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Current Controversies in Values and Science

Edited by
Kevin C. Elliott and Daniel Steel

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Contributors

Gregor Betz is Full Professor in the Institute of Philosophy at the Karlsruhe Institute of Technology. His recent monographs are *Debate Dynamics: How Controversy Improves Our Beliefs* (2012) and *Ethical Aspects of Climate Engineering* (2012, with S. Cacean).

James Robert Brown is Professor of Philosophy at the University of Toronto. His interests include: thought experiments (*The Laboratory of the Mind: Thought Experiments in the Natural Sciences,* Routledge 2010), visual reasoning in mathematics (*Philosophy of Mathematics: A Contemporary Introduction to the World of Proofs and Pictures*, Routledge 2008), and the relations between science and society (*Who Rules in Science? An Opinionated Guide to the Wars*, Harvard 2001), including the effects of commercialization.

Matthew J. Brown is Director of the Center for Values in Medicine, Science, and Technology and Associate Professor of Philosophy and History of Ideas at the University of Texas at Dallas. He has published papers on values in science in *Philosophy of Science, Philosophical Studies, Perspectives on Science, Studies in History and Philosophy of Science,* and *Contemporary Pragmatism*. He also works on American Pragmatism, history of philosophy of science, scientific evidence, engineering ethics, cognitive science, philosophy of physics, history of psychology, and pop culture studies.

Heather Douglas is the Waterloo Chair in Science & Society and Associate Professor in the Department of Philosophy at the University of Waterloo. She is the author of *Science, Policy, and the Value-Free Ideal* (2009), has edited several collections on socially relevant philosophy, and has written dozens of journal articles, book chapters, and essays on values in science, the role of science in society, the responsibilities of scientists, and the science-policy interface.

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CHAPTER **10**

Meanwhile, Why Not Biomedical Capitalism?

JULIAN REISS

Chapter Overview

In this chapter I argue in favour of more private initiative and responsibility in the market for drugs. Specifically, I argue that (a) patents for drugs should largely be abolished; (b) drug regulation by a government body such as the FDA should be abolished. The former claim is based on previous work concerning the efficiency and legitimacy of the patenting system; the latter, on a number of considerations which suggest that drug regulation is epistemically and morally deficient.

1. Introduction

When the editors of this volume first asked me to write a piece on the question 'Should Biomedical Research Be Socialised?' and pair it with another piece by James Robert Brown who has defended a crystalline 'Yes!' for many years, I was very pleased by the proposal and honoured to have the chance to appear side by side with Jim in this volume. At the same time, however, I felt that a set of papers by the two of us would not be the best possible combination. This is for the simple reason that we agree on too much. We agree not only that the current way in which the bulk of biomedical research (BMR) is conducted is deeply deficient, but we also see deficiencies in the same aspects of the status quo. Importantly, we further agree on at least one major area of reform, the current system of patenting.

In order to make the exchange more interesting in light of these agreements, I started to think about reasons to go in another direction than towards more

government involvement in biomedical research, reasons for more private initiative and individual responsibility. The reasons I describe in the following sections, I believe, are pretty strong reasons. I organised them into two main sections. In Section 2, I will argue that patents should by and large be abolished. Although this point isn't very widely appreciated (at least not outside of libertarian circles), patents actually constitute a government intervention that stifles rather than encourages competition. 'Market failure' is often given as a reason for this intervention, but the argument doesn't go through. To eliminate patents means to create *more* room for markets and competition. I will be brief here as I have addressed the issue in previous work and it is also addressed in Jim's paper. Section 3 looks at the U.S. Food and Drug Administration (FDA) and its role in approving pharmaceuticals. Drug approval is more obviously a government intervention, which followed a number of scandals with unsafe drugs that caused grievous harm. What is not so obvious is whether the FDA's drug approval process—or something like it—constitutes an improvement over a situation in which no government body decides which drugs can be marketed. I will argue that it doesn't. Section 4 will draw conclusions for the relative virtues of more government on one side and more private initiative and responsibility on the other.

What I will skip here is a description of the status quo and an argument for why it is fatally flawed. This has been done before, not the least in my own writings (see above) and in Jim's (see, for instance, Brown 2002, 2004, 2008; this volume). I will instead delve into arguments in favour and against government intervention right away. I will also focus on pharmaceuticals here and, in fact, take 'pharmaceutical research' and 'BMR' as synonyms. Finally, I will focus exclusively on drug development in developed countries, especially in the United States. There are important global justice issues that, I believe, can be dealt with in the framework I propose but I cannot address them here (see, for instance, Pogge 2005, Stiglitz 2006, Reiss and Kitcher 2009).

2. Against Patents

Patents are a form of intellectual property (IP), along with copyrights, trademarks and others. I will focus exclusively on patents and ignore all other kinds of IP here. Patents are granted by a state and give patent holders an exclusive right to market their product for a limited period of time. In the United States, patents last for 20 years from the date of filing. This duration is reduced by the time it takes for a drug to be approved by the FDA (see below) because normally, but by no means necessarily, patents are granted before approval. On the other hand, the Hatch-Waxman Act of 1984 provides patent holders on approved products an extended term of protection to compensate for the delay in obtaining FDA approval. Patent protection can also be extended by other means (see Reiss 2010 for details). In order to be granted a patent, the

inventor must normally demonstrate that the invention is novel, non-obvious and useful, although the U.S. Patent and Trademark Office tends to be very lenient in its interpretation of these conditions when it comes to new pharmaceuticals (Angell 2004).

The economic rationale for patent protection is related to the view that 'ideas' (or blueprints for inventions, BFIs, as I shall say henceforward) are public goods. Public goods are goods that are non-rival in consumption and non-excludable. A good is non-rival if one individual's consumption of it does not diminish another individual's ability to consume it at the same time. A good is non-excludable if it is not physically or technologically possible to stop anyone from consuming it, once it is produced. National defence is sometimes described as a typical public good: my 'enjoyment' of it does not diminish your ability to 'enjoy' it; and it's not technically possible to exclude any one: the war on drugs (or on terror or on anything else) 'protects' us all, if we want it or not.

Are BFIs, like national defence, non-rival? Defenders of IP rights think so. If you use a BFI to construct a useful machine, I can do the same or simply enjoy contemplating the idea. Your physically instantiated machine is of course rival. But not the idea behind it. The claim about non-excludability can also plausibly be made. An inventor can stop a competitor from examining physical instantiations of his or her blueprints, that is, the actual blueprints or their instantiations in the inventions. But once a physical instantiation is marketed, it is not possible to stop a competitor from 'reverse engineering' the BFI.

Public goods, so the argument goes, are underproduced in a free market because of a free-rider problem. If you decide to invest in national defence, why should I do the same? After all, if you produce it, you can't stop me from consuming it. Nor would you really mind, as my consumption doesn't diminish yours. But before modernising the army, you'll think twice. After all, if I paid for the modernisation, you wouldn't have to. And so the reasoning goes back and forth, until no public good is produced.

Patents create artificial temporal monopolies in producing and selling the products that derive from protected BFIs. The monopolies are created in order to create incentives to invent. If BFIs are public goods, then inventors will likely underproduce, or too few inventions (than would be socially optimal, according to this theory) will likely be made. A monopoly in producing and selling their invention will allow them to recoup the investment that had to be made in order to create the BFI. But as it gives them the exclusive right to produce and sell their product, it prevents competition and thus cause prices to be higher and volumes to be lower than in a competitive market. Once the good is created, a competitive market is better for consumers. But it wouldn't be created in a competitive market. There is, thus, a trade-off: on the one hand, we need incentives to encourage the creation of BFIs; but on the other, we do not want to encourage anti-competitive behaviour on the part of the monopolist in the BFI. The two desiderata are traded off by providing temporal rather than

indefinite exclusionary rights. The duration of the patent is calculated so that inventors can get their investment back but doesn't prevent competitors from entering the market once that has happened.

Theoretical and empirical analysis shows, however, that the actual picture isn't quite as rosy as the standard economic narrative paints it. As I have discussed previously (Reiss and Kitcher 2009, Reiss 2010, 2013: Ch. 13), there are three main arguments purporting to show that patents can be and frequently are harmful. First, rather than *promoting* new research, patent protection tends to *stifle* it, in part because new ideas build on old ideas and protecting old ideas means new ideas cannot be developed. Moreover, it can be shown theoretically and empirically that patent protection is not necessary for innovation. Second, to the extent that it does promote new research, this kind of research tends to be *redundant*. When a patent runs out, innovators create a new idea that is as similar as possible to the old ('me-too drugs'). Third, it encourages *rent-seeking behaviour*. As the monopolies are government-granted, those holding patents seek to influence government to legislate in a monopoly-friendly manner; they seek to convince consumers by advertising (instead of letting products speak for themselves) or even invent new diseases patients did not know they had ('disease mongering'); and they engage in costly litigation to protect the monopoly.

The current patenting system is inefficient and of questionable legitimacy. I do not think that this justifies abolishing drug patents completely and immediately. The above arguments depend in part on empirical premisses the evidence for which is sparse and shaky. I therefore advocate a step-by-step reduction in the duration and breadth of patents in conjunction with an observation of the effects of the reduction on innovation and industry behaviour. For example, it would be possible to: increase the standards for the novelty requirement of the patentable invention; in a first step eliminate patents for products, but not for processes; repeal the Hatch-Waxman Act and so on. It may well be the case that an optimal system leaves *some* form of patenting pharmaceuticals.[1]

3. Against Regulation

An important premiss in the argument defenders of the current IP system make is that drugs require a huge initial expense, that is, they come with large fixed costs. One reason why drug development is so expensive is that the FDA requires extensive testing that goes through four phases, culminating in large and long randomised clinical trials for a New Drug Application (NDA) to have a chance of success. For that reason, NDAs are often some 100,000 pages long and it takes on average about 12 years for the drug to go from laboratory to approval.

In this section I shall challenge this premiss. There is no doubt that, given today's FDA requirements, drug development is extremely expensive. What

this section aims to dispute is that the FDA requirements are themselves necessary for the production of safe and effective drugs. In particular, I will argue that biomedical science in a free society would not only promote drugs that are better than they currently are, but also that the free society would constitute an ethical improvement over the status quo.

3.1 The Epistemic Dimension: Regulation in the Absence of a Gold Standard?

The FDA section that deals with the approval of pharmaceuticals is the Center for Drug Evaluation and Research (CDER). It aims to ensure that an NDA provides evidence of sufficient quality and quantity to demonstrate safety and effectiveness of the drug. About the latter it states: 'With regard to quantity, it has been FDA's position that Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness' ("Guidance for Industry" 1998, 3).

Why does the CDER require at least two 'adequate and well-controlled' RCTs? The RCT is often regarded as the 'gold standard' of evidence for treatment safety and efficacy claims. An ideal RCT can indeed be proved to yield causally correct conclusions, as long as a number of very stringent assumptions are met (Cartwright 2007).

The recent literature in the philosophy of medicine has challenged the status of RCTs as the gold standard of evidence (Cartwright 2007, Worrall 2007a, b, Scriven 2008, Reiss 2015). In fact, there is now widespread agreement that RCTs should *not* be regarded as the gold standard. The emerging consensus can be summarised as follows: (a) *real* RCTs—as opposed to Cartwright's ideal RCTs—in no way guarantee the correctness of their results (which is one of the reasons why the FDA demands positive results from at least two RCTs); (b) alternative methods such as epidemiological studies can sometimes yield very strong evidence, indeed stronger evidence than that which would be produced had an RCT been conducted to test the same hypothesis; and (c) RCTs always require other forms of evidence in order to be applied to new populations or individuals. Another challenge comes from rare diseases and personalised medicine: the standard model of 'conduct a large, long RCT' is inapplicable when the number of potential trial subjects is very low (Teira forthcoming).

In the absence of a gold standard of evidence and mechanical decision rules based on the gold standard, one might wonder what regulation is supposed to achieve. It can only subject the New Drug Application to a review by a committee of experts. But who is to say that that expert committee is guaranteed or even tends to make a better decision than the pharmaceutical industry's experts? There are at least three considerations that speak against this.

First, it is not clear whether there always exists an objectively better decision, even in the idealised case in which all involved parties have the same information at hand and conflicting interests do not play a role.[2] There are a

number of reasons, all having to do with the fact that the line between good and bad evidential reasoning is not always crystal clear. For example, in the absence of compelling evidence in the form of an ideal RCT, large effects often play an important role in establishing a causal conclusion. The reason is simply that the larger the effect, the less likely is there a reasonable alternative explanation that can equally account for the data. A large effect played an important role in establishing the link between smoking and lung cancer, for instance. But how large is large? Two equally informed, competent and disinterested scientific committees can, at least in some cases, legitimately come to different conclusions.

Second, giving up the first idealisation, experts from the pharmaceutical industry will tend to be better informed than experts from any regulatory agency. They have helped to develop the drug and worked with the drug for many years. There will always be knowledge about the drug's behaviour that cannot be made fully explicit and thus find its way into the NDA. This is why FDA Drug Approval Committees usually have representatives of the pharmaceutical industry as members. It has been argued that this undermines the independence of these committees (Biddle 2007). Of course this is true, but there is more than one solution to this problem. No solution should ignore the informational advantage of industry experts, however.

Third, giving up the second idealisation, a worry one hears time and again is that industry experts are biased because they have a stake in the matter. True, big pharma wants to make big money. But it would be as naive to assume that it's in the best interest of pharmaceutical companies to flood the market with expensive and harmful drugs and mislead the public about them as it would be to assume that the government in general, or a regulatory agency such as the FDA in particular, are disinterested or benevolent actors.

Pharmaceutical companies want to make money, but they are held liable for harms their products cause, especially when they fail to warn their customers of potential dangers. Tort law describes numerous aspects of product liability including manufacturing defects, design defects, and marketing defects (that is, the failure to warn consumers). Courts tend to treat liability cases very seriously. The Food, Drug, and Cosmetic Act was passed in response to a tragedy that occurred in 1937 when Massengill Company introduced a new product, Elixir Sulfanilamide, which used toxic diethylene glycol as a solvent, leading to the deaths of 107 people. Massengill was successfully sued, and the chemist responsible for the disaster committed suicide.[3] Grünenthal, the maker of thalidomide, the scandal about which led to the Kefauver-Harris Amendments of 1962, paid 100 million Deutschmarks in indemnities, had to be rescued by its owners, and never profited from the drug again, even though it is being used in the treatment of leprosy and some cancers until this day (with FDA approval!).[4] If anything, the presence of a regulatory body such as the FDA provides reasons to pass on responsibility. I am not arguing

that the current tort law is sufficient and would solve all the problems. What I am arguing is that there is a system in place and problems can be addressed within that system.[5]

Nor is it the case that we should believe that any government agency is a disinterested body, or a body whose sole interest is the public good.[6] There are issues relating to electoral cycles, rent-seeking behaviour, pork-barrel politics and many others that have been described and analysed in over half a century of literature on public choice since Duncan Black's seminal *Theory of Committees and Elections* (1958). There is one issue of particular significance in the present context. In the absence of clear and judicially enforceable evidential standards, a regulatory agency such as the FDA has incentives to set the bar too high. This is because of an asymmetry in making two kinds of error. The FDA can approve of a drug that is not safe and effective, or it can fail to approve of a drug that is safe and effective. Making the two kinds of error will affect the FDA differently, however. If it were to approve of a drug that turns out to be harmful, this will soon make the news and the FDA will be blamed for its failure. No regulator will want to be responsible for having approved of another thalidomide. The harms due to the absence of beneficial drugs that have not been approved are silent, by contrast. A beneficial drug that doesn't get approved at all will probably never make the news. A beneficial drug that gets approved later than it could have been will likely be presented as a success story—by focusing on the benefits it brings now and not on the harms that were caused by not bringing it to the market earlier.[7]

There are several objections I need to address here.[8] There is first, ample evidence for a 'funding effect', that is, the tendency of scientific research to support the positions of those who sponsor the research (e.g., Als-Nielsen et al. 2003). If there was such an effect and we expect drug makers to behave similarly or worse in a regulation-free environment, doesn't that mean that they would run pseudo-trials aimed to convince the public of the safety and efficacy of the drugs without demonstrating this? However, there are several explanations for the correlation between sponsorship and results. Pharmaceutical companies may be more selective and only test those compounds of which they are nearly certain that they will succeed; industry- and government/non-profit-sponsored studies may differ in quality and methodology; there may be publication bias in that industry-sponsored research with a negative outcome is less likely to be published (Krimsky 2013). Of these, only the last is clearly undesirable from an epistemological point of view and can be associated with industry behaviour aimed at suppressing negative results. The first, selectiveness, is nothing bad if the goal is to keep unsafe drugs out of the market. At any rate, one cannot blame pharmaceutical companies for not investing large sums of money in the development of drugs they expect not to meet FDA standards. Study quality appears to speak in favour of industry-sponsored research (Als-Nielsen et al. 2003, 925).

Methodological differences are difficult to judge in the absence of clear and precise standards. A possible explanation for divergent results may be that industry trials compare the new treatment against a placebo whereas government/non-profit trials compare it against the current standard. Given that the FDA only requires treatments to be safe and effective, rather than safe and more effective than the current standard treatment, the government/non-profit choice does not seem obvious. Nor is it obvious that the FDA *should* require more than safety and efficacy. A new drug that is no more effective than an existing competitor *on average* may be a lot better for some patients and come with fewer or different side effects. Similar points can be made about other methodological choices.

Let us nevertheless assume that (a) there exists a 'funding effect' in the current regime, and (b) it is best explained by industry's conscious or unconscious manipulations of trial set-up, execution, interpretation and publication of results in order to make new drugs appear in a favourable light. What would happen to this effect if there were no FDA? The first thing to note is that I am not advocating the abolishment of the FDA, leaving everything else in place. Patents have to go first. Now, in a competitive industry, are pharmaceutical companies likely to cheat? No doubt, some will try. However, one should not underestimate the power that consumers (as a whole) have in a competitive market. When consumers have no way of telling the quality of a product, but know that they have a certain chance of getting a washout, they simply pull out of the market, as in Akerlof's 'lemons model' (Akerlof 1970). The market for new drugs would collapse. Then companies would *have* to come up with credible ways to signal quality. This might happen through (legally enforceable) guarantees, branding, industry associations and other mechanisms. Without government-sponsored monopolies and seals of approval, companies have to compete for business. Credible product quality is one way to do so.

Next we might ask: if the drug producers have to produce the evidence that their products are safe and effective anyway, what is the advantage of my proposal over the status quo? This objection is based on a confusion between what I called 'quality' in the previous paragraph and 'safety and efficacy' in the FDA's terms. There are two aspects. One is that no one knows how best to demonstrate product quality, even if we all agreed that a good product most be 'safe and effective'. A free market would allow several approaches to compete so that in good time we can learn what works. The other is that a good product does not have to be 'safe and effective'. A good product can be a highly risky product. What matters is that consumers are made aware of the risks when they are known, or that they are facing unknown risks (or 'uncertainty') when they are not. There is no reason for a regulatory body such as the FDA to decide for patients what levels of risk to accept. I will discuss this point more fully in the next subsection.

3.2 *The Moral Dimension: Who Should Decide How to Trade Off Risks and Benefits?*

As numerous authors have pointed out, evidential reasoning does not proceed in a moral vacuum. Here is one mechanism by which values enter the game. Hypothesis acceptance is always subject to what Carl Hempel called 'inductive risk': the risk 'that the presumptive law may not hold in full generality, and that future evidence may lead scientists to modify or abandon it' (Hempel 1965, 92). Thus, if the FDA approves of a drug, thereby accepting the hypothesis that it is safe and effective, it risks that future evidence may demonstrate that it wasn't safe and effective for everybody or that it was simply mistaken in its judgement. As described in the previous subsection, there are two types of error it might make: accepting a hypothesis that is in fact false ('type-I error') or rejecting a hypothesis that is in fact true ('type-II error').

Setting our evidential standards higher or lower, we can influence the chances of either type of error happening. In the extreme case, we can eliminate one type completely: by accepting every hypothesis we can eliminate type-II errors; by rejecting every hypothesis we can eliminate type-I errors. There is thus a trade-off: the more conservative or cautious we are, we will reduce type-I errors, but thereby increase the chance of making a type-II error; the more adventurous we are, we will reduce type-II errors but increase the chance of making a type-I error.

A judgement about how to trade off the two error types will involve normative reflection (Rudner 1953). This is because making a type-I error will typically have different consequences from making a type-II error. If the FDA approves of a drug that is not in fact safe and effective, patients who take the drug will be harmed. If the FDA fails to approve of a drug that is safe and effective, patients who suffer from a disease for which the drug provides relief will be harmed. One cannot make a judgement about how to trade off the two types of error optimally without taking into consideration which of the two harms is worse.

Probably because of the history of drug approval legislation (recall that the two main pieces of legislation were enacted in response to scandals caused by harmful treatments having been marketed), the FDA's main focus is on avoiding type-I errors. But this means that many drugs that are effective never reach the market. Because of the lengthy testing process the FDA requires, many effective drugs reach the market much later than they could. This also creates harms: patients who die or suffer unnecessarily because essential drugs do not reach them, or do not reach them soon enough.

A question one might raise is whether the FDA is legitimised to make this decision (about how to trade off type-I and type-II risks) for us. The Food, Drug and Cosmetic Act of 1938, which gave the FDA the authority to oversee the safety of drugs (and food, and cosmetics), and the 1962 Kefauver-Harris

Amendment to it, which extended the FDA's authority to also require proof of effectiveness, were passed by the U.S. Congress and can therefore be said to have some democratic legitimacy. But it is obvious that the decision about how to trade off the two kinds of risk should not be made once and for all but rather in a case specific manner. Richard Rudner wrote (Rudner 1953, 2):

> Thus, to take a crude but easily managable example, if the hypothesis under consideration were to the effect that a toxic ingredient of a drug was not present in lethal quantity, we would require a relatively high degree of confirmation or confidence before accepting the hypothesis—for the consequences of making a mistake here are exceedingly grave by our moral standards. On the other hand, if say, our hypothesis stated that, on the basis of a sample, a certain lot of machine stamped belt buckles was not defective, the degree of confidence we should require would be relatively not so high.

One can make the same argument when comparing different drug approval cases. We should require one standard when, say, approving of a potentially life-saving drug for a new disease that threatens a large number of people and for which there does not exist a treatment. We should require a different standard when there already exist numerous treatments, and the new drug might make, at best, a marginal difference to patients.

No doubt, the FDA does use discretion for exactly these kinds of reasons. For example, in 1987, after massive pressure from HIV/AIDS activists, it approved of azidothymidine (AZT) for use without phase-III trials and after only two years of testing (as compared to the usual twelve!) (Collins and Pinch 2005, 163). If the original standard was democratically legitimised due to the acts that Congress passed, one can certainly not argue that deviations from the standard are equally legitimised.

In the literature on expert judgement in science it is sometimes argued that the public should participate in scientific decision making in order to enhance democratic legitimacy in cases where value judgements matter (e.g., Douglas 2005). From a democratic point of view, including consumer representatives would constitute an advance over a purely technocratic approach. Indeed, FDA Human Drug Advisory Committees regularly have, apart from scientific experts and representatives of the pharmaceutical industry, consumer and patient representatives.[9]

But we should ask whether this is enough to make approval decisions democratically legitimate. Having consumers and patients represented is certainly better than not having them represented. But neither is it clear that consumer and patient 'representatives', who self-select into these committees and, in addition, have to fulfil a number of criteria to be eligible, and share the values of those they are supposed to represent. Nor is it clear that these values find their way into the ultimate decision. On the one hand, there are groupthink and other phenomena that can bias group decisions in numerous ways (Solomon 2006). On the other, the FDA can, but does not have to, follow the recommendation of the Advisory Committee. At the end of the day, the administration decides.

There is, in addition, a deeper problem. Suppose FDA decision-making is fully democratically legitimate. Perhaps we vote for our representatives. Perhaps, before a decision is taken, the general public is consulted and there are mechanisms for everyone to contribute his or her preferences, or at least all those affected by the disease targeted by the drug to be approved. Perhaps, drug referendums are organised, leaving the ultimate decision to the public. The question is why the decision about what risks to accept should be a democratic decision at all. Shouldn't it rather be an individual who, in consultation with his or her physician, family and insurer, decides what level of risk is appropriate in his or her life circumstances?

I cannot enter a general discussion over paternalism here. But it seems to me that the same arguments that apply to a case where someone has to decide whether a patient should undergo mammography when there are *known* risks of radiation, false positives and negatives, anxieties associated with outcomes and so on, also apply to cases where the sizes and natures of the risks are not known (and the patient faces *uncertainty* rather than *risk*). And he or she who defends that the individual patient should have a say in the former case, should, to be consistent, also defend that the individual should have a say in the latter case. Instead of telling patients what levels of risk they may and may not accept, we can all become more risk savvy and take decisions ourselves (Gigerenzer 2014).

4. Socialised Science vs Biomedical Capitalism

The arguments given in Sections 2 and 3 all point in the same direction: while it is true that much is wrong with the way in which much biomedical, in particular pharmaceutical, research is practiced, the right response does not seem to be less competition, which we would have if BMR was socialised, but rather more competition. I do not see how 'socializing the whole shebang' (Brown 2004) would solve any of the problems discussed here. Brown and I agree that there is something wrong with the current patenting system. So it should be changed. With what do we replace the current system? In the absence of government-sponsored incentives, potential inventors have to be motivated to invent somehow. Of course, there is such a thing as an intrinsic motivation. I have no doubt that many true inventors are intrinsically motivated or motivated by non-monetary extrinsic factors such as fame and academic reputation. Jonas Salk, inventor of the polio vaccine, once dismissed the idea of patenting his invention because it would be 'like patenting the sun' (Kealey 2010, 369).[10]

But it is important to understand that the true social benefit of drug development lies not (or only to a small extent) in the original idea. Ideas are a dime a dozen. What matters most is turning the idea into a marketable product. Unfortunately, this is not a very prestigious task that will win one the Nobel Prize or some other kind of fame or academic reputation. It is not an accident that by the late 1970s, before the Bayh-Dole Act gave universities, small businesses and the NIH control over their inventions stemming from government-funded research and the ability to charge royalties to the pharmaceutical industry in exchange for licenses, the U.S. government had amassed 30,000 patents in biomedical inventions, 95% of which were never commercially exploited.

It is this part of the job that requires an extrinsic motivation,[11] and the motivation associated with the freedom to own property and defend its value in markets appears to be the greatest motivator of all. Socialist systems have tried to replace this kind of motivation with other forms of extrinsic motivation in medals and (pseudo) positions, but for all we know the socialist analogue does not work so well.

This might still leave a role for socialised drug testing. In previous work, I myself argued that drug development and testing should be conducted independently (albeit by private bodies, see Reiss 2010). I now think that development and testing is too entangled for this to be feasible. If this is correct, then either both should be private or both should be done by the government. As the government isn't likely to be an efficient drug developer, both should remain in private hands.

But surely, one might argue, drug *approval* should remain in public hands. As argued in Section 3, I believe that there are good epistemic and moral arguments speaking against this. The epistemic argument is, in essence, that regulation does not make sense unless there are clear and public standards against which to assess a New Drug Application. But there aren't. A system in which several approaches compete is more likely to come up with a solution that works best—and that works best in a world in which our knowledge, the phenomena it describes and our aspirations and values continuously change—than a system in which there is, necessarily, a single approach that is regarded as transcendental, universal and independent of context.

This last point also speaks against socialised medicine even if we ignore the problems concerning invention, development, and testing. To the contrary, a system in which all four—invention, development, testing, and approval—are in one and the same hand is likely to be much worse than the status quo. As argued earlier, the view that the government pursues what it takes to be in the public interest is a legend. At the moment it can at least sometimes declare itself to act in the public interest, when it keeps the 'evil' pharmaceutical industry in check by requiring exhaustive tests to keep unsafe or ineffective drugs out of the market. But if the government is

now—its employees magically motivated to expend their time and efforts on this—itself the drug inventor, developer and tester, how could it continue to play this role? Why would the left hand stop what the right hand has invented and developed at a large cost?

It would therefore be down to courts of law to make judgements about compensation for harms the government causes. So far, no improvement over biomedical capitalism. In fact, the situation is worse than under biomedical capitalism. First, the more power the government has, the harder it will be for courts to be independent. Under biomedical socialism, courts are likely to rule in a government-friendly manner. Second, as there is one body rather than many bodies in competition, it is less likely that the drug approval body will find a recipe for a drug quality proof. In both respects biomedical capitalism is likely to be superior.

Notes

1 A fringe benefit that I cannot discuss in the detail here is the following. Patents skew the market towards solutions that are patentable—pills over environmental approaches, for example. In a competitive market, no such skewing would obtain.

2 I shall ignore values here (or rather, assume that all involved parties share the same values) because values will be treated in the next subsection.

3 http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm

4 Most of this is public information, though the claims about the family having to rescue the company is from the company's website: http://www.contergan.grunenthal.info/grt-ctg/GRT-CTG/Die_Fakten/Chronologie/en_EN/152700079.jsp.

5 In order for tort law to deter negligent behaviour, three conditions must be met: (a) the penalty must be large enough; (b) the risk of detection and punishment must be non-negligible; (c) the company owners must bear the cost of the penalty without being able to pass it on to the public or others. These are non-trivial issues, and the existing system of litigation is surely not perfect. Due to space limitations, I cannot pursue the matter further here.

6 Geoffrey Brennan and James Buchanan speak of the 'myth of benevolence' (Brennan and Buchanan 1985, Ch. 3).

7 Arguably, the FDA is also under pressure from the pharmaceutical industry to lower the bar. Exerting pressure on regulators is typical of the kind of rent-seeking behaviour that is characteristic of monopolistic industries as described earlier. In a (patent) free market, one would find less of it, partly because there would be less money around to invest in these activities. At any rate, the point I am making here is that (with or without industry pressure), regulators are not disinterested agents motivated by the 'public good'.

8 Many thanks to the editors for urging me to discuss these.

9 http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/MembershipTypes/default.htm

10 Today's biomedical researchers are much less timid in asking to patent apparently natural phenomena such as human genes.

11 Whether intrinsic motivation suffices to produce a range of useful pharmaceuticals is certainly an empirical question that cannot be settled by a single figure. Following Richard Titmuss's seminal study of the U.S. and UK blood procuring systems (Titmuss 1970), there is now a large literature looking at the relations between intrinsic motivations and market mechanisms. Other than noting that the debate is certainly not settled in favour of intrinsic motivations, I cannot go into the issue here.

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