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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.

Chapter 1

The purpose of this chapter is to establish that biomedical research is a goal-oriented social institution, and that global welfare-consequentialism is an appropriate ethical theory to assess public BMR as a social institution. This in turn will have implications about how the institution is structured, and the role of industry funding and commercialisation that will be discussed in later chapters.

The first section of this chapter will discuss what biomedical research is. Although an exact definition in terms of necessary and sufficient conditions is not required, it will still be important to clarify what is meant by biomedical research in this thesis. In order to do this, I will discuss the different activities of biomedical research and how it is funded.

The next section of this chapter has two aims: to offer a working definition of social institutions in terms of their salient properties; and to establish public BMR as a goal-directed social institution by arguing that it possesses all the important properties of a social institution.

The final section will set out the appropriateness of a consequentialist assessment of public BMR. I will suggest that for any goal-directed social institution, a primary justification for the institution will rely on the evaluation of the value of its goal and its effectiveness in attaining this goal. In light of this, I will argue that global welfare consequentialism is an appropriate theory for providing this sort of evaluation of public BMR. The final part of this section will address objections to a consequentialist assessment of public BMR.

Section 1 – *What is Biomedical Research?*

In order to provide an explanation of what is meant by “biomedical research”, I will discuss some of its facets, including how and by whom it is funded, where it is performed, and the activities performed within it. The purpose of this should be clear; some explanation of biomedical research is required before any further discussion about it can be had.

Biomedical research as an endeavour is similar to other types of scientific research and, as such, has broadly similar aims. The National Health and Medical Research Council (NHMRC) states that research is an “investigation undertaken to gain knowledge and understanding or to train researchers”¹⁴. A British Research Assessment Exercise in 2008 stated that research,

*includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performance, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experiment development to produce new or substantially improved materials, devices, products and processes, including design and construction.*¹⁵

In other words, research aims: to search for facts knowledge and understanding; to develop novel methods, techniques, technologies, products, theories and ideas; and to solve problems and answer questions.

Biomedical research has more narrowly defined goals than scientific research in general, as it is interested in certain types of knowledge and discoveries within a

¹⁴National Health and Medical Research Council, *National Statement on Ethical Conduct in Human Research*, 2007 (updated May 2015), Australian Government, <https://www.nhmrc.gov.au/book/glossary>, accessed 24/10/2016

¹⁵Research Assessment Exercise, *Research Assessment Exercise 2008: the outcome*, 2008, pg.5 <http://www.rae.ac.uk/results/outstore/RAEOutcomeFull.pdf> accessed 24/10/2016

more limited area of investigation. I will not offer a precise definition of the goal of biomedical research in terms of an exhaustive list of necessary and sufficient conditions. Instead, I will offer a list of uncontroversial claims about the goal of biomedical research. Biomedical research's focus is on understanding: biological, biochemical and biomechanical processes; disease pathways and pathologies; and producing novel methods, technologies, products and theories; often with the aim of solving particular problems or questions. In other words, biomedical researchers want to better understand how the human body works and how these processes can fail or be improved, as well as the mechanisms underlying diseases, including how they infect us and affect us. Biomedical researchers also look for methods of treating these diseases, disabilities and conditions, such as medical devices, pharmaceuticals, surgical procedures and techniques, lifestyle changes, and environmental changes.

1.1 – Basic and Applied Research, and Research Funding

In order to render my previous generic description of biomedical research more accessible, it will be helpful to further explain what is meant by BMR by looking at the types of research done within it. Research is often divided into two categories: 'basic' and 'applied'. The distinction between these categories of research is blurry, existing along a continuum rather than as distinct categories. Nonetheless, the distinction between the two is important as it is used by those who conduct and fund research, including government.

The goal of 'basic' research is to "increase understanding of a subject or natural phenomena, rather than the creation of specific applications"¹⁶. Thus, basic research is interested in the underlying processes, mechanisms and understanding of phenomena, without any immediate interest in producing

¹⁶ P. A. David, D. Mowery, W. E. Steinmueller, *Analysing the Economic Payoffs from Basic Research, Economics of Innovation and New Technology*, 1992: 2, pg. 74

applications or technologies. An example of basic research would be the examination of the physical structure of proteins to better understand how they are folded.

In contrast, the Australian Bureau of Statistics defines applied research as,

*original work undertaken primarily to acquire new knowledge with a specific application in view. It is undertaken either to determine possible uses for the findings of basic research or to determine new ways of achieving some specific and predetermined objectives*¹⁷

As the name and this definition suggests, applied research focuses on the production of applications or the solving of a specific technical problem. Thus, while basic research may enquire into the mechanism behind how proteins are folded and misfolded, applied research might look for a compound that fixes misfolded proteins or the broken folding mechanism.

While the examples of basic and applied research given thus far are relatively clear cut, in reality most research does not fall so cleanly into just one of these research categories. Again, the distinction between basic and applied research is often indistinct, with much research straddling a position between the two. Basic research can inform applications and technologies, and research into applications can inform underlying theories and basic knowledge. For example, the discovery that the hormone erythropoietin was responsible for the stimulation of red blood cell production not only informed researchers regarding the mechanisms behind red-blood cell genesis, but was also the first step towards a treatment for problems such as anaemia¹⁸.

¹⁷ Australian Bureau of Statistics, *Research and Experimental Development: All Sector Summary*, 2008-09, catalogue number 8112.0, pg. 33
[http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/FE58F9E5232F039BCA2577B6001601AF/\\$File/81120_2008-09.pdf](http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/FE58F9E5232F039BCA2577B6001601AF/$File/81120_2008-09.pdf) , accessed 24/10/2016

¹⁸ Anaemia is a deficiency of red blood cells or haemoglobin in the blood.

Again, while the distinction between basic and applied research should be treated as a matter of degree, the distinction is nonetheless an important one, as different sectors tend to be involved in particular types of research.

Industry, which is a major research investor, has its own research capacity often in the form of in-house research facilities. Despite this, however, it still outsources much of its research, either to universities or increasingly to contract research organisations (CRO's)¹⁹. Notably, industry's research focus is almost entirely on applied research²⁰.

The other major sector besides industry that is involved in biomedical research is the public sector. The public sector is heavily involved in research in terms of both funding research and conducting research. Public research funding in Australia comes from both state and Commonwealth governments. While governments have some research capacity, much of the research they fund is through universities and research hospitals associated with universities. Government funding is provided to these institutions through direct funding, but also through research grants provided by bodies such as the Australian Research Council (ARC) and the NHMRC. University based research²¹ accounts for the majority of basic research and also applied research²².

¹⁹ T. O. McGarity, W. E. Wagner, *Bending Science; how special interests corrupt public health research*, Cambridge: Harvard University Press, 2008, pg.66

²⁰ Australian Bureau of Statistics, *Research and Experimental Development: All Sector Summary*, pg. 21

²¹ I will henceforth refer to this as "public"

²² *Ibid.*

Section 2 – *Social Institutions*

Public biomedical research should reasonably be considered a social institution and in order to establish this, this section will first give an account of what a social institution is. A full examination of social institutions is unnecessary for my purposes and beyond the scope of this thesis. Instead, by drawing on the literature, I will attempt to identify core features that any plausible definition of social institutions will include. I will argue any entity possessing these features should reasonably be considered a social institution.

To begin, it is important to demarcate social institutions from other smaller and larger social phenomena. For example, social institutions are more complex than “social forms such as conventions, social norms, roles and rituals”²³, many of which are constituents of social institutions. For example, primary education institutions have conventions regarding when the school day begins, but clearly the institution itself is far more complex than this convention.

Social institutions, however, are less complex than “complete social entities, such as societies or cultures”²⁴. For example, a nation state will contain any number of social institutions, but is itself vastly more complex than any one of its social institutions.

This, however, gives little guidance on what a social institution actually is, and thus I will highlight two standard definitions of social institutions from the literature. Jonathon Turner offers such a definition, suggesting social institutions are:

a complex of positions, roles, norms and values lodged in particular types of social structures and organising relatively stable patterns of human

²³ S. Miller, *The Foundations of Social Institutions: A Philosophical Study*, Cambridge University Press, 2010, Introduction, section 4.

²⁴ *Ibid.*

*activity with respect to fundamental problems in producing life-sustaining resources, in reproducing individuals, and in sustaining viable societal structures within a given environment*²⁵

Another definition is given by Rom Harre who suggests,

*an institution was defined as an interlocking double-structure of persons-as-role-holders or office-bearers and the like, and of social practices involving both expressive and practical aims and outcomes*²⁶

Many but not all social institutions are organisations²⁷. The definitions I have offered thus far apply to those social institutions that are organisations. This is appropriate, as the concern of this thesis is biomedical research, which is an organisation or a number of separate but related organisations. Thus, from the definitions given, it can be understood that institutions have roles which are filled by people and are defined by their tasks and their relation to other roles; and that these people-as-role-holders are nested within the broader culture and norms of the institution.

While any given definition may vary, and these variations may be substantive, there are also often salient similarities between them. It is on the basis of these similarities that important properties of social institutions can be reasonably established. Miller argues that social institutions have certain relevant features: a structure, a function, norms, and sanctions²⁸.

Miller explains that, “the constitutive roles of an institution and their relations to one another can be referred to as the structure of the institution”²⁹. Thus,

²⁵ J. Turner, *The Institutional Order: economy, kinship, religion, polity, law, and education in evolutionary and comparative perspective*, New York: Longman, 1997, pg. 6

²⁶ R. Harre, *Social Being*, Oxford: Blackwell, 1979, pg. 98

²⁷ S. Miller, *The Foundations of Social Institutions*, Introduction, section 4.

²⁸ *ibid*

²⁹ *ibid*

“structure” not only refers to the “roles” of the institution, but also refers to how these different roles are related to one another. For example, many institutions that are organisations have roles structured in a hierarchical form. The roles themselves are defined in terms of the tasks the person within the role is expected to perform and “the rules regulating the performance of those tasks”³⁰.

The “function” of the institution refers to the purpose of the institution. For example, the function of government, “consists in large part of directing, regulating, assisting, maintaining, or otherwise organizing other institutions”³¹. Thus, for example, one function of government is to regulate economic institutions.

“Culture” or “norms”³² refers to the implicit and informal rules of the institution, its values and attitudes; its ethos³³. The culture of the institution can determine the manner in which those within the institution behave and how they execute their role-related tasks. For example, there is the classic Hollywood situation where a police officer attempts to reveal another officer’s corruption. This honest behaviour is often met with contempt, and the honest police officer being ostracised by their peers, because “ratting out” a fellow officer is to violate the norms of the institution.

Finally, social institutions have as a feature, sanctions. As suggested above, there are informal sanctions, such as moral disapproval or ostracism by one’s peers. This, however, is somewhat misleading, as informal sanctions are a part of culture. Whether or not formal sanctions are an important feature of social institutions is less obvious. If only informal sanctions are a salient feature of social institutions, then this should be subsumed by the suggestion that norms are the

³⁰ *ibid*

³¹ *ibid*

³² I will use both terms interchangeably

³³ *ibid*

important feature. Having said this, for those social institutions that are also organisations, formal sanctions do appear to be a common feature.

Whether social institutions necessarily have goals or aims is debatable. Although Harre, Milller, and Turner suggest they do, there are accounts that argue a goal is not a necessary part of a social institution. I, however, will not engage in this debate, as it is clear that at least *some* social institutions do have a goal and biomedical research bears all the hallmarks of one of these goal-directed social institutions, as it seems *prima facie* that it must have a goal. This is made apparent by the definitions of research given earlier in this chapter, the language of which hints heavily at it being goal-directed. Language such as: “invention and generation”, “increased understanding”, “acquire new knowledge”, and, “achieving specific or predetermined objectives” is difficult to interpret as suggesting anything other than biomedical research being goal-directed.

This section suggested that while definitions of social institutions may vary, any plausible account will suggest that an entity with a function, a role-constituted structure, norms, and sanctions, qualifies as a social institution. Moreover, it was suggested that while some social institutions may not be goal-directed, it is clear that certain kinds of social institutions can be regarded as such.

2.1 - Biomedical Research as a Social Institution

Based on the criteria established in the previous section, biomedical research qualifies as a social institution, as it possesses all the salient features including; a role-constituted structure, a culture, a function, and sanctions. Furthermore, while not all social institutions are necessarily goal-directed, it is clear that BMR is goal-directed.

BMR comprises people as role holders, and these roles are structured in relation to each other as well as in relation to the goal of the institution. The structure of

roles between those within BMR is complicated in that while some of these structures are hierarchical, there are also other structures such as collaborative structures. An example of a hierarchical structure is the head of a laboratory, and the research assistants within that lab. Conversely a collaborative structure might be one where two physician-researchers require each other's skills in order to conduct a particular trial, and thus agree to collaborate.

The structure of BMR is made more complex due to having many separate but interdependent parts. Notably, research itself is performed in a number of different places, whether it be government labs, university labs, or research hospitals, all of which have their own structures. Many of these are also situated within the broader structure of the institution they reside in. For example, a university laboratory resides within the broader structure of the university itself. Moreover, researchers and their laboratories also have to interact with other researchers and labs, as well as with other important parts of the institution such as funding bodies and journals. This is all to say that BMR clearly has a structure but this structure is complex and multifaceted.

The function of BMR has already been covered in this chapter but I will reiterate that a reasonable working definition would suggest that the goal of public biomedical research is to enhance welfare through an increased understanding of: biological, biochemical and biomechanical processes; disease pathways and pathologies; and producing novel methods, technologies, products, theories, etc.; often with the aim of solving particular problems or questions.

Biomedical research also has a culture, although I will not discuss this here, as the next chapter is almost entirely dedicated to a discussion of the norms of BMR.

Finally, BMR also has the properties of both formal and informal sanctions. Formal sanctions can include suspension or termination of employment, and given that BMR has a culture, by extension, it has informal sanctions.

Any entity that has all of the following properties of a role-constituted structure, norms, a function, and sanctions, should be considered a social institution. Therefore, public BMR should be considered as such, as it has all of these properties.

Section 3 – *Biomedical Research and Consequentialism*

One aim of the previous section was to establish biomedical research as a goal-directed social institution. This is important because for any goal-directed social institution, a primary focus for its justification will lie in the evaluation of both the value of its goal, and its effectiveness in achieving this goal. Therefore, the aim of this section will be to argue that consequentialism is an appropriate ethical theory for evaluating BMR as a goal-directed social institution. More specifically, it will be suggested that global welfare consequentialism is an appropriate theory for this assessment.

The goal of the institution of BMR has been discussed previously and can be summarised as being: improving welfare through enhanced health. Any assessment of a welfarist social institution should include an assessment of its goal and how successful it is in achieving its goal. Welfare consequentialism provides the appropriate tools for this sort of institutional assessment. This, however, says nothing about what *the* correct ethical theory is more generally and I make no claims regarding this. Instead my claim is a modest one: welfare consequentialism is appropriate for assessing the welfare production of welfare-directed social institutions. Any other plausible ethical theory will think that welfare is morally significant and thus any ethical theory will partly coincide with global consequentialism in its evaluation of BMR. Thus, while other theories may have concerns beyond welfare, they should still recognise the importance of welfare and insofar as this is true will agree, at least in part, with the sort of consequentialist assessment of institutions I have outlined.

Part of the assessment of public biomedical research will focus on the assessment of the constituent parts of the institution, the norms, the structure, etc., and how effective they are in assisting the institution in achieving its goal. The right constituents will be those that best help the institution to achieve its goal; this is

a requirement of both procedural rationality and consequentialism. Procedural rationality is satisfied if an agent with a goal takes steps that are most effective in achieving said goal, although procedural rationality is silent regarding the value of this goal. The application to institutions here is clear, in that an institution with a goal should be comprised of those constituents that are most effective in helping achieve its goal.

In regards to consequentialism, its principle is that the right x is the best x , and the best x is the x that maximises value³⁴. More specifically, welfare consequentialism suggests that the right x is the best x , and the best x is that which maximises welfare. Moreover, welfare consequentialism often looks to promote basic goods that are believed to be basic constituents of welfare, such as health, education, adequate shelter, and other goods of this nature.

Thus, in order to satisfy the demands of consequentialism, the constituents of public BMR must be those that best help the institution best achieve its goal, providing that the goal is morally good. Therefore, according to consequentialism the norms, structure, and sanctions of public BMR should be those that are best suited to achieving its institutional goals.

This provides scope for the evaluation of public BMR.

3.1 - Global Consequentialism

This subsection will outline what Pettit and Smith refer to as “global consequentialism”³⁵. This outline will be established, in part, by explaining what is meant by “direct” and “indirect” consequentialism. Finally, I will offer a brief

³⁴J. Louise, *Right Motive, Wrong Action: Direct Consequentialism and Evaluative Conflict*, *Ethical Theory and Moral Practice*, 2005: 9(1), pg. 65

³⁵P. Pettit, M. Smith, *Global Consequentialism*, in *Morality, Rules and Consequentialism*, pg.122

explanation as to why global consequentialism is useful in assessing the social institution of public BMR.

When discussing consequentialism, there is often an assumption that what is being referred to is *act* consequentialism, which only applies the consequentialist principle directly to acts. Thus, for an act consequentialist, the right things are specifically those acts which best maximise value. There are numerous forms of consequentialism, which also only apply the consequentialist principle directly to a single “evaluative focal point”³⁶ such as, acts, motives, or rules. There is, however, an alternative consequentialist approach wherein the consequentialist principle is applied more broadly. This is what Pettit and Smith refer to as “global consequentialism”³⁷. Global consequentialism argues that the consequentialist principle should be applied directly to all relevant evaluands. That is, consequentialism should apply directly to, “not just acts and outcomes, but also desires, dispositions, beliefs, emotions, the colour of our eyes, the climate, and everything else”³⁸.

The use of the terms “direct” or “directly to” in the context of applying the consequentialist principle to all evaluands is meaningful. This is to differentiate it from forms of *indirect* consequentialism. Global consequentialism determines all evaluands' rightness by applying the consequentialist principle directly to them. This means that an act is the right act if it is the act that best maximises value; a motive is the right motive if this motive when possessed by an agent would be the motive that best maximised value; a rule is the right rule if it is the rule that amongst all potential rules would maximise value should it be followed; and so on.

³⁶ S. Kagan, *Evaluative Focal Points*, in *Morality, Rules and Consequentialism*, B. Hooker, E. Mason, D. E. Miller (eds), Edinburgh: Edinburgh University Press, 2000, pg.134

³⁷ P. Pettit, M. Smith, *Global Consequentialism*, in *Morality, Rules and Consequentialism*, pg.122

³⁸ *ibid*

By contrast, indirect forms of consequentialism apply the consequentialist principle directly to one primary evaluand and then determine the rightness of other evaluands indirectly by reference to the primary evaluand. For example, rule consequentialism is an indirect form of consequentialism, wherein the right rule is the best rule, and the best rule is that rule which, if followed, would maximise value. Thus, according to rule consequentialism, a right act is a right act if and only if this act was produced by correctly following the right rule.

Thus, the difference between global consequentialism and indirect forms of consequentialism is that the former applies the consequentialist principle directly to all relevant evaluands, whilst indirect forms of consequentialism apply the principle only to a single principle evaluand of their choice and all other evaluands are assessed by their relationship to the primary evaluand.

The reason for choosing global consequentialism over other forms of indirect consequentialism relates to the sort of assessment I am interested in undertaking in this thesis. Global consequentialism will be particularly useful for assessing public biomedical research as a social institution. The reason for this is that global consequentialism offers the ability to directly evaluate the various facets of the institution. Thus, while the moral evaluation of the actions of biomedical researchers is of interest to this thesis, so are their motivations, and so are the constituent parts of the institution, such as the institutional norms and the goal of the institution. Global consequentialism is unique in that it allows the direct assessment of all parts of a social institution, a possibility no form of indirect consequentialism can offer. Any indirect form of consequentialism could only evaluate a single evaluand and all other evaluands would need to be assessed by their relationship to the primary one. This would impede the proper assessment of an institution.

3.2 - Objections to a Consequentialist Assessment

The previous sections argued that any reasonable assessment of a goal-directed social institution should include an evaluation of how good the goal of the institution is, and how effective the institution is at achieving this goal. Due, in part, to this, I suggested that global welfare consequentialism is an appropriate ethical theory for assessing public BMR. This section will briefly address other concerns for a consequentialist assessment of social institutions.

While I addressed one immediate concern with global consequentialism from within the consequentialist literature, this does not mean there are no other reasonable objections. Other ethicists might object to a consequentialist assessment on the grounds that it will fail to address any other ethical concerns beyond welfare maximisation. Most notable of these concerns is likely to be that a consequentialist assessment will fail to properly recognise whether an institution appropriately respects rights, fairness and justice. Of course, any ethicist arguing from a particular ethical standpoint other than consequentialism will likely have their own specific concerns regarding what a consequentialist evaluation will overlook, but the classic objections to consequentialism tend to focus on rights, fairness and justice. For example, the case wherein consequentialism may entail that doctors harvest the organs of one healthy patient in order to save the lives of five more sickly patients³⁹.

Regardless of whether or not these are truly damaging objections to consequentialism, they are not problematic in the context of this thesis. The aim of this thesis is not to provide a full and proper defence of consequentialism but to provide a consequentialist assessment of public BMR. Even if consequentialism is unable to offer a proper evaluation of other ethical concerns

³⁹ R. E. Goodin, *Utilitarianism as a Public Philosophy*, Cambridge: Cambridge University Press, 1995, pg.23

such as rights, it is unreasonable to deny that the evaluation of the value of an institution's goal, and its effectiveness in achieving this goal are important. Thus, even if one believes other ethical factors bear on the justifiability of an institution, it cannot reasonably be denied that the ones I am assessing *are* important. The value of the goal of BMR and how effective it is in achieving it should be of importance to any ethicist, even if they have concerns beyond these two points of assessment.

Conclusion

This chapter first sought to establish public BMR as a goal-orientated social institution. I argued the salient features of social institutions include a structure, norms, a function, and sanctions, and that since public BMR possesses these features, it should be considered a social institution.

This chapter also outlined the nature and the appropriateness of a consequentialist assessment of public BMR as a goal-directed social institution. It was suggested that the primary focus of any evaluation of a goal-directed social institution will involve the evaluation of the value of the institution's goal, and the institution's effectiveness in realising this goal. Given this, and the welfarist goal of public BMR, welfare consequentialism was presented as an appropriate theory for assessing the institution. Moreover, it was argued that global consequentialism was the most appropriate version of consequentialism to use in the assessment of public BMR as a social institution.

Finally, the potential problem that a consequentialist assessment of public BMR or any other social institution will fail to address any number of potentially important ethical facets, such as rights or justice, was considered. In response, it was argued that while those other ethical issues may indeed be important, so too is the evaluation of the value of the institution's goal and its effectiveness in achieving it. In other words, while valid ethical concerns may exist beyond the

scope of this analysis, the importance of the ethical evaluation I am undertaking cannot reasonably be denied by those who are not consequentialist.

Chapter 2

The previous chapter asserted that public biomedical research should be considered a goal-directed social institution. The goal of BMR indicates how the institution should be organised in regards to its roles, structure, formal rules and norms. This chapter will discuss what norms are best suited to achieving the goals of public BMR. In this discussion, I will refer heavily to the work of sociologist Robert K. Merton and his work regarding the norms of science. I will suggest that the Mertonian norms of science are useful in helping public biomedical research in achieving its goal, and that these norms should be considered action-guiding for individual researchers.

This chapter will begin with a discussion of the Mertonian norms of science: universalism, communism, disinterestedness and organised scepticism. I will also explain that these norms are important for biomedical research, as they help the institution best achieve its goal.

Following this, I will outline my interpretation of the Mertonian norms, which is that they should be considered action-guiding for individual researchers. An important aspect of this argument will be based on understanding the Mertonian norms as being aspirational. In defending this claim, I will also consider certain objections to my position including arguments that if the Mertonian norms are applied as action-guiding for individual researchers they would be impossible to achieve, and it would be undesirable if researchers were to fully achieve them.

Section 1 - *The Mertonian Norms*

In the previous chapter I maintained that biomedical research should be considered a goal-directed social institution and because of this, the design (the structure, roles, norms, etc.) should be that which best helps it achieve its institutional goal. This section will explore which norms are best for BMR in achieving its goal, arguing that the Mertonian norms, when applied as action-guiding best fits this criterion.

Therefore, this section will be divided into three subsections. The first will discuss the Mertonian norms: communism, universalism, disinterestedness, and organised scepticism⁴⁰. The second subsection will discuss why these norms are important for the social institution of biomedical research in best realising its goal. The final subsection will explore my interpretation of the Mertonian norms as action-guiding to individual researchers and what this means.

Before proceeding, however, it will be important to establish what is meant by a “norm” or “norms”. A full discussion of the definition of “norms” is beyond the scope of this thesis. Instead I will offer two standard definitions of norms and will assume they are adequate for my purposes. The Oxford Dictionary of Sociology suggests that, “in sociology a norm is a shared expectation of behaviour that is considered culturally desirable and/or appropriate. Norms are similar to rules or regulations in being prescriptive, although they lack the formal status of rules”⁴¹. A similar definition is given by Lapinski and Rimal who state, “norms serve as prevailing codes of conduct that either prescribe or proscribe

⁴⁰ R. K. Merton, *The Sociology of Science: theoretical and empirical investigations/ Robert K. Merton; Edited and with an Introd. By N. W. Storer*, Chicago; University of Chicago Press, 1973, pg. 270

⁴¹ Norm, *A Dictionary of Sociology*, J. Scott (ed.), Oxford University Press, 2016, from <http://www.oxfordreference.com.proxy.library.adelaide.edu.au/view/10.1093/acref/9780199683581.001.0001/acref-9780199683581-e-1576>. Accessed 4/11/2016

behaviours that members of a group can enact"⁴². In other words, norms are prescriptive and informal codes of conduct for members of a group. In the context of this thesis, the "group" is considered to be the social institution of biomedical research and its membership is the researchers within the institution. Deviance from norms is often met with informal social sanctions which for example can include the colleagues voicing disapproval of the deviant behaviour or damage to the reputation of the offender⁴³.

1.1 - The Mertonian Norms Explained

In his seminal book *The Sociology of Science* Robert K Merton outlines four norms of science: communism⁴⁴, universalism, disinterestedness and organised scepticism. Merton suggests that the legitimacy of his norms is established via their reference to the goal of science, stating, "the institutional imperatives (mores) derive from the goal and the methods"⁴⁵. This is consistent with two suggestions I have made thus far; firstly, that the constituent parts of an institution should be determined by reference to the goal of the institution; and secondly, that the Mertonian norms are the appropriate norms for the institution of public BMR. Furthermore, Merton argues that his norms are not only functional, but also normative, explaining, "the mores of science possess a methodological rationale but they are binding, not only because they are procedurally efficient, but because they are believed right and good"⁴⁶. The rest of this section will now be devoted to an explanation of Merton's norms.

⁴² M. K. Lapinski & R. N. Rimal, *An Explication of Social Norms*, *Communication Theory*, 2005: 15(2), pg. 129

⁴³ Sanction (social sanction), *A Dictionary of Sociology*, J. Scott (ed.), Oxford University Press, 2016, from <http://www.oxfordreference.com.proxy.library.adelaide.edu.au/view/10.1093/acref/9780199683581.001.0001/acref-9780199683581-e-2001>>. Accessed 06/11/2016

⁴⁴ Also referred to as communalism and I will use both interchangeably.

⁴⁵ R. K. Merton, *The Sociology of Science*, pg. 270

⁴⁶ *Ibid.*

The first of Merton's norms is "universalism", and there are two central points to make about this norm. The first is that as Merton puts it, "truth-claims, whatever their source, are to be subjected to *pre-established impersonal criteria*"⁴⁷ (italics in original). The claims of science are independent from any personal qualities of the researchers, as John Ziman explains, "contributions to science should not be excluded because of race, nationality, religion, social status or other irrelevant criteria"⁴⁸. In other words, the validity of truth claims in science is established only by reference to the properties and quality of the research itself. One historical example of where this norm was breached was Nazi Germany where "Jewish physics", and in particular the work of Albert Einstein, was rejected as pernicious and fundamentally opposed to "Aryan Physics"⁴⁹. Instead, according to universalism, the work of Einstein and others should not be judged by the race or any other personal properties of the researcher, but by a set of impersonal criteria that relates only to the work.

The other central point of universalism is that research should be conducted in such a fashion that its results are universally applicable, insofar as that is possible. By this I mean that scientific studies should endeavour to include participants of different genders, cultures, etc., in order to make claims that are universal. Participants in a trial should be representative of the population you intend to treat. This is not to say that a trial for a drug meant only for men must include women. It does, however, mean that in this circumstance researchers should attempt to enrol men of all races, social backgrounds, ages, etc., if the drug is meant to be a treatment for all men. Having said this, for those drugs that are

⁴⁷ *ibid*

⁴⁸ J. Ziman, *Real Science: What it is and What it Means*, Cambridge, GB: Cambridge University Press, 2000, pg.36, ProQuest ebrary, accessed 10/11/2016

⁴⁹ E. N. Da C. A, *Deutsche Physik*, *Nature*, 1937: 139(3528), pg. 983

meant to be used in both male and female populations, researchers should be sure to enrol representative numbers of both sexes in their trial.

An example of this issue arising is the case of women often being excluded from clinical trials until relatively recently. Reasons for this included concerns about more hormonal variability in women, and the assumption that research results from men could be extrapolated to women⁵⁰. This last assumption has been shown to be misguided, especially in regard to cardiovascular disease⁵¹.

The next of Merton's norms is communism or communalism, which is not to be confused with the political or economic theory. The norm of communalism suggests that the "substantive findings"⁵² of research do not belong to any one scientist or group of scientists, but belong to the scientific commons of knowledge; or as Merton himself puts it, "the substantive findings of science are a product of social collaboration and are assigned to the community"⁵³. According to Merton, "secrecy is the antithesis of this norm; full and open communication its enactment"⁵⁴. Krimsky suggests that the implications of this are that "results of research should be shared; information should be freely communicated within and across national boundaries; and a responsibility to the integrity of the 'intellectual fruits' should be ensured"⁵⁵.

The third Mertonian norm is disinterestedness, which is summarised concisely by Howard Smokler as the "disavowal of personal or material interest in the

⁵⁰ Committee on Women's Health Research, and Institute of Medicine, *Women's Health Research: Progress, Pitfalls, and Promise*, Washington, US; National Academies Press, 2010, pg.16, ProQuest Ebrary, accessed 10/11/2016

⁵¹ *Ibid.*

⁵² R. K. Merton, *The Sociology of Science*, pg. 273

⁵³ *Ibid.*

⁵⁴ R. K. Merton, *The Sociology of Science*, pg. 274

⁵⁵ S. Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?*, Lanham: Rowman & Littlefield Publishers, 2003, pg. 76

product of scientific research”⁵⁶. This description of disinterestedness is echoed in the literature by a number of authors^{57,58,59}. Merton himself understands disinterestedness as a “rather distinctive pattern of institutional control of a wide range of motives which characterizes the behaviour of science”⁶⁰. That is, the design of the institution itself constrains scientists from pursuing behaviour motivated by personal, material or any other unwanted interests. It is through the activities of the institution itself that disinterestedness, according to Merton, is policed. Since the activity of science involves,

*the verifiability of results, scientific research is under the exacting scrutiny of fellow experts. Otherwise put... the activities of scientists are subject to rigorous policing, to a degree perhaps unparalleled in any other field of activity. The demand for disinterestedness has a firm basis in the public and testable character of science.*⁶¹

Thus, the idea is that as a scientist, in order to have research published and its findings accepted, the research will first be rigorously scrutinised and others may potentially attempt to replicate your work. Therefore, if financial or professional interests have unduly influenced your research and its results, it will fail the scrutiny of other experts and you will be sanctioned.

Merton’s final norm of science is organised scepticism, which is “both a methodological and an institutional mandate” involving “the temporary suspension of judgement and the detached scrutiny of beliefs in terms of

⁵⁶ H. Smokler, *Institutional Rationality: The Complex Norms of Science*, *Synthese*, 1983: 57(2), pg. 131

⁵⁷ ⁵⁷ S. Krimsky, *Science in the Private Interest*, 2003, pg. 77

⁵⁸ F. M. Berardo, *Scientific Norms and Research Publication Issues and Professional Ethics*, *Sociological Inquiry*, 1989: 59(3), pg. 250

⁵⁹ A. Schafer, *Biomedical conflicts of interest: a defence of the sequestrian thesis – learning from the cases of Nancy Olivieri and David Healy*, *Journal of Medical Ethics*, 2004: 30 (1), pg.14

⁶⁰ R. K. Merton, *The Sociology of Science*, pg.276

⁶¹ R. K. Merton, *The Sociology of Science*, pg.276

empirical and logical criteria"⁶². Researchers should take a sceptical approach to their own and others' work. They are to suspend judgement until the research has been scrutinised as objectively as possible, according to certain empirical and logical standards. All findings must be scrutinised in this fashion and presented, regardless of whether they challenge or adhere to any particular religious, political, economic, etc., dogma. Findings that challenge popular ideas should not be treated with any more or less scepticism than research that supports popular ideas.

1.2 - *The Mertonian Norms and Biomedical Research*

So far I have given an explanation of Merton's norms and what they mean. This, however, fails to provide an explanation of why they are important in achieving the goal of BMR, which is the focus of this subsection. While some arguments in favour of the value of the Mertonian norms may seem obvious, it will still be important to make them explicit.

I will start by reiterating two general points about the relevance of the Mertonian norms in this thesis. Firstly, Merton thought that the legitimacy of his norms was derived in part because they played a functional role in achieving the goal of science⁶³. Secondly, the purpose of this assessment of these norms is in order to satisfy a consequentialist evaluation of the public BMR as a social institution. Consequentialism will demand that the norms of science that the institution ought to have are those norms that are best (or close enough to) for achieving its goal, so this will be a central concern in the analysis.

In order to explain why universalism is important I will return to my example of Nazi Germany and the dismissal of Einstein's work. The validity of his work continues to be confirmed even to this day, and the reason for this does not

⁶² R. K. Merton, *The Sociology of Science*, pg.277

⁶³ R. K. Merton, *The Sociology of Science*, pg.270

ostensibly hinge on the fact that he was Jewish, or male, or that he immigrated to the United States. Instead the validity of his work is ensured because he accurately described and predicted facts about our universe, which have been shown to be demonstrably true insofar as this is possible.

Thus, if we think gravity is a real phenomenon and that science should try to explain it, the criteria by which any scientific research of gravity should be judged should focus on whether or not the research accurately describes the phenomenon, not on any personal characteristics of those who produced the research. To do otherwise would potentially close the door on quality research that would better help us understand and explain certain phenomena for reasons that do not pertain to the quality of the research itself. In other words, if science is interested in searching for truth, then it is the truth that matters, not the gender, race, or politics of the truth-seekers. To focus on these latter properties would be to hamstring ourselves in the search for the truth.

The reason for believing that communism as a norm better helps BMR achieve its institutional goal invokes Newton's famous quote, "if I have seen further, it is by standing on the shoulders of giants"⁶⁴. That is, science is a communal activity and the work of any one scientist relies, in the strongest sense of the word, on the work of other scientists who have committed their findings to the scientific commons. As Merton puts it, "the communal character of science is further reflected in the recognition of scientists of their dependence upon a cultural heritage to which they lay no differential claims"⁶⁵. In other words, the proper advancement of science is reliant on the dissemination of research findings into a shared intellectual commons. Again, the functional aspect of this is stressed by

⁶⁴ I. Newton, in S. Ratcliffe (Ed.), *Oxford Essential Quotations*, Oxford University Press, 2016, <http://www.oxfordreference.com.proxy.library.adelaide.edu.au/view/10.1093/acref/9780191826719.001.0001/q-oro-ed4-00007865>>. Accessed 10/11/2016

⁶⁵ R. K. Merton, *The Sociology of Science*, pg.274

Merton who says, “the pressure for diffusion of results is reenforced [sic] by the institutional goal of advancing the boundaries of knowledge”⁶⁶.

Disinterestedness is important as a norm of science because it controls behaviour that might produce bias and thus undermine the reliability of our knowledge. It is reasonable to suggest that the production of reliable knowledge is consistent with the institutional goal of biomedical research. It is also reasonable to suggest that since disinterestedness helps to curb self-interested behaviour, which might otherwise unduly bias research, it therefore helps produce more reliable knowledge. Thus, disinterestedness as a norm is functional in helping BMR best achieve its institutional goal.

Just as organised scepticism is, as Merton suggests, “variously interrelated with the other elements of the scientific ethos”⁶⁷, so too are the reasons for its importance interrelated with other norms. The temporary suspension of judgement and sceptical scrutiny of research, according to certain empirical and logical standards⁶⁸ demanded by organised scepticism, helps raise the probability that BMR will collectively arrive at the truth. Organised scepticism means that research that challenges the status quo (or maintains it) is not discouraged and all research is to be held to the same scrutiny. Thus, no potential truth-seeking avenues are cut off unnecessarily.

Ultimately, the importance of the Mertonian norms lies in the fact that they help science to function properly. Universalism, disinterestedness and organised scepticism are functional in that they increase the reliability of knowledge claims and produce knowledge that corresponds more closely with the objective realities of the world, while communalism serves to make research more efficient

⁶⁶ *Ibid.*

⁶⁷ R. K. Merton, *The Sociology of Science*, pg.277

⁶⁸ *ibid*

by encouraging the effective dissemination of knowledge. This reliable and efficient production of knowledge is clearly in line with the goals of the social institution of biomedical research. Moreover, this is consistent with consequentialism, in that these norms can be expected to produce more utility than would be achieved in their absence.

1.3 - An Interpretation of the Mertonian Norms

Having detailed the Mertonian norms and suggested why they are important to the proper functioning of science, the aim of this subsection will be to give my interpretation of these norms as action-guiding for individual researchers. This view is not inconsistent with much of what Merton writes, but I intend to stress that these norms should go beyond mere patterns “of institutional control”⁶⁹. Finally, I will outline my view that the Mertonian norms should be considered aspirational.

In Merton’s discussion of disinterestedness, he makes reference to it applying at an institutional level, but also at a personal level. He clearly thinks that it applies at an institutional level, describing it as “a distinctive pattern of institutional control of a wide range of motives”⁷⁰. This control is established through the functioning of the institution itself, with research being scrutinised by other experts on publication. This part of the institution, peer-review of publication, is designed in part to catch and detect fraudulent research. This process is consistent with the idea that researchers themselves may not need to internalise the norm, as there are safeguards built in to the institution to catch fraudulent research in lieu of this.

Despite this possibility, Merton also makes reference to the individual scientists themselves, suggesting that those who have internalised the norm of

⁶⁹ *ibid*

⁷⁰ *ibid*

disinterestedness will act in accordance with the norm on pain of “psychological conflict”⁷¹. Still, there remains a possibility that this is unnecessary in regards to individual researchers. In other words, this norm can be enforced in a top-down fashion without the need for any participants within the institution to have internalised the norm.

This possibility also arises in the case of communalism, wherein the norm is in part instantiated as part of the institutional functioning through publication of results and scientific journals. Again, the obligations of communalism to publish can be enforced from the top-down without any need for any individual institution members having internalised it. For example, the institution could require, through a formal rule, that a researcher publish their research often and promptly. The fact that publishing of results is a requirement for many academic positions indicates that regardless of whether the norm is internalised or not, the functioning of the institution can still require adherence to the norm.

I am willing to accept that these norms may exist as what Merton calls the “distinctive characteristics of science itself”⁷², and that these norms are in part instantiated through the processes of science itself. Again, for example, in disinterestedness it was suggested that through the peer-review process the norm could still be enforced without any particular researcher having internalised it. Although I am happy to concede the possibility that the norm could be enforced this way, I also believe that it is insufficient, and that the norms should be internalised by individual researchers and considered as action-guiding.

In one sense the norms applying at the institutional level can be considered as action-guiding for individual researchers, insofar as they will deter individual

⁷¹ *ibid*

⁷² R. K. Merton, *The Sociology of Science*, pg.276

behaviour that contravenes the norms. That is, an individual researcher may have their action guided by a norm in order to avoid sanctions associated with violating the norm. This, however, is not my intention when I suggest norms as action-guiding for individual researchers. Instead, I will argue that it is the internalisation of these norms by the researchers that should guide their behaviour.

There are two main reasons for thinking that these norms should apply in this way. The first is that having the Mertonian norms applying only at the institutional level, in the top-down fashion as outlined, is to fail to fully capture the potential benefits of the norms. For example, expert scrutiny alone may not be enough to guarantee disinterestedness. There are a number of examples of overly interested scientists skewing results in a fashion that has been subtle enough, or masked by incomplete publishing of results, that the bias produced has been difficult to detect and not immediately obvious to other experts. I will discuss these problems in greater detail in later chapters. It seems in these situations, and any other situations where interested science may be produced but not detected, it would have been more effective if the offending the scientists had internalised the norm of disinterestedness and thus been compelled to act in accordance with this norm.

An obvious response to this is to suggest that the institution needs to more effectively police this problem. Many have suggested this and some have made moves in this direction which, will be discussed in later chapters. It, however, will suffice to suggest that there is a sense in which extra policing is an unsatisfactory response. One argument is that prevention is better than cure; preventing a problem is more effective than treating the symptoms of that problem. For example, preventing crime and addressing the causes of crime is, all things being equal, better than dealing with the symptoms of crime. Presumably most people would prefer that their property not get stolen in the

first place, rather than having their property stolen but then returned by the police.

Moreover, it seems reasonable to suggest that a fuller adherence to norms should be produced by an internalisation of norms, rather than just through threat of punishment from violating them. Surely, most citizens do not commit crimes out of fear of retribution, but from an understanding that certain acts are immoral. Similarly, most people feel obliged to help those in need, for example to save a drowning child, not out of fear of judgement for failing to do so, but out of a sense of ethical obligation.

The second reason that I believe the Mertonian norms should be considered action-guiding for individual researchers is the idea of professional obligations. To be motivated by professional ethical obligations, not the fear of punishment, is part of what it means to be *professional*. For example, most patients would find it unacceptable if their doctor acted beneficently towards them only from fear of sanctions should they fail to do so. Rather it seems that doctors should act beneficently towards patients because they feel a normative drive, stemming from their professional ethics, to do so.

Thus, the arguments for my position can be summarised as; (a) the internalisation of the norms as action-guiding for individual researchers should be expected to produce a fuller and more beneficial adherence to the norms, and; (b) the internalisation of norms and acting in accordance with them is a reasonable expectation of professionals.

This leads me to the final part of my interpretation of the Mertonian norms, which is that they should be considered aspirational. Understanding these norms as aspirational means that researchers are not expected to fully satisfy or adhere to the norms. This, however, begs the question; if we do not expect researchers to fully adhere to the norms, then what purpose do they serve? My response to

this is that there is value in aspiring to lofty goals, even if we do not achieve them, as the pursuit of aspirational goals may produce more and better outcomes than if we had simply not tried at all.

Section 2 - *Objections*

The application of norms as action-guiding for individual researchers prompts two immediate objections, addressed in this section. The first is that the Mertonian norms, when considered this way, are impossible for individual researchers to achieve. Secondly, not only are these norms so high-minded that they are unachievable, achieving them may also be undesirable. The work of Ian Mitroff and his sociological study of the Apollo moon scientists will be useful in this regard. This section will discuss how both the impossibility and the undesirability apply to each norm in order.

Krimsky neatly summarises the first problem associated with applying the norm of universalism to individual researchers by explaining “it is doubtful that bigotry turns on and off like a spigot”⁷³. In other words, it is unlikely that when a scientist enters the lab or reads a paper that they are completely able to leave behind all cultural, religious, national or similar biases at the door. This expectation is simply unrealistic.

Mitroff also suggests that adherence to universalism by individual researchers may in fact be counter-productive in some circumstances. He proposes that the counter-norm of universalism is “particularism”, which tells us that the reception of a certain scientist’s work will be influenced by the individual social and psychological characteristics of that scientist⁷⁴. The reason this counter-norm is useful is that it serves as an effective heuristic for scientists when judging the

⁷³ S. Krimsky, *Science in the Private Interest*, pg.76

⁷⁴ I. I. Mitroff, Norms and Counter-Norms in a Select Group of the Apollo Moon Scientists: A Case Study of the Ambivalence of Scientists, *American Sociological Review*, 1974: 39(4), pg.592

work of others. That is, rather than considering every paper in isolation, it may be more effective to consider research by a certain scientist in the context of the work they have produced in the past. In other words, it may be beneficial to be more accepting of new research from a scientist who has a record of consistently producing good science, and more sceptical of those with a history of poor quality research, as opposed to giving equal time and consideration to the work of the bad scientist and the good scientist. This touches on the idea of 'thought-leaders'; those researchers who in their field have repeatedly produced high-quality and often ground-breaking work.

Of course, this is not to suggest that researchers should blindly accept the work of thought-leaders, or that they should simply dismiss the work of a researcher with a poor research record. The thought-leader may of course produce low-quality work and the bad researcher may produce high-quality work. It is just that it may be not only natural but also more efficient to be more accepting of the thought-leader's work and wary of the bad researcher's work; heuristics are not to be followed as rules.

Like universalism, communism as a norm may place unrealistic expectations on researchers. Researchers who have an interest in their career continuing and advancing have a strong reason not to completely and openly share their results. This is certainly true of sharing research openly through informal means of communication, such as conversations or emails with colleagues. Sharing too much information may lead to other researchers 'scooping' them when it comes to discoveries and publication. There is also danger in sharing too much data openly and freely through more formal channels such as publications, symposiums or seminars. Data-collection can often be a painstaking and time-consuming venture and after spending potentially months or even years collecting data, researchers may well feel compelled to keep their data until they are satisfied they have wrung every possible result out of it. All things being

equal, it seems that if complete and open sharing of information by the scientist who collected the data risks them being ‘scooped’ with all of the repercussions of that, it seems a matter of fairness that they not be compelled to do so. Even if this were not true, it would still provide a powerful counter-motivation to the free and open sharing of their data. The issue of fairness and the reasonable motivation to not fully share data, suggests that the expectation that scientists ought to comply fully with the norm of communism is at least somewhat unrealistic.

Mitroff suggests that out-and-out stealing is unusual in science and it instead takes a much subtler form; “the unconscious, unintended appropriation of another’s idea”⁷⁵. For this reason, he thinks that secrecy may in fact serve a rational function for science, arguing that “with no protective counter measures at its disposal, the social system of science would be continually racked by...open internal disputes for priority”⁷⁶. The idea is that without *some* measure of secrecy, the cooperation of scientists and the functioning of science would be harmed because scientists would invest more of their time into disputes over priority. Therefore, wholesale commitment of communalism may in fact impede the functioning of BMR, and thus some level of secrecy seems desirable.

Disinterestedness is perhaps the most problematic of the Mertonian norms when applied as action-guiding for individual researchers, both in regards to whether it is realistic, but also whether its full realisation is desirable. Just as it was unrealistic of universalism to expect that researchers can leave behind all of their biases once they enter the lab, it is unrealistic to expect that they will not become heavily invested in their research. Krimsky argues this point, explaining that the concept of disinterestedness is “highly idealistic...scientists are not neutral to the

⁷⁵ I. I. Mitroff, *Norms and Counter-Norms in a Select Group of the Apollo Moon Scientists*, pg.593

⁷⁶ *ibid*

outcome of a study in which they have so much at stake"⁷⁷. He is certainly correct in suggesting they have a lot at stake, as Ziman states "the precept of 'publish or perish' is not a joke"⁷⁸. Not only is there pressure to publish, but the fact is that positive results are far more likely to be published (than null results)⁷⁹, and publications are in many cases a prerequisite not only for academic promotion, but even ongoing academic employment. This 'publish or perish' paradigm produces a counter-motivation for researchers to adhere to disinterestedness.

It is not only the potential to publish results that has scientists invested in their research. Scientists who have championed certain theories or ideas, especially over the course of their career, are going to be invested in the outcome of research which agrees with or contradicts their 'pet' theories. Even over the course of a single study, it seems reasonable to suggest that researchers are invested in confirming their hypotheses. Being invested in their research this way seems natural and unavoidable, and thus seems to render complete disinterestedness unrealistic.

The idea that researchers will inevitably become invested in their research also raises questions of whether disinterestedness as action-guiding for individual researchers is desirable. The reason disinterestedness may be undesirable is that some passionate advocacy amongst scientists of their favoured theories may be best for science. That is, the progress of science may be impeded if scientists were to abandon promising theories at the first sign of evidence that contradicted those theories. Mitroff points to a number of philosophers of science such as Feyerabend and Churchman, who argue that science depends on the

⁷⁷ S. Krimsky, *Science in the Private Interest*, pg.77

⁷⁸ J. Ziman, *Real Science*, pg.33

⁷⁹ M. S. Rosenberg, *The File-Drawer Problem Revisited: A General Weighted Method for Calculating Fail-Safe Numbers in Meta-Analysis*, *Evolution*, 2005: 59(2), pg.464

disagreements between scientists about phenomena⁸⁰. It is through a sort of ‘battlefield of ideas’, where these ideas are championed by their researchers, that ideally the best theories and ideas can be expected to emerge victorious and are made better in the process.

In fact, according to Mitroff, the fact that researchers are often so committed to their pet theories allows for the discovery of bias and ultimately objectivity. He claims “the fact that men differ greatly in the make-up and degree of their commitments and biases enables scientific objectivity to emerge from conflict and passion”⁸¹.

One biomedical research example where the passionate commitment to a theory led to the acceptance of a better theory is the story of Barry Marshall and the discovery of the *helicobacter pylori* as the cause of stomach ulcers. The prevailing wisdom had been that gastric ulcers had a psychosomatic genesis, being caused by too much stress⁸². Marshall was convinced that gastric ulcers were caused by *helicobacter pylori* bacteria. According to Marshall, his idea and his work was met with “constant criticism” and was “disputed and disbelieved”⁸³. Convinced that his idea was correct, he took the extreme measure of drinking a solution of the bacteria himself in order to induce stomach ulcers⁸⁴. His experiment was

⁸⁰ I. I. Mitroff, Norms and Counter-Norms in a Select Group of the Apollo Moon Scientists, pg.590

⁸¹ *ibid*

⁸² H. Charisius, When Scientists Experiment on Themselves: H. pylori and Ulcers, Scientific American (Blog), July 5, 2014 retrieved from <https://blogs.scientificamerican.com/guest-blog/when-scientists-experiment-on-themselves-h-pylori-and-ulcers/#> accessed 11/11/2016

⁸³ B. J. Marshall, Barry J. Marshall Biographical, 2005, retrieved from http://www.nobelprize.org/nobel_prizes/medicine/laureates/2005/marshall-bio.html accessed 11/11/2016

⁸⁴ H. Charisius, When Scientists Experiment on Themselves, 2014 retrieved from <https://blogs.scientificamerican.com/guest-blog/when-scientists-experiment-on-themselves-h-pylori-and-ulcers/#>

successful and his theory was confirmed, and for this discovery he was awarded a Nobel Prize.

It is because Marshall was so committed to his theory that he was not dissuaded by the chorus of critics, and that we ultimately discovered it was a bacterium and not stress that caused stomach ulcers. The case of Barry Marshall highlights the idea that it is through commitment to, and the passionate advocacy of scientific ideas, that science can best progress.

Perhaps there is a distinction to be made between different types of interestedness. The story of Barry Marshall highlights a certain sort of interestedness, one in which a researcher was deeply committed to his pet theory because he was convinced it was *true*. Presumably, this is the same sort of interestedness that Mitroff had in mind when discussing his counter-norm. There is a sense in which this sort of interestedness does not contradict Merton's norm of disinterestedness. If disinterestedness is understood to mean that researchers should not be motivated by any personal benefit but by the pursuit of the truth, then it seems that the interestedness of the sort Marshall displayed may not be contradictory, providing my assessment of their motivation is correct.

This, however, does not mean that other sorts of interestedness are beneficial in this way. Motivations from personal gain, such as financial or professional gains, should still be considered problematic as these motivations are not concerned with arriving at the truth. Since they are not concerned with discovering the truth, they should be considered at best, unhelpful to scientific research as they do not encourage researchers to pursue the truth, and at worst, detrimental insofar as they may encourage researchers to mislead themselves or others.

Therefore, it seems that the sort of interestedness that is found in researchers advocating for their pet theories is an acceptable sort of interestedness, but that other sorts of interestedness caused by personal gain are unacceptable.

Moreover, it seems that the former may not contradict the Mertonian norm of disinterestedness.

Finally, there are also reasons to suspect that organised scepticism may place an impossible demand on researchers. Again, scientists are human and thus suffer from all the same cognitive biases as any other person. Therefore, it stands to reason that researchers will be far less likely to be able to suspend judgement regarding research that challenges a deep-held belief, or conversely, that confirms a strong belief. The challenging of deep-held beliefs should be expected to cause the same cognitive dissonance in a scientist as it would any other person. This cognitive dissonance encourages us to ignore or rationalise information that contradicts our beliefs and making us far more accepting of information that confirms them⁸⁵. Thus, just as it was unrealistic for universalism to expect that researchers could simply 'turn off' any prejudices, it is just as unrealistic that organised scepticism should expect researchers to turn off any other biases.

It is important to examine the impossibility and undesirability objections to the idea that the Mertonian norms should be considered as action-guiding for individual researchers. These objections, however, should not be considered problematic, due to the aspirational nature of the norms I have outlined. The fact that full compliance is not expected nor even suggested addresses both the impossibility and undesirability issues. Since I consider the norms to be aspirational, this means that the impossibility of individual researchers realising these norms is not only expected but also acceptable. The expectation, in both a normative and predictive sense, is that they will aspire to these norms, but not achieve them.

⁸⁵ E. Harmon-Jones, J. Mills, *An Introduction to Cognitive Dissonance Theory and an Overview of Current Perspective on the Theory*, in *Cognitive dissonance: progress on a pivotal theory in social psychology*, E. Harmon-Jones, J. Mills (Eds.), Washington, DC: American Psychological Association, 1999, pg.3

The aspirational and counterfactual nature of my model of the Mertonian norms also means that there is plenty of room for the sort of behaviour and counter-norms described by Mitroff. Again, the Mertonian norms, according to my understanding, derive their value from being aspirational, not from being fully adhered to. In other words, my model allows for some level of the counter-norms and their functionality to exist while also constraining serious breaches of the Mertonian norms.

Conclusion

The purpose of this chapter was to expound an understanding of the Mertonian norms demonstrating why they are suited to supporting biomedical research achieve its goal. In doing so, I explained Merton's four norms of science; universalism, communism, disinterestedness, and organised scepticism. I argued that these norms provide functional benefits to biomedical research in relation to its goal, and thus these norms are valuable to BMR.

My interpretation of the Mertonian norms was then discussed. I argued that the norms should apply to individual researchers as action-guiding and that they should be considered aspirational and counterfactual. This, however, produced two immediate objections; impossibility and undesirability. The objection from impossibility suggested that the Mertonian norms place unrealistic and unachievable expectations on researchers, as full adherence to the norms by a researcher is impossible. The objection from undesirability considered the work of Mitroff and his counter-norms, and suggested that the full realisation of the Mertonian norms by researchers impedes the goals of BMR. I dealt with these objections by reference to the aspirational nature of my model of the Mertonian norms, which allows for Mitroff's counter-norms and actively has no expectation of full compliance from researchers.

Chapter 3

The first chapter of this thesis explained the sense in which public biomedical research is a goal-directed social institution. That chapter also suggested that welfare consequentialism was a reasonable theory for assessing the goal and the effectiveness of the institution. The aim of this chapter will be to examine and summarize the case in favour of industry funding of biomedical research within a consequentialist framework.

The first section of this chapter will examine how industry funding and commercialisation in academia occurs and how it has been encouraged. Since this ground has already been well covered by others I will briefly summarise existing literature charting its development.

The second section will look at justifications for IFaC. I will focus on arguments that tend to cluster into two categories; arguments from non-health benefits to society, and arguments from benefits to biomedical research and health. Arguments from non-health benefits to society suggest that biomedical innovation leads to economic growth and job creation, and all things being equal, that is good for society. I will identify three main suggestions within arguments from benefits to BMR and health. The first is simply that, all things being equal, more money means more research and more research helps BMR better achieve its goal. The second suggestion is that IFaC is more effective at bringing discoveries to market from academic journals. The final argument from benefits to BMR and health is that the private sector might be necessary in order to bring almost any medical product to market and without this involvement, achieving the goal of BMR would be seriously impeded.

Section 1 - The Trend Towards Industry Funding and Commercialisation of Public Biomedical Research

There has been a strong trend over the past several decades towards commercialisation, industry funding and other interactions and collaborations between industry and academia⁸⁶. Traditionally, universities have been viewed as “ivory towers”, insulated from any other interests besides those that are purely academic. Regardless of the truth of this claim many governments both here in Australia and other major research producing countries such as the United States, have actively encouraged collaboration between industry and academia, and academics focussing on producing practical, patentable discoveries. This section will refer to the literature in order to explain the mechanisms through which this collaboration has been encouraged, and summarise the major milestones on the way to our current situation.

There have been two main ways through which industry funding and commercialisation of public biomedical research has been fostered. The first has been legislation that has encouraged or allowed for “technology transfer” (TT), including changes to intellectual property laws (IP) in some cases. The second category of change has been legislation designed directly to encourage investment and/or collaboration between academia and industry.

“Technology transfer” is the transfer of technology or knowledge from one sector to another, in this case the transfer of knowledge and technology from public biomedical research to the private sector. What this generally means is the translation of scientific research into useful new products⁸⁷. This happens mainly in one of two ways; the university can patent its discovery and sell or license this

⁸⁶ S. Krimsky, *Science in the Private Interest*, Oxford; Rowman & Littlefield Publishers, 2003, pg. 27

⁸⁷ M. Angell, *The Truth About Drug Companies*, New York: Random House, 2004, pg. 7

patent to a company, or the university can create a “spin-off”. When a patentable discovery is made the university or those within the university will create a “spin-off” company with the aim being to “commercially develop and exploit the knowledge generated in the university”⁸⁸.

As for the major legislation and other events that have affected TT, I will begin by looking at the US context. This is relevant because such a significant portion of biomedical research is performed there and moreover, much of the literature focuses specifically on this context. One of the most commonly cited watershed moments in the USA regarding technology transfer is the 1980 Patent and Trademark Amendments Act, more commonly known as the Bayh-Dole Act⁸⁹. This legislation gave universities and not-for-profit institutions the right to patent discoveries made through research that was paid for by federal grants. The aim of this legislation was to encourage “collaboration between commercial concerns and non-profit organizations, including universities”⁹⁰. Prior to the introduction of this legislation, any discoveries from research conducted with federal funds were placed unpatented into the public domain^{91,92}.

The other major change in the USA was a decision made by the Supreme Court in the case of *Diamond v. Chakrabarty*, which allowed for the patenting of a bacterium that had been genetically engineered to digest crude oil⁹³. The significance of this ruling was that it was the bacterium itself, not the process of producing it, that was allowed to be patented. This opened the door for the

⁸⁸ H. Jousma, V. Scholten, *Chapter 4 The Roles of Scientists in the Start-up of Academic Spin-off Companies in the Life Sciences in the Netherlands in New Technology-Based Firms in the New Millennium*, Published Online, 2015, pg. 39

⁸⁹ S. Krimsky, *Science in the Private Interest*, pg. 30

⁹⁰ 1980 Patent and Trademark Amendments Act, in A L. Monotti & S. Ricketson, *Universities and Intellectual Property*, Oxford: Oxford University Press, 2003, pg. 238.

⁹¹ M. Angell, *The Truth About Drug Companies*, pg. 7

⁹² M. N. Kumar, Ethical Conflicts in Commercialization of University Research in the Post-Bayh-Dole Era, *Ethics & Behaviour*, 2010: 20(5), pg. 325

⁹³ M. Goozner, *The \$800 Million Pill*, Berkeley: University of California Press, 2004, pg. 64

patenting of other genetically engineered life forms. Since the decision of the Supreme Court in this case in 1980, patenting in the area of biotechnology has outstripped any other branch of science⁹⁴.

Other legislation less focused on TT and IP has also been enacted with the purpose of encouraging more collaboration and industry funding of public biomedical research. Much of this is something of a 'grab bag' of ideas, ranging from financial incentives for industry to invest in public biomedical research, to grants for researchers and their institutions to facilitate academic staff being seconded to industry labs, to the production of model guidelines for policy development at universities. Two key pieces of legislation are indicative of the kinds of strategies employed.

The first in the USA was the Stevenson-Wydler Technology Innovation Act of 1980, introduced in order to "foster technological innovation in the United States by encouraging cooperation between industry, government, and universities"⁹⁵. The other was the Economic Recovery Tax Act (1981) which gave financial incentives to industry through tax concessions for contributing to research equipment in universities⁹⁶.

The story is similar in Australia. Just as in the USA, the push for closer industry-academia ties began in 1980 with a report from the Australian Science and Technology Council (ASTECC) to the Prime Minister. The report concluded that increased interactions between industry, government and tertiary education institutions would benefit not only those parties, but also academics and the quality and relevance of Australian research and development⁹⁷. With the aim of

⁹⁴ M. N. Kumar, *Ethical Conflicts in Commercialization of University Research in the Post-Bayh-Dole Era*, *Ethics & Behaviour*, 2010: 20(5), pg. 327

⁹⁵ S. Krimsky, *Science in the Private Interest*, pg. 31

⁹⁶ *Ibid.*

⁹⁷ A L. Monotti & S. Ricketson, *Universities and Intellectual Property*, Oxford: Oxford University Press, 2003, pg 221

increased cooperation between industry and the public sector the report goes on to outline four possible mechanisms for increasing cooperation:

*a) the establishment of industrial fellowships to allow academic staff to spend time in industrial laboratories; (b) research associations; (c) co-operative research projects involving academic and industrial researchers working together on projects of interest to industry grants; and (d) the establishment of a technology transfer network to provide effective links between researchers and potential users of the new technology*⁹⁸.

In Australia, there were also several pieces of legislation and policy passed, which were designed to encourage collaboration and TT. These policies included establishment of: Special Research Centres (1982), Key Research Centres (1985), a 150 per cent tax concession for Research & Development (R&D)(1986), the introduction of the Australian Postgraduate Research Awards (Industry) (1989), the Collaborative Grants Scheme, and the Cooperative Research Centres Program (1990)⁹⁹. Again, as most of the names imply, these moves were designed specifically to encourage greater collaboration and technology transfer between public and private sectors.

This approach has maintained its prominence in more recent times, with three out of seven of the 2009-10 Australian Research Council (ARC) Annual Report priorities mentioning better technology transfer and commercialisation of research, as well as greater collaboration with industry¹⁰⁰.

⁹⁸ A L. Monotti & S. Ricketson, pg 222

⁹⁹ *Ibid*

¹⁰⁰ Australian Research Council, *Australian Research Council Annual Report 2009-10*, Commonwealth of Australia, 2010, pg. 18

http://archive.arc.gov.au/archive_files/Media%20Centre/Publications/Annual%20Reports/2009-10_ARC_Annual_Report.pdf accessed 22/09/2011

Australian universities reacted to these encouragements in a similar manner to how the US universities reacted to their own domestic encouragements; by setting up technology companies or development offices with the purposes of “promoting and managing research, consultancy services, and developing small innovations”¹⁰¹.

These examples provide an overview of the key moments, policies and actions, that have changed the landscape of industry-academia relations. They demonstrate how policy makers here and abroad have actively pursued legislation to encourage closer ties between the private and the public sector in biomedical research. Commercialisation, industry funding and closer ties between academia and industry is now the status quo and this has been thoroughly incentivised by policy makers.

Section 2 – The Good: Arguments for Increased Commercialisation and Industry Funding of Public Biomedical Research

In this section I will offer consequentialist arguments in favour of industry funding. As explained above, these consequentialist justifications fall broadly into two categories. The first is the argument from non-health benefits to society that suggest industry funding and commercialisation spur innovation, and this produces auxiliary benefits other than health to society.

The second argument in favour of IFaC are arguments from the benefit to BMR and health. There are three major propositions that fall into this category: firstly, IFaC provides extra money to BMR resulting in more research, and more research is good for BMR; secondly, the incentives provided by IFaC more effectively bring discoveries out of academic journals and into the market place where they

¹⁰¹ A L. Monotti & S. Ricketson, pg 224

can then produce better health outcomes; and finally, the private sector may be necessary in a number of ways in order to bring products to market.

Section 2.1 - Arguments from Non-Health Benefits to Society

One of the common justifications in the literature for commercialisation and industry funding¹⁰² is by reference to the non-health benefits it produces for society¹⁰³. Often this justification is made by pointing to the importance of innovation to the economies of nations¹⁰⁴. One such example comes from Prodan, Drnovsek and Ulijn who argue that,

It is widely acknowledged that the commercialisation of scientific and technological knowledge produced in public funded researcher institutions, including universities and researcher centres, into the marketplace have a fundamental role to play in wealth creation, supporting economic growth and technological innovation, and plays a significant role in new venture creation, growth of existing firms and new job creation¹⁰⁵

Or as Judith Sheft succinctly puts it: “university inventions and discovery are playing an increasingly important role in economic development”¹⁰⁶.

I have previously argued that the goal of public biomedical research as an institution should be the promotion of welfare via health. The above claim suggests that commercialisation and industry funding benefit the economy by

¹⁰² It should be noted that this justification is often made more broadly in the context of public research in general not just public biomedical research.

¹⁰³ L. L. Glenna., R. Welsh., D. Ervin., W. B. Lacy., D. Biscotti, Commercial Science, Scientists’ Values, and University Biotechnology Agendas, *Research Policy*, 2011: 40(7), pg.957

¹⁰⁴ G. D. Markman., P. H. Phan., D. B. Balkin., P. T. Gianiodis., Entrepreneurship and University-Based Technology Transfer, *Journal of Business Venturing*, 2005: 20, pg 244

¹⁰⁵ I. Prodan, M. Drnovsek, J. Ulijn. Chapter 12 A Conceptual Framework for Studying a Technology Transfer from Academia to New Firms, In *New Technology-Based Firms in the New Millennium*. Published online, 2015, pg.187

¹⁰⁶ J. Sheft, Technology Transfer and Idea Commercialization, *Nature Biotechnology*, 2008: 26, pg. 711

creating jobs and new sectors of the economy while growing those that already exist, which is not the goal of biomedical research. According to consequentialism we should attempt to capture all possible potential welfare and this economic argument should be understood as helping to promote welfare, all things being equal.

Having said this, the justification for biomedical research is contingent on whether or not its goal is 'good' in a moral sense and how efficient it is at pursuing its goal providing that the goal is good. Clearly, all things being equal, broader economic development is a morally good goal. There are numerous other social institutions whose aim is economic development that are designed in accordance with this goal. Public BMR, however, has a different goal and should be designed in accordance with its goal. Therefore, it makes sense to suggest that the auxiliary economic benefits should only be considered a justification for commercialisation and industry funding insofar as they do not change the goal of public biomedical research and do not impede its effectiveness in achieving its institutional goal. I will discuss the effects of IFaC on public biomedical research further in later chapters, but for now it will suffice to come to the following conclusion: all things being equal, the auxiliary benefits that accrue from commercialisation, which are largely defined as being economic, provide a consequentialist argument in favour of commercialisation.

Section 2.2 - Arguments from Benefits to Public Biomedical Research and Health

The benefits that accrue from innovation will not exclusively be auxiliary benefits. We should reasonably expect them to have health benefits, as they are medical innovations. These sorts of benefits are clearly aligned with the goal of public BMR. Therefore, if industry funding and commercialisation increases the number of medical innovations and thus improves health, there are consequentialist reasons to encourage them. I will refer to arguments assuming this form as arguments from the benefits to public BMR and health.

The first of these arguments suggests that IFaC provides more money to public BMR, which produces more research and this should, all things being equal, better help achieve the goal of public BMR.

PhRMA, a leading trade group representing the pharmaceutical industry in the USA, certainly does think their involvement is beneficial to the discovery of useful new medical innovations. They claim to be part of the development process for “7,000 innovative drugs” and having invested “\$500 billion... in R&D since 2000”¹⁰⁷. Not all of this money will have gone into funding research in the public sector, but at least some of it will have. It is reasonable to assume that this extra funding would result in more research. All things being equal, more money equals more research which should lead to more discoveries. Extra research and more discoveries help public BMR research to better achieve its goal.

Of course, not all research will result in useful discoveries that can immediately be applied to produce better health outcomes, but a certain percentage of research will. Thus, we are left with a probabilistic claim, which is that the more funding put into public BMR, the more research that can be conducted and the

¹⁰⁷ PhRMA, <http://www.phrma.org/innovation>, accessed 10/05/2016

more research that is performed, the greater the chance of the research turning up useful discoveries.

Furthermore, even the research which does not have immediate applications is still useful. For example, better understanding how certain disorders or diseases affect certain receptors in the brain might not produce a treatment for the disorder. It can, however, help other researchers narrow down the search for a treatment as this research indicates that a treatment should involve chemicals that affect this specific receptor.

Thus, the argument is that, all things being equal, more research is desirable. It can produce useful new discoveries or enhance our understanding of medical products and disease in order to hopefully make our search for treatments more efficient. Therefore, providing the assumption that, all things being equal, more money means more research and this helps public BMR achieve its goal, then there are consequentialist grounds for accepting industry funding and commercialisation.

A further way in which commercialisation and industry funding of public biomedical research may improve the effectiveness of the institution is by more effectively moving discoveries from the public sector to the market. Part of the justification for the Bayh-Dole Act was the concern that without encouraging technology transfer, potentially useful inventions would “languish” in academic journals or government offices “without ever being brought to market”¹⁰⁸. There are two mechanisms through which this may work. The first is that it provides incentive for researchers and their institutions to patent their potentially useful discoveries rather than just publish their results among academic peers. The

¹⁰⁸ A. S. Kesselheim, R. Rajkumar, Who Owns Federally Funded Research? The Supreme Court and the Bayh-Dole Act, *The New England Journal of Medicine*, 2001: 365(13), pg.2

second mechanism is that the Bayh-Dole act allowed the private sector to buy or license these discoveries so they could bring them to market.

Clearly it is contrary to the goal of biomedical research to have discoveries that could be beneficial to its goal not being brought to market, assuming these discoveries would result in products or services. This would impede the goal of public biomedical research and fail to maximise welfare. For example, had Jonas Salk's polio vaccine been successfully tested, but instead of it being brought to market he had contented himself with merely publishing the findings in an academic journal, this would fail to maximise welfare. Therefore, it should be apparent that, all things being equal, discoveries which could potentially help achieve the goal of public BMR should be brought to market as efficiently as possible. If this is best achieved by commercialisation and industry funding, then there are consequentialist reasons for accepting this.

There is at least some evidence to suggest that this may be the case. According to Sheldon Krimsky the number of patents awarded annually among the top one hundred research universities rose from 177 in 1974 prior to the Bayh-Dole Act, to 408 in 1984, four years after the Bayh-Dole Act. This number eventually rose to 3,200 patents awarded in 2000¹⁰⁹. Therefore, if this increase in patenting by universities is in fact indicative of more useful discoveries being pushed out of academic journals into the marketplace, then it is reasonable to conclude that commercialisation and industry funding helps the efficiency of public BMR in achieving its goal.

Of course, this argument also makes an "all things being equal" assumption, wherein any costs from this increased patenting are outweighed by the benefits. Again, I will question the accuracy of this assumption in the next chapter. If this

¹⁰⁹ S. Krimsky, *Science in the Private Interest*, pg.81

assumption is true, it seems there are clear consequentialist grounds for accepting IFaC in terms of it increasing the effectiveness of public BMR.

The final argument from benefits to public BMR and health is that industry, at least to some extent, seems to be a necessary part of bringing products to market. There are two central reasons to think this. The first is that the public sector lacks the appropriate infrastructure to bring products to market. The second is that the public sector lacks adequate funding to conduct the appropriate number of late stage clinical trials.

Generally speaking, the infrastructure the public sector is lacking in order to bring products to market includes the manufacturing capacity, as well as the necessary legal, administrative and marketing structures. Eliminating industry involvement would potentially be a serious impediment to our ability to bring useful discoveries to market wherein they could benefit people.

Not only do universities lack the capacity to bring products to market, for the most part they also lack the resources required for conducting late stage trials¹¹⁰. The first resource they lack is the appropriate amount of funding. Late stage trials are almost without fail the most expensive part of drug development¹¹¹. While governments will occasionally pay for these late-stage trials, as I have pointed out in earlier chapters they already bear the cost of being the exclusive funder of basic research. Therefore, without serious growth in government spending on research, which is unlikely, it would be difficult to get many of these late stage trials funded without some additional source of funding.

In addition, late stage clinical trials often involve a large number of patients. According to the Australian Government, late stage clinical trials can involve

¹¹⁰ This stage is referred to as stage 3 trials

¹¹¹ M. Goozner, *The \$800 Million Pill*, pg. 158

several hundred patients or more¹¹². It is difficult for a single university or public research laboratory to recruit such a large number of patients, thus late stage clinical trials are often conducted across several labs, teaching hospitals and universities.

Even if universities are able to overcome this hurdle through collaboration, the issue of funding remains. The cost of late stage clinical trials are prohibitively expensive for universities and their partners to fund, and the government will for the most part not fund these trials.

Not conducting these trials is a deeply problematic prospect for public biomedical research. Late stage clinical trials are a necessary part of ensuring a new discovery is safe and effective. Therefore, in order for public BMR to achieve its goal as effectively as possible, we need stage 3 trials for promising discoveries to be properly funded. If industry funding and commercialisation help fund these trials, then they help public BMR achieve its goal. Therefore, again we have a consequentialist justification of industry funding of public biomedical research.

This section has surveyed some of the main arguments for commercialisation and industry funding of public biomedical research. I suggested that they fell into two broad types of arguments; arguments from non-health benefits to society and arguments from benefits to public BMR and health. I suggested that these provide a consequentialist justification for IFaC.

The argument from non-health benefits to society suggested that the extra innovation produced by IFaC produced auxiliary societal benefits. I argued that, insofar as we could capture these auxiliary societal benefits without undermining

¹¹² NHMRC, <https://www.australianclinicaltrials.gov.au/what-clinical-trial/phases-clinical-trials>, accessed 10/05/2016

the goal or effectiveness of public BMR as an institution, then there are consequentialist reasons for doing so.

The second group of arguments were arguments from benefits to public BMR and health. Of these sorts of arguments, I suggested there were three main sub arguments. The first was that IFaC provided extra funding to public BMR which can be expected to produce more research, and this helped BMR more effectively achieve its goal.

The second was that IFaC helped bring useful discoveries to market by incentivizing researchers to patent their research and allowing the private sector to buy or licence this research. More effectively bringing more products to market rather than having them sit idly in academic journals helps public BMR better achieve its goal.

Finally, I suggested that the private sector might be a necessary part of public BMR, in that public BMR does not have the infrastructure to bring products to market or the appropriate funding to conduct the majority of late-stage clinical trials.

Conclusion

The aim of this chapter was twofold. The purpose of the first section was to give a brief overview of IFaC. It outlined the main mechanisms through which this occurs: technology transfer and direct collaboration and/or investment of the private sector into public biomedical research. It showed how commercialisation and industry funding has been encouraged historically, and currently remains the status quo. I gave an outline of some of the major legislation and policy from regulators designed explicitly to encourage commercialisation and industry funding.

The second aim of this chapter was to survey some of the main arguments given for industry funding and commercialisation of public biomedical research, and explore whether they can be justified on consequentialist grounds. Two main justifications were identified. The first focused on the broad societal benefits that IFaC brings through increased innovation. It was argued that these innovations help develop the economy, create jobs and thus make people better off. I argued that although these are not the goal of public BMR, as a consequentialist this still helps to justify IFaC insofar as it does not impede public biomedical research in pursuit of its institutional goal.

The other arguments given for industry funding and the commercialisation of public biomedical research were that it helps public BMR more effectively pursue its goal. IFaC seems to be a necessary part of the funding process, it provides more money for research and more efficiently brings useful discoveries to the market.

All of these arguments offered a consequentialist justification for industry funding and commercialisation of public biomedical research. This justification, however, is predicated on all things being equal, an assumption I accepted for argument's sake in this chapter. The next chapter will explore this assumption.

Chapter 4

The previous chapter used consequentialism to review the benefits produced by industry funding and commercialisation of public biomedical research. With that in mind, this chapter has two central aims. The first aim will be to look more closely at the negative impacts of IFaC, which is a necessary part of a consequentialist assessment.

The second aim of this chapter is to anticipate the discussion of solutions in the final chapter by examining particular debates and concepts within consequentialism that suggest a way forward.

Therefore, this chapter will be divided into four sections. Initially, I will review the relevant literature to explicate arguments against IFaC on consequentialist grounds. In doing so I will argue that the main problems are epistemic issues, with IFaC affecting what we know and the reliability of what we know in a way that fails to maximise welfare.

Section 2 will proceed to show that the problems caused by IFaC are not merely a coincidence of circumstance but are instead an inherent risk of IFaC.

Section 3 will look at a substantive debate within the consequentialist literature between Actualists and Possibilists, which considers how consequentialists should manage predictable wrongdoing.

Finally, I will explain Michael Smith's account of capacities which suggests that capacities are not an all or nothing phenomena. While not a comprehensive analysis of the concept, this account is a credible and useful interpretation which provides a valuable mechanism for understanding researchers' capacity to resist perverse incentives from IFaC.

The discussion of Actualism versus Possibilism and Smith's account of capacities will provide a framework for assessing proposed solutions to the problems

caused by IFaC in the next chapter. Moreover, the discussion in this chapter will be used to better illuminate an alternative possibility that has been largely ignored in the literature.

Section 1 – *The Bad*

The purpose of this section will be to explore the well-documented problems caused by IFaC. As a consequentialist, it will be important to consider the numerous negative impacts of IFaC, just as it was important to consider the positive effects in the previous chapter. The problems identified are largely epistemic and significant insofar as they negatively impact on health outcomes. These epistemic concerns divide into two separate problems; IFaC affecting what we know, as well as the reliability of what we know.

I discussed in the previous chapter that there were some positive outcomes, all things being equal, resulting from IFaC. Part of what this chapter will aim to show is that the ‘all things being equal’ assumption is not a fair one, and that the benefits derived from IFaC do come at a cost. It is still important to note however, that the ideal situation may well be one in which we can capture the benefits of IFaC, while being able to fully address the problems created by it, insofar as this may be possible.

Before launching into the problems caused by IFaC it is necessary to explain something about the nature of academia. Firstly, it is *highly* competitive. Resources, primarily public research funding, are limited and the pool of researchers trying to secure their share is large. Moreover, the growth of PhD graduates has outstripped the number of academic positions, especially in the life sciences, in many countries who are members of the Organisation for Economic Co-operation and Development (OECD)¹¹³. Thus, many academics are

¹¹³ D. Cyranoski, N. Gilbert, H. Ledford, A. Nayar, M. Yahia, *Education: The PhD factory*, *Nature*, 2011: 472 (7343), pg. 276

clamouring for a limited pool of funding in order to produce the research/publications necessary not only for promotion but in order to retain their positions. Again, as the saying goes in academia, “publish or perish”.

This provides strong incentives for researchers to find areas of research where they can gather additional funding from other sources. One obvious source of extra funding is through IFaC. This is not necessarily problematic, providing it does not negatively skew the patterns of research across public BMR. The following sections, however, will show that it in fact does just that.

1.1 - *What We Know*

As I mentioned earlier, the primary concerns about the impact of IFaC are epistemic ones. I will first address the issue that IFaC influences *what* we know, in ways that should be considered, at best, sub-optimal.

One of the clearest examples of this is to look at which diseases and disabilities attract the most attention from industry. Industry naturally focusses on those diseases for which producing a treatment will be most profitable. This makes sense, as the primary goal of industry is to produce returns on investment to their shareholders¹¹⁴. While there is often a significant overlap between what is best in terms of profit and in terms of health, there is also a great deal that is optimal for health, but not profitable enough for industry to invest in. In other words, what is best in terms of health is often not necessarily what is best in terms of profit.

Of course, this begs the question of what *is best* in terms of health? To this I offer that, at the very least, two important features need to be considered: prevalence and seriousness. The reason for this is simply that by focussing on treatments that affect more people, we help more people, and by producing treatments for

¹¹⁴ There will be further discussion of this later in the chapter.

more serious diseases, we help people more. This, clearly, fits within a consequentialist model.

To evidence this, I offer the contrast between investment and outcomes associated with research into statins¹¹⁵, versus those associated with research into antibiotics and tropical diseases. Heart disease, of which high cholesterol is a contributing factor, was the leading cause of death in Australia in 2013¹¹⁶. Heart disease is also the leading cause of death in developed nations¹¹⁷. This clearly justifies significant investment into research and treatments for heart disease, and satisfies both of my conditions of prevalence and seriousness. It could be argued however, that there has been too much focus on one facet of treatment of heart disease, which is the treatment of high-cholesterol with statins.

There are currently six different types of statins on the market today, the first of which was Mevacor in 1987. As the first pharmaceutical of its class, it was ground-breaking¹¹⁸. It is hard to imagine how this discovery and the research that led to it failed to help meet the goal of public BMR. The market for statins is an excellent one from a profit standpoint in that the target market is well-populated and wealthy. This is presumably why we now have a total of six different statins on the market from different companies, which Marcia Angell accuses of being “all variants of the first”¹¹⁹, and of which “there is little reason to think one is any better at comparable doses”¹²⁰. These are often referred to as “me-too” drugs; drugs that are small variations on an existing treatment that offer little discernible advantage.

¹¹⁵ Statins are drugs that help lower blood cholesterol

¹¹⁶ <http://www.aihw.gov.au/deaths/leading-causes-of-death/> accessed 11/07/2016

¹¹⁷ T. A. Gaziano, A. Bitton, S. Anand, S. Abrahams-Gessel, A. Murphy, Growing Epidemic of Coronary Heart Disease in Low- and Middle-Income Countries, *Current problems in cardiology*, 2010: 25(2), pg 72

¹¹⁸ M. Angell, *The Truth About Drug Companies*, New York: Random House, 2004, pg. 80

¹¹⁹ M. Angell, pg. xvi

¹²⁰ M. Angell. Pg. 81

This sort of investment is, in itself, inefficient in terms of health as it seems producing several treatments for the same problem should produce seriously diminishing returns, all things being equal. Once you have an effective treatment y for disease x , it is, all things being equal, inefficient to further invest in treatment z if there is little reason to believe it will be *significantly* better than the original treatment y in treating disease x .

There are presumably situations where this does not hold true, such as a new treatment producing a large leap in efficacy over the pre-existing treatment. This, however, is not the case with the half dozen statins we currently have on the market, providing that Angell's assessment of them is at least close to correct.

Thus, if this sort of research is indeed so inefficient, we should not want public BMR investing in it. This is not just in terms of spending valuable public research funds, but other academic resources including researchers and facilities. The assumption here is that this holds insofar as there are in fact more optimal research projects. Of course, ultimately, this is a question of balancing value. As a consequentialist, although this situation looks grossly inefficient on the surface, it must be conceded that there is a possibility that this investment might still have been best. The following two examples, however, will provide reasons to think that this is not the case and that there are far better investments in terms of welfare maximisation.

The first of these comparison cases is antibiotics. The emergence and spread of antibiotic resistant infection has grossly outpaced our ability to deal with the issue¹²¹ and it is a "serious, growing threat to global public health"¹²². Yet despite

¹²¹ M. Frieri, K. Kumar, A. Boutin, Antibiotic resistance, *Journal of Infection and Public Health*, 2016, pg. 3

¹²² M. J. Selgelid, Research Priorities, Profits and Public Goods: The Case of Drug Resistant Disease, in G. Hanekamp & F. Wutscher (eds.), *Business Ethics of Innovations*, Dordrecht: Springer-Verlag Berlin and Heidelberg GmbH & Co., pg. 29

this, it took almost forty years until the discovery of a new class of antibiotic, teixobactin in 2015^{123,124}.

The central reasons for this are related to potential profits. While there is serious disagreement about exactly how much drug development costs, it is undeniably an expensive venture. Given this, there are a number of reasons that the private sector would ignore research into new antibiotics in favour of other drugs. The first is, antibiotics are used, generally, over very short periods of time relative to chronic conditions¹²⁵. That is, antibiotics tend to be used for weeks at a time, while something like statins are used for years. Thus, private investors are left with a choice of possibly spending hundreds of millions of dollars on a drug that patients use for potentially less than a fortnight, or spending those hundreds of millions developing a drug that patients take for the rest of their lives.

A further disincentive is that because of drug-resistance, new antibiotics run the risk of being immediately shelved as the last line of defence¹²⁶. That is, the new antibiotic will be used as a last resort, meaning that new antibiotic should be expected not to be used nearly as much as older antibiotics.

Finally, new antibiotics run the risk of faster obsolescence than their predecessors, with some multi-drug resistant bacteria apparently adapting more rapidly to new drugs than they had in the past¹²⁷.

¹²³ L. L. Ling, T. Schneider, A. J. Peoples, A. L. Spoering, I. Engels, B. P. Conlon, A. Mueller, T. F. Schaberle, D. E. Hughes, S. Epstein, M. Jones, L. Lazarides, V. A. Steadman, D. R. Cohen, C. R. Felix, K. Ashley-Fetterman, W. P. Millett, A. G. Nitti, A. M. Zullo, C. Chen, K. Lewis, A new antibiotic kills pathogen without detectable resistance, *Nature*, 2015: 517, pgs. 455-459

¹²⁴ M. J. Selgelid, Research Priorities, Profits and Public Goods: The Case of Drug Resistant Disease, in G. Hanekamp & F. Wutscher (eds.), *Business Ethics of Innovations*, Dordrecht: Springer-Verlag Berlin and Heidelberg GmbH & Co., pg. 32

¹²⁵ A. Aiello, N. King, B. Foxman, Ethical conflicts in public health research and practice: antimicrobial resistance and the ethics of drug development, *American Journal of Public Health*, 2006: 96 (11), pg.1911

¹²⁶ *Ibid.*

¹²⁷ *Ibid.*

This, however, does nothing to change the fact that drug resistant microbes are a serious threat to health. Thus, antibiotics provide at least one example of where concerns for health and concerns for profit diverge in a seriously detrimental way.

A further example of this decoupling of health and profit is found in diseases that predominantly affect poor people. We know less about these diseases and have fewer treatments for these diseases, including tropical diseases, despite the health burden they produce. The problem is summarised by Thomas Pogge: “Malaria, pneumonia, diarrhea, and tuberculosis, which together account for 21 percent of the global disease burden receive 0.31 percent of all public and private funds devoted to health research”¹²⁸. Moreover, a survey by Patrice Trouiller, et al., of new chemical entities brought to market over a 25-year period between 1975 to 1999, showed that of 1393 new chemical entities, a mere 16 were for tuberculosis and tropical diseases¹²⁹.

Admittedly, Trouiller et al’s survey is relatively old, and there has been at least one significant change between now and then, with a regulatory application for a malaria vaccine currently being submitted to the European Medicines Agency. In other words, there is now a potential vaccine for malaria currently in the process of entering the market. The company responsible for the regulatory application of this drug is the world’s largest pharmaceutical company GlaxoSmithKline (GSK). Yet, the development of this drug was funded largely

¹²⁸ T. Pogge, *Could Globalisation Be Good For World Health?*, *Global Justice: Theory Practice Rhetoric*, 2007: 1, pg. 7

¹²⁹ P. Trouiller, P. Olliaro, E. Torreele, J. Orbinski, R. Laing, N. Ford, Drug development for neglected diseases: a deficient market and a public-health policy failure, *The Lancet*, 2002L 359 (9324), pg. 2188

by the US military, and GSK only went through with paediatric testing in Africa after a \$200 million donation from the Bill and Melinda Gates Foundation¹³⁰.

The point is that this vaccine was developed off the back of a specific government interest (potentially protecting soldiers in tropical climates) and philanthropy. While the generosity of the Bill and Melinda Gates Foundation is commendable and is to be encouraged, the way to fix research priorities is surely not best dealt with through philanthropy. The fact that the world's wealthiest people *happen* to also be great philanthropists who happened to take an interest in eradicating malaria and other tropical diseases, is an incredibly lucky series of events.

The point of these examples, (statins, antibiotics and tropical diseases), is to show that industry funding skews research agendas, affecting what we know in a way that does not best help public BMR achieve its goal. This is a clear negative outcome of IFaC.

The inefficient focussing of research by industry interests in terms of health, does not manifest itself only in terms of what diseases get researched, it also skews the sorts of treatments for diseases that get researched and developed. Industry can be expected to invest only in research that they can reasonably be expected to capitalise. That is, private enterprise invests in treatments *they can sell*. This means funding research into certain sorts of treatments, which are overwhelmingly pharmaceuticals or medical devices, such as gastric bands¹³¹. This is of course not to say that research into pharmaceuticals and medical devices is not useful. Many diseases can effectively or solely be treated by certain products, and many people's lives have been hugely and positively affected by these products. The problem, however, is that research into preventative measures such as lifestyle

¹³⁰ D. G. McNeil, Scientists See Promise in Vaccine for Malaria, *The New York Times*, October 18, 2011, <http://www.nytimes.com/2011/10/19/health/19malaria.html?ref=world> accessed 24/10/2013

¹³¹ Gastric bands are used to constrain appetite in morbidly obese people.

changes, and research into the biological, social, economic and psychological dynamics of disease and disability are left with far less support. This sort of research can in many ways be more optimal in terms of achieving the goals of BMR than research into treatments.

The reason for this is because, as the cliché goes, prevention is indeed better than a cure. It is far more efficient to find ways to stop people from starting to smoke tobacco than it is to try to treat the plethora of conditions that can come from long-term use, whether they be cancer, emphysema or chronic obstructive lung disease. The seriousness of this cannot be stressed enough. An Australian Government study from 2011 suggests that 9% of Australia's *total* burden of disease was associated with tobacco usage¹³². It also found that tobacco usage was “responsible for 80% of lung cancer DALY¹³³... 75% of the COPD¹³⁴ DALY”¹³⁵ and “around half of the total burden of oesophageal cancer (54%)”¹³⁶. Furthermore, lung cancer, which is primarily caused by smoking, has the highest mortality rate of any cancer in Australia with a five-year survival rate of only 14%¹³⁷.

Therefore, in terms of welfare, research into how to educate and change behaviour that can lead to such poor health outcomes, such as smoking, is just as important as research into products that treat these outcomes. Yet industry has no interest in researching these sorts of programmes, as they cannot be turned, for the most part, into products that can be sold.

¹³² Australian Institute of Health and Welfare 2016, Australian Burden of Disease Study: Impact and causes of illness and death in Australia 2011, Australian Burden of Disease Study series no. 3, BOD 4. Canberra: AIHW, pg. 171

¹³³ DALY is public health term, defined by this study as “disability-adjusted life years”.

¹³⁴ COPD is the acronym for chronic obstructive pulmonary disease, a condition that limits airflow into the lungs

¹³⁵ *Ibid.*

¹³⁶ *Ibid.*

¹³⁷ Australian Institute of Health and Welfare & Australasian Association of Cancer Registries 2012, Cancer in Australia: an overview, 2012, cancer series no. 74, Cat. No. CAN 70, Canberra AIHW, pg. 20

This also holds true for other treatments such as some surgical techniques, with many surgical procedures “developed without external funding”¹³⁸. Although industry does not completely ignore surgical innovation, their funding of it tends to be directly related to surgical techniques that apply to their medical devices¹³⁹.

Thus, one of the negative outcomes of IFaC is the inefficient refocusing of research priorities. There is insufficient focus on research into certain areas of disease despite these diseases and problems that have huge associated health burdens. There is also inefficient focussing into research to produce artefacts and products to treat conditions, while taking focus away from environmental and lifestyle research to prevent these conditions. This shifting of research priorities associated with IFaC does not help public BMR as an institution best achieve its goal, nor does it maximise welfare.

1.2 - Is What We Know Reliable?

IFaC is not only negatively impacting what we know; there is reason to believe that IFaC has affected the reliability of what we know. There are two general reasons to believe this. The first is there is evidence to suggest that IFaC produces findings that are biased towards positive results of the product where the studies are funded by the manufacturer. The second is there is evidence that negative and null findings have been suppressed by industry, and thus we should be sceptical about the weight of evidence regarding products whose research was funded by industry.

¹³⁸ S. W. Chang, H. S. Luft, Reimbursement and the Dynamics of Surgical Procedure Innovation, in Institute of Medicine Staff, A. C. Greljns, E. A. Halm, *Changing Economics of Medical Technology*, National Academies Press: Washington, 1991, pg. 100, accessed via ProQuest ebrary, 12 July 2016

¹³⁹ L. F. Rikkers, K. I. Bland, B. K. Kinder, P. F. Lawrence, T. G. Lynch, I. M. Modlin, J. A. Schulak, W. M. Whitehouse, Funding of Surgical Research: The Roles of Government and Industry, *Journal of Surgical Research*, 1985: 39, pg. 210

This is problematic, as we want our knowledge to be as reliable as possible when it comes to biomedical research. There are a number of reasons for this. The first is a failure to properly and adequately report adverse side effects of pharmaceuticals can be dangerous. It has in the past led to hospitalisation and even death for some patients. These sorts of outcomes, if preventable, are clearly examples of a failure to maximise welfare.

The second is that researchers, clinicians, regulators and patients want to know whether a drug is truly effective as a treatment, at least insofar as this is possible. Ineffective drugs could be harmful if they do not work, as they may not actually be treating a patient's condition, potentially leading to a condition worsening or at least not improving. This is especially true in situations where there are viable treatment alternatives. It is also inefficient for a system to invest in products that do not work as advertised, even if they are not harmful. These sorts of outcomes also clearly fail to maximise welfare.

Regarding the concern that IFaC is biasing research, there are at least two potential positions to take. The first is a strong claim that IFaC produces a systematic bias in research. This claim is too difficult to prove categorically. Instead I will endorse a much weaker claim; we have reason to be sceptical of research sponsored by industry.

There are several studies that have investigated the relationship between IFaC and research outcomes, and these provide evidence to support my claim that we should be sceptical of the outcomes of industry-sponsored research. A study by Richard Davidson found that research sponsored by industry was more likely to favour new interventions¹⁴⁰. That is, research sponsored by industry was likely to favour their new product over the traditional or existing product.

¹⁴⁰ R. Davidson, Source of funding and outcome of clinical trials, *Journal of General Internal Medicine*, 1986: 1(3), pg. 156

A further study by Mark Friedberg et al, found that industry sponsored research into pharmaceuticals used in oncology were significantly less likely to report unfavourable conclusions¹⁴¹.

Henry Stelfox et al, found that researchers who had financial ties with companies that produced calcium-channel antagonists were far more likely to be produce positive studies than those without these ties¹⁴². In fact, Stelfox et al reported that ninety-six percent of authors who were supportive of calcium-channel antagonists had financial ties to the manufacturer. For those authors that produced negative studies of the drugs, only thirty percent had financial ties to the drug's producer.

Mildred Cho and Lisa Bero found similar results between positive articles in symposiums and industry sponsorship¹⁴³. They found that ninety-eight percent of symposium articles, whose authors had financial ties to the producer of the drug they were reporting on, produced positive results. This is in contrast to a still very high seventy-nine percent positive report rate in symposiums from authors without financial ties.

Finally, a more recent systematic review by Bekelman, Li and Gross, of studies looking into how industry funding affects research outcomes, found that industry sponsored research tends to produce more industry friendly results¹⁴⁴.

Again, none of this confirms the strong claim that IFaC systematically biases biomedical research, as there are at least two potential explanations that could

¹⁴¹ M. Friedberg, B. Saffran, T. Stinson, W. Nelson, C. L. Bennett, Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology, *JAMA*, 1999: 282 (15), pg. 1445

¹⁴² H. T. Stelfox, G. Chua, K. O'Rourke, A. S. Detsky, Conflict of Interest in the Debate Over Calcium-Channel Antagonists, *The New England Journal of Medicine*, 1998: 338(2), pg. 103

¹⁴³ M. Cho, L. Bero, The Quality of Drug Studies Published in Symposium Proceedings, *Annals of Internal Medicine*, 1996: 124 (5), pg. 488

¹⁴⁴ J. E. Bekelman, Y. Li, C. P. Gross, Scope and Impact of Financial Conflicts of Interest in Biomedical Research: A Systematic Review, *JAMA*, 2003: 289 (4), pg. 456

account for these findings. The first is that perhaps pharmaceutical companies are particularly shrewd investors and simply choose those projects that have a higher probability of success. After all, pharmaceutical companies largely only fund late stage trials after proof of concept has been established.

The second challenge to the strong claim is that these studies have no way of establishing which came first; a positive attitude towards certain pharmaceuticals by researchers which then led to industry supporting their research, or whether their positive stance came after and because of industry sponsorship of their research.

Regarding the second, the problem of which way the causal relationship in fact goes, there might be reasons to suspect that positive attitudes towards industry follow funding. The reason I offer is a psychological/social reason; the principle of reciprocity. As Arthur Schafer explains, “much of social life is based on reciprocity. The need to return benefit for benefit, kindness for kindness, and favour for favour is a basic motivator in virtually every human society”¹⁴⁵.

There are two main points to this argument. The first is that researchers, like most people, have a deep psychological drive to act favourably to those who act in their favour. By funding researchers’ work, industry is acting favourably towards these researchers and we can reasonably expect that this will usually engender some feeling of good will from the researchers towards their industry benefactors. This perhaps may be enough to allow some semblance of bias to creep in. It certainly gives the appearance of a conflict of interest.

Yet for researchers, it may also be more than just reciprocity, there is also the idea that one should ‘not bite the hand that feeds’. If producing and/or publishing negative or null results might threaten ongoing funding from industry one may

¹⁴⁵ A. Schafer, *Biomedical conflicts of interest: a defence of the sequestrian thesis – learning from the cases of Nancy Olivieri and David Healy*, *Journal of Medical Ethics*, 2004: 30 (1), pg. 21

be wary to do so. Again, research is expensive and for the academic, necessary to maintain or advance their employment. A case in point here is a 2005 study of thirty-two hundred US scientists in which 15.5 percent of respondents admitted to changing the design, methodology and even the results of a study due to pressure from a funding source¹⁴⁶.

I should note, however, that I find it unlikely that the majority of researchers would engage in wholesale fraud because of reciprocity. That is, I do not think that researchers often act *consciously* on these motivations, but rather the influence they produce is far more subtle.

The other point of this argument from reciprocity is that pharmaceutical companies are businesses, not charities. It seems unwise from a profit standpoint and therefore unlikely that pharmaceutical companies would invest in research and researchers if they did not expect this would benefit their bottom line. In other words, pharmaceutical companies are in some sense, banking on the fact that their contribution to researchers' work will be profitable for them.

This, however, still fails to fully establish the direction of causation I was originally concerned about. Suffice to say, it provides some reason to believe that industry funding might be followed by positive attitudes from researchers, however these arguments are not conclusive.

Even if the relationship is one where a positive attitude from a researcher towards a company's products precedes that company's sponsorship, perhaps there are reasons to think this may also be problematic. It seems that the problems of reciprocity and biting the hand that feeds both hold in this scenario.

¹⁴⁶ M. Wadman, [One in three scientist confesses to having sinned](#), *Nature*, 2005: 435(7043), pg. 718

That is, even if a researcher publishes a positive result of a company's drug and then that company funds their next research project, this funding should surely still engender feelings of reciprocity. Moreover, they may feel inclined to present their sponsors product in the best light possible in order to maintain ongoing funding for future projects.

Previously I mentioned that perhaps the relationship between industry sponsorship of research and positive outcomes of that research could be explained simply by industry predominantly backing research that already had a higher probability of success. There is reason, however, to doubt this claim too. The literature catalogues numerous examples in which research can be, and has been, influenced either by the companies themselves or those conducting the research. I already mentioned the survey in which 15.5% of responders admitting to changing significant aspects of their research due to pressure from a funding source. This is but one example of how IFaC can subtly or otherwise influence research and its reliability.

The ways in which research can be purposefully designed to produce positive results rather than produce reliable knowledge are numerous. One way to do this is to test your new drug against placebo instead of the current standard treatment¹⁴⁷. It may not be immediately clear why this is problematic because this sort of testing should show whether a new drug is effective or not. The problem, however, is that this is not the best information, as what we actually want to know is whether the new treatment is *better* than other current treatments? If we are looking to promote health optimally, then we are looking to discover and develop new treatments that are more effective than their predecessors or else there is, generally, little to be gained from the new treatment.

¹⁴⁷ M. Angell, *The Truth About Drug Companies*, pg. 107

A further way in which methodology can bias research is through the inappropriate use of comparator drugs. A new treatment can be made to look better, such as having less side effects, or more effective than older treatments, by using unequal doses of the two drugs. An example of using unequal doses of drugs to make a new treatment look better is a study examining treatment for fungal infections in immunocompromised patients. The study compared the old treatment, amphotericin B, at .6mg/k, to the new treatment AmBisome at 3mg/kg¹⁴⁸. It was not just that the new drug was administered at a much higher dose, but that the old drug was administered at the lowest possible clinical dose when a dosage of 1-1.5 mg/kg was considered far more appropriate¹⁴⁹.

Administering treatments differently can also bias results and this was again seen in another study comparing amphotericin B to another new treatment, fluconazole. In this study, the researchers administered amphotericin orally, which dramatically reduces its effectiveness, while the new treatment was administered intravenously in order to maximise effectiveness¹⁵⁰.

The participants that researchers enrol and the way these participants are grouped in the research can also be used to bias the results of a study. McGarity and Wagner give a hypothetical example of a scientist exploring whether exposure to a certain industrial chemical used in a manufacturing plant is dangerous or not¹⁵¹. The scientist could bias the results of the study by the way they choose to group the “exposed” and “unexposed” groups. The scientist could choose to group all employees of the plant as “exposed”, including lawyers, administrators and receptionists, some of whom work in offices off-site. The

¹⁴⁸ T. O. McGarity, W. E. Wagner, *Bending Science; how special interests corrupt public health research*, Cambridge: Harvard University Press, 2008, pg. 63

¹⁴⁹ *ibid*

¹⁵⁰ M. Angell, *The Truth About Drug Companies*, pg. 108

¹⁵¹ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 68

researcher could also include all non-employees as “unexposed”, including contractors who would in fact have had a high level of exposure.

Marcia Angell offers a different example of how the choice of participants can influence the results of a study. If the researcher wants to make a treatment that will be used predominantly in an older population appear better, they can test it in a younger population. This is because younger people tend to suffer fewer side effects than elderly people¹⁵². Therefore, by testing a product in a younger population, even though it is for a problem that largely affects older people, one can make the drug seem more effective and safe. The exclusion of older people from clinical trials is not merely Angell’s opinion, with one author suggesting that “older people are proportionately under-represented or even absent from most drug trials”¹⁵³. Moreover, the evidence suggests that this problem is widespread¹⁵⁴.

Research can also be biased by the questions it asks, for example by asking overly narrow questions, researchers can make a treatment appear more effective than it actually is. One way to do this is by using “surrogate endpoints”, which is a measure that is meant to but does not necessarily correlate with a real clinical endpoint. A researcher might, for example, use blood cholesterol as a surrogate endpoint for their study. This can make a drug appear more effective than it really is and is not very useful given what we actually want to know is whether this drug helps people live longer, healthier lives.

These are just some of the numerous ways in which research design can and does influence the results of a study. For now, I will suggest that there is ample

¹⁵² M. Angell, *The Truth About Drug Companies*, pg. 108

¹⁵³ G. Watts, *Why the exclusion of older people from clinical trials must stop*, *BMJ: British Medical Journal*, 2012: 344, pg. 1

¹⁵⁴ M. E. McMurdo, H. Roberts, S. Parker, N. Wyatt, H. May, C. Goodman, S. Jackson, J. Gladman, S. O’Mahony, K. Ali, E. Dickinson, P. Edison, C. Dyer, *Improving recruitment of older people to research through good practice*, *Age and Ageing*, 2011: 40(6), pg. 1

evidence that there are ways in which studies can, and have been, influenced by their design to encourage certain results.

It is not solely through study design and methodology that research can be influenced. The interpretation and analysis of data can also mislead, overstate or generally bias the conclusions of a study. One example of misleading reporting was the case of Vioxx, which is a class of drug referred to as non-steroidal anti-inflammatories (NSAIDs). These drugs are most commonly used to treat pain and inflammation. The problem with many NSAIDs is that they can increase the risk of ulcers and gastric bleeds. The hope was that a new class of NSAIDs, of which Vioxx was one, would significantly reduce this risk.

Vioxx was tested against an older NSAID, naproxen, but what the researchers found was that subjects in the Vioxx treatment group had a five times greater risk of heart attack than those in the naproxen group¹⁵⁵. Yet because there was no non-treatment control group from which a baseline risk of heart attack could be determined, this meant the data could be interpreted in one of two ways. Either Vioxx increased the risk of heart attack by roughly 400%, or naproxen reduced the risk of heart attack by about 80%. There was no reason to believe that naproxen was protective against heart attacks, it was an old drug that had been on the market for decades and there had been no indication of this protective effect. Yet despite the lack of plausibility for this interpretation, this was the result that was reported.

There are of course any number of statistical and interpretive tricks that can be used to bias results. For example, removing outliers from either end of the scale or selecting sub-groups for which positive results were found. Considered one of the worst of these is “data-dredging”. Normally, high-quality research is “double-blinded” and the endpoints are predetermined. Double-blinded means

¹⁵⁵ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 76

neither the patients nor the researchers know which patients are in which treatment group. Predetermined endpoints mean that the researchers set out at the beginning of the study, what endpoints they intend to measure.

The reason for doing this is to prevent researchers from abusing the raw data they collect by doing ad hoc or exploratory analysis in the hope of finding some desired result. While doing this exploratory analysis after breaking blinding conditions can be useful, such as for offering direction for potential future research, it is hugely misleading to report ad hoc analysis of data as though it were the original intent of the research. In other words, setting predetermined endpoints prevents researchers from shifting the goal posts, as was the case with the antidepressant drug paroxetine.

A major study into using paroxetine to treat adolescent depression is a classic example of data-dredging and researchers shifting the goal posts in order to produce specific results. Originally Keller, Ryan, Strober, et al., specified two primary outcome measures and six secondary measures. After the blind was broken, according to Jureidini, McHenry and Mansfield, there was “no significant difference between the paroxetine and placebo group on any of the eight pre-specified outcome measures”¹⁵⁶.

In the time between breaking the blind and publishing the paper, the researchers removed four out of eight negative outcome measures and replaced them with four positive measures that had not been pre-specified¹⁵⁷. The researchers then removed the distinction between primary and secondary measures, describing all eight outcomes as primary¹⁵⁸. Jureidini, McHenry and Mansfield also found

¹⁵⁶ J. N. Jureidini, L. B. McHenry, P. R. Mansfield, *Clinical trials and drug promotion: Selective reporting of study 329*, *International Journal of Risk & Safety in Medicine*, 2008: 20, pg. 74

¹⁵⁷ *Ibid.* pg.75

¹⁵⁸ *ibid*

that despite significantly higher risks of adverse side effects (including self-harm and suicidal ideation), these events were not properly reported¹⁵⁹.

Despite this, the final report from the researchers concluded that paroxetine was “generally well tolerated and effective for major depression in adolescents”¹⁶⁰. This drug it seems, was neither safe nor effective for use in depressed adolescents, and is yet another example of how IFaC’s influence on public biomedical research can produce serious negative outcomes.

The failure to properly report the negative outcomes by the researchers involved in the paroxetine study, is also an example of incomplete reporting, wherein to make a treatment look better they fail to report all the data completely or properly. Another example of this is the clinical trial of Celebrex, an arthritis treatment. The study concluded that Celebrex caused fewer side effects than two other arthritis treatments¹⁶¹. It, however, was revealed that this conclusion was based only on the first six months of data from a twelve-month trial, and when all of the data was analysed, Celebrex appeared no better than the other two drugs¹⁶².

When attempts to introduce bias in a study through its methodology or interpretation of results fail, industry has historically demonstrated a willingness to suppress, or attempt to suppress, unfavourable studies. There is no shortage

¹⁵⁹ *Ibid.* pg. 77

¹⁶⁰ M.B. Keller, N. D. Ryan, M. Strober, R. G. Klein, S. P. Kutcher, B. Birmaher et al. Efficacy of paroxetine in the treatment of adolescent major depression: a randomised controlled trial, in, J. N. Jureidini, L. B. McHenry, P. R. Mansfield, *Clinical trials and drug promotion*, pg. 73

¹⁶¹ M. Angell, *The Truth About Drug Companies*, pg. 109

¹⁶² *Ibid.*

of examples of this in the literature, and it is well documented^{163,164,165,166}. Various authors give examples of attempts to bully and influence researchers and their institutions through a variety of means, including litigation, in order to try and suppress unwelcome findings. It should also be noted these examples only represent those cases we know about. We can reasonably expect that there are other researchers who have succumbed to such pressures such as the threat of litigation, potential loss of employment, and loss of reputation, which amongst other costs have proven too great.

All of the issues I have listed above are seriously problematic. In order to best maximise welfare, research needs to be as impartial as possible. The examples I have taken from the literature give reason to believe this. Promoting ineffective or even sometimes dangerous treatments is clearly antithetical to promoting welfare, yet it seems that as a result of IFaC, this is occurring.

This provides reason to question the “all things being equal” assumptions I made in the previous chapter regarding the benefits of IFaC. There is, of course, still a question of balancing the benefits and costs of IFaC, for it is still possible the extra funding and research it offers might outweigh the costs. I believe, however, that we should be somewhat sceptical of this. After all, there seems to be limited benefit to more research if the knowledge that is produced by this research is unreliable.

This section has shown how IFaC is affecting not only what we know, but the reliability of what we know. I used examples to demonstrate that IFaC inefficiently warps research programmes away from public interest science and

¹⁶³ S. Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?*, Lanham: Rowman & Littlefield Publishers, 2003, pg. 41

¹⁶⁴ M. Angell, *The Truth About Drug Companies*, pg. 109

¹⁶⁵ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, Lanham: Rowman & Littlefield Publishers, 2008, pg. 97

¹⁶⁶ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 102

towards more profitable projects with limited welfare impact. This was seen with the neglect of research into new antibiotics and treatments for diseases such as malaria and by the overinvestment of resources into areas such as statin research.

I also showed that industry sponsorship of research and commercialisation produces research that is unreliable. I argued there is reason to believe that IFaC biases researchers towards their products and explained the ways this could and has happened. Finally, I suggested that when this has failed, industry has not been shy about attempting to suppress unfavourable results.

Ultimately, these problems inhibit welfare maximisation and they should be considered as clear negative impacts of industry funding and commercialisation of public BMR.

Section 2 – *No Coincidence: A Tale of Two Institutions*

The previous section detailed some of the already well-elucidated problems caused by IFaC. Many have argued that these problems are not simply coincidental; they are not just facts about problems that have arisen due the current empirical state of affairs. Rather these problems are *inherent risks* of IFaC due to a changing or undermining of public BMR as a social institution by IFaC. In other words, the risk is due to institutional differences between private and public biomedical research.

It will now be important to reiterate certain arguments I established in previous chapters. I suggested that public BMR was a goal-directed social institution with the goal of maximising welfare through health. Insofar as this is true public BMR should be designed in a way that best achieves this goal. This means that its structure, roles, norms and other constituents should be those which best help it achieve its goal. I suggested that the Mertonian norms of communalism,

universalism, organised scepticism and disinterestedness were the most appropriate norms for public BMR.

Private biomedical research is also a social institution, with a goal and all the other relevant parts of a social institution, including norms. Like public BMR, private BMR should be designed in a fashion that best helps it achieve its goal. It is uncontroversial to propose that private BMR, like almost all private enterprise, has the goal of being profitable. More specifically, like many other companies, most biotech and pharmaceutical firms are owned by various shareholders and the goal is to maximise returns on investment to shareholders. There of course appears nothing wrong, *prima facie*, with this goal assuming it is pursued within certain constraints.

The day-to-day activities of both public and private BMR appear very similar: they use similar equipment, techniques and technology, the same theories, in order to try and address certain scientific questions. Yet there are still fundamental differences between the two institutions.

As I mentioned, these institutions have different goals and insofar as they have different goals we can expect them to have different norms. John Ziman offers a brief explanation of the norms of industry science, saying it is, “Proprietary, Local, Authoritarian, Commissioned and Expert”¹⁶⁷. Private BMR,

produces proprietary knowledge that is not necessarily made public. It is focussed on local technical problems rather than on general understanding. Industrial researchers act under managerial authority rather than as individuals. Their research is commissioned to achieve practical goals, rather than undertaken in the pursuit of knowledge.

¹⁶⁷ J. Ziman, *Real Science: What it is and What it Means*, Cambridge: Cambridge University Press, 2000, pg. 78

*They are employed as expert problem-solvers, rather than for their personal creativity.*¹⁶⁸

These norms are antithetical to the Mertonian norms of public BMR in many ways, just as the Mertonian norms would be grossly dysfunctional in a private setting. For example, the proprietary nature of industry research is antithetical to the open and free sharing of data proposed by Merton's norm of communalism. Moreover, communalism, for the most part, can simply not work in a private setting where there needs to be a strong emphasis on secrecy in order to properly capitalise on discoveries. Private enterprise cannot have their scientists freely sharing data with other scientists, as this increases the likelihood of competitors discovering their proprietary secrets and/or potentially beating them to the patent office and losing their investment.

The tendency towards secrecy for private research is not just about protecting patentable discoveries. It also makes sense, in some cases, to not fully share data from completed studies if this data suggests your product is not as effective as you had hoped. In other words, secrecy makes it easier to effectively spin the numbers regarding the efficacy of your product. Celebrex, the arthritis medication I mentioned earlier in this chapter, is such an example.

Disinterestedness is also antithetic to private research as these companies are heavily invested in the outcome of research regarding their products. They have strong financial reasons for trying to produce research or influence research in ways that favour their products.

Therefore, it should be clear that that private and public biomedical research have different goals and thus different norms. It seems that in this situation the norms of the two institutions are antithetical in many ways. So, the question

¹⁶⁸ *Ibid.*

becomes, what happens when these two institutions begin to merge in the way they have?

Ziman's answer is that it has given rise to what he refers to as "post-academic science"¹⁶⁹. Ziman sees this new institution as largely being borne from academic science and maintaining many of the elements of it, but also of adopting and integrating "within academic science a number of practices that are essentially foreign to its culture"¹⁷⁰. That is, much of public biomedical research will remain in place but the influence of industry will also force many of its interests and practices into an institution that once had no place for them.

Arthur Schafer's view is that the ongoing collusion of industry and public BMR means "the norms of commerce may swamp traditional norms of science and the best interests of the community: disinterested pursuit of knowledge may give way to the entrepreneurial pursuit of financial self interest"¹⁷¹. Presumably, this may lead to a similar conclusion to Ziman's: the collusion of industry and public BMR may well give rise to a new social institution. If the goal and the norms of public BMR are changed and institutions are to be defined at least in part by reference to these two things, it seems that should they change enough we may have to consider it a new institution.

In fact, whether the closeness of industry and public/academic science has either undermined the norms of the latter or given rise to a new institution is irrelevant. Either way we are left with a situation wherein the norms are substantially different to the Mertonian norms; the norms that Merton believed were a functional and moral imperative for science. It is these new norms' departure from the Mertonian norms towards norms of private enterprise research from

¹⁶⁹ J. Ziman, *Real Science*, pg. 67

¹⁷⁰ J. Ziman, *Real Science*, pg. 79

¹⁷¹ A. Schafer, *Biomedical Conflicts of Interest*, pg. 16

which the risk of the problems outlined earlier in this chapter seemingly are derived.

There remains the possibility that this new institution is better than the traditional institution of public BMR. Determining this will be a matter of balancing the value of benefits provided by IFaC, as discussed in the previous chapter, and the costs detailed in this chapter. This section, however, is not interested in answering this question of value. According to the aims of this thesis the task I set was to establish that the problems caused by IFaC are an inherent risk caused by the departure from the Mertonian norms. These problems are exactly the sorts of problems we would expect to see from research that is increasingly interested and proprietary.

Section 3 – Potential Interlocutors, Actualism and Possibilism: How We Should Treat Researchers

The previous sections sought to not only identify the problems caused by IFaC, but also to establish these problems as inherent risks, stemming from the undermining of the norms of public BMR by IFaC. These problems naturally give rise to questions about how to best rectify them.

How we best deal with these problems will depend at least in part on whether researchers themselves will be able, in the face of perverse incentives, to appropriately adhere to the Mertonian norms. This section will, therefore, refer to a substantive debate within consequentialism between Actualism and Possibilism¹⁷². This discussion will be useful to help inform us as to how we should treat researchers and what strategy might be best to adopt in order to combat the problems caused by IFaC.

¹⁷² F. Jackson & R. Fargetter, Oughts, Options, and Actualism, *Philosophical Review*, 1986: 95(2), pg.235

Philip Pettit, while discussing the overdemandingness objection to consequentialism, offers a useful summary of the Actualism/Possibilism debate. He discusses the difference between treating agents as “parametric” or as “potential interlocutors”¹⁷³. To treat an agent as parametric is to assume their wrongdoing as a background condition in your decision-making. It is just one among many different factors that can affect a decision, such as traffic or the possibility of rain. Conversely, to treat an agent as a potential interlocutor is to treat them as agents who are also subject to moral demands and whose wrongdoing cannot simply be assumed. That is, when I am deliberating about the correct course of action, I do not assume an agent’s wrongdoing as a background assumption, but instead treat them as though they will be responsive to moral demands.

How to treat agents in our deliberations has evoked a substantive debate amongst consequentialists, with the two sides being referred to as Actualists or Possibilists. Actualists argue that in our deliberations we should take into consideration the wrongdoing of others as part of background information. Possibilists, however, believe that it is an agent’s *capacity* to do the right thing that should be relevant to our decisions.

This debate largely focuses on cases where the agent has the capacity to act towards the best outcome, but we can reliably predict that they will not do so. Actualists argue that since we can reliably predict an agent’s wrongdoing, or at least suboptimal-doing, we should assume this as part of our decision-making. Possibilists suggest that regardless of our ability to reliably predict the

¹⁷³ 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

wrongdoing of another, we should only consider whether or not they have the capacity to act in such a way that would achieve the best outcome.

Much of the debate between Actualists and Possibilists centres around predictions of one's own wrongdoing. The paradigm thought experiment is Frank Jackson and Robert Pargetter's "Professor Procrastinate"¹⁷⁴. Procrastinate has been asked to review a book in a field of study where he is the foremost expert. The best outcome is for Procrastinate to accept the invitation to review the book and write the review. He, however, is a chronic procrastinator and will fail to review the book within a reasonable timeframe. If, however, he declines the review, the best outcome can no longer be achieved. Although a second-best outcome can be achieved, an outcome where the book review is passed on to another professor who is not quite as proficient in the field as Procrastinate, but will in fact write the review in a timely manner. Should Procrastinate accept the review, the best *possible* outcome remains available, but seeing as he will not write it, we are actually left with the worst possible outcome, wherein the review is not written at all.

In the case of Procrastinate, Actualists argue that it is appropriate to choose a suboptimal outcome based on the reliable prediction of his wrongdoing in order to avoid the worst outcome. Possibilists, however, argue that Procrastinate is an agent with the capacity to choose the correct decision and we should not preclude the best possible outcome based on predictions of his wrongdoing. For Possibilists,

the fact that Procrastinate would not write the review were he to say yes is irrelevant. What matters is simply what is possible for

¹⁷⁴ F. Jackson & R. Pargetter, Oughts, Options, and Actualism, *Philosophical Review*, 1986:95, pg. 235

*Procrastinate. He can say yes and then write; that is best; that requires inter alia that he say yes; therefore, he ought to say yes.*¹⁷⁵

Clearly, and especially in real world analogues, much of this hinges on us being able to reliably predict future wrongdoing or the likelihood of wrongdoing.

As mentioned, the Actualism/Possibilism debate has focussed on predictions of one's own future wrongdoing, but this problem applies to the prediction of others' wrongdoing too. While there is something of an intuitive chafe when making decisions based on predictions of my own future wrongdoing, taking into consideration the potential future wrongdoing of others does not seem as intuitively disagreeable. This, however, does little to solve the fundamental problem of whether or not it is appropriate to make decisions which take agents' future wrongdoing as a given.

Lloyd Humberstone, in a paper about the semantics of conditional obligations in deontic logic, also discusses the issue of how we should deal with the future actions of others when considering our own future actions. He argues that it is more or less a truism that our obligations depend on our circumstances, where circumstances are understood as "those features of the situation which lie – loosely speaking – outside the agent's control, constituting the limits within which he is to act"¹⁷⁶. Yet *exactly* what features of a situation should be considered as qualifying as a "circumstance" is unclear. As Humberstone points out, it is particularly unclear "when the determinants of the objective rightness of several agents' actions include the effects of each others' actions"¹⁷⁷. While the parallels with the Procrastinate example here are clear, Humberstone instead discusses it

¹⁷⁵ *Ibid.*

¹⁷⁶ L. Humberstone, *The background of circumstances*, *Pacific Philosophical Quarterly*, 1983: 64, pg. 20

¹⁷⁷ *Ibid.*

in the context of Bernard Williams' seminal thought experiment of 'Jim and the Indians'¹⁷⁸.

Jim is an American visitor to a South American town, where the local captain of police, Pedro, makes Jim an offer. Pedro has in captivity twenty prisoners, and in honour of the American's visit he explains to Jim, that if Jim is willing to shoot one of the prisoners, Pedro will let the remaining nineteen go. If Jim refuses, however, Pedro will shoot all twenty.

Williams' thought experiment was initially meant as an objection to consequentialism. Humberstone, however, notes that there is something else interesting about the example, which is that

*the reaction people commonly have to the case, when they first meet it: they say... that it is Pedro, not Jim, who has set this awful situation up and so it is Pedro, not Jim, who must bear the responsibility for any deaths that follow Jim's refusal. Since Jim can thus refuse to shoot and walk away blameless, it cannot be that he is under any moral obligation to accept*¹⁷⁹

Those who think that Jim should shoot the one take Pedro's wrongdoing as given, as part of the background circumstances that should inform his decision. Conversely, those who disagree argue that it is inappropriate to take Pedro's wrongdoing as merely background circumstances because "to do so would involve acknowledging the right of the wicked to coerce the rest of us into a grudging complicity with their schemes"¹⁸⁰.

¹⁷⁸ J. Smart & B. Williams, *Utilitarianism; for and against*, Cambridge: Cambridge University Press, 1973, pg. 98

¹⁷⁹ L. Humberstone, *The background of circumstances*, pg. 26

¹⁸⁰ L. Humberstone, *The background of circumstances*, pg. 27

Although Humberstone suggests that it is common for people to defend Jim's decision to not shoot the one, it is difficult to find a defence of this view in the literature. This tells us that most philosophers seem to accept that if Jim refuses to shoot the one then Pedro *will indeed* shoot the twenty. Thus it does seem that many philosophers find it acceptable to treat Pedro's wrongdoing as parametric.

This does not mean that we should always accept others' wrongdoing in this way. If the example is manipulated slightly, it might change the way people respond. So let us say that rather than Pedro, it is Juan who is the police captain. Juan makes the same offer to Jim; shoot the one to save the nineteen or all twenty die. Juan, unlike Pedro, looks deeply upset by his orders to shoot the twenty and appears to be desperately looking for a way out, and may in fact be open to persuasion. In this example it now seems quite inappropriate to suggest that Jim has the same obligation to shoot the one.

This is because Juan, as opposed to Pedro, seems far more like a potential interlocutor, as made apparent by his discomfort with his situation. It seems in the case of Juan and the Indians, Jim's best option is to refuse to shoot the one and try to remind Juan of his moral duty.

We are still left with the central question: when is it appropriate to treat agents as potential interlocutors and when should we treat them as being parametric? More specifically, how should we, as regulators, treat biomedical researchers? Should we treat them as we do Pedro – technically capable of resisting industry pressure but so unlikely to do so that we should dismiss any option that relies on it? Or should we treat them like Juan – as 'potential interlocutors' who are capable of living up to their responsibilities given enough rational persuasion and reminders? The answers to these questions will inform how we best deal with fixing the problems caused by IFaC; which strategies are viable and optimal.

To best answer these questions we should look at why so many assume that Pedro cannot be treated as a potential interlocutor. It is possible that people assume Pedro will not be moved by rational argument, based on the description of his behaviour. We assume that he will fail to recognise the moral reasoning behind his obligations to not shoot the twenty. There are two potential explanations for this, neither of which are mutually exclusive. Either he is so irrational that he would be unable to follow an argument explaining why he should not shoot the prisoners. Or his beliefs and attitudes are too far removed from what they should be, so that he would simply not be able to accept any argument based on them. It seems that people believe that Pedro will be unable to be made to understand why he should not shoot the twenty, and it is unlikely that he will come to this understanding himself. Thus, we feel that since Pedro cannot and will not be made to understand his obligations, his wrongdoing is to be taken as parametric.

Therefore, it seems reasonable that whether or not we treat agents as parametric or potential interlocutors should be determined by the probability of them responding to reason. In other words, an agent's potential to be an interlocutor will depend on their capacity to respond to reason.

Section 4 - *Capacities*

This section will discuss what it means for our researchers to have 'capacity'. In order to do this, I will refer to Michael Smith's account of capacities, which suggests that capacities are not all-or-nothing, but rather sit on a spectrum. While a full account and debate on capacities is well beyond the scope of this thesis, Smith provides a useful working account that offers a mechanism for understanding capacities in the context of public BMR and its researchers. Based on Smith I will look at whether we can reasonably say that biomedical researchers

have the capacity to adhere properly to institutional norms, and under what conditions we can expect this to happen.

Smith is interested in finding out what we mean when we say that an agent “could” (or could not) do something. To suggest that an agent could x is to suggest that they have the capacity to x , even if they fail to x and thus fail to realise their capacity to x . Or as Smith puts it, “could” claims signify “the presence (or absence) of a rational capacity which we take to explain the relevant behaviour”¹⁸¹.

Smith, in order to elucidate his argument about what could claims mean, gives us the example of The John’s¹⁸². Blanking John (BJ) and Ignorant John (IJ) are asked a philosophical question by one of their colleagues and both are unable to answer the question at the time it was asked. BJ goes home and as he is cooking dinner the answer comes to him. His reaction to the answer occurring to him is one of embarrassment at failing to think of the answer at the time, as the answer now seems so obvious to him. He feels that he really ought to have thought of the answer at the time, as there was no reason for him not to have, “he just blanked”¹⁸³.

Ignorant John on the other hand, goes home and the answer does not occur to him. Instead he has to sit down with some literature relevant to the question and it is through his literature review that he discovers the answer.

Smith argues that BJ could or had the capacity to answer the question, while IJ did not.

¹⁸¹ M. Smith, *Ethics and the a priori: selected essays on moral psychology and meta-ethics*, Cambridge; New York; Cambridge University Press, 2004, pg. 115

¹⁸² M. Smith, *Ethics and the a priori*, pg. 116

¹⁸³ M. Smith, *Ethics and the a priori*, pg. 117

In reviewing what a 'could' claim means, Smith refers to how BJ and IJ perform in close possible worlds. A close possible world is a possible world with very similar, but not identical, laws and history to the actual world. Ultimately, Smith comes to the conclusion that if BJ did in fact have capacity to answer the question at the time he was asked then we should expect that he would be able to answer a "whole host of slight variations on the question he was asked, variations in the manner the question was asked, and perhaps in the exact content of the questions, and in the exact timing of the questions, and so on"¹⁸⁴. If we believe that BJ had the capacity to answer the question then we expect that he would routinely succeed, in a raft of nearby possible worlds to answer numerous slight variations of the question he was asked in this world. We believe that IJ, although he may answer the question in a nearby possible world, will systematically fail to answer the question across a raft of nearby possible worlds.

In short, an agent has the capacity to do something if, in a host of nearby possible worlds, they routinely perform the action indicative of the capacity. This is directly relevant to this thesis since the capacity of biomedical researchers to resist perverse incentives and act in accordance with norms of public biomedical research, will inform which strategies we adopt in dealing with IFaC.

Conclusion

The aim of this chapter was threefold. The first was to explain the numerous issues caused by IFaC and explain how these problems failed to maximise welfare. These problems were largely epistemic in nature, with IFaC not only influencing what we know, but also influencing the reliability of that knowledge. The second aim was to explain that these problems were not merely a coincidence brought about by the current model of IFaC, but were instead inherent risks. I argued that this was due to underlying institutional differences between the

¹⁸⁴ M. Smith, *Ethics and the a priori*, pg. 124

goals and norms of public and private biomedical research and their incongruence. Finally, in order to open the way for a discussion in the next chapter about fixing the problems caused by IFaC, I addressed the Actualism and Possibilism debate, and discussed Smith's concept of capacities. The purpose of exploring the Actualism/Possibilism debate was to establish that whether we treat researchers as parametric or potential interlocutors will depend on their capacity to respond to their ethical duties. I then used Smith's account of capacities to explain what it means for our researchers to have capacity.

Chapter 5

Having analysed the chief problems caused by industry funding and commercialisation of public biomedical research in the previous chapter, this chapter will proceed to explore a number of proposed strategies offered as solutions to these problems. The proposed solutions fall into one of two categories, which Howard Brody refers to as the *divestment* and the *management* strategies¹⁸⁵. Within both of these strategies is a broad range of solutions that I will explore. The *divestment* and *management* strategies contain different ideas regarding the extent of what needs to be done, and importantly, they also make very different assumptions about researchers and their capacity to resist perverse incentives from industry.

This chapter will be divided into five sections, with the first offering a brief synopsis of the *divestment* and *management* strategies.

The second section of this chapter will examine the *divestment* strategy, which suggests that there needs to be some level of separation between industry and academia. I have divided *divestment* into two major approaches; the popular ‘firewall’ strategy, and full *divestment*. Both strategies assume that researchers will be unable, in the face of perverse incentives, to adhere appropriately to institutional norms.

The next section will discuss in greater detail the *management* strategy within which I suggest there is a useful division to be made. As I did with *divestment*, I have separated the *management* strategy into two loosely defined sub-strategies: weak and strong *management*. Weak *management* is the current paradigm solution for dealing with problems caused by IFaC. Strong *management* on the other hand makes a series of proposals that go well beyond the limited suggestions of its

¹⁸⁵ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, Lanham: Rowman & Littlefield Publishers, 2008, pg. 288

counterpart, although it too allows industry and academia to continue interacting more or less in the way they have been. I will argue that the assumptions that the *management* strategy makes about researchers' capacities depends on whether we are referring to the strong or the weak version. Weak *management* assumes researchers have a fairly robust capacity to resist perverse incentives, while strong *management* assumes a less robust capacity. In other words, weak *management* treats them as potential interlocutors but does so inappropriately, while conversely strong *management* treats researchers as merely parametric.

The fourth section will examine the shortcomings of both the *divestment* and *management* strategies. While both strategies make some recommendations worthy of consideration, I will suggest that both are ultimately unworkable. I will argue that the weak *management* strategy has failed, at least thus far, to properly address and fix the issues caused by IFaC, and while strong *management* makes a host of reasonable suggestions that should be adopted, those suggestions are insufficient. Conversely I will suggest that while *divestment* may in fact be a necessary condition in properly addressing the problem of IFaC, the probability of its recommendations being implemented in the current climate are problematically small.

This paves the way for the final section, in which I will explore an alternative strategy: the *educational-cultural* strategy. This strategy will call on several of the arguments I have made in the previous chapters, including understanding public BMR as a goal-directed social institution, my interpretation of the Mertonian norms, and Smith's concept of capacities. The *educational-cultural* strategy hopes to engage researchers as potential interlocutors by enhancing their capacity to resist perverse incentives and act in accordance with the Mertonian norms. This will rely on training researchers in the nature of the problems of IFaC, the ethical problems relating to research, and their professional obligation regarding research and the Mertonian norms.

Section 1 – *Divestment & Management: A Brief Overview*

In a world where we have no industry pressure on researchers, there should be little doubt that, all things being equal, it would be reasonable to suggest biomedical researchers would have the capacity to adhere appropriately to the Mertonian norms. This, however, is not the world we currently live in, which instead has multiple sources of pressure pushing researchers to conduct themselves increasingly according to industry norms. More than this, both Brody and Schafer argue that there are a number of psychological factors produced by the current relationship between academics and industry that further reduce researchers' capacities to resist perverse incentives^{186,187}.

This problem raises the obvious question of how we should best deal with the problems of IFaC. This section will offer a very brief overview of the two major strategies, while later sections will deal with them in greater detail. The *management* and *divestment* strategies are the two most common proposed solutions to IFaC. As explained, these two strategies take different approaches and make different assumptions about researchers and their capacities. While both of these strategies have variations within them, the overall implications of each strategy are consistent.

On the one hand the *divestment* strategy demands some level of separation between industry and academia in order to address the issues caused by IFaC. It argues that the current status quo is untenable and if it is allowed to continue as it has been, the problems of IFaC cannot be solved. Therefore, *divestment* proposes a fundamental shift in the way public biomedical research and its

¹⁸⁶ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, pg. 290

¹⁸⁷ A. Schafer, Biomedical conflicts of interest: a defence of the sequestrian thesis – learning from the cases of Nancy Olivieri and David Healy, *Journal of Medical Ethics*, 2004: 30 (1), pg.21

industry counterpart interact, with each being kept at arm's length from the other.

On the other hand, the *management* strategy according to Brody, "begins with the premise that, like it or not the pharmaceutical industry and the medical profession will have to relate in more or less the fashion they have been"¹⁸⁸. The implication being, we therefore "manage the relevant concerns and conflicts of interest, using means appropriate to the specific level and institution in question"¹⁸⁹. In other words, the *management* strategy assumes that the current types of interaction between academia and industry will continue, more or less, as is. Therefore, if we are to overcome any problems caused by IFaC it will need to be achieved within this paradigm. Thus, many of the proposals and solutions within the *management* strategy refer to increased openness and the management of any conflicts of interest by researchers themselves or their institutions.

To borrow a metaphor from Lewis, et. al. who discuss university-industry relationships, the *management* strategy has us "dancing with the porcupine"¹⁹⁰ trying to avoid the quills, while *divestment* has us refusing to dance.

¹⁸⁸ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, pg. 288

¹⁸⁹ *Ibid.*

¹⁹⁰ S. Lewis, P Baird, R. G. Evans, W. A. Ghali, C. J. Wright, E. Gibson, F. Baylis, Dancing with the porcupine: rules for governing the university-industry relationship, *CMAJ: Canadian Medical Association Journal*, 2001: 165(6), pg. 783

Section 2 – *The Divestment Strategy*

While the previous section gave a brief introduction to the two major strategies for dealing with IFaC, *management* and *divestment*, this section will be dedicated to a more in-depth discussion of the latter in three states. The first subsection will examine the common suggestion that a ‘firewall’ be established between academia and industry, while the second subsection will look at a possibility hinted at by Schafer; a more radical complete *divestment*.

The final subsection will look at what assumptions the *divestment* strategy makes about our researchers and their capacity to appropriately adhere to the Mertonian norms. I will argue that both the firewall approach and complete *divestment* make the same assumption; that in the face of strong perverse incentives from industry, researchers lack the capacity to behave in accordance with the Mertonian norms.

2.1 – *Firewall Divestment*

Proponents of the *divestment* strategy believe that it is simply too dangerous to dance with the porcupine when it comes to academia-industry relationships. They believe the only way to fully address the problems caused by IFaC and identified in the previous chapter, is to fundamentally change the way academia and industry interact. This subsection will focus on the ‘firewall’ approach to *divestment*.

A number of authors in the literature such as Howard Brody, Sheldon Krimsky, Marcia Angell and Arthur Schafer, amongst others, put forward the idea of a firewall^{191,192,193,194}. The pivotal idea of this firewall is to set up a central, public and

¹⁹¹ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, pg. 321

¹⁹² S. Krimsky, *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?*, Lanham: Rowman & Littlefield Publishers, 2003, pg. 227

¹⁹³ M. Angell, *The Truth About Drug Companies*, New York: Random House, 2004, pg. 244

¹⁹⁴ A. Schafer, *Biomedical conflicts of interest*, pg. 23

independent institute through which money from industry could then flow to researchers. Since a number of authors refer explicitly to Krimsky's proposal and then offer some variation on it, I will begin by discussing Krimsky's firewall proposal.

Any company wishing to generate data for market authorisation would have to submit their product to what Krimsky calls, "an independent national institute for drug testing (NIDT)"¹⁹⁵. From here the NIDT would notify researchers that they had a product they wanted researched. Appropriately qualified researchers would then submit applications to perform the research, and the NIDT would choose a research group based on these proposals.

Krimsky and Brody offer slightly different ideas regarding what conditions must be satisfied in order to be a successful applicant for NIDT research. Krimsky suggests "no tester or testing institution could have equity in a company poised to benefit from the testing results"¹⁹⁶. Krimsky then proposes a period of negotiation between the NIDT and the contractee regarding research protocol, "data utilization, and publications"¹⁹⁷. Brody instead prefers that, "universities would be required to have strong conflict-of-interest policing policies as a condition of being awarded [NIDT] grants"¹⁹⁸. He then suggests that as the initial trials are completed, there may be a need to "reconsider both the design and the cost of later trials in light of any unexpected results"¹⁹⁹. This process would need to be done with the NIDT acting as an intermediary between the researchers and the trial sponsor in order to maintain quality control and the integrity of the research. Once the trials are complete, the data would be registered by the NIDT and then sent to the sponsor. This means that all results, negative and positive

¹⁹⁵ S. Krimsky, *Science in the Private Interest*, pg. 229

¹⁹⁶ *Ibid.*

¹⁹⁷ S. Krimsky, *Science in the Private Interest*, pg. 229

¹⁹⁸ H. Brody, *Hooked*, pg. 321

¹⁹⁹ H. Brody, *Hooked*, pg.321

would be registered. Only data that had been produced through this NIDT process would be considered valid research for the purpose of gaining drug approval.

In this scenario, the company who is having their product put through clinical trials would still pay to fund the trials. The difference is that instead of the money going from the sponsor directly to the researchers and/or their institutions, the money from the sponsor would go to the NIDT and from there would be dispensed to the researchers.

The purpose of setting up the NIDT is to establish a firewall between “those who assess and those who would benefit from a particular outcome”²⁰⁰. In other words, the NIDT represents a systematic barrier between the interested sponsors of clinical trials and those who conduct those trials.

Brody regards Krimsky’s proposal as too narrow in scope and further suggests the need for the NIDT to not only organise sponsored clinical trials, but also to conduct research focussed more directly around public interest. The examples of public interest research he gives are: more “head-to head comparisons of existing drugs”²⁰¹, “development trials for drugs needed in developed countries, but for which sales are projected to be low”²⁰², and drug trials into drugs for diseases that affect largely poor and developing nations²⁰³. It should be noted that this sort of research is precisely the sort of research that I suggested in the previous chapter was neglected due to the undue influence of IFaC on research agendas. Brody further recommends that this extra public interest research should be publicly funded²⁰⁴.

²⁰⁰ S. Krimsky, *Science in the Private Interest*, pg. 229

²⁰¹ H. Brody, *Hooked*, pg. 322

²⁰² *ibid*

²⁰³ *ibid*

²⁰⁴ *ibid*

While Angell's proposal is similar to that of both Brody and Krinsky, it is sufficiently different to warrant discussion. Her version of the NIDT would still have the institution contracting out clinical trials to researchers and stipulations similar to those made by Krinsky and Brody, including who controls trial design, conflict of interest requirements, etc. Despite this, Angell's vision for a NIDT departs in a number of important ways.

Firstly, rather than companies paying only for those trials they want performed, instead all companies would be required to pay a certain percentage of their revenue to the NIDT²⁰⁵. This means that regardless of whether or not a company had submitted a product for consideration by the NIDT, they would still need to pay a certain amount to them.

Secondly, while companies could still submit molecules or other products to be studied by the NIDT, the basis on which research actually got conducted would be the scientific merit of that research²⁰⁶. In other words, products would not be researched merely because they were submitted to the NIDT. Rather there would need to be some scientific merit to performing clinical trials for that product. Moreover, products would be prioritised on the basis of their merit. That is, products that appear to offer genuine improvements over previous treatments, or a new treatment for a disease or disorder that previously did not have one, would be prioritized over research into areas that already have several treatments, or new treatments that are merely slight variations on existing treatments.

Schafer also offers a slight variation on how the firewall model might work. Like the other authors, he suggests a similar independent drug research institute, however his suggestion as to how it might be funded differs. Schafer prefers a

²⁰⁵ M. Angell, *The Truth About Drug Companies*, pg. 245

²⁰⁶ M. Angell, *The Truth About Drug Companies*, pg. 246

special tax “raised from corporations which make use of discoveries originating from university scientific research”²⁰⁷. In other words, industry would still be allowed to license and produce discoveries from academia, but a special levy would be introduced and applied to those companies that do so.

The strengths of this sort of divestment are clear. By placing a firewall between researchers and their industry sponsors, there can be a reasonable expectation that there will be less undue influence of the latter over the former. This is because researchers will no longer be directly reliant on industry funding but instead will rely on funding from the NIDT, which requires researchers to adhere to strong conflicts of interest policies or have no financial conflicts at all. This should reasonably be expected to remove any conscious or unconscious motivation from researchers to bias results in favour of their industry sponsor, as there is no longer anything to be gained from doing so. Moreover, as an extra safeguard, research must be registered with and have the design approved by the NIDT.

Of course this discussion does little to determine the usefulness of this approach. Therefore, it will be useful to look at how, in regards to the specific problems explained in the previous chapter, this approach could reasonably be expected to address them.

I have argued that there is a substantial body of evidence to suggest that IFaC is negatively impacting on the reliability of our biomedical knowledge. One reason I identified is a link between industry funding of researchers and those researchers producing positive results of industry products. Admittedly it is difficult to establish which way the relationship actually works; whether it is industry funding that leads to positive attitudes towards industry from researchers, or researchers’ positive attitudes towards industry that leads to

²⁰⁷ A. Schafer, *Biomedical conflicts of interest*, pg. 23

funding. Despite this, I offered reasons to suggest it is the former, but I also showed that the latter scenario is not without its problems.

Regardless, I identified reasons to think that IFaC unduly influences researchers. While it would be absurd to accuse most researchers of out-and-out fraud, I suggested there were any number of more subtle ways in which research could be influenced in order to produce more desirable results; whether it be through the design or analysis of the research, or by simply not publishing negative results.

With the introduction of a firewall, we should no longer expect this to be problematic. Again, because researchers are no longer directly reliant on industry sponsorship there should be no undue influence and thus any unreasonable bias. Moreover, since those researchers and researcher institutes who have the strongest conflict of interest policies and/or the least conflicts of interest will be more likely to be rewarded a grant from the NIDT, it gives even more incentive to researchers to not have any relationship with industry that could cause bias.

Furthermore, attempts by industry to bias researchers or not report negative findings should not be possible, or at least far more difficult, under the firewall model. This is due to the research design needing to be approved by the NIDT and all clinical trials being registered with the NIDT. That means the use of inappropriate comparator drugs, or changing primary or secondary outcome measures, or any of the other ways research outcomes can be influenced through its design, should be far less likely to occur. Moreover, as any results from clinical trials will go through the NIDT, which again would be necessary for market authorisation, burying negative results should be near impossible

I also discussed in the previous chapter how IFaC influences what we know by causing research programs to focus on products that are more profitable but not necessarily of great public interest. The examples I offered were the high number

of blood cholesterol lowering drugs on the market, while new antibiotics and treatments for tropical diseases, such as malaria were until recently almost non-existent.

Krimsky's firewall model does not explicitly solve this issue, as he would have NIDT simply act as a neutral intermediary between industry and researchers. Under his model the research that would be conducted would still be that which industry would fund, which would fail to remedy the problems caused by IFaC regarding what we know.

Brody's model and Angell's model both remedy this problem more comprehensively. Brody would have the NIDT receive more public funding to do the sort of public interest research that is currently neglected. Angell's model offers a similar solution, with research grants for genuine public interest research being prioritised over research into "me-too" drugs, although her model differs from Brody's in that this research would still be done using industry money.

The purpose of installing the firewall would be to separate the corporate and academic interests so there would no longer be such a pull away from the traditional academic institutional norms. This approach encourages disinterestedness, not only by driving a wedge between industry and academia, but also by measures that encourage stronger conflict of interest policies. The firewall approach also demands a return to communalism through the registering and publication of *all* research.

Therefore, firewall *divestment* helps to address all of the issues I outlined with IFaC in the previous chapter. At least a number of authors' models give suggestions as to how the firewall model could refocus research into areas of genuine public interest. It also protects the integrity of our research and the reliability of the knowledge it produces. The firewall does this by; (a) removing incentives from researchers to try and influence research in favour of industry

sponsors, and (b) installing a neutral and independent body to police and maintain the integrity of research.

Ultimately, firewall *divestment* removes any of the strong perverse incentives from IFaC for researchers to violate institutional norms. No longer will researchers be allowed to benefit from closer ties to industry, through which their integrity might be compromised. Insofar as firewall *divestment* truly removes perverse incentives from IFaC, and it appears that it should, researchers can be expected to reliably conform with institutional norms, all things being equal.

2.2 – Full Divestment

While the classic reformist solution is the firewall, Schafer hints at a more radical suggestion: full *divestment*²⁰⁸. I suggest that Schafer only hints at this proposal, as he does not dedicate much space elaborating on the specifics of his suggestion. Thus it should be noted that this is one interpretation of his views.

The suggestion that all research should be publicly funded seems to imply full *divestment*, even if there is some attempt to introduce a special tax on those corporations that profit from university discoveries. Furthermore, Schafer himself acknowledges the fact that we may not be able to properly capture the appropriate amount of taxation from his proposal, and thus the funding would ultimately have to come out of other regular public funds²⁰⁹.

Although Schafer, like other reformists, admits that industry may have to play some role when it comes to biomedicine, he seems to suggest that they could simply be limited to the role of manufacturer²¹⁰. The reason for thinking this is that Schafer states that if all “drug research were publicly funded there would actually be a net saving, because drug costs would, in the absence of patents, be

²⁰⁸ A. Schafer, *Biomedical conflicts of interest*, pg. 23

²⁰⁹ *Ibid.*

²¹⁰ *Ibid.*

dramatically lower”²¹¹. This suggests a system wherein pharmaceutical companies merely manufacture discoveries made by university research that is funded by the public.

The benefits of this position are similar to those of the firewall suggestion; by separating industry and academia we prevent the undermining of the traditional academic norms. In doing so we can expect less bias in research and a greater possibility for more public interest research. Whether this position offers any additional advantages over the firewall model is unclear.

2.3 – *Divestment and Capacities*

As already outlined, the *divestment* strategy assumes that biomedical researchers lack the proper capacity to resist industry influence and adhere to the Mertonian norms. In other words, *divestment* treats researchers as merely parametric with the implication being that, according to the *divestment* strategy, researchers would still fail to adhere to the Mertonian norms in a raft of nearby non-divestment possible worlds. This, however, does not mean that researchers lack the capacity to adhere to the Mertonian norms in possible worlds without IFaC. In fact, the implications of *divestment* is exactly this; researchers are capable of reliably adhering to institutional norms *only* in those worlds where the strong perverse incentives of IFaC either do not exist or are mitigated by *divestment*.

Thus, since *divestment* indicates that researchers cannot be treated as potential interlocutors when it comes to IFaC, the suggestion is that only in those worlds where there is a firewall placed between researchers and industry will researchers appropriately act in accordance with institutional norms.

The idea that *divestment* treats researchers more like Pedro and less like Juan is mirrored in the way *divestment* proponents talk about biomedical researchers and

²¹¹ *ibid*

IFaC. As mentioned previously, both Brody and Schafer argue that many of the problems caused by IFaC are brought about by deep-seated psychological phenomena, whether reciprocity or denial, in researchers. These processes, they argue, not only make researchers susceptible to industry influence, but also prevent them from even recognising there is a problem or failing to believe the problems apply to them as individuals. Thus, just as we are unable to reason with Pedro as he will refuse to see what he is doing as wrong, so do researchers fail to see the problems with IFaC.

Again, the *divestment* strategy assumes that researchers will not respond appropriately to reason in regards to IFaC and because of this, the only appropriate solution to the problems caused by it is to install a firewall between researchers and industry.

Section 3 – *The Management Strategy*

The previous section suggested that the only way to fix the problems caused by IFaC is to introduce some level of divestment. This section, however, will look at the *management* strategy, which suggests that industry and academia can continue to interact in a similar way to how they have been, but with better management of this relationship. This section is separated into three subsections: what I will call the “weak” *management* strategy, the “strong” *management* strategy, and a look at what implications these two variations of the *management* strategy have for the assumptions we make about researchers and their capacities

The use of “weak” and “strong” is not necessarily meant as an indictment of one policy or to condone the other. Rather, the purpose is largely to distinguish between two ends of the management spectrum, wherein the suggestions of one end of the spectrum are more *laissez-faire*, whilst the other makes more demanding recommendations.

3.1 – *Weak Management*

The focus of the weak *management* strategy is to properly disclose and manage any conflicts of interest that arise from relationships between industry and academia. What specifically defines “weak” *management* is difficult to pinpoint as between different universities, research institutions and governments, what “management” demands varies and is often unclear. Nevertheless, this strategy is currently the paradigm for dealing with IFaC. This is apparent in the language universities and government use regarding conflicts of interest where the focus is on “disclosure” and “management”. Moreover, the weak *management* strategy presumes that researchers and research institutions will police themselves.

In order to illustrate how weak *management* is implemented the policies of three institutions will be examined as exemplars; the private Bond University’s policy, the policy of the National Health and Medical Research Council and the policy of the research-intensive Australian National University.

The relevant policy of Bond University suggests, “researchers have an obligation to disclose any affiliation with, or financial involvement in, any organisation or entity with a direct interest in the research matter or materials or other resources of researchers”²¹². While this policy also suggests that “failure to declare and manage serious conflicts of interest”²¹³ should be considered research misconduct, it still fails to make clear how these conflicts are to be managed and what constitutes a “serious” conflict of interest. The only other guidance offered by Bond University's policy is that research must follow guidelines set out in the Australian Code for the Responsible Conduct of Research established by the National Health and Medical Research Council (NHMRC).

²¹² Bond University Code of Conduct for Research Policy, <https://bond.edu.au/files/955/TLR506.pdf> , accessed 14/09/2016

²¹³ *Ibid.*

The NHMRC is Australia's peak funding body for medical research, yet even their conflict of interest policy is somewhat vague and places few demands on researchers or their institutions. It does demand that research institutions maintain a conflict of interest policy and does make some suggestions as to what these policies should contain²¹⁴. For instance, the NHMRC requires that these policies include measures to keep records of conflicts of interest and that those with conflicts of interest, whether real or perceived, do not take part in decision-making processes²¹⁵. It also suggests that the institution's policy should "encourage a full disclosure"²¹⁶ of the conflicts of interest.

The NHMRC policy is even less exacting on researchers themselves, suggesting that "researchers frequently have a conflict of interest that cannot be avoided" and therefore "an individual researcher should...be ready to acknowledge the conflict and make disclosures as appropriate"²¹⁷. Beyond this researchers are simply to maintain records of activities that might lead to real or perceived conflicts of interest and to disclose these when they arise.

Some Australian universities have stronger and more explicit policies and while they still often emphasise disclosure of conflicts of interest, they also give clearer guidelines as to what their management involves. The Australian National University (ANU) for example, has a policy to "*disclose* always", "*manage* where appropriate" and "*prohibit* any activity where necessary to protect the public interest or the interests of the University"²¹⁸ [emphasis in original].

²¹⁴ National Health and Medical Research Council, *Australian Code for the Responsible Conduct of Research*, 2007, Australian Government, https://www.nhmrc.gov.au/files/nhmrc/file/research/research-integrity/r39_australian_code_responsible_conduct_research_150811.pdf, accessed 14/09/2016,

²¹⁵ *Ibid.*

²¹⁶ *Ibid.*

²¹⁷ *ibid*

²¹⁸ Australian National University, Policy: Conflict of interest and commitment, https://policies.anu.edu.au/ppl/document/ANUP_000397, accessed 12/01/15

The strongest suggestions of these policies demand full disclosure of conflicts of interest and require that affected researchers either recuse themselves or divest themselves of the interest. There are a number of points to make about this; the first being, that just as there is variation among conflict of interest policies, there is also significant variation in how universities enforce their policies. This means that what qualifies as a conflict of interest or a problematic conflict of interest varies, and often merely disclosing conflicts of interest is viewed as sufficient. Finally, this approach assumes that simply disclosing that a study was industry funded is sufficient. Of course this may be true, but there are reasons to be suspicious of his assumption, which I will present later in this chapter.

In summation, the two central ideas behind the weak *management* strategy are; the assumption that industry and academia will have to continue interacting in the fashion that they have been, and that “disclosure is the key to dealing with biomedical conflicts of interest”²¹⁹. In this paradigm, the disclosure and management of conflicts of interest are often left up to the researcher, their faculty, their institution, or some combination of the three.

²¹⁹ A. Schafer, *Biomedical conflicts of interest*, pg. 22

3.2 – *Strong Management*

Like weak *management*, its strong counterpart does not propose any fundamental shift in the way that industry and academia interact. Despite this, there is a significant difference in their approaches; while weak *management* focusses on disclosure of conflicts of interest, strong *management* focuses on increased transparency²²⁰. This transparency includes but goes beyond merely requiring researchers to declare conflicts of interest. In order to better understand what is meant by strong *management*, it will be best to consider some of the proposals made by proponents of this position.

Ben Goldacre and the ‘alltrials.net’ initiative is one such proponent of strong *management*. The initiative, whose motto is “all trials registered, all results reported”²²¹, stipulates three core proposals. The first is that *all* clinical trials should be registered, including retroactive registration of past trials. For future trials this means registering a summary of the trial protocol before any participants are recruited and having to satisfy the World Health Organisation’s minimum Trial Registration Data Set, which includes trial sponsors, problems studied, intervention, study type, and primary and secondary outcomes²²².

The second proposal is that a “summary of results should be publicly available where the trial was registered, within one year of completion of the trial”²²³. The summary should include information on primary and secondary outcomes and the statistical analysis²²⁴. This means that not only does alltrials want all clinical

²²⁰ There are a potentially large number of possible strong *management* strategies. For the purpose of not expanding the scope of this thesis unnecessarily, I will focus on the suggestions of the main proponents of strong *management*.

²²¹ Alltrials.net, <http://www.alltrials.net/> accessed 15/09/2016

²²² World Health Organisation, WHO Trial Registration Data Set, <http://www.who.int/ictrp/network/trds/en/> accessed 15/09/2016

²²³ Alltrials.net, <http://www.alltrials.net/wp-content/uploads/2013/09/What-does-all-trials-registered-and-reported-mean.pdf> accessed 15/09/2016

²²⁴ *Ibid.*

trials to be registered: it wants researchers and their sponsors to report at least a summary of their findings, regardless of the outcomes.

Finally, those “who produce a full report for marketing authorisation or any other purpose should make this publicly available”²²⁵. That is, researchers or trial sponsors who produce a full research report for the purpose of showing regulators that their product is safe and effective would also need to make this information publicly available. These reports contain a much more detailed account of the methods, analysis, results and conclusions of a study, than the summary of results alone.

Thus, the proposal made by the alltrials initiative is simple; all trials need to be registered and a summary of results reported within a year of the trial’s completion. For those clinical trials that look to move a product to market, a full report would need to be made publicly available. They suggest that these conditions should be made mandatory in order for research to be funded, conducted, published, or the results be used for market authorisation.

The alltrials initiative is not the only proponent to make these strong *management* proposals. McGarity and Wagner, for example, argue that all data should be shared from research that “informs regulation and litigation, even when it is financed exclusively by a private party”²²⁶. Admittedly, they discuss their proposal in the context of tobacco research, wherein tobacco companies (and other industries) are able to access data from publicly funded research while being allowed to maintain the privacy of their own research. Equally, it seems reasonable that pharmaceutical and biotech companies should be subject to this recommendation, given that their products are regulated in terms of whether or

²²⁵ *ibid*

²²⁶ T. O. McGarity, W. E. Wagner, *Bending Science; how special interests corrupt public health research*, Cambridge: Harvard University Press, 2008, pg.244

not they are allowed to be prescribed, whether they should be subsidised by the public²²⁷, for what indications they should be subsidised and prescribed, and what warnings they should carry.

McGarity and Wagner also agree that for any research submitted to regulators, those researchers are legally required to disclose any potential conflicts of interest and certify that they have agreed to be listed as authors and thus “approved the manuscript, its content, and its submission”²²⁸. Finally, researchers are required to disclose any role played by sponsors in the design, analysis, writing and submission of the research²²⁹.

As a further strong *management* measure, McGarity and Wagner also propose that universities require an annual report from all researchers disclosing significant financial interests²³⁰. This information would be made publicly available on a website or some other equally accessible location.

It should be noted that it is not just Goldacre and strong *management* proponents that propose more transparency. A number of *divestment* proponents also advocate for proposals made by Goldacre, including Brody, although he suggests these measures as a first step on the path to *divestment*. Despite this, Brody still argues that “a great deal can be done”²³¹ by adopting mandatory registration of clinical trials.

All of these measures are aimed at providing greater transparency in biomedical research, and there is reason to think that it may have some potential for success in dealing with the problems caused by IFaC. This is at least true when it comes to re-establishing the reliability of what we know.

²²⁷ As they are in Australia through the **Pharmaceutical** Benefits Scheme

²²⁸ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 237

²²⁹ *Ibid.*

²³⁰ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 253

²³¹ H. Brody, *Hooked: Ethics, the Medical Profession and the Pharmaceutical Industry*, pg. 319

The first reason for this is that under the strong *management* strategy, underreporting or outright suppression of negative results should be difficult. The rationale for this is readily apparent: if it is a legal requirement that all clinical trials be registered before they begin and a summary of their results submitted within a year of the completion of a trial, it will presumably ensure that it is exceedingly difficult to not comply.

Research sponsors will want to register their clinical trials, as the purpose of running the trial will be to show regulators that their product is safe and effective and thus should be allowed on the market. If they fail to register the trial, they will not be allowed to submit the research based on that trial for market authorisation.

Moreover, as *alltrials* suggests, any funding/reimbursement agreement could be made contingent on the registration of trials²³². This would also incentivize researchers and their institutions to apply in order to receive government funding for research and industry, as they often benefit from tax credits for conducting research through academic research centres.

Forcing compliance in regards to the submission of a summary of results for trials that produced negative or null results might be more difficult, as without the prospect of using that trial for market authorisation, there is less incentive for researchers and their sponsors to submit it. There are, however, some possible solutions.

A similar funding agreement to the registration one could be made regarding the submission of a summary of all results. That is, any funding agreement could stipulate the submission of a summary of results as a requirement for funding, without which funds could be withheld until the summary is submitted.

²³² *Alltrials.net*, <http://www.alltrials.net/wp-content/uploads/2013/09/What-does-all-trials-registered-and-reported-mean.pdf> accessed 15/09/2016

Moreover, all trials suggests that regulators be given the power to fine those who fail to comply²³³.

If these incentives are effective, and there seems no *prima facie* reason to think they cannot be, then we should expect to see more reporting of negative studies. This is important for establishing the veracity of our body of knowledge. As I argued in the previous chapter, complete reporting of all trials is necessary in order to make properly informed decisions about a products safety and efficacy. If, for example, there are ten separate trials conducted on a drug and five are positive and five are negative but, all five positive papers get published and only one negative, we are left with a skewed picture of the safety and efficacy of that drug.

Another way in which strong *management* might help to reduce the risks of IFaC and improve the reliability of what we know, is by making the more obvious or egregious cases of bad science more easily detectable. For example, the full and proper registration of clinical trials could have helped prevent the paroxetine case in the previous chapter, wherein researchers changed their primary and secondary endpoints several times and produced conclusions that were not only unreliable, but ultimately dangerous²³⁴. Because registration would require the submission of primary and secondary endpoints *before* the trial begins, this behaviour would be made near impossible; as presumably, research that registered certain endpoints but then submitted different endpoints would not be considered for market authorisation, or possibly even publication.

Moreover, exposing bad science through increased transparency might itself provide a disincentive for researchers and industry to partake in it. To put it in

²³³ *ibid*

²³⁴ J. N. Jureidini, L. B. McHenry, P. R. Mansfield, Clinical trials and drug promotion: Selective reporting of study 329, *International Journal of Risk & Safety in Medicine*, 2008: 20

consequentialist terms; bad behaviour, all things being equal, will be less rewarding as the likelihood of being caught increases, insofar as getting caught reduces the expected utility of the poor behaviour. In regards to biomedical research and alltrials, the alltrials initiative cannot necessarily stop biased research being conducted. What it can do, however, is increase the likelihood of bad research being revealed. Insofar as a researcher's reputation, professional relationships and career progression are negatively impacted by being involved in bad science, increased transparency provides them incentive to spurn it.

Overall increased transparency should disincentivize researchers and their sponsors from biasing research in ways that are easily detectable, insofar as their detection has negative outcomes for them. Of course under the alltrials initiative model, there are also some ways in which they simply cannot bias research anymore, such as the suppression of negative results and the shifting of endpoints. Therefore, these measures should reasonably be expected to improve, at least to some extent, the reliability of what we know, thus addressing one of the major problems caused by IFaC.

3.3 – The Management Strategy and Capacities

The differing *management* strategies make different assumptions about the capacity of researchers to adhere to institutional norms and because of this I will discuss them separately, beginning with weak *management*.

Weak management assumes that researchers have a robust capacity to act in accordance with institutional norms even in the face of the strong perverse incentives from IFaC not to. It suggests that researchers and their institutions are inclined to adhere to traditional academic norms to the extent that they can be trusted, as individuals and institutions, to regulate, monitor and manage their own conflicts of interest. This assumes a very robust capacity indeed.

Thus, weak *management* treats researchers as potential interlocutors, suggesting that researchers can be trusted to appropriately respond to perverse incentives. This assumes that when presented with a conflict of interest they will, as rational agents, be able to identify them as such, and deal with these conflicts in a way that does not cause them to compromise institutional norms. In other words, the weak *management* strategy suggests that researchers will be rational in recognising the problem, the degree of the problem and responding to the problem appropriately. Thus, weak *management* assumes that when dealing with IFaC researchers will be sensitive to reason and understand those situations where their integrity may be compromised.

Strong *management* does not assume the robust capacity of researchers that its weak counterpart does. Although not to the same extent as the *divestment* strategy, it assumes a somewhat limited capacity in researchers' ability to behave in accordance with institutional norms under current circumstances. It is reasonable to suggest that strong *management* assumes more capacity from researchers than *divestment*, as strong *management* still allows firewall-free interaction between researchers and industry. Unlike weak *management*, however, it does demand a change in the rules of these interactions.

That is, strong *management* does not assume that researchers will simply adhere to institutional norms when IFaC is involved and thus it changes some of the rules regarding how research is conducted, as well as some of the incentives. This approach involves manipulating the incentives researchers are faced with and assumes that researchers will predictably follow them. Thus, strong *management* treats researchers as merely parametric in two different ways.

First, it assumes that under current conditions, not all researchers will be able to appropriately adhere to institutional norms and thus it changes some of those conditions. This is made apparent by the mandatory registration of trials,

amongst other suggestions, which takes a measure of control out of researchers' and their sponsors' hands when it comes to how they conduct research.

Secondly, by increasing transparency, again through mandatory clinical trial registration, full reporting, and mandatory submission of conflicts of interest, strong *management* tweaks incentives for researchers and assumes they will follow them. In doing so, strong *management* does not engage researchers as potential interlocutors that will respond appropriately to reason; instead it simply places certain restrictions and changes incentive structures.

Section 4 – Criticisms

This section is divided into three subsections, which will consider the arguments against both the *divestment* and *management* strategies. The purpose of this will not only be to show the problems associated with both approaches, but also in doing so it will open the way for a discussion of other possible solutions. I will begin with a subsection looking at the issues with the *divestment* strategy. While there are a number of concerns regarding *divestment* to be considered ultimately, I will suggest that its fatal flaw is how unlikely its suggestions are to be implemented, given the current attitudes towards biomedical research and IFaC.

I will then consider the criticisms of the weak *management* position, the strategy that has been implemented and has thus overseen the slew of problems outlined in the previous chapter. On this basis I will suggest that weak *management* has been a resounding failure.

The final subsection will consider issues with strong *management*. While I advocate for the adoption of the proposals of this strategy, it is not without its flaws. Strong *management* is insufficient, in that it alone does not do enough to fully address the problems caused by IFaC, and the reasons for this will be discussed.

4.1 – Criticisms of the Divestment Strategy

While it seems the case that in order to fully rescue biomedical research from the problems caused by IFaC some level of *divestment* might be necessary, the fact remains that this position seems hopelessly flawed. The actual recommendations themselves may not necessarily be broken in this way; rather given the current environment of academic-industry relationships the likelihood of their successful instantiation seems impossibly small, at least in the short-term. Thus, this subsection will focus on the problems of implementation.

How a consequentialist framework should apply here is clear; the expected utility of an outcome is the product of its potential utility and the likelihood of the outcome²³⁵. Therefore, possible outcomes, even if they have extremely high potential utility can be rendered suboptimal if the likelihood of that outcome is negligible. To illustrate, take for example September 22nd 2016's Powerball Lottery, which had a prize of \$6 million Australian dollars but a mere 1 in 76,767,600 chance of winning the top prize²³⁶. This is an excellent example of where a potentially great outcome, such as winning \$6 million dollars, has extremely limited expected utility due to the extremely low odds of the outcome occurring. This is not to suggest that implementing the *divestment* strategy resembles a lottery, or shares a similar likelihood but it demonstrates how the consequentialist calculus applies in situations of great but unlikely outcomes.

²³⁵ To put this another way, if the potential utility of an outcome should it occur is x , and the probability of this outcome is p then the expected utility = $x * p$

²³⁶ SA Lotteries, https://thelott.com/salotteries/buy-lotto/buy-an-entry?semid=SEM|Lotto|Google|SEM-NonBrand|117218437726|lottery|e|c|1t1&s_kwid=AL!4254!3!117218437726!e!!g!!lottery&ef_id=V@NmKgAABYD5qooH:20160922063351:s accessed 22/09/2016

It is presumably impossible to accurately determine the probability of the implementation of the *divestment* strategy. Despite this I will offer reasons as to why it should still be considered incredibly unlikely.

Firstly, it should be clear from earlier discussion that there has been a large focus from government, industry, and academic institutes to produce close ties between industry and academia. Chapter 3 outlined legislation both in Australia and the US that focussed on encouraging IFaC. Given the level of rhetoric from government regarding the belief that closer ties between industry and academia are good for everyone, again for the reasons outlined in chapter 3, there is little reason to expect this attitude to change any time soon. It is a situation where all parties win even when just considering the fiscal benefits: government can spend less on academic research, industry gets access to academic discoveries and expertise, and universities and their researchers get more funding.

The single deepest problem with instantiating the *divestment* strategy is a problem of collective action. It is a classic 'tragedy of the commons' situation; wherein we need everyone to agree to forego the option that is *best for them individually*, and accept the option that is second best for them, but best for everyone collectively. That is, if in Australia we were to enact a firewall policy separating industry and academia as suggested, what could reasonably be expected is that pharmaceutical and biotechnology companies would simply move their research dollars to other countries without such a policy. Thus, what would be needed is for all major research-intensive places or countries with the potential for intensive research, such as the United States and the European Union, to also implement a firewall. Yet insofar as some countries have this policy, there is an incentive for other countries to defect from its implementation in order to secure investment from pharmaceutical companies.

Unfortunately, the problem deepens from here. Again, let us imagine that Australia instantiated a firewall while other countries failed to do so. An obvious consequence is that pharmaceutical companies might simply refuse to conduct trials in Australia, leaving few equally unattractive options. One would be to forego the products researched overseas by refusing to licence them (or refusing to fund them through the Pharmaceutical Benefits Scheme which is even less attractive). Another option would be to license these products, but at this point we are left with the worst of both worlds; we are left with the same quality of research as before *divestment*, and the funding for the research and the research itself has all moved offshore.

Moreover, even if the current research-intensive countries did all instantiate a firewall policy, this simply gives other countries reason to develop their own research capacity and fill the market left behind by the firewall nations. Of course whether this particular scenario is a realistic problem is hard to determine, as the development of such a skilled and hi-tech sector is presumably difficult.

This collective action problem is a fundamental issue for the *divestment* strategy. This is not to say that all collective action problems are intractable, but they are often, by their very nature difficult to overcome. Not only are they inherently difficult to resolve, but presumably even more so when most of the major interested parties have shown little interest in recognising the problem, let alone resolving it, as I have suggested is the case here.

The problems with the *divestment* strategy are not limited to collective action; rather there is also an issue of how to implement this strategy when so many researchers already have serious conflicts of interest. This issue may be resolved over time, as a new generation of scientists enter into a research system that already has *divestment*. This, however, might take some time and *divestment*

proponents will have to work with current the generation of scientists in the interim.

The breadth of financial ties of researchers to industry is substantial, with several surveys making this apparent. Haeussler and Colyvas' 2011 survey of German and UK life scientists showed that 47% of 2294 respondents had been involved in commercial activity in the past 12 months^{237,238}.

A similar study by Bozeman and Gaughan of academics at US research universities found that of 1564 respondents, just over half, had some type of industry interaction in the past 12 months²³⁹. This includes 18.4% being paid consultants for industry, 16.7% working directly with industry to commercialise or transfer technology, and 15.5% co-authoring a published paper with an industry partner²⁴⁰. While the last set of numbers may not be particularly striking, it is important to note that these numbers were for interactions only *within a twelve-month timeframe*.

Finally, a survey by Klofsten and Jones-Evans of Swedish and Irish academics found that of 1857 respondents, "69% of the academics have had some type of contact with industry during the last five years"²⁴¹. This included 51% of Swedish and 68% of Irish academics being involved with consulting, and 45% and 69% respectively being involved in contracted research²⁴². These numbers are

²³⁷ C. Haeussler, J. Colyvas, *Breaking the Ivory Tower: Academic entrepreneurship in the life sciences in the UK and Germany*, *Research Policy*, 2011: 40 (1), pg. 45

²³⁸ "Commercial activity" is defined by the authors as consulting, patenting or founding a company

²³⁹ B. Bozeman, M. Gaughan, *Impacts of grants and contracts on academic researchers' interactions with industry*, *Research Policy*, 2007: 36 (5), pg. 700

²⁴⁰ *Ibid.*

²⁴¹ M. Klofsten, D. Jones-Evans, *Comparing Academic Entrepreneurship in Europe – The Case of Sweden and Ireland*, *Small Business Economics*, 2000: 14(4), pg. 305

²⁴² *ibid*

substantial, and notably higher than the previous two surveys based only on a twelve-month timeframe.

It is also interesting to note, not only the sheer percentage of academic researchers involved with industry, but also as Hauessler and Colyvas suggest, the “more senior, established...academics with a larger stock of science and personnel are more engaged with industry”²⁴³. This suggests not only that a majority of researchers are already involved with industry in some way, but that the most senior and well-published researchers are the most involved. This is problematic for *divestment* for two reasons; firstly, those researchers who, based on their experience, are best positioned to conduct clinical trials are the most likely to be excluded by *divestment*. Secondly, finding appropriate researchers when so many have problematic ties with industry might prove difficult.

Having said this, just how many researchers will be excluded will depend, again, on the particulars of the *divestment* policy. If it is only current and ongoing industry relationships that are deemed problematic, then finding appropriate researchers may not be overly difficult. However, if the policy demands that a certain amount of time passes before industry–academic relationships are deemed non-problematic, then the difficulty in finding appropriate researchers will be a function of the amount of time required.

If, however, this situation is indeed a problem, the question from a consequentialist perspective remains: what is worse? Potentially biased studies from researchers with conflicts of interest, or potentially inferior research being conducted by less experienced and skilled researchers? While the answer to this question is unclear, it suggests *divestment* is not without its own costs.

²⁴³ C. Haeussler, J. Colyvas, *Breaking the Ivory Tower*, *Research Policy*, 2011, pg. 50

There is also some concern regarding whether the *divestment* strategy is actually good for biomedical research²⁴⁴. While IFaC has clearly led to a number of problems, there is a case to be made that the relationship between biomedical researchers and industry can be beneficial to some degree, leading to exchanges of information, ideas, advice, and techniques that benefit both parties. Thus, it can appear that the *divestment* strategy is throwing the baby out with the bathwater: as Brody argues,

*if our goal is to eliminate unethical behaviour, then banning all conflicts of interest is a very crude tool, which might rule out a good deal of ethically acceptable behaviour, even praiseworthy behaviour, in order to reduce any risk of unethical behaviour.*²⁴⁵

Furthermore, as outlined in chapter 3, it has been argued that IFaC has been responsible for a great deal of innovation in biomedical research. While there is good reason to be sceptical about this claim, it is presumably not entirely without merit. Thus, if there is scope that *divestment* might rule out all conflicts of interest, which in turn may rule out any number of healthy and useful interactions between industry and academia, then this provides some consequentialist justification for rejecting it, all things being equal. Admittedly, however, it is difficult to determine from a consequentialist perspective whether or not this is justified. Despite this, it is still important to highlight some of the potential risks and losses that might result from *divestment*.

While in practice these risks might be manageable depending on the exact nature of the *divestment* policies; it will depend on the particulars. Having said this, seeing as most *divestment* proponents advocate for strong conflict of interest

²⁴⁴ This will depend on exactly how it is implemented and the strength of its conflict of interest policies

²⁴⁵ H. Brody, *Hooked*, pg. 289

policies, it is hard to see how researchers might establish acceptable relationships with industry without contravening the conflict of interest policies. To put it another way, *divestment* suggests that researchers with the fewest conflicts of interest should be rewarded with the relevant research grants, thus incentivising researchers to have no relationship with industry even if those relationships might be useful ones²⁴⁶. It is difficult to determine whether ruling out such beneficial relationships and behaviour might be prudent in order prevent other negative outcomes. Though the fact that Brody, a *divestment* proponent, has expressed concerns about this should give us pause.

Ultimately, the greatest concern with *divestment* remains the limited likelihood of this strategy being enacted. Again, when three of the major decision-makers (government, industry, and academia) have so much to gain from the continued interaction between industry and academia in its current form and do not see this interaction as deeply problematic, it becomes difficult to imagine what could cause a large enough change in attitudes to make *divestment* a realistic possibility.

In fact, it seems odd that *divestment* proponents acknowledge the influence that the pharmaceutical industry has over legislators, at least in the US, while still claiming the radical changes they propose are realistic despite the fact they would face wholehearted resistance from industry. Angell, for example, proposes *divestment* although she acknowledges that, “the pharmaceutical industry has by far the largest lobby in Washington... In 2002 it employed 676 lobbyists (more than one for each member of congress)... at a cost of over \$91 million”²⁴⁷. A 2012 piece in the New York Times suggested that in 2012, \$250

²⁴⁶ Useful in the sense of being useful for biomedical research.

²⁴⁷ M. Angell, *The Truth About Drug Companies*, pg. 198

million was “spent on lobbying for pharmaceutical and health products – more than even the defense [*sic*] industry”²⁴⁸.

Consequentialism instructs that right things are the best things and the best things are those that maximise value. The expected utility of a policy will be the product of: the value of that policy if it were to be implemented and the likelihood of it happening. In the case of *divestment*, the value of the strategy is high but the likelihood of the outcome is negligible. On this basis, the expected utility of the strategy should be considered limited.

4.2 – Criticisms of the Weak Management Strategy

This subsection will explore criticisms of the weak *management* strategy, which as previously mentioned, is the current paradigm for dealing with IFaC. Most of the problems relating to IFaC that I have offered in previous chapters have happened under the purview of the weak *management* strategy. Insofar as this is true, it seems reasonable to conclude that this strategy has failed to address the problems caused by IFaC. This, however, does not tell us whether its failure is due to how it has been implemented or enforced, or whether it is doomed to fail because of the nature of the policy itself.

Opponents of the *management* strategy argue that it is due to the nature of the policy itself; it fails to properly address the problems caused by IFaC in terms of researchers’ attitudes. Brody argues that not only is there an attitude of entitlement to industry funding from researchers, but that researchers are in denial about the influence caused by it²⁴⁹. Thus, he condemns the *management* strategy for having,

²⁴⁸ E. Rosenthal, *The Soaring Cost of a Simple Breath*, *The New York Times*, October 12, 2013, http://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html?_r=0, accessed 09/02/2015

²⁴⁹ H. Brody, *Hooked*, pg. 292

*failed to appreciate that physicians and other players who are in the throes of denial and the associated sense of entitlement are not going to apply, or to understand the need for various guidelines designed to manage this relationship. They will see the guidelines as intended for others and not really for themselves.*²⁵⁰

So, while it is common for researchers to believe that *others* can be influenced by IFaC, they also think their own judgement is not influenced despite evidence to the contrary. Hence, researchers feel entitled to and are compelled to seek industry funding in an increasingly competitive research environment, while simultaneously recognising the pernicious influence of IFaC on others but denying its influence on them personally.

This claim is supported by McGarity and Wagner who argue that there is “strong resistance to the notion that conflicts of interest are an important issue for the scientific community”²⁵¹. To substantiate this claim they offer the results of a number of empirical studies, which show a lack of compliance in the disclosure of conflicts of interests by researchers in the papers they submit²⁵².

Finally, as Krinsky argues because of our current research environment where there is no real recognition of the problems caused by IFaC, “disclosure simply provides a rationalization for continuing to create more serious conflicts of interest”²⁵³. Disclosure can give researchers a *carte blanche* for conflicts of interest because the implication is that conflicts of interest are fine *just as long as you disclose them*, as opposed to recognising them as being inherently risky.

Moreover, the mere disclosure of conflicts of interest, while it may give us reason to take a more sceptical stance towards certain research, fails to appropriately

²⁵⁰ H. Brody, *Hooked*, pg. 294

²⁵¹ T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 235

²⁵² T. O. McGarity, W. E. Wagner, *Bending Science*, pg. 234

²⁵³ S. Krinsky, *Science in the Private Interest*, pg. 197

arm us with the tools necessary to properly detect a great deal of bias. That is, while the disclosure of a conflict of interest may indicate that a study might be biased and thus that its results may not accurately represent the truth, this does not assist in ascertaining the actual truth. A mere disclosure of a conflict of interest does not give the appropriate access to the raw data which could reveal; (a) whether or not the study was in fact biased, (b) if the study is biased, how it is biased, and (c) whether or not the product in question is actually effective. In other words, disclosure of conflicts of interest do little more than alert their readers to potential bias while still leaving them hamstrung when it comes to determining the nature and implications of the bias.

Given the attitudes of researchers towards IFaC and the fact that the weak *management* strategy has presided over many of the problems I outlined in previous chapters, it therefore seems reasonable to suggest that this strategy has not only failed but is simply too weak to adequately deal with the problems caused by IFaC.

4.3 - Criticisms of the Strong Management Strategy

The previous subsection paints a damning picture of the weak *management* strategy, although there may still be hope for the strong *management* strategy. I will begin the discussion about the criticisms of the strong *management* position by briefly considering the concerns of some industry apologists that the proposals of strong *management* go too far. I will suggest these arguments are not persuasive. Finally, I will consider other more persuasive criticisms of strong *management* that it does not go far enough and that although it does a better job than its weaker counterpart, the strong *management* strategy still fails to properly address a number of the problems caused by IFaC.

One argument made by industry apologists is that greater transparency would mean that researchers and sponsors would have to share information that might

or will contain trade secrets. The maintenance of proper secrecy regarding trade secrets is important to industry because if these secrets should be revealed it might allow unscrupulous companies to submarine innovators.

This, however, is not persuasive as it is hard to see how the registration of trial protocol could be regarded as a trade secret. Furthermore, insofar as GlaxoSmithKline, one of the largest pharmaceutical companies in the world, is a signatory to the alltrials initiative, it seems reasonable to assume there is an acceptable way of releasing the required information without also revealing trade secrets.

Moreover, were we to accept that the demands of mandatory trial registration would potentially reveal trade secrets, we should not assume that *even if it did* this would justify nondisclosure. Again, the argument from some parts of the industry is that this disclosure could lead to other companies 'submarining' the discoveries of innovative companies thus discouraging innovation. For argument's sake, let us say this is a possibility; even so, this does not necessarily mean we should abandon mandatory trial registration, as there is much to be said in favour of more reliable and verifiable studies. Therefore, a case would need to be made that showed that while some pharmaceutical companies are willing to sign up for mandatory trial registration, presumably finding a way of following its demands without releasing trade secrets, other companies cannot, and that the risks of protecting their trade secrets outweighs the benefits from trial registration.

Some have also attempted to dismiss arguments in favour of greater transparency by suggesting that it could compromise patient privacy. This concern is more problematic than the concern about trade secrets, as it is unclear whether researchers should be allowed to release patient information, even if it is de-identified, without patients' consent. This, however, lends itself to an

obvious solution; ask for consent. Patients could be required to sign, as part of their consent and information sheets for clinical trials, that their de-identified data can be released publicly.

This fails to solve as easily what to do with patient data from trials that have already been conducted or that are currently underway, as it may prove problematic to retroactively gather consent. Perhaps there is some scope to be able to release de-identified patient information under the supervision of an ethics committee or some other sort of quality assurance mechanism in order to guarantee the minimisation of risk.

Given that the solution to this problem, at least for future studies, seems so straightforward, the issue of individual patient data does not provide sufficient reason to reject greater transparency.

While the previous two concerns from industry about greater transparency do not represent real problems, there are still serious issues with strong *management*. I will begin by addressing concerns about strong *management's* ability to fix problems with IFaC regarding what we know. Finally, although it performs better in regards to fixing the reliability of our knowledge, the last part of this subsection will address the ways in which it also fails to properly address a number of reliability issues.

In chapter 4, I suggested that one of the issues with IFaC was the way it skewed the biomedical research programme in ways that were often undesirable; focusing research on profitable and applied research, while leaving other, more beneficial public interest research, under-resourced. This skewing of research programmes in a way that is inefficient or sub-optimal in terms of welfare production is not addressed by the strong *management* strategy.

Greater transparency through mandatory trial registration and other measures offers no mechanism through which to properly realign research programmes. Thus, while it may produce more reliable research and this is, all things being equal, a good outcome, the utility of this outcome should be considered somewhat limited. The reason for this is that if the research being conducted is not itself welfare maximising²⁵⁴, then the reliability of that research is inherently limited.

Returning to the example in chapter 4 of statin research versus a malaria vaccine. While it would be useful if the information we have on the half-dozen statins currently on the market were as reliable as possible, we still have an inefficient overinvestment in statin research while neglecting research into a malaria vaccine that could produce incredible welfare outcomes. Strong *management* offers no solution in this specific case, nor in any of the examples given in chapter 4 of beneficial but unprofitable research.

Although by advocating for increased transparency strong *management* deals with some of the issues regarding the reliability of our knowledge, there are still a number of related problems it seems incapable of fixing. To illustrate this I will refer back to some of the points I made in chapter 4 about how research can be biased through its design, methodology and statistical analysis.

Firstly, it was shown that a clinical trial could be biased to produce a certain result by choosing an inappropriate comparator drug or only testing against placebo. I gave two examples of two trials of a new antifungal agent AmBisome. In one study, researchers paired the Ambisome against the standard treatment but used the new drug at a much higher dose compared to the older drug, which was administered at the lowest possible clinical dose. The other study administered Ambisome intravenously to maximise effect, while the comparator drug was

²⁵⁴ Or at least satisficing

administered orally to minimise effect. While there may be some utility in maximising reliability in this instance, the benefit of this research in general is limited as it tells us little about the true efficacy of the discoveries being tested. Once again it seems unclear how increased transparency alone can fix this issue.

There is also the possibility for research to be biased by the researchers' choice of who they recruit into the trial in the first place, and this bias will not be revealed in a meaningful way through the raw data and mandatory trial registration. Again, in chapter 4, I discussed how researchers could make a new drug look better by testing it in a younger population, even if the drug is aimed at a much older demographic. This is because as a generalisation, younger participants have fewer health problems than their older counterparts and thus tend to suffer fewer complications and side-effects. This misrepresents the safety of the drug because what we actually want to know is what the frequency and severity of side-effects are in the group that are actually going to be using the drug.

Yet despite the possibility for research to be biased in this way, strong *management* is silent on the issue of how researchers recruit their participants. Such biases in research negatively affect the reliability of our knowledge, as the research fails to inform of us as accurately as possible of the relevant risks or benefits of a product.

Strong *management* also offers no solution to research that is biased by the particular questions asked. Chapter 4 also suggested that what questions researchers asked could influence the results of research. The example given was the use of surrogate endpoints, which meant for example, the effect a statin had on lowering blood cholesterol. While these questions are useful to an extent including in 'proof-of-concept' research, they are not generally appropriate for late-stage clinical trials. The reason for this is because they fail to answer the

questions we actually want answered, which is generally: does this drug actually improve a patient's health and longevity?

To generalise the problem; there are a number of ways in which research can still be biased even in the presence of strong *management*. Thus, while increased transparency might help us address a number of knowledge reliability issues, it does not come close to addressing all of them.

One final issue with strong *management* and its policy of increased transparency is that even with a study's raw data being revealed, the detection of bias can be difficult. There are a number of reasons for this.

The first is that in order for bias to be detected, those interested in its detection will be reliant on someone who is appropriately qualified to be sufficiently motivated to go through a trials entire data set, methodology, statistical analysis, etc., in order to find the ways in which the results might have been biased. One obvious motivation for doing so would be in the context of litigation, and here it would be useful. However, this presumably only applies to a relatively small number of clinical trials/drugs, which have turned out to be seriously harmful and thus resulted in lawsuits.

Again, while the raw data is useful in this context, it is hard to imagine that a sufficient number of people are going to be motivated to go through the raw data of the majority of clinical trials. Thus, so long as the bias is not obvious and the product not dangerous, presumably most clinical trials could still have their numbers massaged. In this sense, the degree to which increased transparency can actually increase the reliability of our knowledge seems limited.

A further related issue is that it can be difficult for people to understand others' statistical analyses, especially when it comes to understanding the raw script data. Raw data is not necessarily as informative as people tend to think, as there

are a number of judgement calls that need to be made when it comes to the statistical analysis of the data. The appropriate analysis of the underlying data often relies on the features of that data, such as whether it is normally distributed. Inappropriate statistical analysis is certainly one way in which a trial could be biased but also potentially one of the hardest ones to detect.

Thus, the greater transparency of strong *management* may be useful in detecting some sorts of bias in some studies but it should also be apparent that there are some serious limitations on this ability, as inappropriate practice is not always easy to detect.

Ultimately the argument against strong *management* can be summarised in this way; it does not and cannot deal fully with the problems caused by IFaC. Like weak *management*, it fails to address the underlying issue, which is the way industry and academia interact; it addresses the symptoms rather than the cause. It does, however, make much stronger suggestions than the alternative *management* strategy, but these still do not fix the underlying problem, nor can they be expected to address the symptoms as completely as some proponents might expect. Having said this, I do believe that strong *management* makes a number of helpful recommendations, which, unlike the suggestions of *divestment*, are far more likely to be realised. Thus there are consequentialist reasons to promote the adoption of these recommendations as part of the solution.

Section 5 – *An Alternative*

The previous parts of this chapter suggested that there were serious problems with both the *management* and the *divestment* strategies; they are both, in their own ways, unworkable and/or insufficient. The *management* strategy does little in the way of addressing the underlying issues in industry-academia relationships, which as I have suggested is fundamentally problematic. Although strong *management* makes a number of useful suggestions, which it was argued

should be adopted, it is not sufficient by itself to fix the problems of IFaC. The *divestment* strategy, although perhaps necessary in properly addressing IFaC, is untenable; at the very least its proposals are unrealistic, at least in the current BMR environment.

This opens the door to a discussion of alternative solutions, although offers no obvious starting point. In order to determine an appropriate starting point, I will return to a discussion about potential interlocutors, capacities and institutional norms. Both strong *management* and *divestment* treat biomedical researchers as merely parametric. While this seems fair in the sense that researchers have clearly been unable to resist the perverse incentives of IFaC, I will argue that these strategies also miss an opportunity in doing so; which is the possibility of engaging researchers as potential interlocutors in order to enhance their capacity to resist perverse incentives.

The next subsection will explore how researchers' capacities to resist perverse incentives and adhere to the Mertonian norms might be achieved. My suggestion, one that seems to have largely been ignored in the discussion of IFaC, is that more and improved ethical training of researchers might be helpful. I will refer to this as the *educational-cultural* strategy (ECS). This ethical training will train researchers in ethical problems relating to research, including the problems caused by IFaC, and their professional obligations regarding research and the Mertonian norms. The hope is that this training will improve their capacity to act in adherence with institutional norms and foster a professional culture that can better resist IFaC.

The final subsection will discuss potential issues that may arise in relation to the ECS, in particular questions of sufficiency, idealism and collective action. There is scope for a raft of potential other problems, but insofar as the ECS has been largely neglected in the literature, a more complete critique of the position is not

available This section will therefore be limited to the more obvious shortcomings of the strategy.

Section 5.1 – *Potential Interlocutors, Capacities and the Mertonian Norms*

Although *divestment* may be a necessary condition in dealing with IFaC, it is unrealistic. This suggests that we take an Actualist approach regarding the industry-academia relationships and look at next best options. Given that *divestment* is not an option, we have to assume that these next best options will still involve industry funding and commercialisation²⁵⁵. Therefore, in the terminology of Smith, we need to determine in which possible worlds, where there are still strong and perverse incentives for researchers to violate institutional norms, do we achieve the least violation of these norms?

Referring back to the assumptions that the main strategies for dealing with IFaC made about biomedical researchers' capacities will be helpful in determining possible alternative solutions. As pointed out strong *management* and *divestment* alike treat our researchers as merely parametric. Although they differ greatly in the extent to which they alter incentives, they both assume that by changing incentive structures researchers will adjust their behaviour accordingly. Thus, strong *management* and *divestment* take an Actualist approach in regards to researchers' capacities, in that they assume the wrongdoing of biomedical researchers as a given.

Conversely, weak *management* treats biomedical researchers as potential interlocutors, suggesting that they have the capacity to successfully manage their relationships and conflicts of interest with industry. This suggestion, however, is inappropriate. Not only have biomedical researchers and their institutions failed

²⁵⁵ This is not to rule out entirely the possibility of changing incentives at all. Any consequentialist analysis should take seriously any realistic possibility of trying to change incentives, as for example, strong *management* proposes.

to resist perverse incentives from industry, they have failed to even recognise their behaviour as problematic. Thus, weak *management* merely assumes that researchers are potential interlocutors but it fails to actually engage them as such.

On the other hand, there is scope for engaging researchers as potential interlocutors in a way that the other strategies have failed or neglected to do. In fact, if we can reasonably assume that the current incentive structures cannot be changed dramatically, it seems we need to look at strategies that assume this or at least allow it. This is where I believe the idea of engaging researchers as potential interlocutors in order to enhance their capacity to resist perverse incentives becomes particularly relevant.

While having the correct incentives is important in order to produce behaviour that does not violate institutional norms, it is not *sufficient*. The same is true of capacities; a meaningful capacity to x is important for you to reliably x ²⁵⁶, but simply having the capacity to x is not sufficient, in all cases, for you to x . Of course, there is also a relationship between incentive structures and capacity. Insofar as an incentive structure encourages a behaviour x , those within the structure presumably have a greater capacity to x , as the purpose of incentives is to try and produce (or discourage) certain behaviours. In this thesis, I have suggested that biomedical researchers' capacity to follow institutional norms has been diminished by the incentives created by IFaC.

Norms, like incentives, can also motivate people to act or refrain from acting in certain ways. Part of this motivation will be intrinsic, that is people who internalise norms will be motivated by the norms themselves to act in accordance with them²⁵⁷. The stronger this motivation, the less important or impactful other

²⁵⁶ You could of course accidentally x but this does not constitute a meaningful capacity

²⁵⁷ Of course, part of the motivation to follow norms is the potential punishment for violating them from others

incentives become, as you do not need to incentivize someone to behave in a fashion they already desire to. If, however, you want someone to behave in way *y* but there are incentives for them to *not y*, they need to have a stronger motivation to *y* than if there were no incentive to *not y*. At some point, for most people, a perverse incentive can overcome any internal motivation to not violate internalised norms. Yet presumably the stronger the intrinsic motivation, the stronger the perverse incentive to overcome it would need to be.

Currently the incentives for biomedical researchers to violate the Mertonian norms are powerful, as I have discussed previously in this thesis. It seems that the perverse incentives are so strong that they have even diminished researchers' ability to recognise them as such. This, however, leads to a potential solution: to increase biomedical researchers' capacity to adhere to institutional norms. In other words, if we are unable to substantially change perverse incentives, but they can at least in part be countered by inculcating stronger intrinsic motivation, then this seems like a reasonable approach to at least explore.

Again, while a fundamental change in the incentive structures created by and in response to IFaC might be a necessary part of fixing the problem, this is improbable. Thus, we need to look to second best options, options that do not rely on substantial changes to the current incentive structures in BMR. One possible way to do this is to engage biomedical researchers as potential interlocutors in order to bolster their capacity to resist perverse incentives and act in accordance with the Mertonian norms, a suggestion that all the strategies for addressing IFaC failed to consider. I think it is reasonable to suggest that in the possible worlds which still have the strong perverse incentives of IFaC, we will get the most reliable resistance of those incentives in the possible worlds where researchers' capacity to resist these incentives is strongest. This, however, is not to suggest that the resistance of the perverse incentives will be in any meaningful way, reliable.

5.2 - *An Alternative: The Educational-Cultural Strategy*

Highlighting the opportunity missed by the other strategies for dealing with the problems caused by IFaC opens the way for considering the possibility of engaging researchers as potential interlocutors.

Of course, ultimately whether we ought to treat researchers as merely parametric or as potential interlocutors should hinge on which approach has the greatest expected utility. The purpose here of highlighting the possibility of treating researchers as potential interlocutors is that this approach has thus far been largely ignored and thus, a whole range of potential solutions have been left unexplored. These solutions may potentially produce better outcomes or as I will suggest below can be used to enhance and improve other approaches. Therefore, treating researchers as potential interlocutors is not necessarily preferable to treating them as merely parametric but to ignore the previous possibility would unnecessarily limit the potential solutions to the problems caused by IFaC.

Highlighting the possibility for engaging researchers as potential interlocutors, however, fails to outline how this possibility might be achieved. This subsection will focus on my suggestions as to how we might engage researchers as potential interlocutors and as to how this may potentially help remedy some of the problems of IFaC. I propose that through improved ethical training of researchers, their capacity to resist perverse incentives may be improved. It is my hope that this improved ethical training will cause, or at least seed the potential for, a grass-roots shift in attitudes of researchers towards their professional obligations and IFaC.

It should be noted, that this is a novel approach and because of this there is no direct empirical evidence that my proposed strategy *will work*. Instead what I will highlight below are reasons and evidence to believe it could be a feasible solution.

Although there is little mention of improved ethical training of biomedical researchers in the literature, I am not alone in making the suggestion that it may be useful. Malhar Kumar when discussing his proposed reforms of biomedical research notes that, “education of academic faculty regarding ethical aspects of commercialization of academic research is conspicuous by its absence”²⁵⁸. Furthermore, although there seems to be adequate ethical education for the responsible conduct of actual research, Kumar observes that, “similar education is probably necessary for inculcating the values of ‘Responsible Commercialization of Research’ ”²⁵⁹.

That is, while there may be sufficient ethical education for biomedical researchers when it comes to conducting research such as issues of consent or how to treat vulnerable groups, there is a lack of ethical training regarding interactions with industry. While ethical training in these sorts of ethical issues in research is admirable, my proposal is that it needs to be expanded to include a number of the issues covered in this thesis. It should include training in the ethical importance of the Mertonian norms and how they apply to researchers, in the same way that medical ethical principles are taught to medical students. It also seems reasonable to include reference to many of the problems caused by IFaC, including how it can affect researchers’ and research integrity. Moreover, it will be important that researchers are made aware that these problems do not just apply to other researchers, but they as individuals are just as susceptible to the influence of IFaC as their peers.

A full discussion of the pedagogy of this expanded ethical education is well beyond the scope of this thesis. Having said this, it should be noted that there are several models that could serve as potential candidates; value based approaches

²⁵⁸ M. N. Kumar, *Ethical Conflicts in Commercialization of University Research in the Post-Bayh-Dole Era*, *Ethics & Behaviour*, 2010: 20(5), pg. 345

²⁵⁹ *Ibid.*

such as Mary Gentile's Giving Voice to Values model, team-based learning models, compliance models, analytical models, or integrated compliance and analysis models^{260,261,262}. It is also worth noting suggestions by Joseph A. Carrese, et al., that,

*there is no single, best pedagogical approach for teaching medical ethics and professionalism. Learning styles and institutional resources vary, so teaching methods need to be flexible and varied to reflect this diversity.*²⁶³

Thus, even though a full examination of the exact details of the content and nature of this expanded ethical education is beyond the scope of this thesis, it will suffice to suggest that there are a number of models that may be appropriate, and there may be reasonable variations in its execution.

The remaining question to be addressed in this thesis is whether or not ethical training can be effective in addressing the identified problems. The most powerful piece of research regarding the efficacy of ethics education in the sciences is a 2009 meta-analysis from A. L. Antes, et al. This study is not only relatively recent, but meta-analyses are generally considered the gold standard in research. In their meta-analysis A. L. Antes, et al., drew evidence from twenty separate empirical studies (into ethics training) involving over three thousand

²⁶⁰ M. C. Gentile, *Giving Voice to Values: How to Speak Your Mind When You Know What's Right*, Yale University Press, 2010

²⁶¹ E. K. Chung, J.A. Rhee, Y. H. Baik, O.S. A, The effect of team-based learning in medical ethics education, *Medical Teacher*, 2009: 31(11). Pg. 1013-1017

²⁶² M. D. Mumford, L. L. Watts, K. E. Medeiros, T. J. Mulhearn, L. M. Steele, S. Connelly, Biomedical ethics education may benefit from integrating compliance and analysis approaches, *Nature Immunology*, 2016: 17(6), pg. 605

²⁶³ J. A. Carrese, J. Malek, K. Watson, L. Soleymani Lehmann, M. J. Green, L. B. McCullough, G. Geller, C. H. Braddock, D. J. Doukas, The Essential Role of Medical Ethics Education in Achieving Professionalism: The Romanell Report, *Academic Medicine: Journal of the Association of American Medical Colleges*, 2015: 90(6), pg. 746

participants ²⁶⁴. Their findings suggest that, “ethics instruction is at best moderately effective as it is currently conducted”²⁶⁵. While this is not a glowing endorsement of ethical training, the authors go on to say that, “when the instructional program quality is high, effectiveness is greater”²⁶⁶. Therefore, there is reason to believe that high-quality ethical training in the sciences can be effective.

Consequentialism would clearly suggest that the expanded ethical education be based on those models that are most effective. While there seems to be a number of effective educational models, those high-quality programmes that show the best results should be those that are favoured. Again, it is beyond the scope of this thesis to investigate exactly which models those are but it is reasonable to suggest that there exist a number of appropriate options.

Thus far in this subsection I have sought to establish a number of related points. The first is that an expanded ethical training can be used to reinforce biomedical researchers’ capacity to resist perverse incentives to act against institutional norms. The second is that regardless of which education model is in fact best; there are a number of potential models. Finally, there is evidence to suggest that ethical education can work and the higher the quality of the course, the better the results. This bodes well for the potential of the ECS.

I have previously suggested several times that the changes proposed by *divestment* were radical enough that they would be strongly resisted by all the major parties involved in IFaC, and this was deeply problematic for the strategy. The suggestions made by the ECS are not radical at all, with the vast majority of

²⁶⁴ A. L. Antes, S. T. Murphy, E. P. Waples, M. D. Mumford, R. P. Brown, S. Connelly, L. D. Devenport, A Meta-Analysis of Ethics Instruction Effectiveness in the Sciences, *Ethics & Behaviour*, 2009: 19(5), pg. 385

²⁶⁵ A. L. Antes, et al., A Meta-Analysis of Ethics Instruction Effectiveness in the Sciences, *Ethics & Behaviour*, 2009, pg. 397

²⁶⁶ *ibid*

institutions already having ethics courses for undergraduate students in biomedical/life science fields, especially in medicine²⁶⁷. In fact, because of this it is significantly easier to realise the suggestions of the ECS than the suggestions of strong *management*. This provides a consequentialist justification for the ECS, or at least the educational part of it, in that even if the gains of this strategy are possibly limited, the probability of realising this outcome is high.

I, however, would like to make an additional suggestion regarding the educational side of the ECS, which is that just as medical doctors are required to undertake a certain number of hours of continuing medical education every year in order to maintain their registration, I would like all biomedical researchers, including doctors, to be required to have ongoing ethical training. In terms of physician-researchers, there seems to be no reason why their continuing medical education could not include as part of it, ongoing ethics training.

Of course, for those researchers who are not physicians this suggestion becomes slightly more difficult, although it should not be prohibitively so. For non-physician researchers, it should be simple enough for their institutions to provide and require a periodic ethics workshop or seminar. Further, the more robust ethical training required by the ECS should be included in all research based post-graduate degrees, especially doctorates.

The educational side of the ECS looks to engage researchers as potential interlocutors in order to increase their capacity to resist perverse incentives from IFaC and appropriately act in accordance with institutional norms. It makes no radical suggestions and there is some evidence that it may be at least moderately helpful, especially in combination with strong *management*. While it would be unreasonable to overstate its likely impact, given the low cost of implementation

²⁶⁷ M. Mumford et al. Biomedical ethics education may benefit from integrating compliance and analysis approaches, *Nature Immunology*, 2016: 17(6), pg.605

and the potential for at least moderate results, the strategy would appear to have a consequentialist justification.

More ambitious, there is hope that this interlocution with researchers might also help produce a cultural shift amongst biomedical researchers. Since institutions, government and industry have so much to gain from IFaC, it seems that the only way the problems related to it will be fixed is with the support of the researchers themselves. Of course biomedical researchers also gain a lot from IFaC, but they also have certain ethical obligations, which arguably their institutions, government and industry do not have. If we can get researchers to recognise these obligations and the problems of IFaC, as well as encouraging their investment in solving these issues, then perhaps the potential for more fundamental changes in the relationship between academia and industry will open up.

There are a number of points to make regarding this idea of a cultural shift. The first comes from Howard Brody who demands a stronger professionalism amongst researchers and doctors²⁶⁸. Similar to my argument, Brody suggests “it is difficult if not impossible for regulators to correct the problems if the physicians themselves are not motivated to do so”²⁶⁹. Moreover, he argues that,

*no group can call itself professional if it does not espouse a moral code, and instead relies totally on external policing to correct misbehaviour among its members. Adopting a moral stance...and insisting that its members place dedication to that moral code...is one of the characteristics that ought to define a profession in modern society.*²⁷⁰

²⁶⁸ H. Brody, *Hooked*, pg. 299

²⁶⁹ *ibid*

²⁷⁰ *ibid*

Even though Brody is a *divestment* advocate, he still argues, as I have suggested, that a change in professional culture and attitude is also important. The difference, however, is that I have offered a mechanism through which this professional capacity might be enhanced in order to produce a stronger ethical culture.

Brody also offers some idea as to how this stronger professional culture might be enforced by those within the profession. He proposes that although ostracism is generally viewed negatively by many people, it is appropriate in this context²⁷¹. Brody argues that researchers can demand a higher professional standard from their peers by shunning those who fail to live up to this standard through their inappropriate relationships with industry or commercialisation²⁷².

It is interesting to note that Brody's suggestion simultaneously treats researchers as parametric and as interlocutors. That is, it treats potential defectors as merely parametric as it changes the incentive structure by discouraging defection. On the other hand, it treats researchers as potential interlocutors in the sense that it relies on researchers themselves to recognise appropriate ethical behaviour and punish those who do not live up to this standard.

Whether or not this is the best way to encourage and maintain professionalism is unclear. The point, however, is that some cultural shift in which professional standards are more reliably met through the enforcement of those standards by members of the profession, should be considered useful. However, in lieu of other suggestions, I will accept Brody's professional ostracism proposal.

The idea that cultural change is possible is made apparent by movements such as "No-Free Lunch", which is a group that encourages doctors to refuse gifts and

²⁷¹ H. Brody, *Hooked*, pg. 309

²⁷² *Ibid*

promotional materials from pharmaceutical companies²⁷³. No-Free lunch understands that the gifts given to doctors, whether they are small like free pens or lunches or more extravagant like an 'educational' event at a golf course, influence doctors' behaviour. The parallel with researchers, many of whom are also doctors, is obvious. Just as doctors can be influenced by gifts from industry, so too can researchers be influenced, whether it be through grants, consulting fees, or a range of other interactions.

The difference, however, between practising doctors and researchers is that while their involvement with industry may be problematic, researchers often rely on industry funding to perform their research, while practising doctors do not rely on industry to practice medicine. In this sense, it is likely to be easier to stop industry from influencing practising doctors as doing so will not presumably affect their careers or livelihoods, whereas by comparison researchers are pushed by their institutions, who are in turn pushed by government, to seek industry funding.

Regardless, the No-Free Lunch movement amongst doctors shows that there is, at the very least, some capacity for the beginnings of a cultural shift. My assumption, however, is that any cultural change will not be made swiftly. In fact, given the positive relationship between IFaC and seniority in academia²⁷⁴, it seems that the best hope for this cultural change will come from younger, newer generations of biomedical researchers.

Thus, the cultural component of the ECS is one in which better ethical education enhances biomedical researchers' capacity to adhere more strongly to institutional norms, as well as produce and enforce a stronger ethical standard.

²⁷³ No Free Lunch, <http://nofreelunch.org/> accessed 02/10/2016

²⁷⁴ C. Haeussler, J. Colyvas, *Breaking the Ivory Tower*, *Research Policy*, 2011, pg. 50

This subsection set out my alternative model, the ECS, as part of the overall strategy for dealing with the problems caused by IFaC. I argued that a more robust ethical training of biomedical researchers could be used to enhance their capacity to more reliably resist the perverse incentives produced by IFaC. This suggestion was reasonable, given that ethical training has been shown to be effective, and the fact that ethical training already exists in institutions, although not in the form I proposed, means that a fuller ethical education programme is a reasonable expectation. Optimistically, the ECS may eventually produce a grass-roots shift in the professional culture of biomedical research.

5.3 – *Criticisms of the ECS*

Like the other strategies for dealing with IFaC, the *education-cultural* strategy is not without possible shortcomings. This subsection will consider three potential problems; it is insufficient, it produces a potential collective action problem and it is idealistic.

The ECS is by no means a comprehensive solution to the problems caused by IFaC. As suggested repeatedly, some sort of *divestment* is likely necessary to fully address these problems. Accordingly, the ECS is not to be considered a panacea for the problems of IFaC, it is still a shortcoming of the proposal that it is insufficient on its own.

The problem, however, is deeper than the fact that it is an incomplete solution. The fact that the strategy itself becomes less likely to succeed the stronger the perverse incentives, and my proposal means introducing the ECS in the context of these perverse incentives, presents a difficulty for the ECS. This concern, however, is most likely not fatal. Firstly, again, the ECS is not intended to be a wholesale fix for the problems of biomedical research and industry funding and commercialisation. It was posited as a partial solution, a solution that admitted the potential for modest benefits but a high probability of realising these benefits. The fact that systemic changes to the incentives brought on by IFaC are necessary but likely near impossible, means that any possible solution will likely face exactly the same problem as the ECS. This is made apparent not only by the problems with IFaC but also by the potential shortcomings of the strong *management* strategy highlighted earlier in this chapter.

The fact remains, however, that even a bolstered ethical education may not produce the desired results. There is a real possibility that although ethical training has been shown to be effective in producing better outcomes amongst scientists, it may not work in addressing the problems caused by IFaC for a

number of reasons. For example, perhaps there will be a difference in reaction from biomedical researchers in how they consider more traditional biomedical research problems such as consent or the treatment of vulnerable groups and the problems caused by IFaC. If critics of IFaC such as Schafer and Brody are right that there are deep psychological mechanisms at work that engender bias and/or blind researchers to this bias but these mechanisms do not apply to many other biomedical ethical issues, this may be problematic. That is, researchers may be more responsive to issues regarding consent but not responsive to the problems of IFaC, because many of the psychological mechanisms that are involved with IFaC may not be present for issues of consent.

Moreover, if researchers are currently not sensitive to evidence that IFaC can unduly influence them, ethical training may not be enough to overcome this, at least amongst current researchers. Perhaps there is more hope for future researchers, a point I have already stressed, but there is also the possibility that the influence of IFaC may still overcome their early ethical training as well. This possibility is presumably especially apparent when new biomedical researchers need to find funding for their research in order to receive tenure or other promotions. This harks back to the problem of introducing any partial response to IFaC that fails to address the underlying issues with the perverse incentives it creates for researchers.

Furthermore, even if an enhanced ethical education curriculum were to successfully make biomedical researchers aware of the influence of IFaC on them as individuals, it still leaves these individuals with a collective action problem. That is, while more individuals may be aware of the pernicious influence of IFaC on them as individuals, for the sake of their career they are still better off involving themselves with IFaC. In other words, it may be difficult for individual researchers to forego the best option for themselves and instead opt for the best option for everyone. Furthermore, any incentives to forego the best option for the

individual become weaker in the presence of any significant defection from others.

Of course, part of the point of the hope for a cultural shift amongst biomedical researchers is to encourage cooperation and punish defection, thus the ECS may have an answer to the cooperative action problem it creates. This, however, leads to a further potential concern with the ECS; it may be too optimistic. It may be too optimistic to expect that a combination of a stronger ethical education curriculum and enough time might lead to a significant cultural shift amongst biomedical researchers. Again, there are a number of reasons to be suspicious of this potential change. The first is the uncertainty of the effectiveness of enhanced ethical education in this context; it relies on ethical training regarding IFaC to be effective when it may not be. Additionally, it relies on the effects to be great enough to produce a cultural shift, which it may not be, especially in a context of ongoing and strong perverse incentives.

These are just a small number of potential problems with the ECS that are immediately apparent. Since the proposals of this strategy are continually overlooked in the literature, a fuller critique of its shortcomings is not available.

Despite its immediate shortcomings, I still propose that the ECS is a viable potential strategy, especially if used in conjunction with a number of the suggestions made by strong *management*²⁷⁵. Even if the pessimistic assessment of the ECS is correct and its benefits are moderate at best it still has two major points in its favour. The first is that it utilises an approach that the other strategies have failed to even consider, to engage researchers as potential interlocutors in order

²⁷⁵ These suggestions include but are not limited to: the full trial reporting as a condition for market authorisation, mandatory pre-trial registration and summary reporting of results, and that all the aforementioned information is made publicly available through a centralised database.

to enhance their capacity to resist perverse incentives. Secondly, even if the benefits of the ECS are modest it remains easy to implement.

Conclusion

The aim of this chapter was to explore possible solutions to the problems of IFaC. In order to do this, the chapter began with an explanation of the two prominent strategies for addressing these problems; *divestment* and *management*. The *divestment* strategy came in two different forms; the popular firewall *divestment*, and full *divestment*. The firewall version of *divestment* sought to establish a barrier between researchers and their institutions, and industry. For most proponents of the firewall approach, this barrier was the establishment of an independent national drug research institute, whose purpose was to act as an intermediary between academia and industry. Full *divestment* suggested that industry would not have any direct involvement in funding clinical trials and all research could be funded by the public purse. It was argued that some sort of *divestment* was likely necessary if the problems caused by IFaC were to be dealt with fully.

While *divestment* may play a necessary part in fixing the problems of IFaC, it suffers from one devastating flaw: from a consequentialist perspective the *divestment* strategy is hamstrung by the unlikelihood of its instantiation. There are two central reasons for thinking this; firstly, the adoption of *divestment* produces a collective-action problem. *Divestment* requires any country or institution that adopts its policies to forego the largesse of industry without a guarantee that other countries or institutions will do the same. The second major reason is the current relationship between regulators and industry, with even proponents of *divestment* acknowledging the powerful influence that industry has over government.

Divestment's counterpart, the *management* strategy, also came in two main variations: weak and strong. Although the suggestions made by both variations were very different, they both share the same assumption, which is that industry and academia will have to continue interacting in more or less the same way as

they have been. It was suggested that weak *management* is the current status quo for dealing with IFaC and its focus was the management and disclosure of conflicts of interest. How institutions and government approach and apply this strategy varies significantly.

I argued that, insofar as weak *management* has been at the helm while many of the issues outlined in the previous chapter have occurred and continue to occur, then it should be seen as a failure. The strategy failed to recognise that researchers and their institutions that benefit from IFaC do not see themselves as being unduly influenced by IFaC, even in the face of evidence to the contrary. Moreover, a policy emphasising disclosure is inherently flawed for a number of reasons. The first is that disclosure only allows readers to recognise the potential for bias, but offers them no tools by which they can determine or detect bias. Additionally, a focus on disclosure for dealing with conflicts of interest fails to recognise them as fundamentally problematic, instead giving researchers a rationalisation for creating more serious conflicts of interest.

Strong *management* makes a number of stronger demands, the focus of which is on increased transparency and openness in the conduct of clinical trials and research. Proponents such as Goldacre proposed that *all* clinical trials should be subject to mandatory registration. This includes the preregistration of clinical trials, including significant information such as proposed endpoints, a summary of results of all registered trials within one year of completion, and submission of a full report be required for any trial that is to be used as the basis for market authorisation.

Many of the suggestions made by strong *management* are useful to the extent that even some *divestment* proponents also agree with them. These solutions, however, are insufficient for addressing the problems of IFaC and I argued they are unlikely to be as impactful as their advocates have suggested. While strong

management may rule out many forms of egregious misconduct, there are number of other issues it is unable to address including a number of more subtle ways in which bias can be introduced into trials and the inappropriate skewing of research programmes. It is also too reliant on the appropriate experts being adequately motivated to comb through the raw data of clinical trials in order to detect bias.

This chapter also explored the assumptions the various strategies made about biomedical researchers' capacities to align with institutional norms in the face of perverse incentives. Weak *management* assumes a robust capacity from researchers and treated them as potential interlocutors. It does so, however, inappropriately, failing to recognise that not only have biomedical researchers unsuccessfully resisted perverse incentives, but have failed to identify the influence of IFaC.

While strong *management* and *divestment* differ in their assessment of the strength of biomedical researchers' capacities, they both treat them as merely parametric. They assume that the best approach for rectifying this behaviour is to reshape incentive structures, although the extent to which they wish to change these structures differs greatly.

This, I argued, was to miss an opportunity to engage biomedical researchers as potential interlocutors. This opened the way for another possible strategy; my *educational-cultural* strategy, which seeks to engage biomedical researchers as potential interlocutors and enhance their capacity to follow institutional norms. An argument was made that the more a person is already motivated to act in a certain way, the less they need to be incentivised to act that way. The intrinsic motivation provided by in the inculcation of norms is one way in which the more reliable production of desirable behaviour could be achieved. Thus, I argued that in order for researchers to more reliably resist perverse incentives from industry

and adhere to institutional norms, ethical education programs that engage researchers as potential interlocutors, should be bolstered.

The exact nature and execution of this enhanced education programme was beyond the scope of this thesis but a number of potential models were highlighted. Since the success of ethical education training is linked to the quality of the programme, it is therefore imperative that these programmes are of the highest reasonable quality.

The hope is that through enhanced ethical education a cultural shift amongst biomedical researchers could occur, and that such a shift might produce a greater professionalism and adherence to institutional norms.

Finally, I addressed a number of potential issues with my ECS proposal, namely that it is insufficient on its own to address the problems of IFaC, it is idealistic and it produces a possible collective action problem. While these problems are realistic concerns for the ECS, I argued that they are not fatal.

Conclusion

This thesis set out to find a possible solution to the problems caused by industry funding and commercialisation of public biomedical research within a consequentialist framework. While there has been a growing recognition of the problems of IFaC and corresponding proposals to address these issues, such proposals have failed to properly engage with the possibility that there is scope to engage biomedical researchers themselves in order to help address these. The ultimate purpose of this thesis was to elucidate this possibility, and I referred to this proposal as the *educational- cultural strategy*, or *ECS*, as a means of doing so.

In order to reach this conclusion, much argument and exposition was needed. The first chapter of this thesis established two main points. The first was to argue that public BMR is a goal-directed social institution. I offered a list of properties that should apply to any social institution, and suggested that any entity that possesses these properties should be considered a social institution. Public BMR possesses these properties, and thus should be considered a social institution. The other main purpose of the chapter was to set up the consequentialist assessment of BMR as a goal-directed social institution. This assessment was based on the notion that, in part, any justification of a social institution will rely on an evaluation of the institution's goal and its effectiveness in achieving this goal. Global welfare consequentialism was suggested as being appropriate for this assessment in relation to public BMR.

Part of a consequentialist assessment involved an examination of the institution's success in achieving its goal, which comprised, in part, an examination of the constituent parts and their effectiveness in promoting the goal of the institution. The second chapter of this thesis focused on which norms best helped public BMR achieve its institutional goal, suggesting that the Mertonian norms satisfied this aim. The Mertonian norms are disinterestedness, communalism,

universalism and organised scepticism. These norms are functional in that they help BMR to more effectively achieve its goal by helping the institution to more efficiently produce more reliable knowledge. Furthermore, I provided my interpretation of the Mertonian norms; that they are to be considered action-guiding and aspirational for individual researchers.

A central part of a consequentialist assessment of IFaC and public BMR was to evaluate the positive outcomes produced by IFaC. Chapter 3 outlined a number of the arguments made in favour of IFaC. These fell into two categories: non-health benefits, and benefits to BMR. The first category focussed on the broader economic benefits to society derived from innovation driven by research. The second category of benefits focussed on how IFaC contributes to the achievement of BMR's institutional goal. The first of these benefits was that IFaC provides additional funding for research and this should produce additional research. Additionally, IFaC helped to more effectively bring discoveries to market, and this should be expected to help achieve the goal of BMR. Finally, IFaC is necessary to bring discoveries to market, as the public sector lacks the ability to effectively do so. These benefits provided consequentialist justifications for accepting IFaC.

Chapter 4, however, argued that the benefits of IFaC come at a serious cost. Significantly,

IFaC undermines the reliability of our knowledge and inefficiently funnels research into areas that are of financial interest but of limited interest to health and welfare maximisation. It was determined that these negative benefits are not caused by mere happenstance, but are instead due to the fundamental underlying institutional differences between public and private BMR. The norms of public BMR, the Mertonian norms, are fundamentally in friction with the norms of private research and enterprise.

This naturally led to a discussion of how to address the problems caused by IFaC. In order to set up this discussion, I referred to a substantive debate in the consequentialist literature between Possibilism and Actualism. This debate looked at different ways to consider the predictable wrongdoing of agents: whether we should take this wrong-doing as merely parametric by assuming it is part of a set of background conditions in our decision making; or whether we should treat biomedical researchers as potential interlocutors, that is, agents who can and should respond to reason.

Finally, chapter 4 considered what it means for someone to possess a capacity. To do this, Michael Smith's concept of capacity was examined, which suggests that for an agent to have a capacity means that they reliably perform an action in a raft of nearby possible worlds. In other words, if an agent has the capacity to x , they must reliably x over a range of nearby possible worlds. Moreover, an agent failing to x in this world does not entail that they lack the underlying capacity to x , as this is determined by whether they reliably x in a raft of nearby possible worlds.

The arguments and exposition of the previous chapters led to chapter 5, where within a consequentialist framework, I examined the proposed solutions to IFaC. Almost all solutions to IFaC in the literature fall into either, the *divestment* or *management* strategies. The *management* strategy is itself divided into weak and strong *management*. The weak *management* strategy reflects the current status quo in regards to addressing the issues that are caused by IFaC. This strategy should be considered a failure, on the basis that it has presided over many of the serious problems of IFaC outlined over the course of the thesis. The strong *management* strategy, however, offered solutions with greater potential to be effective. This strategy focusses on increased transparency, and includes measures such as mandatory registration of clinical trials. I argued that the proposals of strong

management, although insufficient, should be adopted on consequentialist grounds as part of the solution to the problems of IFaC.

The alternative solution, the *divestment* strategy, is similarly separated into two main alternatives. The most popular *divestment* suggestion is the firewall approach, which argues that academic researchers and industry must be kept at arm's length. In order to create this distance between the two, firewall *divestment* proponents argued for the establishment of an independent national agency, which would act as an intermediary between academia and industry. The alternative *divestment* proposal was full *divestment*, wherein industry would no longer be allowed to fund clinical research and instead the burden would fall on the public. It was argued that although some level of divestment may be necessary in order to fully address issues caused by IFaC, the strategy is ultimately untenable. While the utility of *divestment* is considerable should it be instantiated, the problem is the minuscule potential for its instantiation. Thus, the potential utility is ultimately severely limited.

An assessment was made to determine whether these strategies considered researchers as potential interlocutors or merely parametric. Both strong *management* and *divestment* assume that researchers are unable to resist perverse incentives from IFaC to violate the Mertonian norms, and offers solutions that focus solely on changing incentives in some way, thus treating researchers as merely parametric. Only weak *management* treats biomedical researchers as potential interlocutors, but it does so inappropriately. Even in the face of overwhelming contradictory evidence, it assumes that under current conditions, researchers will respond appropriately to ethical demands to adhere to institutional norms, despite strong perverse incentives from IFaC.

It was on this basis that the potential for an alternative solution was forged, where biomedical researchers are engaged as potential interlocutors by attempting to

increase their capacity to resist perverse incentives from IFaC through improved ethical training. The *educational-cultural* strategy both holds scope for addressing the problems caused by IFaC, and unlike the *divestment* strategy, has the potential of being adopted. While the *ECS* has potential to address some of the deeply intractable problems of IFaC, it is not a complete solution in and of itself. Ultimately, without a fundamental change to the relationship between academia and industry, a change not directly offered by the *ECS*, the problems caused by IFaC seem unlikely to be resolved.

Given the incomplete nature of the viable approaches for dealing with IFaC, including the strategy proposed by this thesis, there is still potential for further and ongoing inquiry in this area. There of course remains the possibility that IFaC is now so deeply rooted in public BMR, and so beneficial to the majority of the parties who have the ability to address the problems caused by it, that all solutions would either be untenable or insufficient.

The problems with IFaC and how they are at odds with the underlying principles of a public institution are deep-seated, hence the need for the kind of ethical evaluation conducted in this thesis. The application of consequentialism and other philosophical concepts helped not only to frame and better understand these issues, and why they arise, but also illuminate possible solutions albeit incomplete ones. These philosophical tools highlighted the strengths and failings of both *management* and *divestment*, bringing to light the notion that proponents of *divestment* may be tilting at windmills, but equally highlighting the shortcomings of the *management* strategy, in particular, weak *management*. Thus, through applying ethical theory to an existing real world problem in order to better understand it and examine possible pathways towards solutions, the value of this thesis is confirmed.

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