PART II

Institutions of science and science funding
CONTROLLED FLOWS OF PHARMACEUTICAL KNOWLEDGE

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The pharmaceutical industry, with more than US$1 trillion in sales annually and the highest level of profits of any major industry, is a nearly ubiquitous presence of the modern world. In this chapter I provide an overview of the industry’s “ghost management” of medical science. This is when drug companies and their agents control or shape multiple steps in the research, analysis, writing, publication and dissemination of science, in ways that may not be entirely visible. Through constant and multiple interventions, drug companies have become the most influential of contributors to medical knowledge, and have normalized both their seen and unseen presence. We can see this as part of a political economy of medical knowledge, in which a small set of actors have established a certain measure of dominance over the economy as a whole.

1 The rise of expensive research

Changes in the importance of different kinds of medical research have been in the background of the pharmaceutical industry’s gaining influence over medical knowledge (Edgerton, this volume). Pressures from both government regulators and internal medical reformers have led to the rise of the randomized controlled trial (RCT) as the most valued and important kind of medical research. This amounts to a change in style of scientific reasoning (Hacking, 1992), one that pharmaceutical companies have been well positioned to use to their advantage.

1.1 Medical pressures

Since the 1950s, medical reformers have made steady headway in promoting the idea that RCTs produce the most reliable medical knowledge. In the English-speaking world, credit for the first RCT in medicine is often given to Austin Bradford Hill, for his 1946 trial of the effect of streptomycin on tuberculosis, and for his advocacy of RCTs in medicine – although one can find a number of forerunners, such as Germany’s Paul Martini, who advocated for and performed RCTs on drugs starting in the 1930s, and gained influence in the 1940s (Daemmrich, 2004). The RCT rose in importance over the following few decades to become the “gold standard” of clinical research by the 1990s, following extensive advocacy by statisticians and statistically-minded medical researchers (Marks, 1997).
For statisticians, random sampling in an experiment is the key requirement for making results amenable to statistical analysis. A well-designed and well-conducted RCT, by randomly assigning subjects from a population, produces results that have a defined probability of applying to the population. Perhaps more importantly for the rise of RCTs, random sampling, especially combined with double blinding, addresses some concerns about researcher bias that have long been widespread within medicine (Marks, 2000). Since the 1950s, appeals to RCTs as the center of scientific medicine have been rhetorically successful, and since the 1970s physicians have been repeatedly told that RCTs are the only kind of reliable information on which to base practice.

RCTs are not perfect tools, though. Some of the central concerns are about how the necessary artificialities of RCTs produce knowledge that does not map neatly onto the human world as we find it – the rigorously managed treatments of trials are rarely repeated in ordinary treatments, and populations studied are never exactly the same as populations to be treated (e.g. Worrall, 2007). Related to these problems, RCTs require and promote standardization of treatment that does not fit well the variability of the human world – the most effective standardized treatment may not be the most effective treatment for a particular patient in a particular context (Timmermans and Berg, 2003). In addition to these problems, as normally performed, RCTs are worse at identifying adverse events than they are at showing drug effectiveness (Healy, 2012). Evidence-based medicine’s hierarchy of evidence does not take into account the possibility that unsound RCTs may be of less value than are sound versions of other kinds of studies (Bluhm, 2005; Grossman and MacKenzie, 2005). And illustrating that RCTs are less rigid than they appear is the fact that industry-sponsored studies produce more positive results than do independent ones (Lundh et al., 2012); the method does not eliminate bias.

The rise of what is known as “evidence-based medicine” has further promoted the idea that the practice of medicine should be based on RCTs – multiple RCTs, if possible. Evidence-based medicine’s origins lie in the medical curriculum of McMaster University in Canada, based around practical clinical problem-solving. The clinical epidemiologist David Sackett led the way by developing courses on critical appraisal of the literature, which turned into a series of articles published in 1981 (Zimerman, 2013). A decade later, on an invitation and patronage by Journal of the American Medical Association editor Drummond Rennie, those articles were updated and republished as a manifesto. The approach rejected reliance on intuition – which had been attacked for many years (Marks, 1997) – and even physiological reasoning: “Evidence based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research” (quoted in Zimerman, 2013: 75).

1.2 Regulatory pressures

Medical reform was one of the reasons why RCTs moved toward the heart of medicine. A second reason was the fact that government regulatory bodies made RCTs central to the approval process for drugs.

Much of modern drug regulation descends from the US Kefauver-Harris Act of 1962. Interestingly, the Act did not address the two sets of problems to which its sponsors had responded, though it did have profound effects on the pharmaceutical industry and on medical research. In the years leading up to the Act, Senator Estes Kefauver had put his energies into challenging the pharmaceutical industry on terrain where the US consumer had the most visible complaints: monopolies stemming from patents, and consequent high prices. His efforts at
reform were largely failures. Pharmaceutical companies and their industry association were able to deflect Kefauver’s attacks on drug patents and prices (Tobbell, 2011). The 1962 Act was spurred more directly by the compelling story of how the US had narrowly avoided disaster by not being quick to approve thalidomide – an episode used by the Kennedy Administration to push the Act forward (Carpenter, 2010). Dr. Frances Kelsey of the Food and Drug Administration (FDA) had consistently expressed skepticism about the drug, and had delayed its approval. Meanwhile, in Europe, thousands of pregnancies and babies had been affected by the widespread use of thalidomide as an anti-nausea remedy and tranquillizer.

But while the Act was ostensibly to improve the safety of drugs, it added only a little to the existing regulation of safety. More importantly novel was a requirement that pharmaceutical companies show the efficacy of drugs before they could be approved. The Act specified that evidence of efficacy had to involve “adequate and well-controlled investigations” performed by qualified experts, “on the basis of which it can fairly and responsibly be concluded that the drug will have its claimed effect” (Carpenter, 2010: 272). The FDA structured its regulations around phased investigations that culminated in multiple similar clinical trials, which would ideally be RCTs. It was only on the basis of the evidence from these RCTs that a drug could be approved for sale in the US, and that any particular marketing claims for that drug could be made. Thus the key provisions of the Kefauver–Harris Act were about the appropriate and necessary scientific knowledge for the approval and marketing of drugs.

Over the following few decades, regulatory agencies around the world followed the FDA’s lead, especially in using phased research culminating in substantial clinical trials as a model. For example, Canada’s regulations followed swiftly, in 1963. The United Kingdom established new measures that same year, and followed them up with a framework similar to the FDA’s in 1968. European Community Directives issued in 1965 required all members of the European Community to establish formal review processes, which they did over the following decade. Japan introduced its version of the regulations in 1967.

Especially since the expansion of drug regulation in the 1960s and 1970s, in-patent drugs are usually rhetorically constructed as more powerful than their older generic competitors: The drug patent has become a marker of quality. Meanwhile, the profitability of the industry is in part a result of layers of exclusivity established by drug patents and other regulations that establish marketing rights. This is even though versions of most of the competitors were once patented, and often recently so. There are, nonetheless, complex relations among in-patent, branded and generic drugs, with the generic often serving as a critique of the in-patent drug (Greene, 2014) and yet with brands of generics themselves being asserted as markers of quality (Hayden, 2015; Peterson, 2014).

In general, the pharmaceutical industry has opposed the introduction of new regulatory powers, which increase costs, hurdles, and sometimes uncertainties (e.g. Nik-Khah, 2014). It also has challenged aspects of regulators’ authority in court. For example, in recent years, challenges to a core piece of the 1962 Act have been working their way through US courts: Drawing on the US’s strong protection of freedom of speech, companies have been arguing successfully that the FDA does not have the authority to regulate off-label marketing (Sharfstein and Charo, 2015).

Pharmaceutical companies and industry associations are also continually lobbying regulators and legislators in more quiet ways, to shape regulation in their interests, in the US, Europe and around the globe (e.g. Davis and Abraham, 2013; Permanand, 2006). Industry interest in shaping regulation can be seen clearly in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). It is strongly in pharmaceutical companies’ interest to bring a new drug to market as quickly as
possible, increasing the amount of time it can be sold while still under patent protection. Differences among the regulations for access to major markets slow the process by requiring that the companies engage in different research to meet those different demands. Thus, the International Federation of Pharmaceutical Manufacturers’ Associations organized the creation of the ICH, bringing together the regulatory agencies of the European Union, Japan and the US (Abraham and Reed, 2002). In a series of meetings beginning in 1991, the ICH harmonized testing requirements, keeping the structure of phased investigations but ensuring that one set of investigations would suffice for these three major markets.

Estimates of the cost of bringing a new drug to market vary enormously, depending on whether those estimates are produced by the pharmaceutical industry or its critics, but few people would dispute that the costs are significant. Though the industry complains about these costs, and actively challenges the regulations that increase them, they have the unintended effect of preventing many non-industry researchers from contributing to the most valued kinds of medical knowledge, the RCTs of the kind that regulators require.

2 Integration of the industry into medical research

Novelty, patents and regulation are bound up with the intensification of scientific research. This has led to the accumulation and leveraging of what some scholars are calling “biocapital” (Sunder Rajan, 2006; Helmreich, 2008), which involves a circuit for the mutual cultivation of investment funds and biological products and knowledge (Birch, this volume). We can see this even in the development of public–private partnerships for drug development in the service of global health, with parties contributing so as to maintain claims on the circulating materials, knowledge and capital (see Vessuri; Harrison et al., this volume; Lezaun and Montgomery, 2015).

Because of the expense of RCTs, companies and researchers have had to develop novel formal structures to manage large clinical trials (e.g. Cambrosio et al., 2006; Helgesson, 2010). Because of the costs and organizational overhead, the emphasis on RCTs has significantly shifted the production of the most highly valued medical knowledge from independent medical researchers to pharmaceutical companies. The pharmaceutical industry has become integrated into the medical research community, both because it produces (generally through subcontractors) important medical knowledge itself and because it provides important funding for studies by more or less independent medical researchers.

Pharmaceutical companies sponsor most drug trials, and in so doing affect their results (e.g. Lundh et al., 2012; Sismondo, 2008). The companies fully control the majority of the research they fund, and they can choose what to disclose and how. Recent studies show that these companies do not (despite being mandated to do so) publicly register all of the trials they perform and do not publish all of the data even from the trials that they do register (Anderson et al., 2015). The articles they publish rarely display the full level of control that the companies have had over the production of data, its analysis or its presentation; for example, company statisticians are rarely acknowledged (Gøtzsche et al., 2007). This allows the companies to use RCT data selectively to quietly shape medical knowledge to support their marketing efforts. At the same time, their integration into medical research allows them to participate more overtly and broadly in the distribution of their preferred pieces of medical knowledge. The result is that pharmaceutical companies have considerable control over what physicians know about diseases, drugs and other treatment options (e.g. Applbaum, 2015). So while pharmaceutical companies have generally opposed new demands upon them, they also have benefitted enormously from those demands.
Pharmaceutical companies outsource almost all of their clinical research, some to academic organizations but the majority to for-profit contract research organizations (CROs), which perform 70–75 percent of industry-sponsored research on drugs (Fisher, 2009; Mirowski and Van Horn, 2005). CROs are involved at all stages of research and perform 95 percent of laboratory services related to trials. CRO-conducted trials are designed for either or both of the drug approval process and the further development of data to support the marketing of drugs. CROs, in turn, typically contract with clinics and physicians to do the hands-on work of clinical studies. They recruit patients in a variety of ways, through public advertisements, networks of specialists, or just through physicians’ practices.

CROs tend to have access to large populations in multiple countries both within and outside North America and Western Europe, including poorer, “treatment naïve” countries where costs per patient are considerably lower (e.g. Cooper, 2008; Petryna, 2015). India, for example, is well positioned to provide subjects: India’s Economic Times wrote in 2004: “The opportunities are huge, the multinationals are eager, and Indian companies are willing. We have the skills, we have the people” (Shah, 2006: 17). India has invested heavily to establish the material, social and regulatory infrastructure – for example, providing education in the running of trials and establishing ethical standards – to bring clinical trials to the country (Sunder Rajan, 2015).

North America and Western Europe still have more than 60 percent of the market share for industry trials. Why hasn’t industry moved faster to lower-cost, lower-risk environments? Historical reasons are important. For example, before the ICH, the FDA insisted that the majority of trials used for a drug application be conducted in the US, resulting in the national development of material and social capital for running trials. In particular, Phase I trials (small safety trials on healthy subjects) are often in-patient exercises, which must be conducted in clinics with beds and other facilities, and that material infrastructure continues to be used. As there are in poorer countries (Sunder Rajan, 2015), there are even a number of established US and European populations of “professional guinea pigs” (Abadie, 2010). Also, pharmaceutical companies and CROs have established relationships with physicians who can provide patients and staff for Phase II (dosage and preliminary efficacy trials), III (safety and efficacy trials, typically large), and IV (post-marketing) trials, and perhaps those relationships continue to be useful. But for Phase II, III, and IV trials an important part of the reason for the continued dominance of North America and Western Europe is that contacts with physicians – who recruit subjects for trials – in large markets are important, and clinical trials create and maintain those contacts. Clinical trials can provide opportunities to sell drugs, and physician investigators can be enrolled to further help sell drugs once they are approved.

Although CROs need to perform research of high scientific quality if it is to support the approval and marketing of drugs, they also need to serve the particular goals of the pharmaceutical companies that hire them. CROs’ orientation to their sponsors should lead them to make choices in the implementation and execution of the RCT protocol that are more likely to produce data favorable to those sponsors; they might, for example, skew the subject pool by systematically recruiting in certain populations, or they might close some sites for breaches of protocol, especially if results from those sites are throwing up red flags. Given the enormous complexity of protocols for large RCTs, it would be no surprise if these choices contributed to the relationship between sponsorship and favorable outcomes.

Unlike academics who are occasionally contracted to run clinical trials, CROs offer data to pharmaceutical companies with no strings attached. Data from CRO studies are wholly owned and controlled by the sponsoring companies, and CROs have no interest in publishing the
results under their own names. The companies can therefore use the data to best advantage, as we will see below. Company scientists and statisticians, publication planners and medical writers use them to produce knowledge that supports the marketing of products.

2.2 Planning and developing publications

Some studies suggest that roughly 40 percent of medical journal articles on major new in-patent drugs are parts of publication plans (Healy and Cattell, 2003; Ross et al., 2008). Publication plans lay out the terms for constructing articles that establish consistent profiles for drugs, the scientific face of drugs that will be established in medical journals and conferences. The key organizational work is done by publication planners employed either within pharmaceutical companies or more often by the more than 50 agencies that advertise publication planning on the Internet. Some agencies claim to have hundreds of employees, and to handle many hundreds of manuscripts per year. Indicative of the scale of the activity, two competing international associations of publication planners – the International Society of Medical Planning Professionals and the International Publication Planning Association – organize meetings and seminars, and several for-profit agencies do the same.

At least some of the time, marketing is best done if it is invisible. The director of one agency portrays science and marketing as equal partners (Bohdanowicz, 2005). “Where shall we publish this study?” is paired with “Who are our customers?”; “What can we claim from the results?” is paired with “What are our customers’ needs?” Science and marketing together thus determine what the research says and how the products can be sold. At a 2007 workshop for new planners, one presenter advised that the planning team should be assembled “before too much data has gone unpublished.” Ideally, it would be in place for research design, especially when there is “need to create [a] market” or create an “understanding of unmet need.”

In this and the following sections, unless a citation is provided, quotes stem from the author’s fieldwork at pharmaceutical industry conferences, or from approximately fifteen open-ended interviews with people who work closely with the industry. In all cases, anonymity of speakers is preserved. For some more full accounts, see Sismondo (2015a, 2015b) and Sismondo and Chloubova (2016).

There are many reasons why planners aim to meet high scientific standards. First, and most centrally, the value of their work to pharmaceutical companies stems from its being taken as reputable science by medical researchers and practitioners. Second, scientific standards are considered a necessary part of ethical behavior, marking the distinction between doing publication planning and doing public relations. Third, publication planners can only publish to best advantage if their articles can successfully compete with independent articles. In this, they are apparently successful, because while top medical journals have rejection rates as high as 95 percent, planners claim to have high success rates; one agency claims “acceptance rate on first submission of 94% for abstracts and 78% for manuscripts” (Gardiner-Caldwell Group, 2007).

Academics, who will become the eventual nominal authors of those publications, provide the essential credibility for publications, but sponsoring companies do not trust academics to produce research and analysis that will serve their interests. Thus, as much as possible of the production of manuscripts is done by the company and the agencies it hires. This is suggested, for example, by an email from a publication planner to an author, accidentally forwarded to a journal editor in 2010; it insisted: “It will not be you personally who will have to write those articles but a ghost writer will do this for us/you and you kind of give your good name for this publication!” At a 2011 conference, an experienced planner waved an imaginary manuscript in the air and railed against its imaginary authors: “What is this? They’re promoting
the competitor!” Another planner said: “the approach of having an industry-authored [industry-written] first draft is a good one.” Thus, in the sphere of publication planning, the concept of authorship does not necessarily involve substantial contributions to research, design, or writing.

Individual manuscripts are typically written by hired medical writers on the basis of statistical analyses provided by the company, one or more key messages that match the developing profile of the drug and fit the target journals and audiences, and a list of references. The manuscripts are often reviewed extensively within the company, and are then passed along to their prospective authors, most of them academics, for comments before submission to journals.

Planners sometimes suggest that academic authors are lazy and unreliable, typically offering few substantial contributions to the manuscripts and missing deadlines. The process creates the conditions for such deadbeat authors. According to one planner, 50 percent of companies show only the penultimate draft of a manuscript to authors, to solicit their input. Authors are unlikely to have much to add to a well-crafted and edited manuscript. That becomes especially likely if authors are given tight deadlines. According to one whistle-blowing medical researcher, part of the problem he faced was that he received abstracts only after they were submitted (and accepted) for meetings, and received manuscripts only days before the planners’ deadlines for journal submission. The orderly and efficient rollout of presentations and papers means that the nominal authors are likely to contribute little.

Planners coordinate the work of multiple parties, such as company statisticians, company and agency researchers, medical writers and nominal authors. Their goal is to shape medical science to support drug companies’ marketing efforts. The articles that are published are solid enough to meet the demands of medical journals and to influence readers, but at the same time present science done in the companies’ interests.

3 Dominating the distribution of medical knowledge

3.1 Deploying sales representatives

Pharmaceutical sales representatives (generally known as “sales reps,” but also “drug reps” and “detailers”) use reprints of publications to distribute preferred knowledge directly to physicians. At a conference, a former sales rep giving a pep talk to publication planners said: “Folks, they’re dying for your work, by the way. Field reps are dying every day for more of your work. You know that, right? Because that’s what doctors are going to see.” Distributing reprints creates opportunities to discuss not only the article, but also about how to use its information – setting up possible prescriptions and sales.

That sales reps transmit knowledge legitimizes their presence in physicians’ offices, positioning them as contributors to the project of improving patient health. And although sales reps do much more than provide information (Oldani, 2004, Fugh-Berman and Ahari, 2015), medical knowledge is the tool that enables them to make pitches, offer their friendship, and convince physicians to prescribe specific drugs. The older terms “detailer” for sales reps, and “detailing” for what they do, highlight the idea that they bring useful information on drugs.

In the end, the goal is to increase the number of prescriptions or “scripts” for the sales representative’s products, “changing physicians’ prescribing behavior” in favor of those products. Sales reps do that by establishing relationships with doctors, using whatever common interests they can find; these generally include recent medical research. The relationships often have the appearance of being independent of sales reps’ jobs, as this doctor claims: “A good number of my very close friends are sales representatives. … I like to think that those are real
relationships just because they’re relationships – and even when people have moved on to other companies or don’t sell a product in my disease state.”

Sales reps may also be involved in a further project in the dissemination of knowledge, identifying and then hiring key opinion leaders.

### 3.2 Managing key opinion leaders

The term “key opinion leader” stems from work by the sociologist Paul Lazarsfeld and his students, and entered the world of pharmaceutical companies beginning with research done for the company Pfizer by Lazarsfeld’s group in the mid-1950s (Sismondo, 2015b). Pharmaceutical companies engage key opinion leaders (normally referred to as “KOLs”) primarily as key mediators between them and physicians. A former sales rep says, “[t]here 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).

The most prestigious and highly paid KOLs are well-established researchers, typically academics with significant accomplishments. They might be asked to: serve as authors on medical journal articles stemming from company-led research, recruit patients for trials, consult on medical or marketing issues, be instructors for continuing medical education (CME) sessions, and in some cases, serve as conduits for information to government regulators (Fishman, 2015).

We can see the marketing and commercial goals in how KOL programs are presented. One speaker – a specialist in running KOL programs – at a 2012 meeting on KOLs, enthusing about a new approach to network analysis, said, “So it’s really very, very interesting and starts to give us the tool and the power to be able to actually look at these network maps and start to think about the implication in terms of the things that we are doing commercially.” A marketing firm writes in overview: “Interacting with qualified investigators, physicians experienced in regulatory reviews, well-known and respected speakers, and highly published authors will help to efficiently manage tasks within the critical path of the product and disseminate the message of the product to the end prescribing audience” (InsiteResearch, 2008). Since they usually do not simply present a company’s script, high-level KOLs are nurtured through seminars, close contact, advisory boards and publications. Independent agencies identify KOLs who could serve the pharmaceutical companies’ needs, and may design communication plans for companies to build relationships and knowledge with their prospective collaborators. Companies’ ideal relationships with KOLs are part of general “KOL management” plans, with management implying “handling, direction and control” (InsiteResearch, 2008).

Equally valuable as the researcher KOLs, if less prestigious, are ordinary physicians who, as members of “speakers bureaus” for particular drugs, are paid to give talks to physicians, and occasionally to speak at community events. Explains one KOL, “the sales representatives, if they knew you, if they met you, if they thought that you would have the qualities of somebody that might be a good speaker, they would extend an offer to, to join the speakers bureau for that company.” Then sales reps also organize KOL-led events, at which KOLs are simultaneously salespeople and educators. At a 2012 conference on KOLs, a marketer defined promotion in these terms: “you have a key opinion leader engagement with a group of doctors, and you measure sales before and after the engagement.” Companies buy prescription data from health information services companies, which buy them from pharmacies (Moynihan, 2008), and thus they can track the effects of the KOLs’ talks.

Either researcher or physician KOLs may be employed to sell drugs more indirectly, too. They might, for example, speak on diseases:
Another common objective … is to educate the marketplace and drive awareness of a particular disease state, mechanism of action, or existing treatment alternatives. A goal within this objective may be to successfully engage with key opinion leaders by completing a set number of advisory boards.

\( (\text{CampbellAlliance, 2011}) \)

KOLs are ideal conduits for the marketing process, a range of activities that coordinate products, distribution networks and demand (Applbaum, 2004). KOLs can create awareness of new opportunities and approaches, interest in and concern about particular conditions, and introduce fears about alternatives.

KnowledgePoint360, a company that supports KOL programs, treats KOL speaker-training just like sales employee-training: “Whether it is for external resources, such as speakers, or internal staff, including sales representatives and medical science liaisons, a robust training program is critical to the long-term success of any pharmaceutical, biotech, or medical device company” (KnowledgePoint360, 2010; also Carlat, 2007). Similarly, Wave Healthcare claims:

It’s vital that advocates are able to communicate and influence colleagues with clarity and conviction. To ensure speakers are at the top of their game, we have developed a communication skills programme for clinicians.

\( (\text{Wave Healthcare, 2011}) \)

Like publication planning, KOL programs can be large. Speaking at a 2011 KOL management conference, one manager warned: “When you say ‘I need 700 to 1000 speakers in this activity’, the questions [that are] going to get pushed back to you in investigations are, ‘Why do you need so many? How many is each speaker going to do? Why did you need a thousand?’” The manager was raising concerns that investigators might interpret speakers’ fees as incentives to prescribe or to accept advertising messages – illegal marketing.

In the US, KOL speakers usually must follow pre-packaged PowerPoint slides, without deviating from their scripts. One highly paid psychiatrist said in an interview:

So if I am doing a promotional program for a company, I have to use the slide deck that they provide me – I am not allowed to alter it in any way and every word in that slide deck is basically reviewed by their own internal counsel ….

Answers to standard questions are also scripted, and speakers are trained to avoid providing answers that might be illegal or against companies’ interests.

KOLs acknowledge that they are being used, but nonetheless find value in their role as educators. One interviewed endocrinologist bluntly explained: “The reason for giving the promotional talks is to help the company sell its drug – I mean that’s basically – that’s what a promotional talk is.” A hospital-based hematologist said: “The honest answer is that promotional talks are not really for educating so – and I give plenty of promotional talks – … but some speakers are better than others at bending it into an educational talk.” Every KOL interviewed said education was a reason to work for drug companies, often taking pride in their teaching. One said: “I am educating fellow physicians. I spend my day educating patients, I spend some of my evenings educating fellow physicians” (see Sismondo and Chloubova, 2016).

But, as already discussed, the data KOLs use to educate is produced by pharmaceutical companies, and shaped, arranged and presented to support those companies’ interests. As authors, KOLs lend authority to that knowledge within the medical community. It makes some
sense to say KOLs educate, but their pedagogy and knowledge have been shaped by and in the interests of the companies for which they are working. KOL management, done correctly, facilitates distribution of knowledge. By spreading knowledge, changing opinions, and changing prescribing habits, KOL management generates a good return on investment for companies.

3.3 Orchestrating continuing medical education

CME courses, taken by physicians to maintain accreditation, are supposed to be independent of corporate interests. Directed at receptive audiences with motivation to learn, CME is, perhaps ironically, an ideal form of marketing for pharmaceutical companies. Accredited CME providers are regulated, and a result of this is that sponsors such as pharmaceutical companies are prohibited from controlling the content of courses. However, in many jurisdictions pharmaceutical companies may provide funding for CME, recruit participants, find venues, pay for KOL speakers, help them prepare their talks, and provide entertainment for participants. Sometimes, independent organizations even ask companies to influence content. Soliciting funds for a CME conference, a Canadian medical organization said: “major sponsors will be given the opportunity to nominate participants to represent industry’s interest and to participate actively in the conference” (Brody, 2007: 208).

It is not difficult for pharmaceutical companies to align with their own the interests of KOLs who deliver CMEs. If sponsors have chosen their speakers well, supported the research of these speakers, and given them templates and slides for their talks, the courses will convey preferred messages. As one medical education and communication company advertises: “Medical education is a powerful tool that can deliver your message to key audiences, and get those audiences to take action that benefits your product” (quoted in Angell, 2004: 139).

CME talks are parts of promotional campaigns, and the educational effects are aligned with the interests of the sponsoring companies. According to an industry education specialist, the ideal for CME is “control – leaving nothing to chance” (Bohdanowicz, 2009).

4 Conclusion: The ghost management of pharmaceutical knowledge

The past half-century has seen a dramatic change in political economies of medical knowledge. Between the 1962 amendments to the US Food, Drug and Cosmetic Act, and the rise of the evidence-based medicine movement, medicine has become increasingly focused on the randomized controlled trial as the best evidence to support science-based medical practice. However, this best evidence is very expensive to produce. As a result, the pharmaceutical randomized controlled trial is situated in a political economy of knowledge dominated by pharmaceutical companies.

The companies sponsor the majority of pharmaceutical trials and in so doing demonstrably affect their results. Contract research organizations handle most of the sponsored clinical trial research. Pharmaceutical company statisticians typically analyze the data produced. Publication planners and planning teams shepherd medical journal articles through to publication, hiring medical writers to write those articles and finding academic researchers to serve as authors on them. Sales representatives and industry-paid key opinion leaders give the science further life by presenting it to audiences of prescribing physicians. This process produces interested science, performed and distributed for marketing purposes.

Many aspects of the companies’ activities are either unseen or are normalized. Thus, I call this whole chain the “ghost management” of pharmaceutical knowledge. Ghost management
Pharmaceutical knowledge

may often – perhaps almost always – produce and rest on good scientific knowledge, but the science in question is partial or interested, supporting the companies’ interests. When pharmaceutical companies initiate and fund the design of trials, implement the research and do analysis of the results, they shape the knowledge around their products in terms of their preferences. When they write, choose authors for, and place medical journal articles, they select the messages that they prefer to circulate. When they go on to distribute their preferred knowledge and messages via sales representatives, key opinion leaders, and continuing medical education, they do so much more effectively than independent researchers ever could. Thus, pharmaceutical companies have established themselves as key parts of the political economy of medical knowledge, and are constantly shaping that terrain to support their own positions.

References


