Objectives

My overarching research goals for this project are three. First, I would like to develop a picture of the relationships between pharmaceutical research, education, and marketing. In particular, I would like to understand the extent to which drug research and education can be seen as marketing. I argue below that such a framework is useful and can apply broadly. This large goal includes a number of empirical questions, for example about the diverse meanings of clinical trials, about the association of funding of research and education with outcomes, about ethics review boards, about the economic pressures to produce "blockbuster" drugs, and so on. The study will have a North American emphasis, though it will include an awareness of how, because of regulation or economics, situations are both similar and different elsewhere.

Second, I would like to use this case to develop theoretical tools for understanding political economies of knowledge. Current concerns about pharmaceutical knowledge are primarily about absences of knowledge: about the non-creation of some knowledge valuable to the public good, about drug companies' failure to distribute knowledge that they create and control, and about difficulties in public education. However, on my preliminary analysis there is just as much reason to be interested in abundances of knowledge and information created for particular purposes and by particular interests. Thus I would argue for the value of framing the issues as ones about distributions of knowledge. This amounts to an expansion of the domain of epistemology. Thus looking at the mechanisms by which certain distributions of pharmaceutical knowledge are created might be useful to thinking about mechanisms of other political economies of knowledge.

Third, and less concretely, I hope that this study can produce a foundation for some concrete policy recommendations. Governments are under pressure from the pharmaceutical industry to streamline regulation, to protect their intellectual property, and to buy their products. But they are also under tremendous pressure to contain the costs of health care, a significant portion of which is the cost of drugs. Thus it is important that an understanding of pharmaceutical research and the distribution of pharmaceutical knowledge is available to government bodies. To this end I expect to host a workshop focused on policy issues, for which I would apply for separate funding.

If the project is successful, it will lead to further research, probably of a more ethnographic nature, on interactions between pharmaceutical research, education, and marketing.
Context

Drugs are at the centre of medicine. Much of the success of modern scientific medicine is owed to the effectiveness of extensively researched, well-formulated drugs. When we walk into the doctor's office, we usually hope to walk out with a prescription for drugs that promise to heal us, to improve our quality of life, or to keep us in good health. But which prescription? Why that one? What leads our doctor to write particular words and symbols on her little square of paper?

On the standard view there is a cascade. At the top sit academic researchers, creating knowledge about medical reality by performing laboratory and clinical trials, and authoring the huge number of research papers published in medical journals each year. From them knowledge flows down to articles in medical magazines and more general publications, to medical schools and Continuing Medical Education (CME) courses, to advertisements and drug company representatives or "detailers." At the bottom of the stream are the doctors and patients, relying on partial knowledge and information several times removed from its sources, often transmitted by interested parties or non-experts.

There is, rightly, considerable concern about the partiality of knowledge allowed to flow downward, and about that which drug companies do not allow to flow. This can be seen in attention to situations where researchers are not free to disseminate data, as in the well-known Nancy Olivieri case (Thomson et al. 2001) and more generally when non-disclosure agreements are signed (Krimsky 2003). It can be seen in challenges to particular claims made by drug companies (e.g. Healy 2003). It can be seen in attention to pharmaceutical advertising, and in direct-to-consumer (DTC) advertising in particular (Mintzes 1999, Mintzes et al. 2003, Cassels 2003). It can also be seen in the recent call for a public registry of all clinical trials (American Medical Association 2004), and a number of newspaper editorials in favour of the publication of all trials — calls that several large drug companies have promised to heed.

However, we can enlarge our perspective by observing that pharmaceutical companies create and maintain all of the links in the knowledge cascade at least some of the time. They provide pathways on which knowledge flows, and energy to make it flow. Through bottlenecks and around curves, new knowledge is created, and given shape by the channels it traverses. There can be no firm distinction between the pure knowledge at the top of the cascade and the partial or polluted knowledge at its bottom.

Drug companies invest enormous amounts in scientific research. Their pre-clinical research, screening molecules for therapeutic activity, and developing molecules and formulations to meet specific needs, is largely done in-house, though increasing amounts are being performed by contract research organizations (CROs) (Piachaud 2002), and drug companies also support substantial amounts of academic basic medical research. For clinical research the drug companies turn mostly to CROs, to conduct trials with an eye to the drug approval process: in 2001 CROs accounted for between 60 and 70% of industry-supported clinical trials, versus approximately 20% in 1988 (Mirowski and Van Horn 2005; Lightfoot et al. 1999). The rest of pharmaceutical companies' clinical research support is for medical researchers who perform more independent studies.
Do their sources of support ever influence CROs and academic researchers? Compared to more independent research, publications on clinical trials report positive results much more frequently when investigators have financial stakes in the affected companies (Bekelman et al. 2003), and when the trials are supported by those drug companies (Bhandari et al. 2004; Lexchin et al. 2003). There may be many reasons for this. In general, medical culture does not encourage the publication of negative results. Moreover, drug companies might be making shrewd guesses about which studies or researchers to support, might be preventing publication of negative results and promoting publication of positive results (Melander et al. 2003), or might be unduly influencing the design or interpretation of the trials. Or they might simply be the feeding hands that researchers avoid biting: CROs look to the next contract; and academic prestige is bound up with research, so grants from drug companies are almost obligatory for ambitious professors of medicine. Whatever the reasons, drug company largesse influences the pool of knowledge found in medical journals.

The recent rise in importance of CROs is changing the nature of clinical research. Cost-saving is an often-assumed reason for drug company use of CROs, yet there is little evidence that clinical research by CROs is less expensive than academic research, and pharmaceutical executives rank cost savings low on their lists of reasons for choosing CROs (Piachaud 2002). Unlike academic research, CROs can produce fully proprietary information that can be published where and when drug companies choose, are willing to focus entirely on meeting regulatory requirements with the shortest possible timelines, and can easily operate internationally (Davies 2001). This might increase pressure on academic research to mimic those advantages (Mirowski and Van Horn 2005).

Because they control considerable amounts of information and knowledge, and because they are interested in shaping fields of available knowledge, drug companies are part of an under-recognized information economy. Manufacturing represents a minute portion of drug company costs, but those companies sustain large networks to gather, create, control, and disseminate information.

One study of authorship for major medical journals found that 11% of articles show evidence of having ghostwriters, and 19% of having honorary authors (Flanagin et al. 1998). In extreme cases, drug companies pay for research by CROs, have ghostwriters put together manuscripts, and then give those manuscripts to academic researchers who have had no prior connection to the research (Barnett 2003; Healy 2003; Johnson 2003). Those honorary authors append their names to the tops of the articles, simultaneously sponsoring the research and padding their publication records. They stand as guarantors of quality, even though they may have had little or no control over the claims that are made under their names. They are like celebrity sponsors, though not paid nearly so well.

Even when acting less deviously, drug companies can see the research they sponsor as part of marketing. Medical research increases brand recognition. Detailers need to go to doctors' offices armed with studies showing the effectiveness and safety of the products they promote. Companies need research to demonstrate, increase, and fine-tune the effectiveness of their products. Less obviously, research allows them to "position" their drugs, to define markets and bring them into contact with the products. In some cases, research allows the drug companies to create completely new markets, because
A cure is the best way of identifying an issue as a disease, of creating a new medical reality: Erectile Dysfunction was created and solved by Viagra, its counterpart Female Sexual Dysfunction, a disease in the making, is ready to be cured by promising treatments (Fishman 2004, Katz & Marshall 2004), and its offspring the male menopause by others (Marshall 2004); even the high incidence of Depression is explainable in terms of Prozac and related drugs (Healy 1997, Glenmullen 2000, Schellenberg 2000).

The interests of academic researchers are often nicely aligned with the interests of drug companies. Researchers want to get results, produce articles, help patients, become better known in their fields, and promote their fields — they often see the problems and solutions they study as under-recognized. When they have relevant products to sell, drug companies can support all of these goals, and can provide the funding necessary to meet them. The fortunes of a treatment and the researchers studying it go hand in hand.

Meanwhile, pharmaceutical companies have to portray themselves as research and development organizations only necessarily involved in marketing and sales. Most of their customers want their drugs to be part of a rational world centered on health. They immediately suspect any visible aspect of drug research, development, or promotion that is not part of a logic of health. Though doctors' prescribing habits may be one of the best studied and precisely understood of markets (Greene 2004), doctors routinely claim not to be influenced by advertising and other obvious marketing. Thus marketing cannot be seen to overshadow science in importance.

Pharmaceutical companies claim to provide half of all funding for Continuing Medical Education courses in the United States (Holmer 2001); CMEs have been introduced in Canada more recently, and the figure is probably lower. In the U.S., private interests are allowed to provide organization, pay for speakers, help speakers prepare their talks, and provide entertainment for participants. Drug companies do not control the content of CMEs, but if they have chosen their speakers well, supported the research of those speakers, and given speakers templates and slides for their talks, they can be confident that these courses will contain their favourite messages. On-line courses are even more secure, since vagaries of oral presentation are eliminated. This is the best kind of advertising, directed at audiences hoping to educate themselves, and provided by sources that the audiences have reasons to trust.

Is this picture extreme? Marketers broadcast the ability to do "promotion through education" (Research and Markets 2004), and claim that CMEs can be "custom tailored to meet pharmaceutical marketers' needs" (MD NetGuide 2004). There is a developed industry around all forms of medical communication. Medical communication firms, which are essentially agents of drug companies, create courses, conference, seminars, articles, studies, and surveys, all of which they place in the hands of the educators, researchers, and doctors who will use them to good effect. These firms feed stories to the journalists who write for newspapers and medical magazines, giving them technical details, journal articles, the names of experts to contact, and even narrative lines (e.g. Vwire 2004). They provide video clips for television networks, which can then air stories about the latest advances (Fishman 2004).

Medical communications firms also perform clinical studies aimed at monitoring, defining, and augmenting the markets for drugs. On occasion these
studies attract attention for being thinly veiled marketing tools or even bribes.
For example, drug company Schering-Plough has been accused of bribing
doctors to prescribe its hepatitis C drug Intron A. Physicians were being paid
between US $1000 and $1500 per patient to prescribe the drug, supposedly to
keep records on patient progress as part of clinical trials on the drug (Harris
2004) Almost every other large drug company is facing or has recently settled
lawsuits on similar charges.

Research, education, and marketing are often fused. When a doctor tries
to educate herself, she almost invariably turns to agents of big pharmaceutical
companies, whether they are the local detailers, journalists who needed a story
to write, or researchers and educators sponsored to spread the word. All of
these agents may aim to tell her the truth, but the truths they tell are drawn
from streams of knowledge that have been fed, channeled and maintained by
drug companies at every possible opportunity.

I am developing a broad picture of the natures and meanings of
sponsored research and the distribution of knowledge about drugs, fleshing out
all of the points made above. For this I will rely primarily on secondary and
other published sources. There have been a number of relevant studies in recent
years, including examinations of publication bias in medical journals (e.g. Baird
2003), journalistic accounts of drug discovery (Goozner 2004), insider exposés
of attempted censorship (e.g. Healy 2003), and much work on drug regulation
(e.g. Abraham & Reed 2002). However, there is an important need to assemble
this diverse material into a coherent picture. Given the importance of the
pharmaceutical industry, accounts of its creation and management of knowledge
need to be available and disseminated.

This is not a study of error, or even merely bias. While there is no
question that industry support biases knowledge about drugs, I intend to take
that as background for questions about the political economy of pharmaceutical
knowledge. Interestingly, drug industry-sponsored studies appear to be as
rigorous as other studies (Lexchin et al. 2003).

In this I draw on work on science communication challenging the
“dominant model” of popularization (Hilgartner 1990, Lewenstein 1995, Bucchi
1998). On this model science produces genuine knowledge which must be
translated into simplified forms, and thus distorted, to be widely understood.
The dominant model, however, neglects the extent to which translation into new
contexts creates new knowledge. Analogously, we should understand the
cascade of knowledge about drugs not as a successive dilution of pure
knowledge but as successive creation of new knowledge. Taking this as a
methodological fixed point pushes the analysis away from simply seeing a
distortion of pure scientific knowledge, and toward an attempt to understand
structural issues in the creation and distribution of knowledge.

A very similar point can be developed from the observation that there is
always a possibility of dispute over scientific claims, an observation known in
philosophy as the Duhem-Quine thesis (e.g. Harding 1978). As researchers in
Science and Technology Studies have abundantly demonstrated, the Duhem-
Quine thesis is not merely a theoretical claim (Sismondo 2004a). Scientific
evidence contains "interpretive flexibility" that allows for a permanent possibility
of disagreement (Collins 1991), though in practice disagreements are contained
by conventions, intellectual work, and social management. What this means for
the current project is that it is methodologically important not to draw rigid boundaries between warranted and unwarranted scientific knowledge, but instead to understand the effects of different knowledge regimes (Foucault 1980). Thus my epistemological focus is quite different from the traditional philosophical focus on the quality of or warrant for pieces of knowledge.

I do my research in the context of discussion of the "social construction" of both diseases and scientific knowledge. Much of my work has been an exploration of the meanings of the "social construction" metaphor either directly (e.g. Sismondo 1993, 1996) or indirectly (2000, 2001). Applying that work to the current case should prove productive.

References


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