if they have chosen their speakers well, supported those speakers' research, and given speakers templates and slides for their talks, these courses will convey preferred messages (Elliott, 2004; Steinman & Baron, 2007). An industry education specialist says that the ideal is "control—leaving nothing to chance" (Bohdanowicz, 2009). This is the best kind of marketing, directed at audiences needing to educate themselves, and provided by sources that the audiences have

reasons to trust. Unsurprisingly, MECCs advertise their ability to do "promotion through education" (Research and Markets, 2001) and that CMEs can be "custom tailored to meet pharmaceutical marketers' needs" (MD NetGuide, 2004).

7. Conclusion: Hiding Conflicts of Interest

In the ghost management of research and publication, pharmaceutical companies see value in letting apparently independent academics and physicians serve as their conduits for scientific information. As the title of this article suggests, these KOLs can be thought of as disguises for corporate faces, allowing pharmaceutical companies to market their products through apparently neutral representations of medical science. Pharmaceutical companies let apparently independent experts represent them, and thus successfully integrate marketing and science.

Many industries make use of celebrity endorsers to persuade audiences and give cachet to products. However, KOLs' ghost-managed talks and publications are not just celebrity endorsements—although undoubtedly some KOLs have celebrity status within medical communities. There is a transparency to endorsements that comes from the fact that they are generally publicized in advertisements for particular products, which are clearly marked as such. In contrast, ghost-managed talks and publications are presented as more or less independent research; sometimes not only is the sponsoring company unseen, but so is the product. When it comes to marketing to physicians and researchers, pharmaceutical companies sometimes prefer to be almost entirely invisible and to let academics speak for them. This gives the academic authors an authority that ordinary celebrity sponsors lack.

There are other industries that make use of people like key opinion leaders to shape the knowledge terrain. Major food manufacturers interact with "key opinion formers" to influence nutritional science (Penders, Verbakel, & Nelis, 2009; Penders, personal communication). To deal with specific political and/or legal dangers, industries have funded experts to cast doubt on particular scientific claims. Thus, for example, the tobacco industry has a long history of supporting science that challenges or distracts from links between smoking and cancer (e.g., Proctor, 2008), and the energy industry has funded experts to cast doubt on recent climate science (Oreskes & Conway, 2008). However, it seems likely that the ghost management of research and its dissemination is best developed in the pharmaceutical industry. The only other industry that engages in similar practices in a widespread way is the very closely connected medical device industry; although I have not discussed it here, it also makes use of publication planners and key opinion leaders to market to physicians.

Academics and physicians who participate in pharmaceutical marketing programs deceive their audiences and gain a larger share of intellectual credit for their articles and presentations than they deserve. Both these might seem to be of minor consequence. But these KOLs also allow themselves to be used in the service of pharmaceutical profit, and there is a strong argument that in so doing they do not serve patients and publics well. Although the two are related, pharmaceutical company profit is not perfectly connected with health, and often the two diverge considerably. For example, the companies increase their profits when they convince people that they are ill, engaging in "disease mongering" or "selling sickness" (e.g., Moynihan & Cassels, 2006). Over the past 25 years, the number of reported adverse events from drugs has been increasing dramatically, even while pharmaceutical industry profits have also increased; the companies simply budget for lawsuits (Light, 2010). For this reason, we might see the fusion of marketing and science in the ghost management of research and its dissemination as an ethical problem, and a problem in the political economy of knowledge.

In a classic study of scientific discourse, Nigel Gilbert and Michael Mulkay (1984) identified two repertoires that scientists use to discuss work in their fields: an empiricist repertoire that emphasizes lines of empirical evidence and rational relations among facts and a contingent repertoire that emphasizes idiosyncratic causes of the results and social or psychological pressures on the people holding those beliefs. The empiricist repertoire justifies positions, while the contingent repertoire explains them. Scientists use these repertoires differentially, depending upon whether they agree or disagree with the work they are discussing.

In pharmaceutical companies' use of publication planning and KOLs, we can see a related split. Independent academics are valued because they are understood in terms of an empiricist repertoire. Were the companies to present the same scientific research directly, they would be understood in terms of a particular kind of contingent repertoire: an *interest* repertoire.

Interest repertoires—which I have quietly employed throughout this article—take interests to be real, explanatory, and relatively stable. In this, they sideline the major critiques of interest explanations in Science and Technology Studies (STS): Steve Woolgar's (1982) critique of the way that STS analysts unreflexively employ realist language to describe interests and actor-network theory's insistence that interests are constructed and reconstructed along with everything else (e.g., Callon & Law, 1982). I do not want to reject these critiques. However, they are relatively unimportant in the context of corporate science. All the actors involved treat corporate interests as real, explanatory, and stable, even if they think that they can make those interests unimportant in their own work. Moreover, at least some actors believe that corporate interests differ from what we might consider the objective interests of medical science: I have already claimed that companies' profits are not perfectly linked to publics' health.

To the extent that the interest repertoire for understanding medical science is plausible, pharmaceutical companies are

often better off not producing or disseminating medical science in their own names. Guest authors and KOLs more generally are part of a largely successful attempt to disguise conflicts of interest and the biases that they create. The companies risk the scandals that come from occasional revelations of ghostwritten journal articles, because the value of academic disguises outweighs the cost of those scandals.

It is sometimes difficult to believe that the physicians being marketed to are truly being deceived. There have been many denunciations of corruption in medical science, there are organizations dedicated to freeing medicine from the influence of pharmaceutical companies; presumably these leave physicians suspicious. Sponsored papers have outcomes predictably in favor of the sponsor, KOLs often tout the benefits of a particular drug, and CME courses typically support one product unequivocally: surely physicians see through these forms of dissemination?

For physicians, there may be an element of deniability when company influence is cloaked in science. Certainly for the KOLs themselves, seeing the substantial benefits they receive as parts of a scientific exchange probably makes them feel less uncomfortable. And practices in the medical sciences already legitimately allow people to serve as authors on the basis of relatively narrowly contributions, and therefore many honorary authors would have little reason to feel uncomfortable with their roles. Equally certainly, it makes publication planners less uncomfortable to think that the products for which they are paid are simply science. The same may be true for physicians benefitting from CMEs or the attention of company representatives. But whether an empiricist repertoire disguises interests so that they cannot be seen, or simply so that they need not be seen, the undesirability of commercial interests is clear.

The fact that pharmaceutical companies go to such length to disguise interested science suggests that, at least within medical science, people are prepared to accept that even the most rigorous science can be affected by interests. While this might seem obvious, it runs against the dominant trends within the regulation of medical science, which tend focus on formal criteria for establishing scientific quality. The interest repertoire rejects formal models of science, because it suggests that interests alone can shape results.

Over the past half-century, medical research has become increasingly formalized, and that movement has been driven at least partly by distrust. Statisticians promoted the randomized controlled trial because it facilitated statistical analysis; but part of its broader attraction for other reformers of medical science was that it helped control untrustworthy physician researchers (Marks, 1997). Over its lifetime the randomized controlled trial has accumulated myriad norms, and these form the basis of routine checks and criticisms by internal review boards (doing ethics review) and journal reviewers and editors. Medical journals are increasingly requiring that articles and abstracts be structured along standard lines, even when the research takes an unusual form; the structured abstract is touted as a tool that improves research at its initial stages. The evidence-based medicine movement sets out rigid hierarchies of evidence, based on types of study; evidence-based medicine leads to clinical practice guidelines that formalize and standardize practice (Timmermans & Berg, 2003).

In response to scandals and routine problems involving medical publications, journal editors have tried to establish new authorship guidelines, standardized procedures for the performance and analysis of clinical trials, and standard formats for articles. With these, they hope to weed out fraudulent articles and bias. But importantly, journal editors do not want to reject pharmaceutical industry manuscripts per se—because the industry is a source of many important manuscripts, and because the industry has entangled large parts of current medical research. As a result, journal editors do not want to discriminate against industry research or industry authors.

Editors cannot discriminate on the basis of the quality of ghost-managed work. Industry-funded trials appear to be of equal or higher methodological quality than nonindustry funded trials (Bekelman, Li, & Gross, 2003; Lexchin, Bero, Djulbegovic, & Clark, 2003; Sismondo, 2008). That is, on standardized measures, reports of industry trials tend to look as though they are better performed than independent trials. This is unsurprising, given the resources pharmaceutical companies have to meet methodological standards, and make their research look as though it meets those standards.

Having the resources to construct and run methodologically sound trials does not stop corporate funding and control from affecting a myriad legitimate choices in the design, implementation, analysis, description, and publication of clinical trials. In fact, we might think that abundant resources enable the choices that can bring published results in line with interests. There is plenty of evidence that pharmaceutical companies make exactly those choices.

Medical science has put considerable trust in the power of formal methods to regulate bias. Nonetheless, the interest repertoire remains a powerful way of accounting for results. The pharmaceutical industry assumes that physicians and researchers understand the likelihood of bias when interests are made visible, but are otherwise more apt to treat medical seminars, education, and journal articles as straightforward reports of straightforward fact—however laden with choices they may be. By adopting, at considerable cost, various disguises, pharmaceutical companies try to limit any application of the interest repertoire to the medical science that they produce. It can thus promote its products using the most elegant of marketing tools, apparently disinterested science.

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