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A Consequentialist Evaluation of Industry Funding
and Commercialisation of Public Biomedical
Research

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Abstract

There has been much discussion surrounding the relationship between academia and industry over the last few decades. Many governments have actively encouraged greater collaboration between the two and more entrepreneurial activity from academics, and the institutions themselves and industry have been just as keen to follow these incentives.

Despite the support for closer ties between industry and academia it has not been without its detractors. Many opponents argue that industry funding and commercialisation of public biomedical research (BMR), and research in general, is undermining the goal and norms of the institution of public BMR.

These opponents have tended to offer one of two solutions; the *management* strategy, which looks to mechanisms such as increased transparency to fix the problem; and the *divestment* strategy which looks to increase, to varying degrees, the separation between industry and academia.

The purpose of this thesis will be to examine the problems caused by industry funding and increased commercialisation of public BMR, and the proposed solutions within a consequentialist ethical framework. In order to assess these solutions, I will refer to: the substantive debate amongst consequentialists between "Actualism" and "Possibilism", Philip Pettit's distinction between treating people as "potential interlocutors" or "merely parametric", and will also draw on Michael Smith's concept of "capacities".

Ultimately, I will find that the proposed solutions to the problems of industry funding and commercialisation of public BMR are untenable by themselves, and have ignored the possibility of engaging researchers as potential interlocutors. Finally, I will offer my partial and complementary solution, which is to engage researchers as potential interlocutors by trying to enhance their capacity to adhere to institution norms through an improved and expanded ethical training.

Statement

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name in any university or other tertiary institution and, to the best of my knowledge and belief contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint award of this degree.

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Alexander Greville

Date

Introduction

There has been much discussion surrounding the relationship between academia and industry over recent decades. Many governments around the world including Australia have actively encouraged greater collaboration between the two and more entrepreneurial activity from academics. While this has been promoted by regulators, the institutions themselves and industry have been just as keen to follow these incentives.

Despite the support for closer ties between industry and academia it has not been without its detractors. Many opponents argue that industry funding and commercialisation of public biomedical research (BMR), and research in general, is undermining the goal and norms of the institution of public BMR.

These opponents have tended to offer one of two solutions; the *management* strategy, which looks to mechanisms such as increased transparency to address the problem; and the *divestment* strategy which looks to increase, to varying degrees, the separation between industry and academia.

Both the concerns raised and the solutions offered in response raise complex questions of ethics with potentially profound effects for researchers and for BMR. The purpose of this thesis will be to examine the problems caused by industry funding and increased commercialisation of public BMR, and to assess the proposed solutions within an ethical framework. Having established this framework, I consider how adequately these proposed solutions address the problems of industry funding and commercialisation of public biomedical research, identifying their strengths and weaknesses. Where they prove to be untenable or insufficient by themselves, I contribute a supplementary strategy.

In chapter 1 I aim firstly to conceptualise public biomedical research as a goal-directed social institution. While a full account of social institutions is beyond the scope of the thesis, I will survey a number of accounts of social institutions within the literature and identify commonalities in order to establish a working definition. In doing so I will suggest that Miller's summary of four important characteristics of social institutions offers an acceptable working definition¹. Miller's four characteristics are: structure, which has people as role-holders whose roles are defined by the tasks and rules which govern the performance of those tasks, and by the role's relation to other roles; function, which is oftentimes a practical or expressive aim of the institution; norms or culture, whose purpose is to encourage or inhibit certain behaviour for the purpose of the functioning of the institution; and finally, sanctions which are imposed upon the breach of the norms².

I will argue that insofar as public biomedical research has all of these properties, it is then best understood as a social institution. In addition, I will suggest that it is goal-directed, which is not necessarily true of all institutions, but is true of public biomedical research. Understanding biomedical research as a goal-directed social institution has normative implications for how the institution should be structured and its constitutive roles, sanctions and norms.

Part of what makes an institution ethically justifiable is a) how good its goal is, and b) how effective it is at achieving this goal. That is, ethically speaking the best institutions will be those whose goals are morally justifiable and are as effective as possible in achieving these goals. Not all social institutions are

¹ S. Miller, *The Foundations of Social Institutions: A Philosophical Study*, Cambridge University Press, 2010, Introduction, section 4.

² *Ibid.*

morally justifiable, and some will instead be morally reprehensible, depending in part on their goal.

I will argue that the aim of public biomedical research is to promote welfare via improving health and that this is a morally good aim. Welfare-consequentialism is therefore an appropriate theory for assessing the social institution of biomedical research. While those who are not persuaded by welfare-consequentialists will likely have concerns beyond welfare-maximisation; despite this, welfare-maximisation should still be a major concern for any ethicist. Thus, regardless of whether others agree with welfare-consequentialism, any supporter of a proper ethical theory will take seriously the assessment of the welfare produced by social institutions whose aim is to promote welfare.

Chapter 1 will draw two main conclusions. The first is that public biomedical research has all the hallmarks of a social institution and therefore I will treat it as such. The second is that I will assess the goal of public biomedical research and its design by reference to welfare consequentialism.

Having established this approach, in following chapters I will proceed to assess the positive and negative consequences of industry funding and commercialisation of public BMR.

Chapter 2 will introduce the Mertonian norms as the appropriate norms for the social institution of public BMR. I will draw heavily on this argument in later chapters in relation to the problems and solutions to industry funding and commercialisation of public BMR.

When discussing 'norms' I will use a sociological understanding which identifies norms as "a shared expectation of behaviour that connotes what is considered

culturally desirable and appropriate. Norms are similar to rules or regulation in being prescriptive, although they lack the formal status of rules”³.

It is a requirement not only of consequentialism but also of instrumental rationality, that all things being equal, if a social institution has a goal then the constituent parts of that institution should be those which best help to achieve its goal. Social institutions, such as public biomedical research, have as a part of their make-up specific norms. Therefore, the best norms for an institution to have are those which help it best achieve its aims.

The sociologist Robert K. Merton gives a plausible account of four norms of science which might be useful for public biomedical research in best achieving its goal; universalism, communism, disinterestedness and organised scepticism⁴. Universalism suggests that scientific claims are to be judged according to pre-established and impersonal criteria and that any personal qualities of the scientist making the claim are irrelevant⁵. Communism claims that the discoveries of science do not belong to any one scientist or group of scientists but to the scientific community⁶. Disinterestedness implies that scientists should not be overly invested in their own research whether it be for financial, professional or personal reasons, rather they should be motivated by the search for the truth⁷. Finally, organised scepticism claims that scientists suspend judgement about their own research and that of others until the facts are at hand⁸.

³ J. Scott & G. Marshall. “Norm.” In *A Dictionary of Sociology*, Oxford University Press, 2009 <http://www.oxfordreference.com.proxy.library.adelaide.edu.au/view/10.1093/acref/9780199533008.001.0001/acref-9780199533008-e-1576>. Accessed 26/05/2016

⁴ R. Merton, *The Sociology of Science; edited and with an introd. By N. W. Storer.*, 1973, Chicago: University of Chicago Press, pg. 270

⁵ R. K. Merton, *The Sociology of Science*, pg. 270

⁶ R. K. Merton, *The Sociology of Science*, pg. 273

⁷ R. K. Merton, *The Sociology of Science*, pg. 276

⁸ R. K. Merton, *The Sociology of Science*, pg. 277

Merton argues that these norms are not only important for ensuring the proper functioning of science in respect to its goal, but are also morally good. He states, “the mores of science possess a methodologic rationale but they are binding, not only because they are procedurally efficient, but because they are believed right and good. They are moral as well as technical prescriptions.”⁹

If Merton is indeed correct and these norms help science function by either increasing the reliability of truth-claims or by increasing the efficiency of public biomedical research as an institution, then it stands to reason that it is best for this institution to have these norms, all things being equal. It is therefore reasonable to believe that these norms may indeed be useful to science in the ways I have suggested, the evidence for which will be discussed in chapter 2.

Merton, however, also seems to imply that rather than the norms applying to individual researchers they are found instead as mechanisms within the institution, such as peer-review¹⁰. I will propose an interpretation of the Mertonian norms indicating that they should apply as action-guiding for individual researchers, not just apply at an institutional level.

Chapter 3 will explore arguments in favour of industry funding and commercialisation (IFaC). As context, I will briefly examine the literature concerning the trend towards commercialisation and university-industry relationships. There has been a major push from regulators towards closer relationships between academia and industry and increased commercialisation of academic research. This has happened here in Australia and other major research intensive countries such as the United States.

I will then consider two main types of arguments in favour of industry funding and commercialisation: arguments from non-health benefits to society and

⁹ *Ibid.*

¹⁰ R. K. Merton, *The Sociology of Science*, pg.277

arguments from benefits to biomedical research and health. Non-health benefits from IFaC focusses on the broader economic effects produced by increased innovations spurred on by IFaC. Proponents argue that this increased innovation is good for society at large as it creates new sectors in the economy and enhances already existing sectors and in doing so makes society better off. Therefore, all things being equal, if we can capture these auxiliary benefits as well as the health benefits, then we have consequentialist reasons to do so.

The first argument from benefits to health and BMR is that all things being equal, more money means more biomedical research and industry funding and commercialisation means more money. Therefore, all things being equal, there is a consequentialist justification for industry funding and commercialisation of public biomedical research.

A further health related argument made by proponents of commercialisation and industry funding is that they more effectively bring products to market, for a combination of reasons. Firstly, the private sector has more incentive to bring research from academic journals and on to the market. Secondly, public biomedical research does not have the resources or the capacity to bring products to market. Public biomedical research, generally speaking, does not have the appropriate infrastructure, including manufacturing infrastructure, to mass produce new pharmaceuticals or prosthetics for example. Moreover, public biomedical research does not have the appropriate funding to carry out essential late stage clinical trials, the trials which establish efficacy by testing the drug in very large numbers of patients. Therefore, if industry funding and commercialisation help solve these problems and thus improve the effectiveness of public biomedical research, we have consequentialist reasons to encourage them.

In chapter 4 I turn to the negative consequences of the current model of industry funding and commercialisation of public BMR, surveying the literature and discussing some of the key points raised in opposition to IFaC.

The primary objections against IFaC are epistemic, focussing on how IFaC is negatively affecting our knowledge in two different ways; what we know and the reliability of our knowledge. These problems limit BMR's welfare production.

I will argue that these problems are more than just incidental, problems that *happen* to be occurring, but rather they are inherent risks of IFaC. This argument will rely on the earlier understanding of social institutions, and the goal and norms of public biomedical research established earlier in this thesis.

The argument will draw on these earlier points: that public BMR is a goal-directed social institution trying to maximise welfare through health; that the norms of an institution should be those that best help the institution achieve its goal; and finally, that for public BMR the norms should be something like the Mertonian norms, which should apply as action-guiding for individual researchers. In other words, as previously suggested, the norms are important because they are functional; if you change the norms you should expect to see a change in the functioning of the institution.

Since the goal and thus the norms of private BMR are different to that of public BMR the increasing closeness of the two has served to undermine the norms of public BMR. This gives us reason to appreciate that the current problems caused by IFaC are not merely coincidental but are an inherent risk of IFaC.

These problems naturally give rise to questions about how best to rectify them. How we best deal with the problem will depend at least in part on whether the researchers themselves will be able, in the face the of perverse incentives, to appropriately adhere to the Mertonian norms. Using Phillip Pettit's terminology,

will we be able to engage researchers as “potential interlocuters”, agents who are responsive to reason, or as “parametric” which is to simply assume their wrongdoing as a given in our decision making¹¹? In order to best address this question I will refer to a substantive debate in the consequentialist literature between Actualists and Possibilists¹². The former assumes likely wrongdoing as part of the background information for decision making, while Possibilists argue that we should not take wrongdoing as a given, rather we need to consider an agent’s capacity to do the right thing.

Finally, in order to understand what is meant by “capacities”, I will discuss an account given by Michael Smith. A full discussion of capacities is well beyond the scope of this thesis so I will rely on Smith’s account as a reasonable account of capacity. According to Smith capacities are not an all-or-nothing phenomenon; instead there are degrees of capacity¹³. The mechanism he uses to understand capacities is to refer to whether or not an agent reliably performs an action in a raft of nearby possible worlds. This understanding of capacities will then inform a discussion of solutions to the problems caused by IFaC.

In chapter 5 I will begin by examining the two main proposed solutions to the problems caused by IFaC, namely the *management* and the *divestment* strategies. Both of the strategies have implications for the assumptions we make about researchers and their capacities, and I will discuss these assumptions as well as the benefits and shortcomings of both strategies. Ultimately, I will demonstrate how both strategies are wanting and will offer my own partial and supplementary solution to the problem drawing on my understanding of public

¹¹ P. Pettit, The Consequentialist Perspective in M. W. Baron, P. Pettit, M. Slote, *Three Methods of Ethics: A Debate* (Great debates in philosophy), Oxford, UK; Malden, Mass: Blackwell, 1997, pg.165

¹² F. Jackson & R. Pargetter, Oughts, Options, and Actualism, *Philosophical Review*, 1986: 95(2), pg.235

¹³ M. Smith, *Ethics and the a priori: selected essays on moral psychology and meta-ethics*, Cambridge; New York; Cambridge University Press, 2004, 124

BMR as a goal-directed institution, institutional norms, capacities and potential interlocutors.

The first strategy, the *management* strategy, will be divided into two separate sub-strategies. These sub-strategies are appropriately grouped together as they both maintain that the current relationship between industry and academia is inevitable and thus focus on managing this relationship in some way. The first, weak *management*, which is currently the status quo for attempts to address problems caused by IFaC, provides suggestions that vary greatly across institutions but tends to focus on declaring conflicts of interest. Importantly, this strategy treats researchers as potential interlocutors in that it assumes that they have the capacity to do the right thing, even in the face of strong perverse incentives. I will argue that this strategy has ultimately been a failure.

Strong *management* by comparison demands greater openness and transparency in biomedical research. Its proponents argue that measures such as compulsory pre-registration of clinical trials may help overcome some of the issues caused by IFaC. This strategy treats researchers as merely parametric; rather than engaging researchers as potential interlocutors it assumes their wrongdoing and offers solutions that change incentives structures, assuming that researchers' behaviour will follow these changes. Despite its limitations, I will argue that many aspects of strong *management* are potentially advantageous and should be adopted.

The second strategy is the *divestment* strategy which calls for varying degrees of separation between academia and industry. At one end of the spectrum there is complete divestment of IFaC from academia. This is undesirable if what was argued in chapter 3 is indeed correct regarding the value of extra funding and the other benefits of IFaC. Further across the spectrum of divestment there are those who call for a 'firewall' to be established so there is no direct interreaction between academics and their industry funders. The divestment strategy assumes

that researchers will be unable to resist perverse incentives from IFaC and thus treats them as merely parametric. Ultimately, while some level of divestment seems necessary in order to overcome the problems caused by IFaC, this strategy seems doomed to fail, as overcoming the current attitudes and deeply entrenched interests of all parties involved in IFaC seems nearly impossible in the current climate.

Finally, I propose a supplementary strategy, which has been largely overlooked in the literature. I will refer to this as the *educational-cultural* strategy, and it will call on several of the previous arguments I have made, including understanding public BMR as a goal-directed social institution, my interpretation of the Mertonian norms, and our concept of capacities. The *educational-cultural* strategy seeks to engage researchers as potential interlocutors by improving their capacity to resist perverse incentives and act in accordance with the Mertonian norms. This strategy will rely on improved ethics education: training researchers in the nature of the problems of IFaC, the ethical problems relating to research, and their professional obligations regarding research and the Mertonian norms. This is in the hope that, as we have started to see, there will be a grassroots shift in the culture and greater recognition of the problems caused by IFaC. In doing so I hope to change researchers' attitudes towards IFaC. This strategy is not without its own problems; for one it is highly idealistic.

Notwithstanding its idealistic assumptions, there is reason to believe that coupled with a number of the suggestions made by strong *management* it has some potential to contribute to countering the risks of IFaC.

Regarding the *educational-cultural* strategy's viability all that is required of it to be a reasonable suggestion is that it is more realistic than the *divestment* strategy which it will be shown to be, and that it has the potential to accomplish more

than weak *management* which has been a failure to date, and that together with strong *management* it can produce more utility than strong *management* alone.