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# **BIOMEDICAL ETHICS AND GENETIC EPIDEMIOLOGY**

**Michael Whong-Barr**

## **Abstract**

Biomedical ethics developed in the late twentieth century as a challenge to the self-regulatory ethic that previously governed medical practice. Yet in recent years bioethics has come under scrutiny from the social sciences, which claim that the field relies upon an idealised notion of moral agency and fails to consider the extent to which ethical discourse is embedded in a wider societal context. In addition, bioethical concepts such as patient autonomy and informed consent have also recently been challenged by the rise of genetic medicine. After evaluating debates in the historical and philosophical development of biomedical ethics, this thesis uses a case study in genetic epidemiology (commonly referred to as biobanking) to examine competing normative and empirical claims made by bioethicists and social scientists. The study investigates the views and experiences of potential donors to a biobank in north-west England. Data analysis gives particular emphasis to socio-ethical issues such as consent, genetic donation, altruism, and benefit-sharing. Evidence from the case study illustrates that bioethics is susceptible to many of the charges levelled against it – namely that it lacks proper understanding of the processes by which moral concepts and categories are embedded in ongoing forms of social practice and experience. The thesis concludes with suggestions as to how bioethics may better combine philosophical and sociological methods.

# **BIOMEDICAL ETHICS AND GENETIC EPIDEMIOLOGY**

**Submitted by Michael Whong-Barr**

**For the degree of Doctor of Philosophy  
Department of Philosophy  
University of Durham**

**Submitted July 2004**

**Supervised by Professor A. Holger Maehle**

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## Chapter One

### Introduction: biomedical ethics and genetic epidemiology

*Indeed he knows not how to know who knows not also how to un-know.<sup>1</sup>*

*-- Richard Francis Burton*

This thesis began as a work of history. Dissatisfied with conventional accounts of the emergence and growth of bioethics and motivated by the fact that no one, to date, had adequately researched the history of the field in Britain, I laid out in considerable detail a project designed to fill the gap in scholarship. At the end of my first year of study, however, I was invited to participate in a Wellcome Trust summer school on genetics and society. This experience, and the employment that followed, took me away from the history of bioethics and deep into the ethics of genetic epidemiology (commonly referred to as biobanks, DNA banks, or genetic databases). As a result, the investigation which follows blends an analysis of the history and philosophy of bioethics with a case study in genetics. My aim has been to critically examine the birth of bioethics and the normative assumptions that bioethicists make, then to evaluate many of the sociological critiques of the field and, finally, to view both normative and empirical claims in light of the case study.

First, however, I must address the question of terminology. How does medical ethics differ from bioethics and why have I chosen to title my thesis *biomedical ethics*? The word 'bioethics', it seems, was coined one night in 1970 in Sargent Shriver's Bethesda living room.<sup>2</sup> He used it in reference to plans to develop the Kennedy Institute of Ethics. Apparently, however, around the same time in Wisconsin, Van Rensselaer Potter also invented the word to refer to an ethic that paid greater attention to ecological issues, as

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<sup>1</sup> Cited in B. Flyvbjerg, 2001. *Making Social Science Matter: Why Social Inquiry Fails and How It Can Succeed Again*. Cambridge: Cambridge University Press, p. 166.

<sup>2</sup> W. T. Reich, 1995. The word bioethics: its birth and the legacies of those who shaped its meaning. *Kennedy-Institute of Ethics Journal* 5: 319-336.

well as medical ones.<sup>3</sup> Originally considered an Americanism, the term 'bioethics' is now commonly used throughout the world. It, in effect, differs from medical ethics in that it signifies a shift in the post-War era from an ethic of medical self-regulation to one that permits far greater involvement of non-medical persons (so-called outsiders) in the adjudication of right and wrong behaviour.<sup>4</sup>

In this study, I have chosen the term biomedical ethics for my title in order to capture the full range – that is, both clinical and research – of ethical issues in the life sciences. However, following most others in the field, I unashamedly use medical ethics, bioethics and biomedical ethics interchangeably in my actual writing. I do *not* use bioethics as Van Rensselaer Potter initially proposed. I do recognise, and indeed argue, however, that a true bioethic would certainly expand its agenda to incorporate the nexus between environmental, ecological and medical health.

At this point, it is also useful to make a distinction between biomedical ethics as a clinical encounter and as an academic discipline. As I see it, the former deals with patients, physicians, research subjects, ethics committees, and actual decision-making. The latter is the body of literature where concepts and issues used in clinical and research settings are created and debated. Clearly, the two cannot be neatly separated and are mutually reinforcing. Yet there is a difference, I think, between bioethics in the ward and bioethics in the journals. To the extent that they can be split my target is primarily bioethics as an academic discipline – but, as Chapters Seven and Eight indicate, the whole point is to improve praxis.

### *Setting the scene*

It is now a truism to say that genetic medicine raises many challenges for biomedical ethics. The familial nature of genetic information and the rapid development of biotechnology tests the limits of existing ethical theories. For example, what constitutes

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<sup>3</sup> V. Rensselaer Potter, 1970. Bioethics, the science of survival. *Perspectives in Biology and Medicine* 14: 127-152.

<sup>4</sup> R. Ashcroft, 2001. Emphasis has shifted from medical ethics to bioethics. *British Medical Journal* 322: 7281: 302b.

informed consent? How is confidentiality best protected? How much, if at all, should the public be consulted on matters pertaining to the life sciences? But if genetics serves as a challenge to ethics, it has also served as a boon. If ethics cannot keep up with the science, then obviously we need more ethicists. And yet, amidst the growth and popularity, bioethics has come under heavy and sustained attack. Critics of bioethics have attacked on all fronts: its history, its method, its assumptions, its self-importance, its financial entwinement with those it is supposed to be guarding against. It is this situation, in which biomedical ethics is increasingly cited yet increasingly criticised, that forms part of the background to the current investigation. In other words, I have sought to ask the question ‘what is bioethics?’ – in its historical development, its categories and concepts, its practice and problems. This question, inevitably, has also forced me to ask ‘what is bioethics *not*?’. What has been lost, marginalised, or displaced in the rapid growth of the field?

Two things follow on from this. First, I did not want to set up a straw figure that I conveniently knock down later in the thesis. My decision to incorporate a case study involving empirical fieldwork, I hope, has provided some protection against this. Second, and allied to this, if I *really* wanted to understand what bioethics was all about, I reasoned that I needed to go out and get involved. This was a key reason why, after my Wellcome Trust course, I initiated a grant proposal with Erica Haines at the Policy, Ethics, and Life Sciences Research Institute (PEALS), where I have been employed since 2001. Apart from the practical experience, one premise behind the grant research was that very little was known about the views of actual donors to genetic projects, especially donors to population based genetic research. Crucially, even less was known about those who had been asked to donate but refused. Are the views of these two seemingly opposed camps really at diametrical odds? Are those who refuse to donate better or less informed about genetics research? What perceptions of genetics do donors have? How do those perceptions impact their decision to donate? Above all, perhaps, do people really care about informed consent as much as ethicists do?

It was against this backdrop that the current investigation was conceived.

### *Thesis outline*

Chapters Two through Four of the investigation focus on the history, philosophy, and sociology of biomedical ethics. Chapters Five and Six explore the issue of genetic epidemiology. The remainder of the thesis returns to my examination of bioethics in light of the findings and insights generated from my study of biobanking. For the reader's convenience each chapter ends with a bullet point summary and conclusion that corresponds (more or less) to chapter sub headings.

The proceeding chapter, then, shows how medical ethics, for the greatest part of Western history, was a matter of physicians prescribing for other physicians how and how not to act. Whilst many have dismissed the history of medical ethics as mere etiquette, I argue that such an interpretation is an example of presentism, (the fallacy of reading the past as if it were the present) and fails to appreciate the context and moral content of medical issues in previous eras. My short history concludes in the mid twentieth century.

Chapter Three discusses in detail the historical and philosophical development of biomedical ethics, focusing on events in Britain and the US. I aim to show how early informed consent guidelines were largely ignored by the research establishment until the mid 1960s when wider social trends (such as the rights movement) impacted the medical profession and gave impetus to change. In telling the story of bioethics, I concentrate on the role played by 'strangers' in slowly breaking down the self-regulatory nature of medical ethics described in Chapter Two. The chapter ends with an evaluation of the role of religion in the birth of bioethics and its subsequent marginalization as the demand for a secular ethic grew – the so-called four principles approach, or principlism as most refer to it.

Chapter Four evaluates some of the criticisms of mainstream biomedical ethics through a discussion of alternative methods such as casuistry, care and virtue ethics. My focus, however, is on the social science critique which targets both the method of bioethics and the primacy it gives to the principle of autonomy. The central theme of this chapter is that

mainstream bioethics lacks sufficient understanding of the wider context in which medical decision making transpires.

In order to deepen the critique of bioethics and to test the competing claims made by bioethicists, social scientists, and historians (that is, the claims put forth thus far in the thesis), Chapter Five introduces the issue of genetic epidemiology. Genetic databases are population wide collections of DNA, which are combined with a donors' medical history and lifestyle information for the purpose of epidemiological analysis. The aim of biobanking is to better understand the relative contributions of genetic, environmental and lifestyle factors on the causes of common disease, most notably chronic diseases such as cancer, diabetes, and heart disease. My discussion here begins with a short history of the public health movement (of which genetic epidemiology is an extension), and then considers the range of the socio-ethical issues of biobanking by drawing on examples from Iceland, Estonia, the United States and Britain. The bulk of my ethics discussion in this chapter is on the issue of informed consent. DNA banking presents particular problems for consent guidelines since samples are stored indefinitely and at the time of their collection, not even the researchers know the full range of possible uses. Thus, how can consent be truly 'informed'? I examine the main responses to this problem.

Chapter Six examines these issues in greater detail by drawing on empirical research into a local biobank in Cumbria. Particular attention is paid to the issues of participation, donation, consent, altruism, and benefit-sharing. Again, the theme of context is highlighted as I draw out critical distinctions between the normative ethics literature and findings from my empirical study. Simply put, many of the sociological charges against mainstream bioethics seemed to hold true.

A key question in light of my case study is how biomedical ethics can overcome these charges and develop a form in inquiry that can accommodate both philosophical and empirical methods. The beginnings of an answer, as I suggest in Chapter Seven, lies in the Aristotelian concept of *phronesis* (practical wisdom), critically combined with a method that uncovers the ways in which our ethical ideas are embedded in socio-political

practices – practices so ingrained that we tend to forget that they too have a history. Following the work of Bent Flyvbjerg, I aim to explore and expand the notion of context – a central theme throughout the thesis.

Chapter Eight applies these methodological sketches to actual issues in bioethics, including but not limited to DNA banking. It also brings the thesis full circle with a discussion of how historians may better situate bioethics into a socio-historical framework that better understands some of the causal factors – the attitudes, beliefs, and existential commitments, as well as medical, scientific and commercial pressures – which have governed developments not only in ethics, but crucially in medicine and technology, as well.

The Conclusion re-caps the overall theme of the thesis and briefly considers both its limitations and directions for future work. Finally, I have included two Appendices. The first provides a brief summary of my role in the Wellcome Trust project that serves as the basis for Chapter Six. Appendix II is the detailed interview schedule used in that study. Inclusion of interview questions is common, even expected, in theses that involve an element of empirical social research such as this one and I add it in the interests of research transparency. It should provide the reader with some insight and background into the findings and analysis presented in Chapter Six.

### *Caveats and cautions*

In some ways the principal target of this work is principlism. It is easy enough, I admit, to take pot shots at principlism. Many have done so and some have even built entire careers on it. In my less secure moments, one fear I have for this work is that I do not present a balanced enough approach. That is to say, I fully recognise that principles are an integral part of moral reasoning and that philosophy's commitment to first principles are extraordinary useful in clarifying what is at stake in ethical dilemmas. Perhaps better than anyone in the field, Onora O'Neill has justified the use of principles, albeit in conjunction with practical judgements. My work here does not rely on Kant as explicitly as hers, but I do take her point that 'there is no way of dispensing with principles, unless it is possible

to establish a quite radical form of ethical particularism, a task of the greatest epistemological difficulty.’<sup>5</sup> If my writing leads me astray into such radicalism, it is no doubt because of my experience as lead researcher on a major empirical study – whose central findings were, in essence, that context counts and that we have good reasons to doubt certain claims made by normative bioethics (which, in large measure, is principle based). As one commentator has aptly put it, there are ‘good sociological reasons for bad bioethical outcomes.’<sup>6</sup>

This leads me to another topic worth addressing: what follows, in all honesty, resembles a work of sociology at least as much as it does philosophy or history. Of course it incorporates elements of all three disciplines, the boundaries of which I feel are often over-stated and needlessly, perhaps even dangerously, reinforced by the harsh realities of academia (e.g. budgets, Research Council remits, RAEs and so on). To a large degree my disciplinary promiscuity is intentional and reflects my own particular background. My BA is in political science, my MA is in theology and my PhD is in philosophy. Yet my thesis supervisor is a historian of medicine and my employment at PEALS has been, as I indicated above, heavily informed by sociology. To top it off, before undertaking post-graduate work I spent four years as an English teacher and administrator (in China and in Egypt). Such a varied approach comes at a certain cost. I fear that at times the current investigation is miles wide but only skin deep. That is to say, since I roam freely over source material and since the investigation does not focus on one thinker alone, there are many topics that I touch on but do not fully consider. What binds it together, I think, is my focus on the competing claims of biomedical ethics in light of the case study in genetic epidemiology.

To sum up, Barbara Nicholas asks,

‘Is bioethics becoming a means by which present social structures and assumptions are supported and regulated? Or is it a discipline that is contributing to a fundamental

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<sup>5</sup>O. O’Neill, 2001. Practical Principles and Practical Judgements. *Hastings Center Report* 31: 20.

<sup>6</sup>R. Fox and R. DeVries, 1998. Afterward: The sociology of bioethics. In R. DeVries, and J. Subedi, 1998. *Bioethics and Society: Constructing the Ethical Enterprise*. NJ: Simon & Schuster, p. 272.

questioning of the values that inform relationships between individuals and between different groups?’<sup>7</sup>

The study which follows suggests that it is the former but begins to chart a path in which the latter may be realised.

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<sup>7</sup>B. Nicholas, 1999. Power and the teaching of medical ethics’, *Journal of Medical Ethics* 25: 509.

## Chapter Two

### A short history of medical ethics

#### *Introduction*

In this chapter, I provide a brief but critical review of the history of medical ethics from Antiquity to the early twentieth century. My aim is to provide the necessary background to better situate and contextualise the primary target of the thesis, contemporary bioethics. Of course covering more than two thousand years of history in a short chapter cannot do justice to the richness of the topic with all its colourful characters, texts, and controversies. To skipping detail in order to arrive at my primary target, post War bioethics, I plead guilty. But the general theme and argument of this chapter, I believe, is accurate and well supported: that for the better part of Western history medical ethics was an internal affair, a method by which doctors self regulated other doctors in order to establish medicine as a credible and viable profession. In providing this brief sketch of the self regulatory nature of medical ethics, I have of course not touched on many details, such as the complex interaction between the classical tradition and Christian virtues, the influence of Arab medicine on Western practice, and the relationship between the philosophy of and actual practice of medicine. I begin by addressing recent historiographical debates in medical ethics.

#### *Ethics and etiquette: clarifying terminology*

Robert Veatch has argued that the Hippocratic Oath is an 'immoral basis' for the practice of medicine since it lacks recognition of rights, autonomy, or justice. Veatch asserts that the Oath 'offends Kantians, social utilitarian[s], anyone who is Jewish or Christian or Marxist, Muslims, Hindus, Confucians, and those who subscribe to various African tribal religions'<sup>8</sup>. The Oath, according to Veatch, is 'individualistic, consequentialistic, and paternalistic, a combination that virtually no moral tradition anywhere in the world should find acceptable'.<sup>9</sup>

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<sup>8</sup> R. Veatch, 2003. Revisiting *A Theory of Medical Ethics: Main Themes and Anticipated Changes*. In J. Walter and E. Klein, eds. *The Story of Bioethics: From Seminal Works to Contemporary Explorations*. Washington: Georgetown University Press, p. 70.

<sup>9</sup> Veatch, 2003, p. 70.

Now whilst it is true that the Oath lacks obligations of veracity and says nothing about the need for workers of all classes to unite, it does contain mention of the duty of confidentiality ('whatever I see or hear, professionally or privately, which ought not to be divulged, I will keep secret and tell no one'<sup>10</sup>), and more famously, obligations of non-maleficence and beneficence ('I will use my power to help the sick to the best of my ability and judgement; I will abstain from harming or wronging any man by it'<sup>11</sup>).

I believe that Veatch's claims, as Vivian Nutton points out, seem to reveal more about twentieth century medical ethics than those of the fifth century BC<sup>12</sup>. In other words, Veatch seems to attribute a false unity on the Hippocratic corpus and credits the Oath's wording and interpretation with a universal and unchanging validity that does not reflect the ancient medical world. The corpus of medical ethics texts were far more varied than the mere Oath alone, as historians have shown, and cannot be confined to one document or author, as Veatch seems to do. Indeed, it is likely that the Oath held minimal influence in the fifth century and did not gain its normative status or authority until the Christian era, a time in which the Oath's prohibitions against abortion and 'fatal draught' (euthanasia) fit neatly with the concerns of Christian morality. As Robert Baker has aptly put it, as the 'West converted to Christianity so did the Oath'.<sup>13</sup>

Like Veatch many commentators believe that prior to our enlightened era (i.e. the late twentieth century), 'medical ethics' was a misnomer.<sup>14</sup> Chauncey Leake's famous distinction between 'ethics' and 'etiquette' set the terms of reference. According to Leake, 'ethics' were concerned with the ultimate consequences of physicians' conduct

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<sup>10</sup> *The Hippocratic Oath*. Reprinted in R. Porter, 1997. *The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present*. London: Fontana Press, p. 63.

<sup>11</sup> *The Oath*, in Porter 1997, p. 63

<sup>12</sup> V. Nutton, 1993. Beyond the Hippocratic Oath. In A. Wear, J. Geyer-Kordesch, and R. French, eds. *Doctors and Ethics: The Earlier Historical Setting of Professional Ethics*, p. 10-37. I assume that here Nutton is referring to Veatch's desire to forge a universal ethical system in the face of anxieties regarding moral diversity and pluralism.

<sup>13</sup> R. Baker 1993. The History of Medical Ethics. In W.F. Bynum and R. Porter, eds., *Companion encyclopedia of the history of medicine*, London: Routledge, p. 855.

<sup>14</sup> C. Leake, 1975. Introductory Essay. In C. Burns, ed., *Percival's Medical Ethics*. New York: Robert Krieger. (Reprint of Leake's edition), p. 1. Leake's analysis for the most part dealt with the work of eighteenth century writer Thomas Percival but his criticism of ethics and etiquette applies to pre-eighteenth century medical ethics as well.

toward patients and society as a whole, while 'etiquette' denoted 'the conduct of physicians toward each other'.<sup>15</sup> Following these definitions, Leake argued that 'medical ethics' in fact referred only to rules of etiquette developed to regulate physicians' contacts with *each other*.

Nearly fifty years later, sociologists Ivan Waddington and Jeffery Berlant supported Leake's conclusions. Waddington argued that sociologists had traditionally and erroneously believed that the development of professional ethics ought to be seen within the context of practitioner-client relationships.<sup>16</sup> According to the traditional view, ethical codes helped patients distinguish between competent and incompetent or honourable and dishonourable doctors. Waddington, however, believed that this approach to the growth of medical ethics lacked empirical evidence. Instead, Waddington suggested that the importance of the doctor-patient relationship for an understanding of medical ethics had been grossly overstated and he, like Leake, believed that the development of medical ethics had more to do with regulating relationships *between* physicians. To support his claim that ethics dealt primarily with intra-professional relationships, Waddington emphasized the long portions of Thomas Percival's *Medical Ethics* [1803] that dealt with physician/surgeon consultation.<sup>17</sup>

Utilizing Max Weber's theory of monopolization, Berlant described medical ethics as an 'organizational tool' that operated by subordinating individual interests to the collective of the profession.<sup>18</sup> Ethics, in other words, were little more than appeals to honour, to bring about cooperation within the medical profession for the good of the group as a whole. In short, these 'revisionists' have re-categorized professional ethics as mere

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<sup>15</sup>Leake, 1975, p. 2.

<sup>16</sup>I. Waddington, 1975. The development of medical ethics – a sociological analysis'. *Medical History* 19: 38.

<sup>17</sup> Waddington seemed to overlook Article II of Percival's work, which dealt with *patients'* requests to be treated by a 'favorite practitioner' as well as Article III on how to attend to a *patients'* feeling and emotions; and Article XII which contended with 'new remedies and new methods of chirurgical treatment,' or as Baker writes, 'the regulation of experimentation on human subjects.' Furthermore, it is not the same thing to say that medical ethics in the past were only intra-professional as it to say that they were self-regulatory. The former deals only with doctor-doctor relations whilst the latter relates to physicians regulating other physicians doings with both those within the profession, as well as with patients and the wider society.

<sup>18</sup>J.L. Berlant, 1975. *Profession and Monopoly: A Study of Medicine in the United States and Great Britain*, Berkeley: University of California Press, pp. 68-97.

etiquette and dismissed such writings as being having nothing to do with ethics at all.

But as a matter of course, the revisionists have been revised and rightly so in my opinion. According to Robert Baker, the early critics were guilty of 'presentism' -- the fallacy of reading the past as if it were the present. By confusing the ethic of one time period with etiquette, it seems that the revisionists let contemporary controversies influence their reading and interpretation of past texts. I fully agree with Baker's reading and on this issue, I take inspiration from Alastair MacIntyre, who writes that we should allow 'the history of philosophy to break down our present-day preconceptions, so that our too narrow views of what can and cannot be thought, said, and done are discarded in the face of the record of what has been thought, said, and done'.<sup>19</sup> In regards to medical ethics, Andrew Morrice seems correct when he points out that the historiographical problem is a problem of semantics, generated by the changing content of medical ethics<sup>20</sup>. Many 'historians' of medical ethics, after all, have either been sociologists or health practitioners who have developed an interest in the historical and philosophical basis of medicine. Perhaps it is too much to ask that such scholars look for moral content in a professional ethic that can easily be read and rejected as self-serving. But as Roger French writes,

'Modern medical ethics derives from a particular nature of modern medicine and the society in which it exists. So a history of medical ethics is a history of medicine and of society and of the problems that looked ethical to them, but not necessarily to us. Looked at it in this way it soon becomes clear that ethics have a function, for the group that practices them, other than the internal, explicit injunctions that are normally seen as "ethical" in some abstract way ... Ethics comprise a system of rules that not only characterises the group but which in directing the behaviour of the group contributes to its success'.<sup>21</sup>

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<sup>19</sup> A. MacIntyre, 1998. *A Short History of Ethics: A History of Moral Philosophy from the Homeric Age to the Twentieth Century* 2ed. London: Routledge, p. 4.

<sup>20</sup> A. Morrice, 2002. 'Honour and Interests: Medical Ethics and the British Medical Association. In A. H. Maehle and J. Geyer-Kordesch, eds. *Historical and Philosophical Perspectives on Biomedical Ethics: From Paternalism to Autonomy?* Aldershot: Ashgate Publishing Limited, pp. 11-35.

<sup>21</sup> R. French, 1993. The Medical Ethics of Gabriele de Zerbi. In A. Wear, J. Geyer-Kordesch, and R. French, eds. *Doctors and Ethics: The Earlier Historical Setting of Professional Ethics*, p. 72.

On that note, I shall now turn to a short survey of the history of medical ethics.

*Medical ethics: From Hippocrates to Enlightenment*

The paradigm of Western medical ethics has largely been set by the Hippocratic Oath, which dates anywhere between the third and fifth centuries BC<sup>22</sup>. Whilst, as I cited earlier, the Oath is not the only text from Antiquity to address the topic of ethics in medicine, it is possible to identify at least two key themes throughout ancient writings<sup>23</sup>. The first is what we now refer to as deontology – that is, the prescription of duties and rules that physicians were required to observe if they wished to enter the profession. A second theme was that a doctor’s love for the art of medicine was to be reflected in proper decorum, which was the conduct befitting a member of the profession and included appearance, speech and comportment to put the patient’s confidence to rest. These twin themes run throughout medical ethics in the Middle Ages, through the Renaissance and into the eighteenth and nineteenth centuries.<sup>24</sup>

For example Gabriele de Zerbi’s work *Advice to Physicians* [1528] illustrates the self-regulatory nature of the medical profession<sup>25</sup>. At that time, fees were a crucial ethical issue and Zerbi wrote that it was a physician’s duty to cure their patient as quickly as possible since prolonged treatment would raise suspicions that the physician was only interested in securing greater fees. He also recommend taking cases where a fee may not be forthcoming (e.g. from paupers) since ‘it generates a laudable reputation’.<sup>26</sup> Zerbi’s text provided advice and strategies for preserving the reputation of both individual physician and the art as a whole. Echoing the ancient of proper decorum, Zerbi believed that a doctor must cultivate a life similar to that of a priest, acting faithfully for the good

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<sup>22</sup> Scholarly debates over the interpretation, authorship and influence of the Oath lie well beyond this thesis. See L. Edelstein, 1967. *Ancient Medicine: Selected Papers of Ludwig Edelstein*. O. Temkin and C. Temkin, eds., Baltimore: Johns Hopkins Press, and T. Rütten, 1993. Recent Scholarship on the Hippocratic Pseudepigrapha. *Society for Ancient Medicine Review* 21, pp. 148-160.

<sup>23</sup> M. Whong-Barr, 2001. Medical ethics in historical contexts. *Medicine, Health Care and Philosophy* 4: 233-235.

<sup>24</sup> W. Schleiner, 1995. *Medical Ethics in the Renaissance*. Washington: Georgetown University Press.

<sup>25</sup> D. E. Linden, 1999. Gabriele de Zerbi’s *De Cautelis Medicorum* and the Tradition of Medical Prudence. *Bulletin of the History of Medicine* 73: 19-37.

<sup>26</sup> Zerbi, 1528, f.lxix v. Cited in French, 1993, p. 77.

of the sick. To maintain the proper image, Zerbi thought that a doctor ought to avoid public displays such as dancing, or singing, or use of a weapon in hunting.

Subsequent medical texts similarly employ 'language and conceptions of medical practice, decorum, etiquette, and moral propriety that would be readily understood by ancient Greek or Roman practitioners'.<sup>27</sup> This claim is evident in an examination of eighteenth century medical ethics.

### *The medical ethics of John Gregory and Thomas Percival*

Many observers claim that the roots of what we today refer to as bioethics lie in the work of John Gregory and Thomas Percival. Laurence McCullough, for example, claims that Gregory was the first to use philosophical and secular medical ethics to address medical problems and that Gregory laid the groundwork for the profession of medicine as an intellectual and moral enterprise.<sup>28</sup> True or not, an evaluation of Gregory's work shows that medical ethics in the seventeenth and eighteenth centuries can still accurately be seen as an internal affair.

Gregory, a Scotsman, was Professor of Practice of Physic at the University of Edinburgh. His *Lectures on the Duties and Qualifications of a Physician*, published in 1772, were the textual account of oral lessons given to medical students, fellow physicians, and curious intellectuals of the time. His conception of medical ethics, no doubt, were heavily influenced by the Scottish Enlightenment and it is within that context that they should be seen.<sup>29</sup>

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<sup>27</sup> Baker, 1993, p. 861. See, for example, R. a Castro 1614. *Medicus Politicus*. Hamburg: Ex bibliopolio Frobeniano.

<sup>28</sup> See the two volumes: L. McCullough, ed., 1998a. *John Gregory's writings on medical ethics and philosophy of medicine*, Dordrecht: Kluwer Academic Publishers; L. McCullough, ed., 1998b. *John Gregory and the invention of professional medical ethics and the profession of medicine*, Dordrecht: Kluwer Academic Publishers.

<sup>29</sup> In addition to his adoption of Hume's work, Gregory also relied heavily on Francis Bacon and the Baconian scientific method for his philosophy of medicine and natural science. As is well known, Bacon rejected dogmatic adherence to authorities and systems of abstract classification that were not based on careful description of symptoms and disease categories. Instead, Bacon asserted that the foundation of knowledge ought to be observation and open mindedness to results of experimentation. According to Gregory, evidence that contradicts a doctor's long held beliefs must be accepted. See Gregory's *Lecture V* in McCullough, 1998a, pp. 215-230.

According to Gregory, a professional was someone who lived according to 'fiduciary obligations' of service to patients rather than the dictates of self-interest.<sup>30</sup> Gregory's 'invention' of medicine as such was in response to the considerable disarray that characterized eighteenth century medicine. This state, described as an 'open world', derived partly from the fact that there were competing accounts of the origins of disease and illness. (Of course such circumstances were not unprecedented and could be found in Antiquity, where competing groups vied for patients and medical power). Given the high numbers of practitioners and the lack of a dominant clinical science to evaluate what physicians did, patients in Britain could summon any number of doctors or healers, or merely 'self-physick'. In this context, trust and character often provided the basis for a patient to select their doctor. However, this manner of choosing a physician eventually became problematic. Inferring from ones manners to their actual character became difficult, as 'counterfeit men of feelings' merely feigned their manners in order to suit their own purposes.<sup>31</sup> According to McCullough, Gregory's response to this so-called commodification of character was to base his ethics on moral sense philosophy.

According to McCullough, Gregory based much of his medical ethics on Hume's understanding of moral sense.<sup>32</sup> Of critical importance to both Hume and Gregory was the idea of sympathy, which both believed to be a natural part of human instinct and the cause of many natural sentiments. Sympathy, as Hume used the term, referred not just to

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<sup>30</sup>McCullough, 1998a, pp. 283-293. The phrase is McCullough's.

<sup>31</sup>For more on this, see: M. Fissel, 1993. Innocent and Honorable Bribes: Medical Manners in Eighteenth-Century Britain. In R. Baker D. Porter, R. and Porter, eds., *The codification of medical morality: historical and philosophical studies of the formalization of Western medical morality in the eighteenth and nineteenth centuries*, Vol. I, Dordrecht: Kluwer Academic Publishers, pp. 19-46.

<sup>32</sup> This point is in dispute. Haakonssen believes that Gregory drew his notions of sympathy from Adam Smith's work as much if not more than Hume's. The difference, according to Haakonssen, is that 'sympathy for Hume, consists of an identification of the sentiments of the object of sympathy so that these sentiments become those of the sympathising person as well' whilst for Smith 'sympathy consists in putting oneself imaginatively in the situation of the other person, which may or may not lead one to have the same sentiments as this person'. (p. 71) Again, the finer points of historical interpretation whilst important and interesting, do not concern my overall thesis and are beyond the scope of this work. See L. Haakonssen, 1997. *Medicine and morals in the Enlightenment: John Gregory, Thomas Percival and Benjamin Rush*, Amsterdam: Rodopi.

a 'particular sentiment but to a psychological capacity to feel and arrive at sentiments'.<sup>33</sup> In Hume's moral theory, a person was capable of receptively and responsively sharing another's opinion, distress, pleasure, or emotion. Hume believed, for example, that when we see another person in pain, this impression leads to the same impression of pain in ourselves.

According to Gregory's philosophy of medicine, sympathy, properly trained and regulated, ought to lead to one having the same pain or experience as the sick patient. This feeling then motivates appropriate medical action. Gregory understood sympathy as generating 'tenderness', an asexual virtue that moves us to enter into the suffering of others. The duty of a physician, then, was to relieve that suffering and cure disease. Gregory writes,

'The chief of these [moral qualities required of a physician] is humanity; that sensibility that makes us feel for the distresses of our fellow creatures, and, which, of consequence, incites us in the most powerful of ways. Sympathy produces an anxious attention to a thousand little circumstances that may tend to relieve the patient; an attention which money can never purchase ... Sympathy naturally engages the affection and confidence of a patient, which, in many cases, is of utmost consequence to his recovery ... Real sympathy is never ostentatious; on the contrary it rather strives to conceal itself'.<sup>34</sup>

Real sympathy, in other words, showed strength of character that Gregory believed could be used as a means of distinguishing between counterfeit and genuine doctors. It is this moral basis that differentiates those who practise medicine as an art and those who practised it primarily as a trade. Gregory believed that only a moral physician could cure the ill since it was through sympathy that the physician engaged the patient, enhancing the likelihood of an effective cure. All other practitioners of medicine were motivated by gain and sought to perpetuate the 'sick trade'<sup>35</sup>.

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<sup>33</sup>D. Hume, 1998. *An Enquiry Concerning the Principles of Morals*. Reprinted in T. Beauchamp, ed., Oxford: Oxford University Press, p. 220.

<sup>34</sup> Gregory's *Lectures*, in McCullough, 1998b, p. 170.

<sup>35</sup> Quoted in Jonsen, 1999, p. 61.

Gregory's work has been described as laying the basis for bioethics and on this point I'd like to take a brief digression. McCullough claims that Gregory's *Lectures* 'invented philosophical, secular medical ethics'. McCullough's argument is that Gregory anticipated many of bioethics' themes, particularly by 'laying medicine open' to accountability using the tools of ethics and philosophy<sup>36</sup>. McCullough credits Gregory with writing the first feminine medical ethics, where feminine indicates an ethic based on a 'feminine consciousness that regards the gender traits associated with women as positive human traits'.<sup>37</sup> (Following Rosemarie Tong, McCullough contrasts this with 'feminist ethics', which McCullough takes to mean a political agenda to redress oppression at the hands of men.) For Gregory, women of learning and virtue provided role models for physicians who were concerned with physician-patient relationships. Such relationships should be asexual and disinterested, but *not* detached.

This claim, to me, seems spurious. While not wanting to wade too deeply into debates on interpretation of eighteenth century texts, I'd suggest that McCullough attributes too much to Gregory and ignores the integral role philosophy has played in the formation of medical practice and ethics prior to the Enlightenment. Much depends on how one defines bioethics. My own understanding of the field has less to do with doctors making use of philosophical texts (something which has always happened) and more to do with non-medical actors directly influencing the professions' judgements of right and wrong behaviour. This is not the case in regards to Gregory who was a respected physician. In other words, there is a difference between Gregory using the work of Hume and Hume himself being called to testify before Parliament on medical ethics.

Whether one agrees with McCullough or not, it is evident from Gregory's work that medical ethics was still a matter of doctors prescribing to other doctors how to behave when dealing with each other, their patients, and the wider society. The same thread is evident in Thomas Percival's work.

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<sup>36</sup> L. McCullough, 1999. Laying medicine open: Understanding major turning points in the history of medical ethics, *Kennedy Institute of Ethics Journal* 9: 7-23.

<sup>37</sup> McCullough, 1998a, pp. 6-7.

Percival's *Medical Ethics* (sometimes referred to as the *Code*, shortened from its full title and to signify its later importance in the codification of professional medical ethics) was written in response to a request by the Manchester Infirmary to develop ethical guidelines for the city's new hospital.<sup>38</sup> One of the central aspects of this work was that Percival advocated that individual judgment be subordinated to collective decision making. Such an approach was necessary, in part, because of the nature of hospitals and the real possibility of professional differences between physicians, surgeons and apothecaries (and, of course, trustees). Divergent judgments over treatment were likely given the different training and traditions that each specialization derived from. Percival, by emphasizing formal conferences (today called rounds) and collaboration attempted to solve conflict by suspending the usual hierarchy, favouring collective decisions over individual ones, and providing a hospital faculty board for arbitration and adjudication.

However, historians have differing interpretations of Percival's Code. As I mentioned earlier, Percival's desire to limit professional conflict is seen by Leake, Waddington and Berlant as evidence of his obsession with etiquette. Baker, meanwhile, views it as a contractual duty which enabled Percival to write 'the epitaph for individualistic virtue ethic in medicine', replacing it with notions of a 'collaborative profession committed to the development of a scientific, empirically based medicine, dedicated to treating the sick, whether rich or poor, and subjecting the treatment decision of individual practitioners to intra-subjective validation by their peers.'<sup>39</sup> Jonathan Pickstone believes

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<sup>38</sup>Historians of the hospital have pointed to numerous factors in the rise of the hospital, including the growth of trade, expansion of towns, increased social and geographical mobility, and recognition of the utility of having a single place to study disease and train professional doctors. The 'raison d'être' of hospitals was their charity function: they were aimed at the 'deserving poor', i.e. the working poor, those from 'respectable' families who held promise of returning to the work force and criteria for admission tended to favour young and productive members of the labour force, afflicted by acute but brief illnesses from which rapid recovery was expected. See G. Risse, 1998. *Medicine in the age of Enlightenment*, pp. 149-195, and L. Granshaw 1998. *The rise of the modern hospital in Britain*, pp. 197-218. Both in A. Wear, ed., *Medicine in Society: Historical Essays*. Cambridge: Cambridge University Press; and, G. Risse, 1986. *Hospital Life in Enlightenment Scotland*. Cambridge: Cambridge University Press.

<sup>39</sup>R. Baker, 1993. Deciphering Percival's Code. In R. Baker, D. Porter, and R. Porter, eds., *The codification of medical morality: historical and philosophical studies of the formalization of Western medical morality in the eighteenth and nineteenth centuries, Vol. I*, Dordrecht: Kluwer Academic Publishers, pp. 179-211. Baker does recognize the influence of biopolitics on Percival, but his account is questionable for two reasons: (1) his distinction between biopolitics and bioethics is dubious, and (2) he argues that Percival was

that *Medical Ethics* was the consequence of an Infirmary dispute in which Percival was a central player.<sup>40</sup> Pickstone argues that the Manchester Infirmary Board wanted to make certain that a publicly embarrassing conflict over staffing numbers did not happen again and so asked Percival to devise a code of conduct. While this account is clearly accurate, I think it misses part of the picture. I agree fully with Haakonssen that an important and overlooked part of *Medical Ethics* was Percival's obsession with hygiene and fever control. In other words, the *Code* serves as an early (and exceptional) example of the connection between medical ethics and public health.<sup>41</sup>

Evidence for this connection is throughout *Medical Ethics*. One fear was the risk of spreading disease within hospital wards. Measures to combat hospital born illness pre-occupied Percival. Much of the 'Notes and Illustrations' section of *Medical Ethics* is filled with detailed prescriptions of how to sanitize wards and properly structure hospital grounds. Included are internal regulations for the House of Recovery, such as rules on changing bed linen, cleaning clothes, sanitizing floors and walls and proper removal of the dead.<sup>42</sup>

At least one thing not in dispute is that *Medical Ethics* was syncretic in nature. The large number of sources that Percival drew upon include: an advisory committee of Manchester practitioners, which gathered existing regulations from hospitals across Britain; the work of John Gregory, from which Percival's language of moral sense and sympathy derives; and Thomas Gisborne, whose work provided Percival with the notion that the office of medicine had a professional duty, based in a societal-professional contract, to serve citizens in return for privileges such as the right to secure a 'lucrative occupation'.<sup>43</sup>

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'transformed' from a biomedical politician to a biomedical ethicist, but such a transformation seems not only overly dramatic, it also (again) overstates the distinction between politics and ethics.

<sup>40</sup>J. Pickstone, 1993. Thomas Percival and the Production of *Medical Ethics*. In Baker, et al, *The codification of medical morality*, pp. 161-178.

<sup>41</sup>Haakonssen, 1997.

<sup>42</sup>Percival's *Code*, in Leake, 1975, p. 167-178.

<sup>43</sup>For more on Gisborne, see: R. Porter 1993. Thomas Gisborne: Physicians, Christians and Gentlemen. In A. Wear, et al. eds. *Doctors and Ethics*, pp. 252-273. Porter argues that works like Gisborne's did not have a profound impact on medical ethics per se, but upon 'the ethics behind medicine'. Through their family and education, most doctors were familiar with Gisbornian precepts such as the value of the golden rule over raw ambition or personal glory. Porter credits Gisborne with influencing Percival to the extent that the

Albert Jonsen writes that after the 'significant works' of Gregory and Percival, Great Britain produced little original work in medical ethics for more than a century<sup>44</sup>. The notion that doctors knew best how to regulate doctors was not challenged. According to Roy Porter, 'In a characteristically British manner, professional bodies judged that the decision [of ethical behaviour] must be left to the doctor's scruples. The ingrained habits of individuality, specific to English liberal politics, and the cult of the gentleman that formed the unspoken code of male elites ... meant that in professional eyes and, to a large degree, equally in the public mind the ethical dilemmas raised by medicine were best handled not by the law courts, jurists, academic philosophers or Parliament but by the integrity of private practitioners following clinical judgement and their own consciences'<sup>45</sup>.

In evaluating the ethics of Gregory and Percival, we have seen that medical ethics was a topic discussed almost exclusively by doctors. Despite the changes in the medical world in the following century, this fact remained largely unchanged.

### *Nineteenth and early twentieth centuries*

Medical ethics in the nineteenth century was defined by increased codification of ethical standards.<sup>46</sup> Again, this was a process done from within the medical profession. Indeed, Percival's work was instrumental in this regard. But in order to understand something of

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Code was deontological and not utilitarian. His article also aims to show the continued but sometimes neglected influence of religion in eighteenth century medical ethics.

<sup>44</sup> Jonsen, 1999, p. 62.

<sup>45</sup> R. Porter, 1995. Medical ethics, history of nineteenth century Great Britain. In W. T. Reich, ed. *Encyclopedia of Bioethics*, Vol. III. New York: Simon and Schuster MacMillan, p. 1553.

<sup>46</sup> In the United States Percival's *Medical Ethics* had been influential in the development of a Code of Ethics for the American Medical Association (AMA). Led by the efforts of Benjamin Rush, the AMA's Code accepted both Gregory's medical humanism (based on sympathy) and Percival's regulations on professional consultation and adjudication of disputes. For more on the AMA and its impact, see: R. Baker, A. Caplan, L. Emanuel, and S. Latham, eds., 1999. *The American Medical Ethics Revolution: How the AMA's Code of Ethics has Transformed Physicians' Relationships to Patients, Professionals, and Society*. Baltimore: Johns Hopkins University Press. For more on reciprocity in Anglo-American medical ethics, see C. Burns, 1995. Reciprocity in the Development of Anglo-American Medical Ethics, 1765-1865. In R. Baker, ed. *The codification of medical morality: historical and philosophical studies of the formalization of Western medical morality in the eighteenth and nineteenth centuries* Vol. II, London : Kluwer, pp. 135-144.

nineteenth century medical ethics, it is useful to first examine the context of medical practice. Impetus for greater regulation/codification in medical ethics lies in the diverse and confused state of the medical 'profession' in the eighteenth and nineteenth centuries. The so-called tripartite division of medical men (as many have pointed out, it usually was men) consisted of physicians, surgeons and apothecaries. Physicians held university degrees and did not undertake manual labour. They were recognized as the highest order of the division and because of their education, had the right to oversee the other two branches. Surgeons treated external complaints (e.g. skin conditions, wounds), set broken bones, and performed simple operations. At the lowest part of the division, apothecaries dispensed prescriptions written by physicians but were forbidden – in theory, not practice – from directly treating patients.

Part of the need for greater regulation lay in the fact that the medical field was greatly overcrowded. Estimates indicate that there were approximately 10.7 practitioners per 10,000 people in the 1840s for England and Wales<sup>47</sup>. This is almost double the amount of practitioners as in France during the same time period. Part of the reason lies in popular and thriving medical schools and part in the proliferation of alternative healers, which helped to crowd the market place of medical care. Overcrowding often meant greater choice and cheaper service for the public, but less income for the profession. Irvine Loudon shows how between 1781 and 1851, nominal earnings for surgeons and doctors was far below that of barristers, clergy, and engineers<sup>48</sup>. In this context, it is not surprising that medical practitioners would advocate formal regulation of medical qualification and practice.

The nineteenth century saw the formation of the the General Medical Council (GMC), the most important body in the UK for regulating the medical profession. With its powers granted from Parliament, the GMC controls the register of those people judged competent

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<sup>47</sup> T. Gelfand, 1993. The history of the medical profession. In W.F. Bynum and R. Porter, eds. *Companion encyclopedia of the history of medicine*. London: Routledge, pp. 1119-1150.

<sup>48</sup> I. Loudon, 1986. *Medical care and the general practitioner, 1750-1850*, New York: Oxford University Press.

to practice medicine<sup>49</sup>. The Council regulates entry to the register by deciding what qualifications are necessary to practice and has the authority to remove practitioners from the register temporarily, or permanently, when they have been judged incompetent and unfit to practice. The Council exercises its powers by coordinating medical education within the UK, including the inspection and accreditation of medical schools. As far as competency of practitioners, the GMC also examines complaints against the physical or mental fitness of registered doctors. As the GMC has no inspectorate, (i.e. it cannot act as a 'police force') it must rely upon outside parties to initiate complaints regarding professional misconduct<sup>50</sup>.

In order to regulate the profession, the GMC established a single public register to recognize all legal practitioners. The profession was, in other words, symbolically united and defined over and against the 'Other', i.e., quacks, healers and tradesmen.<sup>51</sup> The practice of healing by non-registered practitioners was not made illegal, but people not on the register were disqualified from holding public medical office. The primary rationale for the establishment of the GMC was 'to enable the public to identify those who were acceptably qualified as opposed to the one in three then thought to be practicing without qualifications'.<sup>52</sup> Added to this of course, was the demand within the profession to create the circumstances in which income and status could be improved and insured. 'Interests of the public', writes Stacey, 'were a secondary, not a primary consideration.'<sup>53</sup>

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<sup>49</sup> R.G. Smith, 1995. *Legal Precedent and Medical Ethics: Some Problems Encountered by the General Medical Council in Relying upon Precedent when Declaring Acceptable Standards of Professional Conduct*, pp. 205-218. In R. Baker, Ed., 1995. *The codification of medical morality: historical and philosophical studies of the formalization of Western medical morality in the eighteenth and nineteenth centuries Vol. II*, London : Kluwer; R.G. Smith, 1994. *Medical discipline : the professional conduct jurisdiction of the General Medical Council, 1858-1990*, Oxford : Clarendon Press; M. Stacey, 1993. *The British General Medical Council and Medical Ethics*. In G. Weisz, ed.. *Social Science Perspectives on Medical Ethics*, Philadelphia: University of Pennsylvania Press, pp. 163-184; M. Stacey, 1992. *Regulating British medicine : the General Medical Council*, New York: Wiley.

<sup>50</sup> Stacey, 1992, p. 215.

<sup>51</sup> R. Porter, 1993. *Disease, medicine and society in England, 1550-1860*. Cambridge: Cambridge University Press, p. 48

<sup>52</sup> Stacey, 1992, p. 1.

<sup>53</sup> Stacey, 1992, p. 20. GMC Minutes from 1858 to 1990 show that the types of cases include allegations of sexual, drug and alcohol offenses, financial improprieties, matters pertaining to abortion, drug prescription, breach of confidence/consent, and obtaining registration by fraudulent means. For a detailed correlation between the types of cases and the years they were brought before the Council, see Stacey, 1992, pp. 231-366.

The GMC, Margaret Stacey believes, is often confused in the public mind with the BMA. While the former is a statutory body charged by an Act of Parliament, the BMA is a voluntary association of medical practitioners concerned to improve their own 'terms and conditions of service'<sup>54</sup>. In accomplishing this, the BMA is naturally keen on making sure its members offer the best possible health care. It often seeks to influence the GMC on behalf of its members and on matters it considers important to the profession. However, neither the BMA, nor the Royal Colleges can directly influence the medical curriculum or strike practitioners off the register.

The BMA, founded in 1832, was set up by medical doctors who were frustrated at the way in which their professional life was organized under the Royal Colleges and wanted a new organization to promote their needs. The primary aims of the early Association was to collect medical information, increase the spread of medical knowledge throughout England. During the 19th century, attempts to form a medical ethics committee within the BMA came to nothing. The subject was not entirely ignored, but ethical issues were addressed on an ad hoc basis. It was not until 1902 that a Central Ethics Committee (CEC) was set up to support the BMA's aim of maintaining the 'honour and interests of the medical profession'.<sup>55</sup> The CEC was the first time ordinary doctors in Britain had a national body to hear ethical matters without having to resort to hearings before the Royal Colleges or GMC. It was also the first time a national body had been available to settle disputes between individual practitioners<sup>56</sup>.

BMA ethics drew heavily from the work of Jukes Styrap, who recommended his own *Code of Medical Ethics* as the professional standard for Britain.<sup>57</sup> The BMA did not adopt

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<sup>54</sup>Stacey, 1992, p. 14.

<sup>55</sup> A. Morrice, 1999. 'Honors and Interests': medical ethics in Britain, and the work of the British Medical Association's Central Ethical Committee, 1902-1939. Unpublished MD thesis, University of London.

<sup>56</sup>According to Morrice, the medico-political pressures that finally contributed to the formation of the CEC included the availability of free medical care in outpatient voluntary hospitals, overcrowding, and interference of non-medical authorities in the profession. See Morrice, 1999 and 2002.

<sup>57</sup> P. Bartrip, 1995. An Introduction to Jukes Styrap's *A Code of Medical Ethics (1878)* In R. Baker, *Codification of medical morality*, pp. 145-148; J. Styrap, 1878. *A Code of Medical Ethics: The duties of medical practitioners to the public and to the profession at large, to each other, and to themselves*. In Baker, pp. 149-172.

his offer, but Styrap's *Code* was recognized as the de facto, if not de jure authority. Styrap drew heavily from Percival in his advice to 'unite tenderness with firmness' in dealing with patients, to limit visits so as to not diminish the authority of the practitioner, to avoid 'gloomy prognostications' and to not use 'secret nostrums' (medicines of undisclosed composition). Styrap also placed a high value on the merit of consultation with other doctors.<sup>58</sup>

Issues brought before the BMA and GMC in the 19th and early 20th centuries included both intra-professional disputes and issues with wider society.<sup>59</sup> Morrice has shown that one key issue brought before the BMA and GMC was advertising, a significant problem within the profession. Adverts were associated with 'secret nostrums' (Percival's phrase) and unlawful abortions. Placing adverts was regarded as making an overt claim to superior quality, and therefore was considered to be not gentlemanly, i.e. unethical. Rather than associating themselves with profit making and trade, doctors relied on word of mouth for new clients. Advertising was seen as damaging to the professions social status and opposed to the ideal of a 'disinterested' professional. Success in curbing adverts was deemed vital in distinguishing practitioners from tradesmen and 'quacks'.

Within the profession, there were disputes between registered and non-registered practitioners. For instance, warnings were issued against associating or seeking consultation from those not on the official register. In addition, the status of homeopaths created tension as to the definition and proper theories of acceptable therapeutics. Another issue was how to define the difference between 'general practitioners' and 'consultants' and ensuring that non-registered practitioners were not being used in consultations. But the most crucial problem may have been finding a proper balance regarding trust amongst physicians (i.e. within the profession), and a doctors' duty to the well being of their patient. In other words, who maintained 'control' over the patient was a particular cause for ethical concern and debate..

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<sup>58</sup> Morrice, 1999.

<sup>59</sup> The following list is compiled from Morrice, 1999 and 2002; and, J. S. Horner, 1994. *The Development of Medical Ethics Within The British Medical Association, 1832-1993*. Unpublished MD thesis, University of Manchester

In relation to physician-patient relationships, secrecy was a prime source of concern. This was often connected with sexual relations (i.e. abortion, illegitimate pregnancy, or divorce proceedings) and venereal disease. Interestingly, matters of consent were raised in the context of confidentiality more than in relation to surgery or other treatment. Morrice notes that this had more to do with 'honor and interests' than rights and autonomy. He writes,

'In medico-legal texts consent for surgery (especially for sterilizing operations) was mentioned in the 1920s and to a greater extent in the 1930s. In terms of medical ethics, consent was cited in connection with the revelation of secrets. 'It is tempting to argue that the most dangerous thing a doctor could do to his best-paying patients at this time was not so much harm them physically without consent, but to ruin them socially without consent. The injury in the latter case seemed as important to both doctor and patient as the possibility of physical harm, if not more so'.<sup>60</sup>

Medical ethics, it seems, was largely a virtue ethic based on gentlemanly values of group and individual honour, mediated by duties to fellow professionals. The goal of ethics was to distance medicine from notions of a 'trade' and establish 'disinterested' norms of medical conduct.

As Morrice aptly puts it, 'medical ethics can be seen as an integral part of medicine's strategy of professionalization, by adjudicating between right and wrong behaviour where this is not defined by the law. It plays a key part in the continual re-negotiation of the social contract between profession, patients, and society, in the definition of the characteristics and role of doctors, and in the definition of who and what lies beyond the medical pale. Whilst the way in which attempts to maintain and promote the position of medicine have shifted as the medical and social context shifted, this basic formulation arguably holds true in all periods.'<sup>61</sup>

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<sup>60</sup> Morrice, 1999, p. 287.

<sup>61</sup> Morrice, 2002, p. 30.

### *Summary and conclusion*

In this chapter I have shown that:

- The sociological writings of Waddington, Berlant and Leake mischaracterise the history of medical ethics by conflating the term ethics with etiquette. Whilst historically medical ethics did appeal to the honour of physicians and the profession, this does not mean that issues lacked moral content.
- The historiographical problem presented by the changing content of ethics can best be dealt with, in MacIntyre's words, by allowing the history of philosophy to break down our contemporary preconceptions, so that our parochial views of 'what can and cannot be thought, said, and done are discarded in the face of the record of what has been thought, said, and done'.
- The Hippocratic Corpus in many ways set the tone for medical ethics by emphasising the importance of duties (i.e. beneficence) and decorum, that is the conduct befitting a member of the profession. The Oath, specifically, is paradigmatic of the history of medical ethics in that it can be read as an attempt by those trained in medicine to debate and adjudicate moral issues in their field. That is to say, medical ethics was self-regulatory.
- Evidence for this claim can be seen in the work of physician Gabriele de Zerbi's influential text *Advice to Physicians* which laid out a series of duties regarding the taking of fees and the preservation of the reputation of both individual doctors and the art of medicine as a whole.
- Further evidence for the self-regulatory nature of medical ethics can be found in the work of Gregory and Percival. The former based his system of ethics largely on Scottish moral sense philosophy as a means of promoting the credibility of the profession in a time of extreme variation amongst different types of healers and

medicines. Percival, another prominent physician, wrote a series of guidelines for hospital medicine, which developed a code that encouraged physicians, surgeons and apothecaries to limit professional rivalry and disputes – again, for the sake of not only patient health but the honour of medicine.

- The nineteenth century, which witnessed a growth in the codification of ethics, still was largely a matter of doctors regulating doctors. As bodies such as the AMA, GMC, and BMA were established, it gave physicians the means by which to mediate intra-professional disputes. Critical issues during this time were the collection of fees, proper rules for consultation, secrecy, and advertising.

I have provided this survey in order to better contextualise the birth of bioethics, in which the centuries long tradition described above began to break down in the face of wider social, political and technological change.

## Chapter Three

### The birth of biomedical ethics: a history

*'And the final model [of the history of bioethics] which the people who drifted toward it would probably not identify as a model, is the one that most of us really secretly believe. This is the model that says history is one damned thing after another.'*<sup>62</sup>

-- Daniel Fox

#### *Introduction*

In the last chapter we saw that historically moral issues were debated and resolved from within the medical profession itself. Whilst some have dismissed this as mere etiquette, I've argued that such distinctions fail to appreciate the moral content of past eras. In this chapter I explore the birth of bioethics, defined as a shift away from intra-professional regulation to a situation which allowed a greater role for outsiders in judging right and wrong in medical affairs. I begin with historians' views on the emergence of the field, and move into the aftermath of World War Two. I then examine the role of the courts and academia in the development of biomedical ethics. An underlying theme of the narrative is the growth of the principle of patient autonomy and the associated doctrine of informed consent. My discussion focuses on events primarily in the US and Britain and includes examples and cases from both clinical and research settings. Whilst there is distinction between the two, there is also potential and important overlap as I show in Chapter Six. That is, it is often in the clinical setting that samples for research are requested, consented to, and collected. Thus, the lines between clinic and research are sometimes blurred.

#### *Received views of the rise of bioethics*

There seem to be two main views or models as to the history of biomedical ethics. One common view is that bioethics developed in response to new and unprecedented medical technologies. This view, commonly identified with Albert Jonsen, holds that the field is the product of the incredible technological developments of the post-War era. Traditional

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<sup>62</sup> D. Fox, 1993. View the second. *The birth of bioethics: Special Supplement, Hastings Center Report* 23: S12.

moral arguments, this version goes, seem unsuited or unable to address new problems such as who should receive kidney dialysis or if (and when) a person could be removed from life support machines. In light of technology's intervention into what were previously and only natural processes, religious and medical traditions have become incapable of resolving new dilemmas. An ethic internal to medicine could not solve these new problems that were more population based rather than patient focused (as in the case of the Tuskegee scandal in the US, or resource allocation conflict with dialysis). Jonsen writes, that 'Almost all the ethical problems faced by the old ethic could be resolved within the framework of a relationship between the professional and the patient; the ethical problems posed by the new medicine reflect the omnipresence of the population that stands behind the patient'.<sup>63</sup>

A second view of the history of bioethics is that the turbulent 1960s rights movements spilled over into patient's rights. Warren Reich, for instance, argues along these lines.<sup>64</sup> As the rights movement grew and courts progressively intervened on behalf of individuals, physicians increasingly feared prosecution. Yet doctors also found it difficult to forgo the beneficence model and simply accede to individual's wishes when those wishes meant harm and in some cases, the death of the patient. Some have suggested that bioethics, when pared down to its basics, is nothing more than assertion of patients' right to autonomy. At face value, this account does have appeal. One of the central tenets of bioethics, consent, is an effort to recognise and protect autonomy. As one observer of the conflict between beneficent paternalism and self-determination put it, the dialogue between professional and patient seemed to be: 'you may be trying to croak buddy, but I'm going to keep you alive whether you want to or not'.<sup>65</sup>

Allied to both of these models is David Rothman's view that so-called 'strangers' or 'outsiders' increasingly played a greater role in answering questions that were once the exclusive domain of medical professionals. Rothman, like Reich, links human research

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<sup>63</sup> A. Jonsen, 1990. *The New Medicine and Old Ethics*. Cambridge: Harvard University Press, p. 35.

<sup>64</sup> Reich, 1995; Whong-Barr, 2001.

<sup>65</sup> S. Alexander, 1993. Thirty years ago. *The birth of bioethics: Special Supplement, Hastings Center Report* 23: S5.

and patients' rights to the larger rights-oriented movements of the 1960s. Such linkage was assured because the 'great majority of research subjects were minorities, drawn from the ranks of the poor, the mentally disabled, and the incarcerated'.<sup>66</sup> Rothman sought to explain the transference of medical decision-making in the US from the authority of individual physicians to committees of lawyers, academics and government advisors. Rothman writes, 'attitudes and practices initially formulated to cope with laboratory practices' quickly spread to bedside practices, and as a result the social distance between doctor and patient widened, as it did between hospitals and communities (thus the 'strangers' in his well known book title reflects a double meaning, as both physician and ethicist were suddenly outsiders to the patient).<sup>67</sup> In time as doctor and community moved apart, the 'practical wisdom that the practitioner had accumulated over the years of clinical experience seemed less impressive and relevant than the wisdom that the philosopher or lawyer had accumulated through the study of first principles. In effect, bedside ethics gave way to bioethics'.<sup>68</sup>

In my view, these models are not mutually exclusive, although, at times, proponents of them seem to suggest so. Whilst I do not mean to minimize differences or conflate accounts, I do believe that various models can be read as more or less complimentary. In the following section, I examine the context and issues that gave rise to changes in medical decision making.

### *The impact of the Second World War: Nuremburg and Helsinki*

The atrocities of the Second World War gave new imperative to the need for the international codification of medical ethics and the involvement of non medical officials in developing regulations. The resulting codes gave primacy to the concept of informed consent but it must be noted that the history of consent pre-dates the Nuremburg Trials. In the nineteenth century there was a considerable body of literature on the dangers of human research, the most celebrated being Claude Bernard who wrote that one should

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<sup>66</sup> D. Rothman, 1991. *Strangers at the bedside : a history of how law and bioethics transformed medical decision-making*, New York: Basic Books, p. 10.

<sup>67</sup> Rothman, 1991, p. 11.

<sup>68</sup> Rothman, 1991, p. 11.

never perform an experiment 'which might be harmful', no matter the utility of the results.<sup>69</sup> Years later, in 1900, a directive from the Prussian Minister of Religious, Educational and Medical Affairs prohibited experiments on incompetent persons and required the consent of subjects in non-therapeutic clinical trials.<sup>70</sup> And finally (somewhat ironically) in 1931 the German Reich had issued relatively strict guidelines (*Richtlinien*) regarding therapeutic and non-therapeutic human experimentation. The provisions, no less stringent than the Nuremberg Code, addressed questions of consent, research design, and special protection for vulnerable subjects.

Despite these early guidelines, human experimentation continued unregulated and unabated. Experiments conducted during the Second World War are well known and require little introduction: oxygen deprivation; prisoners frozen to death; others infected with malaria, typhus, cholera, smallpox, then 'treated' experimentally; forced sterilization; twin studies that involved transplanted genitals and other organs; simulated battle wounds, allowed to infect, then either ignored or selected for sulphanilamide treatment.

In Nuremberg, twenty German physicians and three administrators were charged with murders, tortures and other atrocities committed in the name of medical science.<sup>71</sup> Seven defendants were imprisoned, nine were hung, and the remainder were acquitted<sup>72</sup>. As part of the case, the Tribunal articulated ten basic principles to ensure ethical non-therapeutic medical research. These principles are now known as the Nuremberg Code [1947], the first tenet of which states:

'The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be

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<sup>69</sup> Quoted in Rothman, 1991, p. 23.

<sup>70</sup> A. H. Maehle, 2000. Assault and Battery, or Legitimate Treatment? German Legal Debates on the Status of Medical Interventions without consent, c. 1890-1914. *Gesnerus* 57: 206-221.

<sup>71</sup> T. Beauchamp, R. Faden, and N. King, 1986. *A history and theory of informed consent*. New York: Oxford University Press, p. 154.

<sup>72</sup> Whilst it is generally assumed that Americans were largely responsible for the Nuremberg Tribunal, Paul Weindling has shown how British agencies contributed significantly to the process by conducting their own inquiries, briefing their American counterparts and providing extensive forensic evidence for the trial. See P. Weindling, 2001. The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code. *Bulletin of the History of Medicine* 75: 37-71.

able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision<sup>73</sup>.

The remainder of the first principle goes on to state the investigators' duty to disclose the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon the subject's health or person which may possibly come from their participation in the experiment.<sup>74</sup>

Subsequent principles addressed duties such as: the need for research to be directed towards a human good and not be random in nature; for research to be based on the results of animal experimentation; the need to avoid unnecessary physical or mental injury or death; and requirement that all work be conducted by scientifically qualified researchers. The Code also allows for the subject to withdraw from research and instructs the investigator to end experiments that develop in ways which seem likely to result in harm.

The medical profession had many reservations about Nuremberg. Foremost amongst these was the concern that the Code seemed to forbid research on unconscious patients, psychiatric patients, and children. In addition, 'the Code's professional origin outwith [sic] medicine was a hindrance for its acceptance by the *medical* research community'<sup>75</sup>. As a result, the World Medical Association drafted the Declaration of Helsinki (1964) to address the different types and complexities of medical research and to allay scientists' concerns that Nuremberg may have been too restrictive on legitimate research. Helsinki introduced a division between therapeutic and non-therapeutic investigations. The former

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<sup>73</sup> The Nuremberg Code, United States v Karl Brandt, et al, 2000. Reprinted in J. Tobias and L. Doyal, eds. *Informed Consent in Medical Research*. London: BMJ Books, p. 3-4.

<sup>74</sup> Nuremberg Code, 2000, in Tobias and Doyal, p.3-4.

<sup>75</sup> U. Troehler, 2002. Human Research: From Ethos to Law, from National to International Regulations. In A. H. Maehle & J. Geyer-Kordesch, eds. *Historical and Philosophical Perspectives on Biomedical Ethics: From Paternalism to Autonomy?* Aldershot: Ashgate Publishing Limited, p. 101.

is defined as research 'combined with patient care', whilst the latter is defined as purely scientific research without therapeutic value or purpose for the subjects studied. The Declaration introduces the concept of proxy consent for those incompetent to decide and for therapeutic research reads that consent is not required if it is not 'consistent with patient psychology'<sup>76</sup> – a fairly vague phrase that, according to two observers, relies on the same beneficence-based premises as the physician's therapeutic privilege in [clinical] medical practice<sup>77</sup>. Successive versions of the Declaration made new amendments, including the introduction of the concept of ethics committees as a buffer between investigators and their research subjects.<sup>78</sup>

In 1953, in between the Nuremburg and Helsinki codes, Britain's Medical Research Council's (MRC) issued guidelines regarding proper conduct in human research. The MRC document is worth quoting at some length since it nicely captures the British attitude at the time towards human experimentation:

'To obtain consent of the patient to a proposed investigation is not in itself enough. Owing to the special relationship of trust which exists between a patient and his doctor, most patients will consent to any proposal that is made. Further, the considerations are nearly always so technical as to prevent their being adequately understood by one who is not himself an expert. It must, therefore, be frankly recognised that, for practical reasons, an inescapable responsibility for determining what investigations are, or are not, undertaken on a particular patient will rest with the doctor concerned'.<sup>79</sup>

This extended quote illustrates the tension between an international movement to give research subjects greater rights and centuries long habit of leaving such decisions to physicians. It seems that whilst these codes set the *goal* for medical researchers, they in

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<sup>76</sup> Declaration of Helsinki, 1964. *British Medical Journal* 2: 177.

<sup>77</sup> Beauchamp, et al, 1986, p. 156.

<sup>78</sup> For a personal insight on the evolution of Helsinki and a commentary on its strengths and weaknesses, see P. Riis, 2003. Thirty Years of Bioethics: the Helsinki Declaration 1964-2003. *New Review of Bioethics* 1: 15-25.

<sup>79</sup> Medical Research Council, 1953. Draft Statement on Clinical Investigations, 9 October.

fact 'had virtually no impact on the research community, or the medical elite in Britain'<sup>80</sup>, or in clinical research elsewhere.<sup>81</sup> In other words, the language and culture of beneficent paternalism pervaded the medical establishment as it sought to safeguard its reputation and control of research practice. The continuation of the status-quo is perhaps best illustrated by reference to two so-called 'whistle-blowers' who drew public attention to experiments conducted without consent.

### *Beecher and Pappworth*

Another impetus for change in medical decision making came when two 'whistle-blowers', Henry Beecher in the US, and later Maurice Pappworth in the UK, published articles exposing unethical design and practice in human research.<sup>82</sup> American physician Henry Beecher evaluated published accounts of scientific experiments and noted that consent had been achieved in only two out of fifty cases. Some of the experiments he highlighted involved a high degree of risk to the research participants, whom were often from disadvantaged or minority populations and were unaware that they were being experimented upon. In one case, for example, investigators substituted placebos for a treatment that was known to be safe and effective. Beecher took his cases from published academic journals and reasoned that even if 'only one quarter of them is truly unethical, this still indicates the existence of a serious situation'. Beecher wrote that it was 'absolutely essential to strive for' informed consent and that for the concept to have any meaning, it was necessary that subjects understand what is being undertaken and hazards involved.<sup>83</sup> Beecher further wrote that most of the violations derived from 'thoughtlessness and carelessness' and that only a 'truly responsible investigator' could safeguard against abuses.<sup>84</sup>

In Britain, another physician, Maurice Pappworth, drew considerable attention by also

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<sup>80</sup> J. Hazelgrove, 2002. The Old Faith and the New Science: The Nuremberg Code and Human Experimentation Ethics in Britain, 1946-73. *Social History of Medicine* 15: 109-135.

<sup>81</sup> Riis, 2003, p. 16.

<sup>82</sup> H. Beecher, 1966. Ethics and Clinical Research. *The New England Journal of Medicine* 274: 1354-1360; M. Pappworth, 1968. *Human Guinea Pigs*, Harmondsworth: Penguin. The term 'whistle-blower' has been used by Rothman, 1991.

<sup>83</sup> Beecher, 1966, p. 1360.

<sup>84</sup> Beecher, 1966, p.1356; p. 1355.

publishing accounts of unethical work. Pappworth had collected over five hundred papers that he believed involved unethical research. Pappworth attempted to publish his findings several times in the *Lancet* and was rejected each time, apparently being told that 'there is a wrong time and a right time to address issues like this publicly'<sup>85</sup>. Having chosen the wrong time one too many times, a frustrated Pappworth resorted to publishing his research as a book, *Human Guinea Pigs*, which makes for uncomfortable reading. In it, he detailed experiments on children, newborn babies, pregnant women, the mentally ill and the dying. Pappworth emphasized the need for 'free and comprehending consent' with 'no coercion'.<sup>86</sup> According to him, 'the voluntary system of safeguarding patients' rights has failed and new legislative procedures are absolutely necessary'. Pappworth recommended review prior to the conduct of research, compulsory disclosure during the experiment, especially of any possible risks no matter how minor. He thought that 'public-spirited citizens, generous and courageous enough to accept the unpleasantness and the risk' would choose to volunteer as subjects, even if the real purpose and procedures of the experiment were revealed.<sup>87</sup>

Curiously, the responses to Beecher and Pappworth differed dramatically. Beecher, while greeted with some scepticism, received considerable attention and was able to maintain his considerable public and professional standing. TIME magazine, for example, referred to him as 'Harvard's Dr. Beecher' and his writings were widely cited and reprinted as evidence in the ensuing debates over human experimentation in the US. Pappworth, on the other hand, was called a 'shrill', his work was described as 'slanted' and he was said to 'lack the restraint' to write a 'more effective book'.<sup>88</sup> The *Lancet*, for instance, called his book a 'bitter analysis' by a 'dissatisfied man'. And, unlike Beecher's work, *Human Guinea Pigs* was barely cited in academic literature (and, I've discovered, is not easy to locate).

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<sup>85</sup> P. Edelson, 2000. Henry K Beecher and Maurice Pappworth: informed consent in human experimentation and the physician's response. In J. Tobias and L. Doyal, eds. *Informed consent in medical research*. London: BMJ Books, p. 24.

<sup>86</sup> Pappworth, 1968, p. 209.

<sup>87</sup> Pappworth, 1968, p. 217.

<sup>88</sup> Edelson, 2000, p. 24.

It must be noted, however, that Beecher's and Pappworth's allegations were remarkably similar and in some cases, they had unearthed and reported upon the same experiments. In fact, due to his work being in book form, Pappworth actually provided greater evidence and documentation for his claims, including author's names and institutions<sup>89</sup>. Yet Beecher suffered none of the personal attacks that Pappworth received, and in many respects became a symbol and sponsor of medical reforms.<sup>90</sup>

Official medical bodies in the UK also dismissed Pappworth. The reader will re-call that the GMC is the body responsible for disciplining physicians. Yet when a patient advocacy group wrote to the GMC asking what action they would take in light of Pappworth's book, the response was, 'The Council [is] not empowered to deal with matters of professional conduct which, though they may be open to criticisms, do not raise the question of infamous conduct'.<sup>91</sup> Although the GMC did eventually launch a working party to examine standards of ethical human research, it took six years to make any recommendations public.

The government was hardly more supportive. Responding to a series of questions about Pappworth's allegations, government spokesmen gave the following replies: 'Allegations that doctors in the UK have carried out unauthorised experiments on NHS patients are not based on fact'; 'The allegations cannot be ground on which the apparatus of public scrutiny should be brought into play. They have been promptly denied by hospital authorities', and; 'The medical profession have for generations been guided by strict codes'.<sup>92</sup>

Critical to understanding these differences is the stature and position of both Beecher and Pappworth. Paul Edelson has argued that the responses to Beecher's and Pappworth's allegations were 'intimately associated' with the professional status of each man and not

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<sup>89</sup> Surprisingly, Edelson does not make the connection, but indeed one must wonder if Pappworth's naming of violators was a contributing factor in his dismissal by the British medical establishment.

<sup>90</sup> Writing retrospectively, Pappworth has taken issue with attacks on his professionalism, writing 'those who dirty the linen and not those who wash it should be criticised'. M. Pappworth, 1990. "Human guinea pigs" – a history. *British Medical Journal* 301: 1456-1460.

<sup>91</sup> Edelson, 2000, p.25.

<sup>92</sup> Edelson, 2000, p. 25.

the objective quality of their evidence<sup>93</sup>. When he published his accounts, Beecher was at the peak of a brilliant career that included over two hundred published articles, a chair at Harvard and a post as head of an internationally recognised anaesthesiology programme. Meanwhile, Pappworth was a junior physician and a free-lance medical teacher, specialising in preparing medical students for the entrance examinations to the Royal College of Physicians. According to Edelson, Pappworth was told that he 'would never be appointed to a hospital consultancy' or become a medical specialist since he was Jewish.<sup>94</sup> This, of course, is difficult to prove, but the response to his allegations, in comparison to Beecher's are noteworthy and disturbing.

I agree with Edelson's conclusion that the different reactions to Beecher and Pappworth highlight the social context in which medicine operates, in which personal and professional spheres are not necessarily separated. Edelson argues that no matter the objective and scientific validity of an argument and its supporting data, the acceptance of a thesis is dependent upon personal judgements, preferences, and prejudices of those living in particular cultures, and at specific historical times. Although such contingencies affect whether a community accepts or rejects ethical norms, this point is not often discussed. But, as Edelson writes, 'it should be no surprise that, whatever activities human beings participate in, they are clearly coloured by human culture'.<sup>95</sup>

This rather simple point, I believe, is often overlooked – or, when acknowledged, not given its proper weight. Later, when discussing genetic epidemiology, I shall return to this theme and evaluate the role of social processes that shape the presentation, acceptance and/or rejection of ethical issues in genetics.

Next, however, I examine the growth of consent requirements as dictated by the courts in the UK and US.

### *The development of informed consent*

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<sup>93</sup> Edelson, 2000, pp. 22-27.

<sup>94</sup> Edelson, 2000, p. 23.

<sup>95</sup> Edelson, 2000, p. 26.

Since informed consent originated as a legal concept, it is not surprising that lawyers and judges were the first outsiders to challenge the authority of the medical profession. However, I again stress that these phases in the development of biomedical ethics overlap and are not mutually exclusive. At different times and in different places, both internal and external actors can be seen to be at play to varying degrees. Whilst the role of outsiders grew, obviously this did not necessarily translate into an immediate cessation of authority on behalf of the medical profession. At times the courts involvement did not mean a diminution of physician's authority. For example, courts often left it largely to the profession to decide the standard of information necessary to convey, as well as diagnosis and treatment options.

Historians offer two differing historical interpretations regarding consent. Martin Pernick argues that 'truth-telling and consent seeking have long been part of an indigenous medical tradition, based on medical theories that taught that knowledge and autonomy had demonstrably beneficial effects on most patients' health'.<sup>96</sup> He acknowledges that the social context of previous eras were not rights oriented, but asserts that legal writings on informed consent can be traced back to at least the early twentieth century.

However, Jay Katz believes that 'the history of the physician-patient relationship from ancient times to the present ... bears testimony to physicians' inattention to their patients' rights and need to make their own decisions. Little appreciation of disclosure and consent can be discerned in this history'.<sup>97</sup> Katz argues that none of the previous historical attempts to provide truthfulness are based on a felt need that patients should comprehend their situation so as to be able to determine for themselves whether they wish to participate. While Katz accepts that consent to surgical intervention is an ancient legal concept, he believes that 'there was no right for patients to decide, after having been informed, whether an intervention was agreeable to them in light of its risks and benefits

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<sup>96</sup> M. Pernick, 1982. *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*. *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*, pp. 1-33.

<sup>97</sup> J. Katz, 1984. *The Silent World of Doctor and Patient*. New York: Free Press.

as well as available alternatives'.<sup>98</sup>

In discussing these interpretations, Beauchamp and Faden make a useful distinction between a beneficence model and autonomy model of a physician's responsibilities to their patient.<sup>99</sup> The latter, as they use the term, is the view that 'the physician's responsibilities of disclosure and consent seeking are established primarily by the principle of respect for autonomy' and self-determination.<sup>100</sup> A beneficence model depicts the need to disclose information to a patient on the basis that a doctor's chief duty is to provide medical benefits and maximize the patient's health, even if a decision contravenes the patient's expressed wishes.<sup>101</sup> I would endorse Beauchamp and Faden's distinction and their view that physicians historically have operated out of a beneficence model when 'consenting the patient'. They write, 'The beneficence model not only traditionally dwarfed any nascent autonomy model in medical practice but led to an environment in which autonomy figured insignificantly or not at all in reflections about disclosure. The consent practices emerging from this context were not meaningful exercises of autonomous decision-making, despite the bows in the direction of respect for autonomy and truth-telling found in a few codes, treatises, and practices.'<sup>102</sup>

The evidence, in my view, seems to support Katz. As early as 1767 courts introduced the idea that patients needed to know certain details about the proposed treatment but only in order to maximise the chances of a successful surgery. In that year the British courts heard the case of Slater v Baker and Stapleton, in which the plaintiff (Slater) hired two doctors to remove bandages from his leg, which had been broken and set. Over the plaintiff's protests, the doctors re-fractured the leg and used an experimental apparatus to stretch and strengthen it. Slater took the case to court, which ruled in his favour. My point, however, is that the courts decision was made not from a commitment to patient self-determination but rather out of a practical requirement of preparing the patient for

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<sup>98</sup> Katz, 1984.

<sup>99</sup> Beauchamp and Faden, 1986, p. 59.

<sup>100</sup> Beauchamp and Faden, 1986, p. 59.

<sup>101</sup> Beauchamp and Faden, 1986, p. 59.

<sup>102</sup> Beauchamp and Faden, 1986, p. 60. Italics are original. Beauchamp and Faden, then, largely support Katz' thesis.

treatment. Before administering anesthesia, it was thought to be ‘reasonable that a patient be told what is about to be done to him, that he may take courage and put himself in such a situation as to enable him to undergo the operation.’<sup>103</sup>

Whilst a detailed trans-Atlantic comparison is beyond this thesis, there is some evidence that the doctrine of self-determination had a greater resonance in the US, which is not entirely surprising given the American ethos of individualism (a topic I shall return to in the next chapter). In 1914, the landmark case *Schloendorff v Society of New York Hospital* firmly established the legal principle of self-determination. The importance of this case was that it established that even if physical harm did not result, it was the unauthorised physical touching of the patient and the subsequent affront to bodily integrity that constituted a battery. Even the motives, no matter how benign or noble, of the ‘aggressor’ were irrelevant. Justice Cardozo’s famous declaration has been widely cited in medical jurisprudence:

‘Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without the patient’s consent commits an assault.’<sup>104</sup>

As Mason and McCall Smith note, however, ‘the theory, then, is quite simple – the reality is somewhat different.’<sup>105</sup>

For instance, in Britain, the 1957 case *Bolam v Friern Hospital Management Committee* left decisions as to the amount of information necessary to disclose to the physician.<sup>106</sup> In *Bolam*, a man with schizophrenia was administered electroconvulsive therapy (ECT) without being constrained or being administered relaxant drugs. At the time, there were contrary opinions on whether patients receiving ECT should be given relaxants or else be manually restrained. The debate centred on whether or not such control would increase

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<sup>103</sup> Beauchamp and Faden, 1986, pp. 53-77.

<sup>104</sup> J. Mason and A. McCall Smith, 1999. *Law and Medical Ethics*. London: Butterworths, p. 245.

<sup>105</sup> Mason and McCall Smith, 1999, p. 245.

<sup>106</sup> Mason and McCall Smith, 1999, pp. 280-282.

or decrease the patients' chances of injury due to their convulsive movements caused by the shocks. As it happened, the plaintiff in the case dislocated both of his hip joints and fractured his pelvis, direct results of the shock treatment.

The court, however, found that in restraining the patient and not informing him of the risks of physical injury associated with ECT, doctors had not in fact breached their duties. In a statement that has since become the benchmark of standards, Justice McNair wrote: '[A doctor] is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.' Named the 'Bolam Principle', this essentially leaves it to the medical profession to dictate the standards of conduct and has been found to apply to cases of diagnosis, treatment, and information disclosure.

This decision was supported and extended in *Sidaway v Board of Governors of the Bethlem Royal Hospital* 1985.<sup>107</sup> In this case, English courts were given their first chance to determine the extent of a doctors duty of disclosure. Mrs. Sidaway required an operation to alleviate recurrent neck and shoulder pain. The procedure left her partially paralyzed, as a result of damage to her spinal column. However, there was no question of negligence of performance on the surgeons behalf. The operation carried between a one and two percent risk of damage to the nerve root, a risk that the physician considered too slight to mention. Unfortunately, the doctor died before the start of the trial leaving little hard evidence as to what was said. This however did not stop the court from reaching a fairly conclusive verdict. Although the court agreed that Mrs. Sidaway would not have chosen to have the operation if she had been more informed (thus electing to live with the recurrent pain), the judges nonetheless upheld the professional judgment standard. In other words, the Bolam principle was deemed as applicable to information disclosure. Judges Bridge and Lord Keith agreed that the degree of disclosure 'must primarily be a matter of clinical judgment' to be determined 'primarily on the basis of expert medical evidence, applying the Bolam test'.<sup>108</sup>

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<sup>107</sup> Mason and McCall Smith, 1999, pp. 280-283.

<sup>108</sup> H. Teff, 1994. *Reasonable care: legal perspectives on the doctor-patient relationship*. Oxford:

It should be noted that much has been made of a dissenting view in Sidaway. Lord Scarman, writing in the minority, embraced a patients' rights doctrine of informed consent, arguing that the professional standard 'leaves the determination of a legal duty to the judgment of doctors.' Lord Scarman's view, while a minority in the courts, is reflected in wider opinion. Even while the Bolam Principle remains the accepted legal standard, even many medical organizations recognizes that the true ethical position is indeed Lord Scarman's opinion.<sup>109</sup>

As years passed, the general culture of patients' rights took hold, medical bodies have responded to the changing environment. For example, the BMA's 1980 Ethics Handbook contains two pages on consent; its 1993 edition contains over thirty-five pages on the subject. The later edition states, 'As a prerequisite to choosing treatment, patients have the right to receive information from doctors and to discuss the benefits and risks of appropriate treatment options.'<sup>110</sup> On how much information to provide, 'the ethical viewpoint' is that 'the criteria should be as much information as the patient needs or desires.'<sup>111</sup>

I do not wish to overstate the uniqueness of outsiders having an interest in medical ethics. Critics of the conventional view of bioethics are right to point out that philosophers and theologians have debated medical issues since the dawn of medicine. The difference, I believe, is that non-medical actors have had greater influence in clinical and research settings in a way previous generations of 'strangers' did not. The 'new outsiders' (if I may use such a phrase) have come to hold considerable power by serving on committees, seeking media attention, and appearing before and on government panels (the very establishment of which is further evidence of outside authority being placed on medicine). Many concepts and rules put forward by the new outsiders have come to be

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Clarendon Press, p. 209.

<sup>109</sup> For example, see British Medical Association's *Handbook on Ethics*, 1980.

<sup>110</sup> BMA, 1993, p. 3.

<sup>111</sup> BMA, 1993, p. 3. What these cases show, I believe, is the uneven development and application of consent requirements. Historical change is rarely straight forward or linear. Whilst the twentieth century witnessed a dramatic growth in self-determination, the actual enforcement was slow given centuries long practice of beneficent paternalism.

adopted and promoted by the medical profession, in part, because they have considered it to be in their own interest.

The story of consent forms only part of a larger picture regarding the birth of bioethics. I now turn to the role played by theologians and philosophers in developing many of the normative claims adopted by mainstream bioethics.

### *Academia joins the party*

It is conventional wisdom that the birth of bioethics was greatly encouraged and facilitated by theologians and academic religious scholars. A number of Christian theologians played a leading part in challenging the expanding power of medicine. In this section I wish to continue the story by briefly looking at some of the early writings of these figures before moving on to discuss a particular case where theologically trained persons external to medicine played a critical role in the transition from medical ethics to bioethics. My particular case is that of ethics teaching in British medical schools. From this example, it is clear that whilst religion was present at the birth of bioethics, it soon became marginalised under the demands to reach a wider audience and to achieve greater input in a largely secular society. This point then leads to the following section, where analytical philosophy enters the stage and we see the emergence of the four principles approach, bioethics' most cherished method.

According to Daniel Callahan, 'In the early days of bioethics there was an interesting debate between the views of Joseph Fletcher – who never said no- and Paul Ramsey – who usually said no and who argued that the capacity to do so was a test of moral seriousness ... It appears that Fletcher won the day.'<sup>112</sup> Known for the idea of 'situation ethics' (a topic I return to in chapter seven) Fletcher's ideas seemed radical in the mid 1960s when they were first published, but have become standard fare and part of establishment thinking today. Fletcher advocated a re-thinking of traditional Protestant notions of ethics. He believed that without the freedom to choose and the right to know the truth, patients were only 'puppets', and that 'choice and responsibility' lay at the

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<sup>112</sup> D. Callahan, 1996. Bioethics, our crowd, and ideology. *Hastings Center Report* 26: 3-4.

‘heart of ethics.’ Such ideas committed Fletcher to being far more open minded about topics such as abortion and euthanasia than most theologians at the time (or, perhaps today even, notwithstanding my claim about his ideas now seem commonplace in secular bioethics).<sup>113</sup>

On the other end of the spectrum, as Callahan indicated, was Paul Ramsey who adopted more orthodox Protestant views.<sup>114</sup> Central to Ramsey’s thinking was the idea of a covenant and a cardinal canon of loyalty which joined people together. Ramsey declared that consent was ‘statement of fidelity’ and developed a bioethic that challenged the medical establishment to see the ‘patient as person’. His work was instrumental in establishing the importance of fiduciary obligations between professionals and patients and in highlighting the vulnerability of the latter when ill.

Never to be outdone, Catholic writers also entered the fray. Or, to be more precise, re-entered since Catholic moral theology had long been concerned with medical matters<sup>115</sup>. One of the most prominent writers was Richard McCormick who advocated a theological notion of human dignity. According to McCormick, the highest possible end of human life was a person’s ability to love God and neighbour. If person’s illness led to a quality of life that seriously diminished their ability to love God, then for that person, life had ceased to have value (even though the person themselves were undoubtedly valued by their loved ones)<sup>116</sup>. Thus, under such circumstances, the removal of technological measures would be permitted. According the McCormick, the very purpose of life could be put at risk by serious illness and physical suffering even more than by death, where, presumably the ill would be able to resume their love of God in the Kingdom of Heaven.

Of course my brief review of these three Christian theologians is highly selective and simply intended to illustrate that in the very early days of bioethics, the theologically

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<sup>113</sup>J. Fletcher, 1966. *Situation Ethics*. Philadelphia: Westminster Press, p. 33 and p. 10 respectively.

<sup>114</sup>P. Ramsey, 1970. *The Patient as Person: Explorations in Medical Ethics*, New Haven: Yale University Press.

<sup>115</sup>C. Curran, 2003. The Catholic Moral Tradition in Bioethics. In J. Walter, et al. *The Story of Bioethics: From Seminal Works to Contemporary Explorations*, pp. 113-130.

<sup>116</sup>R. McCormick, 1974. To save or let die. *Journal of the American Medical Association* 229: 172-176.

minded were active in the field.<sup>117</sup> My own research on medical ethics teaching in Britain supports this view, as I explore in some detail in the following section.

### *From medical ethics to bioethics in British medical schools*<sup>118</sup>

Today, ethics is an established component of medical education.<sup>119</sup> This was not always the case however. Whilst John Gregory, discussed in the previous chapter, taught ethics to his students in eighteenth century Edinburgh, ethics has historically been a very minor element of medical education and only recently a part of formal curriculum. In the US, for instance, one of the first medical ethics programs was initiated in only 1967 at the Pennsylvania State University College of Medicine.<sup>120</sup> By 1972, however, seventeen US institutions had special programmes on medical ethics, four schools had a required course, and ethics was discussed, though not the subject of a special class, in eighty-one US institutions.<sup>121</sup>

In Britain, the history of medical ethics education makes for a nice example of an outsider (with theological but no medical training) coming to exert considerable influence on the establishment of ethics curriculum through the London Medical Group.

### *Origins*

The London Medical Group (LMG) was an independent, non-partisan, multi-disciplinary, and largely student run organization<sup>122</sup>. Established in 1963, four years before Pappworth's famous critique of human experimentation, the LMG was one of the earliest

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<sup>117</sup> I have omitted any number of religious voices – not to mention Churches and the Vatican themselves which weighed in from time to time (and still do) with bioethical pronouncements. For a thoughtful analysis that explores the tensions between religion and bioethics, see: C. Messikomer, R. Fox, and J. Swazey, 2001. The presence and influence of religion in American bioethics. *Perspectives in Biology and Medicine* 44: 485-508.

<sup>118</sup> This section is based on: M. Whong-Barr, 2003. Clinical ethics teaching in Britain: a history of the London Medical Group. *New Review in Bioethics* 1: 73-84.

<sup>119</sup> K. W. M Fulford, A. Yates, and T. Hope, 1997. Ethics and the GMC core curriculum: a survey of resources in UK medical schools. *Journal of Medical Ethics* 23: 82-87.

<sup>120</sup> D. Barnard, and K. D. Clouser, 1989. Teaching medical ethics in its contexts: Penn State College of Medicine, *Academic Medicine* 64: 744-746.

<sup>121</sup> R. Veatch, and S. Sollitto, Medical ethics teaching: report of a national medical school survey. *Journal of the American Medical Association* 235: 1030-1033.

<sup>122</sup> This section is based on LMG literature and interviews with two key figures in the history of the Medical Groups, Ted Shotter (former Dean of Rochester) and Kenneth Boyd (University of Edinburgh).

attempts of the medical profession to respond to 'new' ethical dilemmas in medicine. For twenty-five years, the LMG organized a series of lectures, symposia and conferences throughout London's twelve teaching hospitals and was an early impetus for more formal 'non-dogmatic' medical ethics teaching.<sup>123</sup>

The LMG's roots lie in the ecumenical movement of the 1960s when an American (note the irony!) physician and clergyman, Andrew Mepham, first highlighted the need for such an organization (Boyd, forthcoming). In the early 1960s, Mepham was commissioned by the Student Christian Movement (SCM), the student wing of the ecumenical movement within the UK, to study the needs of British medical school students. Mepham's conclusions echoed a frequent criticism of modern medical practice: that it risked becoming pre-occupied with scientific training and diseased tissue, instead of a thorough understanding and care for the 'patient as person'. In response to the report, the SCM asked one of its staff, Ted Shotter, to devise a way for clinical medical students to engage with medical humanities and the wider society.

Shotter, then a university chaplain, was instrumental to the success of the LMG. In 1963, with a budget of only forty pounds, he organized a series of lectures to encourage a dialogue between interested parties. His role grew in time and he eventually became Director of Studies, one of the few paid staff members of the LMG. Funding for the group came from charitable donations. The Queen provided an annual donation and the group relied heavily on funds from the King Edward VII Hospital Fund for London. It also received annual grants from the Trustees and Deans of the twelve London teaching hospitals and medical schools and the Diocese of London.<sup>124</sup> Such diverse sources of funding illustrate the significant interest in ethics not only on behalf of the profession by charitable bodies, as well.

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<sup>123</sup> R. Gillon, 1987. Editorial: Medical ethics education. *Journal of Medical Ethics*, 13: 115-116.

<sup>124</sup>E. F. Shotter, 1984. Unpublished paper delivered to the GMC conference on the teaching of medical ethics. The elements involved in teaching medical ethics to doctors and medical students: the view of the Society for the Study of Medical Ethics.

### *Activities and organization*

Initially, the LMG ran twice weekly symposia, which were held throughout London's teaching hospitals. Crucial to the success of the group was the manner in which topics and speakers were chosen. Topics were first selected by a representative council of approximately twenty medical students. A consultative council comprised of senior members of the medical faculty helped identify the speakers appropriate for the topic chosen by students. It then became Shotter's responsibility to liaise with speakers, who included both clinicians and non-medical specialists from areas such as law, theology, and the social sciences. On average the LMG hosted two hundred speakers per year, all of whom spoke without fee. Presenters never spoke in their own hospital, which allowed sensitive topics to be discussed without the risk of personalizing them or jeopardising confidentiality. Talks were free and open to the public; average attendance varied widely but was approximately one hundred per session.<sup>125</sup>

Although Shotter was an outsider, certain segments of the British medical establishment were keen in debating the dilemmas posed by technological medicine. The system described above, where students selected the topics and consultants identified the speakers, prompted Lord Rosenheim, President of the Royal College of Physicians, to describe the LMG as 'a pincer movement on the profession', undertaken by its 'cadets and senators'<sup>126</sup>. The implication was that if the current and next generation of leaders in medicine combined forces, then the profession as a whole was somehow squeezed into openly debating delicate issues that it may otherwise wish to keep behind closed doors. But, somewhat paradoxically, this process, or 'pincer movement', helped to allow sensitive topics to be raised and openly debated *without* jeopardizing the position of participants. In Shotter's view, once students became junior doctors, they 'lost their tongue' and sacrificed their ability to publicly question contentious issues without risking their newfound position.<sup>127</sup> It seems a plausible claim to make: arguably, medical students are often allowed freedoms not enjoyed once they formerly enter the profession and undertake clinical responsibilities. At the same time, consultants were somewhat

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<sup>125</sup>E. F. Shotter, ed. 1988. *Twenty-five years of medical ethics*, London: Institute of Medical Ethics.

<sup>126</sup> Shotter, 1984.

<sup>127</sup> E. F. Shotter, 2002. Transcript from personal interview with author.

protected by their senior status. The LMG offered them an opportunity to reflect on changing clinical possibilities that occurred in their careers, such as transplantation and euthanasia.<sup>128</sup>

In line with my overall thesis, however, it is clear that the LMG was not entirely an internal movement. Shotter's position as a non-medical official was crucial to the success of the group. Not trained in medicine, he was able to ask questions about medical decision-making that students or doctors could not ask – either because they were expected to be part of the consensus, or else they could not publicly admit to not knowing the answers. Shotter describes his role in the formation of the LMG as being a 'catalyst' who facilitated and helped coordinate dialogue on potentially contentious issues. His role was a delicate one. One colleague at the time described his efforts as a 'fool rushing in where angels fear'.<sup>129</sup> Interestingly, in twenty-five years of involvement, Shotter never gave a paper and only chaired two sessions -- one, when a presenter went to the wrong hospital leaving the LMG in a bind.

Unsurprisingly, there was a degree of resistance to public discussion of ethical issues in medicine. The history of the LMG suggests a reluctance amongst some segments of the profession to allow greater public debate. Shotter has claimed that 'When I started it was quite clear that there was a body of opinion [that] didn't want these topics discussed at all.'<sup>130</sup> One senior paediatrician at the time is known to have said that such issues were only to be discussed 'by consultants with consultants and in camera'.<sup>131</sup> Resistance, however, was weakened by both the structure described above and, arguably, by the sheer pace of developments. Debates in the 1960s on topics such as abortion were subsumed in the 1970s and 1980s by technological developments in reproductive medicine and genetics.

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<sup>128</sup> K. Boyd, 2002. Transcript from personal interview with author.

<sup>129</sup> Shotter interview, 2002.

<sup>130</sup> Shotter interview, 2002.

<sup>131</sup> Boyd, forthcoming.

According to Shotter, allowing students to select the topic helped maintain interest and contributed to the appeal of the LMG. Lecture lists reflect both student interest and societal context. Topics often extended beyond traditional medical issues. They included discussions of: marriage guidance, bisexuality, war, nuclear power and weapons, cannabis use, obesity, guilt, poverty, the welfare state, and unemployment. Alongside these were lectures considered standard fare for today's bioethical agenda, such as: truth-telling, mental health, animal ethics, end of life issues, new reproductive technologies, AIDS, resource allocation, and ethical problems raised by clinical trials.<sup>132</sup> In addition to weekly lectures, the LMG held study seminars and an annual conference that attracted several hundred attendees.<sup>133</sup>

### *Evolution and influence of the LMG*

The success of the LMG enabled it to extend to other locations outside of London. Kenneth Boyd (also theologically trained) coordinated the second group in Edinburgh in 1967; the same year Newcastle became the third group to form. By 1987, the Medical Groups had expanded to seventeen medical schools across England, Scotland, and Wales. All Medical Groups followed a similar organizational structure, with student representative councils and senior consultative councils. Each group also had a coordinating secretary that helped facilitate events. The spread of the LMG into an autonomous but affiliated network of Medical Groups helped illustrate that the relevance of the issues were not limited to London's teaching hospitals.

During its twenty-five years, the LMG underwent several re-organizations and gradually severed itself from its theological roots. It grew independent of the Student Christian Movement in 1974 and joined the Society for the Study of Medical Ethics (SSME), a body developed by former LMG students who wanted to expand ethical discussion beyond the undergraduate level to public and professional discourse. A year later, the LMG and SSME evolved into the Institute of Medical Ethics (IME), which is still active today. Amongst the IME's projects is the highly successful *Journal of Medical Ethics*

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<sup>132</sup> LMG lecture lists, 1963-1989.

<sup>133</sup> Shotter, 1984.

(*JME*) which began in April 1975 with funding from the Kleinwort Foundation. According to Shotter, members of the Foundation became interested in the issue of artificial prolongation of life when an employee had been sustained artificially. The Foundation wanted to impact the debate, so Shotter asked them to help fund the start of the *JME*. As a result, Kleinwort underwrote the *Journal* with charitable funding for its first ten years. Today, the *Journal* is a partnership between the IME and the *BMJ* Publishing Group. It pulls approximately one third of its readership from UK, one third from the US, and a third from the rest of the world.<sup>134</sup> Interestingly, the first editor of the *JME*, Alastair Campbell, was theologically trained and taught Christian ethics. Recent editors, however, have been two of the most anti-religious and secularly minded bioethicists in the business – John Harris and Julian Savulescu.

A number of seminal research projects were also supported by the Medical Groups and the IME. These include *The Dictionary of Medical Ethics*, which appeared in 1977. Revised in 1984, many of its contributors had been Medical Group presenters. Another project was The Pond Report on the Teaching of Medical Ethics. Published in 1987 and edited by Boyd, the Report was named after its chairman, Sir Desmond Pond FRCPsych, who died before the findings were made public. The Pond Report aimed to survey the field of medical ethics teaching in Britain, discuss future options, and make recommendations. The report's findings highlighted the influence of the Medical Groups. Twenty-one of twenty-six medical school Deans responded that students were encouraged to participate in their local Medical Group and that many staff also attended. One Dean stated that the Medical Group 'effectively produced a good alternative curriculum',<sup>135</sup>.

This quote suggests, however, that the Medical Groups, paradoxically, limited the growth of ethics curriculum in medical education. With the existence of a group in a medical school, there was, arguably, less incentive for Deans to outlay financial and human

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<sup>134</sup> Shotter interview, 2002.

<sup>135</sup> K. Boyd., ed. 1987. *Report of a working party on the teaching of medical ethics*. London: IME Publications, p. 25.

resources to develop a more formal ethics curriculum or hire an ethics lecturer.<sup>136</sup> It is difficult to assess how much truth there is to this claim. According to the Pond Report, Deans were reluctant to introduce ethics as a 'separate subject' and preferred informal clinical teaching. In line with this, the Pond recommendations suggested multi-disciplinary teaching spread at regular intervals throughout a student's medical education. In many ways, this is why medical ethics teaching today is spread out through a student's education and not in one-off 'ethics' classes.

As the Pond recommendations were implemented, both the GMC and BMA lent their weight to the establishment of an ethics curriculum in British medical schools.<sup>137</sup> However, as Deans began appropriating funds for ethics lecturers, the LMG received a decrease in contributions. In Shotter's view, this development was a sign of success, that the LMG has essentially fulfilled its task of generating greater opportunities for students to discuss medical humanities and ethical issues raised by the practice of medicine. In 1989, the LMG officially disbanded, although today a smaller group still organises events (e.g. at Guy's, St. Thomas's, and the Royal Free hospitals in London).

Given the influence of the Medical Groups, it is not surprising that many senior figures in British biomedical ethics have in one way or another been associated with them. The late Sir Douglas Black, a pioneer in British medicine and Chairman of the Black Report (famous for its devastating critique of health inequalities) was also a former IME President. At least two Chief Medical Officers, Kenneth Calman and Liam Donaldson were coordinating secretaries of their local Medical Groups (Glasgow and Leicester, respectively).

### *The declining influence of religion in bioethics*

Looking at the origins of British bioethics, we have seen that the LMG began with considerable religious influence. The report which led to the establishment of the LMG was commissioned by the student ecumenical arm of the Church. Many key figures in the

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<sup>136</sup> Shotter interview, 2002.

<sup>137</sup> Gillon, 1987.

Medical Groups, including speakers, coordinators, and *JME* editors, were theologically trained. In addition, the first LMG lecture lists state that the organization aims 'to create in the medical schools a dialogue between belief and non-belief'. By the end of the 1960s however, the lecture lists describe the LMG as 'a student group for the study of issues raised through the practice of medicine which concern other disciplines'.<sup>138</sup> According to Shotter and Boyd (personal communication) the change was not a question of abandoning a religious stance as much as an attempt to involve the widest possible audience of students and staff. It must be said however, that the effect is the same: a decline in religious input.

As the LMG sought to broaden its appeal, it also narrowed its focus. Both the Pond committee and medical school Deans were concerned to avoid medical ethics as a specialist subject, a phenomenon that, in their view, came to dominate US ethics teaching. There was also a consensus on the need to concentrate on clinical issues.<sup>139</sup> Undoubtedly, the emphasis on clinical matters has been crucial to the success of the LMG and the *JME*. Yet such a focus also comes with a price: it discourages analysis of the social processes that combine to create the very technology that helps generate moral dilemmas in the first place. For example, we have seen that medical students identified issues such as nuclear weaponry and the status of nature as ethical matters for discussion. Yet these issues have been marginalized in recent medical education in favour of debate on the ethical status of specific medical procedures and cases. Of course I do not deny the tremendous need to debate clinical dilemmas that students will face upon graduation. But critical review of the LMG lecture topics makes it evident that the agenda narrowed considerably to strictly medical issues. This is an issue I shall address further in Chapter Seven.

The history of the LMG raises the interesting question of the declining influence of theology on bioethics in general. In her work, Renee Fox has shown how a tendency to focus on practical problem solving (as in the LMG, for instance) encouraged the

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<sup>138</sup> LMG lecture lists, 1963-1989.

<sup>139</sup> Boyd, 1987.

development of a secularly oriented bioethics, whose aim was to maximise policy input and to achieve consensus in a pluralistic society.<sup>140</sup>

Fox observes that secularisation in bioethics is also an ‘instrumental, political, and moral response to a basic societal question that the whole phenomenon of American Bioethics poses: How can, and should, an advanced modern, highly individualistic pluralistic, and religiously resonant society, like the United States, founded on the precept of governance “under law”, rather than “under men”, and the sacredly secular principles of separation of church and state and freedom of belief, try to achieve collective and binding consensus about the kinds of bioethical issues that are now in the public domain?’<sup>141</sup>

As Fox notes, the need for consensus in a religiously pluralistic and increasingly secular society has played a large part in bioethics’ methodological and practical commitment to principles. In attempting to adjudicate issues, it is not surprising that Beauchamp and Childress ground their approach on common morality theories, the so-called four principles approach, which I now turn to.

#### *The mother of all methods: principlism*

Arguably, the most dominant method in bioethics is principle-based. The hegemony of this approach owes much to the success of Tom Beauchamp’s and James Childress’ *Principles of Biomedical Ethics*, now in its fifth edition.<sup>142</sup> In early editions of *Principles*, Beauchamp and Childress adopt an approach of ‘convergence’ between rule utilitarianism and rule deontology.<sup>143</sup> Thus, they emphasized prima facie duties (a term borrowed from W. D Ross’s work and meaning, in general terms, that principles are not absolute but can be subordinated to other principles in particular circumstances) for the promotion of the welfare of others. By the fourth edition (1994) Beauchamp and Childress still accepted such a convergence but framed their argument instead on the

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<sup>140</sup> R. Fox, 1990. The evolution of American bioethics: A sociological perspective. In G. Weisz, Ed. *Social Scientific Perspectives on Medical Ethics*, Philadelphia: University of Pennsylvania Press.

<sup>141</sup> Fox, 1990, p. 208.

<sup>142</sup> T. Beauchamp, and J. Childress, 2001. *Principles of Biomedical Ethics*, 5th Ed. Oxford: Oxford University Press.

<sup>143</sup> For insights into the development of this seminal text, see: J. Childress, 2003. *Principles of Biomedical Ethics: Reflections on a Work in Progress*. In J. Walter, et al. *The Story of Bioethics*, pp. 47-66.

assumed existence of a common human morality that, while not comprehensive, forms the starting place of ethical theory. Common morality 'takes its basic premises directly from the morality shared in common by the members of a society -- that is, un-philosophical common sense and tradition' that does not necessarily require shared metaphysical commitments.<sup>144</sup>

The theoretical foundations of this work are four principles that may be applied, in tension with one another, to clinical cases. These principles have arisen dialectically over time from 'considered judgments in the common morality and medical tradition'.<sup>145</sup>

Briefly, the principles are as follows: *Respect for autonomy* is recognising the agent's right to self-governance or self-determination. The two primary conditions for autonomy are having 1) independence from controlling influences and 2) the capacity for intentional action.<sup>146</sup> Unsurprisingly, disagreement exists over the interpretations of these conditions and the necessary criteria for their being met. *Non-maleficence* refers to a moral obligation to avoid intentionally inflicting harm. *Beneficence*, by contrast, carries a *positive* injunction to act for the benefit of others through preventing or removing harm or promoting good.<sup>147</sup> Both non-maleficence and beneficence trace their roots to the Hippocratic oath, which states 'I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them.' Finally, *justice* is fair, equitable, and appropriate treatment in light of what is due or owed to persons.<sup>148</sup> In their discussion, Beauchamp and Childress typically refer to a distributive justice, which takes into account the allocation of goods and rights under conditions of scarcity and competition --- conditions particularly prevalent in modern medical practice.

Direct application of these principles, as Beauchamp and Childress note, are a rare luxury, precluded by the complexity of moral life. It is often necessary to favour one principle over another in an attempt to minimize inconsistency. When applied to detailed

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<sup>144</sup> Beauchamp and Childress, 2000, p. 100.

<sup>145</sup> Beauchamp and Childress, 2000, p. 37.

<sup>146</sup> Beauchamp and Childress, 2000, p. 121.

<sup>147</sup> Beauchamp and Childress, 2000, p. 190.

<sup>148</sup> Beauchamp and Childress, 2000, p. 327.

cases, abstract norms (i.e. autonomy) run the danger of being indeterminate and unable to assist in settling disputes. The method by which principle-oriented ethicists overcome such problems is known as 'specification and balancing.'<sup>149</sup> Specifying a principle entails developing its scope and content. The definition of a principle may be narrowed or expanded, depending upon the circumstances. Balancing refers to judgments made about the relative weight attached to different norms. Principles, in other words, are 'prima facie'.

Principlism, then, begins by evaluating which of the four principles are at play. It then either specifies and/or balances those principles to reach a decision which coheres with other judgments and ethical theories. This process relies upon a common morality framework designed to reach the highest possible degree of consensus about *what to do*.

### *Summary and conclusion*

In this chapter I have shown that:

- The conventional view of the history of bioethics attributes the rise of the field to a combination of interrelated factors. These included: a) the impact of the Second World War; b) the effect of 'whistle-blowers' such as Henry Beecher and Maurice Pappworth, who exposed ethical violations in human experimentation; c) the impact of new technologies, such as dialysis machines, which created unprecedented moral dilemmas, and; c) the rise of minority social movements that carried over into new demands for patients' rights. The result of these events was the breakdown of an ethic internal to medicine (a bedside ethic to use Rothman's phrase).
- The early informed consent guidelines, as developed at the Nuremburg trials and in the Helsinki Declaration(s), had a limited impact on human experimentation and generated a tension between an international movement to give research subjects greater rights and the centuries long habit of leaving such decisions to

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<sup>149</sup>Beauchamp and Childress, 2000, pp. 28-37.

physicians. Related to this, I argued that the reception of Beecher's and Pappworth's 'whistle blowing' was dramatically different in the US than in the UK and the reason for this lied in a range of contingent factors such as the professional status of each man, the wider societal context, and the personal judgements, preferences, and prejudices of the medical profession in both countries.

- Thus, the growth of consent requirements was uneven across time and place. This was because of the sustained influence of the centuries long beneficence/paternalism model of medical care, which depicted the need to disclose information to a patient on the basis that a doctor's chief duty was to provide medical benefits and maximize the patient's health, even if a course of action contradicted the patient's expressed wishes. However, with a series of landmark legal cases the then nascent patient autonomy model began to dwarf traditional patterns and informed consent reached a level of primacy that is still palpable today.
- The birth of biomedical ethics as an academic discipline began, in large measure, with the input of theological ethicists who, in fact, had been debating medical ethics for centuries (but crucially, without the impact they came to hold in the post-War era). I illustrated this through the story of the London Medical Group, which organized a series of lectures, symposia and conferences throughout London's twelve teaching hospitals and was an early impetus for more formal 'non-dogmatic' medical ethics teaching. The LMG's roots lay in the ecumenical movement of the 1960s and was established with the efforts of clergyman Ted Shotter.
- Theology's contribution to biomedical ethics diminished in time, however, due to the need to reach a wider 'audience', and due to the associated goals of reaching moral consensus for the sake of achieving an influence on public policy. The best example of religion's declining power in bioethics is in the growth of principlism,

which bases itself on a 'common morality' – that is, a morality shared in common by members of a society who may not share 'metaphysical commitments.'

In the next chapter I provide a range of critiques and criticisms of bioethics.

## Chapter Four

### The dearth of bioethics: a critique

*I do not have the sales figures for the four editions [now five] of Beauchamp and Childress ... I will assume that many copies have been sold and read to justify so many editions. I do not have the figures for the number of medical professionals who have attended summer workshops at Georgetown, but will assume that the numbers are high. The point is that the principles have been replicated so many times – printed in so many textbooks, spoken in so many meetings – that it becomes hard to imagine any other way of making decisions. The fact that principlism is also the legally required decision-making system for recipients of federal research funds also encourages this process’.<sup>150</sup>*

– John Evans

#### *Introduction*

In the last chapter I described the rise of analytical methods and normative writings which problematised medicine’s internal discourse of ethical judgement. In this chapter I aim to evaluate the main critiques of bioethics method and assumptions.<sup>151</sup> Specifically, I discuss casuistry, care, virtue, and social scientific alternatives to standard bioethics (largely defined by principlism). It is important to stress from the start that these critiques are interrelated – that is, they share a common dissatisfaction with bioethics tendency to reify the principle of autonomy.<sup>152</sup> This chapter adopts the view that notwithstanding attempts to ‘break through the domination of the field by the abstract “principlism” of analytic philosophy, and to ‘incorporate other philosophical systems into the matrix of

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<sup>150</sup> J. Evans, 2000. A Sociological Account of the Growth of Principlism. *Hastings Center Report* 30: 37.

<sup>151</sup> I say ‘method’ since I do not, in this chapter at least, deal with numerous other problems with bioethics, such as its financial connection to pharmaceutical companies or its tendency to merely affirm/justify whatever science does. But in Chapter Eight I touch upon these charges.

<sup>152</sup> I wish to draw notice to two views at opposing ends of the methodological spectrum. There is some debate in bioethics between what H. Tristram Engelhardt claims is an irreducible diversity of methods and Mark Kuczewski’s assertions that a consensus on method has been achieved. Here my chief concern is less with articulating a single method than with what current approaches ignore and why. See H. T. Engelhardt, 1996. *The Foundations Of Bioethics*, 2nd Ed. Oxford: OUP; M. Kuczewski, 1997. Bioethics’ consensus on method: *Who could ask for anything more?* [original italics] In H. L. Nelson, Ed., *Stories and Their Limits*. London: Routledge, pp. 134-149.

bioethical thought ... relatively little change has occurred in the contours, context, style of thought, or the ideology of bioethics'.<sup>153</sup>

As Daniel Callahan points out, principlism is itself a form of reductionism.<sup>154</sup> It is hard to escape the idea that, in the end, all four principles more or less come down to autonomy. For example, Callahan writes that non-maleficence derives essentially from the principle of respect for persons and their bodily sovereignty. And justice, in the end, is a desire for people to have equal opportunity to pursue their autonomous life goals within a system of fair access. Indeed, at times, it does seem that what matters most to bioethics is not the content of choice but simply the right to have a choice.

One of the early critiques of the philosophy of bioethics came from within philosophy itself. Writing in 1990 after the third edition of Beauchamp and Childress's seminal text, K. Danner Clouser and Bernard Gert penned the memorable and now famous quote 'throughout the land, arising from the throngs of converts to bioethics awareness, there can be heard a mantra "... beneficence ... autonomy ... justice ..."'.<sup>155</sup> According to Clouser and Gert, the problem with principlism was that it lacked systematic unity and offered no real course of action in real situations. They write,

'Principles function neither as adequate surrogates for moral theories nor as directives or guides for determining the morally correct action. Rather they are primarily chapter headings for a discussion of some concepts which are only superficially related to each other ... At best principles operate primarily as checklists naming issues worth remembering when considering a biomedical moral issue. At worst principles obscure and confuse moral reasoning by their failure to be guidelines and by their eclectic and unsystematic use of moral theory'.<sup>156</sup>

An adequate moral theory, according to the authors, ought to provide explanation of

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<sup>153</sup> R. Fox, 1999. Is Medical Education Asking too much of Bioethics? *Daedalus* 128, p. 11.

<sup>154</sup> D. Callahan, 1999. The social sciences and the tasks of bioethics. *Daedalus* 128, p. 283.

<sup>155</sup> K. Clouser, and B. Gert, 1990. A critique of principlism. *Journal of Medicine and Philosophy* 15: 219.

<sup>156</sup> Clouser and Gert, 1990, p. 221; 220.

moral agreement (and disagreement), and yield plausible account of what is and is not relevant to ethical judgements. As Beauchamp and Childress put it in the fifth edition of *Principles*, 'Clouser and Gert expect a strong measure of unity and systematic connection among rules, a clear pattern of justification, and a practical decision procedure that flows from a theory, whereas other philosophers are sceptical of one or more of these conditions, and even the language of theory'.<sup>157</sup>

However, Clouser and Gert are certainly not the only philosophers to highlight bioethics inadequacies. A potential ally in the attack on bioethics methodological reductionism is moral phenomenology. Writers such as Drew Leder and Richard Zaner argue that when making diagnostic judgements, medicine has substituted objective laboratory evidence in favour of judgements based on the patient's lived experience and oral testimony.<sup>158</sup> Such reasoning is not unlike Ramsey's work, briefly discussed in the previous chapter, that modern medicine has dehumanised the ill by relying on technological machinery and procedures that leave no space for the embodied subjectivity of the patient.

I shall now turn to the variety of other methods that have arise to challenge the four principles 'mantra'.

#### *Casuistry: using paradigm cases*

Casuistry owes its roots to Aristotle, who believed that in ethics, first principles were derived from what was known in concrete human actions and practice. Influential in Catholic moral theology, casuistry fell into disrepute in the late 17th century with the rise of Protestant and pietistic moral systems. Its most forceful critic was Blaise Pascal who denounced casuistry for its tendency to qualify general moral rules. In recent years, however, Albert Jonsen and Stephen Toulmin have revived the method.<sup>159</sup>

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<sup>157</sup> Beauchamp and Childress, 2001, p. 408.

<sup>158</sup> D. Leder, 1990. *The Absent Body*. Chicago: Chicago University Press; R. Zaner, 1981. *The Context of Self: A Phenomenological Inquiry using Medicine as a Clue*. Athens: Ohio University Press. For an erudite analysis of these two authors, see G. McKenny, 1997. *To Relieve the Human Condition: Bioethics, Technology, and the Body*. New York: SUNY.

McKenny, 1997, pp. 184-198.

<sup>159</sup> A. Jonsen, and S. Toulmin, *The Abuse of Casuistry: A History of Moral Reasoning*. Los Angeles: University of California Press..

It is worth quoting Jonsen's and Toulmin's definition. Casuistry, according to them, is:

the analysis of moral issues, using procedures of reasoning based on paradigms and analogies, leading to the formulation of expert opinions about the existence and stringency of particular moral obligations, framed in terms of rules or maxims that are general but not universal or invariable, since they hold good with certainty only in the typical conditions of the agent and circumstance of action.<sup>160</sup>

Casuistry, according to the authors, is unavoidable.<sup>161</sup> Deductive moral reasoning works only in situations where the application of principles and the relevancy of considerations are not in doubt -- a rarity. Therefore, moral analysis is best grasped if ethicists disregard 'theoretical cant' (a shot at Beauchamp and Childress, one assumes) and pay close attention to insights acquired in the course of 'pedestrian concrete practical experience.'<sup>162</sup> Moral knowledge, according to a casuist, is particular -- so conflict resolution must be grounded in specific cases and circumstances. Paradigm cases serve as guides, providing relevant norms, which, analogically, indicate which judgment or action to take in the case at hand. When paradigm cases conflict, a casuist would be the first to admit that uncertainty follows. Jonsen and Toulmin see moral belief evolving incrementally, from clear, resolvable cases to more complex ones. Casuistry, then, proceeds inductively and is rooted in case-based judgments that, theoretically, always remain open to re-interpretation and exceptions.<sup>163</sup>

### *The bioethics of care*

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<sup>160</sup>Jonsen, and S. Toulmin, 1988, p. 257.

<sup>161</sup>Jonsen, and S. Toulmin, 1988, pp.329-330.

<sup>162</sup>S. Toulmin, 1994. Casuistry and clinical ethics. In E. DuBoise, R. Hamel, and L. O'Connell eds., *A Matter of Principles?* Valley Forge: Trinity Press International, p. 318.

<sup>163</sup> As critics have noted, however, one drawback to this method is the risk of being far too accepting of previously established beliefs and practices. Why take prior decisions at face value? It may be possible, for instance, that court judgments or paradigm cases merely re-enforce unsound policies or institutional discrimination. See D. DeGrazia, 1992. 'Moving forward in bioethical theory: Theories, cases, and specified principlism. *Journal of Medicine and Philosophy* 17: 511-539.

The ethics of care emerged out of feminist moral philosophy and has been a vocal critic of principle based bioethics. Perhaps more than any other work, Carol Gilligan's *In a Different Voice* has brought the perspective of care into mainstream philosophical discussions.<sup>164</sup> Gilligan's study noted that the subjects of Lawrence Kohlberg's influential work on moral development were all male<sup>165</sup>. By applying Kohlberg's test to females, Gilligan found that women employ a different reasoning strategy. Instead of applying impartial rules and measuring moral progress in exclusively cognitive terms (as Kohlberg suggested men do), Gilligan's tests showed that females paid far greater attention to relational and emotional aspects of moral reasoning. Women, she convincingly found, focused on the details of context and narrative and sought solutions to ethical conflicts that attempted to protect everyone's interests.

The bioethics of care, as theorized by Rita Manning, has five central components.<sup>166</sup> Firstly, *moral attention* is the obligation to be familiar with the details of a patient's situation and feelings. This, as commentators have noted, requires the time to listen to patients. *Sympathetic understanding* entails learning what others want, why they want it and how they feel their interests could best be protected. Such awareness requires that health care providers remember themselves in an earlier medical crisis to sympathetically relate with the patient's current circumstances. Thirdly, *relationship awareness* is the recognition that the person exists not as a lone self but in a web of relationships that are central to their identity and can either assist or damage their well-being. Patients are 'fellow fragile humans' in need of help. *Accommodation* is the effort to meet the needs of all, including the care provider. While Manning notes full accommodation is impossible, she argues that there ought to at least be an attempt to give others a sense of being involved and considered in the process. Finally, *response* is the recognition that 'it is not enough to stare at the patient and imagine her in a sympathetic way'.<sup>167</sup> Rather, care must be translated into concrete actions.

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<sup>164</sup> C. Gilligan, 1984. *In a Different Voice: Psychological Theory and Women's Development*. Cambridge: Harvard Press.

<sup>165</sup> L. Kohlberg, 1981. *The Philosophy of Moral Development*. San Francisco: Harper and Row.

<sup>166</sup> R. Manning, 1998. A care approach. In P. Singer and H. Kuhse, eds., *A Companion to Bioethics*. Oxford: Blackwell, pp. 98-105.

<sup>167</sup> Manning, 1998, p. 99.

The bioethics of care emphasizes mutual dependency, vulnerability, relationship, and the role of power and inequality in health care<sup>168</sup>. Many care theorists have taken special aim at autonomy arguing that the principle, as formulated by Beauchamp and Childress has disregarded a patient's self-knowledge and overstated the generalizability of medical knowledge. These are themes addressed above in my brief discussion of moral phenomenology.<sup>169</sup>

However, the limits of this approach should be briefly noted. Susan Sherwin, for example, warns that feminists should be cautious about care ethics.<sup>170</sup> Questioning the role of gender in a sexist society, she raises the possibility that a woman's ability to care is related to her subordinate status in a system that is still patriarchal. Interestingly, Sherwin points out that traits such as nurturing and care are found among formerly colonized people of both genders. In other words, a lopsided emphasis on care may re-enforce oppressive practices. Sherwin argues that while caring is an admirable trait, ethicists must constantly explore the social context in which it takes place – a theme which keeps cropping up in my analysis and to which I will explore in depth later in the thesis.

### *The importance of virtue and character*

The final approach I consider has been advocated by theological ethicists. Virtue ethics, like casuistry, is rooted in ancient Greek philosophy. Virtues, socially and morally valued character traits, held a pre-eminent place in the work of Aristotle, who believed such qualities were acquired through learned habit. Aristotle argued that an action could be right without being virtuous but an action could be virtuous only if performed from the right state of mind, or motivation.<sup>171</sup> His thesis was that practice and virtue ought to have priority over ethical theory in normative decisionmaking. The revival of character ethics

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<sup>168</sup> For a useful insight into the relationship between feminism and care, see R. Tong, 2003. *Feminism and Feminist Bioethics: the search for a measure of unity in a field rich with diversity*. *New Review of Bioethics* 1: 85-100.

<sup>169</sup> A. Donchin, 2001. *Understanding Autonomy Relationally: Toward a Reconfiguration of Bioethical Principles*. *Journal of Medicine and Philosophy* 26: 365-386.

<sup>170</sup> S. Sherwin, *No Longer Patient: Feminist Ethics and Healthcare*. Philadelphia: Temple University Press.

<sup>171</sup> Aristotle, 1998. *Nicomachean Ethics*. New York: Dover Press, pp. 23-24.

is due, in part, to the work of communitarian thinkers such as Alastair MacIntyre and Stanley Hauerwas.

Virtue ethics asserts that goods are internal to a particular and structured communal life (this form of ethics, like care, repudiates liberal individualism). Medicine, as other professions, has a historical tradition which requires physicians to cultivate certain character traits of care and wisdom.<sup>172</sup> Unlike principles-based bioethics, which focuses on right action, a virtue approach is concerned with what kind of person a moral agent ought to be. A character ethicist holds that a virtuous professional can discern the proper action without reliance on rules or coercive laws. A virtuous person will *desire* to do what is right. Traits, such as courage, compassion, honesty, and sincerity, are to be cultivated through education, role models and habitual exercise. Such virtues, if developed properly, will provide a reliable basis, in practice, for morally correct behaviour. In specific relation to bioethics, some have emphasized the importance of creating institutional climates where health care professionals desire not to abuse their subjects. The rationale is that people tend to trust those who have ingrained motivations to perform honest, compassionate actions. Most character ethicists would agree, however, that virtue is the *means* for doing the right thing. Such a method, however, still benefits from being integrated with action-based theories.

In addition to these three alternatives to principles-oriented bioethics, which have emerged largely from within philosophy, I now turn to the observations of the social sciences.

### *The social science critique*

There are a number of ways of characterising the possible relationship between the social sciences (although here I mean mainly sociology) and ethics. For instance, they might be thought of as essentially competing in their attempts to explain the same phenomena, since one could ask which discipline asks the 'better' (more searching, more relevant) questions and which provides the 'better' (more complete, more convincing) answers.

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<sup>172</sup> A. MacIntyre, 1981. *After Virtue: a study in moral theory*. London: Duckworth, pp. 190-194.

This, of course, raises the question of what counts as appropriate questions and answers in the first place. Alternatively one could ask how each discipline complements the other. Then there is the possibility that an ethical scrutiny of sociology, that is, the ethics of doing sociology, raises further questions about the very nature of sociology as a discipline, over and beyond that more commonly raised in the narrower discussion of the ethics of sociological research methods and practices. Similarly there are questions to be raised by the sociological analysis of ethics as a set of interests, practices and institutions.<sup>173</sup>

Traditionally, sociology has been seen as the ‘handmaiden’ or ‘junior partner’ of philosophy, supplying the facts necessary to help make moral judgements.<sup>174</sup> According to this rather linear view, the social sciences gather their findings, which are then used to help ethicists decide what action to take. This linear model seems to ask that bioethicists merely get their facts straight and pay little notice to how those facts might have been produced.<sup>175</sup> But Mairi Levitt has observed, ‘any basic introduction to sociology suggests to students that the “facts” that are uncovered by empirical research will be related to the chosen perspective, the theoretical framework, research questions, and methods used. Facts do not speak for themselves’.<sup>176</sup> Thus, there has been a growing unease with sociology’s role as merely the fact producer.

A pioneer in these matters has been Renee Fox, whose work I used in the last chapter to explain why bioethics moved away from religion and adopted a more secular orientation. In short, Fox argued that bioethics sought greater relevance and authority in an increasingly secular society and could only achieve it by articulating a framework applicable to the widest possible cross section of society (i.e. a *common morality*). More specifically, she has observed how the practical necessity of managing complex decisions

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<sup>173</sup> M. Levitt and G. Williams, 2003. Thirty Years of Bioethics: all grown up now? *New Review of Bioethics* 1: 3-5. This paragraph is taken from a paper currently being drafted by Haines and Whong-Barr.

<sup>174</sup> J. L. Nelson, 2000. Moral Teachings from Unexpected Quarters: Lessons for Bioethics from the Social Sciences and Managed Care. *Hastings Center Report* 30: 12-17.

<sup>175</sup> A. Hedgecoe, 2004. Critical Bioethics: Beyond the Social Science Critique of Applied Ethics. *Bioethics* 18: 120-143.

<sup>176</sup> Levitt, 2003, p. 22. I shall return to this point in Chapter Seven in my discussion of Foucault’s power/knowledge nexus.

and influencing policy encourages a reductionistic method that quantifies variables through logical and rational analysis. Bioethicists, according to Fox, are predominately trained in analytical philosophy, which is heavily invested in utilitarian and positivist methods. She writes, 'An array of cognitive techniques are used to distance and abstract bioethical analysis from the human settings in which the questions under consideration occur, to reduce their complexity and ambiguity, and to control the strong feelings that many of the medical situations on bioethics centres can evoke'.<sup>177</sup> Ethical questions, in other words, are distanced from their phenomenological reality.

However, Fox's argument goes beyond the reductionistic tendencies of bioethics to provide what is now considered to be the first major sociological critique of the field.<sup>178</sup> In many ways her work set the tone, and since her first foray into the field, the dialogue/debate between the social sciences and medical ethics has been robust. Since Fox, a number of sociologically minded authors have added their voice to the chorus of attack on the normative claims made by philosophical bioethics.

Much sociological writing on bioethics has focused on either its unitary version of rationality, its reification of autonomy, or its lack of contextual analysis – all three of which are clearly interrelated. As care ethicists, many sociologists argue that in the prevailing ethos of bioethics the value of individualism is defined and emphasized to such extent that it is cut off from social and religious values concerning the relationships between individuals. This includes a severing of moral agents from their duties, commitments, and emotional ties to one another, and the societal community to which they belong.<sup>179</sup>

The charge that biomedical ethics lacks context means that cases and conflicts presented by bioethicists are a type of data 'totally within the control of the writer'.<sup>180</sup> The moral

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<sup>177</sup> Fox, 1990, p. 207.

<sup>178</sup> R. Fox, 1988. *Essays in Medical Sociology*, Oxford: Transaction Books, pp. 668-670.

<sup>179</sup> B. Hoffmaster, ed., 2001. *Bioethics in Social Context*. Philadelphia: Temple University Press; R. Zussman, 2000. The Contributions of Sociology to Medical Ethics. *Hastings Center Report* 30: 7-11.

<sup>180</sup> M. Levitt, 2003. Better Together? Sociological and Philosophical Perspectives on Bioethics. In M. Hayry and T. Takala, eds. *Scratching the Surface of Bioethics*, Amsterdam: Rodopi, p. 23.

complexity of a problem as well as the options and factors influencing the supposedly autonomous agent are limited by the writers imagination and/or agenda. Such techniques, in Tod Chamber's opinion, are purposefully apsychological, where particular people and relations are defined as incidental rather than essential to the eventual outcome of the case.<sup>181</sup>

Sociologists, then argue that one value of their empirical work is that it can show bioethicists how social structures, cultural settings, and social interaction influence ethics. Adopting a 'sociological imagination' on the practice of bioethics can show how the task of bioethics is constrained by disciplinary habits, professional relationships, cultural ways of seeing, institutional needs, economic demands and arrangements of power and prestige.<sup>182</sup>

Erica Haimes has also suggested that the social sciences have an important contribution to make to the study of ethics.<sup>183</sup> This includes theoretical and empirical contributions, as well as their combination to the enhancement of the understanding of how ethics, as a field of analysis and debate, is socially constituted and situated. Haimes attempts to go beyond the over-simplistic division between normative and descriptive ethics (as indicated above, that which assigns the social sciences the 'handmaiden' role of simply providing the 'facts'). Using examples from reproductive medicine, her article establishes that the social sciences have a longstanding theoretical interest in concepts central to the study of ethics, such as explanations of social change, social organisation and social action; that empirical investigations conducted by social scientists exemplify the interplay of epistemological and methodological analyses which improves understanding of particular substantive issues is extended beyond the conventional questions raised by ethicists; and, that through this combination of theoretical and empirical work, social scientists go beyond the specific ethical questions of particular practices to enquire

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<sup>181</sup>T. Chambers, 1997. What to expect from an ethics case (and what it expects from you). In H. L. Nelson, ed., *Stories and Their Limits*. London: Routledge, pp. 171-184.

<sup>182</sup>R. DeVries and P. Conrad, 1998. Why bioethics needs sociology. In R. DeVries, and J. Subedi, 1998. *Bioethics and Society: Constructing the Ethical Enterprise*. NJ: Simon & Schuster, pp. 233-234.

<sup>183</sup>E. Haimes, 2002. What can Sociology contribute to the study of ethics? Theoretical, empirical and substantive considerations. *Bioethics* 16: 89-113.

further into the social processes that lie behind the very designation of certain matters as being 'ethical issues'.

Thus, Haimés seeks to demonstrate that empirical inquiry is not simply an exercise in 'scooping up the facts', to supply ethicists with the materials from which to conduct their formal analyses.<sup>184</sup> Rather, she views it as a way of accessing human reality and then to analytically display, the various ways in which we all act and think and reason ethically. Haimés also advocates a 'sociology of ethics', to investigate the emergence, definition and delineation of different terms (such as as ethics/ medical ethics/ bioethics/ empirical ethics/ evidence-based ethics etc), as well as their appropriation of particular areas of interest and concern (and its exclusion of other areas of interest).

How does a philosophically minded bioethics respond to these charges? Beauchamp and Childress make the usual distinction between descriptive and normative ethics. The former is 'the factual investigation of moral conduct and beliefs. It uses scientific techniques to study how people reason and act'.<sup>185</sup> Normative ethics, meanwhile, is a 'form of inquiry that attempts to answer the question, "Which general moral norms for the guidance and evaluation of conduct should we accept and why?" Ethical theories attempt to identify and justify these norms.'<sup>186</sup> According to this view, knowing what people think or believe does not make it right; the social sciences, in other words, do not offer action-guides.

Philosophical bioethicists may also point out the dangers in merely following public opinion rather than scrutinising it in light of first principles.<sup>187</sup> They also are critical of sociology's relativism and tendency to accept that 'anything goes' and that all moral values are of equal worth. These counter-charges all, in effect, come down to the fact/value dichotomy – to which social scientists are likely to respond that a rigorous

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<sup>184</sup> In her article, Haimés calls for a dialogue between sociology and ethics, to avoid charges of 'sociological imperialism' – a phrase which I continue to find baffling despite many conversations with Haimés on this topic. I'd suggest that the only people truly concerned about an imaginary 'imperialism' are sociologists themselves.

<sup>185</sup> Beauchamp and Childress, 2001, p. 2.

<sup>186</sup> Beauchamp and Childress, 2001, p. 2.

<sup>187</sup> Levitt, 2003.

separation of the descriptive and the normative is practically untenable. The dichotomy between fact and value or between is and ought could, perhaps, be seen as an artefact of the theoretical project of justification and not an intrinsic feature of moral experience.<sup>188</sup>

### *Summary and conclusion*

The various critiques of mainstream biomedical ethics, as presented, here include:

- That principlism is a reductionistic method which at best offers no more than a checklist of items to consider when judging moral problems and at worse simply confuses matters due to a lack of theoretical unity.
- Philosophically based alternatives to principlism include: casuistry which uses procedures of reasoning based on paradigms and analogies and past cases rather than universal first principles; care, which stresses the realities of dependency, vulnerability and relationships of the patient; and virtue which focuses on the question of an agent's moral character.
- The social science critique asserts that bioethics: a) assumes that moral problems come pre-sorted and ready for the manipulation of rules, principles, or theories; b) ignores the extent to which moral concepts and norms derive their meaning from the social and cultural surroundings in which they are embedded; c) neglects the ways in which moral problems are generated and framed by the practices, structures, and institutions within which they arise; d) and ignores the means by which ideology and power relationships both perpetuate the status-quo and, conversely, can effect moral change.<sup>189</sup>

So far in this thesis, I've argued in the abstract with bioethical theories, methods, ideas and historical trends – but not actual issues. In the next two chapters, I look in considerable depth at one issue, the use of large scale human tissue collections in genetic

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<sup>188</sup> Hoffmaster, 2001; DeVries and J. Subedi, 1998.

<sup>189</sup> Hoffmaster, 2001; DeVries and J. Subedi, 1998.

epidemiological research. By exploring a particular case I hope to look at bioethics in action both in its normative and empirical forms. My case study, in other words, will allow me to put flesh on the bones of the previous three chapters and avoid (hopefully) the all too common error of setting up a straw figure which I can then conveniently knock down with preconceived and pre-packaged arguments.

## Chapter Five

### Genetic epidemiology: mapping the terrain

#### *Introduction*

In the following two chapters the thesis takes a turn in direction to investigate an issue that has attracted a significant audience in bioethics literature, the social sciences and public policy documents. The issue, genetic epidemiology, requires some introduction given its complexity and since thus far, the thesis has been silent on the topic of genetic science. Therefore, I begin by mapping the terrain and exploring the conceptual issues and competing claims in this field. I start with the history of public health. I begin in this way since genetic epidemiology is, in my estimation, a case of public par excellence. In other words, it is the ultimate attempt to improve a society's health on a wide spread scale by combining analysis of DNA with personal medical history. By knowing individual genetic profiles and using that information to increase longevity and avoid disease, researchers hope to bring dramatic long term improvements to the public's health. This is done on the population level since, as we shall see, it is only through large scale DNA collections that such improvement in health can ever be achieved (i.e. knowing the genetic profile of one individual tells an investigator little if there is not a larger 'normal' subset with which to compare the profile).

#### *A short history of public health*

Historically, Western public health was mainly concerned with removing waste products from the public and controlling the outbreak of epidemics. Waste removal dealt with things such as street cleaning, sewage disposal and hygienic measures in public spaces such as marketplaces. A common technique to deal with epidemics (such as the plague) was the quarantine, a method of control developed from the contagion theory of disease causation – the idea that illness spread from one physical body to another<sup>190</sup>. A related

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<sup>190</sup> In the medieval era, many believed that plague was Heaven-sent, and that instead of quarantine, it was only through prayer, fasting and flagellation that towns could be cured. See: R. Porter, 1999. *The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present*, London: Harper Collins, p. 125.

theory of epidemics, favoured by the Greeks, was miasmatic theory, the notion that bad air and the odours of putrefaction led to disease.

The growth of the modern public health movement is best understood in relation to wider trends in Enlightenment political and social philosophy. Until the end of the eighteenth century, notions that the numbers of people reflected the riches and strength of the state went largely uncontested.<sup>191</sup> Mercantilist philosophy (referred to as cameralism in Germany) emphasized the value of augmenting the power and treasury of the state. It was argued that a large population would increase production of crops and goods, provide men for standing armies, and yield sufficient income from taxes and rents. The welfare of the sovereign *was* the welfare of society and the prosperity of both could be attained through an abundant population. Crudely put, the rationale behind this philosophy was that more people meant more revenue. Given this line of reasoning, it is not hard to see that the health of the population was a central concern of state authority. To the extent that it impeded production, disease was -- *is* -- a political, economic and social problem.

Support for these claims runs throughout eighteenth century literature. In 1714, John Bellars, a Quaker cloth merchant, provided an early correlation between lost revenue and needless death:

‘[I]t may be reasonably supposed that a hundred thousand ... die yearly of curable diseases; for want of timely advice, and suitable medicines ... Labouring people are the Kingdom’s greatest treasure and strength, for without labourers there can be no lords; and if the poor labourers did not raise much more food and manufacture than what did subsist themselves, every gentleman must be a labourer and every idle man must starve ... Every able industrious labourer that is capable to have children, who so untimely dies, may be accounted two hundred pound loss to the kingdom.’<sup>192</sup>

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<sup>191</sup>For an overview of mercantilism and public health, see G. Rosen, 1993. *A History of Public Health*, Baltimore: JHU Press, 2nd ed; D. Porter, 1999. *Health, Civilization and the State: A history of public health from ancient to modern times*, London: Routledge.

<sup>192</sup>J. Bellars, 1714. *ESSAY Towards the IMPROVEMENT of PHYSICK*. London: Sowle. Quoted from G.

In noting the importance of the working poor by referring to the food and goods they produce, Bellars highlighted much of the rationale behind early public health movements. (I use the plural since public health was not a unified campaign, especially in Britain). Underlying various public health initiatives was a utilitarian calculation: a country was well off if the majority of citizens were well off. And since in straight numerical terms, most of the people were poor, improving their conditions was a necessary obligation for those in power. In other words, the greatest good of the greatest number was important, in part, because it had a direct impact on the well-being of the privileged. Only when the majority of poor were properly clothed, housed, and treated could they then become the vibrant work force that would insure other peoples' wealth. Both public and private measures to protect the poor (the latter being common in Britain) were not merely humane gestures of enlightenment and progress. They were, in addition, practical measures adopted in order to avoid the day when 'every gentleman must be a labourer.'

John Ferriar, an associate of the medical ethicist Thomas Percival (discussed in Chapter Two) was instrumental in setting up regulations to stem epidemics and offer preventative advice to the public. Many of Ferriar's circulars, such as *Advice to the Poor*, was written in lay language, so it could benefit 'the persons for whose benefit it was designed'. The circular's primary aim was prevention of contagious fevers.<sup>193</sup>

Ferriar's advice ranged from 'avoid living in damp cellars' to encouraging families and friends to report persons afflicted with fever to the health authorities, an act rewarded by

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Rosen, 1944. An Eighteenth Century Plan for a National Health Service. *Bulletin of the History of Medicine* 16: 432.

<sup>193</sup>G. Rosen, 1942. John Ferriar's 'Advice to the Poor'. *Bulletin of the History of Medicine* 11: 223. Ferriar's circular provides an excellent example of the two way nature of the medicalisation of the family. On the one hand, there is a strong paternalism, on the other, the encouragement of self-governance ('much depends upon your own conduct, for preventing the first occasions of sickness'. It should be noted that eighteenth century medicalisation was not the one way phenomena that some have characterized it as being. See for example, D. Porter and R. Porter, 1989. *Patient's Progress: Doctors and Doctoring in Eighteenth Century England*. Cambridge: Polity Press. The Porters' convincingly argue that patients exercised considerable control over medical relations. Yet they do not extend this insight to their account of medicalisation, which they seem to oversimplify as a one-way control of doctor over patient. I touch on these issues below in my discussion on sociological perspectives of modern public health.

two shillings for each fever reported.<sup>194</sup> At times Ferriar was extraordinarily detailed: when visiting sick neighbours, 'you may preserve yourselves from being infected by tying a handkerchief across your face, just below the eyes ... As soon as you return to your own house, wash your hands and face in cold water, and avoid touching any of your family, for half or three quarters of an hour.'<sup>195</sup>

Ferriar also placed considerable emphasis on the well being of the young. His circular goes on to suggest a number of measures for the benefit of children, such as small pox inoculation. By inoculating, 'you ought to consider yourselves as performing a duty to your children, and to the public'. His general advice included: 'Always wash your children from head to foot with cold water, before you send them to work in the morning. Take care to keep them dry in their feet, and never allow them to go to work without giving them breakfast, though you should have nothing to offer them but a crust of bread and a little water.'<sup>196</sup>

However, it was not sufficient for a state to merely claim the importance of a 'population'. As a logical next step, it was imperative to have knowledge of peoples' habits and lives. The birth and use of social statistics provided the means by which a 'population' was an entity capable of being known and studied.<sup>197</sup> One of the earliest proponents of statistical analysis, William Petty, is famous as the father of 'political arithmetic'. Petty collected data on many aspects of the population -- its trade, education, health and disease. He, like Percival, claimed inspiration from Francis Bacon's assertion that the strength of the state could be analyzed mathematically.<sup>198</sup>

Percival had a penchant for applying quantitative tools to the analysis of population and health. Indeed it was no coincidence that Percival was as heavily involved in public health as he was in medical ethics, given his remit to design a code of ethics for hospital medicine. As one historian has noted, 'the underlying premise of new hospitals' was 'that

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<sup>194</sup>Rosen, 1942, p. 225.

<sup>195</sup>Rosen, 1942, p. 225.

<sup>196</sup>Rosen, 1942, p. 225.

<sup>197</sup>See D. Porter, 1999, especially chapter 4.

<sup>198</sup>D. Porter, 1999, pp. 49-50; Rosen, 1993, pp 87-88.

disease could be controlled, removed, and perhaps prevented by the conscious and deliberate application of “enlightened” views about health’.<sup>199</sup> Hospitals were an opportunity to provide short-term relief to the working poor who otherwise may not have received treatment. They formed part of the promotion of a whole ‘politico-economic agenda’ which Foucault dubbed ‘the imperative of health: at once, the duty of each and objective of all.’<sup>200</sup> For his part, Percival presented data on marriage and birth rates, as well as the causes of death, which he correlated to age and gender.<sup>201</sup> In *Proposals for Establishing More Accurate and Comprehensive Bills of Mortality in Manchester*, Percival used his records to support a small-pox inoculation campaign and to prove that cod-liver oil could successfully treat rickets. Later in his career, he explained:

‘The number of inhabitants and progress of population in the kingdom; the increase or decrease of certain diseases; the comparative healthiness of different situations, climate and seasons; and the influence of particular trades and manufactures on the duration of life, are subjects of the highest importance to the community; and equally interesting to the statesmen, the philosopher and physician.’<sup>202</sup>

Having detailed knowledge of a population provided the means for authorities to intervene in the processes of population for the good of state and society. Successful management of people required a health policy able to affect living standards and reduce rates of both epidemics and infant mortality. In the eighteenth century, many urban areas became congested and polluted due to an influx of rural labourers and distressed artisans, who were in search of employment in new industries. These conditions were conducive to the spread of disease and provided a partial initiative to interventionist sanitation campaigns.

The term medical police was used to characterise the trend of state involvement in health matters. Here, ‘police’ refers not to law enforcement per se but to an active programme of

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<sup>199</sup>Risse, 1992, pp. 172.

<sup>200</sup>M. Foucault, 2000. *The Politics of Health in the Eighteenth Century*. In J. Faubion, ed., *Power: Essential Works of Foucault 1954-1984*. New York: Free Press, p. 94.

<sup>201</sup>Unable to locate a copy of *Proposals*, I have relied upon Haakonssen, 1997, p. 113.

<sup>202</sup>Haakonssen, 1997, p. 113.

public sanitation directed by professionals in fields as divergent as government, medicine, law and education.<sup>203</sup> The greatest proponent of medical police was probably Johann Frank, who advocated that governments ought to actively regulate nearly every aspect of human life from marriage selection to transportation systems.<sup>204</sup>

In Britain, in the mid nineteenth century, Edwin Chadwick famously promoted sanitary conditions for the working poor in order to 'remove waste, inefficiency, and corruption' and assist free marketers in leading Britain to prosperity.<sup>205</sup> A Royal commission led by Chadwick recommended improvements in drainage systems, the deterioration of which resulted in the spread of diseases such as typhoid and cholera.<sup>206</sup> By the end of the nineteenth century, public health campaigners relied on the new science of bacteriology which posited the existence of 'particulate, living, microscopic agents' in both causing disease and acting as a means of transmission.<sup>207</sup> Public health in general and epidemiology specifically used this theory to build on old contagion and miasmatic models. As a result epidemiology entered a new phase when 'morbidity and mortality statistics could be related not just to specific infectious diseases, but to specific diseases cause by specific identifiable agents'.<sup>208</sup>

This short history takes us up to the last century when theories of inheritance and heredity emerged as tools in public health campaigns.

### *Twentieth century eugenics*

The word 'eugenics' is used frequently, though its exact meaning is rarely made clear.

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<sup>203</sup> There exists some debate amongst scholars about the difference between terms such as medical police, public health, state medicine and the extent to which events in mainland Europe influenced Britain. These debates, like the ones over eighteenth century medical ethics, make for intriguing reading but lie beyond the scope of this work. See P. Carroll, 2002. *Medical Police and the History of Public Health. Medical History* 46: 461-494.

<sup>204</sup> Risse, 1992, p. 173. Frank's work was known as *A System of Complete Medical Police*.

<sup>205</sup> D. Lupton, 1995. *The Imperative of Health: Public Health and the Regulated Body*. London: SAGE, p. 28; E. Chadwick, 1842. *Report on the Sanitary Condition of the Labouring Population of Great Britain*.

<sup>206</sup> S. Coughlin and T. Beauchamp, eds., 1996. *Ethics and Epidemiology*: Oxford: Oxford University Press, p. 8.

<sup>207</sup> L. Wilkinson, 1993. In W.F. Bynum and R. Porter, eds. *Companion encyclopedia of the history of medicine*. London: Routledge.

<sup>208</sup> Wilkinson, 1993, p. 1274.

Does it refer only to policies that rely on coercion to improve the quality of a population? Or does it include all attempts to better the gene pool, including, say, education, diet and so forth? One distinction observers often make is between positive and negative eugenics. The former encourages 'fit' families (i.e. white, middle-upper class) to breed as much as possible; negative eugenics, on the other hand, refers to efforts to prohibit the 'unfit' from reproducing at all.<sup>209</sup>

Whatever definition one adopts, the racial hygiene campaigns of National Socialism in Germany have been well rehearsed. Here, I wish to bring attention to eugenic movements in the United States, United Kingdom, and (to a lesser extent) Scandinavia.<sup>210</sup> Eugenicians in these countries all shared the conviction that reproduction decisions should be guided by social concerns and that biological knowledge was an acceptable tool in assisting the promotion of those objectives. Whilst in the early part of the century, Britain campaigners never succeeded in passing eugenic legislation, their Galtonian rhetoric had a profound impact on society. According to Diane Paul, 'whole sections of British society now took for granted that talent and character were inborn and fixed.'<sup>211</sup> Throughout Britain, North America and Scandinavia it seems clear that the primary engines which drove eugenics were the interrelated factors of rapid social change, immigration, and economic insecurity. I shall bring this section to a close with the 'chilling' words, expressed in 1914, by the American Charles Davenport,

'We hear a great deal about infant mortality and child saving that appeals to the humanity and the child-love in us all. It is, however, always the saving of the lowest class that is contemplated. I recall the impassioned appeal of a sociologist for assistance in stopping the frightful mortality among the children of prostitutes. But the daughters of prostitutes

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<sup>209</sup> A. Buchanan, D. Brock, N. Daniels, D. Wilker, 2000. *From chance to choice: genetics and justice*. Cambridge: Cambridge University Press. The authors of this excellent text claim that the greatest flaw of eugenics was its failure to take justice seriously. However, I'd argue instead that proponents of eugenics simply *define justice differently* from those who view eugenics as unethical.

<sup>210</sup> My discussion draw on: D. Kelves, 1995. *In the Name of Eugenics*. Cambridge: Harvard University Press; D. Paul, 1998. *Controlling Human Heredity: 1865 to the Present*. New York: Humanity Books; A. Kerr and T. Shakespeare, 2002. *Genetic Politics: From eugenics to genome*. Cheltenham: New Clarion Press; G. Brodberg and N. Roll-Hansen eds., 1996. *Eugenics and the Welfare State: Sterilization policy in Denmark, Sweden, Norway and Finland*. East Lansing: Michigan University Press.

<sup>211</sup> Paul, 1998, p. 76.

have hardly one chance in two of being able to react otherwise than their mothers. Why must we start an expensive campaign to keep alive those who, were they intelligent enough, might well curse us for having intervened on their behalf? Is not death nature's great blessing to the race? If we have greater power to prevent it than ever before, so much the greater is our responsibility to use that power *selectively* for the survival of those of best stock; more than those who are feeble-minded and without moral content.'<sup>212</sup>

### *Sociological perspectives on eugenics and epidemiology*

In recent decades with the rise of genetics and new screening programmes, the issue of eugenics has taken a new urgency. However, in genetic epidemiology, eugenics is not often cited as a major ethical concern. Genetic technologies such as pre-natal screening and embryo selection (in other words, issues in reproductive medicine) raise the spectre of eugenics more clearly than biobanking, which is (to date, anyway) limited to major infectious and chronic diseases and not physical or mental disabilities. Contemporary genetic and ante-natal services do not have eugenic outcomes as their explicit objective. Instead (as I discuss below) today's language is couched in terms of choice and reproductive freedom. Troy Duster has famously referred to this as 'backdoor eugenics'.<sup>213</sup> Duster's fear is that screening programs designed for serious life-threatening disorders will become widely accepted to the point where in the struggle over where to draw the line, more and more *non*-life threatening disorders will be screened and eliminated. His fear, in other words, is not too much government intervention but rather too little. Others have expressed similar concerns. Anne Kerr and Tom Shakespeare, for instance, argue that eugenics is an 'emergent property' of the prevailing structure of reproduction.<sup>214</sup> The problem, according to the authors, is that in reality reproductive 'choice' is restricted by the attitudes and ethos of medical professionals, who tend to provide prospective parents with biased information regarding their pregnancy.

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<sup>212</sup> Cited in Buchanan, et al., 2000, p. 44.

<sup>213</sup> T. Duster, 1990. *Backdoor to Eugenics*. New York: Routledge.

<sup>214</sup> Kerr and Shakespeare, 2002, p. 6. See also: M. Whong-Barr, 2003. Review of R. Song and A. Kerr & T. Shakespeare: Human Genetics and Genetic Politics. *New Genetics and Society* 22: 117-118.

The last ten years have seen a burgeoning sociological interest in the 'new genetics' which is not surprising given the ability of ideas around genetics to transform wider social and cultural ideas about identity, self, the body and kinship. Even in a narrower sense, population and epidemiological genetics (and the development of genetic databases as a particular type of tool in this field) transform ideas about health and illness in certain ways. However, sociologically speaking, such databases extend and enhance notions of certainty in medical knowledge, through the increased surveillance of populations and through extending the idea of potential pathology.<sup>215</sup>

This relatively recent development in population genetics is a further example of a claim made some time ago by de Swaan, that the expansion of the medical regime increasingly transforms us all into 'not-yet-patients':

'The medical regime operates in a light and extensive form throughout modern society. By now, whoever is not a patient is considered a not-yet-patient: a permanent alert for the early warning signs of disease is in operation; mass screenings, routine check-ups, physicals for insurance clients, military recruits and job applicants process the entire population. Entire categories of apparently healthy persons are declared, a priori, medical subjects: pregnant women, infants, senior citizens. Everyone is under constant pressure to stay fit and avoid harmful pleasures.'<sup>216</sup>

In many ways, sociological literature on the new genetics (which grows by the day) revolves around two mutually reinforcing poles: coercion/control and choice/citizenship. Alan Petersen and Robert Bunton write that

'The science of epidemiology, for example, continues to construct particular groups and populations within a broader values of the Western world. Certain groups and bodies continue to be categorised as troublesome, frail or problematic, such as those of women,

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<sup>215</sup> A. Kerr and S. Cunningham-Burley, 2000. On ambivalence and risk: Reflexive modernity and the new human genetics. *Sociology* 34: 283-304. This paragraph and the next are based on work in progress from Haines and Whong-Barr.

<sup>216</sup> A. De Swaan, 1990. *The Management of Normality*. London: Routledge, p. 12.

homosexuals or black people. These forms of knowledge influence self-knowledge and self-formation. As well as providing psychological and experimental forms of self-knowing, through potential genetic manipulation and “choice”, contemporary science also provides techniques for what might be referred to as the “biological body”.<sup>217</sup>

The relationship between control and choice, according to these readings, is reciprocal. Public health aims to police the body (individual and social) by collecting and using statistical information on health, genes, and lifestyle habits. ‘Discipline’, though, is imposed through webs of liberal social power that obliges responsible citizens into good health promotion.<sup>218</sup> The symbiotic relationship between state needs and peoples’ desires has been dubbed ‘neo-liberalism’ and is a common feature of governmentality studies, which have become increasingly influential in the sociology of genetics.<sup>219</sup>

Sociological writings on history and practice of public health are useful in my estimation since they tell a slightly different story from medical historians who tend write a linear and relatively unproblematic progression of improvement in health promotion. That is, they tend to be more critical of medical advances, stressing the losses, costs and dangers involved in scientific progress. I shall have more to say on this in Chapters Seven and Eight. Now I aim to evaluate in detail the contemporary practice of genetic epidemiology and the range of socio-ethical issues that it raises.

### *Genetic epidemiology*

Researchers claim that the next major advance in medicine will arise from developments in genetic technology. Scientists believe that in order to realise clinical and public health benefits from the mapping of the human genome, large-scale population-based studies incorporating information on genetics and health are the appropriate next step.<sup>220</sup> At the

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<sup>217</sup> A. Petersen and R. Bunton, 2002. *The New Genetics and The Public's Health*. London: Routledge, p. 82.

<sup>218</sup> T. Osborne, 1997. Of Health and Statecraft. In A. Petersen and R. Bunton eds., *Foucault, Health and Medicine*. London: Routledge, pp. 173-188.

<sup>219</sup> See N. Rose, 1999. *Governing the Soul: The Shaping of the Private Self*, 2ed. London: Free Association Books.

<sup>220</sup> House of Lords Select Committee on Science and Technology, 2001. *Human Genetic Databases*. Fourth Report.

same time, progress in information technology has improved the feasibility and cost-effectiveness of conducting large-scale epidemiological studies, making it feasible to conduct a large study incorporating information on genetic factors and an individual's health and exposure history.<sup>221</sup>

As I alluded to in the opening, epidemiology is the study of the distribution of disease in populations and of the factors affecting that distribution.<sup>222</sup> In contrast to clinical medicine where emphasis is on the *individual*, epidemiology involves the examination of patterns of disease in *groups* of individuals. Epidemiology originated from investigations of epidemics of *infectious* diseases in the 19th century. Today, however, epidemiological research in western countries is directed largely at *chronic* diseases, such as heart disease and cancer – a point which raises a number of questions about resource allocation and global justice, topics I address in Chapter Eight in my discussion on power in bioethics.

Population genetics studies gene-environment interactions and their role in disease causation. To be successful, it requires large-scale population based sample collections and access to detailed patient medical information, such as clinical medical records.<sup>223</sup> It is thought that an individual's risk of disease relates to three broad areas: their exposure to environmental conditions, their genotype, and the role of chance. As more is learned about gene-disease associations and genetic polymorphisms, researchers hope that it will become possible to understand the relative contribution of genetic risk factors and specific environmental conditions that lead to common multi-factorial (i.e. involving more than one cause) diseases.

#### *Genetic databases: definition and terms*

The House of Lords defines genetic databases as 'collections of genetic sequence information, or of human tissue from which such information might be derived, that are

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<sup>221</sup> A. Bayat, 2001. Bioinformatics. *British Medical Journal* 324: 1018-1022.

<sup>222</sup> For a readable introduction to epidemiological methods, see: A. Silman and G. Macfarlane, 2002. *Epidemiological Studies: A Practical Guide* 2ed. Cambridge: Cambridge University Press.

<sup>223</sup> W. Lowrance, 2001. The promise of human genetic databases. *British Medical Journal*. 322: 1009-1010

or could be linked to named individuals'.<sup>224</sup> While recognizing debates over terminology, I use the terms biobank, DNA bank, gene bank, and genetic database interchangeably.<sup>225</sup> Essentially, all terms refer to collections of biological tissue, from which DNA can be extracted for genetic analysis and linked to personal medical information.<sup>226</sup>

### *Personal medical information*

Scientists claim that in order to make maximum use of genetic samples, they need to be able to link it to a donor's personal medical history and clinical records. This is important since environmental factors, such as smoking and diet, alter one's predisposition to illness and could have a profound influence on one's genetic contribution to disease.

In Britain, there are a number of ways for researchers to access a subject's personal medical information. These include: direct health interviews, access to GP records, and disease registers, which includes personal details of the patient, the site, type, and stage of the disease, the management of the disease and treatment, and the eventual outcome. These data have proved invaluable in epidemiological studies.<sup>227</sup> Another way to access patient's history is through the collection of geographical information such as postcodes. These enable researchers to link data in order to look for the effects of environmental pollution on the health of the population. The value and interpretation of this type of analysis, however, is dependent on the accuracy, completeness and timeliness of the data.

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<sup>224</sup> Lords, 2001.

<sup>225</sup> Most writers use these terms synonymously. David King, however, believes the term 'database' can be misleading, since it implies that information about a person's genes can be somehow 'fished out' from the collection. He correctly points out that information regarding someone's genetic health can only be learned by doing genetic research and tests on the DNA samples contained in the database. See King, 2001. Evidence presented to the House of Lords Fourth Select Committee on Science and Technology: Genetic Databases.

<sup>226</sup> There are many large biological sample collections from which DNA may be extracted since academic, commercial, and clinical laboratories all hold specimens (Lords, 2001). While these collections could theoretically provide material for a national DNA bank, this possibility has been dismissed by scientists since the collections are not well coordinated and the quality of DNA samples in the samples are varied. In addition, many samples cannot be traced back to the donor, making epidemiological analysis difficult. Finally, from an ethical standpoint, there would be questions regarding the lack of patient consent for their sample to be added to a nationally organized collection.

<sup>227</sup> Lords 2001: 5.12.

### *Benefits*

Proponents of genetic research highlight two major aims of biobanking. These are to identify interactions between genes and environmental factors that are involved in the cause of disease, and to better predict and address adverse drug reactions. In other words, the promised benefits involve improved methods of diagnosis and therapy. A third benefit may be in scientific spin-offs and in areas of research that 'cannot yet be envisaged' (i.e. the design of biobank studies means that the data contained within them can be used to address questions of future scientific and public health relevance which have not yet come to light.)<sup>228</sup>

Several benefits have already been achieved through smaller scale biobank collections. These include using the BRCA-2 gene as a predictive diagnostic for breast cancer and genotyping of leukaemic cells which have enabled the correct type of leukaemia to be diagnosed so that appropriate treatments can be made. Currently, more than one thousand disease-related genes (mainly for single-gene disorders) are documented on specialised databases, leading to new screening tests and improvements in diagnosis and disease prediction.<sup>229</sup>

### *Diagnostics*

Disease causation is complex. Previous research into asthma and hypertension, for instance, has found that it is difficult to distinguish abnormalities which might *cause* the disease from those which are its *consequence*. However, it is thought that databases will help researchers understand how small sequence differences in genes influence gene function and hence, lead to disease susceptibility. Pharmaceutical companies believe that databases would increase understanding of the natural history of diseases and help understand factors associated with things such as: onset, severity, how multiple susceptibility genes interact with each other and the environment, and how various health

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<sup>228</sup> Lords, 2001. Of course one spin-off may be 'genetic weapons' which could be dropped on a population and designed to eliminate only people of a certain genetic make-up. In this way, genetic epidemiology may be less a case of public health par excellence than eugenics par excellence. For this and more happy scenarios, see: D. Suzuki and P. Knudtson, 1990. *Genethics: The Clash Between the New Genetics and Human Values*. Cambridge: Harvard University Press, pp. 192-221.

<sup>229</sup> J, Kaprio, 2000. Genetic Epidemiology. *British Medical Journal* 320: 1257-1259.

interventions would impact the onset and course of disease.<sup>230</sup> In British research, conditions that researchers aim to identify susceptibility genes for include: asthma, heart disease, cancer, osteoarthritis, depression, chronic obstructive pulmonary disease, migraine, diabetes, Alzheimer disease, and Parkinson's disease.

To provide one example, over 25,000 people younger than sixty-five die each year from heart artery disease in England and Wales. According to researchers, many of these cannot be connected to risk factors such as smoking, diet, or blood pressure and occur repeatedly in the same families, which suggest a genetic link. It is believed that numerous genes are involved in this condition, hence there is a need to find currently unrecognised molecular mechanisms by searching for novel genetic variants.<sup>231</sup> By using large scale DNA collections and health records, scientists aim to find such variants.

### *Therapeutics*

The development of tailor made drugs, derived from population based genetic research, is known as pharmacogenetics. It is thought that the development of these medicines are likely to take ten to fifteen years from the identification of a susceptibility gene. The main idea behind pharmacogenetics is that by comparing the DNA of patients who have responded badly to a drug with control groups who did not experience an adverse effect, researchers may discover DNA markers which can predict adverse side effects. This may lead to the development of drug response profiles which would determine if a patient is likely to benefit and/or experience serious side effects from medication.

Pharmacogenetics then has the potential to allow physicians to prescribe medicines more accurately based on a pre-determined efficacy and safety profile.<sup>232</sup>

The possibility of specially suited drugs has received much attention. Professor Sir George Radda, Chief Executive of the Medical Research Council, said of Britain's attempt to build a national biobank (described below): 'This exciting project may one day

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<sup>230</sup> Lords, 2001.

<sup>231</sup> Acute coronary event DNA Library Project, 2000.

<sup>232</sup> Lords, 2001.

herald a new era of medicine. In 20 years time, we may see individualised approaches to disease prevention and medicine.<sup>233</sup>

### *Doubts and debates*

The promise of biobanks and pharmacogenetics has not gone unchallenged. Commentators have charged that plans for the British database, for example, are politically motivated rather than being scientifically driven.<sup>234</sup> They claim that the development and awarding of contracts to house the collections have been time consuming and highly inefficient. More damaging, some have cast doubt on the scientific validity of genetic databases.<sup>235</sup> The concern here is that case-control and disease specific studies may yield more useful data than large cohort studies that are based on normal populations.

Others have expressed concern over the 'dubious methodology' of biobanks.<sup>236</sup> Ian Gibson MP, worried that databases could lead to an over emphasis on genetic causes since genetic input would be the only hard data available to researchers. His concern was that many people would have 'patchy recollections' of past lifestyle factors and behavioural habits. Gibson's fear was that, in the case of obesity, for example, genetic research would lead to a stress on DNA tests and minimise the importance of things such as diet and lifestyle. Gene Watch UK, an organisation devoted to monitoring developments in genetics, echoed these concerns, adding that 'people don't always tell the truth about their habits.'<sup>237</sup>

There have also been concerns regarding the anticipated benefits of pharmacogenetics.<sup>238</sup> Even advocates of this field have admitted that it will take at least ten years for new products to be developed. Sceptics worry that given the cost needed to make novel medicines and the specificity of them for individual patients, very few will end up

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<sup>233</sup> For these comments, see [www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk).

<sup>234</sup> V. Barbour, 2003. UK Biobank: a project in search of a protocol? *The Lancet* 361: 1734-1738. For a response, see T. Meade, 2003. The future of Biobank. *The Lancet* 362: 492.

<sup>235</sup> D. Clayton and P. McKeigue, 2001. Epidemiological methods for studying genes and environmental factors in complex diseases. *The Lancet* 358: 1356-1360.

<sup>236</sup> Hansard, 2002. Biobank. *Houses of Parliament* : 365-372.

<sup>237</sup> K. Staley, 2001. *Giving your genes to Biobank UK: Questions to Ask*. A Report for Gene Watch UK.

<sup>238</sup> B. Williams-Jones and O. Corrigan, 2003. *American Journal of Pharmacogenetics* 3: 375-383.

actually benefiting. There are even claims that privately pharmacogenetic companies have expressed grave reservations and have actively and quietly sought to undermine research – again, given the exorbitant amount of resources needed and the level of financial risk involved.<sup>239</sup>

All of these concerns clearly have ethical import. Whilst I will not address them further here, later in the thesis I shall have more to say about the financial associations of bioethics and the lack of ethical analysis regarding the creation of new technologies.

### *Existing and planned biobanks*<sup>240</sup>

National DNA population collections have become common throughout the world.<sup>241</sup>

What follows is a survey of the best known biobanks, the examples of which I will draw on in my discussion of the ethical issues in genetic epidemiology. In the following chapter, I shall introduce a regional database based in north-west England.

The first and most controversial attempt to create a biobank was in Iceland. deCode Genetics, a commercial company based in Iceland but licensed in the US for tax reasons, received permission from the Icelandic government in 1998 to build a DNA bank (known as the Health Sector Database). Much of the controversy arose when it became apparent that deCode planned to forgo traditional informed consent procedures and require donors to take the initiative to opt out of the study if they did not want to participate.<sup>242</sup> Concerns were also raised by deCode's exclusive licensing right to market and profit from new products emerging from the database.

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<sup>239</sup> Williams-Jones and Corrigan, 2003, p. 379.

<sup>240</sup> It should be noted that DNA banks have uses beyond medicine. In police work, for example, the use of DNA has been called the greatest advance in the use of forensic science by police since the introduction of fingerprints. In 1995, a National DNA Database was established in England and Wales which allows police to collect samples both from suspects and from crime scenes. As of August 2000, the database held genetic profiles on nearly one million suspects and nearly 100,000 crime scene samples. See the Wellcome Trust Web site 'Knowledge Bank' links for details on the grant held by Robin Williams, University of Durham.

<sup>241</sup> M. Austin, S. Harding, C. McElroy, 2003. Genebanks: A Comparison of Eight Proposed International Genetic Databases. *Community Genetics*, 6: 37-45; G. Cardinal and M. Deschenes, 2003. Surveying the Population Biobankers. In B. Knoppers, ed. *Populations and Genetics*, Leiden: Brill Academic Publishers, pp. 37-94.

<sup>242</sup> H. Rose, 2000. *The Commodification of Bioinformation: The Icelandic Health Sector Database*. A Report for the Wellcome Trust.

In Estonia, scientists have developed similar plans. A non-profit organisation, the Estonian Genome Project Foundation, started a pilot project in 2002 and aims to recruit 75% of Estonia's 1.4 million population as donors.<sup>243</sup> Participation is voluntary and based on opt-in (that is consent based) procedures. In the following section I address some of the ways in which Estonian researchers have attempted to recruit participants to the biobank.

Unlike these countries, the United States does not have a government sponsored and nationally coordinated biobank. Instead, genetic epidemiological studies are conducted across many diffuse private, academic, and public bodies. Many sample collections, usually derived from whole blood or buccal cells (taken from cheek swabs), are on-going projects. The National Health and Nutrition Examination Survey, for instance, is a continuous study that began in 1999 and collects specimens from approximately 5,000 people each year. More recently, Howard University announced plans for a genetics database that would collect DNA profiles from patients at Howard University Hospital, which serves a predominantly black and medically underserved population in Washington D.C.<sup>244</sup> Organizers at Howard plan to collect samples from 25,000 patients in order to study diseases, such as diabetes and prostate cancer, which afflict African-Americans more than whites. Finally, to cite another, albeit unrepresentative example, Gene Trust, run by DNA Sciences, aims to create a "huge database of information about people" in order to 'drastically speed up the rate of medical advances'.<sup>245</sup> Organizers claim to have registered online over 10,000 donors in its first year of operation. While such private schemes are more frequent in the US than in Britain, the ultimate target of population-based genetic remains the same. That is, research predominately focuses on the two biggest killers in the developed world: heart disease and cancer.<sup>246</sup>

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<sup>243</sup> Cardinal and Deschenes 2003, p. 39.

<sup>244</sup> A. Goldstein, and R. Weiss, 2003. Howard U. Plans genetics database. *Washington Post Online*, 27 May. Available at: [www.washingtonpost.com](http://www.washingtonpost.com).

<sup>245</sup> Gene Trust, 2002. See: [www.dna.com](http://www.dna.com)

<sup>246</sup> K. Steinberg, J. Beck, D. Nickerson, M. Garcia-Closas, M. Gallager, M.Caggana, Y. Reid, M. Cosentino, J. Ji, D. Johnson, D. Hayes, R., Earley, M., Lorey, F. Hannon, H. Khoury, and E. Sampson, 2002. DNA banking for epidemiological studies: a review of current practices. *Epidemiology*, 13: 259-264.

In April 2002, the British House of Lords approved plans for the world's largest biobank, UK Biobank (originally known as Biobank UK). This project is organized and funded by the Wellcome Trust, the Medical Research Council, and the Department of Health, and is estimated to cost upwards of £60 million, or \$90 million.<sup>247</sup> Starting in 2003, UK Biobank plans to collect DNA samples (via blood) from 500,000 British volunteers. Recruits will include men and women aged between 45 and 69, the usual age of onset for many common diseases. Apart from the initial donation, patients will be asked to fill out extensive lifestyle and medical history questionnaires. In addition, researchers will periodically re-contact donors for at least 10 years beyond the original donation in order to inquire about the volunteer's health status. UK Biobank researchers will also monitor general practice, hospitalisation, and prescription records, as well as disease and morbidity registers.

Having briefly surveyed a sample of the existing and planned DNA banks, I shall now turn to the numerous ethical issues raised by these collections.

### *Socio-ethical issues in genetic epidemiology*

#### *Genetic donation and the characterisation of national biobanks*

The success of population based collections depends largely on public acceptance of such endeavours. In order to win such approval, the organisers of national biobanks have undertaken a variety of strategies. However, as Richard Tutton notes, 'there is no neutral language' in which to discuss participation.<sup>248</sup> Requests to donate frequently make assumptions about people's motivations and are promoted by professionals (ethicists, medical researchers, policy-makers) who have clear scientific, commercial and political interests.

In Estonia and in Iceland, the discourse surrounding participation in databases is heavily invested in appeals to nationalism and cultural pride, coupled with potential health and

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<sup>247</sup> UK Biobank, 2002. *Draft Protocol for Biobank UK: A Study of Genes, Environment and Health*. Available at: [www.wellcome.ac.uk](http://www.wellcome.ac.uk); J. Newton, 2004. *UK Biobank Briefing Note*.

<sup>248</sup> R. Tutton, 2004. Introduction. In R. Tutton and O. Corrigan eds. *Genetic Databases: Socio-ethical issues in the collection and use of DNA*. London: Routledge, pp. 1-18.

economic benefits of luring foreign investment. In Estonia, references to international competitiveness have been a common way to frame the Estonian Genome Foundation and promote its public acceptability. One observer has noted that,

‘Mini-societies like Iceland and Estonia that are genetically homogeneous and have a good health-care system and scientific base can accomplish the leap to the new medicine much faster than big countries that are still standing at the starting line ... Estonian Nokia may be hidden in our genes.’<sup>249</sup>

Interestingly, the term ‘Estonia Nokia’ refers to Finland’s success in the telecommunications market. The success of Estonia’s northern neighbour in the mobile phone industry is often cited in Estonia as a symbol of Finnish national pride, innovation and technological advancement. In this context, the Estonian database is a ‘chance’ for the small nation to compete on a global scale.

Whilst the Icelandic biobank met fiercer criticism (largely from academics) than Estonia’s project, nationalism and technological progress were also cited as reasons to support – that is, donate to – the database. Hillary Rose has argued that Iceland remains a very ‘technofile’ country and that the popular and nationalist appeal of deCode’s CEO has done much to enhance the biobank’s reputation in Iceland.<sup>250</sup> In addition, worries over the future of Iceland’s fishing industry has added to the view that development of the island nation’s scientific infrastructure would a long term economic asset. It is in this context then that appeals to participate are made.

In Britain, the language surrounding UK Biobank and genetic donation has taken a very different tone. Here, calls to altruism and gift-giving pervade the literature. For example, the Medical Research Council’s guidelines on the collection, storage, and use of tissue

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<sup>249</sup> P. Tammpuu, 2004. Constructing Public Images of New Genetics and Gene Technology: The Media Discourse on the Estonia Human Genome Project. *TRAMES* 8: 204.

<sup>250</sup> H. Rose, 2000.

samples cite Richard Titmuss's famous study of blood donation<sup>251</sup>. Titmuss argued that a US style of blood donation, based on commercialisation, would lead to exploitation of minorities and the poor, as well as administrative inefficiency, greater costs, and higher amounts of contaminated blood. In contrast, Titmuss argued that voluntary donation systems created a sense of solidarity since donors gave their blood altruistically and could take comfort in the fact that their blood would be used for strangers, rich or poor, and without distinction between class, gender or ethnicity. (Titmuss, as is well known, based his work on the anthropology of Marcel Mauss, whom I shall discuss in the next chapter in the context of the Cumbrian database).

MRC guidelines state that the gift approach is 'preferable from a moral and ethical point of view, as it promotes the "gift relationship" between participants and researchers, and underlines the altruistic motivation for participation in research.'<sup>252</sup> The MRC goes on to say, 'Gifts may be conditional (that is, a donor may specify what the recipient can do with a gift), and it is very important that the donor understands and agrees to the proposed uses of the donated material. The assumption by the donor is that nothing will be done that would be detrimental to his or her interests, or bring harm to him or her.'<sup>253</sup> The organizers of one of the UK Biobank public consultations (discussed below) also cite altruism as a reason for donation. Their final report claims, 'the one primary motivating force that stimulates people to volunteer ... [is] altruism'.<sup>254</sup>

The MRC has several reasons for wanting to characterise medical donations as 'gifts.' First, and most obviously, medical research depends on peoples' willingness to donate. Second, characterizing genetic donations as 'gifts' enables the MRC to avoid legal uncertainties over ownership. In the UK it is not legally possible to own a human body per se. However, the law is not clear whether one can own samples of human tissue or whether donors can have property rights over their samples. According to the MRC, for

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<sup>251</sup> R. Titmuss, 1970. *The Gift Relationship: From Human Blood to Social Policy*. London: Allen & Unwin.

<sup>252</sup> Medical Research Council, 2001. *Human tissue and biological samples for use in research: Operational and Ethical Guidelines*, p. 8.

<sup>253</sup> MRC, 2001, p.8..

<sup>254</sup> People, Science and Policy Ltd. 2002. *Biobank UK: A Question of Trust: A consultation exploring and addressing questions of public trust*.

human research, the important consideration is not legal ownership but ‘who has the right to control the use of samples’.<sup>255</sup> The term ‘custodianship’ is used instead of ownership to imply responsibility of safe storage and control of tissue samples. Thus, by referring to donations as gifts, ‘any property rights that the donor might have in their donated sample would be transferred, together with the control of the use of the sample, to the recipient of the gift’.<sup>256</sup> In other words, theorizing donations as gifts provides the MRC with a ‘practical way’ of avoiding the possibility that donors may later claim legal rights to their samples.

As Tutton notes, the portrayal of the gifted material in MRC guidelines is that of *human tissue* and not the *genetic information* which can be derived from that tissue or the personal medical records which also accompany biobank donations. ‘This delimits the processes of commercialism in a way that insulates participants and their “generous gifts” of samples from the activities of the commercial sector in biomedical research, with public bodies’.<sup>257</sup>

The act of donation is related in many ways to consent since it is only through the latter (in theory at least, not in Iceland) that donors’ give their approval for their tissue to be collected and stored for future use.

#### *Informed consent and sample use*<sup>258</sup>

In chapter four, I drew attention to the early formation of informed consent requirements in the Nuremburg Code and Helsinki Declaration(s). However, biobanking and the information that derives from it seems to challenge traditional consent requirements on at least three grounds.<sup>259</sup> In the following discussion I draw upon the conventional

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<sup>255</sup> MRC, 2001, p. 8.

<sup>256</sup> MRC, 2001, p.8.

<sup>257</sup> Tutton, 2004, p. 33; R. Tutton, 2004. Person, property and gift: Exploring languages of tissue to biomedical research. In Tutton and Corrigan, 2004, pp. 19-38.

<sup>258</sup> My discussion of consent and the alternatives to it is based on: M. Whong-Barr, forthcoming. Informed consent and the shaping of British and US population-based genetic research. In D. Guston & D. Sarewitz eds., *Shaping Science & Technology Policy: The Next Generation of Research*, Madison: University of Wisconsin Press.

<sup>259</sup> R. Chadwick, 2001. Informed consent and genetic research. In L. Doyal and J. Tobias (ed.) *Informed Consent in Medical Research*. London: BMJ Publishing group; pp. 203-210.

definitions and notions of consent (e.g. Beauchamp and Childress), however in the following chapter, I shall add a social science critique to the discussion in keeping with my overall theme regarding the importance of context.

The first challenge of genetic epidemiology concerns the disclosure element of consent, which requires researchers to inform subjects of all relevant facts of the proposed study. Generally, this requirement covers areas such as the potential benefits and risks to the donor, the researcher's personal interest in the project (e.g. financial connections), the aims and methods of the research, and the subject's right to withdraw.<sup>260</sup> However, in the case of biobanking, it is seemingly impossible for the subject to be truly informed of the use of the sample when often the researchers themselves do not know the full range of studies that might be done. Samples are stored in liquid nitrogen tanks and retain their scientific value for well beyond the original donation. Therefore, it is possible that a person who donates their DNA today for a study on breast cancer may not be informed twenty years hence when their sample has been used to study genetic influences on, say, sexual orientation.

Second, population genetics poses problems for the voluntariness requirement of consent, which states that persons must make their decision without being under the control or undue influence of others.<sup>261</sup> Many believe that genetic information is exceptional in nature compared to other forms of medical data.<sup>262</sup> Whether one accepts these arguments or not, it is certainly the case that individual donors share a portion of their genetic profile with family members. Thus, if/when biobank research leads to clinically relevant results, it could potentially have enormous consequences for the donor's relatives. In other words, the predictive value of genetic information could create a situation where relatives of a biobank donor involuntarily learn of their genetic pre-disposition to a certain condition.

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<sup>260</sup> Beauchamp and Childress, 2001, p.

<sup>261</sup> Beauchamp and Childress, 2001, p.

<sup>262</sup> House of Lords, 2001.

Genetic information is exceptional in other ways, as well. Some argue that DNA has become the secular equivalent of the human soul.<sup>263</sup> In addition, the popular press and popular science books often depict the 'gene' as the secret or blueprint to life.<sup>264</sup> Given this representation of DNA, what are researchers asking people to donate -- a mere piece of their biological tissue, or an intimate and unique part of their personal identity?

Third, genetic epidemiology is problematic for the understanding requirement of consent, which holds that subjects must be able to justify the beliefs leading to the nature and consequence of their decision.<sup>265</sup> There is debate about the extent to which the public is or can be aware of genetic science and how that may affect their ability to consent. While this lack of understanding may be true of many kinds of academic research, the potential for misunderstanding may be greater in genetics. Not only is genetic science new, even clinicians have difficulty in keeping abreast of the latest research, due to the sheer speed of developments. To make matters worse, some segments of the media cloud the issue by confusing sensationalist headlines with what is currently known and achievable.

Despite the difficulty of understanding genetics, people do seem to have their own coherent lay understandings.<sup>266</sup> However, lay understandings may not translate well in clinical or research settings (and vice versa). Many people cannot define a Mendelian pattern of inheritance nor differentiate between dominant and recessive disorders.<sup>267</sup> In addition, people have different levels of risk-aversion or tolerance. Lay understandings of the difference between genetically determined and genetically predisposed may not match clinical definitions of the same terms.

Such challenges have led observers to re-evaluate informed consent procedures in hopes of achieving consent while not sacrificing research priorities.

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<sup>263</sup> D. Nelkin, and M. S. Lindee, 1995. *The DNA Mystique: The Gene as Cultural Icon*. New York: W.H. Freeman.

<sup>264</sup> C. Condit, 1999. *The Meanings of the Gene*. Madison, WI: University of Wisconsin Press.

<sup>265</sup> Beauchamp and Childress, 2001, p.

<sup>266</sup> A. Kerr, S. Cunningham-Burley, and A. Amos, 1998. The new genetics and health: Mobilizing lay expertise *Public Understanding of Science* 7: 41-60.

<sup>267</sup> M. Richards, 1996. Lay and professional knowledge of genetics and inheritance. *Public Understanding of Science* 5: 217-230.

### *Approaches to achieving informed consent*

Although an increasing number of writers have addressed the issue of consent in biobanking, the issue is far from settled. Numerous options have been put forth, most of which are not mutually exclusive. A key distinction in these discussions is between broad and narrow versions of consent.<sup>268</sup>

Broad consent would allow investigators to conduct a range of studies, not all of which would be explicitly spelled out at the time of taking consent. The UK's Human Genetics Commission (HGC) advocates broad consent so long as participants are given a 'clear explanation of the potential scope of the research'.<sup>269</sup> The Commission argues that broad consent is 'practically necessary in a fast-moving field with constantly developing new technology'.<sup>270</sup> As part of its call for written evidence, the HGC claims to have received significant support for broad consent – not only from researchers, but from patient advocacy groups as well. Part of my argument, detailed later in the chapter, is to support broad consent on the basis that it best secures donors' expectations of the benefits of medical research.

In contrast, narrow consent would restrict sample use to studies explicitly mentioned at the outset of a research project. If investigators wanted to conduct further studies, they would have to re-contact donors. While narrow consent may help subjects stay better informed, the HGC has claimed that re-contacting people to seek further consent would impose an unnecessary burden on donors and, more importantly, increase risks of a security breach since sensitive medical data would have to be decoded. In addition, narrow consent could be an obstacle to research. Not only would it increase costs for investigators, but it would complicate matters in cases where the donor had since deceased.

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<sup>268</sup> K. Berg, 2001 DNA sampling and banking in clinical genetics and genetic research *New Genetics and Society* 20: 59-68.

<sup>269</sup> Human Genetics Commission. 2002. *Inside Information: Balancing Interests in the Use of Personal Genetic Data*, p. 93.

<sup>270</sup> HGC, 2002, p. 94.

In Iceland, as previously mentioned, the issue of consent has raised considerable controversy. Article 3 of the Icelandic Icelandic Biobank Act distinguishes between ‘free, informed consent’ (consent granted in writing of the person’s own free will) and ‘assumed consent’ (consent that consists of the donor not expressing any unwillingness for a sample taken from them for a clinical test to be permanently stored in a biobank). Thus, Iceland’s Biobank Act mandates informed consent for samples collected as part of a scientific study but permits assumed consent for samples collected as part of routine healthcare treatment. However, in both cases, the sample is permanently stored in the biobank. Thus, people may donate to the biobank without having given consent.

In Britain, consent requirements have been stricter. The MRC states that ‘when obtaining consent to take a sample of biological material for research, it is important that donors have sufficient understanding not only of the process involved ... but also of what the sample is to be used for and how the results might impact on their interests.’<sup>271</sup> The MRC recognizes that a sample could be used for new experiments unforeseen at the time of donation. In these cases, they suggest a two part consent process, where the donor is first asked to consent to the specific experiment planned, and then to give consent for storage and future use for other research. Unless the sample is anonymised and unlinked, the MRC believes that it is not acceptable to seek unconditional blanket consent by using terms such as ‘all biological or medical research.’<sup>272</sup>

If samples can be linked to individuals, then the MRC recommends that possible future research should be explained in terms of the types of studies that may be done, the types of diseases that may be investigated, and the possible impact of the research on the donor personally.<sup>273</sup>

Whether consent is broad or narrow, however, questions still remain as to who is consulted and how the process of consent ought to unfold. Answers offered to these

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<sup>271</sup> MRC, 2001, p. 15.

<sup>272</sup> MRC, 2001, p. 15.

<sup>273</sup> MRC, 2001, p. 15.

questions have included: a re-evaluation of the language and substance of consent forms; some level of group or community consent; and public consultation exercises.

### *A matter of form?*

One approach, more prominent in the US, has focused on the content and language of actual consent forms.<sup>274</sup> Recently the Centers for Disease Control and Prevention (CDC) formed a multi-disciplinary working group to address the issue of consent. Its conclusions were not fundamentally different from existing guidelines in public health research, but rather an extension of those guidelines.<sup>275</sup> The CDC panel concluded that the best way of protecting subjects' interests and autonomy is by making forms as thorough as possible regarding the details of a study. The panel suggested that forms contain information on: why the study is being done, what it will involve, how information will be kept private, the study's risks and costs, the possibility of receiving results, and the status of the sample once the study is complete. An approach that focuses on detailed consent forms is designed to exhaust the disclosure element of consent requirements.

It is worth noting that the CDC recommendations directly connect the probability of harm and benefits to the meaning of the results for the health of the participant. In other words, consent ought to be based from the start on an assessment of whether or not the results would generate information that could lead directly to an evidence-based intervention, such as drug treatment or lifestyle alteration. The CDC panel concluded that family-based research guidelines were not suited to biobank research since they do not distinguish between studies that are likely to yield clinically relevant results and ones that may have significant public health implications but carry few physical, psychological, or social risks to individuals -- as in the case of population-based genetic research. By trying to ensure that no one learns of a meaningful result without having consented, CDC has sought to meet the voluntariness element of consent requirements.

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<sup>274</sup> L. M. Beskow, W. Burke, J. F. Merz, 2001. Informed consent for population-based research involving genetics. *Journal of the American Medical Association*, 286: 2315-2321.

<sup>275</sup> M. Khoury, 2001. Informed consent for population research involving genetics: A public health perspective. Available at: <http://www.cdc.gov>.

Focusing on the language of forms has severe drawbacks, however. One criticism is that this strategy seems to be more for the protection of the interests of researchers and Institutional Review Boards than those of the subject.<sup>276</sup> Sceptics argue that forms end up looking more like legal contracts than documents of explanation and education and that focusing on the language of consent is a legalistic and bureaucratic approach.

US concerns with the content of forms has drawn frequent criticisms in the UK, as well. The British medical establishment has long sought to avoid an American style litigation culture. Thus, critics in the UK argue that by focusing on forms, researchers are too heavily pre-occupied with the so-called 'audit society', in which institutions are monitored for accountability by external review.<sup>277</sup> Such a society seeks accountability through observing and ultimately judging the activities of professionals and institutions.<sup>278</sup> Another criticism is that an emphasis on forms is the product of a consumer-driven culture. 'In a world where medicine has become a good to be consumed, where patients are customers to be wooed, informed consent becomes the disclosure of the contents on the back of the box'.<sup>279</sup>

The danger, in my view, is that concentrating on the language of forms runs the risk of turning consent into a sufficient ethical justification, which it is not. This is a topic I revisit later in the thesis in Chapter Eight.

### *Group consent*

Another way of meeting the challenge posed by the exceptional (or familial) nature of genetic information is by asking for group or community consent.<sup>280</sup> This system has received more attention in the US than in Britain, perhaps because of the presence of the

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<sup>276</sup> G. Annas, 2001. Reforming informed consent to genetic research. *Journal of the American Medical Association* 286:

<sup>277</sup> M. Power, 1997. *The Audit Society*, Oxford: OUP

<sup>278</sup> O. O'Neill., 2002. *Autonomy and Trust in Bioethics*. Cambridge: CUP.

<sup>279</sup> Wolpe, 1998, p.44.

<sup>280</sup> H. Greely, 2001. Informed consent and other ethical issues in human population genetics *Annual Review of Genetics* 35: 785-800.

Native American population and the work of the North American Regional Committee of the Human Genome Diversity Project (HGDP).

Proponents argue that group consent is necessary since genetic research could have implications beyond the individual donor or even local community. Research done on a Chinese community in California, for instance, could have consequences for all Chinese, no matter where they live or if they consented. As mentioned above, the fear is that if research ever established that a population was pre-disposed towards developing a certain condition or behavioural characteristic such as alcoholism, then it could have adverse effects in terms of insurance or employment. In addition, it could unfairly stigmatize the population under investigation.

However, achieving group consent is fraught with so many difficulties that it may be impossible to achieve. How does one define the group or community? Should it include only the subject community, or should it include all who may be influenced by the research? Should the group be limited only to families? Or should it include the so-called disease organizations such as American Lung Association? How would the group actually express consent? Should researchers liaise with 'culturally appropriate authorities', as the HGDP suggests?<sup>281</sup> Or should a vote be held, no doubt at great cost to the research project?

Another factor against group consent is that it may end up re-enforcing controversial stereotypes not grounded in reality. It is open to debate whether there are any genetic differences between ethnic groups. Some scientists believe that the distinctions are miniscule and that race has no real genetic basis. However, asking for group consent from a specific ethnicity implies that race does have a genetic underpinning.<sup>282</sup>

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<sup>281</sup> Greely, 2001.

<sup>282</sup> E. T. Juengst, 1998. Groups as gatekeepers to genomic research: conceptually confusing, morally hazardous, and practically useless. *Journal of the Kennedy Institute of Ethics* 8: 183-200.

In fairness, proponents argue for community consent as an extra layer of ethical protection rather than as a full alternative to traditional consent requirements.<sup>283</sup>

However, despite the communal nature of genetic information, most observers do not take group consent seriously for the reasons highlighted above. Even in the US, group consent seems to have only lukewarm support. Its most vocal advocates in the HGDP have reservations about implementing the idea and recognize that in some situations, e.g. where communities do not have a culturally appropriate authority, group consent would be impossible.<sup>284</sup>

### *Public consultation*

UK Biobank organizers have been concerned that public attitudes towards the practical, social and ethical aspects of such a project are clearly understood and taken into account in the development of the collection. Two public consultations were held.

In the first exercise, an independent research group - Cragg Ross Dawson - was commissioned to consult with a cross-section of the public across the UK, including religious and community leaders, and spokespeople for organizations with a special interest in the issues surrounding genetics research.<sup>285</sup> They found that initial responses among the public were, in general, favourable but unconsidered: in other words, respondents tended not to think through the project's implications. Many people, when informed of potential ethical issues, became concerned about UK Biobank's implications. However, further information and discussion of these issues and governance of the UK Biobank tended to restore their positive views (although, curiously, governance arrangements for the database had not been officially planned until long after the consultation). People with direct experience of illness and their relatives were more supportive and had fewer reservations. Some members of the public and certain religious and community leaders were concerned about the use of the term DNA, because it had associations with police investigations, criminality and state control. Linked to this was

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<sup>283</sup> C. Weijer, and E. J. Emanuel, 2000. Protecting communities in biomedical research *Science* 289: 1142-1144.

<sup>284</sup> Greely, 2001.

<sup>285</sup> Cragg Ross Dawson, 2000. *Public Perceptions of the Collection of Human Biological Samples*. Report prepared for the Wellcome Trust and Medical Research Council.

some concern about possible misuse of samples - for cloning, eugenics or other questionable purposes. Overall, however, the proposed study was viewed positively, and the report's largest recommendation was to establish an independent body, designed to regulate the collection, storage, use and disposal of UK Biobank samples.

The second consultation was carried out by People Science and Policy.<sup>286</sup> The exercise was conducted in January 2002, and involved three groups of 20 people aged 45-69 years (the proposed age for volunteers for the UK Biobank). The consultations were carried out in Hertfordshire, the West Midlands and Glasgow. Respondents were first informed on the basic facts and aims of UK Biobank. Most were supportive but findings showed that people were uncertain as to the benefits and concerned about the burden of time and effort required to travel to and participate in the donation interview. There were also reservations about the type of long term commitment involved on the part of donors. Finally, focus group members were concerned about anything that would increase GPs workload (which would put pressure on GP's to reduce the amount of time spent with patients).

In my view, these consultations are a good example of how social research generally and public consultation specifically can be highly problematic.<sup>287</sup> I endorse both, of course, but one key factor in any project is the methodology used. In the second consultation by People Science and Policy, even the researchers themselves admitted that conducting their consultation in a group setting could have impacted their findings – that is to say, they warned that readers should be 'wary' of 'participants over-claiming their altruistic motivations' when speaking in front of others, especially strangers.<sup>288</sup> In addition, focus group participants were given leaflets regarding the aims and purpose of UK Biobank as part of the consultation process. This raises a question that is a general problem for all social research: how do investigators attempt to record opinions without influencing

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<sup>286</sup> People, Science and Policy 2002.

<sup>287</sup> See also: M. Levitt, 2003. Public Consultation in Bioethics: What's the Point of Asking the Public When They Have Neither Scientific Nor Ethical Expertise? *Health Care Analysis* 11: 15-25.

<sup>288</sup> People Science and Policy, 2002, p. 2.

those opinions? The short answer is that they cannot.<sup>289</sup> This is a topic I will re-visit later in the study.<sup>290</sup>

### *Confidentiality and access*

The fears about confidentiality and biobanks is that at some point in the future, third parties may gain access to the genetic information stored in the database. Of particular concern is that insurance companies, employers, or the police would seek access. In discussing this topic, there has been a good deal on confusion over the terms used. The House of Lords refers to this confusion as 'semantic heterogeneity'. But even if the same terminology were used, the words would not necessarily have the same history, context or meaning in different research areas or countries. As I discussed earlier, researchers require the means of linking data back to the individual, since the whole point was to seek associations between phenotypic data, genetic and lifestyle information. Usefully, the Lords distinguished three broad levels of anonymisation.<sup>291</sup>

- (a) fully identifiable data, where the clinical/genetic record was linked to an identifiable individual;
- (b) de-identified (anonymised) data, where individual identifying information had been replaced by a code (which could be made very secure) allowing data and individual identifiers to be re-linked under certain circumstances; and
- (c) permanently de-linked data, where any link between the data and the individuals from whom they were collected had been completely destroyed. This is truly anonymous data.

In (b), the identifying information (such as name, address, date of birth, NHS number etc) would be removed from data and samples at the earliest opportunity after collection.

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<sup>289</sup> R. Ashcroft, Constructing empirical bioethics: Foucauldian reflections on the empirical turn in bioethics research. *Health Care Analysis* 11: 3-13.

<sup>290</sup> See also: S. Weldon, 2004. 'Public consent' or 'scientific citizenship'? What counts as public participation in population -based DNA collections? In R. Tutton and O. Corrigan, eds, *Genetic databases: Socio-ethical issues in the collection and use of DNA*, pp. 161-180; and, E. Juengst, 2003. Community Engagement in Genetic Research: The "Slow Code" of Research Ethics? In B. Knoppers ed., *Populations and Genetics: Legal and Socio-Ethical Perspectives*, pp. 181-197.

<sup>291</sup> Lords, 2001.



'Sensitive' information such as health and lifestyle data, and samples, would be kept separate from identifying information and only linked using a code that has no external meaning (e.g. not the NHS Number). Only those with access to the 'key' to the code would be able to re-link the participants' identifying information with the data and samples. In addition, in some biobanks, information is encrypted. This means that data is scrambled with meaningless symbols and impossible to read unless the researcher has an additional code to de-crypt the information.

### *Benefits-sharing*

In my earlier comments on participation and genetic donation, I noted the importance of reciprocity in the gift-relationship. It is also a theme highly pertinent to benefit-sharing: the idea that donors (and wider society) will, in time, receive some sort of gain from DNA bank research.

There are several models on benefit-sharing. In the US, PXE International, a patient group, have built a system which gives donors to genetics research a say over the property rights of samples.<sup>292</sup> The Human Genome Organisation (HUGO) has stated that at a minimum research participants ought to receive information regarding research outcomes. HUGO also states that the profit making bodies involved should dedicate between 1-3% of annual net profit to either health care infrastructure and/or humanitarian efforts.<sup>293</sup>

The issue of benefits-sharing relates to a general problem in distributive justice. In biobanking, it is an especially difficult problem because of the time lag between the actual donation and the potential benefit. It is not inconceivable that in some cases the donor will have died. So how does one even go about defining 'benefit'? This is a theme I will return to in later chapters.

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<sup>292</sup> P. Terry, 2003. PXE International: Harnessing Intellectual Property Law for Benefit-Sharing. In Knoppers, pp. 377-393.

<sup>293</sup> HUGO, 2002. Ethics Committee, Statement on Benefit-Sharing, 9 April; S. Wilson, 2004. Population Biobanks and Social Justice: Commercial or Communitarian Models? A comparative analysis of benefit-sharing, ownership, and access arrangements. *TRAMES* 8: 80-89; C. MacDonald, 2003. Patents and Benefit-Sharing as a Challenge for Corporate Ethics. In Knoppers, pp. 505-523.

### *Feedback*

Feedback refers to the process of providing research results to those who have donated to a biobank. Disclosure of results is a factor in clinical genetic testing or screening programs where the patient is suspected from the outset as being at risk. However, population-based research also presents opportunities for disclosure and the issue is no less a minefield in the context of research than it is in clinical testing. There are two main types of feedback, general and individual.

General or community level feedback refers to the dissemination of results that are non-specific to individuals. This form of disclosure is often through peer-reviewed publications, newsletters, Web sites, or group communication amongst researchers and biobank participants.<sup>294</sup> General feedback reports on the progress of research and offers a way for donors to keep abreast of how their samples are being used. More importantly, it allows donors to keep informed of research that may be of personal interest. MRC guidelines state that as part of general feedback, participants should be kept informed of research that may have clinical relevance or that may lead to improved diagnostic tests. General feedback provides a route for donors to obtain advice and information that may be of concern to them or members of their family. This type of feedback is not particularly problematic and nearly all parties involved in the UK BioBank support disclosure at the community wide level.<sup>295</sup>

Individual or personal feedback is when the donor receives information that is specific to their sample, hence their own health status and possible disease risk. One way for a donor to receive this type of feedback is at the point of their physical assessment whilst making the donation. Any abnormal findings that occur during the taking of the sample will be fed back to their general practitioner. This would be done with donors' consent. The Draft Protocol of UK Biobank states that participants will receive this type of feedback.

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<sup>294</sup> HGC, 2002, p. 106

<sup>295</sup> MRC, 2001, p. 19; HGC, 2002, p. 106.

The most controversial type of individual feedback concerns giving donors specific information derived from research done using their sample. On the surface of it, providing such results may seem like the best option and an ethical thing to do. Michael Dexter of the Wellcome Trust claims that he was in favour of personal feedback when plans for the BioBank UK were first drawn up. Since looking at the issue in greater detail, however, he is set against feedback of this type. In fact, the consensus view is firmly against individual feedback. Organisers of the UK Biobank as well as genetic 'watch dogs' such as David King are all opposed to providing it. Nearly every professional body is opposed. Despite the consensus, the issue has been called 'potentially one of the most difficult issues involved in setting up the sample collection, and one of the least easily resolved'.<sup>296</sup> One reason why feedback is a contentious issue may be that public surveys indicate that at least some sections of the public desire feedback. Reasons for providing it range from a) donors may have a 'right to know' research results, and may opt to use the Data Protection Act or European Convention on Human Rights and Biomedicine to receive feedback; b) donors may want access to results in order to make provisions before their death, or even as a spur to make lifestyle changes, and; c) providing feedback may act as an incentive to participate in UK Biobank.

However, those who are against providing feedback have offered three primary reasons for their stance. These include: a) population based research is not conducive to providing diagnosis, and does not have the validity of clinical tests; b) obtaining consent would be more 'tricky' if feedback was required, and would, in effect, turn UK Biobank into a screening program, and; c) those obtaining feedback would require genetic counselling services, which would increase the level (hence, cost) of resources and staff needed, and d) donors may underestimate the psychic impact of being told their risk of developing an illness in the future.<sup>297</sup> Again, the issue of feedback relates to consent since it must be established from the outset whether feedback will be given.

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<sup>296</sup> Dawson, 2000, p. 58.

<sup>297</sup> Lords, 2001.

The consensus view, however, does allow for feedback in certain rare cases. In addition, alternative models of giving feedback (e.g. relying on third parties) have been suggested by general practitioners.

### *Summary and conclusion*

Chapter Five has switched gear from previous chapters and begun to address a specific issue in biomedical ethics. I have argued:

- Genetic epidemiology is best contextualised in light of the modern public health movement which itself is best understood in light of social, political and economic philosophies dating back to the Enlightenment. Such philosophies posit the need for and value of public authorities intervening in the processes of population and health for the good of state, society, and individual. Taken to its extreme, the rationale of public health results in eugenic movements characteristic of the early to mid twentieth century.
- Eugenics, however, is a slippery concept that is often used without clarification. It can, for example, refer to either state coercion in reproductive matters, or it can relate only to outcomes of reproduction, meaning that the contemporary discourse and practice of choice is in fact no less eugenic than previous eras.
- Specifically, I have shown that biobanking is a case of public health par excellence in that it attempts to identify gene-disease associations by combining DNA samples with medical and lifestyle information of the donor. The benefits of such methods are said to include better diagnostic techniques (through a better understanding of disease causation) and therapeutic measures (through designer drugs aimed at reducing side effects). The potential benefits of these fields, however are open to question and critics maintain biobanking will fail to produce meaningful results, much like gene therapy has yet to produce successful new treatments.

- Gene banks raise a number of socio-ethical issues. First, there is the manner in which donation is framed in differing national contexts. Most critically, however, there exists a conflict between informed consent and the need to further epidemiological research. It has been claimed that patient rights may hinder research and that consent requirements may not be sufficient to deal with issues that arise in large-scale population genetic research since it is difficult to obtain informed consent, when even the researchers do not know all the future uses of the samples that they are requesting. The various mechanisms around this problem include more detailed consent forms, group consent and public consultation. All three options carry inherent flaws, however, and to date the problem of consent in biobanking has not been theoretically nor practically solved.
- Confidentiality is an additional ethical concern since genetic information acquired from one individual may unwittingly provide knowledge regarding the genetic profile and health of that person's relatives. Another worry is that proper safeguards, legislation, and oversight mechanisms may not be in place to ensure that data and samples cannot be accessed by third parties, such as the police, insurers, or employers.
- Benefits-sharing and feedback are also potential problems. The former is essentially a problem of distributive justice and relates to the handling of both financial and medical profits. Feedback refers to the process of providing research results to those who have donated to a biobank. With the exception of Estonia, all databases have stated that information on the genetic health of donors will not be given out, even if such information were available. Yet this conflicts with the expectations and hopes of those surveyed in the UK based public consultations. Concern amongst clinicians and researchers is that: donors may misinterpret feedback; sufficient genetic counseling services do not exist to cope with demand if feedback were given, and; donors may underestimate the psychic impact of being told their risk of developing an illness in the future.

The next chapter explores a selection of these issues in reference to a particular case study.

## Chapter Six

### Participating in a DNA bank: lessons from a Cumbrian case study

*'In teaching you philosophy I'm like a guide showing you how to find your way round London. I have to take you through the city from north to south from east to west, from Euston to the embankment and from Piccadilly to the Marble Arch. After I have taken you many journeys through the city, in all sorts of directions, we shall have passed through any given street a number of times – each time traversing the street as part of a different journey. At the end of this you will know London; you will be able to find your way about like a born Londoner. Of course, a good guide will take you through the more important streets more often than he takes you down side streets; a bad guide will do the opposite. In philosophy I'm a rather bad guide.'*<sup>298</sup>

-- Ludwig Wittgenstein

#### Introduction

In this chapter, I aim to show the value of empirical study in helping to define and clarify a selection of ethical issues in genetic epidemiology.<sup>299</sup> My focus is on the gap between normative theory and actual practice on issues such as informed consent, altruism, and donation. In keeping with the overall argument of the thesis, a common theme in the chapter is the value of contextual knowledge. The findings and analysis presented here are derived from a case study of the North Cumbria Community Genetics Project (hereafter NCCGP), a DNA bank formerly operationable in West Cumbria.

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<sup>298</sup> D. Gasking and A. Jackson, 1967. Wittgenstein as Teacher. In K. Fann ed., *Ludwig Wittgenstein: the Man and his Philosophy*. Sussex: Harvester Press, p. 51.

<sup>299</sup> With the exception of the Introduction, this chapter is based on the following publications: E. Haimes and M. Whong-Barr, 2004. Key issues in genetic epidemiology: Lessons from a UK based empirical study. *TRAMES: Journal of the Humanities and Social Sciences* 8: 150-163; E. Haimes and M. Whong-Barr, 2004. Levels and styles of participation in genetic databases: A case study of the North Cumbria Genetics Project. In R. Tutton & O. Corrigan, eds. *Genetic Databases: Socio-ethical issues in the collection and use of DNA*, London: Routledge, pp. 57-77; E. Haimes and M. Whong-Barr, 2003. Competing perspectives on reasons for participation and non-participation in the North Cumbria Community Genetics Project. In B.M. Knoppers, ed. *Populations and Genetics: Legal Socio-Ethical Perspectives*. Leiden: Brill Academic Publishers, pp. 199-216; M. Whong-Barr, and E. Haimes, 2003. Why say no? Reasons for non-participation in the North Cumbria Community Genetics Project. *European Journal of Human Genetics* 11, Supp. 1, P878.

In exploring a particular case and presenting a narrative and conclusions (however ambiguous and tentative), I put myself in a vein of inquiry suggested by Wittgenstein in the epigraph above. It is not my aim in this investigation to develop a closed and coherent theory or system that captures the essence of the NCCGP or genetic epidemiology. I have no such theories. Rather, I hope to capture the phenomenological detail and the rich ambiguity at play in the lived reality of a Cumbrian biobank.

The value of the case study method may, for some, present problems of validity and generalisation. On this point, I take my cue from an author that I present in some detail in Chapter Seven, Bent Flyvbjerg.<sup>300</sup> He describes and demolishes a number of misunderstandings regarding the case method. According to Flyvbjerg, much of the bad reputation case studies have had lie in Plato's Socratic dialogues. Here, I wish to linger and digress on this point since it is crucial to my overall argument in the thesis regarding the value of particular case based knowledge. As the reader may have gleaned from Chapter Four and will see explicitly in Chapter Seven, my views are fairly anti-Platonic. In the following exchange from *Meno*, Socrates has inquired about the nature of the virtues.<sup>301</sup>

Meno: It is not hard to tell you, Socrates. First, if you want the virtue of man, it is easy to say that a man's virtue consists of being able to manage public affairs and in so doing to benefit his friends and harm his enemies and to be careful that no harm comes to himself; if you want the virtue of a woman, it is not difficult to describe: she must manage to home well, preserve its possessions, and be submissive to her husband; the virtue of a child, whether male or female, is different again, and so is that of an elderly man, if you want that, or if you want that of a free man or a slave. And there are many other virtues, so that one is not at a loss to say what virtue is. There is virtue for every action and every age, for every task of ours and every one of us – and Socrates the same is true for wickedness.

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<sup>300</sup> B. Flyvbjerg, 2001.

<sup>301</sup> Flyvbjerg uses a similar example. I have edited my use of the dialogue for convenience from: J. Cooper, ed., 1997. *Plato: Complete Works*. Cambridge: Hackett Publishing Company, pp. 871-875.

Socrates: I seem to be in great luck, Meno; while I am looking for one virtue, I have found you have a whole swarm of them. But Meno, to follow up the image of swarms, if I were asking you what is the nature of bees and you said that there are many and of all kinds, what would you answer if I asked you: 'Do you mean that there are many and varied and different from one another in so far as they are bees? Or are they no different in that regard, but in some respect, in their beauty, for example, or their size or in some other such way?' .... The same is true in the case of the virtues. Even if they are many and various, all of them have one and the same form which makes them virtues, and it is right to look to this when one is asked to make clear what a virtue is?

Meno: I think courage is a virtue, and moderation, wisdom, and munificence, and very many others

Socrates: We are having the same trouble again, Meno .... We have found many virtues while looking for one, but we cannot find one which covers all others

Meno: Socrates, what are you looking for, one virtue for them all?

Socrates: That is likely ....

Meno, then, cannot provide a definition or account of the virtues without reference to particular cases and different examples. In the Chapter Seven I expand this discussion to Aristotle's notion of practical, case based and context-dependent reasoning – *phronesis*. Such reasoning, in my view, ought to form a greater part of bioethics method in analysing moral problems. To briefly return to my opening quotation from Wittgenstein: in this chapter, I aim to examine the Cumbrian case up close and in detail. By showing the 'details of an immense landscape', traversing many side streets, and presenting a wealth of data, I aim to analyse the underlying tensions, contradictions and limitations of the normative policy and regulatory frameworks governing genetic epidemiology.<sup>302</sup>

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<sup>302</sup> R. Monk, 1990. *Ludwig Wittgenstein: The Duty of Genius*. London: Penguin, p. 502.

## *The North Cumbria Community Genetics Project (NCCGP)*

### *Background and operational procedures*

Like UK Biobank, the NCCGP aims to assist the identification of gene-disease associations, and the impact of environmental factors on those associations. The Project, which ran from 1996 to 2003, was a collaboration between the Department of Public Health and the Institute of Human Genetics at the University of Newcastle upon Tyne and the Genetics Unit at Westlakes Research Institute in Whitehaven, Cumbria. The impetus for the NCCGP was to develop a population-based resource that could address local health issues (such as controversies over leukaemia clustering, addressed below) and to promote the scientific infrastructure of Cumbria, reducing the regions economic dependence on the nuclear industry (also discussed).

To build the biobank, the NCCGP collected blood and tissue samples from the umbilical cord of newborn babies, commonly referred to as 'afterbirth'; maternal blood samples, and personal health information derived from questionnaires and maternity data forms.<sup>303</sup> With the consent of pregnant women, the afterbirth was collected during delivery at West Cumberland Hospital in Whitehaven. As of April 2003, when the NCCGP ceased operations, nearly 10,000 samples had been collected. Samples are kept frozen and stored for future use, so that the NCCGP can provide a resource of DNA samples for other researchers to use in genetic epidemiological studies. Studies so far have included investigations on breast cancer and prenatal viability, neuro-degenerative disease, gene repair of damaged DNA, and neural tube defects.

Each pregnancy in the NCCGP was given a unique Project number used to identify the samples. Blood and cord samples, as well as personal information are stored at the University of Newcastle. Personal data is kept 'encrypted, on a stand-alone computer (i.e. not networked), password protected and in a locked room with very restricted access. The Mother's Questionnaire contained questions on twelve sides of A5, covering the

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<sup>303</sup> D. Chase, E. Tawn, L. Parker, P. Jonas, J. Burn, 1998. The North Cumbria Community Genetics Project. *Journal of Medical Genetics* 35: 413-416; D. Chase, E. Tawn, L. Parker, P. Jonas, J. Burn, 2000. *The North Cumbria Community Genetics Project 1996-2000*.

woman's and her partner's socio-demographic profiles, their own health, their history of smoking, their employment history and their family histories of long term or serious illness.

The NCCGP enjoyed a high response rate. Nearly ten thousand DNA samples were collected, which means that nearly 90% of the pregnant women approached agreed to provide umbilical cord samples and maternal blood specimens.<sup>304</sup> However, only 60% of those approached completed the mother's questionnaire as well as donating samples. In addition, a small minority of the women approached did not participate in the NCCGP. Consent to donate was usually requested by community mid-wives during the first antenatal appointment.

#### *Ethics and public consultation*

The NCCGP was approved by the West Cumbria Local Research Ethics Committee and each subsequent study is approved by the same committee (which is appointed by the Local Health Authority). In addition, an Ethics Advisory Group (EAG) advised the NCCGP on procedures and the use of samples.<sup>305</sup> Perhaps its greatest contribution was a statement on the acceptable and unacceptable use of samples. The statement prohibited three areas of research: psychiatric illnesses, behavioural traits, and intelligence. As a result NCCGP samples have not been used in such studies.

The NCCGP raised many of the social and ethical issues discussed in Chapter Four. In addition, the database raised several issues specific to its own procedures. These include the request of samples from a 'captive audience' of women receiving ante-natal care, albeit with the assurance that refusal does not compromise treatment.<sup>306</sup> This distinguishes the NCCGP from all other dedicated DNA banks and is a critical point to which I will revisit. Second, the biobank requested mothers to give consent on behalf of

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<sup>304</sup> Chase, et al, 2000.

<sup>305</sup> Chase et al, 1998.

<sup>306</sup> J. Garcia, ed., 1990. *The Politics of Maternity Care*. Oxford: Clarendon Press; M. Jacobus, 1990. *Women and the Discourses of Science*. London: Routledge.

their babies, although the child can withdraw their sample at the age of 16.<sup>307</sup> Third, mothers were asked to give lifestyle information about their partners, who may or may not have been the actual father of the baby donor. Finally, a major ethical issue was the involvement of British Nuclear Fuels Limited (BNFL) in the initial funding of the NCCGP. BNFL operate a nuclear re-processing plant at Sellafield, Cumbria, which has been associated with allegations about the effects of excessive radiation causing a higher than average incidence of childhood leukaemia. The role of BNFL is a critical point in the history of the NCCGP and deserves detailed discussion.

In 1990, the Gardiner Report found that there were higher than normal rates of leukaemia and lymphomas in young people born in West Cumbria. The report showed a statistical association between paternal pre-conceptual irradiation received whilst working at Sellafield and the development of childhood leukaemia/non-Hodgkin's lymphoma. Since then it has been thought that findings may be due to chance or high level of population mixing dating from the 1950s. However, subsequent work still has not ruled out the risk of paternal pre-conceptual irradiation.<sup>308</sup>

The concern over BNFL was that NCCGP results might be compromised or at least influenced by the company. An evaluation of the local Cumbrian newspapers from the mid 1990s shows that the role of BNFL generated enormous debate and dispute. Some of the debate bordered on acrimony, as many of those opposed to the NCCGP were parents who lost children to leukaemia. Community groups such as Cumbrians Opposed to Radioactive Environment (CORE) and the local branch of Friends of the Earth were outspoken in their opposition. Whilst they supported the DNA bank in principle, they strenuously objected to its links to BNFL. The concern was that research could not be independent since 'the nuclear industry has a vested interest' in the results.<sup>309</sup>

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<sup>307</sup> A. Clarke, 1998. *The Genetic Testing of Children*. Oxford: BIOS; Mason and McCall Smith, 1999.

<sup>308</sup> H. O. Dickinson and L. Parker, 2002. Leukaemia and non-Hodgkin's lymphoma in children of Sellafield male radiation workers. *International Journal of Cancer* 99: 437-444.

<sup>309</sup> D. Siddall, 1994. *Whitehaven News*, 10 November, p. 1.

Another point of ethical contention centred on Westlakes Research Institute, Newcastle University's partner in running the NCCGP, which was described as being independent of BNFL. Opponents claimed that Westlakes independence was a 'myth' since most of the senior staff and directors at Westlakes were former BNFL employees and maintained contacts to BNFL as advisors.<sup>310</sup> In response to this criticism, NCCGP team members argued that they would never have accepted a gag order on their right to publish and thus, all results would remain independent. They also claimed that BNFL were taking a 'gamble' in funding the biobank since if future research proved the leukaemia-radiation links, then it could help CORE shut down the Sellafield.<sup>311</sup>

Ethical concerns over the establishment of the NCCGP received national and international press coverage as well. Much of the coverage dealt with the nuclear industry and not the science or even ethics of the DNA bank itself.<sup>312</sup> Some claims, in retrospect, have turned out to be spurious. For instance, one report claimed that before giving written and oral consent, prospective parents would watch a video explaining how genetic information from their baby will be used – further inspection showed this was not only not true but also a practical impossibility given the nature of the consenting procedures (i.e. at the would-be mothers first antenatal appointment). One NCCGP team member also claimed that research 'could give the world an important break through in medical science – a test to enable mid-wives to spot the gene that pre-disposes infants to cot death.' However, ten years later, no such studies have been conducted.

Prior to the establishment of the NCCGP in 1995, database organisers held two public consultations. Apparently, turn out for these events was very low despite what team members considered to be extensive advertising. However, how extensive was a contested matter. CORE, the community group opposed to Sellafield, considered the consultations to be highly inadequate. They conducted a street poll the day after the two consultations and found that only 1.5% out of 441 people queried had seen/heard of the

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<sup>310</sup> D. King, 1994. Statement for CORE Press Conference, 13 December.

<sup>311</sup> *West Cumbria Gazette* 2 June 1995.

<sup>312</sup> A. Berger, 1995. Nuclear industry link casts suspicion on gene bank. *New Scientist* 17 June, p. 7; J. Younger, 1994. UK nuclear company funds broad study of genetic data. *Nature* 369: 346. R. Waterhouse, 1994. *Independent on Sunday* 2 October, pp. 8-12; *Times and Star*, 11 November, 1994, page 3.

advertisements for the consultations and that 72.5% out of the same sample had never heard of plans to establish the DNA bank.<sup>313</sup>

*The need to study participation and project rationale*

In light of the Cragg Ross Dawson study cited in the last chapter, the NCCGP's high response rate (near 90% up-take on afterbirth collection) raises some questions. Is it the case that participants in the NCCGP: (a) were well disposed towards the NCCGP and/or were not fully aware of the implications of donating samples and information, or (b) did not have the same concerns as those expressed elsewhere, or (c) perceived the benefits of the NCCGP to outweigh any concerns, or (d) felt their concerns had been fully addressed by the NCCGP team and their anxieties allayed, or (e) have a range of other views, interests and concerns that have not yet come to light?

In designing the funding application, it became evident that the extent to which participation and non-participation were attributable to primarily local factors (such as BNFL) or to other, more widely held, interests and concerns, and the extent to which non-participation represents a distinct stance to that of participation, were matters for empirical investigation. Such an investigation would, it seemed, open up the 'black box' of the social processes of decision making between the request to participate and the actual collection of samples. This seemed important since the NCCGP appeared to work in practical terms, i.e. it sustained a high participation rate over the course of seven and a half years of sample collection.

Equally though, it could have been argued that the apparent success of the NCCGP was based on misunderstandings by the participants of what it is they were agreeing to, in which case the practical benefits were achieved at social and ethical costs. Perhaps non-participants were better informed about the implications: it has been suggested that those who are most informed about bioscience have the most polarised views.<sup>314</sup> Also, the

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<sup>313</sup> CORE Street Poll, 1994. Held in Workington, Whitehaven and Cleator Moor, 27 November and 1 December.

<sup>314</sup> G. Voss, 2000. *Report to the Human Genetics Commission on public attitudes to the use of human genetic information*.

reasons for 'partial participation' needed examining to see whether participants distinguished between the two types of information and, if so, how and why.<sup>315</sup>

### *Research design and methodology*

The project was a prospective, interview-based, qualitative study. The key research questions were:

- (a) What is the repertoire of perceptions, concerns, views, and understandings, that women raise as part of the process of deciding whether to participate or not?
- (b) Are there differences in perceptions, concerns, views, and understandings, or in the importance attached to these, between those who identify as participants and those who identify as non-participants?

The fieldwork for the study involved semi-structured qualitative interviews with forty-three women who donated tissue samples to the NCCGP, seven who refused, seven NCCGP team members, two members of the NCCGP's Ethics Advisory Group, two focus group discussions involving ten community mid-wives, and three members of local community groups that opposed the NCCGP when plans for it were first announced in the early 1990s. Interviews lasted one hour and began with discussions of the respondents' own experience and relationship to the NCCGP.<sup>316</sup> Interviews were preceded by a short survey asking for demographic details such as age, occupation, and education, as well as family history of disease.

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<sup>315</sup> P. Martin P. *The industrial development of human genetic databases*. Submission to the House of Lords Written Evidence on Genetic Databases. House of Lords, 1999-2000.

<sup>316</sup> In order to recruit interviewees, women received an introduction letter and consent form as part of their routine discharge packet upon leaving the post-natal ward. I followed up with a telephone call to arrange the interview, which usually lasted from 45 to 60 minutes and was taped for accuracy. Interviews were held in the respondent's home. As is often the case, non-participants were difficult to recruit to the study. In order to try and boost non-donor numbers, a number of options were tried. These included: classified adverts in local papers; a feature story on the 'American researcher in Cumbria' in *The Whitehaven News*; short presentations and requests at four different mother & toddler groups in the area; liaising through community opposition groups; liaising with NCCGP mid-wives who presented 'refusers' with an introduction letter after they had made the decision not to donate; a BBC Radio Cumbria interview. As lead researcher, I took full responsibility for devising and exercising all of these options (obviously in consultation with Haimes and the Project Advisory Group).

### *Initial hypotheses*

From the outset of the study, it seemed feasible that interviews with the NCCGP and opposition groups (CORE and Friends of the Earth) would yield a range of competing normative statements as to why women should or should not donate samples to the NCCGP. In addition, it was possible that there were similar competing perspectives amongst the women themselves, in their attitudes towards the NCCGP, and how this may have influenced their decision to donate or not. However, it was also possible that there may have been more subtle shadings of views amongst the women asked to donate rather than simply a stance of pro- or anti- NCCGP. There might, for example, have been women who were neutral towards the project, those who were indifferent to it, those who were ambivalent towards it and those who felt elements of all these. Indeed it was also possible that women were simply responding to the request to donate samples without having any particular views on the NCCGP itself or its funding or the political opposition to it. In addition, it was also necessary to question the assumption that just because people might hold opposing views on the NCCGP in particular or genetic databases in general, that this necessarily meant that they held opposing *reasons* for participating or not. In fact we took the notion of 'participation' as an essentially contested, and thus open ended, concept. Therefore in seeking to identify women's repertoire of considerations when deciding whether or not to donate, Haimes and I fully expected to find that those who did donate could nonetheless cite reasons for not donating and those who decided not to donate could cite reasons why donation was a reasonable action. All these possibilities needed to be considered and informed by data that could reveal the knowledge, values and processes of donors' and non-donors' decision making.<sup>317</sup>

### *Notions of participation*

It was clear from the data that there are varying levels of donation and non-donation and that there are different ways in which individuals donate or do not donate to such a database. Therefore, rather than use the terms 'donation' or 'non-donation' as descriptors which imply a single meaning attached to a simple, one-way act, it seems that the notion

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<sup>317</sup> P. Spallone and T. Wilkie, 2000. The research agenda in pharmacogenetics and biological sample collections. *New Genetics and Society*. 19: 193-205.

of 'participation' more accurately reflected what was in fact a highly varied social process, with multiple meanings. The notion of 'participation' was taken as an essentially contested, and thus open ended, concept. It implied a more active process of engagement with, and sharing in the creation of, the database. It acknowledged that those who were approached to give samples and information had an active role in creating the database (including even if they declined to provide these items since that too shaped the database).

In terms of the design of the NCCGP as a database, 'full participation' would mean that a woman contributed umbilical cord samples from her baby, a blood sample from herself and health and lifestyle information from herself and her partner by completing the 'mother's questionnaire'. 'Partial participation' would mean a donation of any combination of cord samples, maternal blood, and lifestyle information, but not all three. 'Non-participation' would mean that nothing was given to the database at all. However, during my interviews with the various groups, these apparently clear distinctions became increasingly blurred as interviewees sought to explain how and why potential participants made their decisions over donation. In addition there were variations in the significance attributed to the differing levels of participation.

### *Project Findings*

#### *The NCCGP research team*

The NCCGP team included geneticists, epidemiologists, child health specialists, and Project mid-wives who liaised between the team and community mid-wives in order to develop the infrastructure needed to recruit mothers. Interviews with the NCCGP research team indicated a somewhat relaxed attitude to the actual participation rates they have achieved. Comments from my interviews with the NCCGP team minimised the involvement needed from donors; one said that they assumed that the donations were 'given and forgotten about' and that they would not want women to be worried about the donation nor did the team wish to 'lean on them' to donate (T234). The idea was to make potential donors 'comfortable to say no' (T587) and that if there had been 100%

participation rate the team would be worried that they were overselling the project (T351).

One referred to the 'huge body of altruism in the general public' as an explanation for such a high response rate, which was not seen as a surprise (T587). Another suggested that 'people on average do have an altruistic streak and mostly people are happy to be involved in medical research that they can see might be of greater good' (T081). Another important element was the trust that most people had in the National Health Service and in its professionals (T234), as well as in the fact that the data was being processed by a local research institute and a local reputable university (T351).

However, an overwhelming reason for the high participation was, according to one team member, the fact that: 'We are just taking samples that are normally thrown away and I feel that's a very strong reason why the NCCGP is so successful. It is no use to them unless they want to have a placenta casserole, which very few people do' (T351). This was echoed by all the other members of the team as well: 'I think most people feel reasonably optimistic that it doesn't impact on them particularly and all they are doing is giving samples that would otherwise not be used.' (T177); 'I think it is a neat way of collecting materials no doubt about that. Neat, and efficient. There is nothing to lose' (T587); 'we are not asking much, people don't have to do very much to be part of it, it doesn't take up their time' (T081).

This last set of quotes shows very clearly that 'participation' in the minds of the NCCGP team meant, primarily, giving the blood and tissue samples. Explanations for partial participation (that is, the non-completion of the Mother's Questionnaire) were mixed. One suggested,

'That is apathy, definitely. If they don't have time to do it when you are seeing them, quite often things are always in a rush, if you try to make them make a start on it, I think they would then fill it in. I think if they don't start it, they just can't be bothered. Other than that, people do not like to give information, it does ask for addresses, where you

have lived for the last five years, a bit about your education. I think a few ladies do feel that it is not necessary to have all that information for the research, you could just have a postcode or perhaps it could be a bit more anonymous.’ (T033)

Another drew an interesting distinction between the types of donation:

‘I’m not surprised that people are reluctant to give personal details, because a sample is a sample, stick a number on a sample and it doesn’t give any information, there’s nothing personal about it almost. It’s giving biochemical genetic information that will be useful for disease studies research but it doesn’t given any personal details. You know, there is nothing associated with it that can be linked to the person as it were. The questionnaire, yes, I’m not altogether surprised that people are reluctant to fill it in. As you probably know more women fill it in than their partners so they have a lot of what we jokingly say is immaculate conceptions, you know, got the details on the mother but not the father... A minor or smaller factor is probably the fact that there is higher illiteracy in West Cumbria. Now if people don’t wish to admit to being illiterate they might not wish to fill in a questionnaire’ (T351).

Thus the type of information being asked for and the context in which it was being requested (during pregnancy) was seen as an inhibiting factor:

‘Like all questionnaires, people prefer not to fill them in, there are very few people who love filling in questionnaires...and the smoking issue is something that is interesting...they know they shouldn’t be smoking, but people don’t like actually having to admit to it either, I suspect there is an element of that too. I don’t know, I have not seen it as my role to actually ask too much of participants what they feel about the questionnaire because I’ve ...taken a hands off line there. I have offered it to them and let it at that really’ (T587)

The extent to which this partial participation was seen to ‘matter’ also varied amongst the research team. One view was ‘I think it does matter’ (T033); another was uncertain,

'How it affects the project, I don't know because I don't think we have had a collaborative study so far that has used any data from the mother's questionnaire at all...So I think that you'll probably find that although it was about 60% to start with that filled in all or part of the questionnaire, I believe it's dropped a bit now, since then. As I say, I can understand that but I don't know what impact that will have on the project as a whole' (T351).

This lack of demand from other researchers wanting to use the mother's questionnaire data perhaps explains the team's relaxed attitude to this aspect of their study:

'Most of the information that has been sent out has been anonymous with no attached data so the questionnaire information hasn't been required. It would be nice to have full ascertainment, it would be wonderful, but I mean we can still function as a facility...'  
(T469).

Similarly, another argued,

'It is obviously much better to have more complete data and it reduces the power of your study if you have missing data...but the compliance rate is pretty high...it's a very short questionnaire and it captures the minimum amount of information and any really in-depth study using health information would need to look at other sources' (T081).

The NCCGP team was of the same opinion that more invasive samples would have been harder to consent for:

'[There's] something very definite about sticking a needle in a child. It puts people off, not surprisingly, they don't like it themselves. So no, I think it is a neat way of collecting materials no doubt about that. Neat, and efficient' (T587)

“Again, on a personal basis, if someone came to me and said, ‘oh well you know, we’d like to stick a needle in your arm to take a sample’, I’d probably go ‘Aaagh I’m not sure about this!’” (T351)

‘The only trouble with that is whether people would be willing to take part in research project for asthma that involved their child having a needle stuck in them. [It] might dramatically alter their level of co-operation and if you did it would weaken the data set dramatically ... That was the whole point of the exercise and at very low cost we’ve got DNA from those kids’ (T234)

The team also minimised the reasons for non-participation. One reason was that such women were ‘lost in the system’, another that most people who do not donate simply forget, ‘there’s nothing systematic about it’ (T081). The views were summed up by one member who said the 15% non-participation was a ‘grey area’ which they could not be clear about but on the other hand another team member was keen to point out again that the team do not ask people why they refuse, as this was ‘not suitable’ (T587).

### *Opposition groups*

Whilst interviewees from the community opposition groups had little to say about the different types of donation elicited or the different levels of participation, they shared similar views to the research team about the reasons for the high participation rate, though they saw reasons to be concerned about this:

‘I would assume that it’s that high partly for the reason that we’ve already said. People are assured that what they are doing is being done in absolute total confidence and the other part is, “well, this is BNFL and BNFL are not going to mislead us and Newcastle [University], why should they mislead us about anything?” People are not going to question the motives about this if it’s put to them in a straightforward way, “this is really useful information, we can build on this, use it in all kinds of helpful ways”, people are not going to say no to it. In a way, maybe I feel that people are being taken advantage of, that maybe the whole thing isn’t explained as fully as it should be. Maybe if [one of us]

was included on a counselling team and was able to put another perspective of this project to the potential donor, then maybe it would be different' (C002).

This comment is tied to a view about why those who chose to donate to the NCCGP made this decision: a view which, like those of the NCCGP team, is linked to ideas about styles of participation too (see next section). On the whole, those who apparently opposed the NCCGP were reluctant to make strong statements about the issues surrounding participation and why women ought not to participate. They were more outspoken about their opposition to the involvement of BNFL rather than to the NCCGP specifically. One acknowledged why some women might want to be part of this research:

'Because I think, well, we all want some research, don't we? We all want to see that people are healthy. Particularly when you get emotive words like child cancer and spina bifida and all these other horrible diseases, neurone diseases. People say that they are doing research into cot deaths [a reference to a newspaper report in the early days of NCCGP when this was mentioned as a possible benefit to the research]. Of course we all want to be a part of that and if you think you can help, that's great.' (C001).

This wish to help is clearly expressed in the mothers' interviews though interestingly it is expressed equally strongly by 'participants' as by 'non-participants' – a point I shall address below.

### *Potential participants*

Whilst the NCCGP research team was clear (though not as concerned as might be expected) about the differing levels of participation, the women were, perhaps surprisingly, very uncertain about the range of donations they were asked to give and just as unclear about what they did actually give. That is to say, most women who were interviewed as participants in the NCCGP were themselves not clear about whether they had in fact given all the samples and information that would constitute full participation. This is partly attributable to not remembering what they had been asked to give and partly to not being able to distinguish between the information and blood samples they

were asked to give as part of routine ante-natal care and that asked specifically for the NCCGP.

Donors that I interviewed also expressed a similar attitude towards the afterbirth. One woman said, 'Once you get to that stage, you have got your baby and whatever else comes out, you know, you are never wanting to see it again.' (M003). Another expressed the view that 'the afterbirth wasn't something that I was particularly attached to' (M008). Others replied that: 'the placenta means nothing to me' (M009), or that 'it's just waste, isn't it' (M013), or 'it was of no use to me.' (M029).

In most cases, mothers never saw the material that they were donating and were, instead, pre-occupied with the birth of their child. 'That was the furthest thing from my mind,' said one woman (M003). Others said: 'I couldn't tell you what it looks like, I didn't see' (M009), and 'you don't even know that it is being taken' (M011). I just told them they could do what they wanted with it. (M021)

In contrast to views of afterbirth as a source of donation, women expressed the view that a different sample type, such a cheek swab or blood sample from the child, would have necessitated greater thought before agreeing to donate. There was a view that no harm could be done by taking a non-invasive sample but that 'it would probably have been a harder decision' had the request not involved waste material (M036). Examples from the interviews include:

'No, I mean it wasn't as if they were wanting to stick pins my daughter, you know, I wouldn't have liked that very much' (M006).

'I think if they had asked for a blood sample from him I would probably have been less likely to do it, because it's more traumatic' (M008).

'I probably would have consented to a blood sample, but I probably would have had a bigger chat with somebody to know more' (M013).

Difficulty in remembering what they had been asked to give was a recurring theme. In terms of the Mother's Questionnaire, despite its purple colour, many women said they did not remember ever seeing it, let alone completing it: 'No, I can't remember seeing one of those' (M007); 'I don't think so... certainly don't remember any purple paper (laughs)' (M070); 'No, I didn't fill out the purple form' (M046). Even those who thought they had completed it were vague about its contents and purpose. For example,

'I can't remember to be honest, I think I did. Is it all about me having a history, yes, I think I did' (M011)

and,

'I wouldn't say I was totally clear on it, I can't remember, I just assumed, obviously, that they can relate it to medical [matters]' (M030).

Similarly, with the maternal blood samples, there was a high level of uncertainty as to whether they were asked to provide one for the NCCGP, let alone whether they consented to doing so: 'No, I don't think so, I don't think I was asked to' (M002); 'I honestly don't know' (M044); 'I've no idea if they took one or not' (M049); 'If they'd wanted one I would have, but I can't remember' (M0101); 'No, I just think it was from the umbilical cord' (M046).

The difficulty many women had distinguishing between that which they were asked to provide for routine antenatal care and that asked for the NCCGP database applied to both the mother's questionnaire and to the maternal blood samples. One woman said about the questionnaire,

'Well, it's difficult to say because I filled that in at the same time as I filled in my medical notes...I had to fill that in as well and I think they were both the same kind of

questions...so I have trouble thinking which one...I think maybe I did fill something in' (M024).

Another said about the maternal blood sample, 'I don't know whether I did or not...they're taking test tubes off you for this, that and the other, it may well have been one of the other. I don't know. I'm sorry I don't recall, no' (M003).

Similarly, 'No, I don't know...well, another test, one more to add to the list. You know, the longer you're pregnant, the more things progress, the more tests you have...' (M006).

And, 'I'd imagine, yeah. I never refused anything that they asked me to do' (M026).

Surprisingly there was even a small element of uncertainty amongst the non-participants as to whether a maternal blood sample had been taken for the NCCGP. One said that she had not given a sample, at least, 'not knowingly...they took a lot of blood at my antenatal' (M060). Another said, 'They might have taken one doing some of the antenatal stuff but I don't remember it. They took so much blood that they could have' (M067). In other words, I do not mean to imply that non-participants were suggesting that the NCCGP research team took illicit samples from them. Rather, it simply indicates just how difficult it is for any woman to be absolutely clear about who takes what samples, and for what purposes, during the context of antenatal care. This is a crucial point which I shall expand upon later in the chapter.

By now, it should be apparent that a simple two-way distinction between women who decide to donate and women who decide not to donate does not reflect the complexities in the *levels* of participation, let alone in the reasons *why* some donate (even partially) and some do not. In trying to tease apart the reasons given in the interviews for 'participation' and 'refusal' it becomes clear that apparently a core reason for donating (wishing to help) is rated as equally important by participants as by refusers (again, a point I will revisit). In addition, however, those who do donate expressed their wish to

help in a number of different ways which suggests that there are different *styles* to donating and 'helping'.

### *Why donate?*

Analysis of the participating mothers' interviews revealed two very strong strands: a wish to help and a sense that not very much was involved in providing that help. The wish to help was expressed in a number of ways with different views as to who it was they wanted to help. Some felt their donation was helping the future in some unspecified way, others that it would help their own children's generation, others that it would help babies and children in general, or simply 'other people' in the future. A couple of women specifically mentioned helping Cumbria with their donations. This last point might be tied to another very common reason given for donating, which was to assist research into the eradication of disease:

'I would say it was just the sort of research for medical purposes, to help towards illnesses, such as cancer, Parkinsons, MS, all these types of things, yes, just to use them in connection with treatment in the future' (M012).

Several were aware that they themselves had benefited from research done previously and this influenced their own decisions:

'...because we had had the IVF treatment, you think, "well, if they hadn't done a lot of research about that then", you know...I think that was the main reason why we agreed that we would donate. We thought that anything that helps, you know helps with cancer or anything like that. And there was no harm to me or the baby so we thought, well, "yes, it's a good idea".' (M013).

'My understanding of what the Cumbria Genetics Project is about, it's something that is worth doing. My contribution to it is very small for me, it's not as if it was an ongoing thing, it's not as if I'm being asked to do something every week or every year, it's a one off thing, it was a one off donation but really, you know it didn't impinge on me at all.

I'm glad to have the opportunity to be involved in something like this because I think it's important but it's not something that preys on my mind. I just think if you don't have medical research you don't move forward' (M008). This woman then went on to compare what was asked of her for the NCCGP with a project that her husband contributed to as a child when his mother agreed to have him be a 'guinea pig' for the measles vaccine – 'and at the end of the day what we did in giving a sample and afterbirth was nothing compared to actually having your child vaccinated with a vaccine that was, well it would have been through a lot of trials but was still, you know, at the forefront'.

This quotation is very useful in showing how these two strands intertwined. The sense that not a lot was involved was expressed in a number of other ways also. Interviews included remarks such as 'it was no harm to me or the baby'; 'there wasn't much involved'; 'it was no cost to me'; 'the afterbirth would just be thrown away other wise', 'it wasn't a big issue', 'it was an easy decision to make'; 'there was no reason not to donate'; 'I don't know why I just did it'. For example,

'It doesn't affect me personally, it's only part of the procedure which is done anyway. I mean, after you have given birth, that is the last thing on your mind, I don't care what they do with it, they can do what they want with it. I don't need it anymore, the baby doesn't need it anymore, so you know it's matterless and they had to take blood anyway after you've had the baby so I mean it's just a little drop extra' (M006).

'...it wasn't anything detrimental to me so if it helps somebody else in the future then they're more than welcome, particularly if I don't have to do the work' (M028).

'It's basically why not? I couldn't think of any good reason why not really' (M034).

Only one woman expressed regret at donating:

'"Do you want to donate your umbilical cord?". I think someone said it was for asthma. Was it for asthma, I'm sure that what's somebody said it was for, something to do with

asthma. And I don't know, at the time I said "yes". I wished I hadn't have done, I must admit. I really wished that I had more information and that I was better informed and I wish I wasn't put on the spot to make that decision because I don't think that I was in the right frame of mind to make the right decision' (M040).

### *Why say no?*

Initial discussions with the NCCGP team suggested possible reasons for this: either some women are missed out by mistake or some make a conscious decision not to participate. Possible reasons for refusal were thought to include concerns similar to those already cited (and a view that the NCCGP failed to address them sufficiently) or an organised opposition to the NCCGP because of the involvement of BNFL (Chase et al, 1998).

Reasons for refusal fell into two broad categories: local factors regarding the funding of the NCCGP and wider concerns over future use and control of the samples. Interviews with those who refused to donate indicate that concerns regarding BNFL were a factor. One woman, whose daughter had died of leukaemia, said:

'It's like when this woman said to us it's privately funded and I said who by, and she said it's done by Newcastle University, there is a professor over there or something, and I said yes but who is it funded by? I said anything to do with Sellafield? ... Why, have you got a problem, she says, with research into cancer? I said I think you are asking the wrong person that, my daughter died twelve years ago with leukaemia. I said any research is good research but when it is being funded by [BNFL], we are being used as guinea pigs'. (M039)

Another non-participant replied that when she discovered that the project was financed by BNFL, 'everything became more clear' (M041). Interviews with the NCCGP's Ethics Advisory Group and with community groups opposed to the database raise similar concerns that if BNFL funded the database, 'they would in some way manipulate [the research] to their own ends.' (C002)

Some NCCGP team members directly addressed this point in their interviews. One said about CORE, 'They felt that BNFL were going to control this [NCCGP] and therefore they were controlling the DNA and controlling the information, blah blah blah'. (T351)

Another claimed that,

'Well, BNFL is not an issue in this community, that's a misconception. There are a few vocal people in the community, but this area depends on BNFL. They have lived here in proximity to the site for so long that they do not really perceive it as a problem, and I think that sometimes people from outside forget that'. (T177)

Apart from funding issues, some 'refusers' were worried about the use and control of their samples. For instance one woman (M060) established the fact that she had donated stem cells to another project but was not happy to donate to the NCCGP because she thought the purpose of their research was vague and she also did not want to provide access to her medical records as she could not understand why this was needed. Another woman stressed how guilty she felt about not donating:

'[They're] storming forward with advances and I thought, "I just don't know enough about this". I didn't want to be hurried into a decision and I think at the time they were saying...it was going to be used to find out, for research on asthma and I felt terribly guilty saying "no" because I had four healthy children and I appreciate how lucky I am.' (M056).

This interviewee said she wanted to protect her baby but could not do so if she donated to NCCGP as she had no control over what was done to the samples. Lack of control was cited in several accounts as a reason for not donating, rather than not wanting to help. One said, 'I feel like I've got some paranoid conspiracy thing going on but there you go. It's with not knowing anything about it, I suppose. I find that really spooky' (M035).

Another said, 'Before I had a child of my own, it was just a general concern about the database and what they might abuse in the future – that you might have very little control

over that despite the best safeguards and the best intentions in the world. But when actually the child is there, it's their consent as well that you're giving...maybe it's being used for something you're not aware of and you don't know that you ought to withdraw your consent on such and such a day' (M071).

Thus, our study suggests that non-participants are also eager to help medical research and feel a generalised cultural pressure or imperative to donate, which is perhaps particularly acute during pregnancy when they are recipients of much medical support. However, despite their willingness to help, our work shows that 'refusers' felt they could not supply samples in this case partly due to the particular circumstances of the NCCGP and partly due to more generalised concerns for their baby's welfare<sup>318</sup>.

### *Risk, communication and understanding*<sup>319</sup>

The NCCGP's literature emphasised that all information would remain confidential and only be used for medical research. Interviews found that the written forms provided the only detailed source of information for donors about the NCCGP. Little was said about the biobank and any risks associated with it during the consenting process. Community mid-wives usually spent 'about thirty seconds' on the consenting process since so much other information must be passed on to the mothers-to-be (CMW02). In general study findings revealed that donors were told little about the database and had a relatively limited understanding of the aims of the gene bank and use of their samples.

Again, it is important to note that the request was usually made during the first antenatal appointment, which involved a large amount of information and literature that took pregnant women 'a good two or three weeks to work their way through' (CMW01).

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<sup>318</sup> A third possible reason, of course, is parents' unwillingness to give consent for their child. Whilst this is a crucial point in medical ethics generally, interviewees in general attached only variable importance to it. For instance, many women expressed doubt that they would even remember to tell their child about their donation to the NCCGP. For more on the issue of children's involvement in database research, see: Williamson, E., Goodenough, T., Kent, J., Ashcroft, R., in press. Children's Participation in Genetic Epidemiology: Consent and Control. In Tutton, R., and Corrigan, O., eds. *Donating and Exploiting DNA: Social and Ethical Aspects of Public Participation in Genetic Databases*, London: Routledge, pp. 139-160.

<sup>319</sup> The notion of 'risk', as it is used here, is a social science term. NCCGP forms make no mention of the word. The term 'communication' would be characterised on NCCGP forms as 'information giving' and 'requests for consent'.

As one mid-wife in a group interview put it,

'[Requesting samples for the NCCGP is] only a very very small portion of our care and after this we've got so many other things to talk about because they are having diagnostic tests on their own baby and we've got a lot to cover so, I've got to be honest, after the first interview I don't really bring it up again unless they come back to me with any questions.' (CMW01)

Many women felt that compared to other tests and procedures undergone during pregnancy, donating the afterbirth was a minimal risk. One interviewee compared the donation to an amniocentesis. 'Because of my age being over 40 I had an amniocentesis. [The] amnio could have damaged her but nothing in the database could damage her.' (M037)

In addition, women also seemed to have a limited understanding of the NCCGP's aims and the use of their samples. For example, many were surprised to learn that samples would be kept for as long as sixteen years, at which point their child would have the right to withdraw their sample<sup>320</sup>. Many had little idea who would benefit from the research and what type of research would be conducted. For example, responses include:

MWB: 'I'm starting to feel like I'm quizzing you'

Participant: 'I don't know a lot about it, I'm not really read up in the genetics or anything at all. I can't remember [what it was for]' (M007)

'I don't think an awful lot was said about it' (M028)

'Maybe I read it wrong but I thought they were doing it individually, your placenta individually, to see how they've worked during the pregnancy. Is that what they are

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<sup>320</sup> The child's right to withdraw is clearly stated in both NCCGP consent forms and further information leaflets.

doing? To tell you the truth, I just thought I would do it and whatever, see what happened when' (M042)

'They didn't really say anything at all, just like, when you say Genetics Projects, I just thought it would help to look for, I don't know, a cure or something. I don't know' (M046)

As one mother said, 'The midwives didn't provide much additional information because for them, the primary concern was helping myself ... they said here's a leaflet if you have any questions ask next time you come' (M060)

'She didn't go into great detail she just asked if the after birth could be taken away and be tested for genetics' (M002)

Data also showed that women tended to ask very few questions about the NCCGP. Consistently, interviewees said that agreeing to donate was an 'easy' decision to make. This may be because of the nature of the sample, as I have shown, or it may be due to the fact that women, when interacting with their mid-wife, tend to focus on issues involving the status of their pregnancy and health of their child.

Data suggested that women had a limited understanding of the aims of the DNA bank as well as of the uses and storage of their sample. Responses include:

'Just a genetic study, genetic disorders' (M006)

“It could have been a bit more informed ... She was very nice and she answered what she could instead of pretending so, but I would have rather have more, you know, 'what are the people, what sort of research, what part, what immediate impact on all that research', you know, just wanted to know 'where is it going'" (M010)

‘How they put it to me was, when you have the baby, your placenta can be sort of sent away and you know they sort of look into it for different things, different studies ... they didn't really go into a lot of details, they just said they would take it away for studies’

(M043)

‘They would monitor my sample for the next 20 years and maybe connect it if I got breast cancer, or if Jenny had any other anything occurred, to link it back to her genetics’

(M045)

In addition, answers varied as to whom donors thought the research would benefit. One thought that it was for ‘family illnesses’ and ‘social and medical disease within West Cumbria’ (M012). Another thought that: ‘what I understand it helps, like if there was something wrong with somebody in the family that they're maybe connected to a certain gene or something’. (M052).

One NCCGP team member expressed various reasons for the lack of understanding, ‘A lot of the women who are approached, don't have much of a deep understanding of genetics in general and scientists in general. They have more pressing concerns of where the next meal's coming from and other more pressing concerns, probably violence, poverty, illiteracy’. (T351)

### *Project Analysis*

#### *Informed consent*

As discussed in Chapter Four, one key issue in population genetics is informed consent. The findings described in this chapter provide empirical insight into this issue.

Data show that: a) the decision to donate to the NCCGP was a relatively easy one for women to make since they felt the afterbirth was of no use to them, or their baby, post delivery; b) that donors were informed of the NCCGP's aims and details in the briefest of terms and that they asked few questions about the database; c) that women felt they would have asked more questions if the sample had been of a different type, such as

blood or a cheek swab<sup>321</sup>, and d) that donors' understandings of the NCCGP were usually limited. Thus, the social context of pregnancy raises the ethical question of informed consent: if women are uncertain about what they donated, how clear can they be about the rationale of the research to which they contributed, or about the nature of the uses to which their information and samples would be put? Whilst a high response rate is important in biobanking, it seems that in future studies researchers and policy-makers should attend to the social processes that result in achieving a particular response rate, not just the actual rate itself.<sup>322</sup>

The lack of clear memory and that of distinguishing the provenance of requests could be explained in terms of mothers' failings as individuals (for example, their poor memory and poor understandings because perhaps of poor concentration) but are, it would appear from the data, much more likely to be attributable to the fact that they were asked for this information and blood sample during pregnancy.

The point to make here is that pregnant women were obviously alert to issues about the health of their child and are likely to be eager to donate to medical research that they perceive might benefit themselves or their children and families. Clearly, the high participation rates of the NCCGP were due, in part, to the timing and context of the request. In other words, the relative ease of the donation and the setting in which it took place, may have masked the possible risks involved and influenced donors' levels of interest regarding exactly what it was they were donating to and for. It seems, then, that the reason for the high participation rate in the NCCGP (the ease of taking afterbirth as a source of DNA) is also the reason for concern about the validity of its consenting procedures. Whilst afterbirth may be 'waste material' in the antenatal context, and described as such by the NCCGP, such material carries significant and lasting value in the context of biobanking.

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<sup>321</sup> Of course, if a more invasive sample had been requested, this does not necessarily mean that women's understandings of the gene bank would have been greater.

<sup>322</sup> For more on consent and database research, see: R. Chadwick and K. Berg, K., 2001. Solidarity and equity: New ethical frameworks for genetic databases. *Nature Review Genetics* 2: 318-321; and, O'Neil, 2002.

### *Silent participants?*

Having heard the voices of some of those involved in the NCCGP it is also necessary to be aware of those voices that have yet to be heard. Who has a voice in the debates about genetic databases and who remains or is forced to remain silent? In particular the voices of the children who have also donated to the NCCGP will not be heard for quite some time. They are passive participants in the project in a particularly stark way. This is an issue that will need to be revisited as these children grow up into teenage-hood and adulthood, since their rights need to be considered. The NCCGP has stated that the children will be able to withdraw their samples once they reach the age of sixteen but until then they are essentially silent donors whose materials will contribute to medical research but without their consent. In addition, it is not clear exactly how children will be re-contacted or invited to withdrawal. Clearly this relates to other debates within medical ethics on the ability of children to consent to research but its importance here needs to be remembered. To what extent do they have choices, now or in the future, about their levels of participation and to what extent will they later on reflect their mothers' styles of participation? I shall re-visit this issue in Chapter Eight.

### *Notions of community*

Much work has shown that communities are shaped in particular historical contexts. The term 'community' itself can have multiple meanings (for example, in terms of cultural, epidemiological, or political significance) and attempts to divide people into communities and populations are neither natural nor neutral.<sup>323</sup>

There is also a question of whether the wider community has, or should have, a voice in these discussions. As I mentioned earlier in the chapter, the NCCGP undertook a series of public meetings to try to ensure that the community was informed about the project and there are varying accounts about the success of these meetings. Even so, the ability to consult a community is an issue that remains a challenge for anyone involved in genetics research and is a particularly big challenge for the UK Biobank. If it is difficult to

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<sup>323</sup> F. Brunger, F., 2003. Problematizing the notion of "community" in research ethics, in B. Knoppers, ed., pp. 245-255.

achieve adequate consultation with such an apparently small and stable community as West Cumbria is said to be, then the difficulties of doing so on the level of national populations might seem insurmountable. Added to this is the need for a more critical approach to the term 'consultation', which implies a one way relationship between two distinct parties. It is difficult for a community to enter into such a process since this will always be a process of talking, in fact, with representatives of that community, as I suggested briefly in Chapter Five. How those representatives are selected, and how the consultation occurs, is underpinned by political processes which in turn underpin the ways in which ethical issues are handled. Therefore even if the term consultation is replaced with a perhaps more evenly balanced and active term such as 'dialogue', the problem of just who has a voice in that dialogue remains.

This reveals another question for these discussions, which is how 'the community' is characterised. The very title of the NCCGP emphasises both the location of the project (although in fact it is located in West Cumbria rather than North Cumbria) and characterises that geographical location as a 'community'.<sup>324</sup> Why has the title of the project been built around these elements, rather than around, for example, the purpose of the project or its desired outcomes? The analytical question to ask is: what does that use of the location, and its association with the notion of community, achieve? However deliberate or otherwise the choice of these terms has been, the effect of this use is to suggest a degree of ownership of the project by the community, which in turn suggests that they might be assumed to be the main beneficiaries of that project.

Associated with this question of 'community' is the question of the extent to which even the women in the NCCGP study can be said to have shared interests? The NCCGP has constituted all mothers of new born babies in West Cumbria into a constituency of apparently shared interests by virtue of their approach to them as potential donors. Thus, the women have become implicated in a broader set of ethical issues simply through their identification by genetics researchers as potential donors, without active choices or

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<sup>324</sup> According to NCCGP team members, the 'North' in the title represents that fact that it was the *North* Cumbria Health Authority that approved plans for the database.

decisions on their own part. This in itself is an ethical issue since it might well have consequences for how they think about themselves and their children and families.

### *Altruism, reciprocity and benefits-sharing*

As discussed in the previous chapter, a common view is that there is a strong sense of altruism in 'gifting' samples to genetics research. NCCGP team members also mentioned altruism as a motivating factor. One referred to the 'huge body of altruism in the general public' as an explanation for such a high response rate, which was not seen as a surprise (T587). Another suggested that 'people on average do have an altruistic streak and mostly people are happy to be involved in medical research that they can see might be of greater good' (T081).

However, this case study sheds light on the extent to which 'altruism' can be considered a uni-dimensional concept and raises some questions as to whether this is an accurate reflection of people's motivations in donating. When the MRC or when NCCGP team members cite altruism as a reason why some donate, the implication is that those who do not donate are somehow not as altruistic. But this chapter has shown that the language of helping was present in the accounts of both participants and non-participants in the NCCGP. In other words, it seems that participants are not as straightforwardly altruistic as is usually assumed and that those who do not participate are as equally altruistic as their participating counterparts.

Furthermore, at least some donors are motivated by the expectation that someone (perhaps even themselves or their family) would one day benefit from advances in medical research. Donation for these women therefore involved an assumption about reciprocity and benefit-sharing (even if not articulated in those terms) and was not simply an instance of one way gift-giving. This finding echoes Marcel Mauss' original work, which emphasised that the idea of gift giving is based on *reciprocity*. A 'gift relationship' stresses that exchanges are in fact based on *interlocking obligations*. Refusal to give 'is to

reject the bonds of alliance and commonality'.<sup>325</sup> Somewhat provocatively, we may say that altruism is rarely, if ever, uncalculated. In the words of Mary Douglas, 'there are no free gifts ... A gift that does nothing to enhance solidarity is a contradiction'.<sup>326</sup> People are willing to give, it seems, not as unilateral acts of kindness, but as part of an interdependent system of giving and receiving – of *sharing*.

My point here is that these data seem to run counter to notions of altruism and gift-giving that underlie many discussions about genetic research. It has been claimed that 'donations based on economic self interest rather than altruism tend to be devalued'.<sup>327</sup> But my argument is that we need to recognise the element of expected benefits that appears to be present in some peoples' motivations for donating.<sup>328</sup>

### *Ethical styles*

Appeals to ethical concepts are often made to explain why ordinary people do, should, or would want to, donate to such databases. Biobanks seem to construct an apparent, but implicit dependence on certain types of moral behaviour by the general population. The data also show that the four sets of interviews suggest that all parties are constructing themselves as 'ethical beings', that is, they are keen to show that they appreciate the moral dimensions of their role in the NCCGP study. For example, the NCCGP team, and the midwives, demonstrate this through their reported insistence on not pressing the women to donate; the opposition groups show they understand the imperative to help medical research even though they oppose the source of BNFL funding and seek to show that their fight is not with the women or even the research but with the funders of the research; participating mothers were keen to show their willingness to help a worthy

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<sup>325</sup> M. Mauss, M., 1997. *The Gift, The Form, and Reason for Exchange in Archaic Societies* Translated W.D. Halls. London: Routledge.

<sup>326</sup> M. Douglas, 1997. No free gifts, Foreword to M. Mauss, *The Gift, The Form, and Reason for Exchange in Archaic Societies*, London: Routledge. pp. vii-xviii.

<sup>327</sup> Nelkin, 1998, p. 36.

<sup>328</sup> I recognise that altruism is a concept not easily captured. Differing views about the 'true' motivation behind altruistic acts formed part of the early debates in sociobiology and continue to rage in philosophy, evolutionary psychology and the social sciences. See, for example, E. Sober and D. Wilson, 1999. *Unto Others: The Evolution and Psychology of Unselfish Behaviour*, Cambridge: Harvard University Press. My claim is that the data gives voice to the view that donating is often motivated by a degree of rational evaluation of potential benefits. For more on altruism in the context of genetics, see R. Tutton, 2002. Gift relationships in genetics research, *Science as Culture* 11: 523-542.

cause and non-participating mothers show that this 'language of helping' is as important to them as it is to participants, but that it did not apply in these specific circumstances.

Each version of 'ethical being' put forward by interviewees reflects the social context of their actions and motivations as presented by the interviewees. No one referred to an overarching set of principles, external to the context, to guide their actions or by which they felt their actions were guided, other than the very general notion of 'helping'. One possible way of understanding these versions of ethical beings is through Foucault's 'aesthetics of the self' and through his notion of 'practices of the self': that is, the ways in which individuals construct themselves ethically 'without recourse to over-riding moral norms'.<sup>329</sup> Another way of viewing this is through Thomas Osborne's adaptation of Foucault's work in his concept of 'ethical stylisations' which refers to the ways in which individuals within certain social contexts construct and sustain an acceptable sense of self, the acceptability being based on certain social and cultural frameworks for particular groups. Osborne argues that we now have a world of many ethical stylisations but with few rules about ethical content.<sup>330</sup>

### *The importance of context*

Above all, this chapter has highlighted the importance of context in understanding the issues at stake in biobanking and in opening up new lines of inquiry. Interview data reflects the difficulty of distinguishing between making a genetic donation and requests that form part of routine antenatal care. It also draws attention to how local issues (in this case the role of BNFL in first funding the biobank) can influence potential donors' perceptions and views of the database. The request to donate took place in an environment and locality where notions of risk were coloured by the very community in which people lived. In regards to Cumbria, it seems impossible to separate a discourse of biobank risk from a discourse of nuclear risk and researchers cannot presume to know if, how, and to what extent perceptions of one type of risk affect perceptions of the other. Therefore, it is clear from this case study that attention needs to be paid to the social

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<sup>329</sup> M. Foucault, 1984. *The Care of the Self: History of Sexuality Vol. III*. London: Penguin.

<sup>330</sup> T. Osborne, 1998. Constructionism, authority and the ethical life. In I. Velody & R. Williams eds., *The Politics of Constructionism*. London: Sage: 221-234.

context of the targeted population in case particular (hitherto unidentified) characteristics of that population affect levels and styles of consent, altruism, participation and refusal.

All the above points have clear implications for the design and conduct of the UK Biobank and similar database projects, particularly in the recruitment of donors and for understanding how and why potential donors might participate. Beyond the nature of participation, however, the material presented has provided means for greater exploration and comments on a number of related themes in population-based genetics research. In other words, the point I wish to make regards the value of empirical and sociological work as a compliment to philosophical discussion into bioethical issues.

#### *Value of empirical and interdisciplinary research*

In Chapters Three and Four I presented a series of claims and arguments about bioethics. This case study, I believe, has provided a useful example of the benefits that can be achieved when using sociological theory and empirical methods to address normative bioethical debates. An overall achievement of this work is that it puts researchers in a position to ask the sorts of questions raised above regarding the nature and use of concepts such as ‘donation’, ‘altruism’, and ‘consent’.

From this case study, it can be seen that it is necessary to problematize notions of participation and donation and investigate the particular circumstances in which ethical issues arise. It is also necessary to attend to the details of genetics research – ‘on the ground’, so to speak. Who is doing the recruiting and in what medical and social context? How will they seek consent? In other words, attention must be paid to the processes behind donation rates and not just the rates themselves. Whilst much ethical focus is on the governance and on the managers of biobanks, this chapter has shown the importance of also considering the role of those who are actually taking samples and interacting with potential donors. After all, ‘the social’ is the filter through which the ethical and legal issues emerge, take shape, and are given prominence. Thus, only through empirical research can we provide much needed evidence to inform normative discussions and policy-making in the area of population genetics.

### *Summary and conclusion*

In this chapter I have argued that:

- The case study is a valuable method for accessing the rich context and ambiguity that characterises ethics in real life situations. I reported on findings from a particular study of the NCCGP, a biobank that collected DNA samples from pregnant women and their newborn babies and combined those samples with health and lifestyle information for the purpose of genetic epidemiological analysis. The study was based on the premise that we know little about the views of those who have actually been asked to donate to a genetic database.
- The NCCGP raised a number of socio-ethical issues unique to its own history and procedures (itself evidence of the need for contextual knowledge in moral philosophy) . Most critically, it requested genetic samples from women undergoing concurrent antenatal care and secondly, it received its initial funding from BNFL, a nuclear power company whose plant at Sellafield was blamed for causing high rates of childhood leukaemia in the area.
- The case study provided a more nuanced understanding of the nature of participation in genetics research. Data revealed the complexities in the levels and styles of participation, which a simple two-way distinction between those who decide to donate and those who decide not to donate does not reflect.
- It also shed light on non-donors reasons for refusal. Some refusers had donated to other medical projects but could not supply the NCCGP with samples due to a combination of local factors (e.g. funding of the NCCGP) and wider concerns over the control of genetic data and the fact that no one (not even the NCCGP team) could know future uses of their donation. Interestingly, however, the desire to help was rated as equally important by ‘refusers’, as participants.

- The study also suggested that participants are not as straightforwardly altruistic as is usually assumed and that those who do not participate are as equally altruistic as their participating counterparts. Donors are motivated by the expectation that they or those close to them may someday benefit from advances in medical research. Since reciprocity (as opposed to one way gift-giving) is a vital component in donation, the study points to the importance of working out suitable methods of benefit-sharing.
- Interview data also provided empirical insight into discussions of informed consent. In the case of the NCCGP, the reason for the successful participation rate was also a key reason to be concerned. Most women found it easy to donate their afterbirth since the material was to be otherwise discarded. However, the ease of the decision meant that they asked few questions about the project, which, in turn, impacted their levels of understanding of what they were donating to and for.
- Finally, the project suggested that use of terms such as *community consultation*, *consent*, and *participation* must be fully investigated so that genetics researchers and policy-makers understand their usefulness and limitations and avoid false claims regarding levels of community approval for biobank initiatives. It also suggested that researchers and policy-makers should attend to the social processes that lead to genetic databases achieving a high level of participation, rather than see high participation rates as an unproblematic achievement. All the above points have clear implications for the design and conduct of the UK Biobank.

In the next chapter I return to my earlier discussion of bioethical methods, in light of the findings and analysis presented above.

## Chapter Seven

### The importance of context: methodological sketches for a context sensitive bioethics

*'Philosophers constantly see the method of science before their eyes, and are irresistibly tempted to ask and answer questions in the way science does. This tendency is the real source of metaphysics, and leads the philosopher into complete darkness.'*<sup>331</sup>

-- Ludwig Wittgenstein

#### *Introduction*

Throughout this thesis, I have emphasised the importance of context.<sup>332</sup> In the second chapter, I argued that the term 'etiquette', often used by historians, did not adequately appreciate the moral content of medical ethics and mistakenly applied current definitions of 'ethics' to past contexts. Regarding the birth of bioethics, I agreed with those who argued that it was necessary to view the development of the field within the social and political milieu of the right's movements of the 1960s. I also claimed that the principle of autonomy and the doctrine of informed consent ought to be understood in light of the post War context and the supreme value of individualism in Western (especially American) culture. In evaluating the social science critique of bioethics, I evaluated arguments about how standard bioethics is committed to a rational and idealized form of inquiry which marginalises the structure, context, and process in which agents are inevitably situated. Finally, in the last chapter, I argued that to truly grasp what is at stake in the socio-ethical issues of genetic epidemiology, one must attend to the details of the particular case. One cannot simply accept claims about high participation rates or public acceptability of genetic research, for example. One must deconstruct statements to learn where, when and how requests to donate are made. Thus, I provided a concrete case study of the arguments put forth by social scientists and in the process, largely agreed with many of their claims.

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<sup>331</sup> Cited in Monk, 1990, p. 338.

<sup>332</sup> Several paragraphs of this chapter are based on: E. Haimes and M. Whong-Barr, Under review. Linking sociology, ethics and population genetics: the importance of context. Submitted to *Sociology* April 2004.

However, despite my appeal to the importance of context, the concept remains under defined. Of course, one could argue that it is necessarily so. 'Context', inevitably, may be impossible to define or theorise since by its very nature, it is dependent upon – well, context. However, this line of reasoning seems to me like a dead end. Rather, I suspect that many historians, ethicists, and social scientists could benefit from a critical and analytical examination of what is meant by the term. This chapter is an attempt to better understand 'context' through an extension of the discussion begun in Chapter Four of the relationship between bioethics and sociology. My aim here is to explore a set of methodological insights that would help situate ethics in a socio-historical context. My discussion leads to Chapter Eight, which applies the analytical framework developed here to actual issues and cases in biomedical ethics. The approach I advocate would challenge the tendency to frame ethical debates in certain conceptual terms (such as 'altruism', 'informed consent', 'autonomy', 'trust') whilst ignoring or excluding other terms, such as 'power', 'politics', 'scepticism' and 'authority'.<sup>333</sup>

One theme to this chapter then is how to extend the discussion about the relationship between the social sciences and ethics, in such a way that both facilitates and requires greater conceptual clarity and rigour from each. This endeavour is not much helped by the use, and indeed institutionalisation, of such common phrases as 'ELSA' or 'ELSI' which are shorthand for the ethical, legal and social aspects/implications of genetics and the life sciences.<sup>334</sup> The considerations encompassed by such phrases tend to blur into one general area denoting concern about developments in genetics, without much clarity about any of them. Having said that, at least the phrase 'legal' operates in a reasonably clearly defined field and the phrase 'ethical' serves to warn us of matters to be concerned about. However, the phrase 'social' in this string conveys an ill defined and blurred domain of activities and considerations, almost as if it refers to whatever is left over once the ethical and legal issues have been identified and resolved. Its presence in the phrasing 'ethical, legal and social' also implies that it is separate from the ethical and the legal. However by taking a critical and socio-historically informed view one could argue that

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<sup>333</sup> Haines, 2002, p. 111; Whong-Barr, 2003, p. 81.

<sup>334</sup> 'ELSI' is a specifically funded element of the Human Genome Project in the USA; 'ELSA' is a specific element in Swedish national funding for research in genetics.

the very designation of an issue as 'ethical' or 'legal' is itself the outcome of a number of complex and intertwining social processes. This, I believe, is a fundamental insight from the Cumbria research. But there is a need to explore those processes and ask what work such labels perform and analyse the consequences of the designation of certain issues in this way. It may well be that one consequence of such designations (e.g. as 'ethical') is to draw attention to certain areas and to deflect attention away from other (political? economic?) areas. Also, it is worth asking if the designation of certain questions as 'ethical' shapes how those questions are addressed and by whom. In other words, does the designation of other issues as being something other than ethical mean that they are ignored or sidelined. Others have voiced related concerns. Nelson suggests that bioethicists are serving particular interests in attending only to certain questions and not others.<sup>335</sup> Bauman wishes to expose the 'sources of moral power which in modern ethical philosophy...were hidden from sight'.<sup>336</sup> Finally, Levitt and Williams claim that 'Many have voiced the suspicion that bioethics is too often a legitimating discipline'.<sup>337</sup>

What is clear is that far from being the rag-bag of issues left over when the ethical and legal questions have been sorted, 'the social' is actually and necessarily the filter through which ethical and legal issues emerge and take shape and are given prominence. That is, ethical and legal issues are socially constituted. Thus, whilst 'the social' will always be contingent, situated and ambiguous, it is because of this very complexity that it must be engaged with – in order to understand and to gain access to other, more clearly defined, areas of concern. However, this also suggests that the notion of the 'social' needs to be more clearly delineated in these debates and not simply tagged on.

### *Ethical beings/being ethical*

In the previous chapter I discussed the various ways donors and researchers in the NCCGP describe themselves and their actions as ethical. In the course of data analysis and in search of a fancy title for a conference paper at the London School of Economics, I

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<sup>335</sup> Nelson, 2000.

<sup>336</sup> Z. Bauman, 1993. *Postmodern Ethics*. Oxford: Blackwell, p. 3

<sup>337</sup> Levitt and Williams, 2003, p. 5.

came up with the phrase 'ethical beings and being ethical'.<sup>338</sup> As it turned out, these terms have proven useful in forcing a closer examination of the assumptions and the language used in empirical research and the relationship between sociology and ethics.

Arguably, the term 'ethical being' suggests a concern with status; with the individual's standing in the moral universe and/or their degree of adherence to a particular moral code. One could argue that that is primarily therefore a concern of ethics: the evaluation of the individual's standing or at least of their actions. As suggested in Chapter Four, virtue ethics is concerned with an individual's moral character and seeks to address questions such as, 'what kind of person should I be?'. The prescriptive task of ethics is to judge that status and perhaps also to suggest ways of improving it. The term 'being ethical', however, suggests a concern with process: with the actions and practices that define ethical behaviour in certain settings. Arguably, this is a primary concern for (a certain type of) sociology. The analytical task is to provide a reflexive interpretation of those processes such that the reader can gain understanding of the ways in which actions, practices and settings are mutually constitutive.<sup>339</sup>

### *The importance of context*

However neither notion of status nor process (let alone of ethical beings and being ethical) makes sense without an understanding of the context in which each is used: this can be seen from the study of the NCCGP, from which the terms were derived in the first place. A consideration of context brings together the two notions of status and process. Hence the power of Bauman's instruction to engage with 'messy human reality' (a plea that one might expect from a sociologist). What is also interesting though is that

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<sup>338</sup> Ethical beings and being ethical: Donor and professional views of population genetics. Vital Politics: Health, Medicine and Bioeconomics into the Twenty First Century Conference. London School of Economics, September 2003. Co-authored with Haimes, though the phrase is mine and emerged from data analysis and interpretation.

<sup>339</sup> Though it is possible to overstate these distinctions: clearly ethics is interested in process (e.g. the analysis of processes of reasoning in some thought experiments, the concern with context and process in casuistry, as discussed in chapter four, and narrative ethics) and sociology, particularly classical, has a long standing interest in status in many different forms. However, the version of process in ethics can often be stylized (that is, manipulated and formalised) and is focussed on the logical progression from one action to the next; it is not the contingent, variable, vulnerable process of, for example, symbolic interactionism, let alone the robust and moment-to-moment concern with process that characterises ethnomethodology.

bioethicists are also beginning to make similar calls. For example, Onora O'Neill has said that she wishes to be both philosophically constructive and practically constructive. She adds,

'Writing on bioethics exacts intellectually troubling compromises. If it is to be philosophically serious it cannot take specific institutional and professional arrangements for granted; if it is to speak to actual predicaments it must take institutional and professional arrangements seriously. Much writing on bioethics fails as philosophy because it takes for granted some of the institutions or practices of particular cultures or times, such as hospital based medicines or advanced biotechnologies, and fails to consider alternatives. Some philosophically interesting writing lacks clear implications for medicine, science and biotechnology because it is oblivious to institutional and professional realities and diversities. These problems can be avoided but not solved by separating philosophical writing from work intended to contribute to policy debates in bioethics. That has so far been my practice; its costs are rather high.'<sup>340</sup>

She continues that she has tried to link serious philosophy with consideration of specific policies, practices and institutions, using the latter to illustrate underlying philosophical questions and arguments.<sup>341</sup> That she has to try to justify this to philosophy colleagues and that she notes the 'costs' of so doing, is somewhat revealing. It implies that any discussion such as this has other consequences, for example, for what counts as 'good' or 'proper' philosophy. It also reveals the (usually unstated or indeed unnoted) institutional and professional contexts of 'doing' philosophy. To a sociologist perhaps, her argument may sound like a call for a discipline that can engage in (that is, interrogate) those 'realities and diversities' and debates, in order to have public policy relevance. Simply put, it seems that O'Neill is suggesting that there is need for an approach that is interested in and committed to, a concern with 'context', whilst also trying to remain philosophically robust.

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<sup>340</sup> O'Neill, 2002, p. x.

<sup>341</sup> O'Neill, 2002, p. x.

However, I return to my original question: what is meant by context? The term, it must be said, is used very widely and loosely, including in the current investigation.

Decontextualization is easy to diagnosis but much harder to solve.<sup>342</sup> If sociologists and/or ethicists are to advocate its importance, then I suggest it is necessary to be conceptually sharper about its meanings and contributions. One very useful analytical line comes from Bent Flyvbjerg's work on the notion of phronesis, which explicitly brings these concerns together and offers a practical way forward about how one might practically do research that attempts to consider all these dimensions.<sup>343</sup>

### *The potential of phronesis*

Flyvbjerg's work is both conventional and innovative. It is conventional because he addresses the differences and difficulties between the natural and social sciences. In so doing he convincingly questions the possibility of the social sciences ever truly emulating themselves on the natural sciences in creating a general theory that is universal and predictive. Flyvbjerg's work is innovative because he uses a well known philosophical concept – the Aristotelian notion of phronesis – to identify the strengths of the social sciences. He considers these strengths to their ability to access, describe and grapple with the social context. And although it is not his primary goal, Flyvbjerg also provides another way of characterising the relationship between ethics and the social sciences.

Phronesis lies in Aristotle's three inter-related terms of episteme (scientific knowledge, universal and context independent), techne (translated as art or often as technology, oriented towards production), and phronesis.<sup>344</sup> According to Flyvbjerg, phronesis is:

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<sup>342</sup> D. Light, and G. McGee, 1998. On the social embeddedness of bioethics. In R. DeVries, and J. Subedi, eds., *Bioethics and Society: Constructing the Ethical Enterprise*. NJ: Simon & Schuster, pp. 1-15.

<sup>343</sup> Flyvbjerg, 2001.

<sup>344</sup> For an insightful discussion on these points, see M. Bertilsson, 2000. From Aristotle to modern social theory. In H. Andersen and L. Kaspersen, eds., *Classical and Modern Social Theory* Oxford: Blackwell Publishers, pp. 488-506. Bertilsson writes, 'The task of finding a moderate balance between Antiquity's three ideals for creating understanding, that is, episteme, phronesis, and poietic-techne, is and will remain, a greater challenge for modern (social) science than it probably ever was for ancient philosophers.'

'Ethics. Deliberation about values with reference to praxis. Pragmatic, variable, context-dependent. Oriented towards action. Based on practical value-rationality. The original concept [unlike episteme and techne] has no analogous contemporary term.'<sup>345</sup>

Usually phronesis is translated a 'practical wisdom' or 'practical reasoning'. In Aristotle's philosophy, it is characterised as one of the intellectual virtues (that is, not one of the moral virtues such as courage or temperance.)<sup>346</sup> 'It [phronesis] is a true and reasoned state of capacity to act with regard to things that are good or bad for man.'<sup>347</sup>

Phronesis, as I understand it, is the ability to judge in a particular situation, to 'deliberate well' and to make a wise choice.<sup>348</sup> One cannot rely merely on a set of ethical theories and norms but must have a cultivated knowledge of what the good life consists of - which can only be gained through experience in life, or praxis.<sup>349</sup> Phronesis involves individual cases and is based on an intuitive grasp of the particulars of each case and the discernment of the relevant actions that manifest good conduct. One who has attained practical wisdom is a phronimos, a mentor of sorts from whom others can learn. The phronimos has a cultivated insight into how to apply general moral knowledge to a particular situation. In other words, without virtue there can be no phronesis.<sup>350</sup> One must have the moral virtues as character states before they can be said to exercise phronesis.

According to one commentator, 'what Aristotle has to say about practical wisdom has occasioned more discussion and more controversy than almost any other part of the [*Nichomachean*] *Ethics*.'<sup>351</sup> At issue, it seems, is whether phronesis, as Aristotle employed the term, relates to only the means used to achieve certain ends or whether it incorporates both means and the ability to 'deliberate well about what is good and

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<sup>345</sup> Flyvbjerg, 2001, p.57.

<sup>346</sup> C. Long, 2002. The ontological reappropriation of phronesis. *Continental Philosophy Review* 35: 35-60.

<sup>347</sup> Aristotle, *Ethics* 1140b 5-6.

<sup>348</sup> Aristotle, *Ethics*, 1141b 10.

<sup>349</sup> As this sentence indicates, phronesis (or ethical particularism, as well) does not – cannot in my view – dispense with theory. Just as Kant did not deny the need for practical judgement, Aristotle is not dismissive of theory or system. See: M. O. Little, 2001. On Knowing the "Why" Particularism and Moral Theory. *Hastings Center Report* 31: 32-40.

<sup>350</sup> To my knowledge, this point is not mentioned by Flyvbjerg – nor his reviewers.

<sup>351</sup> G. Hughes, 2001. *Aristotle: on Ethics*. London: Routledge, p. 84.

expedient' – that is, the ends, too.<sup>352</sup> Some contemporary interpreters, such as MacIntyre, seem to adopt the latter definition, arguing that phronesis is the means by which we apply already given moral truths to our own particular present situation.<sup>353</sup> These truths, in line with MacIntyre's overall philosophy, are inherited from a particular tradition, albeit a tradition that can be transformed over the course of history. For Martha Nussbaum, however, the essence of phronesis is not a means by which to apply historically conditioned ends, but rather an end to itself.<sup>354</sup> According to Nussbaum, practical wisdom is the care and attention one cultivates for the concrete particularities of persons and situations around them. The theme of Nussbaum's philosophy is that the moral agent develops a sense of moral perception - indeed, phronesis – through the literary narrative of plays, tragic poems, and novels.<sup>355</sup>

Beyond the interpretative challenge of the term phronesis, there is also lack of agreement whether or not medicine constitutes a phronetic activity. Jonsen and Toulmin, proponents of casuistry (discussed in Chapter Four), have argued that that the 'central question' of medicine is 'just what specific condition is affecting this particular patient, and just what should we do about it *here and now*?'<sup>356</sup> According to the authors, the answer relies on applying the skills of phronesis. 'Clinical knowledge requires what Aristotle calls "prudence", or phronesis: practical wisdom in dealing with particular individuals, specific problems, and the details of practical cases or actual situations'.<sup>357</sup> Duff Waring, however, disputes Jonsen and Toulmin's account. Waring believes that the authors have conflated the notions of *techne* and phronesis and also failed to see that it is only a

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<sup>352</sup> Aristotle, *Nicomachean Ethics* Book VI, Chapter 5 1140a 26-27. In R. McKeon, ed., 1941. *The Basic Works of Aristotle*. New York: Random House. For the contrast, see also Book IV Chapter 12 1144a 8, where Aristotle is translated as writing, 'practical wisdom makes us take the right means.'

<sup>353</sup> A. MacIntyre, 1988. *Whose Justice? Which Rationality?* Notre Dame: University of Notre Dame Press, pp. 115-116.

<sup>354</sup> M. Nussbaum, 1990. *Love's Knowledge: Essays on Philosophy and Literature*. New York: Oxford University Press.

<sup>355</sup> My brief discussion is not even the tip of the iceberg on this topic. Heidegger, Gadamer, Ricoeur, Dunne and countless others have written extensively on phronesis; there is also an entire academic journal in Classics called *Phronesis*. I cannot profess to know the intricacies of all this literature. My selective account here is simply illustrative and designed to show that I recognise that phronesis is open to much critical interpretation. However, I believe this fact does nothing to undermine my general argument about the importance of context in bioethics or the utility of practical wisdom in unpacking the notion of context. My own use of the term is no doubt open to scrutiny.

<sup>356</sup> Jonsen and Toulmin, 1989, p. 37. Italics are in the original.

<sup>357</sup> Jonsen and Toulmin, 1989, p. 37.

phronimos who can exercise practical wisdom as described by Aristotle.<sup>358</sup> Waring is right, I believe, that it is a mistake to see medicine as a phronetic activity rather than an example of *techne*. Aristotle himself is clear on this point: ‘the art of medicine produces health’ and, ‘the end of medical art is health.’<sup>359</sup> The goal of medicine, in other words, is not contained within the activity itself.<sup>360</sup>

As I alluded in Chapter Four, the concept of *phronesis* has also been discussed within medical ethics, largely in critique of principlism.<sup>361</sup> Whilst commentators differ in interpretation and emphasis, most agree that the application of abstract principles in a field of practical, ethical knowledge is not sufficient. Biomedical ethics must, by definition, rely on practical experience and thus, be phronetic in nature. Of course in reality, as we have seen in my discussion of biobanking, numerous ethicists and policy-makers do not hesitate to make generalised claims that do not fit practical experience.

Rather than – or perhaps in addition to – advocating practical reason in making actual ethical deliberations, I wish to use *phronesis* as a tool in the construction of a bioethical method. Such a method, as I see it, is an amalgamation of philosophy and sociology. It gives primacy to context, as does *phronesis*, and is designed to contribute to ‘the reflexive analysis and discussion of values and interests which is the pre-requisite for an enlightened political, economic and cultural development in any society.’<sup>362</sup> The aim is a bioethic that is akin to Flyvbjerg’s notion of a public philosophy or a successful social science - a ‘practical, intellectual activity aimed at clarifying the problems, risks and

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<sup>358</sup> D. Waring, 2000. Why the Practice of Medicine is not a Phronetic Activity. *Theoretical Medicine and Bioethics* 21: 139-151.

<sup>359</sup> Aristotle, *Ethics* 1144a 5; 1094a 10

<sup>360</sup> For a useful discussion of this point, see F. Svenaeus, 2003. Hermeneutics of medicine in the wake of Gadamer: the issue of *phronesis*, *Theoretical Medicine*, 24: 407-431; and, R. Polansky, 2000. Is Medicine Art, Science, or Practical Wisdom? Ancient and Contemporary Reflections. In Kuczewski and Polansky, pp. 31-56. Polansky argues that medicine is an art.

<sup>361</sup> Beyond Svenaeus and Jonsen and Toulmin, see E. Pellegrino and D. Thomasma, 1994. *The Virtues in Medical Practice*. New York: Oxford University Press; D. Thomasma, 2000. Aristotle, *Phronesis*, and Postmodern Bioethics. In M. Kuczewski and R. Polansky eds., *Bioethics: Ancient Themes in Contemporary Issues*, Cambridge: MIT Press, pp. 67-92.

<sup>362</sup> Flyvbjerg, 2001, p. 3.

possibilities we face as humans and societies, and at contributing to social and political praxis.<sup>363</sup>

The importance of phronesis for an informed and context sensitive biomedical ethics can be better explained through a discussion of three methodological elements. These elements are not meant to be taken as an exhaustive account of a bioethical method. Rather I see them as guidelines, heuristic in nature and meant simply to be, in Flyvbjerg's words, 'cautionary indicators of direction'.<sup>364</sup> The elements are, in brief: situation ethics, genealogy, and power. The final two, the reader will notice, are borrowed from Michel Foucault's toolbox. The remainder of this chapter will explore these concepts in some detail.<sup>365</sup> In the following chapter I will extend these elements specifically to bioethics and genetic epidemiology.

### *Situation ethics*

A theme not far below the surface of this thesis is a problem as old as philosophy itself: foundationalism.<sup>366</sup> Much ink has been split on this topic, the so-called 'failure of the Enlightenment project' – that is, the failure to find an universal and rational justification of morality.<sup>367</sup> Sociobiologists (now called evolutionary psychologists, since the term, if not ideas, of sociobiology have fallen out of favour) attempt to solve this problem, and indeed all problems, through the lens of biology. E. O. Wilson, for instance, writes that ethics are driven by 'hereditary predispositions in mental development' and can essentially be explained by 'brain circuitry and deep, genetic history'.<sup>368</sup> One of the many problems with this account is that when viewed from the right (albeit remote) distance, just about anything can be explained by evolution. Another flaw, of course, is that my

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<sup>363</sup> Flyvbjerg, 2001, p. 4.

<sup>364</sup> Flyvbjerg, 2001, p. 129.

<sup>365</sup> Obviously each element could be the subject of an entire thesis, thus I remind the reader of my self-deprecatory caveat in the Introduction. I am an intellectual gypsy and this comes, I know, at a certain price.

<sup>366</sup> Although it is not a problem for Richard Rorty. To read how a pragmatic ethic deals with the question of foundations, see R. Rorty, 1999. *Philosophy and Social Hope*. London: Penguin, pp. xxvii-xxxii; 72-90.

<sup>367</sup> MacIntyre, 1981. MacIntyre's response to this issue is to look for ethical values in relation to specific communities. However, whilst such values may apply universally within a community, they may well not apply outside of it.

<sup>368</sup> E. O. Wilson, 1998. *Consilience: The unity of knowledge*. New York: Alfred Knopf, pp. 240; 261.

(supposed) inner drive to make babies offers little help in distinguishing between right and wrong behaviour in actual cases.

A more sophisticated response to the problem of foundations in ethics is a radical version of anti-foundationalism, that is an irreducible pluralism. This line of thinking can be found in the the work of thinkers such as Alice Maclean and Tristram Englehardt.

Maclean, for example, attacks utilitarian bioethicists such as John Harris and Peter Singer. In a polemic writing style worth repeating here, she writes that

‘The objection I wish to make to the bioethical enterprise is a fundamental one. It is that philosophy as such delivers no verdict upon moral issues; there is no unique set of moral principles which philosophy as such underwrites and no question, therefore, of using that set to uncover the answers which philosophy gives to moral questions. When bioethicists deliver a final verdict upon the issues raised by medical practice, it is their own verdict they deliver and not the verdict of philosophy itself; it is their voice we hear and not the voice of reason or rationality.’<sup>369</sup>

For Maclean, then, there is no truth in ethics, only attitudes. Engelhardt is as equally as radical, but from a post-Christian point of view. According to his analysis, the loss of religious tradition has removed any hope of providing secure basis for ethical action. As a result, Western society is faced with a ‘hunger for moral guidance’ led by ‘secular priests’ who are all too ready to accept that no particular ‘moral narrative can be generally normative’.<sup>370</sup>

Flyvbjerg rejects both relativism and foundationalism as the theoretical frameworks. Rather he replaces them with contextualism or situational ethics: ‘that is by context; norms are contextually grounded’.<sup>371</sup> However, in rejecting the more confining paradigms of relativism and foundationalism, it is not the case that ‘anything goes’ since ‘the present

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<sup>369</sup> A. Maclean, 1993. *The Elimination of Morality: Reflections on Utilitarianism and Bioethics*. New York: Routledge, p. 5.

<sup>370</sup> T. Englehardt, 2003. *The Foundations of Bioethics: Rethinking the meaning of morality*. In Walter and Klein, eds., p. 101.

<sup>371</sup> Flyvbjerg, 2001, p. 99.

effectively limits the possible preferences; humans cannot think or do just anything at any time'.<sup>372</sup>

Flyvbjerg writes that,

'They take their point of departure in their attitude to the situation in the society being studied. They seek to ensure that such an attitude is not based on idiosyncratic morality or personal preferences but instead on a common view among a specific reference group to which the researchers refer. For phronetic researchers, the socially and historically conditioned context – and not the rational and universal grounding which is desired by certain philosophers, but which is not yet achieved – constitutes the most effective bulwark against relativism and nihilism. Phronetic researchers realise that our sociality and history is the only foundation we have, the only solid ground under our feet. And that this socio-historical foundation is fully adequate for our work as social scientists.'<sup>373</sup>

Society and history are themselves fully adequate as foundations. As Paul Veyne has written, 'try asking the Romans to abolish slavery or to think about an international equilibrium.'<sup>374</sup> In short, norms are based on historical and personal context and cannot be given an universal grounding independent of those contexts. In this way, one can see how the idea of situation ethics helps us to understand the importance of context.

### *Genealogy*

Nietzsche once wrote that 'we wished to awaken the feeling of man's sovereignty by showing his divine birth: this path is now forbidden, since a monkey stands at the entrance'.<sup>375</sup> The meaning, I believe, is that history (properly told) can make for uncomfortable reading – it can, in other words, be *untimely*. In using the genealogical

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<sup>372</sup> Flyvbjerg, 2001, p. 100.

<sup>373</sup> Flyvbjerg, 2001, p. 130. 'Certain philosophers' is a reference to Habermas and his theory of discourse ethics.

<sup>374</sup> P. Veyne, 1997. *The Foucault and His Final Ethics*. In A. Davidson, ed., *Foucault and His Interlocutors*. Chicago: University of Chicago Press, p. 230.

<sup>375</sup> F. Nietzsche, 1881. *The Dawn of Day*, no. 23.

method popularised by Foucault, Flyvbjerg wishes to establish a practical approach that parallels the insights of phronesis.

'Like Aristotle when he speaks of phronesis, the genealogist emphasises a focus on the particular because the genealogical experience says that what is general is often empty and banal, whereas it is often in the deep, concrete detail that genuinely important interrelationships are expressed...the genealogist seeks the large from within the small.'<sup>376</sup>

In this section I wish to explore a certain aspect of Foucault's philosophy (or was it history?).<sup>377</sup> Like numerous others who have used Foucault's ideas (including the hero of this chapter, Flyvbjerg), I begin with a caveat. My use of genealogy is pragmatic, an attempt to better understand the history and failings of biomedical ethics, and how both genealogy (and in the following section, power) may be useful to my investigation. Such a strategy is very much in the spirit of how Foucault wanted his work to be used – as tools and not as an agenda. I begin with a discussion of his methods, archaeology and genealogy.<sup>378</sup>

First, and contrary to what some commentators have written, it is important to note that archaeology is not technique for questioning the possibility of norms. Instead, it seeks to reveal *how* a discipline has developed norms of validity and objectivity.<sup>379</sup> In Foucault's own cryptic terms archaeology 'describes discourse as practices specified in the element

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<sup>376</sup> Flyvbjerg, 2001, p. 114..

<sup>377</sup> Ironically, it is sociologists who make the most use of Foucault today, thanks to the burgeoning field of 'governmentality' studies.

<sup>378</sup> I am not unaware of the many criticisms and drawbacks of Foucault's work. At times Foucault does appear to want to stand nowhere, as Taylor rightly points out (especially in Foucault's early works). I also agree with Taylor that 'we have a history' from which we cannot escape. Yet I am not sure that Foucault would dispute this notion either, despite Taylor's characterisation of him. Habermas's arguments against Foucault are of a similar nature but I am less convinced of their force. Perhaps it depends upon how one defines 'relativism' or 'normative foundations'. One could easily argue, I think, that Habermas's discourse ethics lack a rational and universal grounding – the same charge he makes against Foucault. Either way, my use of Foucault is limited and pragmatic. Thus, I need not endorse his entire project in order to draw from his thought. The relevant sources here are: C. Taylor, 1984. Foucault on Freedom and Truth. *Political Theory* 12: 152-183; and, J. Habermas, 1990. *The Philosophical Discourse of Modernity*. Cambridge: MIT Press, pp. 238-293.

<sup>379</sup>In bioethics, for example, the immediate concern would not be if autonomy is an appropriate or true criteria as a determining norm, but how it became so historically, how it acquired the status of 'truth'.

of the archive', the archive being 'the general system of the formation and transformation of statements.'<sup>380</sup> In slightly plainer English, archaeology is a way to unearth the order and principles of discourse. Specifically, Foucault 'sought to make the history of the human sciences intelligible in terms of rules, which, unknown to the actors involved, regulated and governed all their serious speech acts.'<sup>381</sup> Archaeology seeks to describe the conditions in which certain statements (or certain norms, such as the criterion used to determine if someone was mad, or the standards used in classifying disease) could appear as true. It sought to uncover the rules of formation which govern particular configurations of knowledge and to highlight the epistemological breaks which mark one movement from another. These rules, according to Foucault, are not formulated by the participants of discourse and are not available to their consciousness. Rather they constitute what Foucault calls the 'positive unconsciousness of knowledge': a level which eluded the consciousness of the scientist and yet is part of scientific discourse.<sup>382</sup>

Foucault believed that statements can come into being and relate to one another only under certain conditions, termed 'historical a priori'.<sup>383</sup> This is not a priori in the formal philosophical sense of knowledge attained prior to experience, a type of transcendentalism or 'atemporal structure.' Rather, a priori refers to the necessary conditions for the emergence of certain statements, conditions which themselves have a history. In other words, these a priori rules are themselves mutable and able to be transformed. For example, before it became possible to state that someone was 'mad', as we understand the term today, a whole series of conditions relating to psychological theory had to be in place.

Genealogy also seeks to reveal how a discipline has developed norms of validity and objectivity while bracketing the question of the 'truth' of those norms. The key difference

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<sup>380</sup>M. Foucault, 1972. *The Archaeology of Knowledge*, trans. Alan Sheridan, London: Tavistock Publications, p. 130-131.

<sup>381</sup>H. Dreyfus and P. Rabinow eds. 1983. *Michel Foucault: Beyond Structuralism and Hermeneutics*, Chicago, IL: The Harvester Press, p.102.

<sup>382</sup>M. Foucault, 1966. *The Order of Things: An archaeology of the human sciences*, New York: Vintage, p.

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<sup>383</sup>Foucault, 1972, p. 127.

between it and archaeology, however, is that in his genealogical investigations, Foucault moves beyond the level of discourse and discursive rules to considerations of non-discursive influences. Here, non-discursive refers to social processes and issues of power manifested in institutions such as the family, hospital or prison.<sup>384</sup>

Genealogy, as a method, opposes itself to both metaphysics and traditional history. Foucault understands metaphysics as based on a commitment to the pursuit of the 'origin', meaning in a belief that things have an atemporal essence or a unitary perfection.<sup>385</sup> According to Foucault, genealogy is opposed to both a transcendental subject and the correspondence theory of truth -- ideas which Foucault sees as popular in traditional history. Denial of a transcendental subject refers to a refusal to believe in a human subject who makes history and assures its continuity. In this way, Foucault has much in common with the Annales school which focused on periods of such length (*la longue duree*) that it was impossible to attribute change to a human subject. Instead, the Annales school placed emphasis on material conditions of climate and geology as the engines of historical continuity. For Foucault, it is the role of discourse in his early work and power/knowledge in his latter books that displace the notion of a transcendental subject which shapes history.<sup>386</sup> The correspondence theory asserts that a belief or statement is true if it corresponds to a fact. However, opponents of this theory charge that humans have no access to facts (or to history) independently of belief and statements. Foucault saw both metaphysics and traditional history as committed to the notion that truth is the accurate correspondence of words and things. Genealogy, by contrast, is a method that doubts the possibility that words said universally and fully represent external things.

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<sup>384</sup>David Owen, in a re-vamped PhD thesis done at the University of Durham, has written that a useful way of viewing the shift in archaeology to genealogy is to note Foucault's change in terminology from an *episteme* to a *dispositif*. The former relates to the level of discourse only, while the latter (known in English as an *apparatus*) refers to both discursive and non-discursive practices. See D. Owen, 1994. *Maturity and Modernity: Nietzsche, Weber, Foucault and the Ambivalence of Reason*. London: Routledge.

<sup>385</sup>M. Foucault, 1998. Nietzsche, Genealogy, History. In J. Faubion ed., *Aesthetics, Method, and Epistemology: Essential Works of Foucault, 1954-1984, Vol. 2*, New York: The New Press, pp. 369-391.

<sup>386</sup>Of course there are real differences between the Annales school and Foucault. For one, Annales concerns itself with continuity in history while Foucault prefers to stress discontinuous breaks in knowledge. See G. Gutting, 1989. *Michel Foucault's Archaeology of Scientific Reason*. Cambridge, Cambridge University Press, pp. 228-229.

According to Foucault, genealogy also differs from traditional history of ideas in its account of historical change.<sup>387</sup> In accounting for causal factors of change, he had little regard for notions such as ‘influence or spirit of the times,’ or *Weltanschauungen*. Like most historians Foucault, saw the cause of change in non-discursive factors such as economic or social process. But, contrary to many standard accounts, Foucault maintained that these causes could not be fit into some teleological scheme (e.g. the rise of the proletariat, the ambition of Hitler, etc.). Rather, he held that non-discursive practices change because of a vast number of small, often unrelated factors (chance technological discoveries, ad hoc adjustments of some existing procedures). Gary Gutting notes that these are the sort of ‘petty causes’ that Nietzsche identified in his genealogy of morality. Thus, changes in non-discursive practices that make up a societies ‘power structure’ must be understood as due to an immensely complex and diffuse variety of micro-factors. In other words, this approach does for non-discursive practices what archaeology did for discursive ones: it eliminates the role of a central controlling subject, emphasizing instead chance and accident.

The difference between genealogy and traditional history can be seen in Foucault’s habit of calling his brand of inquiry a ‘history of the present’.<sup>388</sup> This did not mean that he was trying to capture the meaning or significance of a past epoch or get the ‘whole picture’ of a particular institution or person in an earlier era.<sup>389</sup> Nor did he commit the common error discussed previously – that of ‘presentism’, reading the present in terms of the past. Rather, Foucault begins with a diagnosis of a current situation or problem, then locates the manifestations of a certain type of power to see where it arose took shape and gained importance. For example, Foucault took a present situation regarding sexuality and isolated the power of confession as a important force in constituting the ‘truth’ of one’s sexual nature and desire. Of course, he did not claim that Catholic confession had the same meaning in previous centuries that it has today. But he asserted that confession was

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<sup>387</sup> Foucault, 1998, p. 271.

<sup>388</sup> M. Foucault, 1995. *Discipline and Punish: The Birth of the Prison*, trans. Alan Sheridan, New York: Vintage Press, p. 31.

<sup>389</sup> Dreyfus and Rabinow, 1983, pp. 118-119.

still a vital part of modern power and he asked how it functioned in present sites such as psychoanalysis. In other words, he isolated a central component of a current 'political technology' and traced it back in time. In this way, histories of the present seek to disturb the taken-for-grantedness of the current situation to 'show that things weren't as necessary as all that'.<sup>390</sup>

In the next chapter I shall use the ideas presented above to disturb many of bioethics' assumptions and claims about the necessity of its own origins. In the next section, however, I discuss the final element in the phronesis-genealogy-power toolkit.

### *Power relations*

The final methodological element I wish to emphasize in this chapter is power. As Flyvbjerg notes, discussions of phronesis are usually devoid of the issue of power. Arguably, however, a framework of power would assist in the application of phronesis since the practical wisdom is concerned with action and 'understanding how power works is the first prerequisite for action, because action is the exercise of power' – according to Foucault's analytics, as we shall see below.<sup>391</sup>

Of course there are many different ways to theorise power and at least one reviewer has criticized Flyvbjerg for being too restrictive in his reliance on only Foucault's conceptions.<sup>392</sup> To be fair, Flyvbjerg does discuss the work of others, such as Robert Dahl and Stephen Lukes, and claims they are important studies not to be dismissed. Yet his criticisms of these power theorists is that they focus exclusively on *who* holds power and the outcomes or effects of power. They theorise power in terms of 'possession, sovereignty, and control – power as an entity.'<sup>393</sup> One problem with these versions of power is that they overlook the fact that 'seizing power' may in itself not bring any real change. This (as Marxists have learned) is because old patterns of government and

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<sup>390</sup> M. Foucault, 2000. Questions of Method. In J. Faubion ed. *Power: Essential Works of Foucault, 1954-1984, Vol. 3*, New York: The New Press, p. 226

<sup>391</sup> Flyvbjerg, 2001, p. 107. See also: N. Rose, 1999. *Powers of Freedom: Reframing Political Thought*. Cambridge: Cambridge University Press.

<sup>392</sup> P. deLeon, 2003. Book Review of Bent Flyvbjerg's *Making Social Science Matter*. *Policy Sciences* 36: 203-208. However, deLeon writes that Flyvbjerg's emphasis on power in general is 'completely justified.'

<sup>393</sup> Flyvbjerg, 2001, p. 116.

authority may simply be reproduced: 'the class that succeeds in overthrowing the ruling class becomes the new ruling class.'<sup>394</sup> In contrast, Foucault thought power was 'everywhere'. It was not an institution, nor a structure, but rather the name that one attributed to a complex strategic situation in a particular society.

Foucault was not concerned so much with developing a theory of power but rather in separating its 'constituent elements' and in determining its features and the domains formed by its relations -- an 'analytics of power'.<sup>395</sup> In defining power Foucault was purposefully elusive, emphasizing what it was *not* as much as what it was. His reason for doing so (other than to confuse his readers) was to capture its fluid, productive nature. To show the contrast, Foucault distinguished Power from power. The former was a commodity, a state Power which oppressed people with institutional arms of sovereign might. The latter was a 'multidirectional' and 'mobile' matrix of force relations that ran throughout all persons and society.<sup>396</sup> Power with a small 'p' was rooted in social networks and exercised from manifold points. It enabled actions to 'structure the field of other possible actions.'<sup>397</sup> Thus, power was exercised rather than possessed and endowed itself with a flexibility which allowed it to adjust to each new situation.

The above description, I realise, must sound rather cryptic. To better understand this, it helps to consider power as the capacity to do or become certain things.<sup>398</sup> Power in this sense is exercised by individuals or collective human bodies when they act upon each others actions; in other words, when the actions of one effect the field of possible actions of another. For instance, where the actions A have succeeded in modifying the field of possible actions of B, we can say that A has exercised power over B. Of course there are many ways in which agents can exercise power over other agents, only some of which can be detrimental to the interests of the one over whom power is exercised: I can affect

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<sup>394</sup> Flybvjerg, 2001, p. 122.

<sup>395</sup> M. Foucault, 1990. *The History of Sexuality: An Introduction*. Trans. Robert Hurley, Vol. 1, New York: Vintage Press, p. 82.

<sup>396</sup> Ibid, p. 94.

<sup>397</sup> Foucault, 1983. The Subject and Power. In Dreyfus and Rabinow, p. 222.

<sup>398</sup> The following explanation is from P. Patton, 1998. Foucault's Subject of Power. In J. Moss ed. *The Later Foucault: Politics and Philosophy*, London: SAGE, pp. 64-77.

the actions of another by providing moral support, or by passing on certain knowledge or skills. All of these exercises are cases of power but are not necessarily objectionable. Moreover, it is only in exceptional circumstances where A can be assured of achieving the desired effect on B. In these cases, when the possibility of effective resistance has been removed, then the power relation becomes unilateral and one sided -- in other words, it becomes domination. As Foucault indicated:

‘What defines a relationship of power is that it is a mode of action which does not act directly and immediately on others. Instead it acts upon their actions’<sup>399</sup>

and,

‘Power is not a substance. Power is only a certain type of relation between individuals. The characteristic feature of power is that some men can more or less entirely determine other men’s conduct – but never exhaustively or coercively.’<sup>400</sup>

Power relations, then, are not external to other types of relations (such as economic processes or knowledge) but are immanent to them. Traditionally, power has been conceived as an obstacle to autonomy. Seen in the vein of Foucault, however, power is constitutive of autonomy. Our will, in other words, is constituted through relations of power and ethics.<sup>401</sup>

Foucault thought that power played a determinant role in the creation of knowledge. Knowledge, rather than being universal, can be seen as an instrument used in the creation of true discourse. Simply put, it is manufactured by relations of power.

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<sup>399</sup>M. Foucault, 1983, p. 220.

<sup>400</sup>M. Foucault, 2000. *OMNES ET SINGULATIM: Toward a Critique of Political Reason*. In Faubion, p. 324.

<sup>401</sup>Owen, 1994. It is worth noting that one type of power that Foucault studied was ‘biopower’, which refers to the increased organization and knowledge of both individual bodies and the collective population for the sake of productivity and wealth – topics touched on the beginning of Chapter Five.

'Perhaps we should abandon a whole tradition that allows us to imagine that knowledge can develop only outside its [power] injunctions, its demands, and its interests. Perhaps we should abandon the belief that the renunciation of power is one of the conditions of knowledge. We should admit that power produces knowledge; that power and knowledge imply one another; that there is no power relation without the correlative constitution of a field of knowledge, nor any knowledge that does not presuppose and constitute at the same time power relations ... It is not the activity of the subject of knowledge that produces a corpus of knowledge, useful or resistant to power, but power-knowledge, the processes and struggles that traverse it and of which it is made up, that determines the forms and possible domains of knowledge.'<sup>402</sup>

Power/Knowledge, then, is a term Foucault used to highlight the fact that every description also regulates what it describes. This means not only that every description is somewhat 'biased', but also that the very terms used to describe something reflect power relations. Discourses promote specific kinds of power relations, usually favouring the 'neutral' person or professional using the discourse (the lawyer, psychiatrist, professor, doctor, ethicist, etc.). In other words, to know is to participate in complicated webs of power. According to Foucault, knowledge can only be understood in connection with the historical conditions of its emergence and the actual forces that establish, maintain and amplify its authority. Power is not merely or exclusively a negative force. It is productive through the generation of knowledge.

Again, whilst I have spent some time on Foucault's ideas, I do not wish to assert that they are the only ones applicable to bioethics. They are, in my view, especially useful but before closing this discussion, I also wish to draw attention to one other form of power recently developed by the political scientist Joseph Nye.<sup>403</sup> Nye distinguishes between 'hard' power and 'soft' power. Examples of the former include military might, whilst the latter relates to the power of things such as knowledge and culture. Hard power has less

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<sup>402</sup> M. Foucault, 1990, pp. 27-28.

<sup>403</sup> J. Nye, 2002. *The Paradox of American Power*. New York: Oxford University Press.

to do with biomedical ethics than soft, which I believe is relevant to the current study. For now I merely wish to draw attention to Nye's ideas. I shall return to them in Chapter Eight in my discussion of bioethics association with the soft power of the financial networks of pharmaceutical companies.

This chapter has by no means answered all the questions it has raised. Clearly, despite raising the question, the answer to 'what is context?' is still somewhat vague. The imperative to 'consider the context' does not in itself define for us what is meant by that term: for example, how immediate is context? How wide is context? *Whose* context?

### *Summary and conclusion*

In this chapter I have extended my earlier discussion of the relationship between history, sociology and bioethics by defending a set of methodological tools to guide a context sensitive bioethics. I argued from the outset that such tools were needed in light of evidence from Chapter Six which showed that in DNA banking, there were often conflicts between competing normative and empirical claims and a lack of appreciation of context. Specifically, this chapter has argued that:

- Phronesis may be a valuable concept to both clarify the meaning and use of the term context. Translated as practical wisdom, phronesis stresses that deliberations are inevitably made in relation to particular cases. I highlighted three elements that would serve as 'cautionary indicators of direction' for a phronetic bioethic.
- Situation ethics rejects both relativism and foundationalism by arguing that norms are contextually grounded and that society, culture and history together constitute a fully adequate basis for ethical norms of reasoning. Bound by tradition and context, it is not the case that 'anything goes' in situation ethics. Genealogy serves as the way in which bioethics may uncover how its norms are contingent upon chance, not the result of inevitable historical processes. Power emphasises that knowledge and truth are not independent of context but are themselves the

result of certain forms of authority. In this way, power is a productive force in that its exercise enables certain discourses to establish themselves as 'true'.

In Chapter Eight I seek to apply these insights directly to biomedical ethics.

## Chapter Eight

### Towards a phronetic bioethic

*Surely, then, no doctor, insofar as he is a doctor, seeks or orders what is advantageous to himself, but what is advantageous to his patient? We agreed that a doctor, in the precise sense, is a ruler of bodies, not a money-maker? Wasn't that agreed?*<sup>404</sup>

-- Socrates

In the previous chapter I presented a rough methodological sketch that a bioethics sensitive to issues of context would adhere to. Perhaps, at the very least phronesis could act as a framework for the initial guidance of a piece of research or as a way of bringing together a set of ideas about context, values and social actions that, whilst important, lack cohesion. Of course it is possible to go back through any piece of analysis and review what is added by the application of a phronetic framework and in that way one can use Flyvbjerg as providing a set of tools with which to sharpen the initial analysis. In essence that is what my co-author and I have done: having conducted an extensive analysis of our data we found ourselves wanting to bring together a set of considerations about ethics, values, contexts, social action and power into a fairly coherent framework. This is not to say that Flyvbjerg's model answered all our questions but it provided a way of identifying those which can hold together and those which required more detailed and possibly separate consideration. For example, one reviewer has claimed that Flyvbjerg's analysis effectively politicizes social inquiry and implies that Flyvbjerg has not fully considered the consequences of this.<sup>405</sup> The same argument can be made against my alternate rendition of bioethics as phronesis. Yet, as most observers would hopefully admit, bioethics is already a heavily politicised field. However, this fact is often not admitted to or even recognised by those working in the area. Political, indeed ideological, content is often sneaked in through supposedly objective judgements. There is nothing wrong with this per se; I'd argue that it is inevitable. However, a phronetic bioethic would simply make the political nature of the field blatant and ask bioethicists to be more

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<sup>404</sup> Plato, *The Republic* Book I 342d. In Cooper, 1997.

<sup>405</sup>For a critical but also positive evaluation of Flyvbjerg, see: T. Schatzki, 2002. Making social science matter. *Inquiry* 45: 119-138.

'reflexive' (to use a popular sociological term) about their own interests and the perspective from which they work.

In the current chapter I aim to 'apply' to biomedical ethics the loose set of guidelines previously presented. I do this in order to sketch the contour of an alternate bioethical agenda. I indulge in this task not because I have any illusory notions about the influence of what I write or even publish. Rather, for me, this is an exercise in learning how to think differently, an heuristic tool to try and better understand the limitations of the field I've worked in for the last five years. It is also a way to clarify a set of concerns for future work. And, of course, it is a way of bringing the current investigation to a close. My tone and style in this chapter is (upon reflection, not intention) slightly less formal and more personal – but I hope still reasonably academic.

I begin by re-visiting my discussion of donation and consent in light of my reading of Flybvjerg, then move on to consider bioethics' lack of an adequate theory of power. My discussion in this section eventually leads me away from epidemiological ethics to a larger set of concerns about international health inequalities and bioethics' involvement with the pharmaceutical industry. Finally, I conclude by developing a firmer critique of the history of biomedical ethics (including my own work on the London Medical Group) with the aid of a genealogical method.

#### *Practical reasoning, donation, and consent*

In Chapter Six I reported on donors and non-donors views of the NCCGP. In retrospect, the concept of practical reasoning has proven to be a useful way to talk about interviewees' intuitions about donation. This is important since it is easy as a researcher to become frustrated at the apparent lack of reasoning behind some interviewees' actions and thoughts. For example, when asked why they had donated to the NCCGP many women gave responses such as 'it just seemed right to donate'; 'I just trusted what the doctors said'; 'I couldn't see any reason not to donate'; or, the inverse, 'it didn't seem right to donate my baby's tissue'. When encouraged to expand upon these answers about why it 'just seemed right' to act and think in the way they did, many respondents did not

seem able to provide any clear reasons. As an interviewer, I found this as fascinating as I did frustrating. On the one hand, I wanted to acquire the most interesting data possible and such responses seemed, at first, to be rather unsatisfactory explanations of peoples' motivations. Using every technique I could think of, I tried my best to get the interviewees talking in order to elicit more expansive answers.<sup>406</sup> When this often failed, I began to realise that far from being the result of a lack of reasoning or care about the matter in hand, this sort of response was in fact evidence of the embedded nature of that reasoning - such that not only was it difficult to extract, it was also difficult to articulate in the first place.

Flyvbjerg reports Hubert Dreyfus saying to him, 'people are supposed to justify what their intuitions are. In fact nobody really can justify what their intuition is. So you have to make up reasons, but it won't be the real reasons.'<sup>407</sup> Thus an approach influenced by phronesis would take an individual's intuitive sense of the appropriateness of an action to be an indication of their context-dependent experience and knowledge, meaning that they feel they just know what the right thing to do is and which in turn means that they cannot necessarily articulate fully why they do what they do. Thus, identifying what constitutes intuitive action and what counts as counter-intuitive or indeed what counts as surprising or troubling action and ideas, is an important part of the process of understanding the social context in which people operate and indeed how they contribute to the shaping of that context. Phronesis, I believe, can help bioethicists in understanding these issues and in closing the gap that sometimes exists between theory and practice.<sup>408</sup>

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<sup>406</sup> For this reason I did my best to integrate myself into Cumbrian life. For example, instead of renting a car, I used public transport to move between interviews and frequented the same cafes in order to build a 'relationship' of sorts with people there. Since many of my interviewees were younger than myself, I even visited the local night club – the first and *last* time I've done so during my six years in Britain.

<sup>407</sup> Flyvbjerg, 2001, p. 80. The early chapters of Flyvbjerg's book provide a detailed description of the so-called 'Dreyfus model', a phenomenology of human learning. This model delineates five levels of learning, from novice to expert - whereby a reliance on formal rules gradually gives way to a greater ability to 'think on one's feet' to an eventual level of intuition and virtuosity. The model can apply to all aspects of daily life: from riding a bicycle, to performing brain surgery, to learning how to play chess. Flyvbjerg uses the Dreyfus model as a basis for his presentation of a context-dependent social science.

<sup>408</sup> A phronetic bioethic, for instance, would give the 'yuk' factor its 'proper and serious due' and not dismiss the whole moral psychology surrounding people's fears over genetics, cloning, and biotechnology. See: D. E. Cooper, 2002. The 'Frankensteinian Nature of Biotechnology. In Maehle and Geyer-Kordesch, pp. 139-149.

Neither my co-author nor I have ever argued, of course, that donating is necessarily the right or wrong thing to do. Rather, a researcher's task is to identify what interviewees define as right/good or wrong/bad, how they define this and how these map onto their wider interests and concerns, within the context of the request to donate and the wider biographies of their lives. This is why as 'thick' a description as possible is needed so that responses to interview questions can be placed within a more detailed understanding of the context in which those particular articulations, and not others, are given.

Following Flybvjerg, then, intuition, is the ability to use one's experience – bodily, emotional and intellectual – in order to recognise similarities between experiences and to adapt to new situations and requests. It is not devoid of reason, but places rationality along side of ones' gut feelings about the right thing to do. An expert acts without much conscious deliberation and in deciding whether to donate ones' parts to a DNA bank or not, many people, it seems, are experts. That is to say, whilst they may not be phronimos, they are virtuoso at deliberating in relation to particular circumstances that affect them. In retrospect and in light of phronesis, this finding is not surprising at all.

Further evidence for these findings and analysis comes from the work of Klaus Hoeyer, who evaluated a biobank in northern Sweden.<sup>409</sup> He found that out of twenty-one persons who received information sheets on the project they were donating to, only eight claimed to have actually read them. Yet donors did not feel that they had an insufficient understanding of the biobank and when asked about their reasons for donating, many people echoed the rather simple sounding sentiment that 'research is good'. Importantly, Hoeyer also found that donors did not reason independent of the context. In this case, donors' relationships with the nurses who requested samples and their views of the wider Swedish biomedical establishment led them to make what seemed like fairly quick judgements. He also argues that the history of the Swedish welfare state, which has continued to prosper into the new century, has helped to create a 'narrative of progress'

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<sup>409</sup> K, Hoeyer, 2003. 'Science is really needed – that's all I know': informed consent and the non-verbal practices of collecting blood for genetic research in northern Sweden. *New Genetics and Society* 22: 229-244; K. Hoeyer, 2004. Ambiguous gifts: public anxiety, informed consent and biobanks. In Tutton and Corrigan, pp. 97-116.

which contributes to a climate of acceptability of scientific research. Of course none of this is to say that donors' decisions are not reasoned – only that lack of detailed explanations does not mean lack of considered judgement.

The notion that only a particular individual can make wise deliberations about a particular request in a particular time and place may seem fairly obvious. Yet it runs counter to recent bioethical obsession with informed consent: How much should researcher's disclose on the consent form? What should the layout of the form look like? Who should be asked for consent? There are questions I addressed in Chapter Five. But as it turns out, many are content to donate without knowing much at all. And those who have refused do so because of something particular to their situation – they knew someone with leukaemia, for instance. The point is that people decide, it seems, in light of the context at hand and their own specific life stories. In other words, people do not seem to make decisions based on abstract theoretical calculations. In her recent work on genetic donation, Helen Busby has argued that many participants feel 'that genetic research was now very much on the agenda and could be seen as an indicator of good modern science, and so in a sense was not particularly novel, troubling or noteworthy.'<sup>410</sup> She also goes on to add that 'policies, discourse, and institutions of bioethics have often seemed to float above the specificity of the lives, circumstances and histories of individuals and communities.' Arguably, this is another way of saying that bioethics, as an academic form of investigation, could benefit from a greater appreciation of the role of phronesis in ethical decision making.

As mentioned in the previous paragraph, one consequence of these findings regards the suitability of informed consent guidelines. Whilst I do not want to argue too strenuously for any specific policy, I do not agree, for example, with some of the suggestions made by Jane Kaye on this matter. She argues for a consent system in which 'every individual would have to re-consent to the use of the data in the population collection every five

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<sup>410</sup> H. Busby, 2004. Blood donation for genetic research: what can we learn from donors' narratives? In Tutton and Corrigan, p. 47.

years.’<sup>411</sup> Whilst this may encourage researchers to better explain how they intend to use samples, it may also impose a degree of burden upon donors. Throughout the data on participants’ views there is a clear theme of ‘letting them get on with it’ – that is, of entrusting the research establishment to do the work they were trained to do. Kaye seems to believe that putting research information on the Internet and in health centres would enable donors to exercise choice in opting in or out of specific studies. Her system is ideal, perhaps, but I am not sure it is entirely practical. So far anyway, it seems that the evidence suggests a large majority of donors would simply not take notice of such information. As O’Neill has phrased it, ‘donors and relatives, like patients, may find that being confronted with the full detail of research protocols provides excess, unassimilable information, to which they can hardly hope to give genuinely informed consent ... there is a good deal of evidence from other areas of life that insisting on consent to every detail may not be the most serious or convincing way of seeking genuine consent.’<sup>412</sup> O’Neill notes that most people, even when not ill or in a clinical setting, have little time to read all the fine print details on things such as insurance policies, or financial transactions. Thus, asking them to constantly keep up with the details of medical projects may not only be unrealistic, it may, ironically, undermine trust in the service of an ‘audit culture’. As I suggested in Chapter Five, consent is not an ethical panacea, but part of a much wider set of obligations and rights that underlie ethically acceptable medical practice. Part of this equation is proper institutional structures and professional competence, both of which relate to the issue of trust – or the perceived lack of it.

In her work, O’Neill makes reference to a series of MORI polls conducted in the UK on biotechnology and medicine.<sup>413</sup> Paradoxically, large swaths of the public claim to have lost trust in science, industry and politicians and yet continue to place trust in those very same professionals. ‘Reported perceptions about trust are not mirrored in the ways in which people actually place trust’.<sup>414</sup> One explanation for this maybe the influence of the media which often reports stories of professional irresponsibility, combined with most

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<sup>411</sup> J. Kaye, 2004. Abandoning informed consent: the case of genetic research in population collections. In Tutton and Corrigan, p. 131

<sup>412</sup> O’Neill, 2002, p. 157.

<sup>413</sup> O’Neill, 2002, p. 9.

<sup>414</sup> O’Neill, 2002, p. 9

peoples' experience of receiving good care from their *particular* health care provider. Of course another very plausible explanation may be that we simply want, indeed need, to trust our own physicians. Speaking for myself, no matter how many horror stories I heard on the news, I would still have a vested interest in trusting *my own* doctor to do the right thing and until that particular trust was broken, my recovery and general health would depend (in part) upon it and my continued faith in my physician.<sup>415</sup> The same can be said for my involvement in medical research studies. And, crucial to the current discussion, having to read or sign more detailed consent forms would do little to influence my perceptions. To conclude, O'Neill writes that, 'consent forms are not fundamental for restoring trust. Evidence that refusal is possible and respected, as well as tone, attitude and recognition of generosity are of greater importance. The generosity of those who give tissues, who allow research use of tissue that has to be removed and the generosity of relatives who give tissue *post mortem*, deserves gratitude. The best 'thank you' is not a legalistic form or an audit trail.'<sup>416</sup>

To conclude this section, a bioethics with a phronetic outlook would (as O'Neill suggests) pay attention to donors' motivations and intuitions and place less emphasis on legalistic consent documents. (Crucially, I hasten to add that this does not mean regulation and governance are unimportant. To the contrary, enforceable governance mechanisms are vital. But sharing every last detail with potential donors may not be the best way to protect their overall interests).<sup>417</sup>

### *Power and justice in bioethics*

A frequent criticism of biomedical ethics is that it pays insufficient attention to issues of power and justice. Again, Flyvbjerg's framework is a reminder of the need to look more closely and more explicitly at communication and power within the NCCGP study. The actual power relationships in NCCGP (or in developments such as the UK Biobank) do not just lie with the researchers but with potential donors too, particularly the power to

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<sup>415</sup> Of course technically speaking, in the UK GPs are not 'doctors' in the strict sense of the word unless they have gone on to complete an MD.

<sup>416</sup> O'Neill, 2002, p. 160.

<sup>417</sup> For more on this, see O'Neill, 2002, pp. 145-164.

withhold their samples. In the study of the database, it would have been useful to try and identify the power relationships that exist, for example, throughout the wider community within which NCCGP operates (such as, within the West Cumbria community itself and within the local press and media networks) and also within the NCCGP researchers' wider professional community and in the funding systems for the research itself.

One way of understanding the power relations is to get closer to the actual communication between the researchers and the potential donors (as well as between the potential donors and their wider community) in order to evaluate the communicative processes that take place. What versions do the various parties seek to present of themselves during the request for samples? (This would be especially interesting, perhaps, for those cases in which women refused to donate). Does the antenatal setting for consent produce an unequal power relationship between those asking for the consent (or interestingly in medical parlance, those 'taking the consents') and those giving it, the pregnant women? How power relations operate and in what directions requires clarification, particularly in relation to informed consent. One weakness of the study was that I did not gain access to the actual settings in which the NCCGP requests for donation were made or to the settings where consent was actually given (or was considered to have been given). Whilst vital to understanding the process referred to as 'informed consent', actual observation of that process was not allowed on the grounds of patient confidentiality. Thus, a concern for ethical practice acted as a barrier to research on ethics.<sup>418</sup>

Another critical area related to issues of power and justice was alluded to in Chapter Six – the 'silent' voices of children who had donated to the NCCGP through the proxy consent of their mothers. As interviews showed, many parents claimed that they probably would not remember to tell their children about their donation. In addition, the NCCGP

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<sup>418</sup> A topic not addressed in my thesis is the ethics of social science research itself – although I have worked on this as part of my PEALS position and the recent ESRC consultations to develop national social science ethics guidelines. A useful piece related to this is C. Bosk, 2001. Irony, Ethnography and Informed Consent. In Hoffmaster, pp. 199-220. Bosk argues that it is impossible to do hospital or lab based ethnography without violating informed consent and breaking promises about confidentiality. He argues that as strangers come and go, you cannot break the flow of interaction to tell each newcomer they've just entered a 'research zone' and ask them for their informed consent.

team has not yet decided how or even *if* they will re-contact donors once they reach the age of sixteen. It has been said that biomedical ethics is 'adult-centric', and the evidence largely supports this claim.<sup>419</sup> Only very recently have researchers attempted to engage with children's views despite the fact that children have been used in medical experiments since (in all likelihood) the dawn of medical experimentation.

In recent study of epidemiological donors, the EPEG project (standing for Ethical Protection in Epidemiological Genetic Research: Participants' Perspectives) highlighted several relevant themes for the issues of power, control and justice.<sup>420</sup> Their findings support many conclusions of the Cumbria biobank study, but also had the added element of interviewing children who had donated material to a genetics project. Interestingly, the EPEG team found that parents and their children had different views on what constituted personal information. (This is important since the reader will recall that in epidemiological studies, health and lifestyle questionnaires must be completed). Children attached significance to information that they perceived to be potentially embarrassing or uncomfortable, whilst parents incorrectly assumed that their child's views of what was personal would not conflict with their own. Parents identified financial information, medical history, contact details and sexual past as sensitive information. Children viewed private information as that having to do with friendships, parental relations, being bullied or hurt, feelings/emotions, and body image. Such findings, the authors argue, question the adequacy of proxy consent in epidemiological studies because of the 'transitory' nature of childhood.<sup>421</sup> The goal of consent, as everyone claims, is to minimise harm. Yet 'protecting children from harm they may not fully appreciate does not explain why the concerns which children do identify are not taken seriously.'<sup>422</sup> As one author puts it,

'Inquiry about matters related to health clearly intrude on one's privacy. Control over knowledge about oneself and particularly about one's body is basic to respect for the

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<sup>419</sup> P. Alderson, 2002. Utopia or dystopia? The new genetics as an environment for childhood. In M Gollop and J. McCormick eds., *Children and Young People's Environments*. Dunedin: Children's Issues Centre, p. 10.

<sup>420</sup> E. Williamson, T. Goodenough, J. Kent, and R. Ashcroft, 2004. Children's Participation in Genetic Epidemiology: Consent and Control. In Tutton and Corrigan, p. 139-160.

<sup>421</sup> Williamson, et al, 2004, p. 157.

<sup>422</sup> Williamson, et al, 2004, p. 157.

person and is often constitutionally protected. Young people, with their growing wish for self-determination, are particularly sensitive to infringements of privacy, and may strongly object to others learning particulars about their personal lives or behaviour. Loss of control over such information, whether through compelled disclosure or breach of confidentiality, subjects many young individuals to embarrassment and degradation.<sup>423</sup>

Thus, in epidemiological ethics, power relations within families, as well as between families and researchers, deserves further attention to ensure that mechanisms designed to protect children do not end up inadvertently harming them, psychologically or otherwise.

Even aside from epidemiology, I wish to assert that justice is an overlooked and undervalued concept in bioethics generally. Despite being one of the four principles laid out by Beauchamp and Childress, many observers argue that justice has not received its proper due. For example, Alastair Campbell writes that 'on the topic of justice, bioethics has been at its weakest and most unclear. Yet, in terms of overall human welfare, it surely must be the most important topic of all.'<sup>424</sup> Campbell traces the slow increase of interest in justice in the Congresses of the International Association of Bioethics (IAB). He notes that global health inequalities and poor health services in developing countries has only recently emerged onto the bioethical agenda and even then has not received enough attention. In part, Campbell believes that this is because bioethics lacks the conceptual tools and theories to address health issues in an era of globalisation.

Earlier in the thesis I noted that throughout the history of medical ethics (excluding original trends in *bioethics*, as the LMG study showed) much focus has been on physician-patient relations rather than on societal issues – thus, in the face of genetic medicine and economic globalisation, we see academics and practitioners struggling to find a language and vocabulary to meet the ethical demands of a changed context. In her address to the Sixth Annual IAB Congress, Solomon Benatar also noted that traditional bioethics, to the extent that it addressed power, did so through the lens of the doctor-

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<sup>423</sup> S. Leikin, 1996. Ethical Issues in Epidemiological Research with Children. In S. Coughlin and T. Beauchamp eds., *Ethics and Epidemiology*. New York: Oxford University Press, p. 209.

<sup>424</sup> A. Campbell, 2003. Secularised Bioethics and the Passion of Religion. *New Review of Bioethics* 1: 124.

patient relationship. Benatar's article (originally delivered as the IAB Presidential address) makes a number of useful points and directs the way towards a bioethic that incorporates power. In what I suspect was a deliberate attempt to provoke, she writes that 'we live in a morally depraved world, one that promotes preference for continuing economic growth and the acquisition of luxuries for a small proportion of the world's population over ensuring the production and access to essential subsistence requirements for the majority.'<sup>425</sup>

Nowhere are these issues more pressing than in the developing world. Benatar's argument that medical research agendas are determined by markets in developed countries rather than by health needs in the developing world is hard to dispute.<sup>426</sup> For example, between 1975 and 1999, only 1% of new drugs produced by the pharmaceutical market were for tropical diseases and tuberculosis, illnesses which account for 12% of the global disease burden.<sup>427</sup> Nearly 80% of investments in the year 2000 and DNA patents in genomics in the period between 1980-1993 were held in the United States alone, the so-called birthplace of bioethics.<sup>428</sup> This trend has been exacerbated by commercial genomics, whose bottom line is, all too often, the bottom line.<sup>429</sup> It would take a brave bioethicist to deny this, which, quite possibly, is why bioethics remains so deafeningly silent on the topic.<sup>430</sup>

Of course, to be fair, some international bodies have stressed the importance of justice, solidarity and equity in medical research. The Human Genome Organization, for

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<sup>425</sup> S. Benatar, 2003. Bioethics: Power and Injustice: IAB Presidential Address. *Bioethics* 17, p. 391.

<sup>426</sup> Although Benatar does not explicitly make the point, one can easily argue that addressing the power imbalance in global health is in the long term interest of the affluent. The connection, for example, between disease, security, migration, and political instability has been well documented. See M. Whong-Barr, 2003. Singer's world: Review of Peter Singer's One world: the ethics of globalization. *International Studies Review* 5: 406-408.

<sup>427</sup> Global Forum for Health Research, 10/90 Report on Health Research 2003-2004. See <http://www.globalforumhealth.org/pages/index.asp>

<sup>428</sup> Editorials, 2002. Genomics and Global Health: Hype, reality, and a call for action in the developing world and developed world. *British Medical Journal* 324: 1051-1052.

<sup>429</sup> L. S. Cahill, 2003. Biotech and Justice: Catching up with the Real World Order. *Hastings Center Report* 33: 34-44.

<sup>430</sup> The exceptions prove the rule, I think. For one exception, see: J. Floury and P. Kitcher, 2004. Global Health and the Scientific Research Agenda. *Philosophy and Public Affairs* 32: 36-65.

instance, claims that 'justice is a central issue' in genomics<sup>431</sup>. Yet, in practice, justice is hard to achieve due to differing socio-economic, cultural and political contexts and the lack of enforceable global regulations. Some individual bioethicists have also begun to shift away from frameworks of autonomy to values of solidarity and the common good.<sup>432</sup> Whilst I support such moves, I also think a true shift in consciousness is extraordinarily hard to achieve. Flyvbjerg quotes Paul Valery as saying that 'long years must pass before the truths we have made for ourselves become our very flesh.'<sup>433</sup> Unfortunately, attempts to theorise a new social contract will always run into the realities of local context and power imbalance. Arthur Kleinman writes that

'Beneficent social contracts make good philosophical theory, but they deny empirical evidence in local social worlds ... real communities are sources of suffering at least as much as of assistance. They do not contain explicit social contracts, but they are filled with different interests, status division, class divisions, ethnic conflicts, and factionalism.'<sup>434</sup>

In India, for example, a key issue regarding justice is gender discrimination. Although existing laws prohibit sex selection, many in-vitro fertilization (IVF) clinics have been accused of screening embryos to select for males. The 2001 Census showed that the child sex ratio in the age group of 0 to 6 dropped from 962 females per 1000 males in 1981, to 927 females per 1000 males in 2001<sup>435</sup>. Thus, rather than empowering women, it seems that India's 1971 Medical Termination of Pregnancy Act has led to increased gender discrimination since the abortion of female foetuses is often the result of greater genetic knowledge. In pre-arranged marriages, families are increasingly seeking information on a potential spouse's pre-disposition to genetic disease. In effect, this makes some women unmarriageable or puts them at risk of harm if they give birth to a disabled child. While justice is frequently cited in official Indian guidelines, in practice, reproduction takes

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<sup>431</sup> HUGO, 2002. Statement on Human Genomic Databases.

<sup>432</sup> See for example, Chadwick and Berg, 2001.

<sup>433</sup> Flyvbjerg, 2001, p. 141.

<sup>434</sup> A. Kleinman, 1995. *Writing at the Margin: Discourse between Anthropology and Medicine*. Berkeley: University of California Press, p. 48.

<sup>435</sup> Census of India 2001. Provisional Population Totals (0-6).

place in a context of unequal power relations.<sup>436</sup> In addition, the lack of effective regulation of IVF clinics provides a resource for India's growing stem cell research. Such research, however, is in tension with other urgent health needs such as 'vaccines, drugs, and clean water'<sup>437</sup>. Again, these topics rarely see the light of day in mainstream bioethics literature. But their effects are felt beyond India given the reality of economic, scientific and political globalization.

The effects of a globalising world brings new importance to the concept of soft power (described in the previous chapter as the power of culture, finance, or ideas) for bioethics. Bioethics would do well to study the effects of power relations in international public health since these type of studies would expose the roots of corruption and the practices of marginalisation that contribute to and help sustain health inequalities.

Although Carl Elliot does not explicitly mention the term 'soft power', the phrase also neatly captures his well known attempts to implicate bioethics in the business of big business. Elliot believes that bioethics is in danger of becoming a 'medically knowledgable, media savvy, academic-corporate wing of the advice industry'.<sup>438</sup> Following the critiques of others, Elliot writes that bioethics suffers from 'intellectual arrogance and moral weakness'.<sup>439</sup> For example,

'Commenting on the testimony of a bioethics expert witness in Florida, a district judge wrote: "His testimony was often very abstract, describing such things as the "metaphysical" and "epistemological" issues associated with a "post Kantian world"'. The judge went on to classify the bioethicist's remarks as "harmless error", noting: "It is not surprising that all of the lawyers essentially ignored this testimony during the closing arguments".'<sup>440</sup>

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<sup>436</sup> Indian Department of Biotechnology, Ministry of Science/Technology, 2002. Ethical Policies on the Human Genome, Genetic Research and Services.

<sup>437</sup> R. Lakshmi, 28 August 2001. India Plans to Fill Void in Stem Cell Research. *The Washington Post*; Page A07.

<sup>438</sup> C. Elliot, 2002. Diary. *London Review of Books*, 28 November, p. 37.

<sup>439</sup> Elliot, 2002, p. 36.

<sup>440</sup> Elliot, 2002, p. 36.

If such abstractions were not bad enough, however, Elliot's real problem with bioethics is its alliance with business and its pandering to science. He approvingly quotes Francis Fukuyama as saying, that the 'most permissive position' of anyone discussing ethical issues in medicine, is usually the 'professional bioethicist'.<sup>441</sup> (One must wonder if this is the reason why there are so few bioethicists on President Bush's Council on Bioethics?). One cause of such pandering, Elliot believes, is the nature to which bioethics relies on medical and commercial funding.

A key problem for bioethicists is the extent to which their public acceptability (especially in the US, it must be said) has led to a financial conflict of interest. This is because the pharmaceutical industry seeks out ethicists (who are all too willing, of course) to advise them as pseudo-regulators. This allows drugs companies to promote their public image as being ethically sensitive – but all the while, they are paying handsome consultation fees to those who are supposed to be giving them impartial ethical guidance. 'Once bioethicists begin to take money from the corporations whose actions and policies they are supposed to be judging, it is no longer clear that their moral judgement on those actions and policies can be trusted in the same way.'<sup>442</sup>

From my limited experience in bioethics, Elliot's critique rings true. The problem is not just as he identifies, but that ethics centres rely on the medical establishment (including pharmaceutical companies) for access to clinical settings in which to conduct their research. One published article that is perceived as being too critical of the practitioners in question, and the researcher must go looking elsewhere for a site to study and for patients to interview. (As Elliot puts it on a slightly different topic, 'I only know that I have never read an industry-funded ethics article that is critical of the industry that funds it'.<sup>443</sup>) In addition, with the marketisation of academia, medical ethicists are sometimes reliant on commercial funds for the very buildings in which they work. For instance,

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<sup>441</sup> Elliot, 2002, p. 36.

<sup>442</sup> C. Elliott, 2004. Six problems with pharma-funded bioethics. *Studies in History and Philosophy of Science Biological and Biomedical Sciences* 35: 125-129. The issue of this journal also contains responses to Elliot defending bioethics against his charges. Whilst contributors nearly all agree with his diagnosis, they also assert that bioethics is not a unitary field and that their experience in moral reasoning can often help companies negotiate ethical quandaries.

<sup>443</sup> Elliot, 2002, p. 37.

SmithKline Beecham recently gave Stanford University \$1 million to start a new program in ethics and genetics.<sup>444</sup> Increasingly, commercial funds are needed if universities are to secure high quality faculty, facilities, financial scholarships, and research grants. Whilst this trend is prevalent in fields other than just bioethics, it is arguably the case that bioethics is particularly susceptible to business influence given its associations with the medical and scientific establishment.

For example, one is reminded of two recent cases in which industry withdrew funds because of published material it did not agree with. David Healy, a psychiatrist based in Wales, recently published a piece in the *Hastings Center Report* which was critical of the anti-depressant drug Prozac, made by Eli Lilly & Company.<sup>445</sup> As a direct result of the article, Eli Lilly suspended a \$25,000 grant to the Hastings Center and Healy's new appointment at the University of Toronto was revoked. An even worse case was that of Nancy Olivieri, who lost her post at the University of Toronto (perhaps I've confused the nature of causation here?) after showing that a drug made by the pharmaceutical company Apotex caused harmful side effects.<sup>446</sup> Apotex, it seems, was close to making a \$12.7 million donation to the university and was clearly threatened by Oliveri's intention to publish her results. After an acrimonious investigation, she was re-appointed but by then, in my view, the game had clearly been given away.

Understanding how bioethics is embedded in cultural values may help to explain why it mirrors rather than challenges society and has remained relatively inattentive to issues of power and justice. The work of Renee Fox and Carl Elliot is useful in establishing how bioethics is embedded in and limited by a narrow range of concepts, norms and cultural values. But the question remains as to the historical reasons for bioethics' silence on these topics. This is where a critical and effective history may prove valuable.

### *Towards a genealogy of biomedical ethics*

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<sup>444</sup> S. Stolberg, 2001. Bioethicists find themselves the ones being criticised. *New York Times* online 2 August. Available at: [www.nytimes.com](http://www.nytimes.com)

<sup>445</sup> D. Healy, 2000. Good Science or Good Business? *Hastings Center Report* 30: 19-22.

<sup>446</sup> R. Horton, 2004. The Dawn of McScience. *New York Review of Books* 11 March, pp. 7-9.

Perhaps it is a bit late in the day to be introducing the work of another thinker. However, the thought of Gerald McKenny is where my PhD study began five years ago so it is fitting that it is where it should also (begin to) draw to a close.<sup>447</sup> Thus, in this section I aim to bring the thesis full circle by re-visiting the history of biomedical ethics. In Chapters Two and Three, I presented a rather standard version of the development of biomedical ethics. With the exception of my research on the London Medical Group, much of my thinking and writing in those chapters relied on fairly conventional and received views. I argued that bioethics began when medicine ceased to be able to regulate its own affairs. I sympathised with those accounts that connected the emergence of the field within the context of the civil and social rights movements of the 1960s. Yet this can hardly be the whole story. Here, in line with my sketch of a phronetic bioethic, I aim to show how the history and historiography of biomedical ethics may be re-drawn.

McKenny's work is important because he is one of the few authors to bring a genealogical perspective to bear on bioethics - although this is not his real aim.<sup>448</sup> Rather, his book develops a Christian bioethic grounded in the body and redemption of Christ. In laying the groundwork for his Christian rendition, however, McKenny outlines a fairly complex but insightful explanation of why biomedical ethics has been so successful and yet such a failure.

According to McKenny, there exists a deep but implicit moral agreement between bioethics and the effort to overcome human subjection to fate or natural necessity. He writes that Western society has developed an obsession with bodily perfection, an obsession dangerously linked to a moral imperative to eliminate suffering and expand the realm of human choice. Modern medicine, with its ability to intervene into the body, continually holds out the promise of fulfilling this imperative.

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<sup>447</sup> G. McKenny, 1997. *To Relieve the Human Condition: Bioethics, Technology, and the Body*. New York: SUNY. Having originally been accepted to do a PhD in theology, I defected to philosophy since I was not eager to write about Christianity or the narrative of Christ. Yet I am grateful to Robert Song for drawing this book, which formed much of my early thought about the history of biomedical ethics, to my attention.

<sup>448</sup> But see also: N. Rose, 1994. *Medicine, history and the present*. In R. Porter and C. Jones, eds., *Reassessing Foucault*. London: Routledge, pp. 48-72.

Not surprisingly, McKenny disputes most standard models of the history of bioethics. One model, the reader will recall, asserts that bioethics was a product of new technological developments that made the field necessary in the face of obsolete medical traditions. Technology, this story goes, has made it possible to intervene into natural processes in ways that religious and medical traditions never anticipated, producing moral dilemmas which those traditions were not capable of resolving. As a result, society was forced to make moral choices that required a new approach. Hence, a philosophically grounded bioethics became necessary and replaced the older traditions with a core of common, secular principles. A second model held that the bioethics movement originated with an 'outsider' ethic, characterized by general principles and rules, that were able to replace a traditional 'bedside ethic' (an anecdotal case ethic taught largely by example, such as in John Gregory's *Lectures*). Allied to this account was a third model stressing the role of the rights movements of the 1960s in pushing medicine to be more transparent in its decision making and priority setting.

McKenny argues that it is in the interests of bioethics to find its origins in these cultural and political needs. 'If technology presents moral problems that standard bioethics alone can resolve or if standard bioethics can claim a public moral authority that traditional moral schemes have lost, then as long as technology and contested moral authority are inevitable features of our culture, the agenda of standard bioethics – the questions, the range of concerns, and moral issues it addresses – would be rationally vindicated.'<sup>449</sup>

McKenny then refers to the 1968 Harvard declaration on brain death to show why he thinks the received accounts of the origins of bioethics are mistaken. The declaration was a response to moral difficulties created by the ability to sustain respiratory functions through mechanical ventilation. On the surface, the Harvard declaration appears to support the view that technology created an unprecedented problem requiring a novel solution. However, McKenny doubts this conclusion on two fronts. First, he argues that rabbinic Judaism arrived at a similar position on 'brain death' without recourse to the tools and principles of secular bioethics. In other words, traditional moral and religious

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<sup>449</sup> McKenny, 1997, p. 10.

systems were just as capable of reaching insights to problems posed by technological medicine as bioethics, despite the latter's attempts to push traditional systems to the margins of the bioethical discourse. McKenny claims that however novel problems seem, they are often not as 'unprecedented' as claimed. Concern about how to define death has a long history in medicine and religion. The same can be said for many other issues such as euthanasia, abortion, and eugenics. Secondly, McKenny notes that continuing controversies over the definition of brain death show how impossible it is to generate moral principles and apply them to cases without involving oneself in deeply held cultural or religious beliefs and practices. His overall point is that while technology has been a major factor in medicine and ethics, the 'reign of technology' does not necessarily require 'the reign of standard bioethics.'<sup>450</sup>

McKenny argues that the degree to which bioethicists cling to claims of a common morality is indicative of a modern anxiety regarding an actual *lack* of moral agreement in an era of diversity. According to proponents of standard bioethics, a secular rationality supplies moral unity where religion failed. However, McKenny believes that bioethics fails in its attempt to arrive at a morality that is substantive enough to resolve moral disagreements, yet common enough to compel the rational agreement of all. In other words, it fails to resolve the crisis of moral authority on its own terms: through shared reason. Yet the question clearly remains: why do so many professionals and lay people still find bioethics compelling? McKenny argues that it has little to do with its alleged rational authority and much to do with its success in articulating and supporting certain modern moral convictions. He asserts that the deeper roots of the crisis of moral authority involve the loss of tradition in the West. 'The loss of tradition means the loss of a certain moral discourse -- one that places the pursuit of health in the context of a pursuit of a good life within limits set by fate or necessity -- and its replacement by a new moral discourse -- one that is dedicated to overcoming the human subjection to natural necessity. This places the narrative of the origin of bioethics squarely within a narrative of the emergence of modern moral theories.'<sup>451</sup>

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<sup>450</sup> McKenny, 1997, p. 12.

<sup>451</sup> McKenny, 1997, p. 15.

The loss of a religious tradition means that society has lost a way to describe how bodily health is related to the ends and goals of life, and a way to understand how suffering thwarted or helped one to realize those ends. Previously, when technology brought new areas of life under medical intervention, both the goals themselves and certain norms and prohibitions within the tradition would question the continual pursuit of health and the means by which it was pursued. Specifically, McKenny is concerned that we have lost the tradition of medicine as an *art* (or *techne*, one could say). Medicine as an art requires not just general knowledge of excellent bodily functioning but also awareness of the relation of this functioning to the capacities and roles of each particular patient and the limits of restoring excellent bodily functioning for that particular person. McKenny believes that religious and medical traditions helped human beings accept that they were destined to suffer disease and eventually die. Yet today, he argues, health seems to have become an end in itself rather than a component of a virtuous life. The wisdom of learning the limits of healing have given way to Bacon's assertion that no disease is incurable and medical knowledge is to be dedicated to the prolongation of life. Finally, the loss of tradition seems to bring with it a loss of limits as to what can be done to the body in the name of curing suffering.

Unquestioned commitments to technological control of the body for the sake of eliminating misery constitute what McKenny calls the 'Baconian project' – that is, a project 'to relieve the human condition of subjection to the whims of fortune or the bonds of necessity.'<sup>452</sup> According to McKenny, medicine is utopian to the extent that its task in the modern era seems to be to indefinitely expand our choices and end suffering, thus relieving our subjection to fortune and finitude. Given the degree to which medicine participates in modern values, McKenny thinks there is a cultural expectation that medicine should eliminate whatever people consider a burden or to provide whatever anyone might require for one's natural fulfillment. In other words, choice, *per se*, appears at times to be the highest good and to be immune to criticism. This sketch of the modern moral discourse makes it possible to identify the major cultural values that both

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<sup>452</sup> McKenny, 1997, p. 19.

medicine and bioethics draws on and why the latter is silent on questions regarding the proper limits of medical science – or to cite Fukuyama, why bioethicists are so ‘permissive’.

McKenny asserts that the ‘modern moral discourse [which bioethics participates in] provides no vocabulary with which to deliberate about the meaning of corporeality, what moral purposes the body serves, what goods health should service, or what limits the control of our bodies by technology should observe. Hence, it allows for no discussion of what kinds of suffering should be eliminated, what kinds of choices human beings should make, and what role technology should play in all of this.’<sup>453</sup>

According to McKenny, any challenge to the agenda of bioethics is difficult to undertake because the ‘reign of technology’ is not neutral but rather expresses and is produced by the deepest moral commitments of our time: to relieve the human condition and expand our self-determination. Modern technology does not render traditional moralities obsolete, or call for a new morality so much as it *expresses and carries out* an existing modern morality. In short, technology is infused with moral purpose - which makes questioning it inherently difficult.

McKenny draws upon the philosophy of Charles Taylor to show the historical sources of why certain moral convictions are attractive or worthy to those who adopt them. His historical explanations are schematic at best and can be faulted on any number of grounds for the leaps, bounds and assumptions that it makes. Yet it carries immense intuitive appeal. In stressing the modern drive to eliminate suffering, McKenny outlines the project of Francis Bacon who sought the development of a scientific method that would benefit the condition of humanity. Bacon’s philosophy, as is well known, adopted the view that humanity could be liberated from disease, toil, and suffering through the control and domination of nature. This instrumental view of nature received theological support from the conviction that God had ordered nature for the enhancement of human life. It also took a secular bent with the Enlightenment, utilitarian philosophy of Bentham

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<sup>453</sup> McKenny, 1997, p.21.

and Mill, who developed the idea that the prevention of pain was intrinsically good. As Taylor argues, this created a new standard by which to judge moral, legal and religious orders: do they lessen or increase suffering in the world?<sup>454</sup> Unsurprisingly, this new moral agenda coincided with a decrease in the belief of divine providence. By combining a mechanistic approach to nature with a loss of a religious explanation of suffering, the latter became not only avoidable but something that human beings had the responsibility and means to end. The second current contributing to our moral discourse concerns what Taylor refers to as 'inwardness.'<sup>455</sup> The roots of this idea run through Augustine (the belief that self-affirmation was achieved through a Trinitarian God) to the Romantics (the importance of meeting one's own natural fulfilment) to Kantian philosophy (in the form of self-determination and autonomy). In the last century, autonomy became equated with rights of entitlement and immunity.<sup>456</sup>

According to McKenny,

'In the modern discourse, moral convictions about the place of illness and health in a morally worthy life are replaced by moral convictions about the relief of suffering and the expansion of choice, concepts of nature as ordered by a telos or governed by providence are replaced by concepts of nature as a neutral instrument that is brought into the realm of human ends by technology, and the body as an object of spiritual [sic] and moral practices is replaced by the body as object of practices of technological control.'<sup>457</sup>

I have dwelled at length on McKenny. The essence of his argument, to me, is the insight that the prevailing moral discourse leaves us without a framework or vocabulary to deliberate on the role and limits of medicine and technology. One reason his version has intuitive appeal is because of my study of the Cumbrian DNA bank. Many interviewees

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<sup>454</sup>C. Taylor, 1989. *Sources of the Self: The Making of the Modern Identity*. Cambridge: Cambridge University Press, p. 331.

<sup>455</sup> McKenny, 1997, pp. 111-207.

<sup>456</sup>McKenny's account no doubt misses *many* elements of this phenomena. It may be worthwhile, for example, to connect the right to entitlements with the rise of the nation-state and the expansion of self-choice with the growth of market economies. McKenny does neither, however – again, his model is highly schematic, a fact that he readily acknowledges.

<sup>457</sup>McKenny, 1997, p. 21.

expressed a desire to ‘help’ medical research. Although none of the donors put it in such terms, I often got the sense that there was a ‘research imperative’ at play in their accounts. In other words, the sentiment amongst donors seemed to be that ‘science needs to advance’ and ‘any research or testing that could be done can only be beneficial.’ (M067; M003). Crucially, along side this imperative, was a distinct feeling of ‘why have a disabled child if you don't have to?’ (M006). One woman expressed this view in the following way:

‘It sounds awful but she [a disabled relative] is going to have a hell of life basically. She has got a lot of problems now but she is going to have a hell of a lot more before she gets older and as I say with genetics it could have been avoided, you know with tests. Although some people argue that it is God's will isn't it, but you know if you believe that, it's hard on the parents, it's hard on the children.’ (M006)

In my own experience, I have absolutely no doubt that it would be hard – extraordinarily so. To me, that is precisely the point. We’ve lost the resources to make sense of our vulnerability. At the same time, we’ve developed powerful new resources to fool us into thinking that we never should have been vulnerable in the first place.

Of course McKenny’s claim regarding bioethics’ inability to question the use and limits of technology has been made by many others (though few in bioethics, at least, have attempted to trace the historical reasons for it).<sup>458</sup> Daniel Callahan, for example, writes that bioethics task ought to be to determine ‘what is right and wrong, good and bad, about the scientific developments and technological deployments in medicine.’<sup>459</sup> He argues that the decline of religious input in bioethics has led to a ‘paucity of concepts, a thin imagination and the ignorance of traditions, practices’ and alternative forms of moral analysis. According to Callahan, bioethics was meant to be grounded in a broad examination of all the larger problems of the meaning and purpose of human life and religion helped us think about those meanings. Yet one can search in vain in the bioethics

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<sup>458</sup> I am all too painfully aware that I’ve ignored the growing literature on the philosophy of technology. I shall touch on this in the Conclusion.

<sup>459</sup> Callahan, 1999, p. 276; p. 280.

literature for any real effort to connect questions of meaning to questions of ethics. Instead, these questions take second place to regulatory matters and individual preferences and choice. To make this point, Callahan relates a popular joke amongst analytical philosophers: 'Life has no meaning. Only propositions do'.

Following on from my presentation of genealogy in the previous chapter, my argument here is that the growth of the bioethical discourse has brought with it a certain range of norms of reasoning, moral concepts and categories that have re-placed and marginalised earlier discourses and ways of relating the medicine and the body to moral life goals. As a consequence, the secularity of bioethics masks many essential issues and contributes to a tendency to define certain ideas and concerns as outside its orbit. While each decade a new series of problems arise, little effort is spent on the underlying social structures or priorities that cause such issues to arise in the first place.

Let me put this another way: historical work into biomedical ethics ought to extend beyond mere description and narrative to a critical evaluation of the wider social and cultural context, including the deep historical and contingent trends that have made us what we are today. The history of bioethics needs to be *embodied*. It must involve an understanding of some of the causal factors – the attitudes, beliefs, and existential commitments, as well as medical, scientific and commercial pressures – which have governed developments not only in ethics, but crucially in medicine and technology, as well.<sup>460</sup> Such a history would be what Foucault called a 'curative science' -- a way of recovering some of the costs and losses involved in framing the bioethical agenda as we have done.<sup>461</sup> It would be a proper genealogy and it would be phronetic in that it would focus on what is variable in human affairs. Crucially, it would also be aimed at praxis.

In some ways, my own history of the London Medical Group was as far from genealogical as one could get. That is, I wrote a straight forward old fashioned oral history narrative. But a descriptive account, as I have provided, can only be the start.

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<sup>460</sup> R. Song, 2002. *Human Genetics: Fabricating the Future*. Darton, Longman and Todd.

<sup>461</sup> Foucault, 1998, p. 382.

There is also a need for a history of bioethics that extends beyond a traditional narrative account of the great men and great events that have defined the discipline. Important as they are, such narratives primarily offer grist for the mill of critical analysis.

Unfortunately there has yet to be a history of medical ethics that refuses the ethics/medical divide: the idea that somehow the social/ethical are distinct and can be studied separately from the biological/technological. Both, in fact, are part of larger processes and larger histories, which shape and mutually influence each other. Medical technology itself is a result of various social processes of 'emotion, communication and cultural valuation' – it is not a 'caricatured and one dimensional bogeyman, an assumed culprit imposed upon, [but] not of society.'<sup>462</sup>

When, for example, the emphasis in medical ethics education is on *what to do*, there is less room for critical analysis, which seeks to explore the historical constitution of the systems of knowledge that both define ethical problems and offer 'solutions' to those same problems. The field of bioethics may benefit if further work into its history begins to understand some of the ways in which ethics and science are both embedded in socio-political practices – practices that are so obvious and seemingly necessary, that we forget, they too, have a history.

### *Summary and conclusion*

In this chapter I have argued that:

- One way to make sense of NCCGP donors' apparent inability to elaborately discuss and justify their donations is by viewing their actions in light of phronesis, that is practical reasoning in a particular context. Viewed in this way, people possess expert knowledge over their own lives and over their own bodies. Additional data from very recent studies of genetic donation seems to confirm the notion that many people are content to donate without knowing much detail regarding the nature of the project they are donating to. Rather than viewing this

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<sup>462</sup> G. Belkin, 2002. Review of Hoffmaster. *Journal of the History of Medicine and Allied Sciences* 57: 373-375.

as ignorance or apathy, it seems that people have clear ideas – intuitive notions – of right and wrong and need not ponder endlessly or pour eternally over detailed informed consent documents. A phronetic bioethic would recognise the embedded nature of moral reasoning and that it cannot separate from people's life stories and institutional, local, national and even international context. It would refrain from unfounded claims regarding people's motives in donating tissue samples or the importance attached to informed consent.

- Power (and to a lesser extent justice) is notoriously undervalued in bioethics. Taking these notions seriously would lead to a bioethics that gave as much consideration to the plight of people in the developing world as it did to people in developed countries. A phronetic bioethic would expand its agenda to the less well-off, to the hidden connections between research into obesity in America and the famines of Africa, or the development of cosmetics for use in Britain and the lack of clean water in India. It would look at how the embedded nature of bioethics into systems of finance, power and knowledge blinds the field from seriously critiquing the unrealistic expectations people have of technological medicine and how ethics participates and contributes to those false expectations.
- A critical and effective history would use the tools of genealogy to write a strategic history of the field, looking at underlying assumptions, structures, and mechanisms which have made the bioethical phenomenon possible. It would examine the ethics of technology itself, and the cultural desire for perfection, as well as the loss of traditions which previously provided a framework that enabled us to make sense of loss and vulnerability.

In short, I advocate a bioethics that mirrors the diversity and complexity of lived reality.

## Chapter Nine

### Conclusion: why baseball is integral to bioethics

*Jacques Barzun once remarked that if you want to understand America, you must first understand baseball. There is some truth to that remark – some truth about baseball, to be sure, but also some truth about how American concepts, and American problems, are inseparable from their broader cultural context. For instance, non-Americans occasionally find it difficult to understand all the furor over the “right to die” debate in America, and the vehemence with which it is sometimes argued. Why would anyone want to continue treating a patient in a persistent vegetative state with virtually no chance for recovery? Ah well, I usually explain, you must also understand how the right to die is related to the right to life, and to the debate over abortion, and to American churches and to the role of the church in small-town life; you must also understand something about American hospitals and feminism and libertarianism and fundamentalism and natural rights and John Locke and Thomas Jefferson, and so on and so on, ad infinitum. To understand America, I explain, you must first understand baseball.*<sup>463</sup>

-- Carl Elliot

Like baseball, bioethics is entwined into the fabric of life.<sup>464</sup> I have examined the history and philosophy of biomedical ethics and its limits according to the social sciences. I have spent sixteen months testing a particular case against competing claims. I have then returned to the questions ‘what is bioethics’ and ‘what is bioethics not?’ and struggled to forge a conception of the field that could take better account of its own epistemological and methodological assumptions. In the process, I have left much unsaid.

In the Introduction I mentioned that one of the costs of my broad stroke approach to this topic was that I touched on many issues without exploring them in depth. For instance, a solid reading of phenomenology and the philosophy of technology are not where the bulk

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<sup>463</sup> C. Elliot, 1999, p. 157.

<sup>464</sup> C. Elliot, 1999, p. 157.

of my investigation took me but, it seems, this is where it has left me. Paradoxically, both are peripheral to biomedical ethics per se, and yet, I've discovered both are central to it as well. Both are relevant in that one cannot divorce questions of ethics from these larger 'background practices.' Yet such is the rapid growth of bioethical literature (both clinical and research) that one can easily get away with calling themselves an ethicist whilst having never opened Husserl or Heidegger.

Another area that I am cognisant of ignoring is the normative assumptions built into the social sciences. Although I have said very little in this regard, it is not because I think sociology or ethnography somehow stand apart. To assert this would run against the grain of everything I have tried to articulate. The moral convictions and assumptions of the social sciences (i.e. about the nature of the subject, or relationships, or society) are as embedded as the assumptions of bioethics – or as my own for that matter.

Finally, I have said too little about the utility of theory. Charles Bosk writes that 'there are not many areas where we equate theoretical and practical wisdom ... the idea that moral theory can be used to solve practical problems cuts against so many beliefs prevalent in the medical, academic, or larger political culture that we might wonder about its centrality to the bioethics enterprise'.<sup>465</sup> Whilst I am generally sympathetic to this line of thinking, I also believe that bioethicists should not entirely dismiss theory. Thus, a central plank of my future research agenda is to think through and better articulate the relationship between theory and context, principles and practice.

And on that note, I draw to a close a study whose central task, I fear, has been a crude attempt to kick bioethics in the assumptions.

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<sup>465</sup> C. Bosk, 1999. Professional Ethicist Available: Logical, Secular, Friendly. *Daedalus* 128: 55.

## **Appendix I**

### **A Study of Participation and Non Participation in the North Cumbria Community Genetics Project, October 2001 to February 2003.**

#### **A project grant funded by the Wellcome Trust Biomedical Ethics Division**

In September 2001 I attended a Wellcome Trust sponsored summer school on 'Genetics and Society'. In anticipation of establishing UK Biobank, the Trust was keen to encourage research into population-based sample collections. As part of the summer school, I developed some initial ideas for a study of the NCCGP and formally presented those ideas to summer school participants and tutors.

Since I lacked an academic post or the skills to obtain funding, I sought out Professor Erica Haimes (Newcastle) to work with on the application. Though the initial idea for the grant was my own, I could not have served as principal investigator or even co-applicant since I did not have an academic post. Nor would I have been able to secure the funding with out the experience of Haimes.

The grant began in October 2001 and ran for sixteen months, to February 2003. Haimes served as principal applicant, I served as named researcher. My full duties included:

- initiated and co-wrote (with Haimes) successful funding application
- co-negotiated Local Research Ethics Committee approval (in Whitehaven)
- co-negotiated interviewee recruitment through NHS facilities
- co-developed interview aide-memoirs
- conducted all interviews
- co-analysed interviews (see below for details)
- managed £73,003 budget
- coordinated day to day operations of the project
- co-wrote Final Report
- co-authored all publications

The interview schedules were devised by both team members in consultation with the local research ethics committee and the projects' own advisory group (which consisted of Richard Ashcroft, Martin Richards and Angus Clarke). Interviews were transcribed by the University of Newcastle Data Preparation Service but all transcripts were re-checked by myself for accuracy. Haimes annotated/coded transcripts. I loaded all coded data onto NVivo 2.0 software to assist with category building and identifying themes. Both Haimes and I had responsibility for analysis, which developed through personal discussions as well as national and international conference presentations.

## Appendix II

### Mothers' Interview Aide-Memoire

#### A Study of Participation and Non Participation in the North Cumbria Community Genetics Project, October 2001 to February 2003.

Opening notes:

*Greetings and introduction*

*Thanks for helping the project*

*Reminder of why project needs their help and is interested in their views, as people who have actually been asked to contribute to a genetics database*

*Repeat request to tape*

*Assurance of privacy and confidentiality regarding all names, addresses and information*

*This looks like a huge set of questions but don't worry, I won't be asking them all!*

*Any questions before we start?*

#### SECTION 1:

Demographic information:

*I'd just like to ask you a few general questions about yourself so we have a broad picture of those people helping us with the project:*

(Complete the telephone survey questions)

#### SECTION 2: DECIDING TO PARTICIPATE OR NOT

2.1 Being asked to participate:

*OK, now I'd like to ask you a few questions about the genetics project, starting with when you first heard about the project.*

When did you first hear about it: was it when you were asked to participate or had you heard about it before then? (eg press/tv/ newspapers/leaflets/friends/community groups/WI?).

What had you heard about it before you were asked yourself?

2.1a Do you remember first being asked to take part in the project yourself?

Who asked you to take part in it?

When did they ask you to take part? How far into your pregnancy? What was this appointment originally for? How did you feel about being asked to take part in the genetics project during this appointment? (Appropriate/inappropriate?) (Why?)

Was it with this most recent baby or for an earlier child?

2.1b Can you remember what they said?

What did they say the project was for?

What did they ask you to do?

Did they say why they were asking you in particular to donate?

What were you asked to donate?

Baby's afterbirth?

Own blood?

Questionnaire info?

Other info?

Did they say why they needed these?

What were they going to use them for?

Overall, can you say what the genetics project was about/was for?

2.1c Were you surprised that they asked you to take part or were you expecting it?  
(Why?)

Do you know why pregnant women in particular were being asked to take part?

Some people say pregnant women are good people to ask to donate to a genetics project because they are having so many tests and screening that one more thing won't make any difference; others say they are the worst people to ask, for exactly the same reasons: what do you think?

Did you know why they needed samples from babies?

2.1d Did you ask any questions about the genetics project? (What? Why were these issues important to you?)

Did you ask any questions about the samples they wanted to take? (What? Why were these issues important to you?)

Who did you ask?

What were their answers like? (Clear? Confusing? Satisfactory? Led to more questions?).

Did they help? Did they address your concerns?

Did you have any other discussions or questions at that first mention of the project?

2.2 Making the decision to donate or not (most recent baby):

2.2a Did you decide to take part/refuse there and then, or did you leave it for a bit?  
(Why?)

Was it an easy decision to make? (Why/why not?)

Did you feel that you had the option to say 'no'?

Did you feel under any pressure to say 'yes'? (Why? From whom?)

Did you feel able to discuss this with them? (Why/why not? What was their response?)

2.2b Did you want to discuss this with anyone else first? (Why/why not?)

Did you have the chance and time to do this? (Why/why not?)

What did you want to discuss? Why? Why were these issues important to you?

Were you worried about anything? What? Why?

Who: Did you discuss it with anyone else? Who? Why them in particular? (Why not?)

Did you discuss it with the baby's father? (Why/why not?)

What about with your own family – mother, father, siblings etc? (Why/why not?)

Were there any particular reasons why you chose to discuss it/not to discuss it with these people? (What? Why?)

Was there anyone you wanted to avoid discussing it with? (Why?)

Did you know anyone else who had been asked to take part in the genetics project? Did you discuss it with them? Did they take part or did they refuse? Do you know why they made their decision this way? Did you agree with them?

2.2c Were these discussions helpful? Why/why not?

Did they raise any other issues you hadn't thought of? What? How important were these? Did the conversations with others influence your decision in any way? How? Why?

2.2d Was there anyone who influenced your decision particularly strongly? Who? How? Why? What did they say? Why was this important?

2.2e There were some people who publicly opposed the Cumbrian genetics project: did you have any contact with them at all? Did they influence your decision in any way? How? Why? Have you heard of CORE? Any contact with them?

2.2f Did you have any further conversations with the antenatal staff/ doctors/nurses/midwives about the project? What about? Was this helpful? Did they lessen your concerns at all? Did any concerns remain? What and why? Was there any particular member of staff who was particularly helpful? How? Why? Who did you have most contact with about this?

Did you read any of their leaflets? Newsletters? Did this influence you any further?

2.2g Overall, what do you think was the most important reason why you decided to donate/not donate? Why was this so important? What are the benefits and risks of donating? For you? Your baby? Others?

Have you made the same decision for all your babies? Why/why not? What was different about this latest birth?

2.3 The samples

*Can I ask you a bit about the samples that they were asking you to give? We're interested in whether this makes any difference to why women agree or not to take part in the genetics project.*

2.3a What samples were you asked to give?

*Clarify: So it was tissue from the baby's after birth and...? (To see if they know/remember the full range of tissue samples, cells, plasma, blood)*

Could you tell me why they wanted each of these?

What did they want to do with them?

Did you have any questions about the samples that they wanted? If so, what and why? Did you ask anyone? Who? What did they say? Were you happy with this?

2.3b Baby's samples:

Did you mind the idea of giving a sample from your baby? (Why?)

How did you feel about them asking to use the afterbirth? Did you mind? Did you care? Is it important to you? To the baby?

How would you feel if they had asked for a blood sample from the baby? Why? Is this different from the afterbirth sample? In what ways? Is it the material itself or the way of taking the sample (from the cord versus an injection?).

It is possible to take a cheek swab from the baby (by using a cotton bud on the inside of the mouth): would you have minded that? Why? Is that different from the after birth?

How? In what ways? Or different from a blood sample? How? In what ways?

So, do you have a preference what sort of sample they take from the baby? (Why?)

Did the type of sample influence your decision to donate or not? How? In what ways? To what extent? Can you say more about this?

Have you ever given samples for any of your other children before? What was that for? Was this the same or different? Why?

Did you feel that it was appropriate for you to give permission on your baby's behalf for these samples to be given? Did you have any doubts about that?

2.3c Mother's sample: What about their request to use the blood left over from your antenatal blood tests: did you mind that? Why/why not?

What if they had asked you to donate more or other samples, such as a cheek swab or hair: would you have minded that? Why/why not?

So, do you have a preference for which sort of samples they take from you? (Why?)

To what extent did this influence your decision to donate or not?

Have you ever given samples from yourself before (eg blood, urine, biopsies)? Was this the same or different? In what ways?

Did you feel differently about giving your own sample to giving one from your baby? (Why? How? In what ways?) Did this influence your decision to participate in the genetics project? In what ways?

#### 2.4 Mothers' questionnaire:

*As well as being asked to donate samples from your baby and yourself, you were asked to complete a questionnaire about you and your partner's lifestyle (show sample). I'd like to ask you a bit about this q'naire.*

2.4a Did you receive a q'naire?

2.4b What did you think about the contents? Was it easy/difficult to answer?

Did you understand why they wanted this information about you? (*ethnicity; exams; jobs; smoking; medical conditions*)

Did you understand why they wanted this information about your partner? (*ditto*)

Did you understand why they wanted this information about your wider family? (*medical conditions*)

2.4c Did you mind the idea of sharing this information with the genetics project?  
Did you discuss giving this information with your partner first? Or with your wider family?  
Did they mind the idea of giving this information?

Did you or your partner or family have any questions about the q'naire? If so, did you ask anyone about them? What was their response? Were you happy with this? (Why/why not?)

2.4d So, did you actually complete the q'naire? Why/why not? (Difficulty? Intrusiveness? Repetition? Relevance? Family objections?)  
Had you completed one before for your earlier births?

Do you know how they are intending to use this information?  
Do you know why they need this information as well as the tissue and blood samples?  
(*Seek their explanation*).

2.4e Did the q'naire influence your decision to participate in the genetics project or not?  
How? In what ways? Why? Was this an important consideration? How important compared to the other factors?

Which is the most important to you: the baby's sample, your own blood sample or your personal information? Why?

2.5 Consent form:

*Everyone who agrees to take part in the genetics project has to fill in a (yellow) consent form (show sample). Do you remember receiving a copy of this? Can I ask you a couple of questions about the form?*

2.5a Did you receive a copy?

When did you receive it?

Did you read it all the way through? What did you think of it?

Was it clear to you?

Did the consent form reassure you about any uncertainties? In what way?

Did it raise any other uncertainties? What? Why?

Did you ask any questions before deciding whether to complete it or not? Who did you ask? Were their answers clear? Were you happy with their answers? (Why/why not?).

Did the consent form influence your decision to take part or not? If so, in what ways?

2.5b For participants:

Did you complete it straightaway? Was there anything on it that puzzled you or that you didn't understand? (What and why?). Did you ask anyone about this?

When did you actually complete it?

Can you remember what you have consented to, in signing it? (*Collection, storage and use of samples from afterbirth; collection, use and storage of mother's blood sample; q'naire about mother and family; 'may involve reference to the health records of my baby and me'*).

Why do you think they need each of these pieces of information? (*Seek explanation*).

Are you happy about each of these items? Are there any that concern you?

Did you realise that the project also wanted to use your health records, as well as the samples and questionnaires? Was that OK with you? (Why/why not?)

Did you keep your copy? Do you know where it is?

2.5c For non-participants:

Was there anything about the consent form in particular that put you off from taking part in the project? What was that? Why?

Did you discuss this with anyone before deciding not to fill it in? Who was that? What was their response? What did you think of their response?

2.6 Actually giving the baby's sample: participants

You did (eventually) decide to donate to the genetics project – why was that? Who or what was the biggest deciding factor?

Was it an easy or hard decision? Why? Which parts?

When did you actually decide?

Had you decided before the day of delivery or did they ask you again then? Who asked you? How did you feel about being asked then? Why?

Had you changed your mind at any point during that time?

Did you have any final minute uncertainties or were you quite happy by then to give the samples?

2.7 Actually declining to give baby's sample: non-participants

You did (eventually) decide not to donate to the genetics project – why was that?

Who or what was the biggest deciding factor?

Was it an easy or hard decision? Why? Which parts?

When did you actually decide?

Had you decided before the day of delivery or did they ask you again then? Who asked you? How did you feel about being asked again then? Why?

Had you changed your mind at any point during the pregnancy? Why? What happened?

Did you have any last minute uncertainties about your decision? What? Why?

### Section 3: BROADER SOCIAL AND ETHICAL ISSUES

*It has been said that there are other factors, beyond those that concern the mother and baby directly, that might influence why people do or do not donate to a genetics project. Can I ask you about some of these to see how you feel about them and how important or otherwise they are to you?*

#### 3.1 Use of samples:

3.1a Do you know what the samples of the baby's after birth and your blood will be used for?

Do you know who they will be used by?

Do you know how the q'naire information will be used? Or who by?

Do you know what your medical information will be used for? Or who by?

3.1b Do you know what research work has been done using the Cumbrian genetics samples?

Do such studies have any particular importance to you or your family? In what ways? Why?

Do you know what research work will be done in the future?

Do you think these are appropriate uses? Are you happy for your baby's samples to be used in these ways?

Have you had any feedback on the studies that have been done? Would you like that?

3.1c Are there any particular studies that you would like them to do? That you would like your samples to help with? What? Why?

#### 3.2 Storage:

3.2a Do you know how long the baby's samples will be stored for? Your baby will have the right to withdraw their donation when they are 16 – do you think this is important?

Do you think s/he is likely to want to do that? Why?

Do you know how long your blood will be stored for?

Do you know how long your q'naire information will be stored for?

Do you know how the samples/ the information will be stored?

Do you know where they will be stored?

Do you know how long the genetics project will have access to your medical records for?

3.2b Was it explained how the samples / q'naires / records would be stored?

Were the time of storage and the storage system explained to you?

Was this something that bothered you? Why? How?

Did you ask any questions about this? How were they answered? Were you happy with their answers? Why/why not?

#### 3.3 Confidentiality:

3.3a Was it explained who would have access to these stored samples/ q'naires/ records?

Were you happy about that? Why/why not?

3.3b Do or did you have any concerns over what might happen to your samples? and personal info? Why? Did you ask about this? How were your questions answered? Were you satisfied with this?

3.3c Are you aware that you can ask for your baby's sample to be withdrawn from the study – can you ever see yourself doing that? Why? Under what circumstances?

3.3d Were you worried about third parties gaining access to these materials? (*prompts as above*)

Did you trust the security systems they described?

3.4 Possible misuse of databases:

*Some concern has been expressed that once these samples and information are stored on a genetics database that others might have access to that database either legally or illegally – is that something that worries you? In what ways? Why?*

*(Concerns break down into: who might gain such access; how they might use it; whether the donors might be identified and consequences of that)*

*(Prompts to use below: did this influence interviewees' decision about participating in any way? In what ways? How strongly?).*

3.4a There are some things that the Cumbria genetics database won't be used for – do you know what these are? Do you know why there are limits on the uses of this information? Do you agree with those limits?

3.4b In particular some people are concerned that insurance companies might seek the right to access this information: does that worry you? In what ways? Why?

3.4c Others have mentioned that employers might want access to this information? Again, does that worry you? In what ways? Why?

3.4d Some have argued that the police might be interested in having access to such a large database: does that concern you? In what ways? Why?

3.4e It has been suggested that there should be a special organisation regulating and protecting databases to avoid misuse – do you agree with this? Why/why not?

3.5 Role of BNFL:

3.5a The Cumbrian genetics project is unusual in that it was partly funded in the beginning by BNFL; did you know that? Does that surprise you? Was that something that concerned you? In what ways? Why? Do you know anyone who was concerned by that? Did this influence your decision about participating in any way?

3.5b It has been suggested that BNFL is such an important employer in the area that people don't mind their involvement in projects such as these? Another view is that because they are so important they shouldn't have a role in projects such as these since

people might feel that they've got to donate – do either of these positions apply to you?  
In what ways?

3.5c What about the fact that the genetics project was partly run by Newcastle University – did this make any difference to you?

### 3.6 Commercial uses

Another issue that has been raised is the possibility that private companies, like drug manufacturers might use genetic databases to develop their products – does that bother you? What about the fact that someone might be making a profit using samples that have been given for free? Do you feel that donors should be paid for their donations or that these should be given for free? Would you want something in return? Some people say that these donations are a gift – is this what you think? A gift to whom? How does that tie in with companies possibly making a profit from such gifts? Who do you feel owns those samples now? And the personal information – same or different?

### 3.7 Feedback:

Another issue that worries policymakers about genetic databases is whether those people who donate their samples should be given feedback about their own genetic health.

3.7a Was this something that interested you? Was this something that you wanted? In the NCCGP you cannot have access to this information – did that bother you?

3.7b Did you understand why the genetics project can't provide that? Did you want it? Did you ask about this? What was said?

3.7c Can you imagine any difficulties with individual mothers and babies being given such feedback?

### 3.8 Re-contacting donors:

Another area that has caused some concern is whether people who have donated samples to a genetics database can be recontacted in later years to see how they are getting on, healthwise

3.8a Would you mind this happening to you or do you feel you've done your bit and don't want to be bothered further?

3.8b What about your baby being recontacted? Do you think that would be alright?

### 3.9 Previous knowledge/views about genetics

3.9a Another suggestion has been that people with lots of previous knowledge or experience of genetics (eg through a family illness) might be more happy about donating than those with less knowledge.

3.9b Does this apply in your case? Do you have any interest in genetics? Have you heard any of the stories associated with genetics (Dolly; human cloning; GM crops). What do you think of these developments?

3.9c Were you influenced at all by things such as family illnesses? Have you heard much about genetic databases before? Had you heard about genetic databanks before being asked to help the Cumbrian genetics project? Where did you hear about them from?

3.9d Some people view anything to do with genetics as being 'bad', others as being 'good' – where do you fall on this? What makes you think this? What are the bad aspects and what are the good aspects of genetics and genetics research?

3.9e Have you had an increased interest since being approached? Has this encouraged you or discouraged you in participating?

3.10 National genetics database:

3.10a It has been suggested that the government should fund a national database, ie not just taking samples from West Cumbria but from people around the whole country – had you heard about this? what do you think of this idea? Would you favour it? Would you have any reservations about it?

3.10b What about the issues just mentioned – would you think they were more or less likely to cause concern if a national database were set up?

3.10c Would you contribute to a national database? Would it make any difference to you if the samples were collected and stored by people not based in Cumbria or Newcastle? In what ways?

3.10d If we had a national database would you think that people should be made to contribute to it or should it be up to them? Why?

3.11 Genetics in the wider scheme of things:

*Related to the previous questions, it has also been suggested that these questions about the ethics of genetics (storage, confidentiality, misuse etc) are not all that important to people being asked to donate to the databanks – is that so, in your case?*

3.11a The general line is that people have far too many other things to worry about (jobs, money, family, health, housing etc) to worry about such matters – does that apply to you? One suggestion is that these other worries mean that people aren't all that interested in donating because they've got these other things to worry about; the other line is that people don't mind donating because it is such a little thing to ask – do either of these apply to you? In what ways?

3.11b Another suggestion is that women are happy to help the Cumbrian genetics project simply because they want to help with research in general – is that the case for you? And that it's so easy to give the samples, which are of no use to them anyway that's it's no big deal – is that true for you? Why/why not? In what ways?

3.11c Do you think it's a good or bad idea to ask pregnant women to donate to a genetics project? Some people have suggested this isn't a good idea because they are so busy preparing for their baby; others say it's a good time because that's when ideas about genetics, family likenesses, inheritance, etc are most on women's minds: what do you think?

3.11d Are there any things that run in your family that you and relatives talk about? Eg hair colour, physical features, illnesses, abilities? Is it a big topic for you and your family? Did this influence your decision to participate or not?

3.12 Cumbria as a community

*It has also been suggested that people in West Cumbria are happy to help as they are a settled, stable community. Also that they are an important community to study because they are so stable.*

3.12a How do you see West Cumbria? Do you think it is like/unlike the rest of England? Britain? How would you describe the people here? Do you think this picture is accurate?

3.12b The majority of women have been happy to help the genetics project – does that surprise you? Why do you think so many women help? Can you understand why some women might refuse, even so?

3.13 Advice to others:

*There are lots of people interested in the views of people such as yourselves (ie the government, the doctors and nurses, other researchers etc):*

3.13a What would you say to these people about genetics databases? What's the most important lesson you want them to hear from you?

3.13b What if another pregnant woman asked your advice about whether to donate from your baby – what would you tell her? Why?

Concluding notes for interviewer:

Ask if the interviewee has any questions

Thank her for her time

Reminder about confidentiality

Reminder that will distribute anonymised report after the study is finished.

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