

THE COMMUNITY OF SCIENCE®

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THE IDEA OF A COMMUNITY OF SCIENCE IS ONE we all hold dear. We think of ourselves—all academics, not just scientists in the narrow sense—as pursuing common goals and doing so in a noncompetitive way. To be sure, there are rivalries, often bitter. And no doubt we would all like the recognition that comes with being the acknowledged discoverer of something new and important. But unlike rival corporations or warring nations, our self-image is one of -serving the common good—knowledge is a gift to all. Robert Merton referred to this as “communism,” one of the ingredients in his famous “ethos of science” (Merton 1973).¹ Cold war prudence induced a change of name to “communalism,” but the sentiment was the same—knowledge is and ought to be freely and openly shared.

Things, however, are changing. Of course, it is naive to believe there was ever a golden age when the community of science was pure and noble. But the situation is deteriorating, and it is doing so rapidly. This is because commercial interests are exacting an unprecedented influence in research. The title of this chapter has the registered trademark symbol ® attached. This is because

the very phrase “Community of Science” is now the property of a consortium founded by The Johns Hopkins University designed to “accelerate the production of knowledge,” as the Community of Science Inc. web site tells us.

Commercial interests are at stake, and when they are, it is both inevitable and fitting to consider a more social approach to science, though we must do so with some care. Among participants in the science wars, two of the most popular positions are little more than caricatures. One of these says that scientists adopt their beliefs exclusively on the basis of various social, political, or psychological interests. Reason and evidence are just mythic entities designed to befuddle outsiders. The other caricature of science says reason and evidence are everything. Champions of the latter view taunt their opponents with this sort of challenge: “If you think the belief that arsenic is toxic merely reflects a self-serving ideology, then you shouldn’t mind taking a mouthful now.” Your refusal to do so is then taken to show you are a deranged hypocrite. At the level of pure academic debate, these views are harmless. But in the public realm they can be a disaster. The one side is right to be skeptical about what is offered to us as objective research in the kinds of science that affect our lives. The financial interests of pharmaceutical companies, for instance, are unquestionably at work in how they pursue research. Yet, it is not social constructivists but rather those who believe in the possibility of reason and evidence in this domain who could actually do something about it. However, we cannot hope to make any contribution until we first realize that the anti-objectivity side is half-right—much of what passes for regular science is in reality deeply conditioned by social factors.² And the solution to the problem may be, at least in part, a social solution. That is, a solution will not merely involve a more rigorous application of existing methods of good science, but will also involve a social reorganization of scientific research, achieved through political action.

Arousing Suspicions

In testing the comparative efficacy of new drugs, we expect that the results could go either way. That is, when a random drug X produced by company A is compared with drug Y produced by company B, we would expect X to prove better than Y about half the time in treating some specific condition. These may indeed be the actual results of serious scientific study, but they are not the results that get published. Remarkably, when the published study in question is funded by one of the pharmaceutical companies, the sponsor’s drug invariably

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does better. Richard Davidson (1986), for instance, in his study of 107 published papers that compared rival drugs, showed that the drug produced by the sponsor of the research was found to be superior in every single case. Lady Luck, it seems, smiles on sponsors.

The Davidson study is typical; there are many like it coming to similar conclusions, though not quite so dramatically. For instance, Friedberg et al. (1999) found that only 5 percent of published reports on new drugs that were sponsored by the developing company gave unfavorable assessments. By contrast, 38 percent of published reports were not favorable when the investigation of the same drugs was sponsored by an independent source.

Stelfox et al. (1998) studied seventy articles on calcium-channel blockers. These drugs are used to treat high blood pressure. The articles in question were judged as favorable, neutral, or critical. Their finding was that 96 percent of the authors of favorable articles had financial ties with a manufacturer of calcium-channel blockers; 60 percent of the authors of neutral articles had such ties; and only 37 percent of authors of unfavorable articles had financial ties. Incidentally, in only two of the seventy published articles was the financial connection revealed.

With these cases in mind, we should naturally become worried about who is funding the research. Whether we attribute these kinds of results to the theory-ladenness of observation, or to outright fraud, or to some new and subtle form of corruption doesn't really matter. The important questions are these: How extensive is the problem? and What are we to do about it? As for the extent of the problem, it's hard to say. The U.S. Congress passed the Bayh-Dole Act in 1980, allowing private corporations to reap the rewards of publicly funded research. Its impact has been enormous. Before Bayh-Dole there were only a couple of hundred patents each year stemming from university research in the United States. Now the annual number is in the several thousands. As all of us who live outside the United States know, American ideas and practices spread quickly. Good ideas get copied. Less than brilliant ideas are adopted, too, often courtesy of the World Trade Organization, the World Bank, or the International Monetary Fund, perhaps in the name of "free trade" or a "level playing field." Patent laws, for instance, are "harmonized," which means that U.S. patent laws must be adopted by everyone. Some of these, such as patenting organisms, have been highly significant.³ The upshot is that commercialized medical research is forced on all.

Sponsor

independent

financial ties

Funding

Journal Policy

The editors of several leading biomedical journals got together to forge a common editorial policy that was published simultaneously in several journals. They had several problems to confront, but in general they were concerned with the commercialization of research and wished to protect their journals from being a “party to potential misrepresentation.” In the first instance, the editors demanded full disclosure of financial relations and opposed contract research where participating investigators often do not have access to the full range of data that play a role in the final version of the submitted article. The guidelines of 2001 are part of a revised document known as “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” a compendium of instructions used by many leading biomedical journals.⁴ The breadth of requirements in these guidelines is considerable, from double spacing to respecting patients’ rights to privacy. The editors, collectively, have added specific new requirements concerning conflict of interest. Here in outline are some main points:

- Authors must disclose any financial relations they have that might bias their work. For example: are they shareholders in the company that funded the study or manufactures the product, are they paid consultants, etc.? At the journal editor’s discretion, this information would be published along with the report.
- Researchers should not enter into agreements that restrict in any way their access to the full data, nor should they be restricted in contributing to the interpretation and analysis of that data.
- Journal editors and referees should similarly avoid conflicts of interest in the peer review process.

These guidelines, if rigorously enforced, should go a long way in helping to improve the situation, and the journals should be warmly applauded for instituting them. Not only is the policy a good thing, but it was also nice to see the attention the issue received at the time in the popular media.⁵ Such publicity is crucial in making the general public aware of the seriousness of the situation.

More recently, the same journal editors have taken another big step. They now require that every clinical trial be registered at the outset, that is, described in detail in some approved public form. No trial-based results would be accepted for publication unless they followed directly from a *registered* clinical trial. The point of this requirement is to prevent selective reporting and the suppression

of negative results. Thus, if negative results are discovered but not published, others will at least have the opportunity to raise appropriate questions.⁶

These sorts of problems can be very serious.⁷ In one troubling case, Celebrex, which is used in the treatment of arthritis, was the subject of a year-long study sponsored by its maker, Paramacia (now owned by Pfizer). The study purported to show that Celebrex caused fewer side effects than older arthritis drugs. The results were published in *JAMA (Journal of the American Medical Association)* along with a favorable editorial. It later turned out that the encouraging results were based on the first six months of the study. When the whole study was considered, Celebrex held no advantage over older and cheaper drugs. On learning this, the author of the favorable editorial was furious and remarked on "a level of trust that was, perhaps, broken" (quoted in Angell 2004, 109).

Selective serotonin reuptake inhibitors, known simply as SSRIs, have been central in the new generation of antidepressants. Prozac is the most famous of these. There are several drugs in the SSRI class, including fluoxetine (Prozac), paroxetine (Paxil, Seroxat), sertraline (Zoloft), and others. They are often described as miracle drugs, bringing significant relief to millions of depressed people. The basis for the claim of miraculous results is a large number of clinical trials, but closer inspection tells a different story.

There are two related issues, both connected to nonreporting of evidence from clinical trials. Whittington et al. (2004) reviewed published and unpublished data on SSRIs and compared the results. To call the findings disturbing would be an understatement. The result was favorable to fluoxetine, but not to the others. The authors summarized their findings as follows: "Data for two published trials suggest that fluoxetine has a favorable risk-benefit profile, and unpublished data lend support to this finding. Published results from one trial of paroxetine and two trials of sertraline suggest equivocal or weak positive risk-benefit profiles. However, in both cases, addition of unpublished data indicates that risks outweigh benefits. Data from unpublished trials of citalopram and venlafaxine show unfavorable risk-benefit profiles" (Whittington et al. 2004, 1341).

The related second point is illustrated in a GlaxoSmithKline internal document that was recently revealed in the *Canadian Medical Association Journal*. GlaxoSmithKline was applying to regulatory authorities for a label change approving paroxetine (Seroxat) to treat pediatric depression. The document noted that the evidence from trials were "insufficiently robust," but further remarked: "It would be commercially unacceptable to include a statement that

efficacy had not been demonstrated, as this would undermine the profile of paroxetine" (quoted in Kondro and Sibbald 2004, 783). I suppose they had lots to worry about from a commercial point of view, since annual sales of Seroxat at the time were close to \$5 billion.

Reversed Policy

The new journal policy requiring clinical trial registration will help put a stop to this sort of thing. It is certainly a welcome change. But not all policy changes have been happy events. Stuningly, one journal reversed its related policy on conflicts of interest. *The New England Journal of Medicine* has modified a part that previously said "authors of such articles will not have any financial interest in a company (or its competitor) that makes a product discussed in the article." The practice applies to review articles that survey and evaluate various commercial products. This class of articles is highly influential with medical practitioners. The new policy says: "authors of such articles will not have any *significant* financial interest in a company (or its competitor) that makes a product discussed in the article" (Drazen and Curfman 2002; my italics). The addition of "significant" makes quite a difference. Anything up to \$10,000 is considered acceptable. Their reasons for this policy change are particularly worrisome. They think that concerns about bias shouldn't arise until significant sums are involved. Perhaps they are right. But it should be noted that someone with "insignificant" commercial connections to several different companies could be adding \$50,000 to \$100,000 to her income without violating the new journal rules.

The editors also claim in their editorial—and this is shocking—that it is increasingly difficult to find people to do reviews who do not have economic ties to the corporate world.⁸ If they left out such reviews, they claim, they would publish nothing at all on new products, leaving readers with no means of evaluation except that provided by the manufacturers themselves. Drazen remarked that he had been able to commission only one review in the two years he then had edited the journal. The idea, one supposes, is that moderately biased information is better than none. If it is true that almost all reviewers have corporate ties—and I shudder to think it may be so—then the current situation is even worse than any reasonable paranoid would have feared.

Policy reversals seem the order of the day. Yale University once proclaimed: "It is, in general, undesirable and contrary to the best interests of medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine." That was in 1948. Now Yale holds lots of patents, including one on an anti-AIDS drug. Yale shares this patent with Bristol Myers, and they

enforce it to the disadvantage of the eight thousand people who die in Africa each day from AIDS because they can't pay the royalties.

Finder's Fees

The daily news is replete with horror stories. For instance, a British newspaper, the *Observer*, reports a particularly shocking case of medical abuse involving a seventy-two-year-old woman in England who was being treated by her doctor for slightly elevated blood pressure (Barnett 2003). This was a few months after her husband had died; otherwise she was in good health. Completely unknown to her, her doctor enrolled her in a clinical trial, gave her various pills that had serious side effects, and regularly took blood to the point that her arms were "black and blue." Some of the pills were given directly by the doctor, not through the usual process of taking a prescription to the pharmacy. Her suspicions were aroused and after a particularly bad reaction to one pill, she complained to health authorities. The subsequent investigation revealed that her doctor had been given £100,000 over the previous five years for enrolling patients in clinical trials at £1000 each. The companies involved include Astra-Zeneca, GlaxoSmithKline, and Bayer. Many of the doctor's patients did not know they were being enrolled, many did not have any of the relevant symptoms to be included in the study in the first place, and many patients who did have relevant symptoms were given placebos, instead of the standard treatment they required.

One might hope that this culprit is just an isolated bad apple. But when we hear that in the United Kingdom more than three thousand GPs are enrolling patients in clinical trials at £1000 each and that the pharmaceutical industry is spending more than £45 million for patient recruitment in the UK, then it is not such a surprise to learn that there are dozens of examples of fraud. In the case of one GP, the consent forms of twenty-five of the thirty-six patients he enrolled were forged. Another who collected £200,000 failed to notify patients of possible side effects. He was subsequently caught offering a bribe to one of those patients not to testify (Barnett 2003).

If this much corruption can be generated by a finder's fee of £1000, imagine what might happen if the fee were tripled. In the United States in 2001 the average bounty was \$7000 per patient (Angell 2004, 31).

Payment for recruiting is known as a "finder's fee." But the term is hardly ever used, since the idea is often thought to be unacceptable. The fee is usually hidden in so-called "administrative costs" or perhaps disguised in some other

way for which compensation is considered acceptable, such as well-paid consultancies or invitations to conferences held in exotic and luxurious settings. In any case, the recruitment can be so profitable that one family practice organization in the United States placed an ad on the Internet: “Looking for Trials! We are a large family practice office. . . . We have two full time coordinators and a computerized patient data base of 40,000 patients. . . . We are looking for Phase 2–Phase 4 trials as well as postmarketing studies. We can actively recruit patients for any study that can be conducted in the Family Practice setting” (quoted in Lemmens and Miller 2003).

There are all sorts of concerns that arise with recruiting. Most of these are ethical issues. Since my focus is on epistemology, I am not concerned with them here but will mention a few in passing.

- Outright fraud. This arises, for example, from forged consent forms.
- Lack of treatment. Some subjects with treatable conditions will be put into the control group and given placebos. Existing treatments, from which they could benefit, will be bypassed.
- Safety. People who have health conditions that make them inappropriate for a particular study are being included because the financial incentives for inclusion are so great.
- Privacy. Health records are gathered over the Internet to build large commercial data bases that are not particularly secure.

My interests, as I said, are epistemic. Here are some of the methodological problems that arise from an epistemic point of view.

- • It is increasingly difficult to find test subjects for government-sponsored research, since typically no finder’s fee is offered. This means that it is becoming more difficult to do research that is relatively independent of economic interests.
- • Incompetence. This arises when GPs, for instance, become involved in clinical trials; they have no particular skill or training in research.
- • Improper inclusion. The criteria for inclusion are improperly expanded so as to make it easier to recruit test subjects. This weakens the reliability of experimental results.

Critics of commercialized research tend to focus on moral improprieties, such as a lack of informed consent or a failure to administer effective known treat-

ments. However, even if these moral requirements are breached, the subsequent science might still be perfectly good from an epistemic point of view. The research itself might, of course, suffer in cases where recruited subjects failed to fit the protocol, that is, they do not have the relevant health condition. This sort of case involves both moral and epistemic failings. Many of these moral and epistemic problems can be controlled, at least in principle, by regulation. Conflict of interest rules should be able to prevent abuses of the sort I mentioned, though not without difficulty; recall that finder's fees can be hidden in so-called administrative costs, thus concealing the otherwise evident conflict. In any case, most discussions of these issues focus on regulating conflict of interest.⁹ But an additional epistemic problem arises that is independent of these considerations and cannot be controlled by the same sorts of conflict of interest regulations. The problems I have been describing so far are sins of commission. The problem I will presently describe is more like a sin of omission. It is a huge epistemic problem, and it concerns a lack of alternative theories.

Skewing Research toward the Patentable

This point is so obvious, it hardly needs to be mentioned. Yet it is of prime importance. Corporations understandably want a return on their investments. The payoff for research comes from the royalties generated by exclusive control of intellectual property. This means corporations will tend to fund only research that could in principle result in a patent. Other kinds of information are financially useless.

Imagine two ways of approaching a health problem. One way involves the development of a new drug. The other way focuses on, say, diet, exercise, or environmental factors. The second could well be a far superior treatment, both cheaper and more beneficial. But obviously it will not be funded by corporate sponsors, since there is not a penny to be made from the unpatentable research results. It should be just as obvious that a source of funding that does not have a stake in the outcome but simply wants to know how best to treat a human ailment would, in principle, fund either or both approaches, caring only to discover which is superior.

To get a sense of what is at issue here, consider a comparative trial carried out on patients who were at high risk of developing diabetes. Over a three-year period, 29 percent of the placebo group went on to develop diabetes; 22 percent who took the drug metformin developed diabetes; but only 14 percent of those who went on a diet and exercise program developed the disease (Angell 2004,

170). Clearly, the best result came from a treatment that is not patentable. This trial, by the way, was sponsored by the U.S. National Institute of Health, not by commercial interests.

In a study of the effects of exercise on depression, Dunn and coresearchers found significant results. "In summary, aerobic exercise in the amount recommended by consensus public health recommendations was effective in treating mild to moderate MDD [major depressive disorder]. The amount of exercise that is less than half of these recommendations was not effective. Rates of response and remission with a PHD [public health dose, commonly recommended amount] are comparable to the rates reported in trials of cognitive behavioral therapy, antidepressant medication, and other exercise studies" (Dunn et al. 2005, 7). These are valuable findings, but they are not patentable.

Of course, there is also the problem that members of the public often want a quick solution and are not that keen on diet and exercise. Yet, if they were not so bombarded with industry propaganda, or if they got an equal amount of publicly sponsored information about the relative benefits of diet and exercise (perhaps presented in a humorous way like the Viagra ads), then we might well see more people opting for the better solution. Public funding is clearly the answer to several aspects of this epistemic problem.

Even within patentable research, some areas will be less profitable than others. Consequently, diseases of the poor and the developing world (for example, malaria) have gone relatively unexplored, since the poor cannot afford to pay high royalties. We are also in danger of losing a genuine resource in the form of top-notch researchers who do not do patentable work. In an example outside medical research, the University of California at Berkeley formerly had a Division of Biological Control and a Department of Plant Pathology, but neither exists today (Press and Washburn 2000). Why? Some people close to the scene speculate that it is simply because the type of work done in these units is not profitable. Typical research in these units involved the study of natural organisms in their environments carried out with a view to controlling other natural organisms. This type of work cannot be patented. Is it valuable? Yes. Is it profitable? No.

Trends being the way they are, top graduate students will not go into the field. Fewer and fewer people will work on agricultural and environmental problems through biological control. Perhaps the petrochemical industry will be able to solve all our agricultural problems. It is not the job of a philosopher

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to speculate on this possibility, but it is the job of philosophy of science to make the methodological point that without seriously funded rival approaches, we will never know how good or bad particular patentable solutions really are. The epistemic point is a commonplace among philosophers. Evaluation is a comparative process. The different background assumptions of rival theories lead us to see the world in different ways. Rival research programs can be compared in terms of their relative success in the long run. But to do this, we need strong rivals for the purposes of comparison.

Deliberate Ignorance

There is considerable evidence that the tobacco industry took legal advice to the effect that they should *not* do any research into the possible harmful effects of tobacco. Had they come to know of any harmful effects, their legal liability would have greatly increased. When such information came into their hands, they tried to suppress it. Obviously, from their viewpoint, it is better not to know about it in the first place. Given the potential for lawsuits over liability, ignorance is bliss. Interestingly, many of the lawyers who advised the tobacco industry also advise pharmaceutical companies. The legal firm of Shook, Hardy & Bacon, for instance, advises both the tobacco industry and the pharmaceutical firm Eli Lilly (Schulman 1999).

This legal strategy assumes a distinction philosophers know well—the distinction between discovery and justification. The thinking seems to be that a vague hunch that tobacco causes lung cancer or that SSRIs sometimes induce suicide are just that—vague hunches. And hunches do not constitute evidence. For that we would need extensive clinical trials. Since these trials have not been done, we simply have no evidence at all, according to the relevant corporations. There is no justification, according to them, for making these claims about the harmfulness of tobacco or SSRIs.

There is a great deal of naiveté about scientific method—sometimes amounting to willful ignorance. Some researchers claim that clinical trials are both necessary and sufficient for definite knowledge and that anything short of a full clinical trial is useless. (Champions of so-called Evidence Based Medicine occasionally make this claim.) This all or nothing attitude is ridiculous. We choose which clinical trials to run on the basis of plausibility; circumstantial and anecdotal considerations play a decisive role. This, too, is evidence, though usually not as strong. Often, though, these plausibility considerations are

enough, or should be enough, to launch a serious study. Refusing to take action on the grounds that there is nothing but “anecdotal evidence” is not only bad philosophy of science, it can also be criminal. Even the Nazis clearly established the link between smoking and lung cancer in the 1930s (Proctor 1999). Commercial interests elsewhere stood in the way for more than two decades, during which time millions of people died.

I mentioned SSRIs above. Selective serotonin reuptake inhibitors are widely used for combating depression. Prozac is perhaps the best known of these. There is a lot of interesting stuff to be discovered here. It may be that SSRIs actually improve depressed people’s condition to the point of suicide. This sounds paradoxical. What seems to happen is that extremely depressed people are sometimes in a “nonresponsive or lethargic” state. The SSRI will improve their condition to the point where they have the energy and the wherewithal to commit suicide. At the other end of the spectrum, even some healthy nondepressed volunteers have become suicidal after taking SSRIs. Needless to say, this is something a profit-seeking corporation is reluctant to investigate.

David Healy is a British psychiatrist, currently the director of the North Wales Department of Psychological Medicine at the University of Wales. He has spoken and written extensively on mental illness, especially on pharmaceuticals and their history (see, for example, Healy 2001). In September 2000, he was offered a position as director of the Mood and Anxiety Disorders Program in the Centre for Addiction and Mental Health (CAMH) affiliated with the University of Toronto. As part of the deal, Healy was also appointed as professor in the university’s Department of Psychiatry. He accepted this appointment. Before he moved permanently to Canada, he took part in a Toronto conference in November 2000, where he gave a talk that was quite critical of the pharmaceutical industry. Among other things, he claimed that Prozac and other SSRIs can cause suicides. Within days of his talk at Toronto, CAMH withdrew the appointment. Healy was, in effect, fired before he started.

Needless to say, this has been quite a scandal. What happened? There are, of course, rival views. The official account coming from CAMH is that they realized they had made a mistake, that Healy would not be a suitable appointment on purely academic grounds. Another view suggests that pressure from Eli Lilly did him in. Neither of these seems very plausible. Much more believable is the view that Lilly did not put any pressure on, but that self-censorship was at play. Lilly contributes financially to CAMH, a fact that lends credence to this last

speculation. There would be no need for direct pressure, if the recipients of Lilly's largess are ever ready to take the initiative themselves. This need not be conscious; some values are easily internalized.

More recently there have been very serious charges that drug companies have tried to suppress data on the harmful effects of SSRIs on children. I described this above in connection with journal policies requiring full disclosure. It is a clear vindication of Healy's concerns. But we need not worry about the details of the Healy case. The crucial thing is that it is not in the interest of Eli Lilly or other pharmaceutical companies to "know" that Prozac or other SSRI products cause suicide, since that would increase their potential liability. If work is to be done on this issue, it will have to be publicly funded. Lilly is not likely to foot the bill.

Creating a New Disease

Let us consider a different type of example. Eli Lilly has recently promoted a product called Sarafem for those who suffer from premenstrual dysphoric disorder, or PMDD. PMDD is an updated version of PMS, premenstrual syndrome. This alleged mental disorder is said to affect some women in the luteal phase of the menstrual cycle, just before the onset of menses. The American Psychiatric Association has not yet accepted that PMDD is a disorder, but it does list it in the appendix of the bible of this field, *Diagnostic and Statistical Manual of Mental Disorders*, known in its latest version as DSM-IV. To be diagnosed as having PMDD, a woman must have five or more of the following eleven symptoms, which characterize the disorder:

- markedly depressed mood
- marked anxiety
- marked affectivity
- decreased interest in activities
- feeling sad, hopeless, self-deprecating
- feeling tense, anxious, or "on edge"
- persistent irritability, anger, and increased interpersonal conflicts
- feeling fatigued, lethargic or lacking in energy
- marked changes in appetite

- a subjective feeling of being overwhelmed or out of control
- physical symptoms such as breast tenderness, swelling or bloating

Frankly, I don't know anyone—male or female—who fails to satisfy at least five of these conditions from time to time. In any case, Sarafem's active ingredient is fluoxetine hydrochloride, the same active ingredient as the anti-depressant Prozac, which is also made by Eli Lilly. However, Lilly is definitely promoting Sarafem in a different way. Marketing associate Laura Miller said, "We asked women and physicians about the treatment of PMDD, and they told us they wanted a treatment option with its own identity that would differentiate PMDD from depression. PMDD is not depression. As you know, Prozac is one of the best known trademarks in the pharmaceutical industry and is closely associated with depression. They wanted a treatment option with its own identity" (quoted in O'Meara 2001).

What then is the difference between taking a dose of Prozac and a dose of Sarafem? In either case, it is 20 mg of fluoxetine hydrochloride (though the pills have changed color from green to lavender—surprised?). "The difference," according to Miller, "is that PMDD is a distinct clinical condition different than depression. PMDD is not depression. PMDD is cyclical—women suffer from PMDD up to two weeks before their menses, and the other two weeks of the month they don't have the symptoms of PMDD" (O'Meara 2001).

Lilly was about to lose much of its patent protection on Prozac. It is hard to resist speculation on the connection to the promotion of PMDD and Sarafem. Patent laws will protect a discovery if it is a distinct new use of an already existing entity. For patent protection, then, it was crucial that Lilly find a new use for fluoxetine hydrochloride. If PMDD is depression, they are out of luck.

Once again, the philosophical moral is evident. Through clever marketing, advertising, and public relations, Lilly (in some sense), is creating a disease. If they can first sell the psychiatric illness, they can then sell the cure. How this takes place is an enormously curious and philosophically interesting thing. I think it is safe to say that PMDD did not exist in the past, but it might start to exist in the near future.

Let me explain. The tame sense of saying Lilly is "creating" a disease is the sense in which they are merely getting us to believe that such a disease exists. There is no doubt that they are trying to do this. But there may be a deeper sense in which they are creating the disease. Ian Hacking (1995, 1998) has written extensively on so-called "transient mental illness," which is not just

transient in an individual, but in a society. Multiple personalities, mad travelers, and anorexia are likely examples (though debatable, of course). This type of mental illness comes rather suddenly and spontaneously into existence at a specific time and place, and just as quickly disappears. Taking a cue from this, there are three interesting possibilities for PMDD.

- The disease PMDD has always existed. Lilly is merely bringing to light a fact that their research has uncovered and is promoting Sarafem as a way to treat it.
- The disease does not exist. Lilly, however, is trying to get us to believe that it does, anyway, since that will lead to sales of Sarafem.
- The disease has not existed in the past, but the public relations activities of Lilly will create the disease (perhaps like other transient mental illnesses), and that will lead to sales of Sarafem.

In the first case we should be thankful to Lilly, since a problem will have been brought to our attention and a remedy provided. If the second or third possibility is actually the case, then the dangers of private funding of market-oriented medical research are manifestly clear.

There are a number of additional topics I have not even touched upon. These provide even more reason for serious concern with current medical research practice. For one thing, vaccine research has declined, since vaccines are nowhere near as profitable as drugs for chronic conditions. For another, respectable medical journals, in order to help finance themselves, allow special supplemental issues. These are often little more than advertising outlets for the corporate sponsors, but they have the same format as the regular peer-reviewed issues, so readers are easily misled. The list goes on.

The Bold Entrepreneur

We are all familiar with the popular image of the entrepreneur, the bold and innovative risk taker, whose initiatives benefit us all. Well, it is certainly true that some have benefited. The pharmaceutical industry in the United States does well over \$200 billion a year in business. Profit levels are at a staggering 18 percent of sales, the highest of any U.S. industry listed in the Fortune 500. (The median of that group has profits of less than 4 percent of sales.) How could we account for this extraordinary success? Does it have something to do with the 11 percent of the \$200 billion that goes into research? That is certainly a lot of

money. Or does it have more to do with the 36 percent that goes into marketing? That is more than triple the research budget.

In 2002 the U.S. Food and Drug Administration (FDA) approved seventy-eight new drugs. Only seven were classified as improvements over older drugs. The rest are copies, so-called “me too” drugs. Not one of these seven was produced by a major U.S. drug company. There is nothing special about the year 2002. During the period 1998–2002 the FDA approved 415 new drugs and classified them as follows:

- 14 percent were new innovations;
- 9 percent were significantly improved old drugs;
- 77 percent were no better than existing drugs.¹⁰

The last of these are the “me too” drugs. They are copies of existing drugs (not exact copies, since they have to be different enough to be patentable). By U.S. law, the FDA must grant approval so long as a new drug is “effective,” which just means that it does better than a placebo in a clinical trial. Once approved, marketing takes over and monstrous profits can be made. A cheaper and better generic alternative will not be similarly promoted, since there is no hope of stupendous earnings.

Not surprisingly, there are calls for clinical tests to compare new drugs with the best existing alternative, not just with placebos. The importance of such comparative testing is illustrated by a massive comparative study on various types of blood pressure medication. It was carried out by the National Heart, Lung, and Blood Institute (part of NIH) and was almost completely publicly funded. The result was striking: the best medication turned out to be an old diuretic (“water pill”); it worked as well or better than the others, had considerably fewer side effects, and costs about \$37 per year, compared with several hundred dollars annually for each of the others (Angell 2004, 95).

It is clear that licensing should then be based on relative performance. This is the sort of problem that could be obviously and easily controlled with proper regulation. It is hard to imagine a more poorly constructed regulatory system than one currently in place in the United States. It leads one to think that U.S. lawmakers are either a pack of fools or as corrupt as the pharmaceutical companies who lavishly lobby them. There is ample evidence for either conclusion.

Where does genuine innovation come from? Consider the case of Taxol (paclitaxel). It is a very important drug, widely used to treat various forms of

cancer. It was derived from the bark of the Pacific yew tree in the 1960s. The cost of this research was \$183 million, paid for by taxpayers through the National Cancer Institute. However, in 1991 Bristol-Myers Squibb signed an agreement with NCI. The upshot is that they, not taxpayers, make several millions in royalties each year on annual sales of up to \$2 billion (Angell 2004, 58). This is a common pattern: Risk and innovation are paid for by the public purse; profits are privatized. How profitable can this be? When Taxol was brought to market, the cost of a year's treatment was \$10,000 to \$20,000, a tenfold increase over the cost of production (Angell 2004, 66). It is hard to know whether we should feel outrage or admiration. Imagine getting the public to pay for this research not once, but twice.

The swaggering entrepreneurs of the pharmaceutical industry boast that they are doing risky, innovative research. This is pure nonsense. The only innovative business they are in is marketing. They are utterly dependent on the advice of their scientists; their only expertise lies in the skilled promotion of their products. Even if we admired the genuine entrepreneurial spirit in principle, it is only a joke here. They are nothing like Alexander Graham Bell inventing the telephone, Marconi the radio, or even Bill Gates developing software for the home computer. Big Pharma consists of business people exploiting the intellectual work of others. Frankly, who needs these parasites? Their only contribution to medicine has been marketing, and it is far from clear that the public has benefited from being told they may be suffering from PMDD or erectile dysfunction. On the other hand, the public has certainly been hurt by the suppression of discoveries of harmful side effects and by financial decisions that set prices at the highest level the market will bear. People suffer, and people die.

If the "me too" drug dealers do not quite fit our image of the heroic innovator, perhaps they can live up to their other highly touted virtue—efficiency, a principle part of the "magic of the market." Could it be that publicly funded research cannot hope to compete with the highly efficient private organizations? I will say more on this below.

In any case, one has to wonder to what extent the combination of entrepreneurial medical research and the promotion of creationism in its schools is turning the United States into a scientific backwater. There are many strong voices opposing both trends, but unless the apathetic majority of U.S. scientists takes up the cudgels, further degradation of a once great scientific establishment is all we can expect.

Epistemology and Science Policy

Epistemology has always had a normative component. We *ought* to accept the theory that provides the best explanation; we *ought not* to accept any theory that is inconsistent; and so on. Typically, however, philosophers of science stay away from public policy. Probably we all would just smile if our political leaders were to ask: "What should our policy on patents be, if the Bayesians win out over the Popperians?" or if the Minister of Science and Technology should inquire: "In light of the failure of Hempel's account of explanation, how much money should we put into high-energy physics?" We don't think of it as our job to tell governments how to organize science. Policy decisions must be based on social goals and other factors that have nothing to do with epistemology.

However, the considerations we have described so far strongly suggest that such a hands-off attitude is insupportable. Those of us interested in the epistemology of science have to get involved in science policy, unless we mean epistemology merely to be a descriptive enterprise, perhaps in the spirit of SSK (the sociology of scientific knowledge). The social constructivist David Bloor, for instance, thinks of himself as describing but never prescribing anything to do with science (Bloor [1976] 1991). By contrast, it is those of us who believe in genuine objective norms for science who can have something meaningful to propose. There is such a thing as objective science, we would say, and its canons are being seriously violated in current medical research *because of the way research is socially organized*. Policy pronouncements can and should be made by those with a concern for good methodology. This advice need not be at a very detailed level, but neither would it amount to merely uttering a few pious platitudes about the need for intellectual honesty.

Steven Shapin, a well-known historian of science, writes amusingly about the reliability of observers in the context of seventeenth-century English science (Shapin 1994). The prevailing opinion was that servants and women were not to be trusted to tell the truth, since they were not appropriately independent. Nor were Catholics, since they could be under the influence of the Jesuit doctrine of "mental reservation." This doctrine allowed English Catholics after the Reformation to avoid telling a lie by mentally adding "It is certainly false that" to their voiced avowal "I am a Protestant." It may be a neat trick for avoiding religious persecution, but it is disconcerting for collectors of empirical data who rely on the reports of others. The ideal observer is, as you might imagine, the English gentleman: rich, independent, and possessing sufficient moral fiber

as to resist all corruption. His observations, and his alone, we can trust. There are not, alas, enough English gentlemen around to serve the considerable needs of contemporary science. However, plan B is waiting in the wings. The next best thing is to guarantee the independence of the researchers by doing a few simple but significant things. I will confine my suggestions to medical research, since that is scope enough and I quite deliberately want to associate my view with existing social policy in most countries where some sort of national health service is in existence. But first, let us consider the available research options. I see three.

1. Free market
2. Regulated market
3. Socialized research

The first and second options share the view that medical research should be conducted on a market basis. They differ on how regulated this market should be. The difference between them is a matter of degree, but it could be considerable. Champions of the first view would, of course, allow that fraud should be outlawed, but after that they would want as little regulation as possible. Champions of the second view could conceivably want to instill very strong regulations.

The following are the kinds of regulations I have in mind. I have mentioned several possible regulations already, but they are worth repeating, briefly. Of course, would-be regulators would likely not agree with all of these, but they include the kinds of things that champions of a regulated market might consider:

- Require full disclosure of any financial interest when publishing
- Require advance registration of any clinical trial as a condition of publishing, or better yet, establish an independent agency to design, conduct, and interpret all clinical trials
- Require clinical trials to test products against leading alternatives, as well as against placebos
- Disallow finder's fees (including disguised equivalents)
- Disallow corporate-sponsored "education" of doctors
- Disallow public marketing of drugs

Regulations such as these could be instituted to control some of the problems of market-driven medicine. But there are still shortcomings in any market model of research, even with massive regulation. For one thing, it is almost impossible to get the regulations to cover all the serious cases. The rules must be fleshed out in considerable detail in the hope of anticipating all serious problems. The first, involving financial disclosure, for instance, needs to cover not just the obvious direct cases, but indirect ones, too. For example, a prominent cardiologist who strongly criticized Vioxx turns out to have been a consultant for a hedge fund that was betting that the stock of Merck (the maker of Vioxx) would fall (Pollack 2005). Perhaps he was not influenced, but the potential for problems are glaring. Trying to anticipate the full scope for corruption is almost hopeless. Even when anticipated, how good will enforcement be? As they currently stand, conflict-of-interest policies instituted by medical journals are largely based on an honor system. Sheldon Krimsky's preliminary investigation (2003, 199) suggests that compliance is far from ideal.

Though I doubt regulation will handle all the problems that prevail in medical research, licensing, and so forth, some regulation will be required in any system. Rules with teeth and government agencies that operate at arm's length are essential. Such agencies must be free of any sort of governmental or industry influence. This is not currently the case in the United States. David Willman, an investigative journalist for the *Los Angeles Times*, has uncovered a number of troubling cases:

- Dr. P. Trey Sunderland III, a senior psychiatric researcher, took \$508,050 in fees and related income from Pfizer Inc. at the same time that he collaborated with Pfizer—in his government capacity—in studying patients with Alzheimer's disease. Without declaring his affiliation with the company, Sunderland endorsed the use of an Alzheimer's drug marketed by Pfizer during a nationally televised presentation at the NIH in 2003.
- Dr. Lance A. Liotta, a laboratory director at the National Cancer Institute, was working in his official capacity with a company trying to develop an ovarian cancer test. He then took \$70,000 as a consultant to the company's rival. Development of the cancer test stalled, prompting a complaint from the company. The NIH backed Liotta.
- Dr. Harvey G. Klein, the NIH's top blood transfusion expert, accepted \$240,200 in fees and 76,000 stock options over the last five years

from companies developing blood-related products. During the same period, he wrote or spoke out about the usefulness of such products without publicly declaring his company ties (Willman 2003).

It seems unnecessary to comment further on these three examples. Sometimes facts really do speak for themselves.

Yet another episode will help to undermine any remaining confidence in U.S. regulatory agencies. The FDA suspended marketing of a number of pain-killers following the release of data suggesting seriously harmful side effects. These included Celebrex, Bextra, and Vioxx (known as Cox-2 inhibitors). The decision was reviewed by a committee of 32 government drug advisers. They voted to endorse continued marketing. It turns out that 10 members had financial ties to the drug makers. If they had excused themselves on grounds of conflict of interest, the outcome would have been quite different. Had they not voted, two of the drugs would not have been reinstated (Celebrex would have been reinstated either way). The votes would have been 12 to 8 against Bextra and 14 to 8 against Vioxx. The 10 members with ties to the drug makers voted 9 to 1 in favor in each case (Harris and Berenson 2005).

Getting good regulations in place is vitally important. Nevertheless, the problems that regulation actually solves tend to be the lesser ones, and often they can be solved in a different way. More serious is the problem that there is no incentive to do research on medical solutions to health problems that cannot be patented. It is the crucial generation of a wide class of rival theories that is totally lacking in for-profit research. And that is my main reason for preferring the third option, socialized research. I recommend the following actions:

- Eliminate patents in the domain of medical research
- Adjust public funding to appropriate levels

What can be said in favor of these two points? It might be thought that patents are necessary to motivate brilliant work. Nonsense. The most brilliant work around in mathematics, high energy physics, and evolutionary biology is all patent-free. Curiosity, good salaries, and peer recognition are motivation enough. What about the problem that a great deal of medical research is simply drudge work, namely, massive clinical trials? This may be true, but clinical trials are going to be needed for some types of research that are clearly not patentable and just as clearly are of great use to society. If public funding works for clinical trials for the influence of broccoli on health, where nothing is patentable, then public funding can work for drugs, too.

Why do I call for “appropriate” levels of funding rather than for matching current levels? For one thing, it is hard to tell what current levels are. Drug companies claim that it costs on average more than \$800 million to bring a new drug to market. This, however, is a gross exaggeration. Something like \$100 million is a more reasonable estimate, since marketing costs (which they include) are not part of genuine research.¹¹ Moreover, many research projects are for “me too” drugs, which bring little or no benefit to the public. When we take these factors into account, it is clear that we can maintain a very high level of research for considerably less public money.

Can these proposals actually be implemented? Methodological issues are tough enough. Policy is vastly more messy, since it must be instituted in a social context. Radical proposals have little chance of success, even if they are impeccable from a methodological point of view. My proposal to socialize medical research may seem quite radical, but it actually is not, at least not in many societies. In Canada and other countries with socialized medicine, the attitude of the general public is that medicine is one place where the market should not rule. (Education is another area where, at least at lower levels, there is near universal support for free publicly funded schooling for all.) In this context a proposal such as mine fits seamlessly into the existing national health care system. If anything, private enterprise medical research is the oddity. Needless to say, this is not true in the United States, but elsewhere in the industrialized world it is. This means that as a policy, it should be relatively easy to implement. In short, socialized research goes hand in hand with socialized medicine.¹²

But isn't this an invitation to government waste? Won't free enterprise research be more efficient in every respect? After all, isn't it a well-known fact that socialists, however well-meaning, are bad with money and hopelessly inefficient? Since I'm tying medical research to socialized medicine, we would do well to compare the relative efficiency of two types of health care. Woolhandler et al. (2003) compared the cost of health care administration in the United States and Canada. They concluded: “In 1999, health administration costs totaled at least \$294.3 billion in the United States, or \$1,059 per capita, as compared with \$307 per capita in Canada.” They noted that the spread was getting worse and draw the obvious moral. “The gap between U.S. and Canadian spending on health care administration has grown to \$752 per capita. A large sum might be saved in the United States if administrative costs could be trimmed by implementing a Canadian-style health care system” (Woolhandler et al. 2003, 768).

The comparison is even more stunning when examining the costs of the

two systems as percentages of GNP. Health care in the United States costs 15 percent of GNP and yet leaves roughly a quarter of the population uncovered. In Canada the cost is less than 10 percent of GNP and everyone is covered.

So much for socialist inefficiency. Of course, one needs a government that is committed to being efficient. Even the most pro-market political parties in Canada realize that there is no going back on socialized medicine in Canada (or so they say), and large corporations support it, since it keeps their costs considerably lower than their U.S. competitors. So it is in the government's interest as well as in the general public's to run things efficiently. By contrast, some politicians do not want any government agency to run efficiently, as that would be a challenge to the private sector. Consider the politicians who took the following action: Medicare, a U.S. health program for senior citizens, was prohibited by a law passed by the U.S. Congress from using its potential buying power to bargain for lower prices. That government agency must pay top price. Hands up, all those who think this law was passed by socialists.

Values and Methodology

There are a handful of human activities that are completely ennobling. The list is no doubt headed by anything that alleviates poverty and suffering. It also includes the production of great art and great science. Medical research should be near the top of this list. Yet all that is wonderful and noble is corrupted by commerce and degraded by greed. Half a century ago, Jonas Salk discovered the polio vaccine. He prevented millions of deaths and millions of hearts from breaking. When asked if he would patent his finding, he replied: "There is no patent. Can you patent the sun?" We can't all make the sort of contribution Salk made, but we can, each and every one of us, avoid the slimy swamp. ✱

It might seem that my insistence on eliminating patents in medical research, on being involved in policy decisions, and on the particular policy advocated, is a mere reflection of various values that I happen to hold. Perhaps this is so. Indeed, I am sure that it is. But there is another way to consider this issue, a way in which values do not play any determining role at all. In fact, I consider the whole business a question of good methodology, not morals.

Scientific method is not fixed for all time but rather seems to evolve, often under the influence of scientific discoveries. For instance, the discovery of placebo effects led to the introduction of blind and double-blind tests. That is, the discovery of a fact led to the institution of a norm: In situations of such and such a type, you *ought* to use blind tests. Though this is a norm, it is not

ordinarily what would be called a value. That is, it is not a social or moral value, though it is certainly an epistemic value. The practice of blind testing, as others have noted, is best seen as science simply adopting what it has itself established as appropriate methodology. I suggest that we can view the current situation in a similar light. We have learned empirically that research sponsored by commercial interests leads to serious problems, so serious that the quality of that research is severely degraded. This was the point of my citing so many examples. The switch to public funding solves many, if not all, of these epistemic problems. Therefore, as an epistemic norm we should have public funding for medical research. This line of reasoning is no different than, first, discovering the placebo effect, next, discovering that blind testing can overcome the difficulties that the placebo effect entails, and then, as a result of all this, adopting the methodological norm of employing blind tests.

Let me take a moment to anticipate a possible objection. If the case I made for eliminating intellectual property rights holds in medical research, shouldn't it hold in general? And if it does, shouldn't patents everywhere be eliminated? Or, to put it the other way around, if it's a bad idea to eliminate them everywhere, then it must be a bad idea to eliminate them in medicine. My reply is simple: I deny the universality of the argument. When it comes to the economy, few people today take the all-or-nothing view that the government should own all the means of production or none whatsoever. The most successful economies are mixed. Some industries and institutions (trains, schools) are best run publicly, while others (restaurants, clothing) are best left to free enterprise. Trial and error is the sensible thing. I take the same attitude with patents. I'm sure they are very beneficial to society in some areas. But medicine is not one of them.

Scientific Socialism

The expression "scientific socialism" might be taken as a fair description of the view of medical research I have been urging. But those who have some acquaintance with Marxism may conjure up a different image. Marx and Engels famously distinguished their outlook from utopian socialism. The difference is quite important. The motivation for utopian socialism is primarily moral. It is promoted by those who are outraged—as they should be—by poverty and social injustice. Social change, if it comes, would be an ethical response to the horrors of the prevailing situation. The scientific socialism of Marx and Engels

takes quite a different view. Capitalism, according to them, contains the seeds of its own destruction. Capitalist competition leads inevitably to the concentration and impoverishment of the working class. Socialism will grow out of this state of affairs in a perfectly natural and inevitable way. Though morally superior, socialism, according to any traditional Marxist, is not the result of moral choice, but rather the outcome of an inevitable historical sequence, the result of something akin to a law-like process.

I see the problems involved in medical research in a somewhat similar way. This is, to repeat, quite different than advocating public funding for moral reasons. The policy I urge is motivated by epistemology. The contrast is not unlike the contrast between utopian and scientific socialism. It is not moral outrage—though I certainly acknowledge its presence—but rather the internal logic of capitalism (according to Marx) or of current medical research (according to me) that drives things along.

There is, however, one glaring disanalogy. According to Marx's scientific socialism, the internal logic of capitalism leads inevitably to socialism. However, the internal logic of current medical research does not lead inevitably to socialized research. It still requires political action to bring it about. And that is anything but inevitable. It is at this point that philosophical argument in the public domain becomes essential. And here I would expect nothing less than a long, hard battle.

Wilfrid Sellars once remarked that philosophy is a Dedekind cut between the introductory remarks and the conclusion. In these terms my introduction was the long list of problems that arise from the commercialization of medical research. My conclusion was a call for the elimination of patents in medicine. The Dedekind cut was that bit that went by in a flash distinguishing moral outrage from methodological fine tuning. It might be worth repeating.

Advocating public funding for research in the health sciences might appear to stem from one's socialist ideology. This is so in part, but it is very much more than that. The need for patent-free public funding in medical research is like the need for blind testing. It is, to put it simply, an epistemic discovery made by many people. Facts have been uncovered that require a methodological response, not a moral one. The right response, I urge, is to socialize medical research. The fact that scientific socialism, as I am here calling it, harmonizes well with one's moral sense, at least for me, is a happy accident.

NOTES

1. There are four ingredients in Merton's ethos of science: universalism, communism, disinterestedness, and organized skepticism (1973, 270).

2. For a discussion of these issues, see my earlier book, *Who Rules in Science? An Opinionated Guide to the Wars* (2001).

3. In 1980, the same year as the Bayh-Dole Act, the U.S. Supreme Court ruled in favor of patenting living organisms in *Diamond vs. Chakrabarty*. The 5-4 decision shows how contentious the issue was. The organism in question is the microorganism *Pseudomonas*, useful for cleaning up oil spills. The decision opened the door to patenting living things in general, and in 1988 the Harvard OncoMouse was patented. Interestingly, the Supreme Court of Canada has bucked this trend and refused to allow patents on the Harvard mouse.

4. It can be found, for instance, in *Lancet* 358 (15 September 2001): 854–56. The same document is also in *JAMA*, *New England Journal of Medicine*, and in many other journals in issues published at roughly the same time in mid-September 2001. It is also available online at <http://www.icmje.org/index.html>.

5. For example, see "Medical Journals to Set New Policy," *New York Times*, 6 August 2001.

6. The joint editorial stating the new policy can be found in several journals (for instance, DeAngelis et al. 2004). It is also available online at: <http://jama.ama-assn.org/cgi/content/full/292/11/1363>.

7. See Dickersin and Rennie (2003) for a discussion.

8. It should be noted that Jerome Kassirer, the preceding editor, sharply disagreed (McKenzie 2002).

9. For instance, Lemmens and Miller (2003) explore the use of criminal law in regulating conflict of interest.

10. Angell (2004, 75). Relevant information can be found at the FDA Web site: www.fda.gov/cder/rdmt/pstable.htm.

11. See Angell (2004, 40). The Public Citizen Web site contains relevant information on the topic: <http://www.citizen.org/>.

12. Sheldon Krimsky is a strong critic of current medical research and champion of extensive regulation. He remarked that "no responsible voices call for an end to corporate sponsorship" (2003, 51). I hope the reasons that I've given will make my proposal seem sensible, but it is a sign of the times, especially in the United States, that advocating a return to the pre-1980 funding situation is called "irresponsible."

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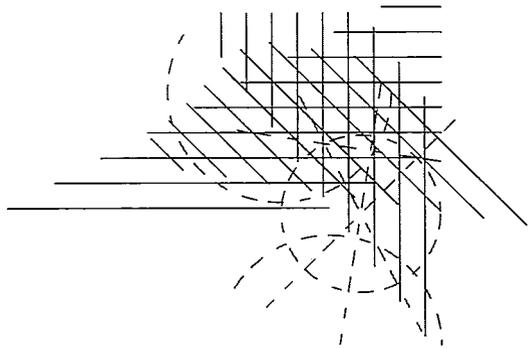
THE CHALLENGE OF THE SOCIAL AND THE PRESSURE OF PRACTICE

Science and Values Revisited

Edited by

MARTIN CARRIER, DON HOWARD,

and JANET KOURANY



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