

Chapter One

Introduction

“Would you tell me, please, which way I should go from here?” Alice asked the Cheshire Cat. “That depends a good deal on where you want to get to,” said the Cat (Carol 1988).

Background to the study

Towards genetically modified health

Technological change is enabling the world to become a smaller place. With each passing day, there is news of breakthroughs in research and development unleashing a wave of new technological possibilities upon a global community that has grown to expect, even rely upon, the capacity for continuous change. Indeed, for many in developed nations it is difficult to think of life without, for example, mobile telephones, e-commerce, and babies on demand, whether through *in vitro* fertilisation or the caesarian section. And while the pace of change shows no sign of slowing down, history shows us that it is exceedingly difficult to anticipate, let alone understand, all the likely consequences of technological change. The slow environmental degradation of the planet through chemicals such as DDT, even as they yield benefits for humans, illuminates the difficulties in predicting the impacts of technological change. As pointed out by David Suzuki, “[h]owever beneficent, technology always has a cost” (1990, p.56).

Now the promise of genetically modified (GM) health is coming under scrutiny. More commonly known as “molecular medicine”, so far its development has escaped the intense public scrutiny that has characterised the drawn-out and contentious development of GM foods (see Coveney and Carman 1999; Prowse 1999). Instead, there is a growing portrayal that molecular medicine will revolutionise healthcare delivery and medical practice, and thereby usher in a new and unprecedented era of good health (see Time 1999). At the heart of this vision is “the gene”, which has achieved an elevated status over the last decade.

This popularisation owes much to the work of eminent scientific figures, such as James Watson. Subsequent to his work on the structure of deoxyribonucleic acid (DNA), he

boldly declared that “we used to think that our fate was in the stars. Now we know, in large measure, that our fate is in our genes” (cited in Hubbard and Wald, 1997, p.vii).

Molecular medicine is spearheaded by innovations across several areas of scientific activity, including molecular biology, biotechnology and genomics. Molecular biology seeks to understand biological phenomena in terms of molecular structures (Wheale and McNally, 1988, p.3), whereas biotechnology relates to the deciphering and application of biological knowledge. A central technique of modern biotechnology is genetic engineering, which relates to processes of isolating, modifying, multiplying and recombining genes (Ho, 1998, p.19). Genomics is the most recent innovation and is the study of genes and their function (Poste, 1995, p.165).

Together, these scientific fields are reshaping notions of health and health care. Krinsky (1991, p.25) perhaps best explains the promise of the innovation possible through molecular medicine, which is capable of generating

[P]roducts never before available, products that are currently in short supply, products that cost substantially less than products made by existing methods of production, products that are safer than those that are now available, and products made with new materials that may be more plentiful and less expensive than those now used.

Gene therapy is the epitome of molecular medicine. It involves supplanting “defective” genes with their “normal” counterparts in an attempt to cure disease. It is increasingly seen as the new horizon in health care — the fourth great advance after sanitation, anaesthesia, and pharmaceuticals (Morgenthaler, 1993, p.10).

The sheer strength and scope of the GM vision for health care has captured broad popular appeal and there is a clear sense of inevitability about it, although this is also the message of those promoting it. A “flood” of genomics news stories and press releases found on wire services carry that popularisation, attesting to breakthroughs in research related to the role of genomics in the treatment of a growing number of ailments. That list includes significant sources of human suffering and premature death in industrialised societies, including Alzheimer’s disease, breast and other common cancers, coronary heart disease and diabetes.¹ Additionally, it also includes areas of

¹ See, for example, random stories from various wire services: “Stem cells may restore neurons”, 8 June 1999a, Associated Press; “Scientists homing in on a cancer-killing gene”, 6 January 1999a, Reuters;

human social behaviour, for which modern research methods are now portraying as new frontiers.²

Such news releases fuel the perception that particular health problems originate within the genetic structure of individuals. However, there is also a contesting view, not widely propagated outside academic circles, that many of the reported research claims are not particularly noteworthy. Instead, they draw attention away from other health issues that need to be adequately addressed (Hubbard and Wald, 1997, p.5), as well as from other viable health approaches. Some commentators critically point out that while such articles suggest that genes are involved in all sorts of conditions and behaviours, all that is really indicated is that a great deal of money is being spent on genetic research (Hubbard and Wald, 1997, p.5).

The Human Genome Project

The Human Genome Project (HGP), which formally instigated and popularised genomics, is the greatest source of funding for basic genetic research into the human condition. Acclaimed as biology's first "big science" project, it is an international collaborative research program, supported by various governments and private sector interests (Lewin, 1990, p.20). Established in 1990, the HGP incorporates a variety of research goals, strategies and resources including a US\$3 billion commitment from the US government. Although governed by a number of scientific aims, the US government supported the project for four key reasons. These include the scope to boost biomedical research, keep the US in the lead in biotechnology advances, enhance national prestige and stand as a major cultural achievement (Cook-Deegan, 1991, p.157).

Most significantly, the project seeks to map and sequence the entire human genome in order to contribute to an understanding of the processes underlying human disease. Initially, researchers envisaged that it would take 15 years to map and sequence the estimated 80,000 – 100,000 genes in the human genome. However, the discovery of various "short-cuts" in research, breakthroughs in information systems, and the

"Cervical cancer vaccine on the way", 20 February 1999, BBC; "Gene therapy might help cholesterol", 10 June 1999b, Reuters; "Gene found that may cause diabetes", 13 May 1999b, Associated Press, *Genomics Today*, <http://www.phrma.org/genomics/today/index.html> (accessed September 1999).

expansion of the project to include at least 18 countries and an ever-growing number of private interests, significantly reduced the time frame.³ The rough draft of the estimated three billion nucleotides, which when arranged in sequences represent genes, was completed in June 2000. It was thereby established that the human genome “only” contained approximately 30,000 genes (HGP Information 2001). The entire high-quality sequence is predicted to finish in 2003 and will precipitate many other research projects, including work to define all the common variants in the genome and the hereditary factors in virtually all common diseases (HGP Information 2001; Collins and McKusick, 2001, p.542). Like the HGP, those other projects will involve years of work. Even so, the current rate of progress indicates that the prospect of GM health is looming near.

Yet, in contrast to many other controversial technological breakthroughs, high-level public recognition has emerged about many ethical, legal and social issues raised by human genomic research. Notably, this led to the establishment of the Ethical, Legal, and Social Issues (ELSI) working group by the US public institutions funding the HGP, namely the Department of Energy (DOE) and the National Institutes of Health (NIH). Since the HGP’s inception in 1990, the ELSI working group has investigated and documented varying ethical, legal and social dimensions and implications of the research. Genetic information and health insurance and safe and effective genetic testing are key topics examined (Clayton, et al. 2000, p.3), and has generally contributed to a better understanding of how genetic information may affect peoples’ lives.

Nonetheless, such research has fallen short of substantively critiquing the HGP and where it is leading, which is not surprising as ELSI was conducted by those developing the project (Annas and Elias, 1992b, p.275). Consistent with the minimal critical analysis by which to seriously gauge the potential impacts of the HGP, powerful scientific, government and business interests have all enthusiastically hailed human genomic research as the way of the future for health (Hubbard and Wald, 1997, p.6). But what are the real implications of such “Big Science” for health? And, in light of the

² For example, “Genetic factors linked to anxiety in females”, 30 September 1999c, Reuters; “Is happiness genetic? Twin study shows strong link”, 8 October 1999, PR Newswire, *Genomics Today*, <http://www.phrma.org/genomics/today/index.html> (accessed October 1999).

³ Beyond the United States, large research programs have been established in Australia, Brazil, Canada, China, Denmark, the European Union, France, Germany, Israel, Italy, Japan, Korea, Mexico, the

increasing scale of the investments made in such research, does it represent the most effective use of scarce resources? Who will have access to the new technology, and on what terms? Will the interests of the private sector predominate, or will public input be used to ensure that the technology will be used in the widest possible way? Does the molecular approach really offer the solutions for community health, especially given the existence of other alternative low cost approaches, and the escalating problems of modern medicine as evidenced by more people becoming ill and continually expanding national health budgets? These are just a few of the profound questions that such research raises.

The research problem – definitional problems and background

Health is described as the most individual of all private possessions, and is difficult to define let alone measure (Hart, 1985, p.2; Reisman, 1993, p.5). A myriad of different definitions relate to conceptualisations of health as soundness of mind and body (Sax, 1990, p.1); as a state of total physical, mental and social well being that extends beyond the absence of disease and infirmity (WHO 2002a); or as a fundamental right without which an individual cannot access other rights nor enjoy quality of life (Hancock, 1999, p.6). The most widely accepted definition of health, however, is biomedical, which is overwhelmingly concerned with biological processes of health and ill health (Mishler, 1981a, p.3). By way of contrast, other models of health, including the biopsychosocial, ecological, and new public health models, place much greater emphasis on the varying social, economic and environmental factors associated with health and ill-health (Germov 1998). Specific factors such as the sense of control an individual has over his or her own life and whether the individual is exposed to pollutants in their background environment, are indicative of the broader health approach.

The biomedical model of health, manifest in a style of care individually and technologically focused, cure-oriented, hospital-centred and professionally dominated, is credited by proponents with advancing health status for individuals and populations alike in developed nations. On average, people in those countries can expect to live long and productive lives. Immunisation and the technical prowess of procedures such as open-heart surgery have been fundamental to biomedicine's success. And other

Netherlands, Russia, Sweden and the United Kingdom. A number of developing countries are also participating in the project (HGP Information 1999).

procedures, especially those associated with the HGP, such as gene therapy, appear central to its future.

Yet, beyond biomedicine's achievements, some observers argue that it may be reaching its outer limits, and that other approaches are also needed to confront many contemporary health challenges:

We may have won the struggle against a large number of diseases, especially the infectious ones, but instead we are facing other health problems, especially degenerative diseases, malignant diseases and the so-called psychosomatic disorders, which are much more difficult to treat and at present impossible to prevent. Anybody who follows the development of medicine will know that progress continues in a large number of fields, but at the same time it is impossible to suppress the suspicion that the major health problems of the day cannot be solved within the conventional framework of ideas (Wulff, et al. 1990, p.10).

That situation brings into question the appropriateness of biomedical dominance, which has been achieved and sustained, to a significant extent, by efforts that aligned biomedicine with political and social elites but which also undermined support for other health models. It also provides additional context by which to seriously question the purpose and viability of human genomic research.

Although significant arguments in favour of reforming the health context may exist, any policy process has considerable capacity to be shaped by broader political and economic environments. A key factor in the background or "framing" environment is the phenomenon of globalisation, which has become an increasingly important analytical concept within the last decade. While capable of being represented on different levels, and as a concept that is both modern and historically defined, globalisation refers to a complex process synonymous with the continuing advance of the modern age. It is most evident in a process of accelerated and rapid economic change that is blurring traditional geographic, political, economic, social and cultural boundaries (Waters, 1995, p.3).

Globalisation is emerging as a powerful dynamic that exerts a growing influence on our daily lives. While this influence is perhaps most pronounced in the escalating international trade in goods and services and the vicissitudes of financial markets, globalisation also has significant potential to shape other areas of contemporary policy

debate, including the future directions of health. Health is, after all, one of the largest sources of global expenditure, that is also steadily increasing, and which accounted in the early 1990s for approximately nine per cent of the world's total product annually (WHO, 1999, p.31). This fact alone ensures a keen level of interest in the future of health and, in the context of this study, suggests that the dynamics of globalisation significantly influence particular approaches to health, advantaging some and disadvantaging others. Exploring that power dynamic and its distinct ideological and industrial tenets is the dominant theme in this study and leads to the central research problem.

As noted earlier, great expectations exist about the HGP and its role in the future of health and health care. The thesis explores this rapidly emerging approach in a way that raises questions about its capacity to meet ongoing and growing health needs, and its impacts on alternative and perhaps more viable approaches to health. Within this context, globalisation is potentially extending the dominance of the biomedical model, which may further marginalise alternative models of health while consuming greater resources for fewer real health outcomes. Exploring that possibility involves gaining an understanding of who and what is driving the current directions of human genomic research, and what the research agenda represents, both globally and locally, for health care delivery. This leads to the research questions of this thesis: how does the HGP shape ways of thinking about health; what influence does globalisation have on this process, particularly on decisions about models of health; and what has this meant for smaller nations such as Australia?

In addressing this problematic, the thesis employs a multi-disciplinary research focus, which offers an insightful nexus drawn from the extensive academic literature on biomedicine, the literature more recently established around globalisation, and the literature on the topic of the HGP. By drawing links between these traditionally "stand-alone" subjects, the thesis engages a wider perspective than conventionally sought on the potential outcomes of human genomic research. The broader perspective is important given the sheer magnitude of the change foreshadowed by the HGP and the very real difficulties in anticipating the implications of such change. Finally, the focus on Australia differs from the preoccupation with much larger nations, namely the US, which with a different historical, institutional and cultural background, is bound to participate in human genomic research very differently.

Theoretical framework

No singular theory dominates the thesis. Instead, an eclectic theoretical framework is adopted, but one that draws heavily upon political economy and historical sociology to provide a largely structuralist analysis of the emerging health context. This approach was selected because it offers the most useful conceptual framework for providing answers to the kinds of questions raised in this thesis — questions which relate to the power to allocate resources and influence the direction of research, where actors influencing those elements primarily occupy structural positions of power.

Biomedicine, noted earlier as the dominant health model, provides a key theoretical frame of reference for the analysis. This model, which is the subject of a rich and extensive sociology, generally characterises health as being scientifically based, curatively focused, professionally-dominated and hospital centred (see Mishler 1981a; Hart 1985; Freund and McGuire 1991; Gerhardt 1995). Those specific characteristics, which emanate from a predominantly mechanistic and reductionist perspective, helped the biomedical model become, by the 1930s and 1940s, politically and economically aligned to the capitalist infrastructure (Brown 1980). That alignment was vital to the successful establishment of biomedicine as a tradition in its own right. Up until that juncture, the biomedical model enjoyed no special status and was often an unpopular option in a range of competing health care choices. The future prospects for biotechnology, and GM health in particular, may also be seen as tied to capitalist infrastructure. Without the same political and economic structures and dynamics, it is extremely doubtful whether human genomic research would receive the scale of endorsement and interest that it does today.

Political economy assessments of health argue strongly that it is biomedicine's links to the capitalist infrastructure, as opposed to its inherent efficacy and efficiency, which sustains this paradigm over "other" or non-biomedical health approaches, such as the biopsychosocial, ecological and public health models (Brown 1980; Navarro 1986; Doyal 1994). Over time though, growing evidence that society has overestimated the effectiveness of the biomedical approach, and simultaneously underestimated its limitations, has created interest in reforming health care. That momentum is most apparent in the perpetual sense of "crisis" that seems to envelope biomedical care (Navarro 1986; Moynihan 1998), and also in the steadily increasing popularity of non-

biomedical or complementary approaches amongst consumers (Sharma 1995). Widespread calls advocate a broadening of the base of the dominant biomedical model to better incorporate social, economic and environmental determinants addressed more explicitly by other models (Evans and Stoddart 1994; Germov 1998). In that regard, it is arguable whether the dominant biomedical model is the only way, or necessarily the optimal way, of conceptualising and delivering health. If so, this raises the possibility that if GM health is structurally consistent with the biomedical paradigm, it may be inappropriate, and ultimately unable, to meet the broad population's ongoing and future health needs.

Economic globalisation provides the other dominant frame of theoretical reference. It provides a rich background by which to better understand the forces driving the biomedical model and the capacity for systemic change to conceptualise and ultimately manage health better. Globalisation as a process may be understood from a variety of theoretical perspectives. Marxist analyses of globalisation draw from the observation that capitalist accumulation occurs in patterns or cycles, which cause it to be uneven and crisis prone (Harvey 1992, pp.180-181). Those patterns have been distinguished as "long" or "Kondratiev" waves of economic expansion, recession, depression and recovery that may last for several decades (Delbeke, 1981, p.248). Innovative science and technology is acknowledged as playing a key role in this process. Schumpeter, for example, argued that technological innovation is at the centre of both economic growth and cyclical instability, and that innovations tend to cluster around points of time, known as "neighbourhoods of equilibrium" (Rosenberg and Frischtak, 1984, pp.22-23). Hindmarsh (1998b) has tied those strands of theory to biotechnological innovation and change.

In turn, regulation theorists provide additional insights into the cyclical nature of the capitalist system, and, in particular, illustrate how labour relations are historically produced and the ways in which the system is prevented from collapsing (Bonefeld, 1991, p.37). Such analysis typifies cyclical crises as evidence of historical junctures and disjunctures between "regimes of accumulation" and "modes of regulation" (Aglietta 1979). The interplay between innovation-based and regulatory elements are central to understanding the modern structural context of globalisation, and, in turn, whether it is extending the dominance of the biomedical model. To that end, the theoretical framework also draws significantly from historical sociology, and the

assessments by McMichael in particular, to explore globalisation as an evolving historical project with distinct institutional and ideological relations (McMichael, 1996a, p.28).

Given that broad picture of the methodology and research problem, we can now better identify the structure of the thesis.

A note on methodology

The theoretical approach adopted defines the methodology. The approach for observing the shaping of health through human genomic research and the role of globalisation is largely descriptive and historical, and informed by a variety of interpretations from political economy and sociology including structuralist theory, science and technology studies, health studies, feminist perspectives and post-structuralist perspectives. Data collection included both primary and secondary sources and archival materials. This allowed a broad perspective to be gained on the future of health care.

Structuring the thesis

Chapter Two explores the definitional basis of what we commonly understand as health, and focuses on the dominant or biomedical tradition. It highlights the origins and development of the biomedical model, its central features and the processes by which it attained prominence over other models of health by the 1930s and 1940s. Dominance aside, the biomedical model represents only one of a number of ways of conceptualising the delivery of health care.

Chapter Three continues the focus on the biomedical tradition, but offers a critical perspective. This employs an array of approaches, broadly synthesised in terms of a political economy of health care. A key element in the analysis is the exploration of the dialectical position where the biomedical model is both at the height of its popularity and is also subject to unprecedented criticisms (Porter 1996; Moynihan 1998). The latter are evidenced in the growing appeal of, and demand for, alternative models of health (Sharma 1995). This exploration facilitates an assessment of the continued viability of the biomedical model in its current form. With regard to the practical limitations of the biomedical model, the discussion highlights the looming importance

of broadening the basis of biomedicine to explicitly incorporate the social, economic and environmental factors in the experience of health and illness championed by other health models.

Chapter Four addresses the globalisation process, and in particular, how it frames the contemporary health policy environment. The chapter examines the role of regulation and innovation in stabilising processes of capital accumulation and puts this into historical context. Globalisation is explored as a project that evolved out of what McMichael (1996a) refers to as “the development project”. Assessing the specific ideological and institutional bases on which globalisation rests allows us to understand the capacity of policy processes to adopt and comprehensively support novel responses to health problems. Indeed, the chapter shows that globalisation narrows the basis of policy decisions, including those related to health, and would instead promote the continued evolution and domination of the biomedical model over any alternate model or combination of models.

Chapter Five provides an examination of the historical political economy of molecular biology and biotechnology. It seeks to establish whether such innovations are consistent with the frameworks supported by globalisation dynamics. In doing so, it explores the origins and development of molecular technologies, the associated political and economic interests, and any attendant or background issues associated with their ongoing development. The chapter concludes that, in ideological and industrial terms, molecular biology and biotechnology have indeed shaped and, in turn, been shaped, by processes of economic globalisation. They did not evolve autonomously.

In turn, *Chapter Six* explores whether the HGP is consistent with that political economy. An important consideration in the critical analysis is the likely scale of private sector involvement in such research and development, and how that may affect the outcomes. The chapter establishes that the HGP can be understood as a globalised and contemporary solution to health premised on the logical extension of the biomedical model. Multinational pharmaceutical firms have gained the controlling stake in the fast emerging genomic map and have much to gain, politically and economically, by explicitly reshaping the health context around molecular “models”.

Chapter Seven provides an account of the origins and development of genomic research in Australia and contextualises this development as part of the local social history of health care. In the context of the nation's particular historical and institutional background and the specific responses to globalisation, the chapter highlights how Australia's medical biotechnology and genomic interests have come to enjoy increasing political and economic patronage over the last decade, but, at the same time, how this process has inevitably strengthened the power of local medical elites.

Finally, as the concluding chapter of the thesis, **Chapter Eight** sums up the findings of the study and reflects upon their likely implications.