

**How does the operation of PHARMAC's 'Community
Exceptional Circumstances' policy align with the
distributive justice principles of fairness and equity as
described by John Rawls and Amartya Sen?**

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List of Abbreviations

ABS	Australian Benefit Scheme
ACC	Accident Compensation Corporation
AIDS	Acquired Immune Deficiency Syndrome
AMA	American Medical Association
AUT	Auckland University of Technology
AUTEC	Auckland University of Technology Ethics Committee
BMJ	British Medical Journal
CAC	Community Advisory Committee
CADTH	Canadian Agency for Drugs and Technology in Health
CaEC	Cancer Exceptional Circumstances
CaTSoP	Cancer Treatment Sub-Committee of PHARMAC
CEC	Community Exceptional Circumstances
COX-1	Cyclooxygenase 1
COX-2	Cyclooxygenase 2
CT	Computerised Tomography
CUA	Cost-utility analysis
DAP	District Accountability Plan
DHB	District Health Board
DHBNZ	District Health Board's New Zealand
DoH	Department of Health
DPMC	Department of Prime Minister and Cabinet
EC	Exceptional Circumstances
FSH	Fluorescence in Situ Hybridization
GDP	Gross Domestic Product
GP	General Practitioner
HER	Human Epidermal Growth Factor Receptor
HEC	Hospital Exceptional Circumstances
HPC	Hospital Pharmaceuticals in the Community
MMP	Mixed Member Proportional
MNZ	Medicines New Zealand
MP	Member of Parliament
MRI	Magnetic Resonance Imaging

MS	Multiple Sclerosis
MSD	Ministry of Social Development
NCWNZ	National Council of Women New Zealand
NICE	National Institute for Clinical Excellence
NHC	National Health Committee
NHS	National Health Service
NPPA	Named Patient Pharmaceutical Assessment
NZAF	New Zealand AIDS Foundation
NZCHP	New Zealand Chartered Health Practitioners
NZMJ	New Zealand Medical Journal
NZORD	New Zealand Organisation for Rare Diseases
NZPDA	New Zealand Public Health and Disability Act 2000
NZPHA	New Zealand Private Hospitals Association
OECD	Organisation for Economic Co-operation and Development
OIA	Official Information Act (1982)
PHARMAC	Pharmaceutical Management Agency
PHANZ	Public Health Association New Zealand
PTAC	PHARMAC Therapeutic Advisory Committee
QALY	Quality Adjusted Life Year
OPD	Out Patients Department
QC	Queen's Council
RACS	Royal Australasian College of Surgeons
RHA	Regional Health Authority
RMI	Researched Medicines Industry
TPPA	Trans Pacific Partnership Agreement
TSQ	Text Search Queries
TV3	Television 3 (Ltd)
TVNZ	Television New Zealand (Ltd)
UA	Urgent Assessment
UCC	Unique Clinical Circumstances
UK	United Kingdom
WHO	World Health Organisation
WINZ	Work and Income New Zealand

Attestation of Authorship

I hereby declare that this submission is my own work and that to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor any material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signed:.....

Dated:.....

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Ethical approval

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Abstract

This thesis explores how government funded public health agencies distribute or ration resources to citizens. Utilising John Rawls' (1971) and Amartya Sen's (2009) principles of distributive justice, four test-questions are proposed to assist decision makers analyse the fairness and equity of their rationing decisions. PHARMAC, the agency responsible for the procurement and subsidisation of medicines in New Zealand, is used as an exemplar through which to investigate the elements of distributive justice described by Rawls and Sen.

Specifically, research was conducted into PHARMAC's 'Community Exceptional Circumstances' (CEC) policy. Under this policy, in a capped government funding environment, the pharmaceutical needs of the whole society are rationed against the needs of people whose needs are considered 'exceptional'. Data were gathered from official documents, PHARMAC's governing legislation and a New Zealand Court of Appeal case which tested the legal validity of the CEC policies and procedures. Data were also gathered through studying 23 media stories about CEC. Key informant interviews were conducted of past or present PHARMAC senior staff, Ministers of Health and patient advocate groups.

The research shows that PHARMAC's general allocative policies have been highly successful in procuring an adequate range of quality medicines at internationally low prices, saving the New Zealand health system approximately \$1.17 billion in 14 years. This has been achieved by methods of utilitarian efficiency analysis (cost-utility analysis and Quality Adjusted Life Years) and careful purchasing decisions based on evidence of clinical effectiveness. PHARMAC has also taken advantage of its exemption from Part II of the New Zealand Commerce Act (1986) using market dominance to exercise monopsonistic procurement practices. PHARMAC has been accountable to Parliament and the public and demonstrated effective use of substantive opportunities imparting the greatest pharmaceutical benefits for the greatest number of people with the funding provided to it. However, PHARMAC's success has been achieved, in part, by managing the claims of individuals in

exceptional circumstances in a way that has not closely aligned the Rawls' and Sen's principles of fairness, equity, openness and consistency.

The research shows that using the functions required of it by governing legislation, PHARMAC well achieves its statutory purpose. However, in doing so, PHARMAC must deal with the tension between justice as fairness to individuals whose needs are exceptional, and fairness to the needs of wider society. The test-questions developed in this thesis propose a template for decision makers to explore and understand this tension.

Chapter 1: Introduction

What is this Thesis About?

The central theme of this thesis is distributive justice. This type of justice deals with the fair and equitable distribution of a country's resources. This subject has been written about by many people in the past, however I have drawn on contemporary philosophers John Rawls and Amartya Sen for a view of distributive justice. These philosophers have provided a useful framework by which to examine how countries meet the competing demands for all types of government services on the basis of fairness and equity.

Relative to other Organisation for Economic Co-operation and Development (OECD) countries, New Zealand is not a rich country in terms of gross domestic product (GDP) per person. One important competing demand for resources is publicly provided health care. New Zealand is not alone in having limited resources for health care. Perforce, it must be decided what treatments will be provided and to whom. Some will receive treatment and some will not. The most difficult and complex problem facing all OECD governments is deciding what economic processes and what measures of justice should be applied to these decisions.

People have expressed strong feelings about rationing and writers have theorised and philosophised about it. Over my life I have developed a personal and professional interest in health rationing across a variety of roles in the New Zealand public health system. I have worked as a podiatrist, health company director, university educator, health service manager, senior civil servant, principal advisor to a large non-government organisation and I have been a user of the service. I find the question as to which resources are distributed by which people, on behalf of whom, for the benefit of which people, and controlled by which people a deeply complex and fascinating study of justice and power. I have been puzzled by these questions from the first day I stepped into a hospital to begin work in 1977.

There are very many types of health rationing, too many to explore in this thesis. Consequently, I have decided to examine one aspect of government

health rationing: the subsidisation of state funded pharmaceuticals in New Zealand. I do so in order to understand more generally how distributive justice principles can develop learning which might translate to rationing in other areas. However, the question I am more fully examining is *how* this is actually done. What are the policies and processes which bring us to the point of providing or withholding medicines to a person needing pharmaceutical health care?

In this thesis I will be studying New Zealand's government medicine management agency, PHARMAC¹. This agency is responsible for making decisions about the supply of medicines to both the wider population and to people whose circumstances are considered 'exceptional' (Ministry of Health, 2006).

My experience as a clinician has been that in some way all people are exceptional. As my career progressed, I came to understand the uniqueness of each person, and the distinctiveness of each clinical condition. Everyone is different, not only clinically and anatomically but also personally. There are even marked differences between people suffering the same diagnostic condition. It has also been my experience that many people required only ordinary uneventful low-cost care and others enjoy such good health that they did not need very much from the health system at all. Conversely, some individuals were 'exceptional' insofar as they needed expensive treatment and placed a very high cost on the system. In meeting the needs of these individuals, I saw that many others may have been denied access to the care they needed when high-cost treatments were provided to these 'exceptional' patients.

How much cost per person is too much? As a country do we have processes to decide this? Are the processes rational and fair? Should the government provide the decision makers with more money so that the health needs of many more people could be met? Indeed, if the government did provide more health dollars for more services, would this necessarily mean that more people will receive care? Would providing more money for public health mean that other sectors like education, police, welfare or public housing would be given less? Should balancing the financial costs and benefits be the yardstick of decision

¹The name PHARMAC is an acronym of Pharmaceutical Management Agency

making? Should a person's level of need be the yardstick? Should clinical assessment trump all other considerations? Should the government be distributing maximum benefit to the greatest number of people? Should there be an abandonment of the needs of those who are at the margins? These questions all appeal to the principles of distributive justice for answers.

An Introduction to Distributive Justice

The many resource allocation questions posed above are pragmatic moral, social and political questions. They are all underpinned by sets of beliefs and values which we each hold to be true. If these beliefs and values were to be developed into conversations, they would generate many thousands, possibly hundreds of thousands of differing opinions on these questions. Therefore, an examination of the sets of values which underpin rationing decisions is necessary.

Raanon Gillon (2006) contends that when thinking about public distributions, there are few notions of distributive justice which can command a wide acceptance among Western jurisdictions. When we ask how an individual should be treated in relation to the whole society in which that person is a powerless (or powerful) member, Rawls points to one answer and Sen to another.

John Rawls and Amartya Sen have contributed much to the descriptions and understanding of the principles of justice as fairness. Professor John Rawls was an American philosopher and teacher whose major contribution to moral and political philosophical theory was based on the equity principles of Aristotle, Kant, Hobbs, Bentham and Mill. Aligned to Nozick's real world views of justice, Rawls developed a definition of a theory of justice as fairness. He published two books, *A Theory of Justice* (Rawls, 1971) and *Political Liberalism* (Rawls, 1993) which articulated this theory.

Amartya Sen is a contemporary welfare economist, philosopher and winner of a Nobel Prize for economic science in 1998. He developed a modern view of dominant philosophical theories of justice which stand apart from the enlightenment theories of Kant, Bentham, Mill and Dewey. Aligned to the work of Martha Nussbaum, Sen draws on *A Theory of Justice* in his own work *The*

Idea of Justice published in 2009. In this book, like none before him, Sen took Rawls' predominant theories of distributive justice, which identify what perfectly just societal arrangements might be, and expanded on them. Sen has included an understanding of how costs and benefits fit into a justice paradigm and clarified different perceptions of distributive justice in terms of a person's capability to experience justice. Sen's notions of justice are ultimately linked with the lives of people and how those lives are lived in the world.

State Distributions in New Zealand

The starting point for analysing social policies which result in the distribution of government funding is an examination of the social and theoretical traditions which are built up over time. These have been established from accepted sets of underlying assumptions (Cheyne, O'Brien, & Belgrave, 2005). These assumptions are difficult to describe and cannot be universally accepted. Deane's (2000) description of the New Zealand social and political landscape included viewing New Zealand as a liberal democracy with a rule of law and courts, property rights, a fair electoral system, limited powers of the state and respect for the partnership between Maori and the Crown as described in the Treaty of Waitangi.

Based on these assumptions, there are collections of loosely and commonly held views which underpin the opportunities for government through a range of institutions and service policies (Cheyne, et al., 2005). These institutions of government (and their operating policies) aim to utilise the underlying assumptions described by Deane, to establish guidelines and interventions (Baehler, 2000, 2003). A normative social theory looks principally at the consequences of drawing on these ideas which define our government in New Zealand to validate knowledge of the social distributions made by it.

However, such an approach requires the presence of a social theory by which solutions can be arrived at (Cheyne, et al., 2005). A social theory does not simply assume that a set of facts exists and the analysis of these facts will bring an obvious conclusion as to what state interventions and distributions should be made. It is tempting to think about the distribution of state resources in this way (a calculation which is limited to a quantifiable analysis) as a measure of how social policy should determine fair and just and desirable outcomes. However,

there is no mathematical calculation, no reproducible clinical trial or meta-analysis to quantify human need. Nor is there a formula which calculates exactly how people or groups of people will act. Indeed, a normative social theory is only a guide that holds these compromises together to meet as many individual needs as possible, marginalising as few people as possible along the way (Cheyne, et al., 2005).

Consciously or unconsciously, state distributions are essentially political. The size and impact of such distributions vary with the priorities and policies of each elected government. Some examples of state funded social distributions made by the New Zealand government are in the areas of public education, public health care, pensions, defence, care of the environment, the arts, energy distribution, economic development, housing and social assistance support to those in need.

The distributions made through the welfare benefit system in New Zealand are the major part of the government's 2011 budget (NZ Treasury, 2011). Such distributions account for \$24 billion of the government's \$74 billion of revenue in 2011. These distributions are made to the elderly and retired, people who are unemployed, people in financial hardship, independent youth living away from home, women (occasionally men) at home alone caring for children, war veterans, persons who are sick or infirm and widows living without financial support. The eligibility for these state distributions is determined by eligibility criteria attached to every type of benefit. Pensions for the elderly are universally provided in New Zealand to citizens who meet the single criterion of achieving the age of 65, irrespective of need. However, the universal pension is rebated by taxation for people on higher incomes.

Second to welfare payments in the New Zealand government's 2011 budget, is the distribution made to the public health service of \$12.7 billion. Public health spending in New Zealand has traditionally been expressed as a proportion of GDP. The government has implemented policies since 2000 which aim to increase the growth of GDP, restrain growth in public spending to maintain economic stability and ensure sustainable public services (Ashton & St John, 2008).

The third highest State distribution of taxpayer's funds in New Zealand is made to the area of state education. In 2010 the government's distribution in this area was \$12.4 billion (NZ Treasury, 2011).

Government funding is also directed at state housing in the provision of rental accommodation for people who meet an income eligibility test. However, being on a low income does not guarantee access to a Housing New Zealand Corporation rental house. There is a long waiting list and priority is given to people deemed to be in greater need than others. This distribution is subject to judgment and decision making by officials.

Funding of utilities such as transport, public housing, superannuation, welfare payments, police, education, security and protection of the environment do impact on the nation's well being. Non-health government allocations are also entirely relevant to improving the health status of the nation. The distribution of funding then becomes a competitive process, among the wide and varying calls within society, to reflect such values. It is the government which must decide. In democratic countries such as New Zealand, public perceptions of alignment to our democratic traditions and notions of fairness of state distributions are ignored, rewarded or punished by voters.

Introducing PHARMAC

The New Zealand health services delivery system is dominated by the public health provision of free and subsidised services. These are provided through a network of 21 District Health Boards (DHBs) throughout New Zealand². The DHBs are provided with funds by Parliament to meet the needs of the populations in the districts they serve. The Ministry of Health is responsible for the surveillance of the performance and quality of the public health services and interfaces through policy advice and reports to the Minister of Health and Parliament.

The Ministry of Health also requires DHBs to align their services with substantive government strategies. The current health strategies are documents which describe the government's intentions in relation to public

² Throughout this thesis I refer to 21 District Health Boards which were established under the New Zealand Public Health and Disability Act 2000, however by agreement, in 2011 the Southland and Otago DHBs combined their Boards, assets and funding to become the Otago-Southland DHB. Consequently, there are now 20 DHBs in New Zealand.

health, disability, treatment of older people, primary care, medicines and a Maori health strategy³. It is through the medicines strategy that PHARMAC is directed to make a contribution to the wider public health service.

The genesis of PHARMAC dates back to an agreement between the four Regional Health Authorities (RHAs) in 1993 to jointly incorporate a non-profit company to negotiate with suppliers of pharmaceuticals. The RHAs signed an agency agreement with PHARMAC to take full control of the pharmaceuticals which would be paid for by the RHAs (Sim, 2000). Thus, PHARMAC took over the function of the Drug Tariff Section of the Department of Health and importantly, the applications by pharmaceutical manufacturing companies for the listing of medicines and the Pharmaceutical Schedule. PHARMAC inherited the management of the Schedule of a pre-existing subsidy list containing around 3,000 medicines that were already subsidised and approved.

The government's structural health reforms of 1999–2000 in New Zealand transformed PHARMAC (Gauld, 2004) into a Crown-owned agency with the passing of the NZPHDA 2000 (Ministry of Health, 2000). It became abundantly clear that PHARMAC's sole purpose was containing the burgeoning costs of pharmaceuticals which had occurred under the four RHAs (Kletchko, Moore, & Jones, 1995).

This formalised PHARMAC's role of securing, for eligible people suffering injury, disability and disease, the best health outcomes that were reasonably achievable with pharmaceuticals from within the capped amount of funding provided by the DHBs (McSoriley, 2000).

PHARMAC signed an annual funding agreement with the DHBs and the government, and began to implement the National Medicines Strategy. PHARMAC utilised panels of medical experts to examine the relative costs and merits of all medicines and thereby establish the subsidy schedules. The largest schedule established was the Community Pharmaceutical Schedule.

³http://www.moh.govt.nz/moh.nsf/wpg_index/publications-index

This list of subsidised drugs became available on prescription by registered prescribers⁴ to people living in the community.

PHARMAC was also required under the new legislation (Ministry of Health, 2000) to be responsible for the provision of medicines for individuals who required rare and/or high-cost medicines which were not subsidised for the general population.

PHARMAC's Community Exceptional Circumstances policy attempted to meet the needs of individuals who suffered from rare diseases, sometimes also referred to as 'orphan diseases'. Aronson (2006) noted that there is no satisfactory definition of an orphan disease; however Wikipedia reflects several informal opinions on a definition. The term 'orphan disease' is the widely accepted terminology for definition for rare diseases. In the United States⁵ rare diseases are so defined according to prevalence, specifically about 1 in 1,500. Japanese health authorities describe an orphan disease as 1: 2,500 people suffering a rare disease. There is no single agreed ratio for the definition of an orphan disease in New Zealand or any cutoff number which has been agreed upon. A disease may be considered rare in one part of the world, or in a particular group of people, but still be common in another.

PHARMAC variously describe people suffering from rare clinical conditions as 'exceptional'. The cost to PHARMAC of meeting the pharmaceutical needs of some of these people is extraordinarily high and challenges PHARMAC's overall budget. In some cases PHARMAC's decisions not to provide medication have serious health consequences on individuals, including death.

Developing the Research Question

Initially, I began looking at the question of how the health needs of individuals can be met at the same time as meeting the needs of all others in society. After considering the literature around individual entitlement to health services and financial performance of New Zealand's DHBs and service outputs of public health institutions, I realised this question was too wide (Coyle, 2011).

⁴Medical practitioners registered with the New Zealand Medical Council, dentists registered with the New Zealand Dental Council, nurses who are registered with the New Zealand Nursing Council who hold a scope of practice as a nurse practitioner, midwives registered with the New Zealand Midwifery Council, and optometrists registered with the New Zealand Optometry Board are able to issue prescriptions for drugs on the schedule for which the patient will receive a government subsidy. Some of these professions have only a limited access to the subsidised formulary.

⁵ http://en.wikipedia.org/wiki/Rare_disease

I then moved to the subject of rationing of government's resources in order to meet these two sets of health needs: those of individuals and societies. This narrowed my focus to studying the decisions that are made and their relative validity. I found that setting funding priorities at the individual patient level was widely practiced in the public health services, but it was done by methods which were not obvious. Research has shown the lengths health practitioners will go to avoid discussing limiting care (Morgan & Simmons, 2009; Strech, Persard, Marckmann, & Danis, 2009; Ubel, 2000). This level of rationing individuals' care principally involves denying patients the treatment they need due to lack of resources. These methods were almost never discussed.

Consequently, I looked for an example in the New Zealand public health service where decisions about distributing funds to individuals were made in the most explicit manner possible. I reasoned that through explicitness I might be able to find the elements of decision making. I might also be able to study the matters which influence the decision makers in making the distributions they are required to make. My search led me to New Zealand's drug subsidising agency PHARMAC.

Many New Zealand and international authors (Cumming, Mays, & Daube, 2010; Higgins & Ruddle, 1991; Laugesen, 2011; Mays & Smith, 2005; Morgan & Simmons, 2009; OECD, 2009) have praised PHARMAC's success in managing pharmaceutical budgets, particularly in aggressively exercising its dominant purchasing power. Others have criticised PHARMAC policies and initiatives as being short-sighted. These critics have claimed that PHARMAC's success will eventually lead to a situation where the major pharmaceutical companies will withdraw co-operation from New Zealand. The concern was that pharmaceutical companies will deny PHARMAC choices in new and improved pharmaceuticals (Gray & Frizelle, 2005; Holt, Harwood, Aldington, & Beasley, 2005; Menkes, 2000; Sundakov & Sundakov, 2005). Others (Blue, 2006) have said that there is basic unfairness in the way PHARMAC has applied policies and procedures in making difficult rationing decisions.

However, under the NZPHDA 2000, PHARMAC must decide what medicines will be subsidised and which individuals, whose needs are considered exceptional, will be granted a subsidy for the medicines they need. In order to

do this, PHARMAC has promulgated rules and criteria. My question of PHARMAC developed into a study of exactly how this decision making system works. Is the process fair? How would we know if it was fair? Who are we trying to be fair to? What principles of fairness and equity are they aligned to? Consequently, I developed the following research question:

How does the operation of PHARMAC's Community Exceptional Circumstances policy align with the distributive justice principles of fairness and equity as described by John Rawls and Amartya Sen?

My Study

To research this question, I designed a research project which involved a qualitative iterative policy analysis utilising a justice methodology (Prah Ruger, 2010 p79). I examined PHARMAC's Community Exceptional Circumstances policy by collecting data from the widest possible sources. These sources included published literature, parliamentary records, the media and a court case transcript. I also used key informant interviews and made extensive use of the Official Information Act (OIA) 1986 to procure documents held by government officials. This data were analysed using Braun and Clarke's (2006) thematic analysis method which produced five themes describing PHARMAC's policy.

The Structure of This Thesis

Chapter 2 provides the background and context for this study and outlines why this research question needs to be answered. There has been a large amount of literature written about governments rationing public spending. I have organised this chapter to provide the background of PHARMAC's allocative practices. This chapter begins with a discussion about the necessity to ration health care and a section on the terminology used to describe these allocative practices. This is followed by a section which explores whether it is better to ration explicitly or implicitly. I have chosen to examine the literature around four types of rationing: 'macro-level' rationing, 'meso-level' rationing, 'micro-level' rationing and rationing by the 'Rule of Rescue'. These rationing types provide the context for seeing how PHARMAC's activities and purpose fit into this large subject area.

In Chapter 3, New Zealand's past attempts to manage health care spending are discussed. I also provide a context for my research project by discussing the policy settings, rules and criteria used by PHARMAC in its decision making.

Internationally, PHARMAC has played an important part in demonstrating how to manage a particularly difficult, uncertain, risk-laden area of public health provision. New Zealand has one of the rare forms of explicit rationing for pharmaceuticals, and there have been few empirical research studies done on how these types of policies are managed.

In Chapter 4, I look at the philosophical framework of justice in which the thesis question is developed (Prah Ruger, 2010 p79). I discuss the principles of distributive justice as fairness and equity developed by Rawls and Sen. There have been many authors who have described the theoretical descriptions of justice, distributive justice and distributive justice in health. However, few have given advice about how to apply the theories and much of the literature is presented in the Socratic fashion posing rhetorical questions about distributive justice.

Following in this tradition, I have taken the principles of distributive justice, as presented by Rawls and Sen, and developed them into some test-questions which enquire into the fairness and equity of decisions which are made. The test-questions are not intended to extract all the elements of distributive justice ever presented, but rather to give some structure to the conversation about fairness and equity. I also present the test-questions so that decision makers might use them to guide or review their decisions.

Chapter 5 is a description of the qualitative thematic analysis method employed to conduct the research using the example of PHARMAC's Community Exceptional Circumstances. I explain what I did to identify data from five sources and how the data were managed, particularly using the NVivo 8 (Lavery, 2009b) computer programme. The chapter includes a description of some of the limitations I experienced in using the tool. Ethical approval was provided by the Auckland University of Technology Ethics Committee and ethical considerations are discussed here.

In Chapter 6, the data from the five sources are presented. The data are revealed in a way that provides insights into how the PHARMAC policy was enacted. The sources are triangulated and each triangulation gives diverse perspectives. This chapter includes a description of the thematic analysis of the data by the six Braun and Clarke (2006) phases. This chapter concludes with the emergence of five themes which are presented and named. Collectively, the themes develop a wider view of how public health agencies like PHARMAC operate within the landscape of government.

Chapter 7 is a discussion of the themes utilising the test-questions which were developed in Chapter 4. In so doing, Rawls and Sen's principles of distributive justice are explored to show how these principles are supported (or not supported) by PHARMAC in the operation of its policy.

Chapter 8 is the concluding chapter in which I discuss the usefulness of the test-questions and explore how well they assisted examination of the Community Exceptional Circumstances policy. The outcome of the research is discussed along with the learnings about distributive justice and how this research may also be useful for other government departments and agencies. The limitations to the research are also discussed and give an indication of further research work on the questions which may be needed.

The thesis concludes with a discussion on the contribution of this research and some final comments about the thesis question.

There have been some government announcements made which impact on PHARMAC since the research was concluded in February 2011. These are noted in a postscript.

Chapter 2: Background

Introduction

In this chapter, I provide the background for my research into the operation of PHARMAC's Community Exceptional Circumstances policy and the various descriptions of rationing.

The literature in this chapter is organised into the following sections:

- Why ration health care;
- Rationing terminology;
- Explicit or implicit decision making;
- Macro-level rationing;
- Meso-level rationing;
- Micro-level rationing;
- The Rule of Rescue;
- International attempts to ration; and
- Rationing by social inequality.

The chapter begins with a discussion about why health rationing is necessary. There are four categories of rationing described. The first category is macro-level rationing. This is done by governments making budgeted appropriations to the various health agencies, for example New Zealand's DHBs. The second category of rationing is meso-level rationing. This is where the funding from agencies is provided to services in regions, districts or where agencies are funded to provide services which are nationally directed. The third category is micro-level rationing. This is the distribution of public health funding to (or on behalf of) individuals. PHARMAC's Community Exceptional Circumstances policy is an example of micro-level rationing. The Rule of Rescue is discussed as another form of rationing. This is where health funding is provided in

emergency or last chance situations. Specific examples to illustrate each category of health rationing are presented.

The international attempts to ration involve significant projects and references to New Zealand as a leader in this process and for this reason I have given international comparisons. Finally, the subject of social inequality is discussed because this was a primary purpose for the health reforms which established PHARMAC as a Crown Agency.

Literature Search Strategy

A literature search was conducted utilising AUT Library access to Proquest database and conducting a Boolean Search using 3 search strings of words. These were:

1. Health AND rationing AND fairness AND “New Zealand
2. Rawls AND Sen fairness AND equity AND Health
3. “Decision Making” AND criteria AND “New Zealand” AND
Pharmaceuticals AND PHARMAC AND Exceptional Circumstances

This search strategy produced peer reviewed journal articles, books with relevant chapters, theses and national and international government reports. Assistance for the construction and activation of the search of this topic was provided by the AUT Postgraduate Librarian, Robyn Ramage and AUT Faculty of Health and Environmental Sciences Librarian, Andrew South.

During the course of the research and writing of the thesis a literature watch was activated (again with the assistance of librarians). This consisted of RSS, and Bloglines and a set up on the TicToc Website. The export RSS feeds were set up to watch for the following journals on my reader;

- Health (1363-4593)
- Health economics (1057-9230)
- Health economics, policy and law (1744-1331)
- Health policy (0168-8510)
- Policy studies (0144-2872)

The following journals have no automated alerting functionality. For these journals, I regularly visited their websites and reviewed the latest issues:

- Health policy research (1496-466X)

<http://www.hc-sc.gc.ca/sr-sr/pubs/hpr-rpms/bull/2010-reg-mod/index-eng.php#a17>

- New Zealand Medical Journal (0028-8446)

<http://www.nzma.org.nz.ezproxy.aut.ac.nz/journal/index.shtml>

- Policy quarterly (Victoria University of Wellington, Institute of Policy Studies)

<http://ips.ac.nz.ezproxy.aut.ac.nz/publications/publications/list/10>

Hand searchers were conducted at the AUT Library and Victoria University Law Library searching for titles related to Rawls and Sen. I also utilised the personal collections of two friends (lawyers) who had books particular to their interest in Rawls.

Why Ration Health Care?

Health care services are broadly described as preventive, curative or rehabilitative treatment and intervention and social support services for people with physical and mental illness and/or disability (Daniels & Sabin, 2008). No country can provide completely unlimited health care services for all its citizens (Ashton, Cumming, & Devlin, 1999; Ashton & St John, 2002; Blank & Burau, 2004; Churchill, 1987; Coulter & Ham, 2000; Edgar, 2000; Helco, 1974; Higgins & Ruddle, 1991; Manning & Paterson, 2005; Mariner, 1995; Mays & Smith, 2005; Mooney, 1998; Morgan & Simmons, 2009; Smith, 2008; Strech, et al., 2009; Ubel, 2000) Among OECD countries, few authors have questioned why rationing is necessary and most agree that rationing is positive in that it clarifies a government's objectives and sets aspirational budget levels to achieve these objectives. Consequently, the rationing debate is not about whether governments should or should not ration, but rather how they should ration. More particularly debate concerns which health services should be provided and in what quantity, and when and to whom they should be provided?

Governments must decide where their priorities lie. For example, should priority be given to publicly provided primary care or should secondary and tertiary hospital care take larger proportions of the health budget? Decisions must be made about the resources applied to the care of the elderly compared to the care of the young. Should priority be given to treating some diseases aggressively such as obesity, cancer, diabetes, heart disease or AIDS to the detriment of other forms of care such as preventative public health programmes to reduce the harm of cigarette smoking? Should the government make available resources to prolong life or limit these resources in desperate situations and allow death to occur? Is the desired outcome in health care only for those who have a high likelihood of successful (and therefore cost-effective) treatment, compared with very ill people who are perceived to be near death with no hope of survival?

I pose these questions to demonstrate that resource allocation questions are not simply answered by the operation of a lexicon of rules; rather they are value-laden. Health Ministers face the reality of setting funding levels which create service dilemmas primarily because of the rising annual costs of health care (Boston, Martin, Pallet & Walsh, 1991).

OECD Health Data 2010 shows that member governments shoulder the larger share of health care costs compared to the private sector (OECD, 2010). The macro-level rationing question for OECD member countries is what proportion of a country's GDP will governments allocate to health care? The average share of government expenditure among member countries in 1990 was 12% of GDP. This share of government expenditure rose to 16% in 2008 mainly as a result of increasing costs of new technology such as diagnostic magnetic resonance imaging (MRI) and computerised tomography (CT) scanners, pharmaceuticals and the increasing wages of medical staff. Most governments in the OECD are trying to promote more rational use of both pharmaceuticals and MRI and CT machines at this macro level (OECD, 2010). All OECD countries have faced yearly increases in the costs of medical staff which are exacerbated by the high levels of international recruitment particularly from poorer countries to countries with stronger economies.

Technological and pharmaceutical diagnostic treatment enhancements have produced both real and perceived benefits to patients. This particularly applies to pharmaceuticals where countries have tried to contain health spending on new products. OECD member governments have been vulnerable to the economic pressures of price increases and exchange rate fluctuations related to supply and demand cycles in the international pharmaceutical market place. In the past 20 years the pace of pharmaceutical and imaging technological innovations have outstripped OECD countries ability to fund them (OECD, 2010). There is a limit to what governments can afford to provide.

Governments in the OECD have tried to manage these economic pressures by setting limits and trying to define them. Authors have used a confusing number of terms to describe funding decision making including such as words like distributions, allocations, funding, prioritisation, budget levels, priority setting and rationing (Ubel, 2000). The term 'rationing' is often used interchangeably with the term 'priority setting' or 'prioritisation' (Ham & Coulter, 2000). Ham and Coulter (2000b) use the terms to describe choices in health care that are made which affect individuals, communities or countries.

Some authors refer to the distribution process only as the means of deciding allocations of services to individual patients (Klein, 1995). Other authors' definitions of rationing include inequitable distribution of resources based on inability to pay (Hadorn & Brook, 1991). Brook and Lohr (1986) describe rationing as any set of activities which determines who gets needed medical care when resources are insufficient to provide for all. A more recent definition describes the withholding of some medical services from selected individuals who would probably benefit from them, because such services are not being purchased and therefore are not available for everybody who needs them (Rech, 2010).

Other authors (Blank & Burau, 2004; Hadorn & Brook, 1991) discuss health service priority setting as a euphemism for the denial of a treatment to a patient who would benefit from it. However, the fact that a person would benefit from an investigation or treatment does not mean that, in every case, the investigation or treatment can be provided, particularly among state funded services. Scarcity and lack of affordability (Hall, 1994; Mariner, 1995) dictate

that the treatment may not be available, and in such circumstances a conscious decision may be taken by administrators that the service is restricted or simply not offered (Ubel, 2000).

The term 'rationing' has also been used to mean societal toleration of inequitable access to services deemed necessary, as defined by reference to appropriate clinical guidelines (Hadorn & Brook, 1991). Early in the health rationing debate, Hadorn (1991) introduced the connection between equity and the provision or prohibition of needed health services. His central idea was to try to show what was considered 'necessary' and by whom it was considered 'necessary'. This approach has been challenged by many attempts since 1991 to define the term necessary. This has not proved to be simple. Neither has it always been easy to be explicit about who benefits from rationed health funds- the patients, the doctors and staff, the service owners or the funders.

There are, however other ways of thinking about what health care provision might be considered necessary and unnecessary. Malin, Wilmot, and Manthorpe (2002) divided the elements of distributive justice relating to the fairness of distributing health care into four areas: need, rights, desert and utility. I present these four categories here. Need was described as the ability to benefit from a treatment and is associated with the level of severity of the condition and the effectiveness of the remedy. However, this is problematic because of the existence of layers of need. Malin et al. point out that a person may need a pair of shoes or we could say they need education and up-skilling to be able to enter the labour market to earn enough income to buy a pair of shoes. There appears no obvious method of analysing needs and efficiency in such terms.

The second element of distributive justice described by Malin et al. (2002) is rights. Two types of rights are described. Firstly 'ideal' rights which are claimed on the basis of general moral principles and stand independently and prior to laws as ideal arrangements for human societies. This too is problematic because the exercise of such rights in terms of the right to life or the right to adequate health care is generally determined by access to adequate resources. Therefore, the gatekeeper who provides such access has power over the rights

in every sense, and attenuates the right by deciding what the client will or won't get.

The third element of distributive justice described by Malin et al. (2002) is the idea of desert or that which one deserves. This criterion is not generally an acceptable one on which to apportion health care because it attempts to assert blame for the causes of disease or provide a reward for avoidance of disease. Other factors such as genetic inheritance, family history, educational opportunities, physical, social and political environment are not subject to what a person can claim to deserve. Given and acquired talents are also incomparable and defeat allocations based on this element.

The final element described by Malin et al. (2002) is utility or maximising well being. Primarily this element rests on the assumption that the well being of every person is equally important. Secondly it asserts that taxpayers paying taxes are doing so on the basis of fairness and thirdly it asserts that the distributions are efficiently applied and there is no wastage. The main problem with distributing on the basis of utility is that the indicators for utility and efficiency are value-laden and not easily agreed upon. Given that there is not an unlimited resource to meet these priorities, we are taken back to the questions of how society can agree on levels of priority while at the same time satisfying any level of equality.

Klein and Williams (1998) debated in the literature the question of prioritisation of scarce resources in the United Kingdom. Klein argued that the process of priority setting is inevitably a process of debating the values of the institutions making the decisions. Such a debate generates wide discussion about values and context. For this reason, institutions must be equipped to hold the debate and analyse the answers. He believed that the right process will produce socially acceptable answers and will be arrived at by an expression of societal values and not by any amount of cost-benefit analysis.

In the same article Williams argued the opposite position to that of Klein. Williams (1998) stated that priority setting required clarity about objectives, information about costs and outcomes and an ability to measure the performance of competing interests in the priority line of choices. This is because the decisions about priority must be framed in a context of adequate

information. Williams stated that the more cost-benefit analysis and analytical data available to support the investment in one service over another, the better (Kein & Williams, 1998). William's argument that the more information one puts into the cost-benefit analysis the better the rationing decision, militates against treatment of chronic disease, again because of the high cost over a long period. However, cost-benefit analyses do not describe spending large amounts of scarce health resources on the elderly as a sound investment. This is because of the high costs and the small number of years left to produce a 'return' on the investment.

The question is also affected by ethical considerations when deciding who is to receive the care. In 2001 Beauchamp and Childress developed a set of four principles of bioethics which examined the philosophical and ethical theories as a basis for guidance for physicians (and other health services personnel). The principles were: respect for autonomy, the principle of beneficence, the principle of nonmaleficence and the principle of justice (Beauchamp & Childress, 2001).

The principle of respect for autonomy contains a negative obligation in that a person's autonomous actions should not be subjected to constraints by others, for example by medical personnel. This principle also contains a positive obligation by medical personnel to foster and facilitate autonomous decision making by the patient. The principle of beneficence determines that medical personnel ought to prevent or remove harm, promote doing good, and weigh the balance of possible harm against possible good when providing care. The principle of nonmaleficence decrees that one ought not to mentally or physically hurt other people in providing care. Beauchamp and Childress (2001) discuss the principle of justice examining many philosophical and ethical positions. They propose that society should recognise that every person has a right to decent minimum health care within a framework of allocation that incorporates both utilitarianism and egalitarianism.

Explicit or Implicit Decision Making

When services are either not funded or withdrawn from public access and this is done explicitly, this subverts the equity aims of public health services (Scott, 2001) and opens the way for a dilution of services. Scott (2001) described examples of 'dilutions' in the New Zealand public health services such as a long

waiting time for first (or subsequent) specialists appointments, a long waiting time for investigations, and waiting lists for treatment – particularly surgical treatment. Dilution also involves a lack of choice of physician or surgeon being available to those in the public system, as opposed to those who purchase their care in the private system. Dilutions of service also involve a lesser range of investigative or treatment options being offered to patients. A lack of confidence in the public health service, often driven by criticism from the senior medical and surgical staff from within also dilutes the public's faith in the social contract of public health being available to all when they need it.

Other types of rationing have been described such as formal rationing, informal rationing and deterrence rationing. Formal or 'explicit' rationing refers to subsidies, queues, priority need classes and eligibility rules which should treat all equivalent patients equally (Scott, 2001). Informal or 'implicit' rationing occurs throughout the health services by clinicians making resource allocation decisions at the individual patient level. This implicit rationing has always been within the power of the medical profession. Hope, Spriggins and Chrisp (1993) have described the difficulty doctors have in this activity. They describe the terms 'not medically indicated' as having two possible meanings. The first is that the proposed (or possible) treatment is not clinically indicated and unlikely to produce significant benefits to the patient. The second meaning is that the treatment is not an economically sound use of scarce resources. The decision delivered by the clinician to the patient is often presented in the parlance of the first meaning, when in fact the clinician knows that he/she was forced to offer rationed care because of resource constraints (Manning & Paterson, 2005) consistent with the second meaning.

The rationing process can also differ in relation to processes or actions which occur between patient and clinician. Brook and Lohr (1986) describe explicit rationing as conscious decisions which are taken at an administrative level that ultimately mean services are not available to clinicians to provide or prescribe to their patients. Daniels and Sabin (2008) describe explicit rationers as people who believe that open public accountability is essential in making decisions which have moral implications. Such people "leave the experts to the task of 'muddling through' behind the scenes and actually delivering reasonable distributions" (Daniels & Sabin, 1998, p. 67).

Daniels and Sabin (1998) have also presented a framework for organisations to use entitled 'Accountability for Reasonableness'. This framework occupies a middle ground in the debate between those calling for explicit and implicit rationing. It does not require an explicit proclamation of the principles of distributive justice before decisions need to be made. Rather it calls for transparent and informed debate including reasoning which choices all people involved in the case can agree are relevant. This provides a process for discussion somewhere between the explicit and implicit approaches which allows the construction of principles that will produce fair decisions about real cases. Daniels and Sabin believe that the social capacity that this facilitates provides the best prospect of achieving agreement over sharing medical resources fairly (Daniels & Sabin, 2008).

A further form of implicit rationing has been described by Higgins and Ruddle (1991) which involves prioritising by deterrence as a method of reducing the pressure on scarce resources. This type of prioritisation relies on patient ignorance or high levels of frustration to reduce the usage of public services. This is done by public systems which make rules about access complex, bureaucratic and prohibitively difficult. These rules and processes can be so confusing that patients become frustrated to the point of discontinuing seeking services. This rationing has been described as a predilection of physicians in the United Kingdom (Higgins & Ruddle, 1991) and can be a factor in elderly people not receiving the care they need.

Another form of frustration which leads people to discontinue seeking health services is a lack of first language fluency when dealing with health professionals speaking in other languages. Waddell and Petersen (1994) argue that such fluency is one of the crucial factors in being able to access UK NHS health services.

Each of the above (and many other) definitions of health care rationing has its own unique set of costs and benefits, however authors (Klein, 1995; Malone, 1998) have described the fairness of such distribution as an equal access for an equal need.

Macro-Level Distributions

Macro-level health rationing is what happens when governments allocate national budgets for health spending. This fits into the whole of government view of health care (Calman, 1994). Macro-level distributions of health funding also include providing utilities such as public housing, transport, police, education, security and care of the environment. Calman (1994) argued that these considerations will have more of an impact on improving the health status of the nation than spending on health care.

The Hon. Helen Clark, a former Prime Minister of New Zealand and experienced New Zealand politician, stated that she felt she was more effective as a Health Minister when she was Housing Minister. This was because of her greater ability to change health status by providing adequate, affordable, safe, clean and dry public housing for the poor, than her ability to directly affect the determinants of health through managing health services as the Health Minister⁶.

Ubel (2000) argues that the overall allocation of funding for health services, particularly by neo-liberal governments setting appropriations, is based on political perception of performance. Those responsible for macro-level rationing must somehow observe the relationship between the effort and performance of the service and the costs of providing it (Olsen & Street, 2007).

Ham in *Health Policy in Britain* (Ham, 2009) described this phenomenon in the UK NHS attempt to manage problems of escalating health costs. He suggested that extra government money provided to the NHS for the purpose of providing funds for areas considered to have extraordinarily high needs did not achieve the intended outcomes. This was because the extra funding did not create new services to vulnerable groups such as to the elderly; it simply provided more money for existing services. The reason for this, in Ham's opinion, was that the control of spending in the NHS was largely in the hands of the doctors who had their own spending priorities. These priorities were to provide more money to satisfy calls for more wages and greater levels of staff within the existing service. This demonstrated the complexities of health policy and the potential

⁶Personal Communication Hon. H. Clark on 2 February 2008.

for creating unintended consequences trying to make access to health services more equitable, but in fact achieving the opposite.

Up to 2006, New Zealand public health spending had been rising as Ministers responded to political pressure. Cullen and Mallard (2006) stated that increases in government funding to health services in New Zealand did not mean increases in the number or quality of services. They argued that the government was rationing at the macro-level greater proportions of public expenditure to the health services and the public were receiving the same or lesser health services in return. Cullen had previously warned that spending in health had outpaced New Zealand's economic growth by about 1.5% of GDP per year, for the last 10 years (Cullen, 2005). In other words, New Zealand has been increasing public health spending by approximately \$1.50 for every \$1.00 of GDP growth.

Regardless of what levels of GDP are allocated to public health services, governments try to achieve the highest levels of service possible with scarce resources. However, it is well known (OECD, 2010) that such resource constraints applied by governments are necessary, but the public acceptance of an open debate about policies which ration, perforce limit the supply of services, is still a very unpopular one. Morgan and Symonds (2009) contend that New Zealand politicians have historically tried to pretend that macro-level rationing does not take place because of the difficulty of facing electors with the stigma of having reduced or restricted health services.

Meso-Level Rationing

Meso-level rationing occurs at the regional level where distributions are allocated to regions by government. Meso-level rationing also refers to distributions to institutions within a region. The New Zealand Public Health and Disability Act 2000 (NZPHDA 2000) established 21 District Health Boards (DHBs) and required each DHB to conduct a health needs assessment of the needs of the population they serve. The Act required the preparation of a District Accountability Plan (DAP). Having received their allocations from government, the DHBs must decide the spending they allocate to various health services throughout their region. This meso-level rationing should be based on the DAP. Health care needs assessment processes were described by Coster

(2000) in a report for the Ministry of Health. The report defined the assessment of community health needs as “the population’s capacity to benefit from health care services prioritised according to effectiveness, including cost-effectiveness, and funded within available resources” (Coster, 2000).

This annual DAP consists of considerations for funding for the following year and must reflect the current economic and fiscal environment and the government’s national health goals and expectations (Ministry of Health, 2010). This plan is the basis for negotiation between the DHB, the Ministry of Health and the Minister on the actual level of funding the DHBs will receive.

One of the major difficulties with the establishment of 21 DAPs is that some DHBs will prioritise local health needs and make different services available to their populations than other DHBs. This creates national inconsistencies. Similar problems have been noted in the United Kingdom’s NHS model where local rather than national level decision making creates shortages of supply of some services and an overabundance of others (Malone, 1998). This system potentially creates greater inequity, not less, on a national basis.

In the case of pharmaceuticals in the UK, to inform the meso-level decision making, The National Institute of Clinical Excellence (NICE), an equivalent healthcare organisation to PHARMAC, employs a cost-utility model to determine which drugs to list for public funding through the NHS. Their basic unit of measurement is the same as PHARMAC’s. This is a measure named the ‘Quality Adjusted Life Years’ gained or QALY. This measurement tries to define the added benefit gained by a treatment which provides increments to a person’s quality and length of life added by the treatment. One QALY is a year of predicted patient’s change in life expectancy and/or health related quality of life as a result of medical, surgical or rehabilitative treatment.

NICE has recently (2009) decided to adopt similar analytical economic and clinical effectiveness studies of pharmaceuticals presented by the industry for listing in the NICE recommendations to NHS providers. The scale of the assessments carried out by NICE now depend on whether the appraisal concerned is a single or multiple technology appraisal. Drummond (2009) has given examples of four funding applications for cancer drugs that were

terminated by NICE because the applications made by the drug companies were not robust enough to meet NICE's evidential standard (Drummond, 2009).

QALYs are used extensively in health economics to make comparative analyses and to establish value for money determinations. The key factor in the use of QALYs as a comparative measure is that each QALY is considered equal to any other QALY. PHARMAC uses the QALY as the basis for the cost-utility analysis when deciding on adding pharmaceuticals (and some medical devices) to the national subsidised formulary. PHARMAC ascribes a monetary value to each QALY and will not usually pay for a drug which is estimated to cost in excess of \$30,000 per QALY.

In the UK, NICE will recommend the funding of a drug up to a cost threshold which has been set at £20,000 per QALY (Edlin, Round, Hulme & McCabe 2010). These authors point out however, that NICE also approves listings of drugs and technologies above this range. This is because NICE considers additional factors such as equity considerations. NICE must decide on these equity considerations (or judgments) and be informed by a set of justice principles plus any special circumstances of the beneficiaries of the decisions. Edlin et al. point out that once NICE moves away from the cost-utility model, either in small or large part, the process becomes as much enlightened by judgment as by economic calculations. When this occurs, the QALY dominated cost-utility analysis system itself is undermined.

Drummond (2009) stated that another problem with NICE's meso-level approach is that drug companies will not submit applications which fail to show evidence of QALY defined 'value' as defined by NICE. He argues that 'absence of evidence is not necessarily evidence of absence' because hospitals and doctors find ways of circumventing NICE's assessments (Drummond, 2009). This is done by clinicians or patient organisations, fuelled by drug company interests, bringing pressure to bear on local decision makers. They collaborate against NICE to provide the drugs which fail the value for money test. When this happens, it undermines the reason for NICE's existence.

New Zealand also has meso-level bidding within the DHBs which is dominated by the internal power struggles within the largest institutions (hospitals) and the large Primary Health Organisations. Many agendas are played out at DHB

level, too many to discuss here. One example is given in Chapter 4 where there is an examination of a decision made by the MidCentral Health DHB. This example demonstrates how meso-level rationing affects multiple interests and how these interests are met or not met by the process.

Micro-Level Rationing

Micro-level rationing occurs at the individual patient level of health care systems. This level of decision making, rationing, distribution or prioritisation (whatever we wish to name it) immediately drops the focus from the whole society's allocative values down to the needs and rights of an individual person. There is a responsibility on governments to ration between the political derivatives of ensuring that there is minimal granting of special privileges to favoured individuals, and ensuring "the absence of social abandonment of those who require assistance" (Hamilton, 2003, p. 124). This idea advances the need for an ethic of mutual responsibility that citizens equally and fairly should share in the entitlements to collective resources. Hamilton described this as a conflict in government between mutual responsibility and personal entitlement and balancing of the need to promote equal opportunity for all. This is to be achieved by granting special privileges to none by both rejecting the politics of entitlement and guarding against the politics of social abandonment (Hamilton, 2003 p. 124).

The relationship between clinicians and the managers and governors of health services determines the success of micro-level rationing. Shenkin (1998) maintains that macro-level rationing becomes impossible by governments if they are not prepared to be explicit about micro-level decisions made by their clinicians. Consequently, Shenkin asserts that it would be more pragmatic for policy-makers to concentrate on what minimum standard of health care a country should supply its citizens. Then decisions about macro-level rationing of health care could compete with all other commodities and services. Ubel (2000) uses the term 'bedside rationing' for micro-level of decisions made by clinicians. He describes bedside rationing as consisting of three components. Firstly withholding, withdrawing or failing to recommend a service that, in the clinician's best judgment, is in the patient's best medical interests. Secondly, bedside rationing occurs when the clinician is acting primarily to promote the

financial interest of someone other than the patient, including an organisation, society at large, or the clinician him or herself. His third component of bedside rationing states that the clinician him or herself must have control over the use of the medically beneficial service. Notwithstanding the descriptions of bedside rationing, as a system it bears no regard or concern for people who do not have access to health services and are unable even to get onto the bed to receive medical care.

The Rule of Rescue

The Rule of Rescue refers to last chance or life-saving attempts by proven or unproven health treatments. These rescues are mounted by health services, physicians, families or patients when they believe a treatment has the slightest possible chance of making a difference between life and death (Daniels & Sabin, 2008 p67). When life is ebbing away due to terminal disease, patients' access to the Internet provides a wide range of information about treatments and treatment centres which claim success in treating terminal disease. These become desperate last chance grasps at life. Patients and families often expect state distributions to pay the costs of international travel, accommodation and very high private facility treatment costs. Such rescue attempts can also attract the attention of the media and develop public sympathy for the plight of the dying person.

When the Rule of Rescue applies, and funding is provided through state distributions, this means that other people, who may be equally deserving of state funding, may not be able to receive the treatment they need. In the data section of this thesis in the media study of stories relating to PHARMAC's Community Exceptional Circumstances, I discuss some Rule of Rescue stories which have been highlighted.

In 2001 Andrew Moore, a philosopher at the University of Otago, Dunedin, New Zealand, was the Chair of the New Zealand National Ethics Advisory Committee, which advises the Minister of Health on medical ethical issues. He described the Rule of Rescue as the urgent response to urgent health needs. These responses should not be considered in reaching funding decisions (Moore, 2006) because, according to Moore, the Rule of Rescue offends the requirement of funding to demonstrate benefit in terms of efficiency and cost-

effectiveness of treatment. However, not providing funding to terminally ill people for experimental treatments which ultimately prove to be beneficial, even curative, may mean that people will die unnecessarily. Not paying for treatments which exist, but come at a prohibitively high cost, may leave people who are critically ill with a sense of abandonment in their hour of need (Daniels & Sabin, 2008).

An example of the Rule of Rescue lobbying occurred in 2008 in the UK when NICE declined to place four cancer drugs on the national formulary. One of these drugs was described by the *London Daily Telegraph* as being able to “double life expectancy” and called the NICE decision “a devastating death sentence for cancer patients” (Tapu, 2008). The drug referred to was Herceptin⁷. Even if Herceptin was shown to improve the life expectancy (not provide a cure) of patients after twelve months of treatment, the costs might be too large for Britain and other European countries, compared with other priorities to publicly fund other health services. The newspaper article claimed that this drug, plus a raft of other designer cancer drugs, was so expensive that they could spell the end of Europe’s tradition of social health care (Tapu, 2008). Funding difficulties related to the provision of Herceptin in New Zealand is also discussed in the Research Findings (Chapter 6) of this thesis.

The Rule of Rescue develops questions about just what is a prohibitively high cost. How much is too much to save a person’s life? How much is too much to attempt to save a person’s life? How much is too much to spend attempting to prolong a person’s life? How much is too much to attempt to prolong a person’s life for a few more days or hours?

Hadorn (2006) acknowledged these questions are real dilemmas for individuals. However, he advocated that public health services should rule ‘out of bounds’ any appeals to the imminent death or ‘only hope’ treatments which fail the

⁷Throughout this thesis I have used the AMA Manual of Style (10th edition) protocol for using the names of branded medicines. Specifically the AMA states that a trademark, for example ©, TM or SM, should not be used in scientific journal articles or references, but the initial letter of a trademarked word should be capitalised (American Medical Association, 2007). Note that I have capitalised ‘Herceptin’ because it is a branded trademarked name of a medicine. The use of scientific component generic names of medicines is not capitalised, for example prednisone (as seen on p. 194 of this thesis). PHARMAC’s table of Community Exceptional Circumstances claims released under the OIA (Appendix 7 p.272) gives many examples of this convention e.g. Suboxone which is a branded drug and buprenorphine which is a generic drug.

QALY utilitarian test (Hadorn, 2006) Hadorn acknowledged that these Rule of Rescue appeals are difficult for agencies to refuse because of the public and political pressure which ultimately result. However, acquiescing to such pressure contravenes the basic utilitarian assumption that the greatest good should be provided for the greatest number. Such an equation is purported to be possible using the QALY calculation.

Hadorn (2006) also argued that the QALY equation should not be the only rational or moral basis for distributing resources. This is because QALYs do not measure the need to distribute resources, the consequences of doing so or the overall justice of including or excluding individuals from access to these resources (Hadorn, 2006).

The International Attempts to Ration

A celebrated attempt to explicitly ration health services occurred in the state of Oregon in 1989 when the State government tried to define which services should be publicly funded and which should not. A Health Services Commission was established to draw up a comprehensive list of conditions and treatments which would be funded by the state insurance provider, Medicaid (Klein, 1995; Oregon Government, 2007). The Commission consulted the public widely and used research evidence and the judgment of professional people to construct a list of medical conditions to be publicly funded. This became known as the 'Oregon List'. The Commission was careful to avoid discrimination against disabled people in implementing the radical Oregon Health Plan. The list was justified by describing the clinical effectiveness of health treatments and calculating the 'net benefit' of treatments. A line was drawn to indicate which treatments demonstrated to the health plan governors both clinical effectiveness and net benefit. Treatments below the line were not covered by the Oregon Health Plan (Oberlander, 2006).

The list has been expanded to include new treatments and from time to time various treatments are moved up and down the priority ladder. For example, cosmetic dental procedures are near the bottom of the list of funded priorities, whereas severe head injury and loss of consciousness is the top priority (Oregon Government, 2007). There were inconsistencies in the ranking. For example, dental caps for pulp or near pulp exposure were ranked higher than

surgical treatment for ectopic pregnancy. Splints for temporo-mandibular joint disorder of the jaw were ranked higher than appendectomy for appendicitis. Hadorn (1991) points out that neither ectopic pregnancy nor appendicitis can be ignored or placed on an optional 'to do' list.

The intention of the Oregon Health Plan was to provide medical insurance coverage to the high proportion of Oregonians who had no medical insurance cover in the state (Oberlander, 2006). This was proposed by the Plan limiting the number and types of services offered to all people covered by the Plan. Oberlander (2006) described how the numbers of uninsured people in Oregon increased rather than decreased compared to other states. This was not expected nor planned for. It was the result of shocks and recession suffered by the American economy which made the Oregon Health Plan increasingly unaffordable to maintain, particularly at the subsidised end. The other major problem was one of acceptability for both insured and uninsured. There was a lack of confidence by the public in a system which explicitly stated that the levels of care being offered under the plan were limited because of financial constraints.

The experience of Oregon is echoed in other countries who have attempted various explicit approaches. Ham and Coulter (2000) describe the task of being explicit about limiting health services as making a 'square circle'. They list Denmark, Finland, Norway, Sweden, The Netherlands, New Zealand and the UK as countries which have also attempted to explicitly distribute health care (Coulter & Ham, 2000). The Israeli government followed Oregon's attempt to explicitly ration health care when it described, both broadly and generally, the basic package of services the government provided and determined the cost to the patient for the delivery of that package (Chinitz & Israeli, 1997).

NICE is also the government appointed body committed to promoting equality and eliminating unlawful discrimination in the delivery of all health care in Britain (National Institute for Clinical Excellence, 2010). NICE's guidance to the NHS on evidence-based clinical effectiveness of health interventions and public health measures is also a form of rationing. The NHS and Trust Hospitals are required by the Department of Health to demonstrate that they are following the

NICE published guidelines. Their purchasing decisions and delivery of services must also be consistent with the NICE advice.

There are three main ways by which NICE is required to promote equity in the NHS (National Institute for Clinical Excellence, 2010). Firstly NICE promotes race equality by only recommending the use of an intervention for a particular racial group if there is evidence of clinical effectiveness for that group. Secondly, NICE promotes age equality by recommending an intervention of a particular age group where the evidence is compelling that this group cannot be effectively treated any other way. Thirdly, NICE described a policy which stated there is no case for treating people differently on the basis of their gender or sexual orientation.

Within these parameters, NICE takes on a significant role approving treatments, interventions and pharmaceuticals which are publicly funded within the NHS. NICE also has a 'negative' formulary of drugs which it believes should not be funded (Morgan, McMahon, Mitton, Roughead, Kirk, Kanavos, & Menon, 2005)

The Swedish Priorities Commission in 1995 embarked on a national consultation process to identify how much health care should be rationed in Sweden (Swedish Parliamentary Priorities Commission, 1995). This commission established three principles to underpin the work. The first was the right to human dignity. This was interpreted as all people having equal rights regardless of their personal characteristics or their role in society. The second principle was termed 'need and solidarity'. This meant that health care should be provided to those in the greatest need and the health service should pay special attention to those who were less able to represent themselves or articulate their own need. The third principle was the cost-benefit relationship: an expectation that there should be a 'reasonable relationship' between cost and benefit.

The approach was criticised by McKee and Firueras (1996) because it rejected or subordinated several other justice principles, including a person's ability to benefit, selection by the level of demand, feelings of being deserving and a person's autonomy to decide for themselves what health care they want.

In a study conducted by the Commonwealth Fund (2010), New Zealand's largely publicly funded health system was compared to Australian, Dutch, USA, Canadian, German and British health systems for equity, access, quality, efficiency and life expectancy. The Dutch health services scored the highest in all categories (Davis, et al., 2010). This success was credited to the national health reforms of 2006 which introduced a compulsory income-related health insurance system. Care was funded by a mix of mandatory public insurance and voluntary private insurance. The Dutch government introduced an income-related monthly allowance for two-thirds of Dutch households to make the insurances affordable (Schut & van de Ven, 2011).

The Commonwealth Fund found that New Zealand has the highest ranking among countries in the study for quality of care. This measure arises from analysis of levels of effective care, safe care, coordinated care, and patient-centred care (Davis, et al., 2010). New Zealand's highest quality standards were achieved despite having the lowest health expenditure per capita cost in the study of seven countries.

These results indicate that quality health services are not necessarily linked to high levels of expenditure. In the same study, New Zealand ranked sixth of seven (next to the USA) in the equity category (Davis, et al., 2010). In the report, equity was defined by the US Institute of Medicine as "providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status" (Quality of Health Care in America, 2001). In relation to these comparator countries in the study, New Zealand provides very cost-effective care of high quality, but fails to provide health care in the public sector to all citizens equitably.

International Attempts to Ration Pharmaceuticals by Exceptional Circumstances

In a New Zealand thesis for a Masters Degree in 2009, Dr. Dilky Rasiah, the Deputy Medical Director of PHARMAC, outlined the international attempts to ration medicines to individuals by means of exceptional circumstances schemes. The conclusions of Rasiah's research are discussed on page 48 of this thesis.

In summary, Rasiah stated that there appears to be little literature providing the details of Community Exceptional Circumstances type schemes where explicit rationing of pharmaceuticals to individuals occurs. Rasiah found that explicit decision making about the funding of medicines to individuals by state rationers is so rare that such schemes are almost non-existent outside New Zealand.. She noted this type of rationing in other countries is invariably arranged on an ad-hoc basis (Rasiah 2009 p17). She commented that

New Zealand's CEC scheme was the only scheme identified in the literature that used a set number (where it stated that 'rare' and 'unusual' are considered to be in the order of 10 people nationally) as part of its definition of exceptionality and which included an explicitly stated budget. (Rasiah 2009 p20)

The Australian Benefits Scheme (ABS)⁸ provides information to the public and the pharmaceutical industry on medicines which are subsidised by the government. The ABS applies to the Australian Government each year for a specific subsidy to be set aside for very high cost medicines. There is no allocation scheme or criteria for individual claimants for high cost medicines to support this scheme. It is managed, as Rasiah has already pointed out, on an ad-hoc basis.

The literature supports Rasiah's contention that New Zealand stands alone as an OECD country which rations pharmaceuticals by exception with explicit criteria.

Social Inequality and Health

The literature discussed so far in this chapter has drawn on the connections between rationing health resources and the health status of individuals and communities. However a growing area of literature has recently emphasised the connection between social equity and the health of societies. A discussion on inequalities, as related to the health of individuals and societies, is relevant to this discussion on distributive justice because social inequality has become a way of examining access to health care and the fair distribution of resources.

The World Health Organisation (WHO) published a report on the concepts and principles of social inequities in health in 2006 (Whitehead & Dahlgren, 2006).

⁸ <http://www.pbs.gov.au/pbs/home>

They claim that health inequities count and that they are avoidable, unnecessary and unfair. Similarly, the Marmot Review published in England in 2010 (Strategic Review of Health Inequalities in England Post - 2010) demonstrated the link between social opportunities, equality, fairness and life expectancy. This position emphasises the connection between the social conditions and predictable biological pathways (Marmot, 2010).

New Zealand has been criticised for the high levels of income inequity by Wilkinson and Pickett (2007) in their book *The Spirit Level*. They have shown that at the macro-level, unequal levels in income distribution within countries (or within cities) are linked to social pathologies. They have drawn a correlation between income inequity and relative rates of morbidity and mortality, obesity, teenage birth rates, mental illness, homicide, low trust, low social capital, hostility, and racism (Wilkinson & Pickett, 2007). The theory presented linked individual health status to deep-seated social problems associated with poverty, poor formal education, relative deprivation and low social status. They also made the claim that income inequality is related to communities lacking in cohesion, social relationships and bedevilled by mistrust. In these circumstances of high levels of social inequality, increasing access to health care will make no difference to poor health outcomes because their research has concluded the aetiologies of ill health lie in the perpetuating inequalities.

Wilkinson and Pickett (2007) also wrote an article on health inequities titled *The problems of relative deprivation: Why some societies do better than others*. In this article, they reported on a review of 186 studies where a correlation existed between income inequality and population health. The review showed that more egalitarian societies were healthier. They have identified New Zealand, along with the USA, as countries with very wide levels of income disparity and increasing social inequity.

There has been considerable debate about the accuracy of Wilkinson and Pickett's work on social inequity. Snowden challenged *The Spirit Level* in his book *The Spirit Level Delusion: Fact-checking the Left's new theory of everything*, contending that the inequality model proposed is selective because it excludes some richer countries which are more socially equitable and includes a greater number of less equitable countries. He argues that this has

distorted the outcomes of the research and invalidated the findings. Naturally Wilkinson and Pickett dispute this and have subsequently defended their data.

The New Zealand Medical Association developed a 'Health Equity Position Statement' in which the differentiation is made between equity and equality.

This position statement uses the term equity in preference to equality because it better recognises that people differ in their capacity for health and their ability to attain or maintain health. Consequently, equitable outcomes in health may require different (i.e., unequal) inputs to achieve the same result. This is the concept of vertical equity (unequal, or preferential, treatment for unequals) in contrast to horizontal equity (equal treatment for equals).

(New Zealand Medical Association, 2010)

The statement described the link between income inequality, social deprivation and health inequity. The statement called on the government to give doctors adequate information, time and resources (including finances) to work innovatively and collaboratively to develop systems to reduce health inequities (New Zealand Medical Association, 2010).

Successive New Zealand governments have been aware of the widening gap between the highest and lowest income families. The Minister of Health in 2000 introduced legislation, the NZPHDA 2000, with the express purpose of reducing what she described as shameful inequalities (King, 2000a), particularly in relation to the health status of Maori and Pacific people. PHARMAC was established under this Act and has included the improvement of health status of Maori and Pacific people as one of its decision making criteria.

Wilkinson and Pickett (2007) thus posed a fascinating question when they asserted that increasing health status might be more driven by societies achieving greater income equality than striving to achieve ever higher access to increasing volumes of costly health services. The example of the USA shown in the Commonwealth Fund study (discussed on p.32) showed that highest investment in health care of all the countries provided the lowest equitable distribution.

The New Zealand Medical Association has proposed that influencing social determinants of health lies beyond the mandate of the health workforce. If

these presentations are correct, the programme of rationing health services to favour areas of high need and by increasing the size of our health workforce may not in fact reduce New Zealand's health inequalities.

This view is supported by Costa-Font, Hernandez-Quevedo and McGuire (2011) from the London School of Economics who looked at 70 of the most deprived UK local authority areas with the worst health and deprivation indicators; so called Spearhead areas. In these areas the NHS has prioritised health spending to specifically target new health initiatives which were likely to reduce the relative inequalities in the Spearhead areas (Costa-Font, Hernandez-Quevedo, & McGuire, 2011). Their study showed that between 2005 and 2007 there was a slight reduction in measured inequality but there was no difference between Spearhead and non-Spearhead areas. Costa-Font et al. (2011) concluded that these policies were not effective in reducing health inequalities

Wilkinson and Pickett, Marmot, researchers at the London School of Economics, the Commonwealth Fund and others have presented compelling evidence showing the effect of income inequalities on health status. Because poverty and low levels of social capital exclude so many people from access to publicly provided health resources, this work is also relevant to the subject of distributive justice.

Chapter 3: Context of Health Rationing in New Zealand

Introduction

In this chapter, I provide a review of past attempts at health rationing in New Zealand and report research by New Zealand and international authors on this subject. I discuss how PHARMAC has played an important part in providing leadership within the New Zealand public health scene by balancing services and budgets in a difficult and sometimes politically risky space.

Finally, three scholarly dissertations have been written in New Zealand on some aspect of PHARMAC's activities. These documents are also discussed.

Rationing in New Zealand

Two significant historical factors have influenced New Zealand's approach to rationing. The first was the 1938 Social Security Act which established political and legislative foundations for social welfare in New Zealand (Gauld, 2001.p16) The second was the rationing experiences during the Second World War. Both have relevance to health rationing in New Zealand and are discussed here.

The 1938 Social Security Act was a defining piece of legislation in New Zealand's history. This legislation was brought into existence by the first Labour Government elected in 1935. Prime Minister Michael Joseph Savage had a strong interest in health care (Dow, 1995). Following the Great Depression the government established a complete reformation of health services providing free services at the point of use. This included free access to public hospitals, mental health treatment, maternity services, medicines plus a host of allied services such as dentistry (Gauld, 2001 p19).

The medical profession strongly objected to their services being provided by a fully paid fee for service from the government which amounted to them becoming government employees. They manoeuvred Savage into adopting a partial payment system where the government paid the major portion of the costs of each consultation, and the doctor was free to charge the patient a co-payment. Surgery was provided free in the public hospital on the basis of a

waiting list for patient priority. The public hospital surgeons were also permitted to operate in private surgical hospitals and this began what has become known as the 'dual system' for public and private provision of health care in New Zealand.

The legislation also revised pensions and extended benefits for families, invalids and the unemployed. The political motivation for the programme was a desire by Savage's government to establish an equitable distribution of resources through taxation which provided New Zealanders, particularly the poor, with free access to an adequate range of health and social support services.

The wartime experience of rationing in New Zealand was based on government issued 'Ration Books' which were issued in 1945 during World War II (NZ History Online, 2012). The ration books ensured there was an equitable and adequate amount of food, clothing and some household items for families and workers. Many people were able to circumvent the rationing system by inventive legal and illegal means. However, there was a motivation by the government to use ration books to ensure, as far as possible, an equitable and acceptable distribution of scarce resources to the greatest number of people. The Post Office allocated the rations according to rules established by government officials to control consumption. Frugality was considered a virtue largely because the future was uncertain and if goods or services could be done without, this was believed to be prudent to assist the war effort. Rationing was established in the national psyche as a necessary encumbrance citizens were prepared to tolerate as a contribution towards the greater common good.

Daniels and Sabin, writing in their book *Setting Limits Fairly* published in 2008, described the culture in New Zealand of strong community and democratic values combined with one of the most extensive and oldest (Hornblow, 1997) social security systems in the world (Daniels, 2008). These authors attribute the openness of the rationing debate in New Zealand to these historical social and political factors and the country's previous World War II experience of rationing.

Bloomfield (2003) dates the beginnings of the New Zealand experience in explicit health rationing to the Green and White Paper on Health: *Your Health*

and Public Health; A Statement of Government Health Policy (Upton, 1991). This document was presented as part of the 1991 parliamentary budget (Bloomfield, 2003) by the Finance Minister Hon. Ruth Richardson. In the document Health Minister, the Hon. Simon Upton announced a radical reorganisation of New Zealand's health services. The reorganisation was aimed at reigning in health spending and trying to define the government's liability to providing health care to citizens. The Green and White Paper recommended changes to the New Zealand public health services which allowed for a systematic purchase of private hospital care with public money. This was the first time this idea had been promoted by a New Zealand government.

The reforms devolved the responsibility of decision making on health funding to four regional health authorities (RHAs). A previously used population based formula continued to calculate the RHA's distributions which RHAs were allocated to 'purchase' health services in each of the four regions (Gauld, 2001). The RHAs were authorised to purchase health services from public, private and not-for-profit health providers (Upton, 1991). Upton also expressed the hope that new types of providers would emerge to compete with the established providers for RHA funding such as private hospitals, private trusts, and Maori and Pacific health providers. Upton especially wanted to see the development of a few American type Health Maintenance Organisations⁹ (Upton, 1991) to compete with the fully funded public services.

Upton established New Zealand's first attempt at explicit meso-level rationing by appointing the 'Core Services Committee' which later became the National Health Committee (NHC). This Core Services Committee, chaired by broadcaster Sharon Crosby, was given the difficult task of describing the care that should be funded by the public health service, and the relative priority of this care.

Ultimately, the committee could not agree on the relative priorities (Gauld, 2001). It could do no better than to simply suggest that there needed to be a much wider debate among the public about managing the greater demand for

⁹ A Health Maintenance Organisation (HMO) in the United States is a managed care organisation with members whose health care fees are paid by their employers. The HMO covers only health care services provided by doctors and allied health workers who have agreed to treat patients in accordance with the HMO's guidelines and restrictions. The health care services are not provided from an insurance rebate basis but from the membership platform. Consequently, it is cheaper to belong to a HMO's than to than the purchase of insurance policies. However the care provided has limits.

care within finite resources. The committee acknowledged that the public health system would always remain shackled to patients queuing for services and as Scott (2001) had already pointed out, queuing was also a form of rationing. However, the NHC's major work, described by Bloomfield (2003), was a rejection of an Oregon-style list and agreement on prioritisation principles. The NHC developed booking systems to replace hospital waiting lists and promulgated guidelines and clinical priority access criteria.

The general thrust of the NHC was to develop mechanisms for prioritising patients *within* services rather than prioritising *between* services (Manning & Paterson, 2005).

As opposed to the original NHC concept of a core list of *what* would be provided, the Committee saw its task as making it clear *when* services should be publicly funded. The Committee tried to identify under what circumstances services would be beneficial, who should receive the services first and how long individuals should have to wait (Edgar, 2000).

The NHC designed its own framework for thinking about priorities and used four principles: benefit, fairness, value for money and acceptability in its work. They published four reports: the National Advisory Committee on Core Health and Disability Services Reports in 1992, 1993, 1997; and the National Advisory Committee on Health and Disability in 1997¹⁰.

Ashton, Cumming & Devlin (1999) in a major report to the HFA identified the principle of acceptability on which prioritisation should be based. They argued that because there were winners and losers from this process, the rationing¹¹ debate would be clouded by a lack of information and objectivity (Ashton, et al., 1999). They cautioned that the principle of acceptability would carry with it the power of veto. Because the veto was present, there was also a need for detailed analysis, openness and clarity to support the prioritisation decisions. The other side of acceptability was the need for concordance with cultural values and norms. Ashton et al. (1999) presented two further arguments.

¹⁰These 4 reports are available on the National Health Committee's website <http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-publications>

¹¹The word 'prioritisation' is used in the report instead of 'rationing'.

If acceptability was to have the power of veto, a preliminary assessment of acceptability should be placed at the front-end of the prioritisation process. This suggestion was aimed at avoiding wasting time and resources on the detailed analysis of changes in expenditure priorities if they were unlikely to be acceptable. It was also argued that consideration needed to be given to the means by which the principle of acceptability was incorporated in the prioritisation process. This was because protecting any important residual cultural values and norms (which were not captured by the other principles) would not preclude inertia in resource re-allocation (Ashton, et al., 1999).

The NHC's enduring meso-level rationing achievement was the introduction of a booking system for some types of elective surgery. Included were cataract surgery, coronary bypass and angioplasty surgery, total hip and knee replacement surgery and prostate surgery (Dew, Cumming, McLeod, Morgan, McKinlay, Dowell, & Love, 2005). The booking system was introduced because the NHC researched waiting lists and discovered a number of anomalies and a basic level of unfairness in the system. For example, patients were able to game the system. They were able to get a higher place on the waiting list by consulting a private surgeon who also operated in the public hospital. The private surgeons were placing their patients higher up the public lists and the surgery was provided earlier than for those patients who could not afford to see the doctor privately. The other problem was patients and their General Practitioners (GPs) were never clear when, or even if, the surgery would be performed.

Weimer and Vining (2005) described the term 'rent seeking' as an example of market and government failure where the policy objectives of government expenditure are not delivered or deliver unintended objectives. They described how powerful and influential groups in society are able to convince politicians and officials that their co-operation and services are essential. Rent seeking is in essence, policy choices which are made to reward such co-operation on an ongoing basis (Weimer & Vining, 2005). The dual public/private surgical system in New Zealand, where surgeons work as both public and private operators, could be described as a rent seeking service. Without the co-operation of the private surgical market of doctors and hospitals, the surgical waiting time in the public system would be considerably longer and so the government is prepared

to pay for this co-operation. In 2011, to some extent, the private surgical industry had a measure of control over the supply of publicly funded surgical services.

Development of a priority assessment tool to replace the waiting list began in 1994. The Ministry of Health established an Elective Services Policy Unit to report to the government on the performance of the DHBs against national standards. The assessment tool consists of a five-point scale. The scores were based on severity (suffering, disability, clinical cost of delay), and the patient's ability to benefit (degree of improvement anticipated, likelihood of improvement). The scores for each criterion were assessed on the patients' capacity to manage normal life tasks and their pain levels (Dew, et al., 2005). The scores were used in conjunction with financial thresholds below which the hospital was able provide the surgery, given the available resources and funding. There was an expected transparency about when the ceiling of available funding was breached and this became an explicit justification for refusing or delaying the patients' surgery.

This approach was praised by Dixon and New (1997) in the *British Medical Journal* in an article entitled "Setting Priorities New Zealand-Style, can we learn from it?" They discuss the NHC's attempt to set the criteria at providing treatment to the most needy, instead of the NHS tradition of "the squeaky wheel getting the oil" (Dixon & New, 1997).

Mary Seddon, a New Zealand health researcher visiting the Harvard Medical School at the time, cautioned New Zealand health officials from such explicit forms of rationing. She argued in a letter to the *British Medical Journal* that rationing is not simply a matter of making allocative decisions more explicit. She rejected the assertion that 'explicitness trumps all' in the rationing debate (Seddon, 1999). Seddon argued that any allocative decision which involves public funds and the denial of services is concerned with the theories of distributive justice and are more properly dealt with as ethical debates on the so called 'tragic choices'. This involves a much wider audience than just the medical profession and economists conducting cost-benefit analyses of QALYs and utilising waiting list clinical assessments as the measurements.

For more than 12 years, the debate has continued as to how ideas of value can be represented by analytical tools such as cost-benefit analysis. For example, analytical QALYs systems or programme budgeting and marginal analysis (PBMA) can reach a just and fair decision about who should receive care and when (Ashton, et al., 1999). These methods are often the subject of criticism for promoting efficiency over equity, fairness and justice. The use of QALY league table has become a quantitative approach which gives health economists comfort that there is rigour in priority setting (Hamilton, 2003). However, Ham and Coulter (2000) argue that QALY league tables used for priority setting should come with a 'large print warning' about the sometimes fragile basis for the construction of such tables and the overuse and misuse of the QALY. This is because QALY's are being misunderstood and used more widely to make conclusions than cannot possibly be justified (Hadorn & Brook, 1991).

Research into Micro-Level Rationing

There are many qualitative and quantitative systematic reviews which have researched how physicians implicitly ration health services to their patients. The studies generally involve large cohorts of doctors across several participating countries. The studies attempt to understand how clinical decision makers meet perceived needs in an environment where calls are being made on the services which are perceived to be greater than the funders' ability to supply services. The importance of these studies is that they extract anonymously the decisions doctors may make without advising the patients or their families.

Hurst, Slowther, Forde, Pegoraro, Reiter-Theil, Perrier, Garrett-Mayer and Danis (2006) surveyed the attitudes of 656 internist doctors to bedside rationing in Norway, Switzerland, Italy and the United Kingdom. The doctors were asked about their attitudes towards bedside rationing. In the questionnaire sent to the participants of the study, bedside rationing was defined as any implicit or explicit mechanism that allows people to go without beneficial services (Ubel, 2000). The results of the study showed that 82% of the respondents showed some degree of agreement with rationing and 56% said that they had rationed health care in the past (Hurst, et al., 2006).

Other results showed that 81% of the doctors in the study withheld some services from patients because they believed there would be minimal benefit from the proposed treatment. One reason which was given for withholding treatment was that the quality of life provided by the treatment would be low. Another reason the doctors in the study gave for withholding treatment was that the patient was over 85 years of age. Both of these factors which influenced the doctors' decision making were essentially moral considerations involving the doctors' beliefs about what constitutes an adequate quality of life and beliefs about withholding treatment from the 'old-old' (people over 80 years of age). These are not clinical decisions but contain significant ethical and moral content, at the least, worthy of discussion with the patients or their families.

Age has been a factor in the selection of patients for organ transplantation (Hoffenberg, 1994). The ethical considerations related to organs for transplantation that have been retrieved from the dead were discussed by Hoffenberg (1994) during the Biko Lecture of 1994. He described the unstated rule in South Africa that young patients, and patients over 55, were not considered suitable candidates for transplantation. He believed that there were some plausible clinical reasons why these candidates should be excluded, but essentially this form of micro-level rationing was an ethical consideration. The thinking behind this judgement by doctors assessing a patient for transplantation, was that a chance of life or better health should be given to those who could still enjoy a fruitful and productive life, or as Hoffenberg (1994) more crudely put it people who were not "past it".

Such considerations may perhaps be forced on medical practitioners because there is scarcity of resources (in Hoffenberg's case a scarcity of organs for transplantation). However the frequency of rationing in the Hurst et al (2006) study was correlated with the perceived scarcity of resources and significant differences between the countries were found. One might postulate that the countries with the greatest resources would place less pressure on the interns to ration, however the study showed that the doctors in Switzerland with the highest health spending per capital of countries in the study, rationed the most (Hurst, et al., 2006). Italy, the country with the most doctors per capita, rationed the least.

Strech, Persard, Marckmann, and Danis (2009) conducted a meta-analysis of 15 quantitative surveys on rationing experiences of doctors from Canada, Italy, The Netherlands, Norway, Sweden, Switzerland, the United Kingdom and the USA. The research showed ambivalence by physicians toward micro-level rationing. The doctors demonstrated a willingness to set limits on health care to patients generally, however their willingness decreased considerably when they were asked specifically about rationing decisions informed by their own judgment of individual patients (Strech, et al., 2009). These authors concluded that considerable barriers are erected by physicians when they are required to engage in explicit micro-level rationing decisions.

In a similar Swiss study conducted among 1,184 physicians by Perneger, Martin and Bovier (2002) in primary care and hospital practice, doctors were asked in a mail survey about the acceptability of making treatment choices in various rationing scenarios. The doctors were asked if they believed that micro-level rationing should be based on cost-benefit considerations alone or in combination with equity considerations. They were also asked who should make such decisions. The results showed that the Swiss doctors were more concerned about equity than cost-utility. The doctors showed stronger preferences for the equitable allocation of health services than for the maximising of health in the broader society using cost-benefit as a benchmark. Despite their strong dislike for explicit micro-level rationing on the basis of cost-benefit calculations, they preferred that physicians were in charge of all rationing decisions (Perneger, et al., 2002).

Oberlander (2006) critiqued the Oregon Health Plan experience and stated that the opportunity for physicians to be open about rationing does not offer enough opportunities to reveal justice arguments. Oberlander stated that there is a real distinction between medical and non-medical determinants of distributive justice and the Oregon Health Plan failed to address the latter. To make such decisions explicitly, for example, to supply life-preserving intensive treatment or life-prolonging pharmaceuticals, requires physicians and managers to make morally defensible decisions. Swenson (1992) described how the principles of distributive justice can be used to make these calls, however concedes that denying care to patients who need care is seen as purposeful neglect which offends the doctors duty of care and in some countries (e.g., the USA), this

may be grounds for litigation. Hence, the great reluctance by clinicians to be open about such decision making.

PHARMAC's 'Community Exceptional Circumstances' Policy

PHARMAC has three systems of micro-level rationing of medicines to individuals who have rare diseases or high-cost pharmaceutical needs that fall outside the national formulary. They are the Exceptional Circumstances policies; Hospital Exceptional Circumstances, Cancer Exceptional Circumstances and the Community Exceptional Circumstances scheme.

Exceptional Circumstances funding has been in existence since 1994, initially provided for under Section 99 of the Medicines Act 1981 and administered by the Ministry of Health. When PHARMAC came into existence in 1994 as a shared buying agency owned by the four RHAs, the responsibility for deciding on the Exceptional Circumstances schemes was given to PHARMAC. In 2000, PHARMAC was restructured into a Crown Agency and continued to operate the Exceptional Circumstances scheme.

The Community Exceptional Circumstances scheme is the focus of this thesis because it involves an individual person applying to PHARMAC for a drug subsidy. The other two schemes (Hospital and Cancer Exceptional Circumstances) are administered by PHARMAC but through decision making layers within the DHBs.

PHARMAC's Community Exceptional Circumstances policy has a clear application process, there is one committee which makes the decisions, there are appeal procedures, there is a fixed budget and there are published criteria on which the committees make their decisions.

The Application Form used¹² by physicians to facilitate applying, on behalf of the patient, requires a clear identification of a wide range of information. Partially or inadequately filled out applications are not processed. The application form asks for information on the medicine being requested, the entry criteria the application is being made under and evidence of the clinical benefit

¹²Available on
<http://www.pharmac.govt.nz/2009/06/03/1%20Application%20form%20for%20Community%20Exceptional%20Circumstances.pdf>

expected from the drug. The evidence which supports the application is required by way of journal articles and evidence of cost estimates of the drug is also required, although the Research Findings (Chapter 6) in this thesis demonstrate that these criteria were not strictly adhered to.

This thesis is about how this allocative policy, Community Exceptional Circumstances is actually working. Are the outcomes cost-effective? Are the outcomes just for the patients who apply? What criteria are applied? How well is the process managed?

Theses and Dissertations Written About PHARMAC

There have been three New Zealand university masters' degree dissertations written on an aspect of PHARMAC's operation.

In 2000, Victoria Sim wrote a dissertation entitled *Drug deals, dollars and decisions: an ethical and legal evaluation of the role of PHARMAC in health rationing*. In this work, Sim outlined the history and legal establishment of PHARMAC. She discussed the new approach to rationing medicines introduced by PHARMAC. These were the purchasing instruments and the use of cost-utility analysis and the legal implications to PHARMAC of its operating policies and procedures. She called for the abolition of PHARMAC's exemption from Part II of the Commerce Act. This issue is discussed more fully in Chapter 6 (p. 108) of this thesis.

Sim recognised in 2000 what she described as an inherent unfairness about the way PHARMAC managed the distinction between the access to quality medicines and value for money. She criticised PHARMAC for not advising patients who were denied access to medicines under the Pharmaceutical Schedules, whether they were being denied treatment on clinical or financial grounds. This subject is also discussed several times in this thesis.

Trevor Villers, a masters student at the Auckland University of Technology presented a dissertation titled *A Thematic Analysis of Recent PHARMAC New Medicines' Subsidy Decisions* in 2008. Villers undertook a thematic analysis of 20 cases referred to the Pharmaceutical Therapeutic Advisory Committees (PTAC) between February 2004 and November 2006. The researcher aimed to

determine if decisions on the applications for a subsidy were guided by PHARMAC's nine decision making criteria. In the study, the author also sought to discover if other factors were apparent in guiding PTAC's decisions on the 20 cases.

Villers (2008) found that PHARMAC did take account of factors outside the stated decision making criteria. These factors were consistency with prior PTAC decisions and the degree to which a decision might be publicly, politically or medically contentious.

Villers (2008) also showed how PTAC took account of health needs in its decision making as well as the need for PHARMAC to manage competing financial demands on its budget. He examined the minutes of the PTAC committee and found that it was not possible to determine what weighing was given each criterion. He concluded that there was a need for further research to determine the extent to which PTAC decisions are dominated by fiscal concerns above the other decision making criteria.

Dr. Dilky Rasiah, the Deputy Medical Director of PHARMAC, wrote a dissertation in 2009 on the subject of PHARMAC's Exceptional Circumstances schemes. In this document, Rasiah quantitatively analysed the data PHARMAC held on the applications of claimants who were successful in gaining a Community Exceptional Circumstances subsidy. Specifically, she looked at the types of applications, the characteristics of the patients, their conditions and the practitioners who made the applications.

Rasiah (2009) found that between October 2001 and September 2008 there were 3,234 Community Exceptional Circumstances applications made to PHARMAC. Of the 3,234 applications, 420 were approved and 2,144 were declined. This was an overall approval rate of 16% of all the applications.

Rasiah (2009) examined the age, gender, ethnicity and deprivation index of applicants. She noted that there were more female than male applicants however males had a higher approval rate (20%) than females (14%). The highest number of applications was received from applicants in the 45–64 year old age group. Children aged between 0–4 years old had a high approval rate (55%) and 65–80 year olds had the lowest approval rate (6%). There were no

obvious trends in the ethnicity of approvals or declines of applications and no similar trends in the approval rates by deprivation index.

There were a large number of applications for a small number of medicines. Rasiah found statistically significant differences in initial application approval by age. She found that PHARMAC's approval process favoured younger patients who were more successful at gaining approvals than older patients. There was also a much higher likelihood of applications for Community Exceptional Circumstances applications from Auckland being approved than from any other region in New Zealand (Rasiah, 2009). Vocationally registered medical specialists had a greater statistical chance of their patients being successful in a Community Exceptional Circumstances application than a patient of a general practitioner.

Rasiah suggested that the applicant clinicians may have developed insights into the success or failure of applications and this knowledge contributed to some doctors having higher approval rates for their patients than others.

Rasiah noted that 30% of the applications for Community Exceptional Circumstances had no drug costs entered with their applications (a requirement of the process). She noted that the co-ordinator of the Community Exceptional Circumstances applications excluded (declined) applications which were incomplete or, in the co-ordinators opinion, had no chance of being approved.

However, Rasiah did not investigate the claims of unsuccessful applicants for Community Exceptional Circumstances. Consequently, she was not able to develop a clearer picture of the 84% of the claimants whose Community Exceptional Circumstances applications were declined.

Chapter 4: Philosophical Framework

Introduction

The philosophical framework of this research is based on the principles of justice. In this chapter, I describe the main social justice and ethical theories relevant to distributive justice and the principles which have been developed by Rawls and Sen. I then explore how these principles might be interpreted in a contemporary context, for example within public health. I have developed test-questions which I will use to examine the operation and fairness of such social distributions. I conclude the chapter with a description of how these test-questions have been used to examine PHARMAC's Community Exceptional Circumstances policy.

The Theories of Distributive Justice

Any description of justice has a central desire to attempt to define the moral authority of laws. Homer described justice as personal vengeance. Plato saw justice as the will of the stronger. Thomas Aquinas believed justice divine, directing man to do what he feels he ought to do under divine direction. Aristotle described the formal criterion of justice that still wins the greatest agreement: that we should treat equals equally and treat unequals unequally, in proportion to that inequality. Common to all these positions, justice is considered a positive thing which is applied to decisions, procedures, laws, actions and events (Romano, 2009).

Across the wide range of substantial ethical theories and principles of distributive justice, no one theory commands universal acceptance (R. Gillon, 2006). Lamont (2007) outlines seven potentially relevant theories which describe distributive justice. These theories are based loosely on the Aristotelian principle of equity and Kant's principle of utilitarianism.

Lamont (2007) identifies the main foundational theories which are strict egalitarianism, resourced-based principles, welfare-based principles, libertarian principles and feminist principles. Lamont also included a discussion on the

difference principle, which I will include in my exploration of the work of John Rawls later in this chapter. I include feminist principles of justice because Lamont included them in his lexicography; however I note their existence but do not critique them.

Strict egalitarianism is based on the Aristotelian principle of substantive equality, that all people should have the same level of goods and services. This is justified on the grounds that people are owed equal respect and the equality of goods and services gives effect to this respect (Lamont, 2007). However, the principle of strict equality raises the problem of an 'index' of equality. How do we know which level of goods and services should be equally distributed? This question is the basis of the 'categorical imperative' of Immanuel Kant, a position which he asserted, everyone in society could morally accept. Kant established this theory on the justice principle that all people are to be treated not as a means to an end, but as the ends in themselves (Russell, 1946).

Kant's theory of utilitarianism relies on our pursuit of two opposing states—pain and pleasure. He proposes maximising these two states for all in society. Jeremy Bentham developed a quantity factor to the utilitarian principle that utilitarianism should deliver the greatest happiness to the greatest number of people¹³. The argument was advanced by John Stuart Mill who warned however that the greatest happiness must not involve coercion which would breach the harm principle, whether the coercion was in the best interests of the person, or not.

Utilitarianism is a difficult area for health care and health workers. Health professionals aim to benefit people in ways to do with caring for people; however utilitarianism is not as simple as that (Campbell, Gillett, & Jones, 2006). As Bentham and Mill point out, the greater question (which might particularly interest people who are excluded from access to health care) is whose benefit is being advanced and at whose expense?

The primary moral criticism of utilitarian theory is that everyone cannot be better off if a greater utility is to be provided to one person. This is because a decrease in the utility of others creates inequality. Furthermore, providing an

¹³Often restated as 'the greatest good for the greatest number'.

extra person with a good or service the person does not want, even if this is in the person's best interests, also creates inequality.

Resource-based principles or resource egalitarianism, the work of Ronald Dworkin (1981), is presented in two parts. The first, which Dworkin called equality of welfare, holds that distributive justice treats people as equals and distributes resources among them until no further distribution produces more welfare. The second, which he described as equality of resources, holds that people are treated as equals when we make distributions, so that no further distribution would leave a person's share of the total greater than the share of another (Dworkin, 1981). Resource egalitarianism also asserts that the social outcomes of people's lives are to be determined by the free use of their resources. However, under Dworkin's theory, those with natural inequalities, for example people born with ill health or disability, or people who have not had access to education or have low levels of natural talents, are severely disadvantaged and cannot freely use resources under this type of distribution, thus producing the inequality Dworkin aimed to avoid.

Desert-based distributive justice asserts that people deserve the benefits of their toil and industry; considered by Aristotle to be a virtue. John Locke argued that people deserve to have those items produced by the fruits of their own labours and benefits provided by their abstinence (Lamont, 2007). The main criticism of this type of distributive justice is that the theory is based on the distribution of economic benefits. Such benefits more often than not depend on factors over which people have little or no control themselves or they have done nothing to deserve the benefits they enjoy, for example inheritance.

Libertarian theory, as described by Nozick, proposes that a person who justly acquires a holding is entitled to that holding and is entitled to justly transfer the holding. Nozick asserted that markets where transfers take place should be unencumbered and not be subject to a particular distributive pattern. According to Gillon (2006), to libertarians, the number of just transactions of holdings throughout the world constitutes a picture of distributive justice.

The 'difference principle' has been the most widely discussed theory of distributive justice in the last three decades (Lamont, 2007). The development of this principle is based on the concept of fairness, which is fundamental to

Rawls' theory of distributive justice (Rawls, 1971). Rawls used social contract theory to describe ideal forms of social justice aligned to the tradition of Hobbs (Romano, 2009) and Aristotle.

Introducing the Theories of John Rawls

The chief purpose of Rawls' theory of 'justice as fairness' is to ensure the avoidance of a sanction on utilitarian and consequentialist thinking where the interests of individuals would be sacrificed for the greater good. Rawls invited participants to engage in a thought experiment (Adams & Dyson, 2004; Kelly, 2003). The experiment was to devise the kind of society in which a group of individuals are placed in what Rawls calls, the 'original position' or the 'state of nature'. This is a state in which individuals are free from coercion and located behind a 'veil of ignorance'. Such persons are characterised by a lack of knowledge about themselves and the other individuals in the experiment. They would know that it would be useful for them to have what Rawls called comprehensive preferences such as primary goods, rights, liberties, opportunities, powers, income and wealth and the basis of self-respect (Lamont, 2007). Rawls assumed that everyone would want as much of these goods or pleasures as was possible. In the experiment Rawls decided that the participants of the experiment did not know anything about their own talents or abilities nor did they know what status, influence or position they would have in the society (Honderich, 1995).

In these conditions, where self-interested participants will make decisions without knowing how these decisions will affect them, Rawls believed they would devise the principles of justice for the society and its institutions where the fundamental agreements are fair. Rawls expected the participants in this experiment to arrive at general principles that would also protect the most vulnerable in society. This is because any participant could have turned out to be the most advantaged, or the most disadvantaged member and their conceptions of justice would be ranked by their acceptability to persons so circumstanced (Rawls, 1971). Rawls' theory arose from participants' submissions about the characteristics and content of justice for institutions and

just actions by individuals. The theory was characterised by the following principles:

Each person is to have an equal right to the most extensive liberty compatible with a similar liberty of others.

and

Social and economic inequalities are to be arranged so that they are both (a) to the greatest benefit of the least advantaged and (b) attached to positions and offices open to all under opportunities which apply the conditions of fairness and equality of opportunity.

(Rawls, 1971, p. 60)

The first principle is known as the difference principle. To get to this position using Rawls' theory, some explanation of the elements of the thought experiment is necessary. Rawls suggested that it is realistic to search for a utopia where participants are free to make choices that would form a well functioning and moral society. Rawls acknowledged that there are many constructions of society throughout the world, but his theory is a modern demonstration of a conception of justice which applies to functioning democratic societies. In such conditions justice is conceived of as "those principles which rational persons who are concerned to advance their own interests would agree to when they do not know if they are advantaged or disadvantaged by social or natural contingencies" (Rawls, 1971, p. 91).

Rawls asserted that participants in the thought experiment were free and equal. Notes were collated by Kelly from Rawls' lectures to his philosophy students at Harvard University (Kelly, 2003). In his notes Rawls' description of the meaning of 'free and equal' is captured. Kelly described Rawls' understanding of a free person as one fully capable of engaging in social co-operation over a complete life. This definition has two aspects to it. The first is for persons who have the essential minimum degree of moral powers necessary to be able to understand, apply and engage in social co-operation over a complete life. The second aspect of being a free citizen is that the people would regard themselves as "self-authenticating sources of valid claims" (Rawls, 1971, p. 479).

Rawls explained self-authentication as a set of rights which one can impose on oneself, such as self-command, self-esteem, self-movement, self-interest, self-endorsement, self-protection and self-control. Rawls' notion of freedom is that

these interests are authenticated by the person and not by any other person or group of persons.

In contrast to this more recent position, Kant proposed that rational personhood is developed through pursuit of pleasure. He asserted that an individual's dominant pursuit, in this case freedom, justifies a rational person doing and acting as the individual pleases. This conflicts with Rawls' view of justice. Rawls proposed that the pursuit of pleasure or utility must not only be seen in terms of the moral position of rights, duties and obligations to oneself, but also rights, duties and obligations for all.

Notice that self-authenticating includes rights but also duties and obligations to other citizens whose self-authenticating claims might be adversely affected. Rawls' theory of justice includes the utility of the individual and the utility of the whole society around the self-authenticating person being required to serve the interests of the individual and society justly.

Rawls' theory of justice as fairness is also based on the necessity of the two principles cited above to be able to be modified. In the case of competing interests, the principles may be compromised. The purpose of such a compromise is to demonstrate that the principles must satisfy the basic elements of fairness and equity. Where acting on the principles would cause unfairness or inequity, they should be adapted by reflection and moderations. He explains this requirement in these terms:

In describing our sense of justice an allowance must be made for the likelihood that considered judgments are no doubt subject to certain irregularities and distortions despite the fact that they are rendered under favourable circumstances. When a person is presented with an intuitively appealing account of his sense of justice he may well revise his judgments to conform to his principles even though the theory does not fit his existing judgments exactly.

(Rawls, 1971, p. 48)

In this part of Rawls' theory, he showed how people can co-operate with each other while simultaneously holding reasonable but opposing doctrines. These opposing doctrines may be religious or political or indeed general beliefs about what constitutes a good life. Rawls' theory takes account of differences which are led, by deliberations under the veil of ignorance, to reflect on the differences

among the members of the society, and arrive at one set of principles of justice which are fair for the whole group.

Rawls called this the priority problem of assigning weights to the competing principles of justice (Rawls, 1971). He appealed to the use of intuition by decision-makers to decide on these competing interests. Rawls argued that there is nothing irrational about using intuition because ultimately the conception of justice will have to rely on judgments. Rawls asserted that if the principles of justice were to be arranged in a lexicographical order, the order would need to satisfy the principle of the original position. This would require an ordering of inequalities to constrain the original principles of justice. So ordering or weighting principles does not get us very far. This is why Rawls suggests that intuition reflects the need to reach agreement on how the principles of justice are to be balanced on the basis of fairness and equity. Self-examination thus opens the way for the two Rawlsian principles previously mentioned. Reflection moves us closer to perceptions of fairness as a philosophical ideal even though we may never perfectly achieve it.

Interestingly, Rawls omitted health or health care from his lexicon of primary goods which all would agree desirable in the greatest possible account, consistent with the account of all others. Many scholars of Rawls, including Hadorn (1988) have attempted to explain this apparent omission.

Hadorn (1988), in his thesis on Rawlsian distributive justice, discussed the development of an affordable and fair health system in the USA. He argued that the more correct place for health (or health care) within Rawls' theory was on a par with other rights and liberties. Since without adequate health, none of the other rights and liberties can be exercised or enjoyed. Gutmann (1992) argued that ill health interferes with our happiness by undermining not only our freedoms but also our self-confidence and self-respect, which Rawls values centrally under the 'veil'.

An element of Rawls' theory which has drawn criticism is the fact that the language in the theory is positioned in generic male terms. Rawls (1972) refers to 'he', 'his', 'fathers', 'sons' and the 'principle of fraternity' (p. 251 and p. 256). The veil of ignorance makes no mention of the deep gender structures of society and the impact that gender difference has on the notions of the original

position. Rawls ignores gender in discussing a person's class or place in society and excludes sex as a rational basis for discussing natural assets, abilities, strength and opportunities. Whilst Rawls claims the theory of justice is for all, the notions of fairness are generated from a dominant male position. He fails to address justice of the gender system which has its roots in the sex roles as one of the fundamental structures in our society (Moller-Okin, 1989). In this sense gender cannot be 'assumed away' under a veil of ignorance because one cannot 'not know' one's gender (Waring, 2011). Moller-Okin (1989) suggested that this flaw in Rawls' theory leads her to ask "does this theory of justice apply to women?" (p. 91).

Although the family is barely visible in Rawls' theory of justice, in the well ordered society, it is surprising that the family should not be mentioned as a primary structure. Rawls does discuss the heads of families and the responsibility placed on the 'head', and he deals with the utility of the family as being an example of the difference principle. An example is given where the utility of each member of the family may not allow for greater distributions to one, at the expense of the whole family (*A Theory of Justice*). The opposite may also apply where the greater distribution to the one, may enhance the well being of the whole family.

Other critics of Rawls, for example, Lawrence Crocker (1977) suggests that the difference principle appears to describe physical and material (financial) benefits. Crocker points out that not all things are valued or have moral weight because they relate to material or financial benefits. In Crocker's (1977) article titled "Equality, Solidarity and Rawls' Maximin [sic]" he uses the example of people who seek out situations in which they have strong feelings of community and joint responsibility. Rawls' theory would appear not to emphasise such dispositions via the difference principle. This is possibly the most controversial aspect of Rawls' theory.

Cohen (2008), in his book *Rescuing Justice and Equality* criticised the difference principle because whilst it attempted to protect the interests of the least prosperous in society, he felt that Rawls inadvertently licenses greater inequality. Cohen also points out that Rawls' difference principle is based on material incentives to both the most and the least privileged. He uses the

example of well off and powerful people feeling justified by the difference principle to aim to produce more goods and services in society (if they were paid more or incentivised in some way to do so) so that they can provide a greater share of their wealth to the least prosperous (Cohen, 2008). This would in turn produce more wealth for everyone and benefit the least well off by providing them with access to a greater share in such rewards. However, Cohen asserts that in fact incentivising the rich in this way increases their wealth and increases the difference between the well off and the poor, which Rawls' difference principle aims to avoid.

Norman Daniels (2008) wrote in his book *Just Health*, that the difference principle is not a mere trickle down principle, it requires the maximum flow from the most advantaged to the least advantaged to give up some of their wealth, position or privilege, until the worst off receive an adequate minimum of distributions.

Despite these criticisms, Rawls' theory of justice as fairness and equity is formulated on an understanding of the benefits to society as being primary goods, rights, liberties, opportunities, powers, income and wealth and the basis of self-respect. This understanding of justice could equally be applied to gender, talents, race, intellect, strengths, weaknesses and particular circumstances. Rawls still presents us with a useful means of cancelling out privilege and power and an excellent basis for challenging sexism, racism, ageism, rankism and meritocracy (Fuller, 2006). Rawls has provided a method to achieve justice for undervalued, voiceless, weak and dispossessed members of society.

Introducing the Theories of Amartya Sen

Amartya Sen accepted Aristotle's contention that a theory of justice must be centred on equality, but Sen asks "Equality of what?" (Sen,1980). His transcendental and pragmatic approach allowed room for expressions of imperfect descriptions of justice because humans and societies are not perfectly constructed and do not behave perfectly. Such imperfections have consequences. Sen's consequentialist perspective broke away from the Kantian confines of utilitarianism which placed moral significance on utility of choices, and focused on the goodness of actions, rules and institutions in terms

of their consequences (Basu & Ravi, 2008). Consequently, Sen has taken Rawls' difference principle further and validated alternative elements of justice.

Sen advanced the notion of justice as fairness by addressing the issue of the capability of persons and institutions to 'be' just and 'act' justly. Therefore any theory of justice, or a general and adequate theory of normative social choice, has to be concerned with both the fairness of the process involved and the equity and efficiency of the substantive opportunities that people can enjoy (Sen A, 1980). For this reason Sen, unlike Rawls, included the capability of good health and a lack of physical incapability as an element of equality.

In any discussion of social equity and justice, illness and health must figure as a major concern. I take that as my point of departure – the ubiquity of health as a social consideration – and [note] that health equity cannot but be a central feature of the justice of social arrangements in general. The reach of health equity is immense.

(Sen A, 2002, p. 2)

Sen explained in his theory that a developed view of justice, based on capability, should not only concentrate on the utility of an individual's happiness but also concentrate the use of resources in assessing how advantaged a person is in relation to another. This description of justice must take account of a person's capability to access the enjoyment of the things a person has reason to value. The freedom to actually be able to achieve the things we want to do is as important, if not more important, than having access to the resources to achieve what we want to do.

This capability approach to fairness and equity points to the assessment of social disparities and the social consequences of such disparities, both for the individuals concerned and for communities. Unlike Rawls, Sen drew attention to the notion of fairness compared to the 'primary goods' which he identified as income, wealth, self-respect and power. He argued that no matter what quantity of these resources (income, wealth, self-respect and power) a person has, the lack of capacity to use them increased the level of inequity rather than reducing it.

Sen's reasoning in favour of capacity gave a far more advanced view of equity than Rawls reasoning in favour of fairness. For example, a person who has significant wealth but who might be very prone to chronic illness or pain, is not

necessarily much advantaged over a person who has modest wealth but has the capability to enjoy what that person has reason to value.

Sen believed that fairness must also address the need for some element of economic efficiency in the process of distributing resources. This is because the more resources that are available for all to enjoy, the greater the content of equality. He argues that inefficiency or wastage reduced both the level of distributions and the capacity to achieve the maximum possible utility.

Amartya Sen's view of justice includes two different principles: one is capacity which is built around an arrangement focus, and the other view is built around a realisation focused view of justice.

In understanding the contrast between an arrangement-focused and a realization-focused view of justice, it is useful to invoke an old distinction from Sanskrit literature on ethics and jurisprudence. Consider two different words – 'niti' and 'nyaya' – both of which stand for justice in classical Sanskrit. Among the principal uses of the term 'niti' are organisational propriety and behavioural correctness. In contrast with 'niti', the term 'nyaya' stands for a comprehensive concept of realised justice. In that line of vision, the roles of institutions' rules and organisation, as important as they are, have to be assessed in the broader more inclusive perspective of 'nyaya' which is inescapably linked to the world which emerges, not just the institutions or rules we happen to have.

(Sen, 2009, p. 20)

Sen's (2009) *Idea of Justice* stands as a substantial exposé of distributive justice. It not only insists on the constructions of justice as fairness, but also rests on the role of public reason on what can makes societies just or unjust. Sen presented choices to be made between alternative assessments. As an economist, Sen demonstrated that niti defends the idea of economic efficiency assessments, for example a cost-benefit analysis, as being a legitimate part of distributive justice. On the other hand, Sen as a philosopher describes nyaya which defends arguments in favour of the value of outcomes for a person's life.

While niti and nyaya would seem appositional, Sen does not require these pluralities to reduce the limits of reason, but encourages the use of pluralities to develop a theory of justice that can absorb divergent points of view. Rawls faced the same problem in resolving competing viewpoints of fairness and

equity. However, despite the fact that Sen's ideas of justice are influenced by Rawls, on this point Sen placed himself among the critics of Rawls.

The hypothetical social agreement forged under Rawls' veil of ignorance bore no regard for the outcomes of decisions from such social agreement. According to Sen, Rawls took no account of the position of relative privilege in American society and did not discuss under-privilege or prejudice in his theory. Sen's upbringing in India has drawn this point into focus and he argued that merely contending that these negative externalities (under-privilege or prejudice) are eliminated under the veil cannot ensure the true application of the principles of distributive justice.

Sen challenged Rawls' utopian proposition that agreement will always be reached by participants of the thought experiment. Sen's consequentialist side asserted that what really happens to people in life under the veil cannot simply be ignored.

While Rawls placed liberty as a top priority, Sen believed that there are other equally important priorities which should not necessarily be submerged under liberty. On this point, Sen presented the examples of the value of free association, safety, food and shelter, property rights or access to medical care.

This is perhaps Sen's most significant advancement of Rawls' theory of justice. Sen asserted that, even though Rawls did not mention health in his index of primary goods, good health is the capacity which underlies our ability to utilise primary goods. Sen believed that concerns about equality must not only focus on just distributions of these primary goods and benefits, but should also focus on giving people an equal share of capabilities to take advantage of what Rawls describes as primary goods and freedoms (Daniels, 2008).

What really mattered to Sen was that people have the capability to enjoy equal distributions of Rawls' index. He insists people with disabilities, illnesses, lack of opportunities for education, no access to employment; the victims of prejudice and discrimination, poor housing, a lack of public health or nutrition have less freedom to enjoy an equal index of primary goods.

Interestingly Marmot (2006) claimed the converse also to be true: that an inability to do the things one had reason to value leads to health inequalities

among individuals and communities. He stated that poor health (both physical and mental) is significantly improved by individuals and communities having active involvement in the decisions that affect their lives.

Sen used the words Niti and Nyaya as the difference between his idea of justice and Rawls' theory of justice. He described Rawls as Niti and himself as Nyaya (Sen, 2010). Rawls identified the conditions of the social contract in democratic institutions while Sen identified how the social contract plays out in people's lives.

Despite these differences, Sen (2009) still described Rawls' theory of justice as fairness as "the most far reaching example of what is essential for an adequate understanding of justice is Rawls' fundamental idea that justice has to be seen in terms of the demands of fairness" (*The Idea of Justice* p. 53).

Distributive Justice and PHARMAC

The question of distributive justice was examined in relation to the provision of high-cost medicines in New Zealand. This question was raised by the Hon. Tony Ryall, Minister of Health in December 2009. He was pursuing a pre-election commitment he made to look into the access of New Zealand citizens to high-cost highly specialised medicines.¹⁴ The review of the provision of high-cost medicines was undertaken by a three person panel appointed by Ryall and chaired by Dr. Paul McCormack. The review was completed in 2010.

Andrew Moore from the University of Otago contributed to the review (Moore, 2006). Moore's submission was that PHARMAC's approach to decision making on the funding of pharmaceuticals should be to secure 'best value for money' for all New Zealanders. He defined best value as decisions requiring a demonstration of benefit or health gains represented by the QALY equation. He conceded that despite the quantitative nature of the QALY data, the system still relied on substantial ethical beliefs which underpin decision making.

Moore (2006) stated that fairness should play a role in PHARMAC's decision making criteria, and conversely, need (a description of the needs of a person, community or country) should play no part in PHARMAC's funding decision

¹⁴The Terms of reference for the review are available on the Ministry of Health Website. <http://www.moh.govt.nz/moh.nsf/indexmh/hchsmedicines-tor>

making process. He suggested that PHARMAC should give consideration to the procedural value of fairness in its funding decision making including the values of openness, transparency, inclusiveness, responsiveness and accountability.

Philosopher Raanon Gillon's paper which was written for PHARMAC in 2006 was presented by PHARMAC as background material in the discussion papers released with the review. Contrary to Moore, in this paper Gillon suggested that morally relevant inequalities, such that the greater the health care need, meant the greater the presumption of a moral obligation on the State to help meet that need. Gillon acknowledged that economists' interpretations of this position are regularly distorted to mean some economic calculation of need. Gillon strenuously opposed this. He submitted that the principle of the greater the need the greater the State obligation to meet the need should at the very least be considered by PHARMAC in its deliberations on which drugs to fund.

Gillon (2009) proposed his own view that the definition of health care need should be "health care without which one's health is harmed" (p3). He stated that the problem with these needs is that they are individualised and are non-comparable between people. The provision of high-cost medicines required decision makers to make choices between incommensurables, and indeed give weights to incommensurable alternatives.

PHARMAC used a cost-benefit analysis system and Gillon noted that, based on QALY's as the basic unit of measurement of fairness, this system attempts to give weights to alternative choices. When PHARMAC compared the price of one QALY in one treatment with the price of another QALY in another treatment, the system relied heavily on one QALY gained, being of equal value to any other QALY gained. Gillon cited the example of a QALY gained by going to the South of France for a holiday being treated as equivalent to a QALY gained by relieving pain or treating a cancerous tumour. Even comparing QALYs gained within healthcare, a QALY gained by an insomniac is considered equivalent to a QALY gained by a patient being treated for heart failure. Gillon thus contended that QALYs gained by a new treatment (or QALYs gained in the absence of need) afforded no basis for comparing the meeting of health care

needs. This was because distinguishing between two QALYs relating to two different people is not a valid comparison.

In his submission to the Review of High Cost Medicines (2006), Gillon criticised the QALY system for being unable to differentiate between 'meetable needs' and 'non-meetable needs'. For example, health needs that can be met by PHARMAC's provision of pharmaceuticals for successful treatments is an example of meetable needs. PHARMAC also approves the subsidy on pharmaceuticals on un-meetable needs where there is a low probability of the treatment being successful. The moral tension presented here is the conflict between a desire to meet very great health needs at a high cost and the desire to meet the needs of those who will necessarily be denied treatment for lesser health needs at lesser cost. Gillon queried whether the medical professions are skilled at deciding when a treatment has a high or low probability of success (i.e., the 'let's see what happens' approach) which is also a valid approach.

A dilemma faced by the government, and which PHARMAC is required to consider under the Community Exceptional Circumstances policy, is how these requests for high cost medicines, which would benefit a patient, be managed. Gillon argued that the production of sufficient benefit (he is careful to say sufficient, not maximum benefit) can conflict with the just distribution of pharmaceuticals in proportion to an individual's need. However an adequate theory of justice must have some concern for the greater number of people PHARMAC is also charged with providing for. PHARMAC's existing policy requires a cost-utility analysis and a QALY value of at \$30,000 (or less) per QALY before PHARMAC will agree to subsidise a medicine. Gillon suggested this is probably PHARMAC's most important criterion. He added that other criteria could override cost-utility analysis for example avoiding discrimination against the elderly.

Gillon (2006) also explored the right to respect of one's autonomy and preferences which appeal to the utilitarian principle. The 'I want it - so do it' (Crisp, 2002, p. 134) phenomenon is consistent with the principle of autonomy. However, this conflicts with the autonomy of others by reducing the opportunities of a greater number. Gillon stated that under these conditions, if PHARMAC refused to authorise a medication for a government subsidy, despite

the autonomous demand from patients and doctors, PHARMAC is exercising moral concern for the greater number.

The Patient Doctor Relationship

When we consider the rationing of health resources, the professional and psychological relationship between doctor and patient comes under tension. The Hippocratic Oath is an explicit moral commitment by doctors to extend the health interests of their patients. However the oath applies equally to the patients in the immediate care of the doctor and the doctor's patients who are waiting for care. Such a differentiation, in a restrained funding environment where the doctor is restrained as to what can be done, creates the moral tension. This also applies to patients who find themselves unrepresented by doctors and appear to be no ones specific concern.

Applying Kantian deontology, one could expect doctors to prioritise in relation to medical need by giving priority to their own patients first. However, Rawls' difference principle would direct that doctors should meet the needs of the neediest first, irrespective of whose patients they are. This principle would also apply in the case of a medical emergency when a doctor is required to prioritise on the basis of acute and urgent medical need and then return to the needs of his/her own patients as a second priority.

Gillon suggested that these moral dilemmas created by the need to limit the supply of medical care should be handled exercising sound judgment by decision makers who must do the best they can. Unfortunately, the proper approaches to carrying out such judgments are morally disputed and he warned that decision makers must beware of answers to such questions that purport to offer moral confidence or even moral certainty.

No matter what prioritisation system or ethical and moral principles PHARMAC used in relation to decisions to subsidise medicines, pharmaceutical treatment is but one factor in the delivery of effective health care. Professor Toni Ashton, a social scientist at the University of Auckland, submitted to PHARMAC's Review of High Cost Medicines (Ashton, n.d.) that over the last 10 years there have been many attempts by organisations and individuals to make the prioritisation system within the New Zealand public health system more

systematic and transparent. In her opinion few, if any, have succeeded. She contended that a sophisticated method of funding distributions related to high-cost medicines may be all for nothing if these decisions are undermined by poor rationing and wasteful practices in a publicly funded health care delivery system.

Wilkinson (2006) submitted to the review that there are a confusing myriad of moral and ethical theories which can all be taken to endorse a formal principle of equality. However, when we come to elaborate of the equality principle in relation to health care, the theories of equity become inconsistent with each other. Wilkinson stated that despite the confusion among equity theories, he was less confident of a suitable high level theory emerging in relation to high-cost pharmaceuticals than the use of intuition in particular cases.

Wilkinson (2006) reiterated Ashton's problem that the just utility of providing pharmaceuticals is only a small part of the publicly funded health care system. Wilkinson discussed the comparison of priority of health care with other priorities, giving the example of education. One person may have better access to health care than another person's access to education. He suggests that utilitarianism solves the problem because a rise in the utility of one person, without diminishing the utility of another, raises the utility of all. However, the utilitarian principles do not work in relation to the provision of pharmaceuticals by PHARMAC in a capped funding environment. Raising the benefits of one person by providing expensive medicines under PHARMAC's Community Exceptional Circumstances policy may make the overall shares more unjust and less equitable for the greater number.

Wilkinson suggested that PHARMAC should take consequentialist considerations as its default position and PHARMAC focus only on the problems caused by this consequentialism which are directly relevant. He made this suggestion because of his assertion that every moral theory gives some role to consequentialist considerations. A consequentialist can attach weight to equity, give priority to the worst off or simply be a utilitarian (the best known version of consequentialism). But he also pointed out that the sufferers of 'orphan diseases' endured by very small numbers of people, are severely disadvantaged by PHARMAC's use of utilitarian QALY determinations. This is

because the costs of treating orphan diseases are extremely high and these diseases fail the 'value for money' test. This is a moral dilemma not solved by the utilitarian approach and some people are denied treatment for their medical conditions simply because the disease they endure is suffered by few rather than many people.

George Laking (2006), a medical economics researcher in the area of health technology assessment, also took part in PHARMAC's Review of High Cost Medicines. He proposed that the challenge for decision makers who are presented with cost-benefit analysis is to identify trade-offs that are deemed equitable or distributionally just. He did not believe QALYs were distributionally just because of the system's inability to deal with the cases at the margin of the cost-utility exercise (whatever margin PHARMAC might deem to be an acceptable cost per QALY). These cases most matter in human terms because there are people who lose, having almost won, and those who win, having almost lost (Metcalfe, 2003).

However, the cost-utility analysis calculation can and does maximise the benefits of subsidised drugs. Hadorn (2006) proposed that the utilitarian approach taken by PHARMAC should be firm and set the maximum dollar value it is prepared to subsidise per QALY. He submitted that PHARMAC should stick to this upper limit. He also proposed a blending into the decision making of the principles underlying New Zealand public health services approach: fairness and transparency. Hadorn called this a 'Rawlsian wrinkle' which should be introduced to PHARMAC's decision making to take into account the needs of the least well off first. PHARMAC could do this by electing not to consider the adverse effects of co-existing conditions which are more common in older and lower income people. These conditions reduced the net benefit of taking the proposed drug and thus increased the QALY price.

However, Hadorn recognised that this approach would come at a price to PHARMAC and he proposed that the government should set aside 5% of PHARMAC's budget for the subsidisation of drugs it does not consider cost-effective. This would meet society's desires for non-utilitarian preferences. Notwithstanding the intention to strike a more fair approach to the needs of those on the margins of the cost-utility analysis process, Hadorn did not explain

why PHARMAC would subsidise uneconomic outcomes. Caygill (2011) challenged Hadorn on why PHARMAC should set aside 5% of its budget to subsidise drugs that it does not consider cost-effective. Caygill stated that if the government was going to endorse 'wasting' money (relatively speaking), then surely any figure will do (Caygill, 2011).

The discussion which took place in the form of contributions to PHARMAC's *Review of High Cost Medicines* was centred on PHARMAC's utilitarian approach and reliance on cost-utility analysis in its decision making. Yet many of the contributors to the review also stated that non-utilitarian values are very important to ensure that decisions which are made by PHARMAC are fair and just.

Developing Test-Questions about Distributive Justice

Rawls presents a normative philosophical principle in cases where there are limitations on resources, to such an extent that the society cannot provide extensive liberty for all. In this example of limited provision (liberty) of choices of pharmaceuticals, Rawls provided that such inequalities are to be arranged so that distributions are to be provided for the greatest benefit of the least advantaged. He also asserts that such distributions must be attached to positions and offices open to all under opportunities which apply the conditions of fairness and equity (Rawls, 1971). Sen's justice principle is related, as the consequences of fairness, through the content of equality of opportunity.

During the *Review of High Cost Medicines*, contributors such as Gillon, Hadorn, Wilkinson, Laking and Ashton discussed ethical and moral subjects primarily in the form of questions. This tradition is long established. The earliest philosophers, Socrates particularly, but also Homer and Aristotle used questions to explore the constructs of their thinking and to test the theories which arose with their peers. This questioning as a philosophical tradition searches for generally held truths that shape opinion and engage the participants in scrutiny of these truths to determine their consistency with other beliefs. Questions provide insights into what we should do or descriptions of how we have acted. Philosophical theory cannot always be described in formative language, for example how a person or organisation should act, but philosophical questions can enquire into the circumstances of life and living.

This Socratic Method invites the enquirer to consider, by asking and answering questions, the strengths and weaknesses of ideas from the widest possible range of positions.

Hence questions about justice as fairness could play a role in health rationing decisions made by government institutions. Consequently, the background to this thesis question of fairness and equity required a credible definition of fairness. Rawls provided such a definition. Fairness of institutions is based on two background ideas. The first is that citizens are under no obligation to unjust regimes where their consent to co-operate is based on coercion under the pain of punishment (or some other refined tacit acquiescence). Secondly, institutions demonstrate their fairness by avoiding bias, taking note of the interests and concerns of others and avoiding the influence of vested interests, personal priorities or prejudices (Rawls, 1971).

According to Gillon (2006) and Wilkinson (2007) a commonly held set of beliefs about equity and fairness of rationing health resources does not exist. This being the case, the Socratic Method appeals as a method of inviting decision makers to engage in a debate around the questions of fairness and equity.

Medical ethicists are practiced at posing challenging questions trying to make sense of ethical principles as they apply to cases. From the discussion about the particular, comes a point which suggests applications in other more general circumstances. For example in an article in the *British Medical Journal* (Gillon, Higgs, Boyd, Callaghan, & Hoffenberg, 2001) questions were posed about how much detail should be given to families when physicians are requesting permission to harvest organs for transplantation. The authors questioned if a doctor should advise other family (or potential family) members about inherited genetic abnormalities they discover in a patient. They ask if any degree of criminal behaviour (for example tax evasion or murder) justifies breaking medical confidentiality? The article suggests an independent multi-perspective commission to manage a social contract between physicians and healthcare workers and the community to manage these value laden questions. Macklin (2003) cites the “standard” case of a competent adult Jehovah’s Witness patient refusing life saving treatment. Should the physician comply with these express wishes? The case is extended to the competent adult Jehovah’s Witness

parents refusing treatment for their dying child (Macklin, 2003). Should the State intervene on behalf of the child?

The distributive justice problems of state funded health services have been discussed in the rationing literature. These problems are as critical to the wellbeing of patients and society as the ethical issues raised by bioethicists. Therefore, is it possible in this context to develop some specific questions about distributive justice which explore the particular and inform some elements of general meaning?

Can questions be developed using philosophical principles which decision makers could ask, which draw out elements of fairness or unfairness? In an attempt to do this, I have translated the principles of distributive justice espoused by Rawls and Sen, into four test-questions which could be asked about public distributions. Aligned to the Socratic tradition, there are no right or wrong answers. The questions give an opportunity to focus on and discuss decisions which must be made, using Rawls' and Sen's distributive justice principles.

Question 1: Would the most advantaged in society accept this distribution if they, at an instant, found themselves to be the least advantaged in society and requiring such distribution for themselves?

This question challenges decision makers in public health systems, who by nature of their positions are often people from well educated managerial, medical or health professional backgrounds, to place themselves under Rawls' veil. This test-question asks them to ignore the fact that they may be fully functioning achievers in society with adequate resources by nature of their talents, positions and experience. The test-question asks them to place themselves (and their peers) in the position of the most powerless and vulnerable person in society. It asks them to describe the world from the view of a person needing the distribution as if they were this person, without any other options available to them.

Question 2: Is this distribution arranged so that it is attached to positions and offices which are open and accountable to all?

This test-question asks decision makers (and organisations) if they are making decisions based on fairness and equity with particular emphasis on openness

and accountability, and whether they are prepared to defend their decisions. If decisions are open and decision makers are required to declare the reasons for their decisions, the matters which were considered can be drawn out for anyone who has an interest in the outcome to reflect on. This test-question also asks for a discussion on accountability of the distribution and whether decision makers considered all people who had an entitlement to the distribution.

Question 3: Is this distribution based on the efficiency of substantive opportunities and on procedural fairness in defining efficiency?

This test-question seeks to find out if decision makers have considered the utilitarian principles of the greatest benefit for the greatest number. In the health context, the cost-utility analysis (or a variation of it) uses the international standard measurement system of QALYs to determine substantive opportunities. This test-question asks what do such determinations and comparative analyses show. The second part of the test-question asks if there is procedural fairness in the way the analysis is conceived and undertaken. This gives decision makers an opportunity to look at how the systems work, what information is considered relevant and what is considered irrelevant, the consultation that took place and the systems which were used.

Question 4: Is this distribution based on information available to decision makers about the capability of this person to do things he/she has reason to value?

This test-question explores the capability approach to fairness and equity by focusing on how the decisions made, or about to be made, affect people's lives. The question opens up the debate about comparative fairness and consideration of the circumstances of a person's life and how this person will be affected by the decisions. According to Gillon (2006) groups of decision makers do not share a perfectly matched set of values and so this discussion has the potential to draw out, perhaps more than any of the other three test-questions, discussion on the values which drive decisions. This question focuses on the consequences of decisions by requiring consideration of a person's capability. The remedies of reducing barriers to capability may not be available to decision makers. For example in the presence of poverty, racism or sexism these incapacities are brought into focus and decision makers are made aware of them.

The first two test-questions covered the position of justice for the least advantaged, the issue of equality of access to all and the openness and accountability of the persons or offices making decisions. The second two test-questions offered scrutiny of the efficiency of the distribution, procedural fairness at establishing efficiency and of the consequence of the decision on people's ability to achieve that which they value.

An Example to Illustrate the 'Test-Questions'

In this section, I illustrate the use of these test-questions in the recent case of the MidCentral DHB's explicit rationing of chemotherapy treatment for selected cancer patients.

On 6 January 2011 a letter was written by the Chief Medical Officer, Dr. Ken Clark on behalf of the Regional Cancer Treatment Service provided by MidCentral DHB. The service for cancer patients covered a population of 555,000 people over a catchment area which included Gisborne (Tairāwhiti), Hawke's Bay, Taranaki, Whanganui and Wairarapa. I obtained the letter by requesting it under the OIA.

In this letter Dr. Clark advised the health managers and Chief Medical Officers that the MidCentral DHB Regional Cancer Treatment Service was suffering from intractable recruitment problems and was unable to fill two doctor vacancies on the oncology team. For this reason, by consensus, the Regional Cancer Treatment Service implemented a new prioritisation strategy. I quote from the letter:

... which involves a rigorous triaging of referrals with a view to declining referrals of patients for whom there are very limited therapeutic benefits from the provision of chemotherapy. By consensus we have developed a list of clinical presentations for which we will decline referrals.

(Clark, 2011)

The list of conditions which would not be treated with chemotherapy included all prostate cancers, all melanomas, all soft tissue sarcomas, several other cancers and conditions in which the patient had been treated by chemotherapy and was in relapse.

Dr. Clark and his colleagues decided that the patients with the above list of cancers would no longer be selected for chemotherapy treatment on the basis of clinical need. This was because of the insufficient number of oncology doctors in the unit who were currently carrying an unbearably large workload. Dr. Clark had unsuccessfully appealed to the DHB for more funding for the service so that doctors could receive a higher salary and be attracted from other parts of New Zealand or from overseas to work in the service.

They decided that only patients with the greatest ability to benefit from chemotherapy would be treated. An exception was made for patients who were involved with active clinical trials or patients who have 'over-riding clinical circumstances'. All other patients suffering cancers on the list would not be offered any chemotherapy treatment.

After receiving Dr. Clark's letter under the first OIA request, I made a further OIA request for all journal articles, reports, papers or correspondence the doctors considered before coming to their decision. I was advised by the DHB that no journal articles, documents or reports were considered by the doctors when they came to the view that they did. They did not take minutes of meetings they held or kept a documentary record of the decisions which were reached, the matters they considered or the reasons why they made the decision to withhold treatment (Glubb, 2011).

This action by the Chief Medical Officer and his colleagues moves the provision of cancer treatment in the MidCentral DHB to the moral position that the utilitarian principle, of the greatest good for the greatest number, will prevail over the principles of clinical need, fairness and equity or any other moral consideration. In coming to this decision, there was no consultation with the community because the decision was made by doctors acting alone and in secret¹⁵. There were no empirical clinical studies or documentary evidence considered by decision makers. The doctors used their 'clinical experience' in coming to this explicit rationing decision (Glubb, 2011). The decision makers also decided that patients who were in an active clinical trial were given an advantage over similar patients who were not in clinical trials.

¹⁵The letter from Dr. Clark to the Chief Operating Officers of the DHBs involved was not released to the public by Dr. Clark, it was leaked to the press.

There was no clarity provided by the decision makers about patients who were refused treatment in the public hospital, if they could be treated in the private health system. For example, if they paid for the treatment or had the treatment provided under a private medical insurance scheme would they receive the chemotherapy treatment? If any of the doctors were intending to treat any patients privately, then the doctors would be (incidentally or purposefully) creating a private market for the treatment by refusing to provide it in the public system.

Dr. Clark explained in his response to both OIA requests that wider workforce issues were at play in his decision. In his letter, he referred to the workload of the oncology doctors and this was the motivation behind the decisions which were taken. Dr. Clark appealed for more funding to be available for his department to attract oncology specialists to come from around New Zealand or overseas to MidCentral DHB to work.

MidCentral Health were not asked to consider referring any overflow patients for their treatment (who could not be seen by the MidCentral Health Cancer Service) to one of the other treatment centres in the North Island, the South Island or Australia. Dr. Clark and his colleagues did not consider calling on the assistance of the Nurse Practitioners¹⁶ who are specialist nurses trained in diagnosis and have prescribing rights. The Ministry of Health were not consulted on this decision or asked for advice about how the doctors' workforce issues could be resolved (Glubb, 2011).

No cost-benefit analysis was done to test the economic efficiency of the chosen policy option, neither was there any consultation on the emotional or social impact on the lives of the patients who were to be refused chemotherapy treatment for their cancer.

Applying the Test-Questions

An application of the test-questions is not designed to bring out a normative view which would apply in every case. This is because, as Gillon (2006) points

¹⁶Details of Nurse Practitioners are available on the District Health Boards New Zealand website http://www.nursepractitioner.org.nz/Site/Future_Workforce/Nursing-Midwifery/Nursing-Projects/Nurse-Practitioners/NP-General-information.aspx

out, there is no one set of moral imperatives on which to base value-laden decisions to which all people would agree.

Consequently, each person answering the test-questions about the MidCentral Health case would likely come to their own view of fairness based on their moral and ethical beliefs. However, the test-questions do give the reader the opportunity to reflect on the fairness of decisions on the lives of the patients and also on the fairness of the workforce pressures on the doctors and how fair it is to expect the doctors to treat ever increasing numbers of patients and the stresses on them of continuing to do so. Therefore, let us consider the following questions:

Question 1: Would the most advantaged in society accept this decision if they, at an instant, found themselves to be the least advantaged in society and required chemotherapy treatment for prostate, melanoma, sarcoma or other cancers themselves?

The most advantaged in society, measured by a person's private wealth and position of influence in society, as a patient with one of the cancers for which they would be denied chemotherapy treatment, has as much right to be provided treatment in the public health service as any other person. However, following the decision by MidCentral Health to deny them cancer treatment, the most advantaged person would utilise their relative financial advantage by having access to privately provided treatment. They would do this by paying cash or through insurance cover if the public health system had refused them.

Under the conditions of this test-question, this would not be possible if at an instant, such a person was suddenly unable to afford private treatment. They would most likely feel greatly aggrieved at the unfairness of the DHBs decision.

There is considerable doubt about whether the MidCentral DHB decision was taken for the reasons of clinical efficiency or for reasons to do with workload and aspects of the doctors' employment. If this decision was taken to save money for the DHB to enable it to provide the greatest amount of treatment to the greatest number, it is possible that patients who were refused treatment would still feel maltreated. However, it is also possible that both advantaged and disadvantaged people could come to an understanding that the greater

good may be served by their not receiving treatment for their condition for which the benefit is uncertain or indeed unlikely.

However, if this action was taken to put pressure on the DHB (and ultimately the government) to increase the wages of the doctors involved, this reason would fail Rawls' fairness test. The reason it would fail the test is that any decision to ration treatment based on pressure to increase salaries does not avoid bias, take note of the interests and concerns of others, or avoid the influence of vested interests or the personal priorities of the doctors.

Oncologists with more than 4 years experience can expect to earn up to \$240,000 annually and oncologists with more than 10 years experience average up to \$310,000 per year.¹⁷ The least well off in society may feel it an unfair decision to refuse them treatment, if the refusal was based on a campaign to increase salaries beyond these salary ranges. These questions were never put to the patients during the decision making process, so the range of answers from them will never be known.

Question 2: Was this decision to deny some people chemotherapy treatment arranged so that it is attached to positions and offices which are open and accountable to all?

The OIA request demonstrated that the decision was made by people within the DHB who did not consult the public before making the decision. Neither did the doctors consider any documentary evidence, published journal articles, peer reviewed research papers or public policy material to guide their decision. The OIA request information stated that the doctors based the decision on their clinical experience.

The Chief Science Advisor, Professor Peter Gluckman advises against the approach of making policy decisions without the benefit of evidence or without putting in place a monitoring system to gauge the effectiveness of the policy. Professor Gluckman (2011) commented that "many policies developed in isolation from the available evidence, or initiated and continued in the absence of monitoring and formal evaluation of impact and effectiveness may well be ineffective in meeting their primary or secondary policy objectives" (Gluckman, 2011).

¹⁷See <http://currentcancer.com/oncologists-salary-range.html> for salary ranges of a New Zealand Oncologist.

The decision to ration cancer services taken by Dr. Clark and his colleagues was not made public by the MidCentral DHB; it was released by the media in a Radio New Zealand news report on the 5 January 2011 by reporter Ruth Hill.

This rationing decision had considerable moral and ethical significance; however, there was no explanation of the matters which were considered in coming to the decision. No criteria considering distributive justice were used to categorise the patients who were offered treatment or no treatment. The decision was final and no process for appeal to the MidCentral Health Board was put in place.

A person who was refused treatment could have appealed to the High Court for a judicial review of Dr. Clark's decision. Judicial review does not enquire into the propriety of the action, the court only considers whether the public body has acted lawfully in coming to the decision it has¹⁸. Besides, this would have been time consuming, expensive and the stress of such an action would be considerable on a very ill person, possibly with only a short time to live.

The decision to continue to treat people because they were in a clinical trial challenged the equity principle of fair treatment for all. The doctors did not explain the benefits of continuing clinical trials for either the patients in the trials or the benefits to themselves of completing the clinical trials.

Question 3: Was this decision based on the efficiency of substantive opportunities and on procedural fairness in defining efficiency?

The first part of this test-question asks if any analysis of the costs of chemotherapy treatment was done to determine the likely effect of the decision on the finances of the MidCentral cancer services. Had PHARMAC been consulted by the MidCentral DHB, the staff at PHARMAC could have run a cost per QALY exercise comparing the likely costs and benefits per QALY of the pharmaceutical treatment options. However, the information received under the OIA request indicated that no cost-utility analysis was done on the economic efficiency of the treatments or the likely clinical benefits. The response to the OIA request on this subject simply says the doctors used their own judgment (Glubb, 2011).

¹⁸<http://www.courtsofnz.govt.nz/about/visitor-centre/glossary/glossary/judicial-review>

Evans (2003) ranked the various types of evidence which can be considered in making health intervention decisions. He suggested that when deciding about the appropriateness of an intervention that the strongest possible evidence was systematic reviews and multi-centred studies. The next level down in quality of evidence was random controlled trials, observational studies and interpretative studies. The poorest form of evidence described by Evans was expert opinion.

The doctors' judgment led them to the decision that some cancers are not worth treating because there is little likelihood of a successful outcome of the treatment. If the doctors' clinical judgment is correct, this raises the question as to why the patients were being offered the treatment in the first place. This question is indeed worthy of deeper analysis as the answers hold considerable significance for the examination of the use of substantive opportunities, not just for the MidCentral DHB, but every other DHB in the country.

Consider on one hand the possibility that the doctors' judgment was incorrect and there were patients in the DHB who were denied chemotherapy treatment but would have actually benefited from it. Under these circumstances the condition of these patients would have been allowed to unnecessarily deteriorate (perhaps to the point of an early death). On the other hand, if the doctors' judgment was correct and savings to the MidCentral DHB would have ensued, this money would have been available for the purchase of more staff, higher salaries or any other pressing DHB priority. However, the decision makers were not in receipt of any analysis to know one way or the other.

The second part of the test-question asks if there was agreement on the procedural fairness in deciding how the efficiency of the doctors' decision would be defined. Because no economic analysis was done, it was not possible for a member of the public to know on what efficiency basis, if any, the decision was made.

As Professor Peter Gluckman (2011) has pointed out, public policy decisions should be closely aligned to scientific analysis, international scientific evidence and experience of international best practice. This is to ensure government achieves results which are predictable and have less unintended consequences (Gluckman, 2011). However, in this case there was no evidential basis at all for making the rationing decisions Dr. Clark and his colleagues made.

This test-question did not ask if the right decision was made by the doctors. It asks if there was any rational analysis done or evidence gathered to guide the decision makers and who (if anyone) had the chance to have input into the process.

Question 4: Was this decision based on information about the capacity of the patients to do the things they have reason to value?

The decision to ration cancer chemotherapy treatment was taken without any information about the capacity of patients to do the things they have reason to value. This is because there was no information given to the decision makers about the lives of the patients at all. Nor was there any attempt by decision makers to hold a discussion with the patients who were being affected by the decision or the consequences for the people who were denied treatment.

It is possible that some patients may have taken the option, if it was provided, not to seek chemotherapy because they may have believed that their cancer was incurable. They may have weighed up the options and decided that there was reason to value a chemotherapy-free end to their lives, no matter how soon that end might come. It is also possible that some patients, if given the option, may have decided that they have reason to value further treatment and the possibility of a full or partial cure.

In summary, the four test-questions give an opportunity for the chemotherapy rationing decision to be examined in light of the elements of procedural and outcome fairness. The documents obtained from MidCentral Health do not describe why some cancer patients are being offered chemotherapy treatment if they are unlikely to benefit from it. What does this tell us about all the other cancer treatment centres in New Zealand? Are they carrying out expensive chemotherapy treatments on patients who have little hope of recovery?

The examination of this case has highlighted the fact that the justice of decisions about who receives treatment is not simply a matter for arrangements which best suit the providers of health services. There is a considerable element of moral and ethical content in the decisions to refuse some people treatment and grant treatment to others. Such content is informed by the principles of distributive justice.

The Use of the Test-Questions in This Thesis

By drawing on the theories of distributive justice, a set of test-questions has emerged to analyse decision making about government distributions. These test-questions are used further in the thesis in Chapter 7 to examine PHARMAC's decision making in relation to the Community Exceptional Circumstances policy against the principles of distributive justice.

Chapter 5: Research Method

Introduction

This chapter describes the research theory and method utilised to gather and analyse the research data about PHARMAC's Community Exceptional Circumstances policy.

In this chapter the theory behind public policy research is discussed. This research project was approved by the Auckland University of Technology Ethics Committee (AUTEC) and the conditions of this approval are outlined.

The methods of collecting the research data from five sources (interviews, media study, legislation, a court case and official information) are discussed. This is followed by a discussion about the Braun and Clark's (2006) thematic analysis and what is involved in a successful implementation of this method.

Finally, the execution of the thematic analysis describing Braun and Clark's six phases sets out how the research data were handled and analysed.

The Theory of Researching Public Policy

Authors have described the difficulty of managing public policy research (Bardach, 2000; Coleman, 1975). As has been stated previously, the starting point for analysing public policy is an examination of the social and theoretical traditions which are built up over time and which have come to be accepted (Cheyne, et al., 2005). Public policy aims to utilise these underlying assumptions to establish guidelines and interventions (Baehler, 2000, 2003) and also looks at the consequences of drawing on these assumptions to validate knowledge of the subject (Cheyne, et al., 2005).

There are differences between analysing social assumptions through qualitative design and analysing the policy outcomes using scientific quantitative design. Cheyne et al. (2005) argue that this is because policy research operates at the boundary of these two research worlds. Such thinking supports Coleman's earlier work in 1975 which contended that there is no single comprehensive method for analysis of policy questions (Coleman, 1975).

Qualitative research methods were described by Strauss and Corbin (1990) as a variety of useful methods of gathering information when the research perspective is a process or a social distribution. They also advised that interviews are useful in gathering information on what happened and why. In my study I researched the published material, official information and interviews for deeper meaning which could be extracted by raising the particular experiences described in this data to a more general meaning.

Marshall and Rossman (1999) caution that the more general meaning should not be considered in the sense of a total truth, although they agreed that qualitative methods do paint a valid picture of the general meaning. This study searched for that general meaning about PHARMAC's Community Exceptional Circumstances policy from iterative perspectives of written material and the common perspectives of actors and institutions who agreed to take part.

Authors have also described policy research methods as akin to a highly tentative iterative problem solving process (Baehler, 2000; Bardach, 2000; Smith & Robbins, 1982). Policy researchers have to contend with analysing social values and the goals and assumptions that support public policy while simultaneously understanding the effects of policy on society's institutions, budgets and outcomes. For these reasons Smith and Robbins (1982) suggested that the best policy research often finds itself at the margins of existing social science methodology: adapting, combining, iterating and improvising on the methods as the research proceeds. This has certainly been the case with my research as I explored alternative research tools.

The following is a presentation of possible methodological approaches and their relevance to my research question.

I did not choose using feminist theory because there are no gender specific constructs associated with PHARMAC's decision making on the distribution of pharmaceuticals. This is not to say that there are not specific classes of medicines for women, men and other genders. Clearly there are. But decision making about distributions of state funding for medicines is gender neutral. This is required under the New Zealand Bill of Rights Act (1990). The only discernable area of possible alignment with gender specific power differentials is a possible bias towards the proportion of men appointed to PHARMAC's

expert committees in the 1990's. The Ministry of Health could not, or would not, provide me with the names of doctors who had been appointed to such expert committees. This however was not a sufficiently strong basis on which to impede my research on the fairness and equity of PHARMAC's decision making.

My study could not have been conducted utilising a phenomenological approach because it would be necessary to have close association with the lived experiences of the PHARMAC decision makers when they make their decisions. This implies that it would have also been necessary to be in PHARMAC and experience the decision making process by shadowing a group of CEC panellists and living with them through the experience of deciding on Community Exceptional Circumstances claims. Given my experiences with PHARMAC discussed above, a phenomenological approach would not have been possible.

An ethnographical methodology would have required me to experience the culture of PHARMAC and see how this culture impacted on the decision making process. Again, I was denied access to the decision makers. I encountered a polite but obstructive culture. The effect of this culture was referred to many times in the collected data especially through the media study and the key informant interviews.

A critical social theory approach might have been utilised to elucidate the power differentials between PHARMAC and Community Exceptional Circumstances claimants as well as between PHARMAC and the pharmaceutical industry. Whilst this might be an interesting study into the dissected interests which were being served in the decision making process, it would not provide sufficient opportunity to develop understanding of how the policy was being operationalised.

Similarly, remembering that this research was a study of decisions and not applications, discourse analysis might have been instructive. However the operationalisation of the PHARMAC policy was heavily impacted by PHARMAC decision makers and the reasons for their determinations. Such outcomes impacted both on PHARMAC (and its budgets) and the successful and unsuccessful claimants. These outcomes were also impacted by legal

requirements and considerable political drivers. I considered the examination of discourse to be too narrow a methodology to develop insights into such a broad range of interests.

A descriptive statistical method was undertaken by Rasiah (2009) in her study of Community Exceptional Circumstances applications. As a PHARMAC insider, she acknowledged the assistance that she received in the preparation of the statistical data and the analysis which was conducted by PHARMAC staff. In my study however, such a quantitative approach would not have been used in isolation from qualitative data and I was not acquainted with what types of statistical records PHARMAC kept on this type of rationing. The purpose to such quantitative data is to help verify the decision making and I had no confidence that, as an outsider to PHARMAC, I could guarantee I was being given full access to the data. Also I was not confident that PHARMAC's quantitative data was such that I could make an accurate connection between the qualitative information and the quantitative data. If this lack of connection did not exist (or the tacit possibility that the connection did not exist) I would not be able to establish a causal relationship between the numbers of claims and the decisions which were made and why they were made.

Thematic analysis allows triangulation of all the collected data which could be obtained from PHARMAC; from publicly available material and material that I was able to bring into the public domain. I particularly liked this methodology because it is relatively simple. It is a qualitative methodology with the ability to handle large volumes and several different types of data and provides a clear set of research outcomes.

Grounded theory is possibly the closest methodology to thematic analysis which could be used handle this data. It utilises selecting, recording, coding and categorising activities. However the purpose of grounded theory is to establish an emergent theory out of the data which supports a hypothesis. The quest underlying this study however sought to uncover the truth about how this Community Exceptional Circumstances policy was operationalised.

In conclusion, this research required me to explore both social policy values and outcomes simultaneously. Thematic analysis allowed me to achieve these two objectives. This experience was aligned with Smith and Robbins (1982) and

Bardach (2000): by adapting and iterating and combining I discovered as I got more into the search for an appropriate research method, my research question required me to sometimes measure, sometimes count, sometimes to read and sometimes listen.

Ethical Approval

Ethical approval for this research was provided by the Auckland University of Technology Ethics Committee (AUTEC). The letter of approval is attached in Appendix 1.

Potential interviewees were invited to participate in the research and were sent consent forms to sign. A copy of the consent form is provided in Appendix 3. They were also sent a sheet of sample questions which were used to open discussion topics. The sample interview questions are provided in Appendix 4.

The conditions set by the committee required interviewees to be afforded anonymity. This proved difficult to achieve because there were only a small number of people who matched the selection criteria as key informants.

It is important to distinguish between sampling people who have been claimants and people who knew something about the Community Exceptional Circumstances claims decision making process. I did not attempt to examine applications; rather I examined what happens to applications after they were received by PHARMAC. For this reason I did not interview doctors who were making applications on behalf of their patients. There would have been ethical considerations and likely bias in the doctors' views toward supporting their patients and bias because of the the fact they made applications on behalf of their patients. But I did attempt to interview doctors who were involved in the decision-making process. The voice of several of the doctors who made CEC applications were captured in many data sets e.g. media study, key informant interviews, Official Information Act requests and Walsh vs PHARMAC court case.

Patton (1990 p169) describes various quantitative and quantitative sampling logistics that underpin sampling approaches. I employed purposeful sampling because I knew the people who I wanted to interview by reading the published

material and by working through the official information papers which I received. Several of the names of potential interviewees were uncovered by reading copies of emails, file notes and scribbling on the sides of released official documents where the names had been withheld. I did not employ random sampling because the pool of potential interview candidates was too small to guarantee effective coverage by sampling very large cohorts of people. Nor did I use theoretical sampling because I was not searching for a theory that underpinned the decision making process, I simply wanted to discover, as truthfully as I could from actors, how the policy was enacted. Nor did I choose to utilise snowballing as a sampling technique because this would have signalled to interviewees who was being interviewed. Snowballing would have also opened the possibility of contacts coaching and influencing one another, even in tacit ways. It was important to ensure that interviewees remained anonymous to other interviewees.

The difficulties of obtaining primary interview data from PHARMAC officials are discussed in the following section on key informant interviews. My interviewees were all sampled by their roles within PHARMAC, past or present. Ministers of Health who had considerable experience of the policy and patient advocate groups who had experience of the decision making process. I made direct personal contact by phone, email or letter and in the main this worked well as a sampling method.

The text of the data relating to the key informants was written in a way that a knowledgeable person would not be able to identify the source of comments made. I utilised the description 'past or present' when describing an interviewee. For example, I refer to a past or present PHARMAC executive member or a past or present Minister of Health. The eight interviewees are referred to in the Research Findings (Chapter 6) as Interviewee A,B,C,D,E,F,G and H.

The AUTEK addressed the issue of possible psychological distress to interviewees. The Committee identified the possibility of interviewees becoming upset at recalling unpleasant experiences or memories. This risk was discussed in the information sheet which was sent to interviewees. The information sheet is provided in Appendix 2. If any participant required counselling as a result of stress related to recall of events or experiences which

arose in the interview, counselling was to be offered to the participant. No counselling was required as a result of this research.

The participants were given the opportunity to discontinue the interview either temporarily or permanently. The AUTEK conditions required that if a permanent withdrawal occurred another participant would be found to replace the withdrawn participant. No interviewee withdrew from any interview. Interviewee 'H' asked for the voice recorder to be switched off for approximately 3 minutes. The voice recorder was subsequently turned on again after the comments were made.

The AUTEK was advised that the cost of the transcriptions was subsidised by the Director of the Institute of Public Policy, Auckland University of Technology. No koha¹⁹ were made to the participants of interviews with the exception of a few interviews which took place in Cafes, in which case I paid for the coffees.

Gathering the Data

The New Zealand Public Health and Disability Act 2000

The NZPHDA 2000 which established DHBs in New Zealand also re-established the community's ability to elect half of the health board members. This legislation transformed PHARMAC from a shared purchasing agency (owned by the four RHA's) into a Crown Entity wholly owned by the New Zealand Government. The NZPHDA 2000 placed a legal responsibility on PHARMAC to manage the pharmaceutical needs of people whose circumstances were described as exceptional.

The important information for my research was discovering the intention of Parliament in proposing this legislation and the public submissions received on the new structures. The data section includes speeches by the Minister and politicians during the passage of the law through the New Zealand Parliament. This data were collected by searching Hansard, New Zealand Parliament's official record of all the proceedings of Parliament. Hansard is available online through the New Zealand Parliament website <http://www.parliament.nz/en-NZ>

¹⁹ 'Koha' is a Maori word in common New Zealand usage meaning a gratuity payment of cash, goods or kind.

and printed copies of Hansard are also available in the Parliamentary Library. I used both forms of Hansard in my research.

I also researched all the written public submissions received on the Bill from members of the public and government departments. These submissions were only available to be read by appointment in the Parliamentary Library. They were available in bound bundles of papers in boxes in the library. The submissions had to be requested prior to each visit. The papers were found and prepared by the Parliamentary Library staff and were only able to be photocopied by the staff. I attended the Parliamentary Library on approximately 10 occasions for periods of about 4 hours on each occasion to obtain the material required for my research.

Walsh vs PHARMAC

Walsh vs PHARMAC was a case in the New Zealand Court of Appeal bought by Chris Walsh and seven other women against PHARMAC. They appealed an earlier decision by the High Court to allow PHARMAC to fund a drug called Herceptin for a nine week course and not a twelve month course of treatment. The material for this data section was taken from the judge's written decision on the case. I have drawn on this decision because it was a legal test of PHARMAC's Community Exceptional Circumstances policy and a detailed investigation into PHARMAC's policies and procedures.

This was also a rare opportunity to consider perspectives from people and groups who might otherwise be reluctant to talk or write on such matters, especially PHARMAC officials. I considered this judgment was important to my research.

The written judgment was analysed from the perspective of the claims made by the plaintiffs, the responses made by PHARMAC and the legal issues raised and discussed by the judge in his judgment.

Media Study

A media study was undertaken of stories which appeared in the media relating to PHARMAC's Community Exceptional Circumstances policy. This study explored the way in which the policy has been portrayed in the media. It was

achieved by a library search which produced 23 media articles containing 17,420 words.

The articles were accessed electronically from AUT Library database 'Newztext Daily News' in Microsoft Word format. The search covered all Fairfax Ltd New Zealand daily papers, New Zealand Herald, Radio New Zealand, Scoop, Stuff, TVNZ and TV3 Independent News Service.

The search key words were PHARMAC, exceptional circumstances, drugs, and subsidy. This search resulted in 189 hits on this database. Many of the articles found from this search related to general information about PHARMAC and about subsidies but did not contain information about the Community Exceptional Circumstances policy. The search was narrowed to only include the search string of words PHARMAC AND community AND exceptional AND circumstances. This search produced 23 reports.

The types of media stories which were produced from the search included patient interviews, responses from PHARMAC, criticisms of PHARMAC's Community Exceptional Circumstances policy, a report from a Health Select Committee, a letter to the Editor of a newspaper, a report of court proceedings, and two editorial articles from a medical newspaper.

The participants of the 23 media reports related to 13 patients, nine doctors representing the patients, seven representative advocacy membership groups, two families, two Medical Directors of PHARMAC, two manufacturing pharmaceutical companies, two Government Ministers, two PHARMAC Therapeutic Advisory Committees, two DHB service managers, two Members of Parliament (MPs), a General Manager of PHARMAC, a Deputy General Manager of PHARMAC, a care giver, a Government Select Committee, a pharmaceutical industry representative body and a High Court Judge.

The dates of the media reports range from 1994 to 2011. Fourteen stories were taken from regional and metropolitan newspapers, six stories from TV news reports (TV One and TV3), two stories were from New Zealand Doctor (a weekly publication for doctors in New Zealand), and an interview on Radio New Zealand's National Programme.

PHARMAC was criticised in 16 of the news reports, three reports were generally complementary to PHARMAC and four were neutral.

Key Informant Interviews

PHARMAC's Community Exceptional Circumstances policy is a form of micro-level rationing which occurs explicitly between the patient and PHARMAC. Explicit rationing suggests clarity about how the criteria for such rationing are applied (Calman, 1994; Mooney, 2003; Scott, 2001; Woods, 2002). This type of rationing is rare in New Zealand because it is explicit and because PHARMAC personnel are required to make decisions about denying treatment to patients. Such activity carries political risk. Interviewing key informants about explicit rationing was a fruitful method of discovering, not only what they did and how they did it, but also the deeper layer of their attitudes, values, motivations and behaviours.

Another important factor in gathering data about the policy was to try to obtain information about the methods used to apply the criteria. The weighting given to each criterion, if any, and the thinking and discussion which went on was important in coming to an understanding of the elements of justice and fairness.

Anonymity was afforded the informants, as agreed with the AUTEK. This was assured during both the research and reporting phase. This provided them the space to talk without the risk of unfair criticism, public opprobrium, political retribution or impacts on their current or future employment.

The area of obtaining primary research data from this source was the most problematic area in my data collection for the research. At the time, from the PHARMAC website, I calculated a very small pool of PHARMAC staff were knowledgeable about the operation of PHARMAC's Community Exceptional Circumstances policy.

I approached officials in PHARMAC to introduce myself and to advise that I was undertaking primary research into PHARMAC's policy. I was advised that this is a very small and relatively unimportant area of PHARMAC's total budget allocation. I was told that there really wasn't anything to research.

On insisting that I was going to proceed I was advised by officials that the Community Exceptional Circumstances panellists would not be happy about having their decisions exposed in detail and I should remember that the panellist were generous to PHARMAC with their time and expertise. I was advised that I would be welcome to contact the Chair of the Community Exceptional Circumstances Panel for an interview and he would represent the views of his colleagues on the panel.

I subsequently made several attempts to contact the Chair of the Community Exceptional Circumstances Panel. Firstly I did this by email and then with three written letters. I outlined the purpose of the research, the ethical approval which had been obtained, the proposed interview process and the interview questions. On each occasion my requests were ignored.

I subsequently decided to contact the Chair of the Community Advisory Committee to seek an interview. After several emails and posted letters, the Chair indicated that an interview would not be possible.

The Chair of the Pharmaceutical Therapeutic Advisory Committee (PTAC) agreed to speak with me but would not agree to provide a research interview. The Chair advised that PTAC does not make decisions about CEC applications however, but does take an interest in the decisions that were made as they may inform the need to examine medicines which might need to be assessed and listed on the Community Pharmaceutical Schedule.

At this point I became aware of internal resistance to my research within PHARMAC. I was provided with access to an official who assisted me in obtaining official information via my requests, but access to the decision makers proved impenetrable. I considered abandoning the research; however the fact that there was resistance to my reasonable requests became part of the story of the research. PHARMAC's openness (and at times lack of it) is discussed many times in the collected data.

I also realised from considerable investigations, telephoning and discussions with people both inside and outside PHARMAC that some officials were prepared to be interviewed and some officials who had worked for PHARMAC and had moved on were also prepared to be interviewed.

I tried to find an interviewee from each decision making role related to PHARMAC's CEC policy process. I sought out a Medical Director, a CEC Administrator, A Chair of the CEC Panel, a CEC panellist and a PHARMAC Chief Executive.

By the time the interviewees who were past or present employees of PHARMAC had been engaged, each role with a key person, (with the exception of CEC panellists) had agreed to be interviewed. . Under the circumstances, this was a reasonably successful outcome.

In all, I selected eight key informants. Four were past or present PHARMAC employees and four were non-PHARMAC interviewees to participate in interviews as approved by the Auckland University of Technology Ethics Committee. These were people who were holding, or who have held, positions in which they have influenced the formulation or the operation of PHARMAC's Community Exceptional Circumstances policy. Some interviewees were working for PHARMAC at the time; some had left PHARMAC and were in other roles with other organisations or had retired.

I requested interviews with people who held qualifications and experience in politics, policy, administration, medicine, nursing, management, governance or combinations of these. I wanted to explore each person's different experiences and perspectives of operating the PHARMAC policy, people who were closest to it and in my opinion were the most knowledgeable of it.

I interviewed past or present Ministers of Health who had approved PHARMAC funding and managed the policy settings. There have been 38 people in New Zealand who are or have been Ministers of Health between 1900 and 2011. I approached two present or past Ministers of Health who are or have been particularly involved with PHARMAC during the time of their ministerial warrant. Both agreed to be interviewed.

In my AUTEK application, I indicated my intention to interview patients who had been successful and those who had been unsuccessful in a Community Exceptional Circumstances application for drug funding. After beginning this research, I became aware of three people who were potential candidates for an interview in the research because they had been denied a Community

Exceptional Circumstances subsidy. I spoke with each potential interviewee about the possibility of an interview. I found that their experiences were quite removed from the operation of the policy because the process was handled by their doctors. All they could tell me was that they had been denied their applications and did not know why. This outcome is also discussed in the Discussion (Chapter 7) of this thesis.

Consequently, I decided not to interview patients but instead to interview the executive officers of two patient advocacy organisations. These individuals had assisted many patients in the process of making Community Exceptional Circumstances claims and were recognised²⁰ as having a great knowledge of the process. I interviewed the executive officers of the New Zealand AIDS Foundation²¹ (NZAF) and the New Zealand Organisation for Rare Diseases²² (NZORD).

All the interviewees were alerted that the interview would be for approximately one hour, conducted face-to-face and recorded. Each prospective interviewee was sent a letter asking them to consider participation. The information sheet approved by the AUTEK outlined the purpose of my research and a list of questions to be used in the interview.

The prospective key informants were asked to send the consent forms back to me signed in a self-addressed envelope if they agreed to participate in the interview. One interviewee agreed to be interviewed but did not sign a consent form. This person stated that, as far as he was concerned simply his giving the interview was consent enough. I considered this was adequate and I recorded this as verbal consent on the tape.

Each interviewee had a different background and experience of the PHARMAC policy. For this reason, I sent each interviewee different sets of questions relating to their area of expertise. The questions were used as a guide or prompt to discussion and were not rigidly adhered to. No deception was used in the enrolment of the interviewees or during the interviews.

²⁰The NZAF and NZORD representatives were suggested as potential interviewees by a senior PHARMAC Manager as people who they had dealt with on many occasions relating to Community Exceptional Circumstances claims.

²¹The New Zealand AIDS Foundation website is <http://www.nzaf.org.nz/>

²²The New Zealand Organisation for Rare Diseases website is <http://www.nzord.org.nz/home>

The flow of discussion in the interview was important. Interviewees spoke at length about some questions and hardly spoke at all in response to other questions. Each interview took at least one hour and some interviews went over an hour with the permission of the interviewee. One interviewee spoke willingly for over two hours.

The interviews were recorded on a Samsung Voice Pen digital recorder. A second tape recorder was used for backup and hand written notes were also taken during the interviews. The files from the Voice Pen were transferred to my computer and were reformatted into a Wave File format and stored. Once the files were successfully transferred to my computer, the recordings were erased from the Samsung Voice Pen.

All interviews were transcribed. The Wave files were sent to a professional transcriber for transcription. In some of the interview recordings, the questions were not clearly heard by the transcriber. This is because the microphone was facing the interviewee, usually on a table, and the microphone had difficulty picking up sounds which were made by me from behind the microphone.

The transcriber used intelligent verbatim²³ method of transcribing. This is a accurate transcript without transcribing repeated words, unnecessary words which add no value to the context such as 'um', 'ah', 'yeah', 'like', 'ok', 'you know' or 'well...'. These words are omitted from the transcript unless their removal changed the context of the transcription. If the transcriber had difficulty hearing the spoken words from either the questions asked or the answers which the interviewee provided, the transcriber was asked to leave blank spaces (or partial blank spaces). At a later date, the backup tape and the interview notes were checked to confirm the questions or statements. The corrections were then inserted into the transcription text.

Once the transcriptions were all completed the recordings were erased.

A copy of the draft transcription was emailed back to each interviewee. All interviewees were asked to verify the content of the draft for accuracy. Interviewees were asked if they wanted to elaborate on any matter or on reflection remove any material they would rather have not said in the interview.

²³ Intelligent verbatim is a process used by Academic Consulting Ltd and is described at <http://www.academic-consulting.co.nz>.

Interviewees were asked to email back corrections in 'Track Changes'. One interviewee did not return the transcription at all. After several emails asking the interviewee for any changes, the transcription was not returned. It was clear from my correspondence that the interviewee was happy with the transcription and no changes were made.

Apart from the one interviewee discussed above, all other interviewees made some changes to the transcriptions. Some were simply one or two words. Other interviewees asked for a sentence or two to be removed or modified. Some interviewees added to the text of the interview with afterthoughts.

One interviewee asked for entire paragraphs to be removed from the transcription which equated to approximately 25% of the transcription. This request was made because the interviewee had made statements at the time of the interview but later when the material was written down wished to retract the statements.

Requests under the Official information Act 1982

The public's access to documents which are held by Crown Agencies such as PHARMAC is determined by the OIA. This Act entitles members of the public to make requests for official information under certain conditions and the government officials must respond to them. I obtained a large amount of official information about PHARMAC using the OIA process.

The principle of availability of public documents is well embedded and understood by New Zealand public officials. Researchers of the OIA have stated that material has been released which would never have been released before the OIA came into existence in 1982 (White, 2007). However, not all material is discoverable under the OIA and there are several grounds on which officials are allowed to refuse to release official information. The grounds for refusing to release information are:

- that the privacy of an individual person will be breached by the disclosure;
- that national security will be breached by the disclosure;

- that the disclosure is commercially sensitive and release is likely to cause pecuniary loss; or
- that the disclosure will prevent officials from giving Government Ministers free and frank advice.

In the initial stages of an OIA request, officials must make a preliminary response within 10 working days. The initial response outlines the expected timeline for meeting the request and any other information about the request which is relevant. The final response to the OIA includes a letter describing the information which has been released and the released material. These reply letters were signed by the Minister responsible for the department or agency from where the information was released. The MidCentral DHB Board Secretary responded on behalf of the DHB. The material was delivered either by post or provided electronically through email.

I made six OIA requests seeking official information about PHARMAC's Community Exceptional Circumstances policy. Three requests were made to PHARMAC, one to the Ministry of Health, one to the Department of Prime Minister and Cabinet (DPMC) and one to the MidCentral DHB. In these requests I asked for policy documents, ministerial briefings and cabinet papers, copies of letters, reports, notes and emails which have been written about various aspects of the policy. All the requests were responded to within the provisions and requirements of the OIA.

An example of an OIA request to the PHARMAC is provided in Appendix 5 and the response from PHARMAC is provided as Appendix 6.

Four requests produced many documents; however two requests did not produce any documents. Some documents were withheld and many were partly withheld. Documents were not available on some of the requested subjects because officials had not committed to writing material on those subjects. Notwithstanding the material which was withheld, large amounts of data were still collected by this method.

The request which was made to the DPMC was responded to by acknowledging the request and advising that no documents which I had requested were held in

the department. However, the Chief Executive of DPMC referred my request to the New Zealand Treasury and the Ministry of Health. Both agencies responded through their respective Ministers.

Thematic Analysis

Descriptive thematic analysis has been used widely as a qualitative research method (Guba & Lincoln, 1989). It is a method of identifying, analysing and reporting patterns which emerge from the research data (Braun & Clarke, 2006). Boyatzis (1998) stated that thematic analysis frequently goes further and interprets various aspects of the research data. Through careful “reading and re-reading of the data” (Rice & Ezzy, 1999) the recognition of patterns emerge.

In this method of qualitative analysis, the total data is used by dissecting and sampling small pieces of information and placing these pieces into groups (nodes) whose perspectives seem to be most instructive (Flick, 2002) and develop a ‘fit’ with the description of the node (Lavery, 2009b).

Such developed patterns work both to reflect reality and unravel the surface of that reality. This type of analysis deconstructs within each data set and reconstructs themes across all the data sets. This creates new understanding which is consistent and has validity (Braun & Clarke, 2006).

Braun and Clark (2006) have defined the process of thematic analysis into six phases which are necessary to complete the method successfully. These phases are presented in the following table.

Table 1: Braun and Clark Six Phases of Thematic Analysis

Phase	Description of Research Activity
1. Familiarising yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	Collating codes into categories or potential themes, gathering all data relevant to each category.
4. Reviewing themes	Checking if the categories work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic ‘map’ of the analysis
5. Defining and naming themes	Ongoing analysis to refine the specifics of each category, and the overall story the analysis tells, generating clear definitions and names for each emergent theme

Phase One

In the first phase, the researcher is required to familiarise him/her self with the collected material. Familiarisation means reading and re-reading the data many times. In this phase Braun and Clark (2006) suggest noting down initial ideas which step out of the reading, including noting down broad subject areas which begin the deconstruction process.

Braun and Clarke (2006) suggest that pre-forming ideas based on reading of literature can lead the researcher to come to conclusions about the nodes too soon. On the other hand, they advise that reading the literature before coding the data can be useful because the researcher is better informed about coding choices and has a clearer understanding of where things fit. While they do not prefer either pre-forming or informing, the researcher is cautioned to be aware of the possibility of prejudging the formation of themes based on the literature review (Braun & Clarke, 2006).

Adams, Khan, Wayside and White (2007) suggest that reading the previous research is essential to enable the researcher to formulate an awareness of the conceptual framework in which the research is located. Consequently, I decided to read the literature first which helped me to formulate my areas of interest in relation to the interviews and documents. This helped me to ask probing and relevant questions of interviewees and helped me to understand the content of the written data which were collected.

Phase Two

The second phase required the coding of interesting features of the data in a systematic fashion across the entire data set and collating data relevant to each code. This can be done manually or with the use of several computer software programmes which are available. Such programmes allowed the researcher to make codes, or electronic piles of data which related to the same subject. The computer can be used later to interrogate the contents of the electronic plies.

I was assisted by a data analysis software system produced by QSR International Ltd named NVivo 8 to capture, organise, code and interrogate the five data sets. This programme helped me to organise and manage thousands of pieces of information from the component sources. These were research materials such as transcripts from interviews, hand written journal entries, emails, notes made at meetings, media reports, official documents, unofficial documents and court proceedings.

The NVivo 8 programme refers to a technical term “nodes” as synonymous with the term “codes” (Lavery, 2009a). Before beginning to manage material from the five data sources into NVivo 8 nodes, I selected what I thought were suitable nodes and wrote a short description of each node based on my pre-reading. This clarified for me where the data ought to be placed and where material from the research was best placed. I made decisions about which nodes to code the text into, based on my understanding of the material and the relational words or references to topics in the text. It is common for text to relate to more than one node and therefore judgment is required to allocate the pieces of text to the most appropriate node or to several nodes.

I was fortunate to be the only participant on a two-day “Introduction to NVivo 8 Extending Analyses” course run by the firm Academic Consulting Ltd. I was able to begin coding my data with an NVivo expert at my side checking my coding technique into the selected nodes. After the first day, the data which had been entered into the nodes were checked for credibility and categorisation and discussed. This was a helpful exercise and set up clear patterns of coding using the software. There were two types of nodes used in the coding: free nodes and tree nodes. Free nodes were stand-alone nodes for which there was a clear and logical connection between the data and the node. These nodes did not easily fit into a hierarchy of ideas that connect or were dependant on other ideas. Free nodes do not have a structure and are organised in an alphabetical list (Lavery, 2009b).

As opposed to free nodes, tree nodes were organised in a hierarchical structure moving from a general category at the top of the node, named a parent node, to a more specific category named child nodes or even to more specific categories yet called grandchild nodes (Lavery, 2009b).

The following tables outline the nodes I used to code the data sources.

Table 2: Free Nodes Used in NVivo Coding System

Free Node	Description of Information Contained in the Node
A Patient Story	Stories or references to an individual person/patient and their circumstances
Advocacy	An organisation or person advocating for individuals or groups of patients
Affordability	Decisions to fund or not to fund based on the availability of funding
Amartya Sen	References to philosopher / economist Amartya Sen or material about capability to achieve fairness and political realism.
Community Health Interests	References to wider health interests other than an individual person. Opposite to personal health interests.
Complaints re Community Exceptional Circumstances	The nature of complaints and the process for dealing with complaints
Consultation	Consultation with the public or medical professions by PHARMAC or government agencies on exceptional circumstances
Cost-Effectiveness	Relating to decisions made on the basis of cost and patient outcome
Cost-Utility Analysis (CUA)	Material about the CUA process, outcomes and method of analysis.
Decision making	Material about how decisions were made and what participants thought of such processes
DHBs	All references to DHBs including funding and internal processes
EC Before PHARMAC	Material which referred to the time when the Ministry of Health administered Community Exceptional Circumstances policy
Exceptional Circumstances	References to the three types of exceptional circumstances; Community EC, Hospital EC and Cancer EC.
Exceptional Circumstances Panel or Committee	Material which related to the panels and committees which met to consider Community Exceptional Circumstances claims or other related matters
Expensive Treatment	Material related to high cost treatment
Functions of PHARMAC	The policies and procedures of PHARMAC and comments and material about the functions of the agency
Great Quotes	Quotes which stood out in my mind which I wanted to consider using in the text to illustrate the themes
Herceptin	Material related to the funding and decisions made about Herceptin
Individual Health Interests	References to health interests of an individual person other than the wider interests of the community.
Immanuel Kant	References to Immanuel Kant, material about the common good, references to utilitarian decisions and greatest good –greatest number type references.
Legislation	References to various Acts of Parliament particularly the New Zealand Public Health and Disability Act 2000
Litigation Against PHARMAC	References to court cases or legal actions which involved PHARMAC
Media	Media references to PHARMAC or material in the interviews about the actions of the media in relation to Community Exceptional Circumstances policy.

Free Node	Description of Information Contained in the Node
Method of Collecting Data	Comments made by interviewees during interviews or other information about how the data was collected.
MoH and Medsafe	Material relating to and comments made about the Ministry of Health or Medsafe
New Treatment	Material relating to new treatments particularly the costs of treatment and decision making about approving new treatments onto the Pharmaceutical Schedule
NICE (UK)	References to the National Institute of Clinical Excellence which similar body in the UK to PHARMAC.
Not Sure Where to Code	Where references didn't seem to fit or relate to a node. Sometimes material was removed from this node and placed in a new node.
OIA Requests	Material relating to the Official Information Act requests or material about information which was withheld under the Act.
PHARMAC Staff 'Feelings'	Material which expressed, indicated or related to how the PHARMAC felt about what it was like for them to do their work
PHARMAC's Policies and Procedures	Material relating to PHARMACs policies and procedures or the way they went about making decisions which were outside their policies or procedures.
PHARMAC's Relationship with Drug Companies	Information referred to in either the documents or the interviews which described aspects of the relationship with pharmaceutical manufacturing companies.
Political Risk	Material indicating the identification or management of political risk either by PHARMAC or the Government
PTAC	References to the selection, activities, criteria and decisions made by PTAC
Rare treatments	Material relating to rare treatments as opposed to expensive treatments
Rawls	References to philosopher Rawls, material about justice as fairness, providing for those in greatest need, openness and accountability as a function of fairness.
Reference Pricing	Material referring to reference pricing mechanism used by PHARMAC.
Reviews of PHARMAC	Reviews which have taken place and examine aspects of PHARMAC's performance, policies and procedures.
Researched Medicines Institute (RMI)	Material related to the RMI either by the RMI or about the RMI
Rule of Rescue	References to the Rule of Rescue
Source of Material	Where there are embedded references in the interviews or documents to the sources of material the interviewee or document are referring to in the data.
Taxpayers Interests	Comments or written passages which explain issues from the point of view of the taxpayer, or the general health budget
The Number "10"	Material relating to the use of "10" cases nationally of any condition as a description of rarity

Table 3: Tree Nodes Used in NVivo Analysis System

Tree Node (Parent)	Tree Node (Child)	Tree Node (Grandchild)	Short Description
Access to Treatment	-Decisions about Access	Examples of Access	This hierarchy collected statements and written material which described varying issues related to access
Decision Making: PHARMAC's Criteria	-Nine Criteria -Decisions about Systems -Decisions about Patients		Categorised material about decision making by PHARMAC
Justice	-Rule of Rescue -Openness -Fairness -Equity		Categorised material and interviewees comments about justice into the described elements
Rationing	-Utilitarianism -Macro Level Rationing -Meso Level Rationing -Micro-Level Rationing -Other Forms of Rationing	-Affordability (PHARMAC) -Cost-Utility Analysis -Clinical Rationing	Breaking down material into specific categories related to the issue of rationing.
Voice Embedded within Stories	-Voice of PHARMAC Staff -Voice of Patients -Voice of Health Ministers -Voice of Health Service -Managers -Voice of Advocate Organisations		Where stories reflected how material was collected and what the participant was saying in relation to PHARMAC's exceptional circumstances policy

As previously stated, most of the nodes were established at the beginning of the coding process. However, as coding proceeded, I realised that some important nodes were missing; consequently more nodes were added. This created the problem that some data were already coded and may have been more appropriately coded into the new nodes which I had created. To deal with this problem, I re-checked each interview and document and utilised some of the new nodes if they were a more appropriate fit.

On the other hand, as I made progress coding the sources into the nodes, I realised that several nodes were very similar and not sufficiently differentiated from each other. In this instance, nodes were amalgamated.

Researchers (Davidson & Jacobs, 2008) of the implications of using qualitative research software for doctoral work have commented that the quality of the work done with NVivo type programmes is improved with the use of a research diary. Consequently, I kept a methodological research diary of all my activities using NVivo 8. These entries were thoughts, happenings, a record of difficulties, mistakes which were found and a log of how they were corrected.

Phase Three

The third phase involved collating the developed coded data sets into categories. The 'search and find' functions on the computer programmes most helpfully allowed a search for commonly occurring words and groups of words. These words and groups of words became the building blocks for the categories.

The tree and free nodes were all printed and read many times. I developed 'collections' of nodes which naturally joined themselves together. In my diary, I noted down four collections or subject areas which began to emerge.

I then ran Text Search Queries (TSQ) of each tree and free node using the NVivo 8 programme to search the data for the commonly occurring key words (Lavery, 2009a). TSQ provides a check that these words were the most commonly used words taken down from the nodes and provides a link back to the source of the data. This allowed me to revisit the text and check the context of the words. After several runs of TSQ to test the data, NVivo 8 gave me an embedded description of the text by allowing me to see the most commonly occurring words and groups of words.

I then took the TSQ and searches began to construct the categories. These were statements which described each node using the commonly occurring words from within the node. From this process, 74 categories emerged.

Phase Four

This Phase required reviews of the categories to locate what Braun and Clark (2006) describe as the 'essence' of the category and to understand the meaning and impact on the research question.

At this point, I stopped using NVivo 8 because I found that the software could only report on the frequency of word usage and could not describe meaning or identify the diversity of the themes from the data sources which I had collected.

This stage of the thematic analysis called for a critical appraisal of how to organise the categories in relation to the thesis question. These functions were simply beyond the capability of NVivo 8.

I read the categories again many times with the thesis question as the primary focus. By this stage, I was extremely familiar with the research material. I noted areas where the 74 categories related from my knowledge of the research data, the subject literature and my thesis question.

I further analysed the categories by condensing, defining and refining them. I wrote a summary of what each category was about by determining what aspect of the question it captured. This was not simply a paraphrase of the categories but a description of what interested me about the category and why.

The categories were divided into five subject areas which related to my thesis question:

1. Subject areas which relate to PHARMAC's operation as a meso-level rationer (PHARMAC's role).
2. Subject areas which relate to PHARMAC's operation as a micro-level rationer (Community Exceptional Circumstances).
3. Subject areas which relate to PHARMAC's moral and ethical position.
4. Subject areas which relate to PHARMAC's reputation for stakeholder engagement.
5. Subject areas which do not relate to any of the above subject areas.

Table 4 demonstrates the number of categories which related to each of the subject areas.

Table 4: Allocating Categories to Subject Areas.

Subject Area	Themes
Subject areas relating to PHARMAC's operation as a meso-level rationer	14
Subject areas relating to PHARMAC's operation as a micro-level rationer	23
Subject areas relating to PHARMAC's moral and ethical position	13
Subject areas relating to PHARMAC's stakeholder engagement	19
Subject areas which do not relate to any of the above subject areas	5
Total	74

Phase Five

The fifth phase required ongoing analysis to refine the specifics of each category to generate clear descriptions and names for themes as they emerged. This was done by reading and re-reading all the gathered data again, however this time I had clear categories and subjects to work with. I allocated each category of data to one subject area. Many categories were regularly appearing and they were allocated to one (where possible) theme.

I then allocated a name for each regularly occurring theme. The themes are presented at the end of the Research Findings (Chapter 6).

Phase Six

Braun and Clark (2006) describe this phase as the discussion and report writing phase. The themes from this research are discussed in the Discussion (Chapter 7) of this thesis.

Chapter 6: Research Findings

Introduction

There are six sections in this chapter which present the knowledge which has been gained from this research about PHARMAC's Community Exceptional Circumstances policy.

The first five sections relate to the data sources which were collected and analysed in the manner described in the previous chapter.

The sixth section is a discussion of PHARMAC's own review of the Exceptional Circumstances policies which was carried out between 2010 and 2011.

The seventh section presents the regularly occurring themes which were produced from analysing the data. These themes are the findings of the thematic analysis.

The sections in this chapter are:

- Section 1** The New Zealand Public Health and Disability Act 2000
- Section 2** Media Study
- Section 3** Walsh vs PHARMAC
- Section 4** Key informant interviews
- Section 5** Requests under the Official information Act 1982
- Section 6** PHARMAC's review of Exceptional Circumstances schemes
- Section 7** The regularly occurring themes from the data

The material in this chapter does not come with a commentary about what the data mean or what learnings can be taken from the information captured about PHARMAC's Community Exceptional Circumstances policy. The chapter is designed to present the research data in the most detached manner possible so that the material speaks for itself.

Section 1: The New Zealand Health and Disability Act 2000

General Provisions of the New Health Act

The purpose of examining the genesis of PHARMAC's governing legislation was to gain insights into what the government and the public believed were the reasons for the existence of PHARMAC and predictions about how the government expected this health rationing agency to operate. By knowing the intended purposes of PHARMAC, my research acquired a legislative framework and description of the statutory requirements of the agency. This information was contained in the recordings of the parliamentary process from both inside and outside of parliament.

The aims of the New Zealand Health and Disability Bill 2000²⁴(referred to as The Bill) were stated by Health Minister Annette King in Parliament speaking in the First Reading introducing the legislation. These aims were "to improve the health of all New Zealanders regardless of their race and regardless of their socioeconomic circumstances". Minister Annette King went on to say her Bill attempted to reduce the

"shameful' health disparities and inequalities between NZ population groups."

The Bill aimed to establish 21 DHBs and directed them to take a population health focus for geographically defined populations. The Bill attempted to legislate for the development and delivery of the New Zealand Health Strategy and the New Zealand Disability Strategy. It required DHBs to report to Parliament annually on progress they were making in implementing the government's health strategies. The Minister expected the new health law to achieve co-operation and collaboration between the agencies in the sector with the result of delivering better care and support for all New Zealanders.

The Minister aimed to ensure local people could contribute to decision making about health and disability support services in their district. She did this by reintroducing provision for partly elected DHBs (Ministry of Health, 2000). The

²⁴A 'Bill' introduced into the New Zealand Parliament is a proposal for the government to create or change a law. The Bill becomes an 'Act' or piece of law when the Parliament approves the Bill by majority and the Governor General gives his/her assent.

DHBs were given the role of funding (or providing for by contracting) health, hospital and other related services for the population within their region.

The minister stated in her speech introducing the Bill she aimed to create new publicly-owned health and disability organisations to achieve improvements in the areas of health promotion and protection of the health of all New Zealanders (King, 2000a). In so doing, the government aimed to improve the independence and inclusion of people who live with disability. The Minister legislated that people living with disabilities are to be provided the best possible care within the available public health resources.

The NZPHD Bill legislated for a determined effort by public health authorities to reduce health inequalities in New Zealand and particularly sought better health outcomes for Maori, Pacific peoples and other ethnic groups.

The most significant structural change in the new health Bill was the transferring of the funding of public health services from the Health Funding Authority (HFA) to the Ministry of Health. For the first time in New Zealand, DHBs were being made responsible for integrating all health and disability services in their regions, which included the important component of primary care.

The new model included national priorities set by the government. These consisted of two overarching strategies for managing health and disability services and the DHBs were established as a network to implement them. The strategies required the DHBs to integrate primary, secondary and tertiary level care with the wider needs of the communities they served.

The Minister of Health mentioned these wider collaborations in her speech during the Third Reading of the Bill. She emphasised the key ingredient of the legislation was for the health strategy to provide a framework for improving the health of New Zealanders and develop healthier communities.

The Minister made it clear it was her government's intention that the determinants of good health were to be strongly influenced by the government's diligent attention to providing adequate housing, lowering the levels of unemployment, increasing educational achievement and improving access to other social support structures (King, 2000a). She also reiterated an election promise to develop other health strategies such as He Korowai Oranga/Maori

Health Strategy and the Primary Health Care Strategy and the Pacific Health and Disability Action Plan (Health-Reforms-2001-Research-Team, 2003).

The proposed legislation disestablished the HFA which had been the funding and purchasing arm of the public health service. Hospital Health Services (HHS) boards which administered the public hospitals before 1999 were also disestablished.

In their place the Ministry of Health was given the key role in monitoring the funding, performance, planning and reviewing the health needs assessments carried out by the 21 DHBs. The Ministry of Health continued in the role of providing policy advice and ministerial services to the Minister of Health.

The DHBs under the new arrangements were to have a majority of members elected by public election triennially and added to by other ministerial appointments. The Minister wanted to provide for a balance of experience and cultural input onto the DHB to balance the need for community participation and respect for the Crown's partnership with Maori.

The Bill made it clear that the Board members were responsible to the Minister of Health for setting the strategic direction of the DHB. They were not primarily responsible to the electorates who had elected them. They were also specifically directed to be responsible for appointing and monitoring the performance of the Chief Executive. The Boards were required to ensure the DHB acted in compliance with all laws, financial accountabilities (especially to keep the DHB solvent) and the reporting requirements as a Crown Agent.

Recognition of The Treaty of Waitangi

Part 3 of the Bill adopted measures that recognised and respected the Treaty of Waitangi. The Bill presented to parliament, declared that in order to recognise and respect the principles of the Treaty of Waitangi, Part 3 provided for mechanisms to enable Maori to contribute to decision making and to participate in the delivery of health and disability services (King, 2000a). The Preliminary Provisions of the Bill (s3[3]a) also stated that no person would be entitled to preferential access to services on the basis of race.

These measures were in response to the Crown's desire to fulfil their obligations under the Treaty of Waitangi to deliver greater Maori participation in the public health services. The Minister intended by this mechanism to advance the health status of Maori and prevent further deterioration in that status (Ministry of Health, 2000). The government also believed that encouraging greater participation at all levels of the health and disability services, including governance, would contribute to better health outcomes for Maori.

The Establishment of PHARMAC as a Crown Agency

The Bill made provision for the establishment and terms and conditions of other Crown Agencies related to the public health and disability service. One of these agencies was PHARMAC. This was established as a stand-alone Crown Entity with direct accountability to the Minister of Health. The legislation gave PHARMAC the responsibility to create and maintain a Pharmaceutical Schedule for the purposes of consistently applying criteria for providing subsidies to the general public for their prescription medicines (Ministry of Health, 2000).

One of the initial purposes of establishing PHARMAC in the Bill was to improve purchasing of pharmaceuticals by managing relationships with the pharmaceutical supply companies. Another purpose was to cap government funding for a schedule of drugs on which the government would pay a subsidy on behalf of the patient (Ministry of Health, 2005). The establishment of PHARMAC also opened the way for purchasing and planning strategies that would integrate services and provide a rational analysis on which drugs would be purchased (Cumming, Powell, & Barnett, 2004) and a platform for understanding the cost implications to the government for doing so.

The Bill set out PHARMAC's accountability to the Minister of Health and Parliament. Specifically, PHARMAC was required under Section 47 (s47) to secure for eligible people in need of pharmaceuticals the best reasonably achievable health outcomes from pharmaceutical treatment. This was to be done within the funding provided by the DHBs (s47 NZPHDA 2000). The accountability to the Minister was to take the form of service agreements and a statement of forecast of service document signed between the Minister of Health and PHARMAC. Section 48 in the Bill required the agency to also be accountable to the public of New Zealand.

PHARMAC Required to Manage Exceptional Circumstances Schemes

The Bill required PHARMAC to manage incidental matters arising out of the pharmaceutical subsidy including a policy for dealing with members of the public who make claims in Exceptional Circumstances. In this way, PHARMAC would legally provide subsidies to applicants for the supply of pharmaceuticals which are not on the pharmaceutical schedule (NZPHD Bill section 48(b)[a]).

The government preferred PHARMAC to decide, on behalf of all 21 DHBs, which pharmaceuticals should be listed, which subsidies should be provided for them and the eligibility criteria which applied to them. This included managing people who had exceptional pharmaceutical needs. These decisions could then be made consistently across the 21 DHBs. The intention of the Bill was to provide assurance that patients in one DHB would receive the same subsidy and treatment of their exceptional circumstances as patients claims in another DHB.

In order to maintain and manage the Pharmaceutical Schedules, PHARMAC was given a notional budget for itself to pay for staff and operations. This was to be set by the Minister each year after consultation between PHARMAC and the DHBs.

Submissions to the Health Select Committee

Members of the public were invited to make submissions to the government on the NZPHD Bill 1999. There were 153 public submissions received by the Health Select Committee on the Bill. Of these 153 submissions, 16 organisations or individuals who submitted material on PHARMAC are identified in Table 5 below.

The likely reason for the low number of submissions received on PHARMAC may be related to the fact that PHARMAC had already existed as an organisation on the public health landscape for 6 years since 1993.

The issues raised by submitters in relation to PHARMAC are discussed in the following section.

Table 5: The Submitters to the Health Select Committee who made a submission on PHARMAC²⁵

Representing Organisation	Submitter	Submission No.
Citizen	L.A. Smalley	PB/3W
The University of Auckland	Lorna Dyall	PB/8
Researched Medicines Industry Association	Hon. Stan Roger	PB/18 & 18C
Ngati Te Ata	Roimata Minhinnick	PB/37D
Association of Community Laboratories	Mike Fitzgerald	PB/82
Pharmacy Guild of New Zealand	Murray Burns	PB/77
The New Zealand AIDS Foundation	Matthew Soeberg	PB/91
Association of Salaried Medical Specialists	Ian Powel	PB/92
New Zealand Charter of Health Practitioners Inc.	Patrick Fahey	PB/109W
Royal Australasian College of Surgeons	Jay Tyler	PB/111
The Office of the Race Relations Conciliator	Sylvia Bell	PB/123
National Council of Women (Inc.)	Barbara Glennie	PB/132
Citizen	Jocelyn Brooks	PB/142W
Citizen	Coralie Leylend	PB/144W
The Law Commission	D F Dugdale	PB/150W
Royal New Zealand College of General Practitioners	Dr. R. Wyles	PB/14

PHARMAC's Exemption from the Commerce Act 1986

The Bill outlined that PHARMAC was to be exempt from the provisions of the Part II of the Commerce Act 1986. This Act forbids any commercial practice that lessens competition, fixes prices and uses a dominant position in the market. The position of PHARMAC being the sole purchaser on behalf of all the DHBs gave PHARMAC considerable market influence. This was almost complete dominance over the setting of prices for medicines and other associated medical devices and products. The exemption was deemed necessary to allow PHARMAC and the DHBs to establish a lawful and consistent national pricing policy for the purchase of medicines from the pharmaceutical industry.

Submissions on the Bill were received on behalf of the interests of research-based pharmaceutical manufacturers operating in New Zealand, an

²⁵Not including PHARMAC itself and the Ministry of Health who reported to the Committee on their own behalf.

organisation named the Researched Medicines Industry Association (RMI)²⁶. The RMI argued that the only rationale for an exemption to the Commerce Act was to allow PHARMAC the opportunity to establish a national purchasing policy (PB/18 The Researched Medicines Industry Association of New Zealand, 2000). This situation was not dissimilar to the limited exemption which was granted to the four RHAs prior to the Bill to allow them to manage and operate the pharmaceutical schedule of medicines which were subsidised by the government. According to the RMI, the arrangement worked perfectly well without a total exemption and made medicines available at a cheap price or at no cost to the patients.

The RMI²⁷ placed emphasis on the words 'limited exemption' and strongly objected to the provisions in the Bill that granted PHARMAC considerably more price fixing powers than existed under the previous RHA structure.

Essentially the difference in the proposed legislation was that PHARMAC was to be given an exemption to incorporate agreements between purchasing agents and individual pharmaceutical companies rather than limiting the immunity to agreements between the DHBs, Ministry of Health and PHARMAC (PB/18 The Researched Medicines Industry Association of New Zealand, 2000). It was suggested that this would allow PHARMAC and the DHBs to enter into price control arrangements which would distort market forces by virtue of monopsonistic behaviour²⁸.

The RMI argued that the effect would be to limit competition and the ability for the market to differentiate on the basis of quality of health care products. They submitted that PHARMAC's control of the market would also lead to inconsistent prices in New Zealand which would be out of step with world prices. This would damage New Zealand's relationship with international pharmaceutical companies and act as a disincentive for research and investment in pharmaceutical developments in New Zealand. There also existed a potential to antagonise international pharmaceutical companies

²⁶In September 2011 the Researched Medicines Industry Association (RMI) changed its name to Medicines New Zealand (MNZ). The new organisation joined together the RMI current members and several other stakeholders from New Zealand's health sector. MNZ website is found at <http://www.medicinesnz.co.nz/>

²⁷In particular ss27-30 (PB/18 The Researched Medicines Industry Association of New Zealand, 2000)

²⁸Monopsonistic behavior is where a sole purchaser exerts control over the price and supply to a market for goods or services (Mankew, 2001). The opposite of monopsonistic behavior is monopolistic behaviour where the sole seller exerts influence on the price of goods and services.

towards New Zealand and for them to be justified in withdrawing their co-operation with the New Zealand government.

The greater concern expressed in the RMI's submission was that PHARMAC would be restricted in access to newer medicines which would provide more effective treatments to New Zealand citizens. These situations defeat the objectives of the Bill which sets out to promote the best care for New Zealanders through the publicly funded DHBs.

PHARMAC submitted in rebuttal that it cannot and does not control the access to the pharmaceutical market. Any company wishing to sell pharmaceuticals in New Zealand can do so to any willing buyer, so long as the products meet the normal regulatory standards of safety and quality as determined by Medsafe²⁹. Many companies choose to launch and promote their pharmaceuticals in New Zealand without a PHARMAC subsidy. PHARMAC sees this as a form of competition and pointed out to the Committee that it sought to limit the number of competitors it dealt with, but did not seek to limit competition in the wider market place.

The RMI counter argued that the wide exemption to the Commerce Act also defeated the price control and anti-competitive free market principles enshrined in the Commerce Act. These principles are applicable to all other industries and companies operating in New Zealand. These principles are regarded by the government as protections for consumers in respect of quality and prices. The RMI's submission argued strongly that the Commerce Act is there to promote active, workable and effective competition which, in turn produces efficient economic and healthy outcomes.

These outcomes are described as prices close to cost, efficient production and product innovation, all which advance the health and welfare interests of the consumer/citizen (PB/18 The Researched Medicines Industry Association of New Zealand, 2000). The benefits of competition and the protection of the Commerce Act not only apply to consumers but also to suppliers and in the case of pharmaceuticals and ultimately to tax payers.

²⁹Medsafe is a department of the Ministry of Health and is the regulatory body with approves by registration the safe use of medicines and medical products which can be sold in New Zealand. The Medsafe website is <http://www.medsafe.govt.nz/>

The Commerce Act gives protections and opportunities to test the fairness of the commercial and retail market by injunctions and other legal remedies. These legal proceedings can be taken by persons or organisations likely to suffer damages by reason of contravention of the Commerce Act. The Commerce Commission³⁰ is established as an independent authority to protect the consumer from price-fixing and other anti-competitive behaviour.

The Commerce Commissioner must provide surveillance and vigilance, watching trading companies and professional bodies to ensure they all act within an agreed set of rules. The Commerce Commission has considerable remedies available to it to redress any breaches of the Commerce Act. The RMI claimed that these remedies have been swept away by excessive breadth and width of the immunity provisions provided to PHARMAC in Clause 6 of the NZPHD Bill.

The submission made by the Royal New Zealand College of General Practitioners also made the point that the Bill should more clearly state that PHARMAC's objective was to achieve quality patient outcomes and not only price control (PB/ 14 The Royal NZ College of General Practitioners, 2000).

The owners and managers of New Zealand private hospitals, the New Zealand Private Hospitals Association (NZPHA) agreed with the RMI that the exemption from the Commerce Act should be limited and only available to transactions between the DHBs and public health organisations, by application to the Commerce Commission (PB/57 New Zealand Private Hospitals Association, 2000). Lexchin and Caygill (2000) submitted that in relation to the argument of whether PHARMAC should have a wide or narrow exemption, that "economic efficiency is not the only goal of the Commerce Act" (Lexchin & Caygill, 2000).

They described their belief that economic efficiency was a desirable outcome from competition and health equity outcomes, in relation to pharmaceuticals, as also important. Lexchin and Caygill's submission pointed out to the Select Committee that the Commerce Act seeks to promote competition, by prohibiting contracts or arrangements that substantially lessen competition. The misuse of a dominant position in the market does not necessarily create or prevent

³⁰ The Commerce Commission is a legal entity with significant powers to investigate and remedy anticompetitive trade practices. The Commission's website is <http://www.comcom.govt.nz/>

monopolies as such. In their opinion, the government does not need an exemption from the Commerce Act in order to negotiate a single schedule of pharmacy subsidies or to use a single agency such as PHARMAC for this purpose (PB/18c Lexchin & Caygill, 2000). Neither did Lexchin and Caygill support the RMI's suggestion of a partial exemption or PHARMAC's suggestion of a total exemption. They argued that it was within the government's power to grant PHARMAC a dominant market position decided upon by applications to the Commerce Commission. They believed it was the Commerce Commission's role to allow or disallow such applications based on upholding the terms and conditions of the Commerce Act and the strength of the arguments put to it. If Lexchin and Caygill's advice were to be followed, the fate of PHARMAC's monopsonistic intentions would be placed in the hands of the Commerce Commissioner who would have been required to give the pharmaceutical industry equal rights with PHARMAC to be heard and considered.

PHARMAC's Immunity from Prosecution

Another argument advanced at the Select Committee was that PHARMAC's immunity from prosecution under the Commerce Act was a disincentive for litigation against dominant purchasers in the pharmaceutical market. PHARMAC stated in their submission that a single legal proceeding under the Commerce Act brought against it by a pharmaceutical company could cost PHARMAC \$1 million to defend. This is due to the complex nature of the Act and the need to call international expert witnesses (PB/72 PHARMAC, 2000). PHARMAC argued that such litigation would involve it in cost that should more purposefully be used for purchasing pharmaceuticals on behalf of the tax payer.

There are actions available to the Courts to control vexatious litigants. These sanctions are also available to PHARMAC through the Commerce Act. It is for the courts to award costs against any party which would bring legal actions against PHARMAC which were time-wasting, vexatious or troublesome claims which were without substance.

Lexchin and Caygill point out that there have been eight³¹ occasions where international pharmaceutical companies have brought legal proceedings against PHARMAC in the New Zealand courts. All of these cases were successfully defended by PHARMAC. None of these claims could have been regarded as vexatious (Lexchin & Caygill, 2000). Whilst defending court actions taken against it is not a particularly desirable use of public money by PHARMAC, equally as a Crown Agency it should not resile from the need to publicly defend its actions. In light of this, it would not seem appropriate that PHARMAC should be protected from this normal level of legal jeopardy. If the government were to provide PHARMAC with an extraordinary level of legal protection this would create the impression that they are entitled to act in ways that lie outside that which would be considered normal commercial dealings by the Courts.

Past legal actions cannot be a predictor of what would have happened if the full exemption from Section II of the Commerce Act had been removed. This is because the previous actions were taken under the protection of the Commerce Act. PHARMAC may not have fared so well in the nine legal challenges if the full force of Section II of the Act had been directed at it.

PHARMAC argued that the public benefit of saving public funds from litigation costs outweighs any detriment to the pharmaceutical companies and the detriment to side stepping the controls of the Commerce Commission.

This Royal Australasian College of Surgeons (RACS) also complained that by the Bill granting immunity from Part II of the Commerce Act, the government owned public health services were taking an unfair advantage over private health providers.

The RACS submitted that they considered this (immunity) has the potential to disadvantage private providers of publicly provided services. This would result in decreased availability of privately provided health services and cause a higher cost of publicly provided care³². The College would regret such an outcome and suggested that private providers of publicly funded services, such as themselves, should also be exempt from the provisions of the Commerce Act

³¹Prior to the year 2000.
³² See 'Rent seeking' on p40

for the delivery of such services (PB/111 Royal Australasian College of Surgeons, 2000).

The Ministry of Health strongly supported the exemption of PHARMAC from Part II of the Commerce Act. They believed that this position would result in the pharmaceutical companies lowering their prices in order to contract with PHARMAC for the monopoly supply of medicines. They argued that without the exemption, these companies would become subject to litigation from their competitors because they would have been seen to have taken an unfair advantage. This would undermine the ability to operate the reference pricing system in the future and cause a reduction in the savings which were being achieved by PHARMAC.

Reference pricing system is applied to the pricing for sale of a therapeutic group (pharmaceuticals with the same or similar therapeutic effect) of medicines. The subsidy is based on the lowest priced pharmaceutical in that group, and the lowest price is applied to all pharmaceuticals in that group (Sanderson & Goodchild, 2005). The logic here is that companies who offer their product at a higher price will risk PHARMAC applying a subsidy to a lower priced competitors' product. In this way, PHARMAC exercises a dominant market position by choosing preferences based on quality and control of the price. The pharmaceutical companies have the choice of supplying to PHARMAC at the (lower) referenced price, or face the possibility of losing the supply contract to a company who is willing to sell at the referenced price.

The Committee was also told by the Ministry that the positive welfare to the public of using reference pricing to control pharmaceutical prices was not outweighed by the negative welfare of decreased market competition and the threat to loss of innovation in pharmaceutical research and development. This was mainly due to the need for PHARMAC to control prices. Nearly all countries in the OECD have also recognised this need (PB/18c Lexchin & Caygill, 2000). For example, in the United States the Veterans Administration Hospitals require substantial discounts from pharmaceutical manufacturers and some of the state governments (e.g., the State of Maine has passed legislation to lower the price of pharmaceuticals) (PB/18c Lexchin & Caygill, 2000).

Considering all the arguments for and against a full exemption from Section II of the Commerce Act, the Health Select Committee was persuaded that the exemption should stand in the NZPHD Bill.

Submissions of PHARMAC's Functions

The National Council of Women of New Zealand (NCWNZ) made a submission that s42 of the NZPHD Bill was not sufficiently clear about who would be eligible for the pharmaceutical subsidies which were to be managed by PHARMAC. The Clause in the Bill states that PHARMAC is to “to maintain and manage a pharmaceutical schedule that applies consistently through out New Zealand, including determining eligibility and criteria for the provision of subsidies” (Ministry of Health, 2000).

The NCWNZ questioned the notion of ‘eligible people’ referred to in the Bill. They asked if a subsidy would be provided to people who were overstayers or otherwise illegally residing in New Zealand. (PB/132 National Council of Women of New Zealand (Inc.), 2000). The Ministry of Health replied that eligible people are defined in a direction given by the Minister of Health and published in *The Gazette*³³ from time to time. The Ministry of Health stated that it is not appropriate to include such direction in the legislation, as the Minister may need to respond to a new group of refugees who arrive in New Zealand.

The NCWNZ also objected to the reference in the Bill to the notion that PHARMAC would be required to operate in a financially responsible manner to “maintain its long term viability” (PB/132 National Council of Women of New Zealand (Inc.), 2000).

It was considered by the NCWNZ that the financial imperatives for PHARMAC to remain solvent were inconsistent with the health goals and wider set of health strategies. The Ministry of Health countered that there was no reason why this would be so. There were many examples in the private health sector where individuals and companies have remained solvent and in fact have proved to be highly profitable. Such individuals and companies have continued to provide the highest quality of health care services. The Ministry of Health reminded the

³³The New Zealand Gazette is the official newspaper of the Government of New Zealand. It is produced every Thursday (except over Christmas/New Year) by the New Zealand Gazette Office at the Department of Internal Affairs. Each edition of the New Zealand Gazette is divided into commercial and government notices, covering business proceedings, bankruptcies, land transfer notices, departmental and parliamentary notices.

NCWNZ that S42(a) of the Bill, required PHARMAC to do both: remain solvent and produce high quality health outcomes (PB/MOH 8 Ministry of Health, 2000) and in their opinion these were not mutually exclusive imperatives.

Submissions on the Inclusion of the Principles of the Treaty of Waitangi in the Bill

Approximately half of the public submissions received on the Bill addressed Clause 4. This section stated that the Act was to be interpreted in a manner that is consistent with the principles of the Treaty of Waitangi. In this Clause, the Crown primarily asserted its responsibilities to Maori by recognising respect for these principles.

A significant number of submissions supported the inclusion of the Treaty principles in the Bill and some wanted the principles more closely defined and even strengthened (Health Select Committee of NZ Parliament, 2000).

The Submission received from the University of Auckland³⁴ did not recognise the term 'the principles of the Treaty of Waitangi'. Their submission stated that there should be a Maori Advisory Committee of PHARMAC and that there should also be Maori representation on the PHARMAC Board. They stated that the terms of reference for PHARMAC's Board should state clearly that Maori health outcomes and Maori social capacity is to improve through the work of PHARMAC. This would be recognition of the principles of the Treaty of Waitangi (PB/8 University of Auckland, 2000).

There were a number of submissions received opposing the inclusion of the clauses recognising the principles of the Treaty of Waitangi. Submitters objected on the grounds that the principles were not defined and they feared that the Bill would establish different entitlements to health care into the public health system, entitlements which would be based on ethnic origin.

The National Party Members of the Select Committee argued against the inclusion of the Treaty Clause in the Bill. They believed that Treaty references should not be included in social legislation because there was a lack of definition in the Bill about which rights were to be accorded to Maori under the

³⁴Presented by Lorna Dyall, Senior Lecturer Maori and Pacific Health, Community Health, Faculty of Medicine and Health Science, University of Auckland

Treaty, and which rights would be denied to non-Maori. They also objected to the inclusion of clauses relating to mana whenua³⁵ and giving Maori greater governance rights in the running of the DHBs, than non-Maori.

The University of Auckland submission, while applauding the inclusion of the term mana whenua, expressed concern that the principles of the Treaty of Waitangi would not be commonly agreed or understood. Their submission stated that major divisions in the interpretations of the term 'principles of the Treaty of Waitangi' are likely to occur within the DHBs, within the Ministry of Health, across health providers and within communities due to lack of a clear definition in the Bill (PB/8 University of Auckland, 2000).

Submissions received from Ngati Te Ata stated that they are the mana whenua throughout the breadth of Tamaki Makaurau³⁶ rohe (district). They defined the meaning of mana whenua for the purposes of Section 18s(5) as meaning the people who exercise customary authority over their rohe. This was interpreted to mean "traditionally owned or otherwise occupied or used area" (PB/37d Ngati Te Ata, 2000).

Ngati Te Ata's suggestion was that the tribal authority of Ngati Te Ata would organise health services in partnership with the DHBs in Auckland. The tribe presented a model where the tribal authorities would determine the nature and location of health services within their tribal area. They stated that the tribe was planning to present a plan for the Auckland DHB to provide Ngati Te Ata with funding to deliver health services to Maori in the rohe. Their submission asserted that the mana whenua should determine mana whenua interests within these areas and which health policies, structures and processes would be most effective and appropriate to them. They advised the Committee that Ngati Te Ata is currently drafting a plan to take over the responsibilities and work of the Auckland DHB (PB/37d Ngati Te Ata, 2000).

The University of Auckland submitted that while it was pleasing to see the government recognise the mana whenua status of Maori people of a rohe, as mana whenua is currently defined by the Waitangi Tribunal, the issue is

³⁵Mana whenua is a noun referring to territorial rights and power from the land. This power is associated with possession and occupation of tribal land. The tribe's history and legends are based in the lands they have occupied over generations and the land provides the sustenance for the people and to provide hospitality for guests. Reference: New Zealand Maori Dictionary

³⁶North Waikato, Auckland and Northland region.

contentious among Maori Iwi. Any Maori person could claim mana whenua status on the proviso that they could trace whakapapa³⁷ through tupuna³⁸. They concluded on this point saying “if one of the purposes of the Bill is to promote collaboration, integration (of) a public and population health focus, we recommend that the term ‘mana whenua’ be removed” (PB/8 University of Auckland, 2000).

This brought the committee no closer to an understanding of what partnership meant. The Ministry of Health submitted that partnership meant that Ngati Te Ata for example, would consult with the three Auckland DHBs on matters related to the provision of health services for members of Ngati Te Ata in Auckland (PB/MOH 8 Ministry of Health, 2000). This confirmed the concerns of the University of Auckland that the understanding of partnership in terms of the principles of the Treaty of Waitangi is vastly different among the different actors in the health sector.

The Law Commissioner, D F Dugdale presented a submission to the Select Committee which addressed the issue in Clause 4 of the Bill. He argued that this would be bad law if the intention of parliament was to emphasise the harmonious provision of health services and it achieved the opposite, giving rise to public uncertainty, disharmony and division (PB/150w The Law Commission, 2000).

The Commissioner pointed out that Pages 4 and 5 of the Explanatory Notes of the Bill under the heading “Partnership with Maori” were statements of political difference. It would be beyond the functions of the Law Commission to express an opinion on political issues and he refrained from doing so in the Law Commission’s submission. However, the Commissioner pointed out that the Law Commission is charged with a narrower responsibility in relation to the development of laws, namely whether the context of this measure ‘the principles of the Treaty of Waitangi’ should be clarified by a more explicit expression of parliament’s will (PB/150w The Law Commission, 2000). Dugdale explained that the problem is that the statement ‘the principles of the Treaty of Waitangi’ “is not one of legal art” (PB/150w The Law Commission, 2000).

³⁷Family lineage

³⁸Ancestors

The consequence of this type of term inserted into the Bill, as appears in Clause 4, is those citizens and institutions required to comply, cannot know what they are required to do or omit. The only way to discover this with any certainty is through obtaining a ruling from the courts. By using so general a term as ‘the principles of the Treaty of Waitangi’, Parliament in effect is delegating its law making function to the courts. It is the court then who must invent the meaning that parliament has failed to articulate itself (PB/150w The Law Commission, 2000).

Dugdale drew attention to the cases where the expression ‘the principles of the Treaty of Waitangi’ has led to litigation, the best known example is Section 9 of the State Owned Enterprises Act 1986. In this example the court when asked to interpret the expression, sought to understand the intention of parliament and could do no better than to declare the expression “has led to uncertainty” (PB/150w The Law Commission, 2000).

Finally, the Commissioner invited the Select Committee to spell out what particular policy Parliament wished the courts to adopt when referring to ‘the principles of the Treaty of Waitangi’. He made three suggestions which would help the Select Committee clarify thinking on the matter.

The intent might state in the interests (implicit in the preamble of the Treaty) of all New Zealanders, that the Act is to be interpreted in a manner that is consistent with the principles implicit in the Treaty of Waitangi. Namely that in New Zealand the cultural and spiritual values of all New Zealanders must be respected and protected. Institutions and practices must be so shaped and conducted, that no New Zealander is excluded from their benefits, or feels so excluded (PB/150w The Law Commission, 2000).

Or the intent might state, particular to the interests of Maori that this Act is to be interpreted in a manner that is consistent with the following principles implicit in the Treaty of Waitangi. These are that there be special recognition of the values and culture of Maori (for example the promotion of rongoa, Maori methods of healing) and the use of Maori institutions to assist the better delivery of health services to Maori. This could be achieved by a combination of the above or omitting the Clause all together and relying on the explanatory note already in the Bill.

Dugdale further advised that if none of these options expressed what the government had in mind, and unless there was some clearly identifiable reason for accepting the disadvantage of ambiguous general language which almost guaranteed confusion “there should be substituted a provision setting out just what in the view of the Government are the principles consistent with, which it wishes Parliament to command that the interpretation of the proposed statute be governed” (PB/150w The Law Commission, 2000).

The Health Select Committee recommended to parliament the following changes to the Bill in relation to the Treaty of Waitangi: it was recommended that Clause 4 be amended to limit the potential legal risks which may arise by including the Treaty of Waitangi in the legislation. This would be given effect by the Crown granting Maori participation in decision making about health policy, governance and the delivery of services. There was a need to clarify the meaning of the term ‘recognition and respect for the principles of the Treaty of Waitangi’. The principles are partnership, participation and protection as defined by the 1986 Royal Commission on Social Policy. These would be detailed in a Maori Health Strategy prepared by the government.

The Ministry of Health commented in their departmental report that PHARMAC was covered by the requirements of Clause 4 of the Bill concerning the Treaty of Waitangi (PB/MOH 8 Ministry of Health, 2000). However, in relation to the clauses in the Bill establishing PHARMAC³⁹, no inclusion of a reference to the Treaty of Waitangi or the principles of the Treaty of Waitangi was made.

Submission of the Rationing of Medicines

Jocelyn Brooks presented a submission to the Select Committee outlining what she saw as an important weakness in the Bill. She felt that there was an expectation that when a subsidy was applied, in the case of prescription medicines, this caused fewer prescriptions to be issued by GPs. She quoted a paper written by the Coalition for Public Health in 1986⁴⁰ relating to a salaried health service pilot in Northland. She claimed the paper outlined how patients in Northland on public subsidies were not receiving adequate levels of

³⁹Part 4 Sections 46-53

⁴⁰AUT Library Databases Searches on CINAHL, EBSCO Health, MEDLINE (via OVID & EBSCO), Web of Knowledge, Web of Science, SCOPIS and Internet searching Google could not find a reference to the paper or the paper itself.

medications from the service due to cost saving (PB/142w Jocelyn Brooks, 2000).

In a similar vein, Coralee Leyland submitted that when health care is rationed (as in the case of PHARMAC rationing the supply of pharmaceuticals), a person's ability to pay becomes an important factor in their access to care. Leyland believed the NZPHD Bill would accentuate the gap between those who could pay for health care and those who could not (PB/144w Coralee Leyland, 2000).

Another submitter, L.A.Smalley an insulin-dependent diabetic, stated that there were considerable pharmacy costs which diabetics have to bear to stay alive. Smalley complained that under the current regime she was 'means tested'⁴¹ to determine if she was eligible for a state subsidy to cover her extra pharmaceutical costs. In her own words:

To be diagnosed with diabetes a patient is not means tested, yet to receive any form of treatment a diabetic is subject to a means test. Diabetes affects not only the rich who can afford the treatment, but also the poor who cannot afford all the 'necessities' to ensure a normal life.

(PB/3w Linda Smalley, 2000)

Request by The Ministry of Health

Brooks, Leyland and Smalley were effective in their submissions. The Ministry of Health made a submission which dealt with their concerns by recommending that a provision be added to the Bill which allowed PHARMAC to set criteria under which people may be prescribed certain pharmaceuticals (e.g., Ritalin⁴²). This provision would be subject to any directions approved by the PHARMAC Board and inserted into PHARMAC's annual plan (PB/MOH 8 Ministry of Health, 2000).

Submission on the PHARMAC's Decision Making

The New Zealand AIDS Foundation (NZAF) raised objections to the way PHARMAC had unfairly functioned in the past in relation to its decision making processes. They submitted that the processes used were too slow and

⁴¹To apply a means test in New Zealand is to require an examination of a person's financial circumstances, usually by a government official, to establish whether that the person is able or unable to pay for an essential service or be eligible for a government subsidy or government funded programme.

⁴²Ritalin is the trade name for Methylphenidate (MPH) is a prescription stimulant commonly used to treat Attention-Deficit Hyperactivity Disorder (ADHD) in children and adults.

cumbersome and recommended that PHARMAC speed up its decision making processes. The NZAF was also concerned that with the establishment of 21 DHBs (replacing one Health Funding Authority), they would have to deal with many more public agencies to negotiate services and contracts. This would present the NZAF with high and prohibitive transaction costs (PB/ 91 NZ AIDS Foundation, 2000).

They also complained that the cost-utility analysis which has been applied to HIV/AIDS treatment drugs, only takes into account the cost and availability of alternative treatments. This economic analysis system used by PHARMAC did not take into account the capacity of the person or the wider costs and benefits to society of having AIDS patients treated with drugs which were effective and available in other countries. The NZAF submitted that PHARMAC had been unwilling to listen to expert advice on the effectiveness of AIDS medication. They stated that PHARMAC considered it a virtue that decisions were made by generalists, despite the abundance of specialist advice being available to it, and PHARMAC seemed almost completely unwilling to seek such advice or accept external expert advice if offered (PB/ 91 NZ AIDS Foundation, 2000).

NZAF made three substantive suggestions to change the Bill. Firstly, they suggested that PHARMAC should give new consideration to decision making in respect of HIV antiretroviral treatments. Secondly, PHARMAC should incorporate substantially more expert opinion in decision making on HIV antiretroviral treatments. Finally, they suggested that PHARMAC should ensure all costs and benefits to society and to the individual are taken into account when a cost-utility analysis is carried out to decide on applications to the pharmaceutical schedule (PB/ 91 NZ AIDS Foundation, 2000).

Submission on Complementary Medicines

The New Zealand Charter of Health Practitioners Inc. (NZCHP) gave a submission on behalf of its members who practiced complementary health care. They urged the government in their submission to introduce complementary health services into the public health service and fund complementary health products through PHARMAC. Specifically, the government should facilitate access to holistic complementary health care and wellness services. They urged the government to provide payments for complementary disability support

services to members of the public provided by their members (PB/109w NZ Charter of Health Practitioners Inc., 2000).

The Ministry of Health advised that no change to the Bill was necessary because the Minister had set up a Ministerial Advisory Committee on Complementary and Alternative Healthcare. The work of the committee combined with the functions of the National Health Committee will provide information on the benefits of alternative therapies. It would also be expected that the knowledge and experience of PHARMAC in completing cost-benefit analyses of complementary medicines will be utilised in this process (PB/MOH 8 Ministry of Health, 2000).

The Select Committee Report-Back on the Submissions

The submissions which the Health Select Committee received on the Bill relating to PHARMAC (not all other parts of the Bill) have been outlined and discussed. In relation to PHARMAC, the Select Committee recommended several matters which were of a technical nature but did not alter PHARMAC's exemption from Clause II of the Commerce Act. The Committee did not recommend any detraction from the original purpose of the Bill, as far as the establishment of PHARMAC or any of its functions were concerned. The Committee did recommend major changes to the Bill in relation to references to the Treaty of Waitangi, the structure and functions of DHBs, the matters relating to transferring the ownership of PHARMAC from the DHBs to the Crown.

These changes were reported back in early December 2000 and Parliament passed the NZPHDA 2000, which came into law by Royal Assent⁴³ on the 14th of December 2000.

Section 2: Walsh v. PHARMAC

The following section is written from Justice Gendall's decision in the Court of Appeal of New Zealand in the case Walsh v. PHARMAC (BC200860616). Much of this text is taken in paraphrase or quotation from Justice Gendall's written judgment. Where sections of the judgment have been quoted in the

⁴³A constitutional tradition requires the New Zealand Governor General to provide Royal Assent to legislation passed by Parliament.

following text, I have individually referenced these sections by quoting the paragraph number of the judgment.

Description of the Case

Herceptin has been available and registered by Medsafe for use in New Zealand since 2001, when PHARMAC placed this drug on the Pharmaceutical Schedule. The subsidy for Herceptin had been subject to the requirement for Special Authority from PHARMAC. The Special Authority applied for the initial application of the medicine and could only be made by a relevant medical specialist. Approval was valid for nine weeks where the patient had metastatic cancer expressing HER 2 & 3⁴⁴ (or +ve FSH)⁴⁵ characteristics. Renewals could only be approved by a relevant specialist and were valid for twelve months where the cancer had not progressed.

This meant that the subsidy could only be applied for in the early stages of breast cancer treatment for a patient in adjuvant⁴⁶ therapy. Outside this Special Authority, Herceptin could not be prescribed with a government subsidy. This drug could be prescribed without a subsidy but the patient had to meet the full cost of the drug. A twelve month course of Herceptin treatment depending on the dose cost the patient between NZ\$70,000 and \$76,500 in 2011.

In 2007, a case was brought against PHARMAC by Dr. Chris Walsh, who was at the time a senior nursing lecturer at Victoria University, and seven other women who were suffering from breast cancer. Council for the plaintiff was Helen Cull QC who appealed to the Court about PHARMAC's decisions which related to the subsidising of the treatment for only nine weeks in approved cases.

The Case for the Plaintiffs

The plaintiffs made three claims against PHARMAC. The first claim was that PHARMAC's decision not to fund Herceptin for a twelve month period for the treatment of early breast cancer was unlawful and should be set aside. The second claim to the court was that the advice PHARMAC received from PTAC was unlawful and as such the decision not to fund Herceptin for twelve months

⁴⁴HER 2 and 3 are the most aggressive forms of breast cancer, and occur in 15-20% of all diagnosed breast cancer.

⁴⁵FSH refers to 'Fluorescence in Situ Hybridization'. It is a diagnostic technique for viewing DNA genetic changes within a cell. A +ve FSH test means that HER2 genes are over-producing the HER2 protein, and these cells are growing rapidly and creating the breast cancer.

⁴⁶Adjuvant therapy is pharmaceutical treatment following surgery for breast cancer

should be set aside. The third ground for claim was that PHARMAC declined to treat the plaintiffs fairly in denying them an Exceptional Circumstances subsidy for Herceptin. In so doing, PHARMAC denied them entitlement to receive twelve months treatment of Herceptin. This was 'unfair' and 'unjust' and offended the complainants' right to natural justice as contained in the New Zealand Bill of Rights Act 1990.

The lawfulness of the first two claims was challenged for multiple reasons. The plaintiffs argued that PHARMAC had failed to perform its statutory duty. The claim accused PHARMAC of acting ultra vires⁴⁷ of its statutory powers in creating operating policies and procedures. They claimed that in turn, PTAC acted ultra vires in giving the advice it did. Helen Cull advised the Court that PHARMAC required PTAC to act "under its direction" so that PTAC's advice was unlawful and that PHARMAC itself acted under a direction or a dictation. DHBs were also cited because PHARMAC had sought their agreement to the recommendation not to fund treatment of Herceptin for a twelve month course.

The plaintiffs also claimed that PHARMAC had failed to take into account relevant considerations and took into account irrelevant considerations. They claimed that PHARMAC pursued a rigid pre-determined policy or plan, so as to fetter its statutory discretion and function and in so doing, it acted in breach of the plaintiffs' legitimate expectation.

The claim further cited grounds for the decision to fund Herceptin for nine weeks and not twelve months, that PHARMAC acted unfairly and denied "natural justice" to the plaintiffs. This was because they expected to be consulted through groups to which they were aligned, before the decisions were made. They claimed that PHARMAC acted with procedural and substantive unfairness, made decisions that were unreasonable and/or irrational. Another claim was that PHARMAC had breached the plaintiffs' rights to natural justice as contained in s27(1) of the New Zealand Bill of Rights Act 1990

The plaintiffs' third claim related to PHARMAC declining to treat them under the Exceptional Circumstances policy. This would have entitled the plaintiffs to avail themselves of the individual subsidy (funding) for twelve months for

⁴⁷Ultra vires means "without powers". A narrow interpretation of ultra vires means an administrator or entity acted without the statutory authority to do so. A broader interpretation refers to a general abuse of power by a government agency.

Herceptin. The plaintiffs forwarded multiple claims that PHARMAC failed to recommend, or approve the applications for Exceptional Circumstances, was unlawful and reviewable, and this was the subject of this procedural review.

They contended that PHARMAC failed to exercise its statutory function, through acting under the dictation of DHBs, acted ultra vires its powers and did fail to manage the Exceptional Circumstances policy for funding Herceptin. Finally, Helen Cull QC claimed that PHARMAC imposed criteria it was not entitled to fix, which required DHBs to act outside their permitted functions.

In this category of claim, Helen Cull QC submitted that PHARMAC fettered its statutory discretion or function in formulating the Exceptional Circumstances policy. The claim included the allegation that PHARMAC had breached the legitimate expectation of the plaintiffs in that their individual circumstances would be considered and acted unfairly in not considering individual circumstances. Cull claimed that PHARMAC adopted a closed mind by applying rigid criteria and thus adopted a process tainted by breaches of natural justice. The claim included the charge that there had been errors of law, procedural and substantive unfairness when PHARMAC reached a final decision on Herceptin. She submitted that this demonstrated tainted bias because the Review Panel and Medical Director were not, and could not be seen to be, independent of PHARMAC.

Finally, the plaintiffs made a claim that PHARMAC reached an unreasonable and irrational decision and made a decision in breach of the plaintiffs' rights under the New Zealand Bill of Rights Act 1990

In summary the plaintiffs alleged a total of 28 grounds of review, namely 10 in respect of each of the first and second decisions, and eight in respect of the Cancer Exceptional Circumstances (CaEC) applications. The judge noted that almost every course of action or ground for review known under administrative principles had been 'thrown in the ring' by the plaintiffs' counsel.

The Nature of Judicial Review in New Zealand

The judge reminded the participants in the trial that judicial review proceedings are process oriented. They are not concerned with substantive merits of PHARMAC's decisions except on questions of irrationality. The court must be

concerned and restricted to determining whether the public body, namely PHARMAC, acted lawfully.

To illustrate this point, Justice Gendall drew from two cases⁴⁸ of judicial review proceedings. He reminded participants that the Court cannot substitute its own factual conclusions for that of the consent authority in this case, PHARMAC. It merely determines, as a matter of will, whether the proper procedures were followed by PHARMAC, with all relevant and no irrelevant considerations taken into account. The court must determine that the decision was one which, upon the basis of the material available to it, a reasonable decision maker could have made. The weight to be given to particular relevant matters is one for the decision-maker, not the court to determine, but there must be some material capable of supporting the decision (Paragraph 27 Walsh v. PHARMAC BC200860616).

The Relevant Functions of PHARMAC

The judge described the functions of PHARMAC as managing the Pharmaceutical Schedules which contain the list of all pharmaceuticals subsidised by the DHBs. PHARMAC also made decisions about which pharmaceuticals should be listed, the subsidies that should be paid for them and the eligibility criteria for the provision of subsidies. In order to maintain and manage the schedules, PHARMAC managed a notional budget which is set by the Minister of Health (e.g., following consultation between PHARMAC and the DHBs). This budget is notional because, apart from \$3 million, it was not in fact PHARMAC who paid the subsidies, it was the DHBs.

PHARMAC and the DHBs' had come to an arrangement whereby the funding of cancer treatments was decided by PHARMAC on behalf of the DHBs. The judge reported that from the 1st July 2007, PHARMAC established a notional budget for pharmaceutical cancer treatments of \$48-\$53 million. This budget level was accepted by the DHBs.

Therefore, the rules regarding DHBs obligations in relation to pharmaceutical cancer treatments were contained in the PHARMAC Schedule. These rules state that DHBs provided access to pharmaceutical cancer treatments for use in

⁴⁸Progressive Enterprises Ltd v North Shore City Council [2006] NZRMA 72 and Pring v Wanganui District Council [1999] NZRMA 519 (CA)

the treatment of cancer in the DHB hospitals and/or in association with outpatient services provided in the DHB hospitals. The DHBs could not fund pharmaceuticals for the treatment of cancer if the treatments were not listed in the Schedule, unless the unlisted pharmaceuticals met certain criteria. However, the DHBs did provide access to unlisted pharmaceuticals for the treatment of cancer where the unlisted pharmaceutical has Cancer Exceptional Circumstances (CaEC) approval, Community Exceptional Circumstances (CEC) approval or Hospital Exceptional Circumstances (HEC) approval. The DHBs also funded the treatment under Exceptional Circumstances policies if the treatment was being used as part of a bona fide clinical trial which had Ethics Committee approval. The other criteria were that the drug could be provided by the DHB if it was being used as part of the paediatric oncology service and was prescribed to treat a child before or on 21st July 2005.

The most important factor was that if PHARMAC listed a cancer treatment on the Schedule, DHBs had no option but to fund it. Conversely, if the treatment was not on the Schedule but the drug has CaEC (or other CEC or HEC) approval from PHARMAC, the DHBs had the option to fund, or not to fund, depending on their own allocative priorities.

PHARMAC's Herceptin Decision Making

The decision to fund Herceptin was referred by the PHARMAC Board to the PHARMAC Community Advisory Committee (CAC). It was also sent for examination to the Cancer Treatment Subcommittee of PHARMAC (CaTSoP). This was a panel of experts made up of cancer specialists and including other senior physicians from the New Zealand public health service. This committee was a subcommittee of PTAC.

The material before the CAC included information on clinical trials, the likely cost of Herceptin and PHARMAC decision making criteria in its 'Operating Policies and Procedures' manual. The CAC was chaired by a community health advocate, Ms. Sandra Coney.

The following is a quote from the minutes of the CAC committee meeting:

The committee noted the benefits of Herceptin may not be as great as stated by the patient community groups lobbying for funded access. The

committee also noted that a total cost of about \$50 million per annum, Herceptin had the potential to almost double the spending on hospital oncology drugs.

(Paragraph 53 Walsh v. PHARMAC BC200860616)

At this point CaTSoP was considering whether to recommend adding Herceptin to the PHARMAC Schedules. Part of the consideration was the effectiveness of Herceptin, but clearly part of the consideration was also the potential effect on the total cancer drug budget of funding this drug.

The Clinical Evidence Supporting Herceptin

When CaTSoP considered the matter, they took into consideration a USA drug trial and a Finnish drug trial. The USA trial was a very large trial in which patients were given Herceptin for a twelve month period. The Finnish trial involved a smaller number of patients who were given Herceptin, in conjunction with other chemotherapy, for a nine week period. Both clinical trials indicated that there may be a cardiovascular risk with the prescribing of Herceptin.

The minutes of the CaTSoP meeting recorded their concerns that patients who were prescribed Herceptin would place an additional resource burden on the cardiovascular services because the monitoring requirements were significant. Patients would be required to undergo 3-4 additional echocardiograms per year and if any symptoms were detected yet more examinations would be required. The subcommittee noted that this would have the effect of adding additional cost to cardiac departments (Paragraph 56 Walsh v. PHARMAC BC200860616).

These doctors noted that this might mean an increased waiting time for existing cancer treatments and may also adversely impact on non-cancer cardiac services. In taking these matters into account, the committee members were considering not only the needs of breast cancer patients but also the availability of resources for cardiac and other patients in the health system.

Finally, the subcommittee considered that Herceptin could be made available for the treatment of early breast cancer. However, it gave this category of patients a very low or medium priority. When CaTSoP made this decision, the committee felt that there were several matters which were relevant to the criteria to fund this medication. These criteria were the health needs of all

eligible people in New Zealand and the availability and suitability of existing medicines, therapeutic medical devices and related products.

The subcommittee considered that the government's priorities for health funding were either neutral or against a positive recommendation. Members also noted that \$30 million per year could be better spent on other areas of cancer control if such funding were available. One member noted that given the extent of the funding required, consideration may need to be given as to whether the funding would be better directed towards other non-cancer health services (Paragraph 56 Walsh v. PHARMAC BC200860616).

The Use of Cost-utility Analysis

The decision as to whether to fund Herceptin was also referred by the PHARMAC Board to the PTAC committee. This committee was asked for its advice as to the reasonableness of the cost-utility analysis (CUA) provided by PHARMAC staff. A CUA provided in the manufacturer's application (Roche Corporation USA) was also considered by PTAC. The committee advised the PHARMAC Board that there was doubt about the optimal duration and timing of Herceptin treatment. They also stated that there was a high budgetary impact which would have significant consequences for future funding of other pharmaceuticals and could also negatively impact on the availability of cardiology services for non-breast cancer patients.

The committee's recommendation to the Board, based on the interim trials published to date, was that Herceptin may have a role to play in the treatment of primary breast cancer. However, PTAC considered that with the data provided, they were unable to determine the optimum schedule and duration of treatment, the magnitude of treatment or the benefit on the overall survival. Therefore, PTAC could not calculate the cost-effectiveness of Herceptin.

The committee considered that given the high cost of Herceptin, the early nature of the clinical trial data, and a significant impact on other services and investments in health care, which may offer better health outcomes for the money invested, they did not consider it appropriate to make a recommendation for funding this product at this time. It noted that although there was insufficient evidence to make a positive recommendation for funding the product "at this

time”; it was likely that further data would enable the committee to address this question regarding the long-term health benefits, optimal scheduling and cost-effectiveness (of Herceptin). The committee noted that it would welcome any substantial body of evidence from the manufacturer and supplier for consideration at subsequent meetings (Paragraph 61 Walsh v. PHARMAC BC200860616).

The Board accepted this recommendation and instructed PHARMAC staff to progress a proposal to fund Herceptin for nine week courses of treatment. The Board also asked the staff to fund a comparative study of Herceptin with nine weeks versus twelve months treatment regime.

The ‘nine week’ or ‘twelve months’ Debate

The PHARMAC Board recommended to DHB Chief Executives that the DHBs fund Herceptin for a nine week treatment regimen. They also agreed to fund PHARMAC’s associated participation in an international trial. The PHARMAC Board finally commissioned the CaTSoP committee to undertake consultation with oncologists throughout New Zealand to discuss the treatment protocols for a nine week proposal. Following this consultation, the Board resolved to amend the Special Authority restriction in respect of Herceptin to enable a funding subsidy for nine weeks of HER 2 positive early breast cancer patients.

The Court was given evidence that the normal PHARMAC decision making criteria were used to make this decision. These criteria addressed the scientific evidence available to the Board, the advice provided by PTAC and CaTSoP, and recommendations from PTAC to the Board. The committee also evaluated the advice which it received from the PHARMAC staff, the results from community consultation and the available funding from DHBs.

To progress this decision PHARMAC staff and the Board approved criteria which had to be met before a patient could be granted a subsidy.

These criteria were:

- confirmation that the proposed use was evaluated and approved using established DHB review mechanisms involving experienced clinicians;

- confirmation that the DHB hospital providing treatment has agreed to fund the treatment;
- confirmation that the condition is considered unusual (and therefore a decision to treat is unlikely to result in access and inequities across DHBs);
- the proposed use has not been considered or is not currently under consideration by PHARMAC for funding; and
- specification on the
 - product to be used;
 - dose and treatment schedule;
 - duration of treatment;
 - indication; and
 - total cost.

The total cost was to be less than \$30,000 over a 5-year period. If the application is for treatment of \$30,000 or over it will be referred for a cost-utility analysis, followed by a decision from PHARMAC.

This set of criteria was based on peer review within the DHB hospitals to assure equity of access to pharmaceutical cancer treatments across all the 21 DHBs. The scheme was intended largely to be self-assessed by the hospital physicians and relevant DHB officials, provided that the patients met the criteria. Following this process a PHARMAC staff member considered the application and the report of the clinicians and advised if the criteria had been met. If the staff member was unsure, the application was referred to a panel of clinicians. If that panel decision was unfavourable, the applicant may appeal to the panel for its reconsideration of the application. If the application is still declined, or not approved, a request could be made to the Medical Director of PHARMAC for a further review.

Walsh's Evidence

The plaintiff, Chris Walsh, submitted to the Court that she contested the policies and processes of the panel considering her application. Walsh presented evidence that her application under the Exceptional Circumstances policy was made by her solicitor not by her treating physician. This was because her oncologist, Dr. Isaacs, who was also the treating physician of the eight plaintiffs, felt that he was unable to complete their applications for the obvious reason that it did not appear to him that the applicants were eligible under the criteria. He felt that a twelve month therapy was the optimal therapy for them. This he regarded as consistent with the current international standards of care. In his view, the plaintiffs had no access to the course of treatment because they fell outside the proposed nine week Herceptin treatment option. More importantly he agreed that the women were not at the end stage of cancer treatment. These were the reasons he believed he could not support the plaintiffs application.

This placed Dr. Isaacs in the invidious position of not being able to support the application for the treatment that he believed his patients needed. Whilst the nine week and twelve month argument was also part of Walsh's application to the court, this argument did not make part of her Exceptional Circumstances claim. A further difficulty for Walsh arose when a specialist oncologist practicing in Auckland, provided expert opinion that when funding access for an effective treatment is denied, this naturally causes him distress. However, there is no evidence demonstrating that any one treatment duration of Herceptin is better than another. He stated that in his opinion PHARMAC's decision was a direct result of its need to consider the cost of funding and the potential impact funding twelve months Herceptin. This would also have created a negative impact on the ability of the health care system to fund other health service treatments. The constraint on the spending in health care, including pharmaceuticals, was politically determined through the size of the New Zealand health budget. He contended that this is not a matter for PHARMAC to determine but one for the government to determine (Paragraph 152 Walsh v. PHARMAC BC 200860616).

The court received evidence that the Exceptional Circumstances claim on behalf of the claimants was not simply about the exceptional circumstance of

the eight women involved in this case. The Exceptional Circumstances claim was also based on the contention that PHARMAC operated ultra vires in that it acted outside the empowering legislation in making the decision to refuse the appellants' applications.

The Decision – PHARMAC Acted Lawfully

Justice Gendall ruled that PHARMAC and its committees did not act outside its governing legislation in that it took into account the benefits of the drug, the relevant and available evidence relating to treatment duration, and the costs of the treatment. He found that PHARMAC was entitled to seek advice from PTAC, and PTAC was perfectly entitled to give its view. He rejected the argument that PHARMAC and PTAC acted ultra vires the empowering legislation. The judge declared that the Board did what it was lawfully authorised and required to do (Paragraph 162 Walsh v. PHARMAC BC 200860616).

Justice Gendall ruled that the criteria which PHARMAC had established to make decisions on applications under the Exceptional Circumstances policy were lawful. He stated that the criteria were based on peer review within the DHB hospital system and were aimed at ensuring equity of access to pharmaceutical cancer treatments across the country. The judge described PHARMAC's task was to "manage" this process.

PHARMAC was entitled to set up a review or appeal mechanism in the way that it did. He noted that PHARMAC did this even though it was not required to do so. The process was not judicial, or even quasi-judicial, therefore it did not require a formal independent tribunal appeals structure. Justice Gendall ruled that the review appeal mechanisms which were carried out by PHARMAC were fair and were carried out consistently (Paragraph 228 Walsh v. PHARMAC BC 200860616).

Gendall pointed out that the patients did not meet the application criteria for funding quite irrespective of any decision of the DHBs to fund or not to fund. He decided that in the end, PHARMAC, and its review panel of clinicians as well as its Medical Director, had the experience and expertise to be able to assess

where an individual applicant properly came within the established criteria (Paragraph 247 Walsh v. PHARMAC BC 200860616).

Therefore, in the opinion of Justice Gendall, the applicant was entitled to expect to have applications considered fairly and he was satisfied that this had indeed occurred (Paragraph 252 Walsh v. PHARMAC BC 200860616).

The Decision – All Grounds for Appeal Fail

The judgment recorded that the general allegation of a breach of natural justice under the New Zealand Bill of Rights Act fails. He also ruled that the procedure by which the plaintiffs' application was determined was not unfair or procedurally improper or tainted by legal bias (Paragraph 252 Walsh v. PHARMAC BC 200860616).

The judge concluded by saying the generalised pleading, that the decisions were unreasonable and irrational, likewise fails. His comments were:

It goes to the merits of the recommendation to decline the applications, and the court will not enter into such an inquiry, the criteria were clearly not made and, apart from the issue of DHBs' agreement to fund, other essential requirements did not exist. Based on the criteria, the applicants could not have succeeded and I do not accept that the criteria themselves were legally flawed. It may be that some persons will disagree with them, and naturally the plaintiffs will fall into that category.

(Paragraph 243 Walsh v. PHARMAC BC 200860616)

He stated that the criteria should have been promulgated or some deleted, but the legal responsibility of PHARMAC, the subject of this challenge, was to manage the Schedule which defines Exceptional Circumstances. Justice Gendall finally concluded this section of the judgment that the plaintiffs have failed to establish that they are entitled to judicial review and "*therefore all grounds for review fail*" (Paragraph 256 Walsh v. PHARMAC BC 200860616).

Decision – PHARMAC Did Not Consult Adequately

This did not end the matter. Justice Gendall held that the original decision of PHARMAC to fund the nine week course of Herceptin was not considered fairly by the Consumers Advisory Committee. He reviewed the committee's evidence and decided that the committee did not consult widely enough and did not give

the plaintiffs adequate opportunity to have input into the first PHARMAC decision.

He ruled that “a reviewable error arose” (Paragraph 246 Walsh v. PHARMAC BC 200860616). Consequently, he ruled that the decision to fund Herceptin for nine weeks be temporarily put aside. He made an order that the PHARMAC Consumers Advisory Committee must give individuals and groups in the community another chance to present their views and the opportunity to put information before the committee. The committee would then be in a position to examine the material received from the consultation process and advise the PHARMAC Board of its view.

Clarification of Rogers v. Swindon NHS Primary Care Trust

Justice Gendall clarified his position regarding the plaintiff’s reliance on the case of *Rogers v. Swindon NHS Primary Care Trust* in the Court of Appeal in England where the decision not to fund a patient seeking Herceptin was overturned. Justice Gendall pointed out that this did not help the plaintiffs’ case. The Swindon NHS Primary Care Trust had a policy to fund Herceptin, notwithstanding the consultation it had undertaken with NICE which advised the Trust, it was not licensed or approved by NICE to supply Herceptin.

He said that the judge in the *Rogers v. Swindon NHS Primary Care Trust* case found that irrespective of the consultation process, the policy was not capable of being rationally explained and therefore was unlawful. However, in the New Zealand case, Justice Gendall believed that PHARMAC’s policy was capable of rational explanation and therefore was lawful.

Decision on Medsafe’s Non-Approval of Herceptin for a nine week Regime

Justice Gendall’s judgment also dealt with the plaintiff’s claim that Medsafe had not approved the use of Herceptin for a 9week period and this affected the validity of the PHARMAC decision. However, he considered that PHARMAC obtained information through the consultation process with physicians, and based on their clinical judgment, which determined the appropriateness of the decision to prescribe Herceptin. Gendall said that it was the clinicians’ decision to decide on the appropriateness of a prescription of Herceptin for a patient, not Medsafe’s approval or disapproval. This second level of decision making at

physician level must be considered after Medsafe had declared the drug safe to use. He believed that the Medsafe issue did not alter the lawfulness or legal rationality of the doctors' decisions to prescribe.

Judge Comments on PHARMAC's Consultation Processes

Justice Gendall also had concluding remarks to make about the appropriateness of the consultation processes used by PHARMAC. His remarks are divided into two sections; consultation with DHBs and consultation with the public.

Justice Gendall did not accept Helen Cull's view that PHARMAC allowed the DHBs to dictate its decision. He did however feel that PHARMAC should not have asked the DHBs to support its decision. He believed the DHBs should have been asked a more open question about affordability.

The Judge did suggest that PHARMAC desist from its policy of seeking the support of DHBs before deciding to list or not to list a drug for funding. Primarily, this was because the DHBs ultimately fund any listed drug, not PHARMAC. Consequently, the DHBs may be seen to have a vested interest in agreeing with the preliminary decision not to fund. He also felt that PHARMAC was unwise to ask for support for their proposal because in doing so they gave the impression that the PHARMAC Board was not able to act independently.

Justice Gendall said that he found PHARMAC's community consultation processes wanting and this caused the reviewable error and the setting aside of the decision of the PHARMAC Board not to fund Herceptin for twelve months. In directing PHARMAC to reconsider the above decision, he directed that PHARMAC must consult widely with the public, clinicians, and others who had a legitimate interest and/or were likely to be affected by the Roche Company's application for funding for Herceptin for twelve month treatment regimes.

He was clear not to deliver his view on whether or not Herceptin should or should not be funded for twelve months (or indeed any other period) because such a direction would be outside the scope of a judicial review. Conversely, his direction as to the consultation process was made clear to PHARMAC in the judgment.

Judge's Concluding Remarks

The final words of the description of this case are given to Justice Gendall;

I add that the outcome [of the reconsideration of Roche's application to fund Herceptin] may, or may not, be precisely the same, but true consultation is required. The fact that there is in place a decision for nine weeks funding cannot pre-determine any outcome, but is not required to be ignored as irrelevant given that if the final decision as to decline twelve months' funding, the present funding regime continues in place.

(Paragraph 274 Walsh v. PHARMAC BC200860616)

Political Decision re Herceptin

PHARMAC complied with the Court's direction to reconvene a public consultation process relating to the decision to fund Herceptin for nine weeks or twelve month treatment regimes. On the 6th August 2008, PHARMAC announced that it had conducted a wide public consultation as directed by the Court of Appeal. As a result, of the consultation PHARMAC had concluded that there was no strong evidence to support the twelve months subsidy.

PHARMAC claimed that this decision was not taken on the basis of the costs of the twelve months of treatment for women with the aggressive form of breast cancer, but on the international clinical evidence of the effectiveness of the drug.

During the general election campaign in New Zealand in November 2008, the National Party opposition health spokesperson Tony Ryall promised that, should National Party win the election, the new government would fund the subsidy for the drug Herceptin for twelve months continuous treatment.

The National Party did win the election and formed a coalition government with coalition partners the Act Party, the United Future New Zealand Party and the Maori Party. Tony Ryall became the new Health Minister and announced on the 10th December 2008 that a full twelve months course of the breast cancer drug Herceptin will be available.

Ryall stated in a press release that:

We expect that over time up to 300 women a year will benefit from the year-long course of Herceptin treatment. This is being funded from the

extra \$180 million this government plans to spend on pharmaceuticals over the next three years.

(Scoop, 2008)

The decision also applied to patients currently receiving a privately funded course of twelve months Herceptin who had the option of completing the remainder of their treatment funded by a public provider. Patients who had recently completed a publicly funded nine week treatment or recently discontinued a private twelve months course of Herceptin, were able to receive the balance of a twelve month course of treatment publicly funded. However, Ryall made this subsidy subject to the patient's specialist's clinical judgment (Scoop, 2008).

Section 3: Media Reports

This section of data explores the way in which PHARMAC's Community Exceptional Circumstances policy has been portrayed in the media. Such stories have been presented in the interests of patients, the interests of PHARMAC, the interests of other groups and individuals and also the interests of the media themselves. This study demonstrates the way the public has been exposed to the Community Exceptional Circumstances debated through these media presentations.

A library search produced 23 articles from the New Zealand media where the central issue of the article was something to do with PHARMAC's Community Exceptional Circumstances policy. As described in Chapter 4 (Methods), all the media stories were entered into NVivo 8 as sources. They were then analysed using the Braun and Clark (2006) six step method.

I present here only nine of the 23 stories as examples to show the origins and content and voices heard in the stories. I chose these nine stories because each one highlights the range of problems presented about Community Exceptional Circumstances and highlights typical responses from PHARMAC. These examples also demonstrate the range, relevance and impact of the stories.

A Selection of the Media Stories

Case 1: "Patient's problem worse on new pills" (New Plymouth Daily News 20/11/98)

Brian Coombe and Hawera Rae Mathews (patients) complained that Rae's symptoms related to her being switched from an unfunded antihypertensive medication to a funded antihypertensive medication. PHARMAC had transferred the subsidy from one drug to another and consequently Rae's doctor put her on the newly funded medication. She said that the current symptoms she was suffering related to the change in medication.

The General Manager of PHARMAC, Wayne McNee had received advice that Rae's symptoms were not related to the change in medications and said that she could apply for Community Exceptional Circumstances subsidy if she could not tolerate the newly funded drug.

The report concentrated on the concern that the preferences of the patient were not considered a factor in the subsidising decisions. McNee reported that many other people in New Zealand were taking the subsidised drug without complaint. Rae was able to draw a response from PHARMAC but she was unable to effect the changes in policy and have PHARMAC's decision overturned in her case.

Case 2: "Persistent seizures curtail life" (Waikato Times 18/10/04)

Patient Mike Jurisich requested that PHARMAC pay for an expensive epilepsy drug which was not on the subsidised Community Pharmaceutical Schedule. Verity Colgrave, a case worker from Epilepsy New Zealand, stated in the newspaper report that without the medication Mike would have to cease work and go onto a welfare benefit. She stated that the costs of the patient on a sickness benefit should be considered in PHARMAC's cost-utility analysis. Mike's neurologist, Dr. Paul Timmings expressed his frustration at PHARMAC's Community Exceptional Circumstances decision making, saying that in his experience it was exceptionally difficult to get a Community Exceptional Circumstances claim approved by PHARMAC.

There was no evidence produced in the story that the drug recommended by the doctor was any better than the subsidised drug. The media report referred

to considerable suffering which Mike had endured during his life. However, much of this suffering was as a result of the epilepsy and not for the lack of the drug he was applying to PHARMAC for a subsidy.

Dr. Peter Moodie, the Medical Director of PHARMAC said that the Community Exceptional Circumstances policy was there for extremely rare conditions. He said that a panel of New Zealand medical experts examined each claim and made their decision on a case by case basis. Moodie stated that epilepsy is not rare (i.e., 10 cases or less in New Zealand at any one time) and this is why Mike was turned down for the Community Exceptional Circumstances claim.

Case 3: "King refuses to step in for drug" (Christchurch Press 05/05/04)

In this story, Shirley Reid was suffering from motor neurone disease. This is a progressive degenerative neurological disease which ends in a slow and debilitating premature death. Shirley and her husband petitioned the Hon. Annette King, who was the Minister of Health at the time, to pressure PHARMAC to fund a new drug which promised to extend her life. Shirley said that the drug should also be available for other motor neurone disease sufferers. Shirley had been turned down for a Community Exceptional Circumstances subsidy for the new drug. The panel of experts refused to recommend listing the new drug on the Community Pharmaceutical Schedule because in the committee's opinion the cost of the new drug was too high for the limited benefit it offered.

Health Minister Hon. Annette King said that she was sympathetic to Shirley's plight but would not intervene in PHARMAC's decision making. She asked the patient to apply under the PHARMAC rules for a Community Exceptional Circumstances subsidy. This was not good advice because she had already applied to PHARMAC for a Community Exceptional Circumstances and been turned down. The Minister was also wrong to suggest this course of action because motor neurone disease is not a rare condition, by PHARMAC's definition of rare and such a claim would fail. Shirley's husband expressed his outrage and frustration and powerlessness against PHARMAC. He described the PHARMAC Community Exceptional Circumstances system as 'uncivilised'.

Case 4: “Worn out by endless fight” (Dominion-Post 03/07/04)

Ross Hulbert suffered from Rheumatoid Arthritis and he and his wife Sharon wrote to both Health Minister Annette King and Member of Parliament Paul Swain asking for a Community Exceptional Circumstances subsidy. They requested funding for a new rheumatoid arthritis drug which was available overseas. Both politicians would not interfere in directing PHARMAC to subsidise the drug. Ross did not understand why he could not just have the drug and was very dissatisfied with the result of his petition and the way he felt he had been treated by PHARMAC.

His doctor Dr. Sue Rudge (Rheumatologist) acknowledged the usefulness of the new drug but said she could not recommend the drug for Ross because of the cost. She was concerned not only for Ross, but also for all her other rheumatoid arthritis patients. Dr. Rudge said that the system had to be fair to all patients not just the ones who were identified in the media. She was saying that the DHB had to look at the broad picture. Jill Lane (Medical Services Manager, Hutt Valley DHB) stated that PHARMAC could approve the new drug, only if it was ‘cost-effective’. Both the doctor and the manager were advocating for the wider needs of the DHB by maximising the use of the DHB budget. Jill Lane explained that the system is not always able to meet everyone’s demands because of the constraint on budgets. Ross’s Community Exceptional Circumstances claim was not supported by his doctor and therefore it had no chance of success.

Case 5: “A matter of life and death-and how to pay for it” (Dominion-Post 12/02/05)

Nicholas Micklejohn suffered from a terminal brain tumour. He was diagnosed at age 15, and at age 20, his health had begun to severely deteriorate. The brain tumour was inoperable and his doctor suggested a drug named Temodal at a cost of \$70,000 a year. Both Nicholas and his mother regretted the fact that they could not afford to pay for the drug. Nicholas’s mother had given up work to look after him and their financial position was not good, particularly as his condition worsened. They both were very sad that they were not able to afford the drug. Nicholas died at age 28.

Dr. Hamilton, Nicholas's oncologist, described how he agonised over the ethical decision of whether to tell the Mickeljohns about the new drug or not. It was not available on the pharmaceutical schedule because of the high cost and the minimal benefit in prolonging life for an uncertain period. He commented that the drug would not provide a cure for Nicholas but only an uncertain few "percentage gains". He said that New Zealand is reasonably well served by subsidised drugs, most are funded and it is very difficult to place a price on extending life.

Wayne McNee, PHARMAC's General Manager was sympathetic to Nicholas's plight but could not recommend the drug be provided under Community Exceptional Circumstances because his condition is not rare. McNee said that a formula exists to help decision making and these cases. The decisions were becoming increasingly more difficult because drugs were becoming more expensive. He commented that cancer drugs in 2003 cost New Zealand \$22 million and by 2006 the cost had risen to \$41 million. He also noted Temodal has been referred to the CaTSoP, a committee of PTAC, to decide if it would be funded. McNee also stated that "it is a sad fact you have a good chance of getting expensive, life-saving treatment if you're injured in a car crash, and not if you have a degenerative disease."

Wayne McNee was referring to the different funding mechanisms between treatment for accident victims by the Accident Compensation Corporation (ACC)⁴⁹ and non-accident victims being treated by DHBs.

McNee noted that there is a limitation on the availability of publicly funded treatment and as in cases where new and expensive experimental drugs in cancer treatment were prescribed before a subsidy was granted, the patient must fund their own treatment. He stated that, to those who cannot afford to self-fund experimental medications, this situation seems grossly unfair.

⁴⁹Accident Compensation Corporation is a New Zealand social health insurance which is funded by taxpayers and road users. It is a 'no fault' health insurance scheme where all claims which are proven to meet the definition of 'personal injury by accident' are accepted and almost all the medical, surgical and other costs of the injured person's rehabilitation are met by the Corporation. New Zealanders do not have the right to take litigation action against persons or institutions which they believe are responsible for their injury. The access to treatment under the ACC is considered quicker and more comprehensive than under the normal sickness treatment provided through the DHBs.

Case 6: "PHARMAC scolded for MS-drug policy" (The Dominion 3/9/99)

In this story, parliament's Health Select Committee criticised PHARMAC for lack of progress on subsidising the drug Interferon for people with multiple sclerosis (MS). The committee was concerned about the financial pressures on MS patients who were self-funding the drug. The committee was indicating to PHARMAC, that in their opinion, Interferon should be placed on the Pharmaceutical Schedule. Multiple Sclerosis Society spokeswoman, Duillia Rendall also criticised the length of time PHARMAC was taking to establish criteria for Interferon. She stated that the self-funding of Interferon was placing many people with MS in extreme financial distress. Wayne McNee explained to the committee that PHARMAC was working with neurologists for advice about patients who meet Community Exceptional Circumstances criteria. He told the committee Interferon was too expensive to subsidise all MS patients.

The Committee gave PHARMAC their opinion that PHARMAC should fund patients who were self-funding this drug under the Community Exceptional Circumstances policy. The media report noted that PHARMAC took no notice of the Health Select Committee and told the Committee they were working through their processes and would have an answer in due course. This case is further discussed in Chapter 7 (p.231).

Case 7: New Drug rules 'a death sentence' (Evening Post, 13/01/1995)

Shirley Newman was a 65-year-old woman who was taking aspirin for a condition which was not identified in the news report. She was prescribed aspirin for anticoagulation and her doctor had prescribed a medicine named dyprimadole as a substitute for aspirin. Shirley claimed to be allergic to aspirin and she wished to stay on the previous medication which had kept her feeling very well. PHARMAC reduced the subsidy for dyprimadole and transferred the subsidy to aspirin. Shirley claimed that because she was allergic to aspirin she was now required to pay the full cost of dyprimadole. The cost to her was \$171 for a 3 month supply which amounted to \$2.00 per day. Shirley describes this as 'a death sentence'. Shirley had not applied to PHARMAC for a subsidy under Community Exceptional Circumstances.

Her doctor, Dr. Valance, reported that Shirley was allergic to the cheaper alternative. He stated that the problem with PHARMAC regulations was they leave patients no 'options for treatment'. The PHARMAC committee which examined the case decided that on the evidence before them, the drug dyprimodole was no more effective and vastly more expensive than its alternative. Shirley complained to her Member of Parliament Doug Kidd and the Minister of Health, Hon. Jenny Shipley.

Dr. Bennett who was the Medical Director of PHARMAC in 1995, stated that PHARMAC was 'ethically bound' not to subsidise dyprimadole when there was evidence that proved it didn't work any better than aspirin. He described how PHARMAC was able to save \$5 million which could be spent on other people who were in need of scarce health resources. He recommended Shirley apply to Work and Income New Zealand (WINZ) for a disability allowance which he was assured by WINZ she was entitled to. The story did not say if she had applied for extra assistance or not. PHARMAC was resolute in its decision to make the savings possible by switching the subsidy from dyprimodole to aspirin. Neither the Health Minister nor the Member of Parliament made any comment in support of Shirley or in support of PHARMAC.

Case 8: PHARMAC has given me 'a death sentence' (Radio New Zealand Nine-to-Noon Programme, 07/06/2011)

Allyson Lock was a 45-year-old Masterton mother of three who suffered from a rare disorder named Pompe's Disease. There were only three other sufferers of this disease in New Zealand. This disease is in the basket of diseases named 'orphan diseases'⁵⁰ primarily because they are contracted by so very few sufferers in the world. Allison suffered symptoms of a rapid decline of muscle function due to malabsorption of glucose in the muscles. This particularly affected her chest and abdominal muscles and hence breathing and walking had become extremely difficult. Her specialist and GP applied on her behalf for a Community Exceptional Circumstances subsidy for an expensive enzyme replacement therapy which is the only drug in the world that could help her survive the disease.

⁵⁰See discussion on page 8 for a definition of Orphan Disease.

The drug to treat Pompe's Disease is available in 40 other countries. PHARMAC admitted that their investigations showed that the drug would help Alison. However, PHARMAC declined the application because PHARMAC could not afford to provide the drug in the long term. The Medical Director of PHARMAC stated (Moodie, 2011) that PHARMAC could afford to provide the drug in 2011 but could not afford to fund the treatment in subsequent years. Alison said "they have effectively given me a death sentence... because without this drug I will die."

In the interview she also described how she went to see PHARMAC officials to discuss her case and they told her that if she was provided the necessary \$575,000 per year many more other patients would be denied treatment. She was made to feel guilty applying for the therapy. She said that the government had put PHARMAC in that position of having to pick one person over another to allow one to live and one to die. Alison said she felt it was "disgusting" to be treated like that.

When Alison was asked to respond to the question of how the government could justify spending \$575,000 on one person, Alison suggested that the Government should give up spending \$8 million⁵¹ per year on government ministers' chauffeur driven cars. She asked "what's more important, people's lives or politicians being driven around?"

The Medical Director of PHARMAC expressed sympathy for the tragedy of Alison's case but said that PHARMAC had a process of examining the evidence of the expected improved benefit from medicines. He said PHARMAC would not fund medicines which only promised improvement. He stated that PHARMAC could fund a drug which demonstrated a cost-utility analysis of up to \$30,000 cost per QALY and this drug came in at over twenty times that limit.

He stated PHARMAC did this to be fair to the whole community. Alison stated that they were not being fair to her.

⁵¹I am not sure where Alison got this figure from. I have not been able to verify this figure from Parliamentary Services. This information is not publicly available, however could be accessed through an Official Information Act request.

Case 9: Award-Winning Kiwi Scientist Uses Prize Money to Fund Cancer Treatment. (Dominion-Post 20/4/2010)

Professor Sir Paul Callaghan, voted New Zealander of the Year in 2011⁵², is a distinguished scientist and researcher. He appeared in a newspaper article with Lloyd Morrison, the Chief Executive of one of New Zealand's largest companies, Infratil Ltd. Both congratulated PHARMAC on the rationing system it used to determine which drugs to subsidise. This was despite the fact that Lloyd Morrison and Sir Paul were both suffering incurable forms of cancer and faced uncertain futures. They were reported to express concerns for the wider needs of the health service by saying that PHARMAC should "cater for the most common issues, not rarities." The story described how Sir Paul used a \$28,000 prize from the prestigious Gunther Laukin Research Institute of Florida USA to fight his cancer with drugs which were unsubsidised by PHARMAC. Both men acknowledged that they were very fortunate to be able to afford extra treatment which was not available in the public system. Sir Paul commented that cancer is "a rich man's disease-you don't want to be poor and have cancer." He also received a course of chemotherapy which was funded by PHARMAC. Morrison complained that he could not import the unsubsidised drugs and have them administered in the public system. The wealth of both of these patients was a possible reason why they were in a position to demonstrate supportive attitudes towards PHARMAC's rationing systems. Health Minister Tony Ryall said he was "concerned about New Zealander's access to all medications." This comment demonstrated support for PHARMAC's utilitarian approach.

Discerning the Voice of the Participants in the Stories

The participants represented in the media articles which related to PHARMAC and Community Exceptional Circumstances demonstrated a range of opinions and emotions. This section describes these responses in groups; patients, doctors, advocate organisations, DHB service managers, PHARMAC staff, the Health Select Committee and Ministers of Health.

⁵²<http://tvnz.co.nz/national-news/new-zealander-year-announced-4011907>

The Voice of Patients and Family Members

The list of feelings expressed by patients and family members were concern, annoyance, agrievement, friendly, anxiety, outrage, bemusement, dissatisfaction, regret, bitterness, sadness, anger, cynicism, disappointment, and kindness. All of the patients in the articles shared a common desire; to tell their story about access to medications, which for one reason or another were not able to be provided to them for their treatment under the Community Exceptional Circumstances scheme.

Each patient and family member had a different perspective on what this meant to them. These perspectives ranged from headlining that PHARMAC had delivered them a 'death sentence' to statements such as 'patient unable to get medicine.' Some patients seemed not to be concerned for themselves when they did not qualify for a subsidy but were concerned about others who were less fortunate than them and might not be able to pay for their medicine without a Community Exceptional Circumstances subsidy.

Many of the patients who appeared in the media articles complained that their applications for Community Exceptional Circumstances were not successful. They regularly commented that this was unfair. The patient's expectations of being successful were high and they expressed disappointment at being refused. There were there very few comments from patients about the greater needs of the community in relation to their often very expensive claims in contrast to physicians and managers who were aware of the high cost of the claims.

Many patients had gone to the media with their story without exploring possible assistance from PHARMAC or WINZ. On occasions, these agencies may have been able to help them.

The Voice of Doctors

Nine doctors appeared in the twenty three media stories as advocates for their patients. Many doctors expressed their frustration at being in the position of knowing that an expensive drug may have some benefit for their patient and not being able to secure public funding for the treatment. One medical specialist from the UK was critical of PHARMAC because his advice was not accepted by

the PTAC committee. He described New Zealand as suffering from 'severe tunnel vision'.

Only one doctor, rheumatologist Dr. Sue Rudge, took the view that while she agreed that her patient would have benefited from a subsidy on a new and expensive drug, she was more concerned for all the other patients who need financial support from PHARMAC. The eight other doctors who expressed themselves were mainly negative about PHARMAC. These doctors made no comment with respect to the wider patient population and concentrated on the needs of the individual whom they represented.

In three of the media stories PHARMAC was criticised for not providing the patient with a subsidy under Community Exceptional Circumstances, yet the patients had not made a claim for one. Under the PHARMAC rules, the doctor is required to make the case for the Community Exceptional Circumstances subsidy on behalf of the patient. This demonstrated that either the doctor did not know about Community Exceptional Circumstances or they were being unfair to PHARMAC in the media.

The same problem was noted in relation to doctors criticising PHARMAC for not funding a drug when the manufacturing company had not applied for a subsidy for the medicine. It was possible that doctors in the stories did not know the application system and gave a statement to the media in support of the patient's claim, or the doctor was attempting to put pressure on PHARMAC to fund the drug. Through this method, the manufacturing companies used patient stories (and support from doctors) to raise the profile of new medicines.

The Voice of Advocate Organisations

Advocate groups, or diagnosis type support groups for example the Multiple Sclerosis Society, AIDS Foundation, Heart Foundation, Cancer Society appeared in the media stories many times. These organisations advocated for the patients in the media articles, expressing support for members in the most tragic circumstances. The advocate groups often appear in the stories giving information about the clinical conditions of the disease and how treatments work. The advocate groups supported the person in the story and very often implied that there are many other patients in the same situation. The Multiple

Sclerosis Society did this three times in three stories as did other patient advocate groups.

The voices of the advocate groups ranged from sounding righteous, critical and at times accusatory to being a concerned advocate, authoritative, supportive, factual and informative. Their arguments were very persuasive and well argued. Rarely did any of the advocate groups consider the wider needs of the general public.

The Voice of DHB Service Managers

The DHB Managers and staff from the Ministry of Health were guarded in their comments. They presented information in the media stories which was factual, informative, reasonable and responsible. These participants presented a balance of the interests of the patient weighed against the responsibility of the DHB and Ministry to meet their budgets.

Several managers were clearly trying to make the best decisions for the individuals and were trying not to be seen as uncaring. There was one voice of anxiety from DHBs and Ministry officials who did not want to be setting precedents by making exceptions to the rules. One DHB manager worried that if the funding was available to one, would decision might open a flood gate of requests which could not be managed.

These official messages came through the stories, but what was not obvious was how the managers themselves actually felt about the decisions which they had made.

The Voice of PHARMAC Staff

Many times in these media cases the PHARMAC staff sounded reasonable, reassuring, fair, caring and helpful. Often they expressed frustration that they could not meet the needs of all the patients who had applied for Community Exceptional Circumstances claims. At other times they were presented as official, cold and slightly harsh.

PHARMAC was put in the position of defending their decisions against the criticism of the patients and their supporters, but in no story did PHARMAC

indicate that they would change their decisions. On many occasions, PHARMAC staff tried to offer alternative courses of action or give information about change processes. PHARMAC did give strong voice to the utilitarian principle and commented about why it was difficult for PHARMAC to do what it was set up to do.

The Voice of the Health Select Committee

Select Committees are committees of Members of Parliament, where the government of the day usually has a majority of committee members appointed to critique the performance of government departments and Crown Agencies. They also scrutinise virtually all legislation, review the finances of public bodies and can instigate inquiries into policy issues within their subject areas (Shaw & Eichbaum, 2005 p52). The Health Select Committee in this story expressed frustration and irritation at PHARMAC's slow progress and lack of a positive indication that they were coming to a decision about Interferon for MS sufferers. The committee came down on the side of the patients who had petitioned them. Ironically, PHARMAC was implementing government policy, albeit slowly, and in so doing trying to protect the government's budgets. In the Interferon case, PHARMAC appeared not to explain the rationing process involved to the Select Committee. Consequently, it did not convince the Select Committee of the progress which was being made through a detailed scientific examination and cost-utility analysis being done by PHARMAC's committees. This gave the perception that PHARMAC was obstructing the committee by being reticent and slow in coming to a decision.

The Voice of the Ministers of Health

The two Ministers of Health referred to in the media reports were Hon. Jenny Shipley and Hon. Annette King. Minister Shipley did not respond to requests from the patients for help, or if she did respond this was omitted from the story. This was in line with the intention of PHARMAC's governing legislation to avoid political interference. Minister Annette King responded to a request for funding of a drug by a constituent. She was supportive but firm, sympathetic and tried to be helpful. The Minister also tried to recommend a positive course of action for the patient which was wrong advice. She recommended the patient try a Community Exceptional Circumstances claim when the condition the patient

was suffering would not pass the rarity criteria and would not be considered for an Exceptional Circumstances subsidy. In this, King behaved as an electorate MP would, not as a Minister.

What Did the Headlines Say?

The headlines to these media reports did not accurately reflect the content of the report. Some headlines were quite misleading and some were very accurate. For example, the headline “A matter of life and death and how to pay for it” was misleading in its content. The patient in this story had a terminal illness and the drug which the patient wanted PHARMAC to subsidise could not save the patient’s life. The patient’s doctor was not sure if it would even help the patient to feel any better, yet the editor presented the case as ‘life and death’.

Another headline stated “Drug too costly for arthritis sufferer”. This was a misleading headline because it suggested that PHARMAC would not provide a subsidy for the drug and therefore the patient had to pay privately to receive the drug. In fact neither the patient nor the manufacturer had applied to PHARMAC for a subsidy for the drug. The headline gives a false impression that the patient had been rejected by PHARMAC for a subsidy when in fact he had not.

Finally, “New drug rules a death sentence” was an emotive and misleading headline which was misleading in content and tone. The patient in this story was taking a drug which PHARMAC removed from the subsidised schedule and replaced it with another. She had not applied for a Community Exceptional Circumstances subsidy which PHARMAC urged her to do. The unsubsidised drug cost her \$2 per day for which she could claim a WINZ benefit if she could not afford to pay for the medicine herself.

Section 4: Key Informant Interviews

Introduction

Key informant interviews were conducted as part of this research to provide context to the formation, operation and effects of PHARMAC’s Exceptional Circumstances policy. Key informants were selected because of their knowledge and experience of the PHARMAC policy. An outline of the method

of selecting, interviewing, recording, transcribing and analysing the interviews is contained in Chapter 4 (Methods).

Eight key informants were interviewed. They were:

- four past or current PHARMAC personnel;
- two past or current Ministers of Health: and
- two executive representatives of patient advocacy groups.

This data from the interviews are presented in two parts. Part I discusses the interview experience to give readers the background into some of the issues relating to the procurement and conduct of the interviews. Part II deals with material of specific interest discovered during the key informant interviews. Some of this material is taken from the interviewees' own statements.

Part I: The Interview Experience

After giving consent to be interviewed, the interviewees were sent a list of questions to guide the discussion. The questions were different for the interviewees because of the range of knowledge and experience of each person. Most interviewees said they were pleased to receive the list of questions as it gave them time to think about the subjects under discussion. In some cases, the interviewees had time to find documents which they believed may have been useful to me in my research. Not all the questions from the list were used in the interviews. The interviews were about an hour in duration and took place in interviewees' homes, offices or in cafes as they determined.

The two patient advocacy groups who agreed to interviews were the New Zealand AIDS Foundation and New Zealand Organisation for Rare Disorders. Both these organisations agreed to be identified as organisations and anonymity was provided to the person who was interviewed. Both organisations have wide memberships and they have assisted many of their members in the Community Exceptional Circumstances claim process. Due to the complexity of the diseases suffered by both groups' members, these groups have made valuable contributions in researching PHARMAC's policy.

Eight of the twelve persons approached for an interview agreed to be interviewed (ref. p. 84). The interviewees were all generous with their time and were pleased to be asked to discuss the subject and were cooperative during the interviews.

One person withdrew approximately 20% of the interview transcript during the editing of the transcript and validation process. The recanted material was discarded. One interviewee asked for the voice data recorder to be switched off during parts of the interview and gave “off the record” comments. Enlightening as they were, these comments were not entered into the record of the interview. I considered that removing this material from the transcript did not detract from my understanding of the material the interviewee wanted to remove from the transcript. This was because the comments had been made to me and my understanding of their meaning cannot be removed by expunging them from a transcript. These comments were informative and gave a perspective that helped me better understand the PHARMAC policy, albeit that I could not report on them.

One past or current Minister of Health preferred that hand written notes be taken rather than recorded by the digital voice recorder. This request was agreed to and the transcription from the notes was later validated by the interviewee. Similarly, one interviewee requested that verbal as opposed to a written consent be given prior to the interview. This condition was agreed to.

Once the interviews were transcribed, each transcription was entered into NVivo 8, and coded into nodes and analysed using thematic analysis.

There were four interviews transcribed from past or present PHARMAC personnel. The following table describes the varying roles of the interviewees without identifying them.

Table 6: PHARMAC Interviewees

Interviewee	Status	Position
A	A past or present PHARMAC	Senior Manager
B	A past or present PHARMAC	Medical Director
C	A past or present PHARMAC	Medical Advisor
D	A past or present PHARMAC	Exceptional Circumstances Applications Manager

There were two interviews transcribed from past or present Ministers of Health who both had considerable experience dealing with PHARMAC.

Table 7: Past or Present Minister of Health interviewees

Interviewee	Status	Position
E	A past or present	Minister of Health
F	A past or present	Minister of Health

There were two interviews transcribed from patient advocate groups they were the New Zealand Organisation for Rare Disorders and the New Zealand AIDS Foundation. The New Zealand AIDS Foundation has had a long association with PHARMAC and has been involved with many Community Exceptional Circumstances claims. The New Zealand Organisation for Rare Disorders which has represented many patients with orphan diseases which are very rare, have complicated pathology, are difficult to treat and have very high cost treatments.

Table 8: Patient Advocacy Groups interviewees

Interviewee	Position	Group
G	Executive Representative	New Zealand Organisation for Rare Disorders (NZORD)
H	Executive Representative	The New Zealand AIDS Foundation (NZAF)

Part II: The Key Informant Interviews

The purpose of presenting raw text here is to allow the interviewees to do the talking. Readers will hear the opinions expressed by the interviewees on the various subjects discussed and will be able to discern the tone of the interviews and in some cases the depth of feelings and commitment of the interviewees to getting their story told.

Interviewee 'A': "If there aren't any constraints then everybody will become exceptional"

Interviewee A was a past or present senior manager of PHARMAC. 'A' described the Community Exceptional Circumstances policy as a way of dealing with individuals who needed or wanted a subsidy for medicines that were not on the Community, Cancer or Hospital Pharmaceutical Schedules. 'A' described the claims as coming from people who didn't fit the standard schedule of subsidies. Primarily, 'A' saw the Community Exceptional Circumstances policy as a resource allocation mechanism with quite specific criteria around it, however did concede that the rarity criterion was not strictly adhered to by PHARMAC.

This method [Community Exceptional Circumstances] was used for allocation of relatively high costs of medicines for rather a few numbers of individuals. The numbers became a marginal call. It might be that we would provide a drug for the 10 people, it might be a hundred people, it may be 300 people. It's not so much that we were thinking about it in relation to the taxpayer, because this works largely in relation to the amount of money available, so we were trying to think about, well, how you provide a greater overall benefit to a larger number of people. (Interviewee A)

When asked how PHARMAC decided that rare meant less than 10 cases of any particular condition at any one time in New Zealand, 'A' referred to the fact that PHARMAC did not invent the definition but inherited the definition from the

Health Funding Authority⁵³ who operated the Community Exceptional Circumstances policy prior to 2001. There was no analysis of what rarity meant or how they came up with the number 10. It was decided by one person.

*It has always been a kind of a rule that (name withheld) put in place... that says well if you have got more than 10, then it's not exceptional. I guess you could say it established itself as a general rule. I am not saying that we applied this rule very rigidly, however it was fixed in our mind ... as something that they [HFA] suggested, and it kind of made sense. If things started to appear in numbers greater than 10, then...we started to look at it differently.
(Interviewee A)*

'A' discussed the idea of what 'exceptional' meant in managing the policy. Interviewee A referred to the budget limitation as the rationing mechanism because PHARMAC did not have a way of determining the most exceptional and the less exceptional claims they were facing. 'A' described the overall purpose of PHARMAC, which was to ration the pharmaceutical budget on behalf of DHBs and ration in relation to the Community Exceptional Circumstances scheme. The individuals' entitlements to treatment, which was unavailable through the normal schedules, came second in importance in PHARMAC's primary purpose of managing the budget.

*Of the Community Exceptional Circumstances system that we were running, we started from the position of saying...we will have to identify how much we have to spend...if there aren't any constraints...then everybody will become exceptional. There could be thousands of people who we treat as "exceptional". This would undermine the schedules we had fought long and hard to establish.
(Interviewee A)*

It was put to 'A' that one rationing strategy (applied intentionally or unintentionally) to manage the PHARMAC budget initially was to withhold information about Community Exceptional Circumstances from the public. 'A'

⁵³In the 1993 health reforms 4 Regional Health Authorities were established. Purchasing and provision of health services were separated in a policy named the 'Funder- Provider Split'. The existing 14 Area Health Boards were reconfigured in 23 Crown Health Enterprises (CHEs) for profit organisations and subject to ordinary company law. In 1997, the National – New Zealand First Coalition Agreement on health reformed the structure of the health system which took effect in 1998. The 4 Regional Health Authorities were combined into one purchasing agency the Regional

agreed this was done. Secondly, PHARMAC developed an application process which was quite complicated to naturally limit the numbers of applications. The following views were expressed about the application process. This was described in the literature as rationing by frustration (Higgins & Ruddle, 1991).

Well we wrote up a criteria and a policy, which is now publicly available on the website, but in those days it wasn't. We treated it as restricted information, sort of said, well let's keep it hush hush so people wouldn't know about it until they applied. The only people who applied who were people who heard about it on the grape vine, or they had made an application or sometimes people would write to us about it.

and

It [the application process for Community Exceptional Circumstances claims] is reasonably onerous, because of the demands of the [Community Exceptional Circumstances] Panel or information actually can sometimes be quite high...it isn't ticking boxes you actually have to provide the clinical information but there is a barrier there for the doctor[s] in terms of paper work. (Interviewee A)

This person also spoke about how it was personally difficult to make Community Exceptional Circumstances decisions despite the best evidence and advice from the Community Exceptional Circumstances Panels. When Interviewee A was asked to give examples, this is what was said:

The Gleevec example, treatment for myeloid leukaemia was a very personal example. So I was meeting with individuals who had the disease and were going to die. They might like not to die but...everybody dies... but they were looking for a delay ... but for how long?

and

I recall with multiple sclerosis and Alzheimer's. These were hard. Alzheimer's particularly, not because we didn't think the drugs were

effective or the benefit was very great, but because you have very emotional families. That did affect me personally. (Interviewee A)

'A' also indicated that PHARMAC seldom exceeded the Community Exceptional Circumstances budget of \$3 million and kept the numbers of patients on Community Exceptional Circumstances subsidy closely monitored.

There was an amount allocated in the budget. I recall it was \$2-3 million and we tracked it over time. It wasn't normally a problem because we very seldom went over the level. The doctors who were making the decisions weren't persuaded by that [budget] anyway.

and

No, [affordability] wasn't a major factor. I can remember once it got close to the level and we went to the Board and asked for it to be increased and they increased it... over time it did grow a bit. (Interviewee A)

Interviewee 'B': "Exceptional Circumstances can be seen as the prize"

Interviewee 'B' gave a clear description of how PHARMAC saw the Exceptional Circumstances policy, describing the policy as a method of subsidising extremely rare conditions. This idea of 'real rarity' was clear in Interviewee 'B's' mind as a numerical cut off point. This person described claimants who met the rarity test as 'winners of the prize' and those who did not meet the rarity test were 'the losers.'

If there is something very rare it will likely get funded but if it is only quite rare then it is likely that it will not be funded under EC [Community Exceptional Circumstances]...so with EC you win [get funding approved] for real rarity...you however lose if you're not quite so rare.

and

I think one of the great difficulties...that EC can be seen as the 'prize' for having a rare condition. I mean that if you have a rare condition and there is a standard treatment for it, then it probably should be on

the pharmaceutical schedule. The original idea was to help those amazingly rare things ... the things nobody had a clue about. (Interviewee B)

There was a strong link made between rarity and the amount of money available to PHARMAC for Community Exceptional Circumstances subsidy claims. The question was put to 'B' about the connection between rare and the number 10.

We said ok [the number 10]...this is a good place to start with rare... there was nothing more in it than that. We have just said well 10 is rare.

and

Well, you can have whatever number you want to have...as a number...there is a budget of \$3 million and with the current criteria we manage along pretty well on that. Sometimes we go over... but mostly I think we are under that. I mean if we increased the number we would obviously have to increase the budget. This is the same argument we get into with the PHARMAC budget...you can have whatever you like but it has to be paid for and we really have to stick to that. (Interviewee B)

'B' maintained that exceptional did not mean outstanding, unbearable or incomparable, it meant rare as in infrequently encountered. B gave the following example:

In New Zealand we do not consider a person's case exceptional if she has a condition and also has an unhappy set of personal circumstances, for example she is poor and her husband has died... I remember when Herceptin first blew up, there was a ...woman whose child had leukaemia [cancer] and now she had HER 2 positive breast cancer and her husband had left her... and she was saying that her life was exceptional. There is no doubt that she was a very sad case...but...there is nothing exceptional about her case. I mean if we think about fairness, why she should take precedence over somebody who's got three nice children...and the husband is

supporting them and his wife also has breast cancer. What is the difference? There is no difference...there is no difference. (Interviewee B)

When 'B' was asked if PHARMAC always sticks to the criteria for Community Exceptional Circumstances when deciding a claim, 'B' admitted that on occasions PHARMAC uses the policy as a mechanism for solving a problem. 'B' gave the example where Community Exceptional Circumstances subsidy was granted to a lot more than 10 patients with the same problem. In these cases, PHARMAC was not sure if there are enough patients to subsidise the drug on the schedule. Also 'B' explained that when there were some patients where the costs of treatment are extraordinarily high, and there are a low number of patients, drug companies will not take up a contract because the numbers are so low in New Zealand. In these instances, PHARMAC sometimes used Community Exceptional Circumstances subsidy to fund the drug.

On occasions, the EC scheme is used as a mechanism to fund something where there is a pressing need but no other way of doing it. Liothyronine⁵⁴ is an example of this. (Interviewee B)

'B' stated that PHARMAC used the Community Exceptional Circumstances policy more as a cost containing strategy and not strictly a mechanism for ascertaining if an individual should be funded for a medicine which is outside the pharmaceutical schedule. The criteria were used by the Community Exceptional Circumstances Panel to assess each claim. Decisions are based on the panel members' knowledge of the medical condition, rarity and the evidence of cost-effectiveness of the proposed treatment. Cost containment is not stated as a criterion. However, the way 'B' described the management of the Community Exceptional Circumstances, policy; it has been used as an effective cost containment policy.

⁵⁴ Liothyronine is the most potent form of thyroid hormone which regulates protein, fat, and carbohydrate metabolism. It acts on the body to increase the metabolic rate, the synthesis of proteins and increases the body's sensitivity to adrenaline. See http://en.wikipedia.org/wiki/Liothyronine_sodium

No we have never thought that \$3 million is not enough...I mean we have managed pretty well on that. (Interviewee B)

'B' described the problem for PHARMAC where they provide a Community Exceptional Circumstances claim for a subsidy for a particular condition which met the funding criteria and then doctors began to diagnose this problem more regularly. Then the medical condition actually became more common and was no longer rare. This substantiated a claim that the drug should be placed on the general pharmaceutical schedules. This indicated that Community Exceptional Circumstances claims were a route for getting a drug noticed and then funded on one of the pharmaceutical schedules.

With something that is actually stunningly rare...the condition often becomes more common. I don't mean doctors are playing games or anything like that but...when something rare is diagnosed and we fund it under EC [Community Exceptional Circumstances]...it becomes something that people become aware of and other examples of the rare condition just turn up. There are some good examples of this: Pulmonary coronary hypertension is a good example...where doctors are finding that they are able to diagnose it much more readily and then it no longer becomes a rare condition, so yes it does go onto the schedule...eventually. (Interviewee B)

Interviewee 'C': "I am not equipped to worry too much about the fairness to this one or the fairness to that one".

The format for reporting this interview is slightly different to the other interviews presented. This is because the questions which were put to interviewee 'C' were particularly insightful in informing the content of the answers. The questions in the other interviews were conversation starters. I felt that both the questions and flow of conversation which Interviewee "C" were necessary to report.

These questions are identified as Q in the text and the answers are identified as A in the following text. This system is used in subsequent interviews as well.

Interviewee 'C' was had a long experience of deciding on Community Exceptional Circumstances claims. 'C' confirmed this in the interview.

Q *You must have looked at thousands of these Community Exceptional Circumstances cases.*

A *Yes, literally thousands.*

(Interviewee C)

The interview with 'C' extracted considerable comment about fairness and gave a clear description about what 'C' saw as the elements of fairness.

Fairness is not related to the amount of money a person has, rich or poor...the amount of money they, the person I mean, has or hasn't got. It is not related to sex or religion or ethnicity or indeed age. No, fairness is a consistent process where everybody is treated the same way and has the same capacity to get the same sort of things.

and

Fairness is something about meeting the needs of everyone, irrespective of each person's ability to pay. (Interviewee C)

'C' made reference to the needs of the individual and the need to manage the funding and recognised that Community Exceptional Circumstances was an imperfect system. 'C' believed that some people will miss out on the drugs that would benefit them because there is not enough benefit that can be demonstrated. On this point 'C' felt that the system had been in place for such a long time that it had legitimacy because of this. 'C' claimed that his/her understanding of Community Exceptional Circumstances was fair; therefore the Community Exceptional Circumstances scheme was fair.

Well I mean it has worked okay up till now...it has been fair because I understand it and that is the important thing...so what is the problem? (Interviewee C)

When asked if it was possible for another doctor or another person or even the patient to have a different view of fairness, 'C' responded:

No not really. Fair is fair. I am the one making the decision and what I think is fair has to...well...be the right answer. (Interviewee C)

Insights were given as to the independence of the Exceptional Circumstances Panel. 'C' made comment that the panel only made recommendations and not decisions.

We are independent of PHARMAC and that is why we were appointed by the Ministry of Health. We don't work for PHARMAC in that sense. I have always felt free to decide. (Interviewee C)

'C' made reference to the fact that some doctors know how to complete the applications for Community Exceptional Circumstances in a way that ensures their patients will get a subsidy. This situation militates against the patients whose doctors are unfamiliar with the system of application. This contradicts 'C's' own description of fairness to each patient and is a form of rationing itself. This contradiction was put to 'C':

Q *Do you think you are being fair to the patients taking a rules based attitude with their doctors?*

A *If you meet the criteria you get the medicine and if the doctor knows how to work the criteria the person gets the medicine. I didn't ever worry about being hard on the applications. The doctor has a set of instructions and if the doctor does not follow those instructions well...*

Q *The patient misses out?*

A *Yes, the patient misses out.*

(Interviewee C)

The matter of the affordability criteria for Community Exceptional Circumstances was raised with 'C'. The following discussion identified that despite adjudicating on thousands of cases 'C' had no idea of the criteria that 'C' and the Community Exceptional Circumstances Panel were supposed to be operating under. It was revealing to hear by 'C's' own admission, 'C' was not aware of the criteria.

At one stage, condoms were being provided free with medicine as a form of contraception to those who could not afford them. Suddenly every woman in New Zealand couldn't afford to buy them themselves. Doctors didn't want to argue about it, didn't want to go around checking on their income.

- Q *What about if a person had a Community Services Card?*
- A *I don't know that that came into it. Was that part of it?*
- Q *Well I have a document here from PHARMAC which is the eligibility criteria...this document says*
- "The patient needs to meet the following income criteria. Either a person's income circumstances have been assessed or they are eligible for Community Serves Card, they are already receiving the maximum benefit from Work and Income, or it is otherwise unreasonable to expect the person to pay."*
- Q *So how would the Panel know, or you, how would you know, which of these financial conditions or any of the conditions apply?*
- A *Which Panel?*
- Q *The Exceptional Circumstances Panel assessing the eligibility criteria for an Exceptional Circumstances claim.*
- A *Well this certainly isn't an issue that I ever dealt with. Income never came into. I wouldn't have a clue about peoples' incomes.*
- Q *You don't ever recall that? These criteria I mean.*
- A *No. And I was [an advisor]⁵⁵for many years and I never heard of the income criteria...income doesn't come into Exceptional Circumstances, it was never involved. Ever! (Interviewee C)*

After admitting that s/he didn't really know PHARMAC's criteria, 'C' made reference in the interview that the main criteria as far a 'C' was concerned was to "be reasonable" and "act reasonably." 'C' tried to see the problem of reasonableness from many points of view.

'C' made the following comments which identify the approach of medical advice to PHARMAC. 'C' did not have any comment to make about how the conflicting views of reasonableness can be resolved.

At times it is a problem,...where judgment of the circumstances comes into it. We have to say - well I think this is reasonable or no it does not seem reasonable to me. Well it's based on my experience.

⁵⁵The words of Interviewee C were removed to avoid possible identification of C.

Now some people can say that's fine but if you want this you can buy it [yourself].

and

You can go down to Social Welfare and say "The doctors won't give me this but I need it," and they will look at it too. So there are two views of what is reasonable. The trouble comes when we, the Community Exceptional Circumstances people, say you don't need it and Social Welfare agrees with the patient and says you do! Which 'reasonable' do we take?

This difference was further explored with further questioning.

Q *Well how would you resolve these differences? I mean here are two government agencies saying opposing things about what is reasonable.*

A *As a doctor I am entitled to say what I think is reasonable. They will have to accept that because I was asked to make...to rule on all these applications.*

(Interviewee C)

The rarity criteria, being described by PHARMAC as less than 10 cases nationally, are one of the cornerstone criteria for the Community Exceptional Circumstances policy. It was important to explore with 'C' how the number was arrived at and why it was chosen.

Q *Where did the number 10 come from as the definition of rare?*

A *Well I just can't remember that... it was the RHA days... or was it the Department before the RHA? ... well if there are less than 10 it's got to be pretty rare. I don't think there was anything more to it. But we have stuck to 10 all these years.*

Q *Was there any research or did the HFA or PHARMAC apply any models, any test hypotheses to see if this number 10 did in fact mean...well rare.*

A *No...nothing like that...I just said 10 and 10 was it.*

Q *So you think this definition is fair on the patients? What about someone who is 11th or 21st? Is it fair for them too?*

A *Well yes and no. Yes, it is fair to the ones that get it...and I suppose no, the definition is not fair on the ones we say no to. It is fair on the whole...PHARMAC has to deal with the whole PHARMAC budget...I suppose it is fair on the rest of society...if you look at it like that.*

When 'C' was taken back to the answer given about the definition of fairness earlier in the interview being "a consistent process where everybody is treated the same way and has the same capacity to get the same sort of things, s/he made the most telling remark:

Well when it comes to Exceptional Circumstance, look I am just not equipped to worry too much about the fairness to this one or the fairness to that one...no my expertise is in medical things... that is really the advice I was giving PHARMAC...medical advice (Interviewee C).

Interviewee 'D': "Some clinicians were very good at using the system and others just didn't take the time to use it".

Interviewee 'D' was a past or present manager of Exceptional Circumstance claims with considerable experience handling the PHARMAC process. 'D' was responsible for the communication between PHARMAC and the claimant families and communication with the Medical Advisor and the Exceptional Circumstances Panel.

In the discussion, 'D' stated that there were two masters to be served in the Community Exceptional Circumstances area. The first master was advocacy on behalf of the patient. The second master as far as 'D' was concerned was a clear agenda to manage political risk on behalf of PHARMAC.

Q *How did you see your role at PHARMAC?*

A *My role was to co-ordinate the process basically, and again be a voice for the patient or the family and clinician submitting the application.*

- Q *Be a voice for the family?*
- A *Yes, I was someone that they could talk to... to see where the application was at. But I was sort of managing political risk as well, as well as financial risk.*
- Q *... what was the political risk?*
- A *Well if it gets out into the media... case management required sensitivity when dealing with patients. If not managed well, the potential for adverse publicity was high.*
- Q *Then what would happen?*
- A *Adverse publicity around what can be funded and what can't be funded. It would have to be managed...as long as it's managed properly it's okay...and that's what I used to be able to do, because we had very clear criteria for Exceptional Circumstances, I was able to explain to the patient or the family member if they had to be declined, why they'd been declined on the criteria and they could accept that.*
- Q *Over the years you must have managed many hundreds of these applications. Is that right?*
- A *Well...hundreds or possibly thousands...I couldn't be that sure... I managed a great many claims that's for sure. (Interviewee D)*

Related to the issue of the patient's ability to pay, as discussed with 'C', it was clear that the administrator of the scheme had a very different view. This is confusing because 'C' and 'D' worked closely together. On the point of the affordability criteria, this is what interviewee 'D' had to say.

For exceptional circumstances does also involve the ability to pay...were they were financially able to pay?

I pursued this question with 'D', to check that the financial affordability criteria really existed.

- Q *So if they were financially able to pay, you are saying that a Community Exceptional Circumstances claim wouldn't pay for it?*

A *Yes that's right...if someone was able to pay [for Community Exceptional Circumstances claims] it would be denied. That was part of the criteria, the application had to be submitted by the clinician and they would have to answer all these questions.*

Q *And was there a question about peoples' income?*

A *Yeah...yes there was.*

Q *What about a person's assets?*

A *No,...if they could pay for it themselves they were advised not to apply....On the application form it asked if the person's income and circumstances had been assessed and if the person was eligible for a Community Services Card, or whether it was otherwise unreasonable to expect them to pay. (Interviewee D)*

The Community Exceptional Circumstances application form⁵⁶ does not ask for information about applicants' income. There was no guidance given by PHARMAC on the website in relation to the criteria about the meaning of 'otherwise unreasonable to expect them to pay.' It is apparent that a patient's ability to pay was a criteria and it was managed by 'D' as part of the process of approving or declining the application.

'D' also alluded to the fact that a physician knowing the application system was at a distinct advantage in getting funding for the patient. Interviewee 'D' gave an example of this;

An example was patients with cancer, terminally ill, intractable nausea and vomiting, I mean there was a situation where one [doctor and] pharmacist from [name withheld] who were obviously passionate about their patients and managing their symptoms. And it was interesting because I used to get a lot of applications from this particular place.

Q *So one person knew how to work the system?*

A *Yes, my word...because we got applications, probably more applications from some clinicians than others, and I think that's the*

⁵⁶The Form is available on the PHARMAC Website
<http://www.pharmac.govt.nz/2009/06/03/1%20Application%20form%20for%20Community%20Exceptional%20Circumstances.pdf>

key issue here. Some clinicians were very good at using the system and others just didn't take the time to use it. (Interviewee D)

The interview explored how the Ministry, HFA and latterly PHARMAC knew how many cases of a certain condition existed in New Zealand to be able to determine if there were less than 10 sufferers with the same condition at any one time.

Under questioning 'D' admitted other HFAs (or latterly the 21 DHB's) did not consult with each other about how many people at one time had a particular disease. There is no system of asking all the GPs in New Zealand if they are treating a similar number of cases of a particular disease or disorder for which the patient's doctor is making a Community Exceptional Circumstances claim for a subsidy.

'D' was aware that cost-utility analyses were done on applications where the total cost of the subsidy was greater than \$15,000 per year. However, 'D' did not know how the analyses were done nor did 'D' ever scrutinise any of the reports. 'D' was also unaware that the cost-utility analysis excluded personal costs to the patient and these costs were not taken into account.

Like cost-benefit analysis is taking all the costs and taking all the benefits and quantifying the costs, quantifying the benefits and seeing if there's an equality or if there's, you know, not enough benefits or too high costs.

Q *Did you know how that process was done?*

A *No...not really, because I mean these were, they were people that were expert in that field, so I accepted their analysis. A would receive a copy of their cost-benefit report and this was taken into account when making the final decision. (Interviewee D)*

Interviewee 'E': "Community Exceptional Circumstances is used by PHARMAC as an 'escape valve'"

Interviewee 'E' was a past or present Minister of Health with a long experience of public administration and had held many Ministerial portfolios. 'E' had dealt with PHARMAC as Minister and was well acquainted with PHARMAC as a

Crown Entity and also was familiar with many constituents' perceptions of PHARMAC.

New Zealand Ministers are Electorate⁵⁷ or List MPs and are petitioned by both Government MPs and Opposition MPs to assist constituents. This creates a different type of pressure on a Minister, other than the pressure on a Minister responsible for dealing with the legislation, lobbyists, department officials and providing good stewardship of the portfolio.

However, despite Interviewee 'E's wide ministerial experience and close association with PHARMAC, 'E' did not know much about the Community Exceptional Circumstances policy.

Q *Let's start with what you know about Community Exceptional Circumstances... at PHARMAC?*

A *Well not very much. After you asked me to think about this the other day, I was wondering why I didn't know much about this. As Minister, I at least should be, or have been, better aware of it...I think it was probably too small a budget or just in the mix of all the things that PHARMAC was doing at the time, but you are right, I should have known about it. (Interviewee E)*

'E' was impressed with PHARMAC's ability to rationalise the various funding categories and their ability to apply funding criteria to each category. 'E' thought this is particularly rare in the New Zealand public health scene. 'E' also alluded to the management of costs with the pharmaceutical companies and how this was a great advantage to PHARMAC and ultimately the New Zealand taxpayer.

However, 'E' also recognised the position of PHARMAC in relation to the people who fell outside this rational analytical system of funding. 'E' described Community Exceptional Circumstances policy as an "escape valve" for managing these demands.

⁵⁷New Zealand has a mixed Member Proportional Representation electoral system. At elections in New Zealand eligible people have two votes to cast; an Electorate Vote and a Party Vote. Approximately one half of the Members of Parliament are called Electorate Members and are elected by winning the most number of Electorate Votes in an electorate. The other half of the Parliament are called List Members and are elected by the political party gaining a proportion of the Party Vote. List Members are elected in proportion to the party vote gained and their place on the Party List.

I deeply suspect that Community Exceptional Circumstances is used by PHARMAC as an 'escape valve'. It is the sort of thing that does not fit into the general and...so they have this opportunity to say well... it is exceptional and we will look at it on this basis. I would if I were PHARMAC. There is still analysis of the case by experts and whether or not they make the right decisions the cases are looked at by someone outside of the organisation. (Interviewee E)

'E' had been involved in a review of PHARMAC's policies and procedures which called for public consultation on how well PHARMAC was doing in relation to its purpose. 'E' was aware that there was a strained relationship between the Researched Medicines Industry and PHARMAC, and according to 'E', PHARMAC did not consult well.

We looked mainly at the situation of referenced pricing and how it was working. The review showed that there was a strained relationship between the RMI and PHARMAC but that was always going to be the case. The review also showed that the public consultation processes of PHARMAC needed to be improved. (Interviewee E)

Notwithstanding both expressions of support and criticism of PHARMAC, 'E' acknowledged the difficulties PHARMAC faced with and on behalf of the DHBs and ultimately the government. 'E' believed they were carrying out their role well.

Well I have never thought that PHARMAC is doing a bad job, in fact quite the opposite. So the improvements following the review were in the soft stuff between PHARMAC and the companies and the general public. It is always hard for PHARMAC to say "No" to companies who want access to the pharmaceutical schedule and "No" to individuals who want an expensive thing. No matter how nicely you say "No", you are still saying "No". (Interviewee E)

'E' also made comment about the relationships between PHARMAC, the DHBs and government.

Well a State Agency does the work for the government, good or bad, and the Chief Executives are expected to handle the flack on behalf of the Minister, and they do. The DHBs are in a slightly difficult position because they offer up the budget that they think is appropriate for the purchase of pharmaceuticals to PHARMAC to manage for them, and presumably this amount is part of the wider DHB budgeting process...I wouldn't know about that now. But the DHBs also have the Minister approving the final amount to go to PHARMAC. I know that there are some pretty intense discussions which go on to settle this stuff. The DHBs ought not to be too concerned because PHARMAC is delivering internationally... just incredible value for the dollars spent on drugs in New Zealand. (Interviewee E)

'E' discussed the philosophical framework in relation to the political process related to the rationing process, which inevitably ends up approving or denying a pharmaceutical subsidy to either a manufacturing company or an individual.

I have always thought the utilitarian concept of greatest good for the greatest number, which tries to meet the needs of those who have not very much first, is all very well until you hit the political process. Politicians see themselves as trying to manage not just the politics of health but education, welfare, housing, and defence etcetera...everything else. They want to keep doing it [remain in government] because they believe they can do it better than the other crowd. So when the political situation demands a compromise on what we would all like to do, then the slavish adoption of utilitarianism goes out the window. (Interviewee E)

'E' believed that PHARMAC should also be developing a capacity for the political process and the community making rationing decisions together.

Amartya Sen is a pragmatic economist and is much more realistic. He talks about welfare economics and a government's duty to develop the capacity of a society. This is a bit different from the individualist view...you know...rather than the rights of every person to satisfy their self interest. I suppose in these terms PHARMAC

should be developing the capacity of the politicians and the community to make rationing decisions.(Interviewee E)

The point made by Interviewee 'E' about individual rights focuses attention on the tension between the Human Rights Act 1993 which protects citizens against discrimination and the Bill of Rights Act 1990 which sets out the fundamental freedoms each New Zealander is entitled to enjoy. 'E' is saying that PHARMAC has a primary duty under the Bill of Rights Act (1990) to ensure that the community is served adequately. The second priority under the Human Rights Act (1993) is to serve the individual as best as PHARMAC can.

Interviewee 'F': "PHARMAC has been a huge shield for Ministers".

This past or present Health Minister also had a long experience of dealing with PHARMAC and was confronted several times with difficult decisions to make. During Interviewee 'F's' interview, reference was made to the difficulty of splitting the Minister's interests between the role of Minister as public representative on behalf of petitioners, and the role of Minister as overseer of a public institution.

The discussion began with understanding Interviewee 'F's' notions of fairness. 'F' said that each person should be given the chance to participate in society, the same as other persons. Therefore, 'F' believed that social and financial circumstances should be considered in relation to fairness.

'F' was asked if these conditions should be taken into account when PHARMAC decides on Community Exceptional Circumstances claims. The following comments were made.

Q *Do you think these things [an individual's social and financial circumstances] should be considered?*

A *Certainly they should...because I think...she is holding down a full time job, the alternative is that she would be on a benefit...or she would have to have a part time job. But the main thing for her is the condition, because of the nastiness of this disease the interaction she has in the community is priceless actually, even more than the*

job. She is not homebound with worsening health and mental health too. Quality of life, quality of life is just as important in many cases.

Q *What does this say about the patient's needs other than medical needs in PHARMAC's cost-utility equation?*

A *Nothing, I think it's unfair. (Interviewee F)*

When questioned further about fairness, 'F' described fairness being linked to equal access to treatment.

Uniformity of access New Zealand wide, that was for me one of the key criteria in health was that there was fairness to access, because although not everybody would necessarily end up with the treatment, there was access to the treatment. (Interviewee F)

'F' was asked if the Minister can have any effect on the operations of PHARMAC, specifically the Community Exceptional Circumstances policy. 'F' preferred the model of separation of powers where the Minister did not intervene with PHARMAC decisions. When asked what influence the Minister can have on PHARMAC, interviewee 'F' answered:

Not a lot, if you're going to believe in the model. Certainly they can tell, they can express views on what's happening and so on, but actually you want to avoid where possible a political decision on pharmaceuticals. (Interviewee F)

Interviewee 'F' raised the issue of PHARMAC's transparency and relationship with the public and how PHARMAC was perceived.

Because that was where the problem arose, the feeling that PHARMAC is a closed shop...of the public that they [PHARMAC] didn't listen and so on. (Interviewee F)

'F' was also pleased that PHARMAC were able to handle pressure from interested groups and lobbyists and was able to be a shield for political pressure on the Minister.

It's a huge political problem if you're the Minister, and it's always good if you can have others make the decision that you don't have to

make. And so PHARMAC has been a huge shield for Ministers, 'cause we can say, "That's a PHARMAC decision"...it's been made independently based on the best research and the best information, knowledge, international. (Interviewee F)

These decisions were made by the past or present Minister as a result of pressure from patient advocacy groups. 'F' justified this by saying that the PHARMAC Committees had recommended the listing of the drugs and the PHARMAC Board had refused, and on occasions Ministers had decided to intervene.

Q *What level of unfairness would it take for you to intervene as Minister?*

A *Wouldn't necessarily only be unfairness... if there was a strong case put by, evidence based, for example PTAC said, "This ought to be funded," and the [PHARMAC] Board said, "No we can't, or we won't, we've got other priorities," that would be one criteria because I feel as a Minister I was on sound ground with the best brains looking at the international research that said we should do it.*

Q *What grounds convinced you to act?*

A *It would be...clinical effectiveness, I think it has to be. I think that a group of advocates like the [name withheld]⁵⁸ people that have strong evidence, they did a lot of the collation [of evidence] they almost became the clearing house for everything that came in...I would have wanted them to be listened to, but I would, intervene into PHARMAC's decision making, so long as it's transparent, open and there is an element of consultation and so on in it, I think it's held us in pretty good stead. I think in special circumstances that there are things that they ought to look at. It was such a delicate balance between interfering and not interfering, it was so finely balanced you could have unravelled PHARMAC very quickly, and there was a stage where it looked like the opposition was going to attack PHARMAC and wanted to change it. (Interviewee F)*

⁵⁸Name of organisation withheld to protect the identity of the interviewee.

Interviewee 'G': "... too small... too few... too hard... too bad!"

The New Zealand Organisation for Rare Diseases (NZORD) has many times applied for Community Exceptional Circumstances subsidies over the last 7 years and has only been successful once in gaining a subsidy for any of its members⁵⁹. The reason given by NZORD is that PHARMAC usually advise the claimants there is insufficient information submitted on which to make a decision on their claim.

NZORD claims that the diseases suffered by their members are so very rare and often so clinically complex that the Community Exceptional Circumstances Panel either does accept the evidence or does not have the experience to properly comprehend the evidence which is submitted.

The main reason why PHARMAC rejects our applications is because they say there is not enough information on which they can make a decision about the drugs which we are applying for. Quite frankly, some of these conditions and drugs are so rare that the adequate amount of information the PHARMAC Therapeutic Advisory Committee (PTAC) require to consider would take 30 years to develop or would never be developed... this situation causes people to wait interminable or even indefinite periods until such time as information is available. Obviously this could be life limiting or cause death

and

In a way, lots of things which we are going to treat require more information, but really, how much information does one need. For example, if these drugs are available in other countries particularly the UK, Australia and the United States, and people are deriving a benefit from taking these drugs, we would claim the experience of these countries should go toward the experience of the conditions in New Zealand. PHARMAC says no

⁵⁹At the time of this interview in 2010.

and

PHARMAC is not above rationing by confusion, procrastination or bewilderment. Rare disease it can be...“too small, too few, too hard...too bad!” (Interviewee G)

This is seen by NZORD as a form of rationing the available resources for Community Exceptional Circumstances claims because five or six claims for the treatment of extremely rare disorders could deplete the whole Community Exceptional Circumstances budget of \$3 million in one year. This means, as Interviewee ‘B’ stated, the criteria for Community Exceptional Circumstances subsidy are more for managing the allocated budget than deciding the claims on the basis of procedural fairness of the criteria.

The interview explored what is meant by fairness in the context of having a very rare disease and requiring expensive treatment funded by the state. ‘G’ felt that fairness was an avoidance of, and a freedom from, discrimination. When PHARMAC says to NZORD members that their medical conditions are too expensive to treat, then ‘G’ believes this situation amounts to discrimination.

PHARMAC tends to deal with these problems in a somewhat cavalier fashion and the discrimination is based on what we believe to be unreasonable decisions. Public law requires that agencies act reasonably and in the end this is really an unacceptable level of discrimination...if life is to be saved by medical interventions and PHARMAC is not going to provide these interventions and we would say the client is being discriminated against. Rights are not determined by what it costs to exercise the right. (Interviewee G)

Interviewee ‘G’ had a lot to say about PHARMAC’s use of cost-utility analysis in dealing with NZORD members claims for Community Exceptional Circumstances for unsubsidised medicines.

They are using cost-utility analysis, QALYs and DALYs⁶⁰ as legitimate and useful tools. But they are only tools and they cannot be the only thing used in the decision making process. Cost-utility

⁶⁰DALYs refer to disability adjusted life years. This much criticised measure attempts to understand the costs associated with the burden of disease on health care funding organisations.

analysis is simply an analysis of cost and tries to measure out a useful gain of using one medicine against another, or against other things. (Interviewee G)

'G' felt this approach unfair because in almost all of the NZORD cases where cost-utility analysis has been used there were no appropriate alternatives to compare the claimant's application. Therefore, there was no rational basis to compare equivalent costs. This meant that the Exceptional Circumstances Panel had only gross figures of the cost of medicines which appeared to them to be far too high. The other concern 'G' expressed was the narrow range of information which went into a cost-utility analysis. The costs to the patient and the family were not considered and 'G' believes they should have been.

'G' was concerned at the apparent high weighting given to the cost-utility analysis compared to the eight other decisionmaking criteria. 'G' stated that because there was no way of knowing exactly how the decisions on the criteria are weighted by PHARMAC, this caused inconsistency and suspicion. According to 'G', other values were as important, if not more important than the cost-utility analysis.

Well, like I said I think cost-utility analysis is a useful tool, but it cannot completely replace or over-ride other things that really matter for example...ethics matter, values matter, cost to the patient matters, community attitudes and values also matter. These are not considered in a cost-utility analysis and I think they are just as important in deciding what to fund. The problem is these things are not easy to agree between people on their relative importance. (Interviewee G)

'G' referred to NZORD advocacy for a man who had a rare form of brain cancer who applied for a Community Exceptional Circumstances subsidy for a drug to give him greater quality of life. PHARMAC denied the application because the cost-utility analysis showed the cost to be above the allowable maximum. The man died. The public, politicians and the media continued to pressure PHARMAC who then acquiesced and a short time after the man died, they began funding the drug.

This case demonstrated that the cost-utility analysis and budget management did not take into account the bigger picture and the ethical and social considerations. They looked at what they were prepared to see...not the benefit to and their duty to the individual. Quite tragic really. (Interviewee G)

The issue of the adequacy of PHARMAC's Community Exceptional Circumstances budget was raised by 'G'. The savings which have been made by PHARMAC, by their aggressive purchasing strategies, should be redirected into paying for the subsidies on medicines of individual people suffering rare disorders.

Compared to Australia, the amount of money available for the treatment of rare diseases with high-cost medicines is relatively three times greater than the money available in New Zealand for Community Exceptional Circumstances subsidies.

The Australian Benefits Scheme has put aside about \$40 million for rare and exceptionally high-cost medicines for very low numbers of applicants in a life-saving drugs programme. They recognise that even if the numbers are small, there is still a responsibility on behalf of the government to provide healthcare...they fund it this way. On this basis, we should have a fund of about \$8 million for high cost medicines just for that handful of particular diseases. Exceptional Circumstances budget in New Zealand is tiny...three million.

and

Yes the problem is that ethics and values and all that discussion we can all have about where the greatest level of justice or...fairness lies...but if the money is not there the money is not there. That is why it is essential that government increase the total amount in the budget, as a major part of the solution to these issues.

(Interviewee G)

The discussion with 'G' traversed the ground of what PHARMAC defined as exceptional and why the definition of rarity should be 10 cases or less in New Zealand at any one time.

It is ludicrous...well they have this number [10] now, and I think the number is completely arbitrary and some cases will be exceptional and there will be less than three people in New Zealand with this very rare disease and some cases will be exceptional for other reasons. There might be a hundred people with the disease being exceptional. One of our problems is that the conditions are for such few people that double-blind trial studies are so small that they lose validity. (Interviewee G)

'G' believes that PHARMAC would rather take the line that the treatments are not clinically proven to cover for the real reason that the budget simply cannot sustain the high costs involved.

I recall in some conditions Community Exceptional Circumstances would be the right thing to do...in one case they would not agree to fund a few children with a rare genetic disease. This would have placed about \$10 million a year on the books. They simply said... "We agree that Community Exceptional Circumstances ought to be approved in these cases, but we simply cannot fund that. There is not enough money'. (Interviewee G)

Finally, 'G' raised the issue of the New Zealand Medicines Strategy of which NZORD was one organisation that lobbied the government to develop. 'G' said that if PHARMAC and the DHBs had adhered to the principles underlined in the Medicine Strategy, the commitment to funding medicines for orphan diseases would be met.

The Medicine Strategy provides a set of criteria to guide decision making that includes the relative benefits that come from cost-utility analysis, but also includes factors like ethics, community values, affordability, fairness and the health needs. The strategy tries to balance these factors with the cost-utility analysis approach and

budget management. It says this broader way of thinking should apply to all decisions being made on all medicine issues.

and

The problem is that PHARMAC wants to avoid any kind of constraint, and soon after the Medicine Strategy was published it made it clear they would not be changing their decision making criteria. It believes that the PHARMAC Board can consider the ethics and community values but they make no effort to discuss or debate how they should be applied, and they continue to focus strongly and narrowly on cost-utility analysis and budget management, and they stick to their particular agenda... [however] this is about balance it's not just about budget management and rationing tradeoffs through cost-utility analysis and negotiating with suppliers. It is clearly about balance and so is the medical strategy but this has made no difference to the narrow focus PHARMAC has. (Interviewee G)

Interviewee 'H': "Just following the process and the rules is probably the least effective way of working with PHARMAC."

Interviewee H was a past or present employee of the New Zealand AIDS Foundation with a long experience of managing the relationship between the foundation and pharmacotherapeutic companies, clinicians, members, patients and PHARMAC. 'H' had experience of both the Community Exceptional Circumstances policy and the PHARMAC funding schedule applications for medications involved with the treatment of AIDS in New Zealand and internationally.

The interview began by exploring Interviewee 'H's' experience of Community Exceptional Circumstances claims. 'H' did not have a positive experience of the process.

Q *Can we start with your experience of Community Exceptional Circumstances and PHARMAC?*

A *Sure, well when I came on board ...my predecessor was dealing with PHARMAC through Community Exceptional Circumstances and the*

process did not seem to be progressing. I had a good look at the applications and realised that this was in my estimation just too hard...rather cumbersome and quite difficult to get the outcome that was desired in a timely fashion.

Q *So you have done some [Community Exceptional Circumstances applications]?*

A *Yes, but I generally go through a slightly different process which is more lobbying, talking to pharmaceutical companies, encouraging them to give compassionate access, then when it comes time for the funding application we ensure that we have a conversation with both parties. This is usually a more successful avenue than going through the Community Exceptional Circumstances process. (Interviewee H)*

'H' found out that PHARMAC's application of its rarity criteria was a major reason why they have not been successful in obtaining Community Exceptional Circumstances claims for HIV and AIDS sufferers. This is what 'H' had to say about how hard the process was for them:

Q *Why is it hard?*

A *Well it's hard because of their defining criteria. Particularly rare, less than 10 people with HIV? We have got 33.4 million people around the world, so it's not a rare condition. The numbers of people in New Zealand are quite small, but it is still not classified as a rare condition.*

Q *Is that what stumps you?*

A *That's a huge stumbling block...by only allowing it to be for a rare condition. And everyone has a different understanding of what 'rare' is. Rare globally or 'rare' in New Zealand? Is it 'rare' within a specific demographic or ethnic group? So 'rare' is a catch phrase which can be used to stop you in a number of different ways. (Interviewee H)*

The example of the successful gaining of a Community Exceptional Circumstances subsidy for an AIDS drug named Kaletra was raised with 'H'. The discussion lays out the history of the claim and the result.

Q *Do you recall the Kaletra issues and the Community Exceptional Circumstances application?*

A *I do recall it, yes. When I came in to the Foundation, the [Community Exceptional Circumstances] application had already been submitted. I came in on the back of that process. My predecessor was the one that actually did the submission. I came in and it wasn't really going anywhere. Yes, the process at that time had not worked through the Community Exceptional Circumstances process ...it is a hard ask at the best of times.*

Q *However, the Kaletra example is where PHARMAC stepped outside from the Community Exceptional Circumstances criteria?*

A *They did. This [application] in the end was not worked through the Community Exceptional Circumstances process as you would expect. The relationship stuff has a huge impact in New Zealand. It is such a small country...90% of it was talk to the pharmaceutical companies, talk to the specialists, do some lobbying with guys like Peter Dunne⁶¹, get the word around...so that was fairly easy to get through by negotiating with PHARMAC but again I think it would have been a very different story if we had have gone down the Community Exceptional Circumstances road alone. (Interviewee H)*

The Foundation had such little faith in the Community Exceptional Circumstances process that when a case came along where the AIDS Foundation had a good chance of gaining a Community Exceptional Circumstances subsidy, they did not make an application. 'H' describes why.

Q *But for your Foundation it is a far more agreeable process to go straight for scheduling of drugs and forget about Community Exceptional Circumstances altogether?*

A *Yes...I have found this is the best way ...for Fuzeon, it is an injectable antiretroviral, and we worked with the pharmaceutical company to get access to the drug on compassionate grounds... until such time as we got it through... we got it through fairly quickly as*

⁶¹Hon. Peter Dunne is a Member of Parliament who leads the United Future political party. He held the position of Minister of Revenue and Associate Minister of Health (posts outside of Cabinet) until November 2008. He has had a particular interest in PHARMAC over his political career.

salvage therapy because only half a dozen people in the country need it... it is not a particularly nice drug to use... injections every day, quite nasty... leaves a big lump under the skin and it has some side effects... so PHARMAC can reasonably fund it because they know the pharmaceutical company is never really going to take the drug to a wider market. (Interviewee H)

This example shows that the Foundation did not use the PHARMAC policy settings when the rarity criteria could have easily been demonstrated. Similarly, 'H' had little regard for PHARMAC's cost-utility analysis system of calculating costs and benefits which inform the Community Exceptional Circumstances process.

'H' was critical of the cost-utility process exclusion of personal and family costs which have to be met by the patient applying for a Community Exceptional Circumstances claim.

Q *Do you know what goes into the cost-utility analysis?*

A *Yes it is ridiculous that the personal costs of patients and their families are excluded. I have never understood why that should be so. This is an example of PHARMAC saving money on the front end and it costs you money in the long run. Sadly it costs the patient and not PHARMAC and not everyone has the same ability to pay those costs, particularly some AIDS HIV patients. I can't find many people that support it [cost-utility analysis].*

Q *So what does the cost-utility analysis say about fairness?*

A *Well I pay my rent, my taxes, support my family, but if I were to come sick tomorrow, seriously impacting on my [family] I would want the best care and I don't think that QALYs or cost-benefit studies would really convince me of otherwise. (Interviewee H)*

It was evident that despite 'H' being a health professional advocate with many years experience working in several countries in senior positions, 'H' was not able to understand how PHARMAC's cost-utility analysis process worked.

Q *Can I ask you about PHARMAC's cost-utility analysis process? What do you think of their process?*

A *Well the whole use of QALY's is hugely debatable depending on which health economist you talk to...seem to have a different view of how QALYs should be worked out. I have sat in presentations from PHARMAC where they have got the guy saying this is the reason why we need to do A, and someone else has got up using exactly the same data and said this is why we need to do B. If you are not an expert in economics, which I am not, you have to take the word of the so called experts, and this is very difficult when you get very conflicting views.*

Q *Do you know what goes into the cost-utility analysis?*

A *No not really, I have tried to understand the PHARMAC process but I find it very confusing and I get very lost very easily and I have a good knowledge of clinical information.*

and again

I would probably say that the cost-utility analysis is just another way of saying no! (Interviewee H)

On the subject of fairness, interviewee 'H' had some interesting things to say about his/her understanding of fairness in relation to the implementation of the PHARMAC policy.

Q *Let's talk about this in relation to fairness. How would you define fairness?*

A *To me fairness is having criteria that are set up that include an ethical component. So when they are looking at the whole submission itself, the submission process is taking into account how this is going to impact on families, communities and it's a fair process. But the process itself is fixed*

and

It's not one where the Minister can come along later and just override the process...that's not fair. It's very nice for the people who have that particular need and have the Minister's ear, but it is not a fair process. Fair is being open, transparent, its being really clear upfront about what's being looked at, not changing the guidelines half way through the process. (Interviewee H)

These were interesting comments because 'H' contradicted the stated notions of fairness by several times alluding to the fact that the AIDS Foundation do not work within the Community Exceptional Circumstances system. 'H' preferred not to use the policy because of the belief that there was a basic unfairness of the system. 'H' preferred to use the political influence of the AIDS Foundation on the Minister and on the PHARMAC managers to obtain subsidy for both small numbers of clients and large groups of AIDS sufferers.

Well yes, but I have done a lot of that behind the scenes...but my attitude is slightly different...yes, I manage the piece of paper... but 90% of my activity is behind the scenes. The best way to do it is to avoid...[name of PHARMAC personnel withheld]...but go straight to...[name of PHARMAC personnel withheld]...and we would just press our case.

Q *What does that say about these criteria that PHARMAC use, both for Community Exceptional Circumstances and for placing drugs on the schedules?*

A *...arhhh...they are just a means of enabling PHARMAC to say no when they want to.*

Q *Are there really rules by which the systems operate?*

A *Well there might be a few people that think that ... but I take a fairly pragmatic view of PHARMAC and I have found the way to get things funded with PHARMAC is essentially political. I just prefer very different processes...mainly because we have found that this way works. Just following the process and the rules is probably the least effective way of working with PHARMAC. It is a sad state of affairs but at least there is a process and if you are not hooked in...the majority of people don't have the ability to get hooked into*

...successfully...for things especially for Community Exceptional Circumstances. (Interviewee H)

Interviewee 'H' discussed opinions about the New Zealand Medicine Strategy in relation to the activities of PHARMAC. This is what Interviewee H had to say about the Medicine Strategy.

Q *Tell me about your views on the medicine strategy. Did it make any difference to PHARMAC's operation of policies such as the Community Exceptional Circumstances scheme?*

A *Did it make any difference to PHARMAC?... I think the medicine strategy gave PHARMAC an opportunity to meet a set of standards that weren't there before. I don't think that PHARMAC has met those standards. But there is the opportunity to meet standards, whereas before [the Medicine Strategy] there were no standards. I see that they have an inspirational goal now.*

Q *The Medicines Strategy requires or encourages PHARMAC to at least think about ethics, values, community values, what is fairness...how should we be rationing... what do you think about their progress in doing this?*

A *Well, they haven't got there yet. I think they have got the framework...but I think that it all depends on the willingness of the people in PHARMAC to actually do this. We never know how they are doing this in the day to day decisions they make. In some ways, I think it comes down to the individuals that are employed. I suppose ...PHARMAC as an institution on the one hand and the people who work within PHARMAC. We could do with some new faces within PHARMAC. There are some people who have been in roles for a very long period of time. (Interviewee H)*

Finally, interviewee 'H' discussed the PHARMAC decision making criteria in relation to the PHARMAC budget. Interviewee H stated that if the PHARMAC budgets are strained and PHARMAC cannot afford to fund either a Community Exceptional Circumstances claim or put a medication on the schedule, they tend to apply the criteria strictly in order to justify a 'no' decision.

Q *There is a limited budget for Community Exceptional Circumstances...\$3million. Have you ever experienced a case or cases where the Exceptional Circumstances Panel has said “Yes this needs to be funded for this person, all the criteria are met”... and PHARMAC managers or Board say “No, we can’t afford it” ?*

A *Yes on Community Exceptional Circumstances once, but I very well recall that both PTAC Committee on antiretrovirals said PHARMAC should fund Raltegravir and Duranavir. Both went forward with strong recommendations to be funded together ... it was proven by good international research that they work well in combination. PHARMAC chose to fund Raltegravir and not Duranavir. They cherry picked...disregarded the clinical evidence for financial reasons.*

Q *What does that say about these criteria that PHARMAC use, both Exceptional Circumstances and the schedules?*

A *...they are just a means of enabling PHARMAC to say “No” when they want to. (Interviewee H)*

Section 5: Request Under the Official Information Act 1982

As described in Chapter 4 (Methods), documents which are held by government departments and Crown Agencies are available to members of the public under certain opportunities and conditions provided by the OIA. Significant use of this method of gathering official information has been made by academic researchers, politicians and members of the press (White, 2007). Members of the public also use OIA requests for their own political, legal, commercial or general interest purposes.

This section of the thesis examines the five requests and reports on the material which was made available by this method of data procurement. Some of the documents were provided in hard copy and some by Word or PDF files. I entered the Word documents into NVivo 8 as sources, but PDF files cannot be entered into NVivo 8. Consequently, I typed the relevant material into a table and then entered it into NVivo 8 as a source.

This was also done for the hard copy documents which I received. In this way, all the material was captured on Word files. The sources were examined line by line and coded into the appropriate Nodes.

The following is a description of the material which was received from the OIA requests.

First Official Information Act Request to PHARMAC

In my letter to PHARMAC in September 2008, I requested policy documents which PHARMAC possessed on the preparation and implementation of the Community Exceptional Circumstances, Hospital Exceptional Circumstances and Cancer Exceptional Circumstances policies. I requested PHARMAC Board minutes which discuss Community Exceptional Circumstances policy or cases. I also asked for any papers, letters or journal articles written by PHARMAC staff and published by PHARMAC on Community Exceptional Circumstances, Hospital Exceptional Circumstances and Cancer Exceptional Circumstances.

PHARMAC's Chief Executive, Matthew Brougham replied releasing draft papers, papers, letters, e-mails, articles and file notes relating to the requested material. A number of documents and sections within those documents were withheld. Some information was withheld because it was unrelated to the request. Other material was withheld because PHARMAC considered it necessary to protect the privacy of natural persons⁶². Other material was withheld to maintain the legal privilege of staff or persons related to PHARMAC. Finally, some material was withheld because to release it would have, in the opinion of the PHARMAC Board, restricted PHARMAC's ability to maintain and conduct effective public affairs through free and frank expressions of opinions to the Minister of Health.

PHARMAC responded to this request by providing 64 documents consisting of 324 pages of material. Of the 324 pages, 32 pages had a section of the pages withheld and 34 pages were completely blank. In all, approximately 20% of the material provided in the 324 pages was withheld.

⁶² Clause 9(2)a of the Official information Act 1982 refers to protecting the privacy of natural persons, including that of deceased natural persons 'natural person'. The definition of this term refers to a human person not a group of persons or a corporate body or organisation.

The names of most of the PHARMAC staff have been deleted from these documents however many documents contained initials of the PHARMAC staff. An informed reader could, in many cases, decipher which person wrote the document or who was being referred to in the document. The names of many non-PHARMAC people such as the Regional Health Authority staff, medical and pharmaceutical interest groups and the Ministry of Health personnel were not withheld.

Official Information Act Request to the Ministry of Health

In my letter to Stephen McKernan, Director-General of Health, on 5th February 2009, I requested all reports and briefing documents which were given to the Minister of Health relating to PHARMAC's Community Exceptional Circumstances policy between 2000 and 2008. I asked for reports and advice which was forwarded to the Minister regarding the criteria for the appointment of the Community Exceptional Circumstances Panels, the names and backgrounds of all members who have served on this committee between 2002 and 2008.

The request also included all reports and advice forwarded to the Minister of Health or prepared by the Ministry of Health and reports to the Minister regarding PHARMAC's transparency and accountability to Parliament between 2002 and 2008.

Finally, I asked for a copy of the public submissions which were made to the Ministry of Health in relation to the Towards a New Zealand Medicines Strategy consultation document between December 2006 and March 2007. The Ministry of Health advised that the material in this request was available in the public domain on the Ministry of Health website. They also advised that they needed more time to consider my request and extended their response time by 20 days.

On 7th April Deborah Roach, Deputy-Director General of Health (Health and Disability Systems Strategy) advised that 12 documents were being released under the terms and conditions of the OIA in response to my request. Several documents were withheld because release of material would hinder the ability of Ministry of Health staff to maintain the conduct of effective public affairs and provide free and frank expressions of opinions to the Minister of Health.

The Ministry of Health could not locate any papers relating to the development of criteria for the selection of members for the Community Exceptional Circumstances Panels. It advised that the Ministry does not hold the names of persons who have been appointed to the Community Exceptional Circumstances Panels⁶³ and therefore could not provide them. This is most unusual because the Ministry of Health made all the recommendations to the Minister for Panel appointments.

The letter also advised that the Ministry officials had released advice prepared for the Minister of Health specifically relating to the Community Exceptional Circumstances policy and several briefing papers which were prepared for the Minister prior to meetings with PHARMAC, health advocacy organisations and the pharmaceutical industry.

In 12 reports provided under this OIA request, 147 pages were received. There were 25 pages with material withheld either as part of a page or whole pages. In all, 17% of the material was withheld. Several papers appear to be withheld because of commercial sensitivity. The Director-General of Health released draft papers, papers, letters, e-mails and file notes relating to the requested material.

All the documents were read and material which was pertinent to the Community Exceptional Circumstances policy was retyped into a Word file and coded into the appropriate nodes.

Second Official information Act Request to PHARMAC

In my letter to PHARMAC in September 2008, I requested under the OIA a copy of all written decisions made by any of the PHARMAC 'Community Exceptional Circumstances' Panels from 1st April 2009 to the 31st August 2009 and a breakdown of the annual amounts and types of subsidy or payment approved by any panel between 2000 and 2009. I understood that any names and addresses or other identifying information on these documents would be withheld. Secondly, I asked for any documents which identify instructions or

⁶³This is curious because during a Key Informant Interview one person who had been a member of the Panel said he/she was required to submit Curriculum Vitae to the Ministry of Health. The Ministry staff had stated to the interviewee that the CV would be held in case they wanted to appoint him/her to other expert PHARMAC panels. I did not know this at the time of the OIA request. Had I known this I would have pursued this point with the Ministry. This is not possible now because the time allowed for doing this under this OIA request rules had elapsed.

guidance given by the PHARMAC Board to any of the PHARMAC Community Exceptional Circumstances Panels from August 2000 to August 2009.

In response PHARMAC's Acting Chief Executive, Steffan Crusaz replied in response that:

The EC Panel does not write a 'decision' that explains the reasoning for its determination. When the EC Panel meets, its members discuss the application and agree whether or not the application meets the exceptional circumstances criteria for funding or not (or, in some circumstances the EC Panel may consider that it requires further information before it can make a decision). (S Crusaz PHARMAC)

The response to the second request for information identified any instruction or guidance given by the PHARMAC Board to any of the Community Exceptional Circumstances Panels. In response, Crusaz enclosed a briefing paper to the PHARMAC Board which was written in 2006 seeking resolutions clarifying the Terms of Reference and the financial delegations of the Community Exceptional Circumstances Panel.

PHARMAC released a breakdown of the annual amounts and types of subsidy approved by the Community Exceptional Circumstances Panels between 2000 and 2009 in an Excel spreadsheet. This is provided in Appendix 8 on the accompanying CD ROM. The data confirmed there are on average 450 applications each year which includes new and renewal applications. PHARMAC spends approximately \$3 million each year on Community Exceptional Circumstances. The table showed that in some years the \$3 million allocated to fund Community Exceptional Circumstances claims was underspent.

Official information Act Request to the Department of the Prime Minister and Cabinet

I wrote to the Chief Executive of the Department of the Prime Minister and Cabinet (DPMC) requesting under the OIA all cabinet papers submitted by Ministers which mention PHARMAC's Community Exceptional Circumstances and Cancer Exceptional Circumstances policies between 2000 and 2008.

I asked the Chief Executive of the DPMC for any documents which refer to the principles on which PHARMAC was required to make decisions and any public

consultation documents which related to Community Exceptional Circumstances and Cancer Exceptional Circumstances between 2000 and 2008.

I requested all government budget documents provided to Cabinet by the Minister of Finance which indicate the allocations made to PHARMAC for the purpose of funding Community Exceptional Circumstances and Cancer Exceptional Circumstances applications between 2000 and 2008.

Maarten Wevers, the Chief Executive of the DPMC replied that there were no documents at all which were held that fell within the scope of the request. He indicated that my request related to Cabinet papers which would have been prepared by officials for the Minister of Health and consequently my request was referred to the Hon. Tony Ryall, Minister of Health.

The Health Minister replied that no Cabinet papers were submitted by the Minister between the years 2000 and 2009, and no Cabinet papers or Ministers' recommendations which related to public consultation by PHARMAC between the periods. Consequently, there were no documents identified which could be released. Wevers similarly referred my request to the Minister of Finance, Hon. Bill English, because part of the request related to budget preparations and appropriations to PHARMAC. The Minister advised that in his opinion there were no documents which fell into the scope of my request; that is, that the information cannot be found or alternatively does not exist.

The Finance Minister went on to say that the public interest has been served under Section 9 (1) of the Act namely that:

Good reason for withholding official information exists...unless, in the circumstances of the particular case, the withholding of that information is outweighed by other considerations which render it desirable, in the public interest, to make that information available. (Hon. Bill English Minister of Finance)

In summary, as a result of this section of the OIA request, I was told that no papers had been received by the Cabinet or the Finance Minister relating to funding decisions related to Community Exceptional Circumstances and these matters had not been discussed.

Third Official Information Act Request to PHARMAC

I wrote to the Stefan Crusaz, Deputy Chief Executive of PHARMAC, in response to the second OIA request and the material PHARMAC had sent to me. I explained that I was particularly interested in how the Community Exceptional Circumstances Panel made decisions. I wanted to know how the Panel applied the criteria and how the Panel weighted one criteria against another. The letter I received stated that “the Community Exceptional Circumstances panel does not write a ‘decision’ that explains the reasoning for its determination” (Crusaz S, 2009).

However, the Terms of Reference – Procedure and Rules for the Community Exceptional Circumstances Panel (which were released under my second OIA request) in Section 10.1(a) [1] state that (among other things), “there is to be a full and proper record of the committee’s determination in respect of each applicant and the grounds for each determination made by the Committee” (PHARMAC 2009).

There appeared to be a dissonance between the rules of operation of Community Exceptional Circumstances policy and what was actually being done.

Consequently I asked PHARMAC as part of my third OIA request to provide eight recent examples of the Community Exceptional Circumstances Committee’s (or Panel⁶⁴) determinations in respect of applications for funding. I asked PHARMAC to provide four applications which had been approved and four applications which were declined. I asked for all the information which was put before the Committee (or Panel) for their consideration and a copy of any cost-utility analysis requested as part of consideration of any application.

In these eight cases, I requested evidence of the grounds for the Panel’s decision and reference to the criteria outlined in the Terms of Reference of the Community Exceptional Circumstances Committee (or Panel) as required in Part B of the committee’s Terms of Reference.

⁶⁴In the material released which referred to the recommendations made to the PHARMAC Board “Terms of Reference for the Exceptional Circumstances Panel”, PHARMAC some times refers to the ‘Panel’ and sometimes to the ‘Committee’.

The following information was received from Mathew Brougham, Chief Executive of PHARMAC.

When the EC panel meets via a two weekly telephone conference, its members discuss the application and agree whether or not the application meets the exceptional circumstances criteria for funding...the EC Panel Coordinator records the EC Panel's determination (by way of an "approve" or "decline") and is instructed by the EC Panel to write to the applicant to notify them of the decision.

and

Each application for Community Exceptional Circumstances is examined by the Panel in relation to each of the three entry criteria. If none of the criteria are met, this fact is stated in the letter of decline. This is the record of the grounds for the determination made by the Panel.

and

The Panel does not state in its response grounds on which an application is approved, but as each application is made under certain criteria the applicant can assume that ...the criteria was met if the application was approved. (Brougham, 2010)

PHARMAC provided the eight cases requested with the material required to meet the terms and conditions of the OIA; namely removing the identity of persons mentioned in the documents. One of the cases provided from the OIA request is attached as Appendix 7 to this thesis and the other seven cases are attached as Appendix 10 which is presented as PDF Files on the accompanying CD ROM.

Examination of the Eight Cases

The OIA response from PHARMAC produced eight cases which were Community Exceptional Circumstances application forms (with the names of natural persons withheld). The eight cases are discussed in the following section.

Case No. 1 (OIA Document No. 81) June 2010.

This claimant was a prolonged habitual intravenous drug user whose medical specialist applied to PHARMAC for Community Exceptional Circumstances funding. The claimant suffered a recent cardiac arrest and had an abnormal ECG (prolongation of the Q-T wave) indicating arrhythmia and ventricular

myocardial damage. It is believed that oral morphine substitute (methadone) is the cause of the Q-T prolongation. The woman had been diverting this drug by injecting the medicine intravenously and not taking it orally. Her specialist noted that she was at risk of septicaemia and endocarditis if she continued on methadone, particularly injecting it intravenously.

The patient requested that she be given more methadone treatment however the specialist believed this would be contraindicated. The patient's doctor made a Community Exceptional Circumstances claim for a drug named Suboxone. This is a home-based treatment of narcotic medication indicated for the treatment of opioid dependence and an alternative medicine to methadone.

The cost of the treatment was anticipated to be between \$3,790 and \$5,685 annually and the claim was for an indefinite period.

This claim was approved because it met the second criteria (criteria [b]) on the application form which states a 'reaction to alternative treatment unusual (unusual is considered <10 nationally)'.

However, the specialist submitted that she/he would expect to see this condition, requiring the recommended alternative treatment in 1:500 cases nationally. Based on this information supplied by the specialist, there are approximately 8,000 people who fall into the same category of illness as the claimant. Under PHARMAC's own clearly stated criteria this application should have been declined because the application failed the rarity test.

In the Clinical Benefit and Suitability section of the application PHARMAC requires the claimant to attach evidence that the requested drug is safe and efficacious treatment, and full journal articles are requested (not just references, conference presentations or abstracts). A higher degree of proof is required for unregistered medications or registered medications prescribed for non-registered indications.

In this case, no articles were provided with the application to prove that the requested drug was safe and efficacious treatment. If such material had been provided on previous applications for this drug, this was not told to the Community Exceptional Circumstances Panel in the application. The application form requires a letter from the treating specialist however none was provided

with the application. The discharge summary provided by the hospital was supplied instead.

Despite the required process not being followed in this case, the Community Exceptional Circumstances Committee approved the application. There are no reasons given or any determination about the criteria under which the claim was approved. The letter to the applicant simply states that “application for supplies of [Suboxone] ...have been approved ...based on the information you supplied” (Exceptional Circumstances Panel 2010).

The application was successful and the patient was notified through her GP.

Case No. 2 (OIA Document No. 82) May 2010.

This application for Community Exceptional Circumstances subsidy was for a patient with long-standing Lupus Erythematosus, a chronic auto-immune disease. She had been treated with hydroxyethyl quinine, prednisone and topical steroid ointments. These treatments were apparently not as effective as a one month course of chloroquine. The patient reported that she had been in the best health she could remember in the last 10 years on the trial of chloroquine. The anticipated cost of the drug was \$710.00 per year.

The specialist did not specify on the application form under which criteria the application was being made. The doctor attempted to establish that this was a rare condition by writing on the application form “only 2 cases I have treated” (Exceptional Circumstances Panel 2010). However the Lupus Care and Support New Zealand⁶⁵ organisation identifies that this condition is suffered by one or two people in every 1,000 New Zealanders. Consequently, there are between 4,000 and 6,000 sufferers with lupus in New Zealand and there were clearly more than 10 sufferers with this condition in New Zealand at the time of the application.

No articles were provided with the application to prove that the requested drug was safe. Neither was supporting data about the effectiveness of the alternate treatment supplied. There were two specialist letters to the patient’s GP provided with the application and no report from the specialist to PHARMAC

⁶⁵ Website (<http://www.lupussupport.org.nz/index.html>)

was supplied. Despite this, the application was successful and the patient was notified.

Case No. 3 (OIA Document No. 83) June 2010.

This is a case of a man whose specialist has applied to PHARMAC for a Community Exceptional Circumstances subsidy to treat dry eye syndrome caused by an ulcerated cornea. The ulceration was the result of a post-operative complication from surgery on an acoustic neuroma.

The drug the specialist applied for was hypromellose dextran eye drops; the trade name was Bion Tears drops. These drops are preservative free. The annual cost of Bion Tears was estimated to be \$546.00.

This application was made under two of the entry criteria: rare condition and reaction to alternative treatment. The application form does not indicate the prevalence or incidence of this post-operative complication from the surgery. No evidence is supplied supporting the rarity claim.

A retrospective study of the management of acoustic neuroma in the elderly by (Piazza, Frisina, Gandolfi, Quaranta, & Carlo, 2003) states that facial palsy is a common post-operative complication of acoustic neuroma surgery. The Community Exceptional Circumstances Panel did not have any evidence before them to establish if this was a rare condition (i.e., fewer than 10 people suffering this condition nationally). No articles were provided with the application to prove that the requested drug was safe and efficacious treatment. If such material had been provided on a previous application, this was not noted.

In regard to the application entry criteria relating to unusual circumstances, the application described the condition of dry eye and the ulceration of the cornea and how the patient had been helped with the preservative free eye drops. There was no description put before the Panel of what is unusual or what are the unusual combinations of clinical circumstances of the case. The application simply stated the patient was reacting to the preservative and is "...fine with Bion. Preservative free" (Exceptional Circumstances Panel 2010).

The application stated that the patient cannot afford the cost of the treatment however no information was put before the panel to substantiate this statement.

Again no report was attached from the specialist. Only a note to the patient's GP and a clinical summary of an examination carried out in an Accident and Emergency Department was enclosed.

The material put before the Community Exceptional Circumstances Panel failed to demonstrate rarity and failed to substantiate either the exceptional combination of clinical circumstances or that the patient was of insufficient means to purchase the drug himself. Whilst these conditions may be able to be substantiated, no material was given to the Panel on which to base their decision.

Despite this, the approval letter to the patient's doctor states that the application was approved "based on the information you supplied" (Exceptional Circumstances Panel 2010).

Case No. 4 (OIA Document No. 85) July 2010.

This is a case of a child with congenital nephrotic syndrome (Finnish Type) whose specialist applied on his behalf for a year's supply of Indomethacin at a cost of \$240.00 per year. The application was made on the basis of rarity. No information was provided to the Community Exceptional Circumstances Panel to substantiate the claim of rarity.

Congenital nephrotic syndrome (Finnish Type) is an autosomal recessive genetic disease causing severe nephrotic syndrome characterised by elevated levels of protein in the urine. The disease is diagnosable both in utero and after birth.

Niaudet (2004) discussed the incidence of congenital nephrotic syndrome (Finnish Type), citing the disease to be most common in Finland with an incidence of 1.2 cases per 10,000 live births. The incidence is much lower in people of other ethnicities (Niaudet, 2004). There are no data on how many cases exist or are being treated in New Zealand, however if New Zealand had the same incidence of the disease as Finland (which it does not) there would be approximately 42 cases in New Zealand. The Exceptional Circumstances Panel did not have any information in front of them to advise if the disease was fewer or more than 10 cases in New Zealand.

No information was provided on the application form about the rarity, reaction to alternative treatment or unusual combination of circumstances of the case. No articles were provided to prove safety or clinical benefit. No specialist report was provided to the Community Exceptional Circumstances Panel on the case. Only a note to the patient's GP relating to a recent out-patient's consultation was provided. No mention was made of any difficulty managing the patient or unusual circumstances which were prevailing. No mention was made in the note of the need to apply to PHARMAC for a Community Exceptional Circumstances subsidy. The only mention was the following comment to the GP: "Mum says she does have some problems giving him the indomethacin and there also has been a problem with supply more recently" (Exceptional Circumstances Panel 2010).

This comment indicated that the patient had already been prescribed the drug and the information supplied in the application suggested that this process was constructed to approve a subsidy for the medicine despite the application criteria and requirements not being met.

The application was successful and the patient was notified through GP. The Panel did not give any reasons in the letter as to why the application was approved.

Case No. 5 (OIA Document No. 86) July 2010.

This was a case of a GP making a claim to the Community Exceptional Circumstances Panel on behalf of a woman who was suffering interstitial lung disease with a pneumonitis believed to be induced by taking the drug Lefluromide. The 3 month initial application was made for a drug named n-acetyl cystine at a cost of \$412.00 for 100 tablets. The application noted that this drug could be sourced through a company named Life Extension Pacific Ltd for US\$ 21.50 for 60 tablets.

The application was made under the criterion of unusual combination of clinical circumstances. These circumstances were that the patient had developed rare side effects of pneumonitis as a result of taking Lefluromide and Methotrexate together whilst trying to manage her rheumatoid arthritis.

The patient was also prescribed prednisone to manage the inflammation (presumably in the lung and the joints simultaneously) and this was not considered a suitable regime to manage the lung disease on a long term basis.

The requested medicine was not registered in New Zealand for this indication. No supporting journal articles were provided to support the safety or efficacy of the proposed treatment. No information was provided about rarity or the unusual circumstances claimed in the application.

The applicants GP or specialist did not indicate why this was an unusual set of circumstances which would apply in less than 10 cases nationally. The application simply states that this set of circumstances is “unusual” (Exceptional Circumstances Panel 2010).

No specialist report or hospital discharge or supporting letter from the GP was supplied. The Exceptional Circumstances Panel had very little information on which to consider the criteria for a Community Exceptional Circumstances claim.

The claim was denied. The GP was informed that the claim did not meet the criteria for Community Exceptional Circumstances in that the condition was not rare, the response to alternative treatment was not unusual and the clinical circumstances described were not sufficiently unusual.

Case No. 6 (OIA Document No. 86) July 2010.

This is an application made by a GP on behalf of a man who has uncontrolled asthma and was unable to work because of it. The GP was recommending a Community Exceptional Circumstances subsidy of \$834.00 per year for a drug named Singulair.

The application is made on the grounds of an unusual reaction to alternative treatments such as Theothlyne, Flixotide, Seravent, Ventolin and Loratadine and the patient was on a long course of prednisone which was not satisfactory. None of these medicines have provided relief and the GP believed this to be an unusual set of circumstances.

The rarity is estimated by the GP to be 1:1000. No material was provided to the Panel to substantiate the rarity claim. Notwithstanding the lack of corroborating evidence, 1:1000 is estimated to be 3,500 people suffering this condition in New Zealand at one time. There are more than 10 people suffering asthma or the unusual circumstances the GP describes.

The GP did not provide any journal articles to show that Singulair is safe or effective in these clinical circumstances. No specialist report is provided the Panel only a discharge summary from Gisborne Hospital and two GP referral letters.

The Panel refused the Community Exceptional Circumstances claim on the grounds that asthma is not a rare condition. There is no comment from the Panel to indicate if the patient's clinical circumstances are considered rare.

Case No. 7 (OIA Document No. 87) June 2010.

This claim from a GP was on behalf of a woman who was suffering Barrett's Esophagus with gastro-oesophageal reflux. The claim was for the drug Losec (Omeprazole) at a projected cost of \$169.00 per year.

The claim made under the criterion that reaction to an alternative treatment is unusual. The treatments she had tried were Omeprazole, Pantoprazole, Ranitidine and Famotidine which were all ineffective in controlling her reflux. The GP states that the rarity factor is unknown.

No journal article is provided to demonstrate that the drug requested is safe and effective treatment for the condition the patient is suffering. A report from an investigative procedure, an Oesophagal–Gastro Duodenoscopy, confirmed very minor evidence of Barrett's disease and little else was seen. The specialist requested that the patient remain on Omeprazole.

In essence this claim was about the patient wanting funding for a different brand of Omeprazole.

The claim was denied. The GP was informed that the claim did not meet the criteria for Community Exceptional Circumstances in that the condition was not rare, the response to alternative treatment was not unusual and the clinical

circumstances described were not sufficiently unusual. Again, no reason, ground, rationale or elaboration on the criteria by the Panel was given.

Case No. 8 (OIA Document No. 88) June 2010.

This claim is made by a GP on behalf of a patient who was suffering from psoriatic arthritis and depression. The Community Exceptional Circumstances claim was made for a drug named Lyprinol, otherwise known as New Zealand Green Lipped Mussel Lipid Extract. The patient was taking Ibuprofen and Diclofenac and this medication was giving her diarrhoea and stomach ulcers. The GP wanted to try her on Lyprinol because he claimed that these are unusual clinical circumstances prevailing as a result of the current treatment.

The drug Lyprinol is not registered in New Zealand but it is registered for prescription in Australia. PHARMAC have removed the name of the specialist from this document, however the words “Rheumatologistrefer to OPD letter...” (Exceptional Circumstances Panel 2010) can be made out in the document supplied. This indicates that a specialist letter has been provided to the Panel but has been withheld in the OIA response. This is a shame because the specialist opinion would have been informative about the special circumstances which may or may not have applied.

The GP has provided eight published papers including journal articles to support the safety and clinical effectiveness of Lyprinol⁶⁶. These were:

1. An advertising flyer discussing the benefits of Lyprinol.
2. Certificate of Medicine Listing by the Therapeutic Goods Administration , Commonwealth Department of Health and Aging, Australia⁶⁷.
3. Blackmore’s Lyprinol packet information.

A study conducted at the Hong Kong Polytechnic University, Hong Kong SAR, China, by Chi-Ho, Hon-Kei Lum, Kin-Cheung Ng, McKay, Kwok-Chu Butt, Wong, and Chun-Lap Lo (2007) was published in eCAM Advanced Access on September 26th 2007. This is a clinical report of a randomised trial testing the effectiveness of Diclofenac, Lyprinol and a control of olive oil. The trial was carried out on adjuvant induced arthritis rats. The study confirmed the anti-

⁶⁶In fact the only claimant of the 8 cases discussed in this section to provide journal articles in support of the application.

⁶⁷Equivalent to Medsafe in New Zealand

inflammatory effects of Lyprinol, equal to the effectiveness of Naproxen and with long term pain control and anti-inflammatory effects (Chi-Ho, Hon-Kei Lum, Kin-Cheung Ng, McKay, Kwock-Chu Butt, Wong, & Chun-Lap Lo). Lyprinol had almost no side effects in the trial subjects in contrast to naproxen which can cause gastric distress, dyspepsia, reflux, vomiting, and diarrhoea and stomach ulcers.

4. A 12 week drug monitoring study which was carried out on Lyprinol by researchers at PhytoPharm Research Unit, Berlin, Germany (Gruenwald, Graubaum, Hansen, & Grube, 2007). The group studied 50 adult men and women suffering from inflammatory rheumatoid arthritis who were given Lyprinol. On completion of the study, 64% of the subjects reduced or terminated their current therapy and 13 of this group did not require any further treatment. At baseline, 60% of the subjects described their pain as severe however at the end of the study only 25% of the trial subjects were still in severe pain.

A study was carried out by McPhee, Hodges, Wright, Wynne, Kalifatus, Harney and Macrides (2006) at the Natural Products Research Group, School of Medical Sciences, Royal Melbourne Institute of Technology, Bundoora, and the Toxicology Key Centre, School of Medical Sciences, Ringwood, Australia in 2006. The study (McPhee, Hodges, Wright, Wynne, Kalifatus, Harney, & Macrides, 2006) showed green lipped mussels, when purified, were bioactive and potentially inhibiting to the COX-1 and COX-2 inflammatory enzymes and that Lyprinol was a competitive substance to other anti-inflammatory medicines.

A study was carried out by Treschow, Hodges, Wright, Wynne, Kalafatis and Macrides at the Royal Melbourne Institute of Technology, School of Medical Sciences, Bundoora, Australia in 2007 on the novel anti-inflammatory effects of Lyprinol. The study found that Lyprinol has a biologically significant homogenous series of novel omega-3 polyunsaturated fatty acids with significant anti-inflammatory activity.

5. A testimonial letter from Dr. Henry Betts, Department of Medicine, University of Adelaide, Australia in 2000 stating that Lyprinol produces significant anti-inflammatory effects, is comparatively low in fat, has extremely few side effects and is a cost-effective anti-inflammatory medication.

PHARMAC's Community Exceptional Circumstances Panel was unconvinced by the evidence provided and advised the GP that the claim did not meet the criteria for Community Exceptional Circumstances in that the condition of psoriatic arthritis and depression was not rare, the response to alternative

treatment was not unusual and the clinical circumstances described were not sufficiently unusual.

No reason, ground, rationale or elaboration on the criteria by the Panel was given. No comment was made in reply to the GP about the Panel's view of Lyprinol as an acceptable alternate to Diclofenac and Ibuprofen the patient was taking.

Fourth Official Information Act Request (MidCentral DHB)

Details of the fourth OIA request to Mid Central DHB are also presented on page 73.

On 6th January 2011 a letter was written by the Chief Medical Officer, Dr. Ken Clark on behalf of the Regional Cancer Treatment Service provided by MidCentral DHB. The service for cancer patients covers a population of 555,000 people over a catchment area which includes Gisborne (Tairāwhiti), Hawke's Bay, Taranaki, Whanganui and Wairarapa.

I requested the letter under the OIA. I also requested all the information which was placed before the decision making group of doctors by way of journal articles, studies, reports, letters to or from officials and emails. I wanted to enquire as to what evidence supported the decision.

I was provided with the letter in which Dr. Clark advised the health managers and Chief Medical Officers that the MidCentral DHB that some cancer patients were going to be 'triaged' or refused chemotherapy treatment.

The MidCentral DHB advised me that no written material was put before the decision makers by way of evidence. The decision was made on the basis of the doctors 'clinical experience'. This case is fully discussed earlier in Chapter 4 (Philosophical Framework).

Section 6: PHARMAC Initiated A Review of the Exceptional Circumstances Policy

In this section, I present data from a significant review which was carried out reviewing PHARMAC three Exceptional Circumstances schemes between November 2010 and July 2011.

The review was initiated following the recommendations of the Report of the High-Cost, Highly Specialised Medicines Review Panel commissioned by the Minister of Health in 2009. PHARMAC stated that the *Review of PHARMAC's Exceptional Circumstances Policy* was an opportunity to measure its implementation of the *Medicines New Zealand Strategy* document of the Ministry of Health and the accompanying action plan *Actioning Medicines New Zealand*. The strategy states that the government aims to take "account of and balanced against other health priorities, the medicines system is required to be responsive to individual variation, within a population focus" (Ministry of Health, 2006).

PHARMAC sought a broad range of feedback for industry and community stakeholders on the purpose of providing Exceptional Circumstances funding, a description of what constitutes exceptional and the preferred operational arrangements for the administration of funding under the Exceptional Circumstances policy.

In January 2011 PHARMAC published a document named the *Review of Exceptional Circumstances; Consultation on Proposed Changes*. In this document, PHARMAC outlined the nature of the feedback it had received in the review and the proposed changes to the existing Exceptional Circumstances policy. PHARMAC is seeking more feedback on these proposed changes and intends to have final Board recommendations available by late 2011.

In the consultation document PHARMAC proposed to abandon the current Exceptional Circumstances schemes (Hospital Exceptional Circumstances, Cancer Exceptional Circumstances and Community Exceptional Circumstances) and replace them with one new policy: Named Patient Pharmaceutical Assessment (NPPA). This scheme would have three pathways:

1. Unique Clinical Circumstances (UCC)
2. Urgent Assessment (UA)
3. Hospital Pharmaceuticals in the Community (HPC)

The UCC scheme is proposed to provide for individuals with serious and unique clinical conditions. These patients would not be part of a similar group in that

their clinical circumstances would differ from all others seeking that particular treatment. It appears PHARMAC is recommending an abolition of the '10 cases' rule to determine rarity and instead are recommending that clinical uniqueness be the entry criteria. PHARMAC states that in order to meet its statutory obligations, PHARMAC will assess whether they should fund treatments for people in this position. The scheme makes no reference to the principles of distributive justice.

The details of how UCC claims will be assessed have not been determined yet, but it is likely that PHARMAC will appoint a Panel to decide on each claim against its nine decision making criteria. Unless there is explicitness as to why the Panel reaches their decisions and openness in communicating these decisions to the claimants and the public, little will have changed from the current operation of the Community Exceptional Circumstances policy.

The UA scheme is a proposed pathway for individuals with serious conditions who might experience a rapid deterioration in their health or lose the opportunity for a quality of life improvement unless the treatment is provided. The patients in this category would be part of a group of patients with similar conditions where the treatment is potentially life-saving. It is likely that the treatment being applied for under the UA would also be subject to a full Schedule listing approval process. In these terms, the UA is to manage the requests for urgent treatment before the drugs can be listed on the Schedule. If the drug is assessed for listing on the Schedule and declined, then the UA subsidy for individuals who have been granted treatment under UA would be discontinued. PHARMAC state that this is because a patient in this position would be in no different position than a patient waiting for the Schedule approval for any other drug.

PHARMAC also proposed to set out the prerequisite criteria before an application can even be considered under the three new proposed schemes. Meeting the prerequisite conditions would not guarantee the approval of the claim; it simply means that the claim would be passed to the relevant panel for assessment.

In future, PHARMAC will not consider any application for UCC if the drug in question is pending a decision for listing on the Pharmaceutical Schedule.

PHARMAC propose to post a list of such drugs on their website and clinicians will be advised to check the list before making an application.

PHARMAC has recognised that the current Exceptional Circumstances policy contains some very unfair elements. The definition of rare being fewer than 10 patients with the same condition in New Zealand at any one time is simply not able to be managed. PHARMAC have also acknowledged that the application of the criteria has been inconsistent and they have not adequately communicated the reasons for decisions to the claimants.

There is also the recognition in the Review document that moral and ethical considerations do play a part in decision making. They argue that there must be fairness between the treatment of claims by individuals, groups of individuals and hospital patients. However, this does not deal with the inherent unfairness of limiting access to patients who suffer very rare diseases and are unique or part of a small group when the greater population has access to drugs under the pharmaceutical schedule simply because they are greater in number.

A press release in June 2011⁶⁸ by PHARMAC's Chief Executive indicated that PHARMAC had decided to increase the funding for the old Exceptional Circumstances Scheme (now referred to as the Named Patient Pharmaceutical Assessment scheme) to \$8 million per year. In doing so PHARMAC recognised that the current Exceptional Circumstances policy contains elements which were too restrictive for claimants. PHARMAC acknowledged the inadequacies of the current scheme, however they indicated that there is still no purpose an exceptional circumstances scheme could meet which would ensure that all people would be provided all medications which are needed.

Section 7: Regularly Occurring Themes from the Data

The regularly occurring themes which emerged from the thematic analysis described in Chapter 5 (Research Method) are presented here.

⁶⁸<http://www.pharmac.govt.nz/2011/06/27/NPPA%20release.pdf>

Theme 1.

PHARMAC has been extraordinarily successful at managing New Zealand's pharmaceutical budget by providing an adequate supply of quality pharmaceuticals for the lowest cost per drug category in the OECD.

Theme 2.

PHARMAC's Community Exceptional Circumstances is a rational way of managing exceptional individual claims, however the decision making criteria have been applied primarily to control PHARMAC budgets.

Theme 3.

PHARMAC is held accountable to the government through public policy reporting mechanisms, Parliament, the New Zealand Courts and the media. However, PHARMAC has regularly been criticised for not explaining its decisions to Community Exceptional Circumstances claimants and the pharmaceutical industry.

Theme 4.

PHARMAC does not have a stated philosophical position but operates as a utilitarian agency aiming to provide the highest level of benefit for the greatest number of people. It sometimes does this at the expense of people who have rare conditions or whose needs are considered exceptional.

Theme 5.

Ministers of Health King and Ryall have both intervened in PHARMAC's decision making process by directing that selected drugs be made available when PHARMAC had decided against the subsidisation of these drugs.

The Names of Each Theme

I have given each theme a name which captures the essence of the theme.

They are:

- Theme 1. PHARMAC the success story
- Theme 2. Inconsistently applied criteria
- Theme 3. PHARMAC is accountable
- Theme 4. PHARMAC - No stated philosophy
- Theme 5. Political interference in PHARMAC

In the next chapter, I discuss these themes (referring to the names of the themes) utilising the test-questions based on Rawls and Sen's principles of distributive justice to identify the content of distributive justice encased in these themes.

Chapter 7: Discussion

Introduction

In the Philosophical Framework in Chapter 4 of this thesis, I developed a series of test-questions which encapsulated the principles of distributive justice as described by Rawls and Sen. The Research Findings in Chapter 6 presented the regularly occurring themes that were extracted from the research data on the subject of PHARMAC's 'Community Exceptional Circumstances' policy.

In this chapter, I have chosen to use the test-questions as a framework for a discussion about the regularly occurring themes that emerged. I have used each test-question to examine the themes (as well as some excerpts from the literature) to demonstrate PHARMAC's performance⁶⁹. However I have made an exception in the case of Theme 5. I have discussed Theme 5 on its own because it relates to the actions of Ministers and PHARMAC had no control over these circumstances.

Test-Question 1

“Would the most advantaged in society accept this distribution if they, at an instant, found themselves to be the least advantaged in society and requiring such distribution for themselves?”

PHARMAC has two differing purposes under the New Zealand Public Health and Disability Act (2000). The first purpose is to manage the subsidisation of community and hospital pharmaceuticals within the budget that has been set by government. The second purpose is to manage the subsidisation of the

⁶⁹I have chosen to examine the test-questions against the themes not the themes against the test-questions. This is because the thesis question asks how PHARMAC's policy aligns with the principles of distributive justice. The question does not ask how the principles of distributive justice align with the PHARMAC policy.

pharmaceutical needs of people whose circumstances are considered 'exceptional' and whose needs are not able to be met by the first purpose.

Theme 1, '*PHARMAC the Success Story*' demonstrated the efficiency of PHARMAC's procurement policies. These were described as highly effective aggressive monopsonistic purchasing practices that have attracted both positive and negative international attention.

Cumming et al. (2010) commented positively on New Zealand Treasury's reports on PHARMAC. These reports showed that PHARMAC had limited the cost of medicines in New Zealand to an average annual rate of increase of 2% between 1994 and 2008. This compared with an annual rate of increase in the cost of medicines of 15% in the 1980s (Cumming, et al., 2010). Cumming et al noted that between 1994 and 2008 there was an overall annual rise in public health spending of 7.2%. Finally, their research has shown that as a result of PHARMAC's procurement policies, subsidy management and cost containment activities between 1993 and 2007, the New Zealand tax payer has been saved \$1.17 billion.

The OECD Report on Health Spending in 2010 described New Zealand as a country with the lowest cost per drug category in the OECD range of countries (OECD, 2010). PHARMAC has made a strong contribution to the New Zealand economy, and more particularly to health services, by providing access to medicines through subsidies at internationally lowest prices.

This success has been achieved largely by PHARMAC's use of the exemption from Part II of the Commerce Act (1986), which provides PHARMAC with the freedom to act in this manner. PHARMAC's procurement practices required sellers to group their patented drugs with generic drugs when negotiating purchasing contracts with PHARMAC. Sellers were also required to reference the price of all the drugs in each drug category to the cheapest priced drug. In addition, PHARMAC has extensively purchased generic medicines in favour of patented medicines. These practices have reduced the ability of the holder of

the intellectual property to recover development costs and profits from patented medicines.

PHARMAC has also made extensive use of sole supply purchasing contracts which exclude other companies after the deal is done (Cumming, et al., 2010). The winners of PHARMAC contracts are rewarded with the opportunity to provide medicines to the whole country without competition, and for a fixed number of years.

My research also uncovered criticism that PHARMAC is sometimes slow to list new drugs, particularly in comparison with new drugs listed for subsidy in Australia. This has on occasions been to New Zealand's advantage because some drugs PHARMAC has not listed have been listed in Australia and subsequently been withdrawn or replaced. PHARMAC has been criticised by the pharmaceutical manufacturing companies for refusing to include new drugs if the market was sufficiently provided for by drugs which are currently listed on the pharmaceutical schedules. It was claimed by manufacturers that this denied New Zealanders access to modern treatments (Pharmaceutical Research and Manufacturers of America, n.d.). My research also demonstrated that manufacturers and some physicians objected to the fact that PHARMAC's policies interfered with the patient - physician relationship and restricted doctors' autonomy to prescribe drugs they believed were the most appropriate treatment. However, evidence was also presented in the Ministry of Health documents released under the OIA by the Ministry of Health that PHARMAC does subsidise an adequate range of medicines and the needs of the New Zealand population for medicines have been very well met. This was confirmed in the public submissions received during the *Review of High Cost Medicines* which was conducted by PHARMAC.

The test-question asks if the most advantaged person would accept PHARMAC's practices if, at an instant, such advantaged persons became the most disadvantaged themselves. This question draws on PHARMAC's past

performance. Theme 1 *'PHARMAC a Success Story'* demonstrated that in relation to PHARMAC's first statutory purpose, PHARMAC has met the interests of the least advantaged in equal measure to the most advantaged.

PHARMAC's second purpose, to manage the needs of the people whose requirements are not able to be met by the general pharmaceutical schedule, is also examined by test-question 1. A person with a very rare disease and whose needs are truly exceptional would be considered disadvantaged in relation to a person who did not have a rare disease. Theme 4 *'PHARMAC-No Stated Philosophy'* demonstrated that PHARMAC did meet the needs of the wider population, but struggled to meet the needs of the few least advantaged people with rare diseases. PHARMAC's approach ensures that medicines required by those who suffer more common illnesses are subsidised in greater volumes and at a low comparative cost. The pharmaceutical needs of people with rare diseases, or diseases requiring very high-cost pharmaceuticals, cannot all be met by this micro-level rationing approach.

Much of the literature and several contributors to the research questioned the accuracy and fairness of the QALY cost-utility approach in determining the utilitarian position. The first concern was that QALY's cannot be accurately compared to each other, and, if this is a valid criticism, the whole basis for the cost-utility analysis may be fundamentally flawed. The second criticism was that QALY's failed to give consideration to the non-government (actual and opportunity) costs incurred by the patients. QALY's did not have the ability to measure the comparative value to the patient of being returned in a healthier state to the workforce and to the community. This is one of the primary purposes of healthcare. In these 'exceptional' cases, the costs and benefits are impossible to measure. Several contributors to this research stated that while such costs are very difficult to measure, even more difficult to compare, this does not mean these costs and benefits do not exist. It simply means that QALYs are an inadequate tool for measuring such desired outcomes.

The use of QALY's was tested in the Walsh v. PHARMAC case. The written judgment considered that PHARMAC had developed legally sound policies and procedures for deciding on exceptional claims. The court also found however that these legally sound policies and procedures were not always followed. Theme 2 *Inconsistently Applied Criteria* demonstrated that PHARMAC panels do not always adhere to the decision making criteria which are publicly promulgated.

PHARMAC's non-adherence to decision making criteria was demonstrated in the key informant interviews and the examination of the eight 'Community Exceptional Circumstances' cases that were released under the OIA. Without a demonstration of adherence to criteria, PHARMAC decision makers were shown in several cases to engage in what Daniels and Sabin (2008) refer to as "muddling through" decisions. Lindblom (1959) first introduced this idea of muddling through when he described this thought process as a praised and highly sophisticated form of problem-solving (Lindblom, 1959). Ubel (2000) also referred to muddling through as a pragmatic process where quite reasonable and acceptable decisions are commonly reached (Ubel, 2000).

Sen said that being vague about reasons for decisions can be a positive influence in decision making. In *The Idea of Justice* (2009), Sen referred to a jurist Lord Mansfield who advised that decision makers should consider each case and accordingly, decide what justice requires. Lord Mansfield also advised against giving reasons for decisions because the judgments will probably be considered right, but the reasons will certainly be considered wrong (Sen, 2009). It could be argued that the sentiment behind the Community Exceptional Circumstances Panel not recording their decisions and not giving reasons to unsuccessful claimants.

OIA documents from this research demonstrated that PHARMAC's decision making panels did express their sense for which decisions felt right and which felt wrong in these circumstances. Unfortunately, by not providing claimants

with the reasons for their decisions, PHARMAC created frustration and a perception that claimants had not been treated fairly.

Rasiah's (2009) thesis stated that 84% of 'Community Exceptional Circumstances' claims were unsuccessful and there was uncertainty for physicians (and patients) about the outcome for claims. In Chapter 5, interviewees reported that some doctors were able to 'game' the system and gained an advantage for their patients over other doctors' patients in similar circumstances. The 'Community Exceptional Circumstances' policy was described by interviewees as being an escape valve for PHARMAC and the royal road for the 16% of claimants who were successful in their claims (Rasiah, 2009).

PHARMAC's rational and analytical approach relied heavily on medical opinion about clinical effectiveness and on the economic evaluation by cost-utility analysis. Theme 2 *Inconsistently Applied Criteria* showed that these two criteria dominated decisions and at times were used as a proxy for budgetary constraint by PHARMAC. Yet budgetary constraint of these claims is exactly what PHARMAC needed to do to exercise its warrant under the governing legislation.

In summarising the test-question against the data of the research, a Rawlsian consideration of the advantaged and the disadvantaged has demonstrated that Community Exceptional Circumstances policy is fair to the majority because their pharmaceutical needs have generally been well met. However, the data have shown that there is considerable unfairness to the disadvantaged few who suffer rare diseases or whose needs are considered exceptional. Their pharmaceutical needs cannot be met, primarily because of the high costs to PHARMAC and the challenge to the general pharmaceutical provision.

Test-Question 2

“Is this distribution arranged so that it is attached to positions and offices which are open and accountable to all?”

Rawls identifies openness and accountability as necessary components of distributive justice. Test-question 2 explores these aspects of openness and accountability in PHARMAC’s operational processes. Again the regularly occurring themes are drawn on to give examples of PHARMAC’s performance in these areas.

PHARMAC is required to meet the highest standard of public accountability through public policy requirements of the New Zealand Public Health and Disability Act (2000), the Public Finance Act (2004), the Commerce Act (1986), the Official Information Act (1982) and the Crown Entities Act (2004).

PHARMAC also has public accountability touch points other than legislative requirements. These touch points are PHARMAC’s annual report and audited accounts presented to Parliament, PHARMAC’s appearance before the Health Select Committee, ministerial submissions, regular meetings with the Minister of Health, responses to requests under the OIA and PHARMAC’s contribution to the Briefing to Incoming Ministers. PHARMAC has also been involved in many court challenges from members of the public and the pharmaceutical industry. PHARMAC did not resile from legal defences of its allocative policies and practices. The majority of these legal challenges have been decided in PHARMAC’s favour.

PHARMAC has an extensive website and publishes information sheets assisting public submissions on pharmaceutical schedules, news about changing medicines, notifications and consultations, forms etc. There is a section of the PHARMAC website managing public consultation and encouraging feedback from pharmaceutical suppliers, health professionals, health interest groups and the general public. PHARMAC has occasionally run forums for the general public on matters which are of high public interest and

attempts to gauge public opinion from attendees at these forums. Added to this, PHARMAC has a series of seminars⁷⁰ for medical, nursing and midwifery prescribers and pharmacist dispensers. The series provides education on diagnosis and prescribing of medicines in a number of clinical areas and aims to promote the New Zealand Guidelines Group⁷¹ quality level of prescribing.

All PHARMAC's annual reports are available on their website, as are the minutes from the Consumer Advisory Committee and the Pharmaceutical Therapeutic Advisory Committee (excluding matters dealt with in-camera⁷²). There are opportunities provided by PHARMAC for contributors to submit their views on a wide range of subjects including funding applications and tenders to list drugs onto the Community Pharmaceutical Schedule. PHARMAC has conducted significant reviews, including a review of the Community Exceptional Circumstances scheme and given the public several opportunities to provide feedback on the position papers prepared for the reviews.

Further openness and accountability is demonstrated when PHARMAC officials are interviewed in the media. PHARMAC staff members are often contributors to the New Zealand Medical Journal (NZMJ) with research articles, occasional papers and opinion pieces, as well as responses to challenges in the NZMJ's editorials and letters to the editor. PHARMAC's research and literature can also be found in the British Medical Journal and other international peer reviewed health policy journals.

Notwithstanding the above, a different picture was painted by contributors to this research in Theme 3, *PHARMAC's Accountability*. This was a picture of dissatisfaction by some stakeholders at PHARMAC's failure to explain why it makes the decisions it makes. Specifically, the complaint was that unsuccessful

⁷⁰<http://seminarseries.pharmac.govt.nz/>

⁷¹<http://www.nzgg.org.nz/>

⁷²In-camera is a legal description coming from Latin meaning 'in a chamber' or 'in private'. In-camera describes the portions of meetings or whole proceedings of meetings, that the public or members of the press are excluded from. This is because these sections of the proceedings are likely to disclose personnel, financial, medical or other sensitive information which should be kept secret to protect the right to privacy of participants.

claimants (and unsuccessful drug company tenderers) could not know under which criteria their applications were or were not successful.

One contributor to the literature (Seddon, 1999) and a past or present Health Minister interviewee, pointed out that simply being explicit and open about decisions will not necessarily satisfy people that the right decisions were made. The media study identified Community Exceptional Circumstances claimants who were refused access to medication, who rightly or wrongly believed their lives were being unnecessarily shortened by PHARMAC's decisions. The main reason for their complaint was that they did not really know why these micro-level rationing decisions were made.

This same complaint was also made by drug companies and their representative body Medicines New Zealand, who sought to have new drugs listed by PHARMAC for subsidy. PHARMAC's approach to openness was also discussed by the NZORD. They stated that the PHARMAC's panel members do not listen to NZORD clinical experts or evidence of experience in treatment regimes from other jurisdictions. This lobby group complained that PHARMAC unreasonably delayed decisions and made unnecessary requests for information when the same medicines were accepted and listed in other comparable countries, for example Australia.

Curiously, evidence was presented in the key informant interviews and in the media stories that pharmaceutical companies sometimes encourage patients and their doctors to make Community Exceptional Circumstances claims about medicines that are available in Australia. This begins PHARMAC's assessment process and is a way of medicines becoming discussed in the media. This is an example of manufacturing companies not being open about their motives or the financial implications of their gaining favourable decisions.

In Daniels and Sabin's (2008) 'Accountability for Reasonableness' framework, they described the need for openness as an important element of a fair process. This element referred to the need to be public about the reasons and

rationales which play a part in decision making. The authors stated that where distributive justice is involved for groups or individuals, there should be no secrets. Claimants should not be expected to accept decisions that affect their well being unless they are aware of the grounds for making those decisions (Daniels & Sabin, 2008).

Other views of openness and accountability were uncovered, demonstrating that individuals and communities are ready to accept unpalatable decisions if the capability and the opportunity existed for them to debate the issues (Klein & Williams, 1998). This was not possible for unsuccessful 'Community Exceptional Circumstances' claimants because PHARMAC did not explain why they were unsuccessful in their claims and they had no information on which to discuss the fairness of the decisions that went against them. Lord Mansfield's view (Sen, 2009) that decisions are more explainable than reasons for decisions goes some way to understanding the making of unpalatable decisions.

PHARMAC have recognised their poor management of the 'Community Exceptional Circumstances' policy in the Review of Exceptional Circumstances Schemes conducted in 2010. One of the recommendations of the review suggested that PHARMAC identify which drugs are not being funded and which drugs are still under investigation. However, the subject that PHARMAC did not address was any requirement for improved openness by their committees of experts at times when they believe medicines would be effective for claimants, but the medicines cannot be afforded by PHARMAC.

To explore the balance here, it is useful to again think in the context of the two different purposes for PHARMAC in public policy terms. In relation to its first purpose, PHARMAC is required to be open and accountable to the government, the general public, community groups, the medical professions and the pharmaceutical industry. PHARMAC is simultaneously required by the NZPHDA (2000) to make allocative decisions on its \$680m annual budget

(2011-2012) in an open and transparent way and be accountable for the distribution of these funds. There is clear evidence that PHARMAC achieves this objective, notwithstanding the complaints from the pharmaceutical manufacturing companies who seek to gain access (or greater access) to this PHARMAC budget.

Test-question 2 then becomes a question not so much whether PHARMAC is an open and accountable agency, but how open is PHARMAC and how accountable is it? Papers uncovered through the use of the OIA and the Walsh vs PHARMAC judgment, show that whilst PHARMAC has legally valid policies and procedures it does not always follow them. The New Zealand AIDS Foundation submitted that they do not make 'Community Exceptional Circumstances' claims or engage in public consultation and debate in order to obtain subsidies for the drugs which are needed to treat AIDS in New Zealand. This is because so few cases are decided positively and the outcomes are so uncertain. Rasiah's (2009) research into 'Community Exceptional Circumstances' claims confirmed this point.

The decisions made by the Community Exceptional Circumstances Panel do have an impact on the Community Exceptional Circumstances budget and ultimately, PHARMAC's total budget. My research has shown that the decision making panels on occasions have decided that claimants have met the criteria for a Community Exceptional Circumstances subsidy, but the claim has been denied because of the fiscal impact of the decision.

The claim made by Alison Locke, who suffered from Pompe's Disease, was a case in point. Her claim for medicines met all the Community Exceptional Circumstances criteria, except the most important one; PHARMAC's affordability criteria. This was due to the high QALY cost of the drugs Locke needed to extend her life. The QALY calculation demonstrated that PHARMAC could not fund the medicines in subsequent years.

So, in the first purpose, PHARMAC is recognised as a very open and accountable agency. However, in the second purpose, particularly with regard to the operational management of 'Community Exceptional Circumstances', there is a tension for unsuccessful claimants between PHARMAC making decisions and describing why decisions are made. Rightly or wrongly, this leaves unsuccessful claimants with the impression that PHARMAC's decision making is a closed off, irreversible and unfair process.

In my view the data suggest that test-question 2 has explained PHARMAC's lack of openness when making allocative decisions and developed insight into how PHARMAC (and its allocative committees) work. The question has opened up the discussion about the relationship which PHARMAC has developed with the pharmaceutical industry, the general public and stakeholders with a specific interest in Community Exceptional Circumstances. This research has demonstrated that the reticence of PHARMAC to provide reasons for decisions have been shown to be understandable but in violation of the Rawlsian principles of openness and fairness to claimants.

Test-Question 3

“Is this distribution based on the efficiency of substantive opportunities and on procedural fairness in defining efficiency?”

This question based on Sen's principles, has two parts. The first asks how PHARMAC defines rationality (or manages the analysis of rationality) to ensure pharmaceuticals are available for the greatest number of people within the resources available. This first part of the question explores PHARMAC's management of relevant inequalities through the rationing of pharmaceuticals. Gillon (2006) has acknowledged that economists' interpretations of this position have come to mean some sort of comparative economic calculation of meeting need. PHARMAC has chosen the cost-utility analysis (QALY's) and the analysis of clinical effectiveness as two instruments by which it can measure the substantive opportunities of the pharmaceutical budget.

The cost-utility analysis system has been well discussed in this thesis and the strengths and weaknesses of the system do not need to be re-litigated here. However, Theme 4, *PHARMAC - No Stated Philosophy* confirmed that PHARMAC policies operate on a comparative cost analysis as the basis for its utilitarian decision making. Contributors for the research have stated that this criterion dominates all other decision making criteria. The reason for this is to enable PHARMAC (through its allocative committees and panels) to make decisions, the consequences of which do not exceed PHARMAC's budgets.

As far as the measure of clinical effectiveness is concerned in determining which medicines PHARMAC will subsidise, data presented in this research indicated that the use of committees and panels of experts to examine available research and published journal articles has served PHARMAC very well. The NZORD suggested that PHARMAC's panels may not be expert enough when dealing with very rare diseases. The McCormack Review of High Cost Medicines (PHARMAC, 2006) suggested that paediatric Community Exceptional Circumstances claims were not adequately understood by the panel members.

PHARMAC's non-economic criteria, which aim to meet the Medicine Strategy's aspirational goals, have been shown to be less important to PHARMAC than economic considerations. This raises the question why does PHARMAC have other criteria, if they these criteria can never override the affordability criterion?

One answer to this question is that PHARMAC's economic calculation is very important to Ministers as a political imperative. This was confirmed in the interviews with both past and present Health Ministers. They stated in Chapter 5 that despite the debate about cost-utility analysis and whether or not it was an adequate system, it is a system which is internationally recognised and does represent some level of comparative economic analysis. On this basis, Ministers stated that there was no political appetite to change this way of doing things. The Horn Report to the Minister of Health in 2010 sought to encourage

the government to extend the use of PHARMAC's cost-utility analysis processes (Ministerial Review Group, 2010). The report recommended other areas of public health and hospital procurement would benefit from creating PHARMAC-like savings. Since the Horn Report has been presented to the Minister of Health in 2011, the Cabinet has changed the role and focus of the National Health Committee (NHC)⁷³. Recently, the Committee has been directed by the Minister to concentrate on "value for money" and "prioritising" existing and new publicly funded health services. The aim of the refocus is to develop systems for evaluating new technologies and assist the health and disability sector to direct its expenditure in ways that make effective improvements to the health status of New Zealanders. Dr. Anne Kolbe⁷⁴ has been appointed Chair of the NHC. She is also a PHARMAC Board Member and brings to the NHC governance experience of decision making based on clinical effectiveness and cost-utility analysis. The NHC's Terms of Reference (published on their website⁷⁵) state that in prioritising services, the NHC will apply criteria, agreed to by the Minister of Health, which place a strong focus on cost-effectiveness and affordability. Equity and fairness are not recognised explicitly (or at all) as important criteria in the value for money equation promulgated by the NHC.

From the point of view of the individual (at the micro-rationing level), the use of the cost-utility analysis does militate against those who suffer rare diseases for which the treatment costs are very high. This was recognised by the McCormack Review of Funding for High-Cost Medicines in 2010. McCormack did not recommend the abandonment of the cost-utility analysis model, rather he suggested that high-cost medicines should not be treated any differently than lower cost medicines in that they should be subject to the same cost modelling.

⁷³<http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-aboutus-role>

⁷⁴<http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-aboutus-members>

⁷⁵<http://www.nhc.health.govt.nz/moh.nsf/indexcm/nhc-aboutus-tor>

Another form of decision making used by PHARMAC to determine allocations under the 'Community Exceptional Circumstances' policy has been the use of the definition of rarity, referred to in this thesis as the "10 cases" rule. This rule was applied to some claims and not applied to others. There was no rational basis for choosing this rule. A key informant interviewee said he/she felt the number 10 was a good idea and it "felt about right". Many contributors to this research stated that this was a mechanism for managing PHARMAC's budgets rather than a definition of the term exceptional. Contributors said that it would be better for PHARMAC to drop the '10 cases' rule and instead, where Community Exceptional Circumstances claims cannot be afforded PHARMAC should be open and say this is the real reason for the decision. Such an action would not please Ministers of Health, because pressure would be then directed at the government, implying that PHARMAC is not being provided with adequate resources to meet these exceptional needs.

The second part of test-question 3 asks if there has been general agreement on how these substantive opportunities have been assessed. Theme 4, PHARMAC - No Stated Philosophy demonstrated that there was a range of opinion in New Zealand about how one should measure the costs and benefits of such spending. Behind any measure of good, value for money or a general public good, is a value proposition of the social conditions (Cheyne et al., 2008), the nature of the problem and the remedy which should prevail. No one philosophical position is agreed to manage such a proposition, other than the broad acceptance that PHARMAC is doing a good job and so its processes are reasonably effective and reasonably fair.

Many contributors considered that the personal costs and benefits (to themselves and their families) should also be considered in the QALY measurement of the value of providing for meetable needs (Gillon, 2006) PHARMAC claims that the model must remain blind to a claimant's personal circumstances because to do otherwise would create unfair, un-measurable and incomparable results and this would invalidate the cost-utility analysis.

In summary, the data suggests that PHARMAC enjoys internationally recognised success at managing the needs of the wider population (substantive opportunities). There is considerable debate about the fairness and accuracy of the system used by PHARMAC to decide on costs and benefits. This system cannot guarantee fairness of decisions for small numbers of people whose pharmaceutical needs have a potential to exceed New Zealand's budget for medicines.

Test-Question 4

“Is this distribution based on information available to decision makers about the capability of this person to do things he/she has reason to value?”

This test-question asks if PHARMAC's decision makers know the capabilities of the applicants and what they have good reason to value in their lives. This question centres on the value of capabilities and the consequences on the lives of the people making claims on the pharmaceutical budget. Unlike Rawls, Sen contends that good health is an underlying liberty which is essential for the enjoyment of all capabilities. Consequently, Sen presents us with two questions. Firstly, do the decision makers know if the distribution will add to or subtract from the person's capability? Secondly do the decision makers know about the consequences on the lives of claimants requiring the distribution?

It should be noted that Sen's question does not ask decision makers which set of capabilities should be granted or provided for, or which values their decisions should develop capability for. Rather Sen's question asks decision makers do they have information about which set of capabilities the claimants feel are desirable and the consequences of the decisions on the person or their life. Sen asserts that without this information, distributive justice cannot be assured.

In examining this test-question, I will discuss PHARMAC's first purpose, to meet the pharmaceutical needs of the wider population. Secondly, I will

discuss how (or if) PHARMAC meets the needs of those who are described as exceptional.

Starting with PHARMAC's first purpose, as a Crown Entity it must provide access to the public for an adequate range of affordable pharmaceuticals. This focuses on the PHARMAC Board and staff having a system of identifying which medicines will meet the clinical needs of New Zealanders. This is done by PHARMAC operating an analytical system for deciding how to effectively meet these needs. Singer and colleagues (Singer, Martin, Giacomini, & Purdy, 2000) stated that the first step in deciding what should be done to make such decisions legitimate and fair, is to understand how groups such as PHARMAC make these allocative decisions.

At the meso-level, PHARMAC is required to implement the government's stated health strategies. PHARMAC has at its disposal the District Accountability Plans which are conducted by the 21 DHBs. PHARMAC also has access to the knowledge and experience of expert committees of medical specialists who are recognised as leading practitioners and academics in their clinical fields. They make assessments of the clinical effectiveness of medicines based on internationally available research and their own clinical judgment. To not do so, opens PHARMAC up to the possibility of spending tax payers' money on ineffectual treatments that only promise to add to a person's capability (Moodie, 2008). PHARMAC's approach comes down to quantifiable evidence of likely benefit verses a promise of benefit.

This is little comfort however to unsuccessful Community Exceptional Circumstances claimants whose applications have been ruled either unlikely to provide significant clinical benefit, or, medicines which come at too high a cost.

At the micro-level, having decided on the effectiveness of meeting particular health needs with pharmaceuticals, PHARMAC then engages in the cost-utility analysis to see if the cost of the drug is affordable within the resources allocated to it. Theme 4, 'PHARMAC - No Stated Philosophy' demonstrated

that in adopting the cost-utility analysis as the basis for a utilitarian approach, PHARMAC attempted to meet the needs of the greatest number within the budget provided to it. However, what was also established in Theme 2, Inconsistently Applied Criteria was that doctors acting either as advocates or as decision makers have no more understanding of moral content of allocative decisions than anyone else. This was clearly articulated by the key informant interviewee who had adjudicated on thousands of 'Community Exceptional Circumstances' claims. This interviewee stated that he/she was simply not equipped to rule on the fairness component of Community Exceptional Circumstances claims, only on clinical medical matters related to the claims. This discomfort may also explain why PHARMAC's Exceptional Circumstances Panel did not record their decisions in writing and why they did not disclose what relative weighting was given to each criterion. To do so would require panel members to articulate, for public gaze, the personal, moral and ethical positions which underpinned their decisions.

The second part of this test-question asks if decision makers know about the capability of the person to value the distribution being provided. The question explored what decision makers know about the people to whom they are providing access to pharmaceuticals. The test-question also asks what they know about the consequences on the lives of people who are granted or denied access to pharmaceuticals.

For example, a Community Exceptional Circumstances claimant with terminal cancer may claim that he/she has good reason to value the extending of his/her life for as long as possible with whatever medical or surgical interventions are available. Another person in similar circumstances may have reason to value refusing chemotherapy treatment and having a drug-free end of their life, albeit possibly a shorter life. Sen contends that decision makers should be in receipt of this information.

Test-question 4 also raises the problem of the QALY calculation being blind to the circumstances of the claimant's capabilities. When PHARMAC utilise the QALY calculation, it tries to quantify what contribution (or part of a contribution) a medicine makes to one added year of life. The NHC also intend to take this approach for the more general provision of health services. The second part of this approach determines the cost of adding a year (or part of a year) of life. As has been discussed previously, the cost-utility analysis only considers the quantifiable costs to the public health service in providing the treatment.

For example, the costs which are not considered in the QALY calculation are the costs to other government agencies of having a member of society out of the workforce. Similarly, there are financial and non-financial benefits to the patient of being an able family member and being able to work and contribute to society. One case in the media study described a woman with terminal cancer who requested a drug to enable her to cuddle her daughter. It was suggested that these non-financial capabilities that claimants have good reasons to value should be considered as well.

PHARMAC has strenuously avoided knowing these capacities because such commensurables are impossible to compare from one patient to another and the basic principle of a QALY (one QALY is equal in every way to another QALY) would be impossibly undermined. Secondly, if PHARMAC were to calculate the QALY's gained for people who cannot work because of reduced capability for example chronic illness or age, these people would be put at an immediate disadvantage to those who can work and contribute a measurable monetary value. Thirdly, people with co-morbidities, where several pathological factors are at play, would immediately be put at a disadvantage. This is because people suffering more than one condition may be considered of lesser economic value to society than a person with only one illness to contend with.

These examples are what Sen refers to as the underlying capability, that is valuing good health. This research has uncovered the many interpretations of

valuing health particularly faced by decision makers who are confronted with media attention or sustained political exposure. This was seen as pressure placed on PHARMAC to provide a subsidy for applicants whose applications have not passed the effectiveness and affordability test. If PHARMAC acquiesced to such pressure it would have to abandon the utilitarian principle and invoke the Rule of Rescue. The NICE in the UK has declared that it will not consider Rule of Rescue applications for pharmaceuticals. PHARMAC has also been resolute, sometimes evoking considerable unpopularity in applying the nine decision making criteria instead of reacting to Rule of Rescue claims.

The media study in this research identified leveraging off the anguish and heartbreak of tragic situations in which people have found themselves. The media presented the plight of the unfortunate person against the bureaucratic might of PHARMAC in an adversarial contest. Evidence in the research showed how PHARMAC staff members were personally pejoratively affected by this process. One PHARMAC interviewee described how he/she felt when a family brought an Alzheimer's patient into the PHARMAC offices to demonstrate the awfulness of the condition. The interviewee described this episode as being grossly unfair on both the manager and the patient, and personally upsetting for all involved.

The media stories showed that when PHARMAC adhered to its utilitarian approach by requiring satisfactory evidence of effectiveness and determined their inability to fund a drug, the patient was presented in the media as the loser and PHARMAC the winner. The media showed no concern if PHARMAC abandoned its rational approach and no concern for many other people with other conditions who may have been refused treatment on account of the cost of a mediagenic rescue.

It is a widespread human desire to want to save endangered lives and to do so in times of an emergency. This is the moral norm in medical fields and is also the compassionate proclivity of the media. But the cost of rescue, particularly

when there is no profound evidence that the life saving rescue will achieve a cure or even prolong life, is often done without too much thought for the opportunity cost of doing so (Moodie, 2008).

Several possible remedies to this moral difficulty have been suggested and are worthy of discussion. Hadorn (2006) suggested that PHARMAC should set aside 5% of its budget to subsidise drugs that it does not consider cost-effective but would meet the needs of claimants whose needs cannot be met by cost-effective medicines. In effect, this approach endorses wasting money because there is no effectiveness or efficiency component to the spending (Caygill, 2011). Hadorn does not give a rational explanation as to why 5% should be set aside. Caygill remarked that if PHARMAC is going to endorse non-cost effective spending then there is no rational basis for choosing 5% as opposed to any other percentage figure (Caygill, 2011).

The NZORD interviewee suggested that PHARMAC should significantly increase the budget for Community Exceptional Circumstances. The example of Australia was given previously, where the Australian Benefits Scheme (PHARMAC's equivalent) has put aside \$40 million for rare and exceptionally high-cost medicines for very low numbers of applicants. These reimbursements are also applied to a life-saving drugs programme. This approach recognises that even if the numbers of patients requiring expensive drugs are small, there is still a responsibility on the government to provide healthcare to these few people. This responsibility is met from this special budget. The NZORD interviewee stated that if PHARMAC was to allocate a similar proportion per head of population, as is provided by the Australian Benefits Scheme, PHARMAC should set aside approximately \$8 million. If this were to occur, PHARMAC could approve more than double the number of claims for Community Exceptional Circumstances it now approves.

Whilst there is some logic to this approach, there are two elements to approving 'Community Exceptional Circumstances' claims; affordability and clinical

effectiveness. The NZORD approach, which would ensure more claims could be afforded, would only solve half the problem. This is because the test of clinical effectiveness still needs to be passed for each claim. As one of the PHARMAC past or present managers stated, it would not matter if PHARMAC had \$8 million or \$80 million available to it, agreeing to fund ineffective pharmaceutical treatment would always be a waste of public money. Notwithstanding this, the same interviewee stated, that if more money was available to PHARMAC for Community Exceptional Circumstances, more claims would be able to be approved.

The data from the media study also demonstrated the anxiety of officials around their decisions setting precedents on which other claims might follow. Consequently, taking up NZORD's suggestion of increasing the Community Exceptional Circumstances budget to \$8 million would almost certainly encourage a lot more claims as the public became aware of the available distribution. This would not necessarily help those who cannot get access to medicines (for example NZORD's members) under the current regime because there would be a lot more people competing for the larger amount of subsidy.

Hansen (2006) suggested in submissions to the McCormack Review of High-Cost- Medicines in 2010, that PHARMAC should utilise one of the multi-criteria decision making frameworks to assist PHARMAC's decision making panels. These frameworks (of which there are a few to choose from) would try to computerise PHARMAC's preference values by giving weightings to the nine criteria. Hansen has designed a multi-criteria decision making framework named '1000Minds'⁷⁶. This framework allocates point scores to each of the criteria. These scores are weighted to reflect the higher priority criteria against the lesser priority criteria. Decision makers are then asked to prioritise alternative outcomes from the highest ranking priorities to the lowest ranking priorities on the basis of implicit tradeoffs. The programme assists decision makers to select alternatives which are subject to appropriate considerations,

⁷⁶<http://www.1000minds.com>

for example value for money, equity or affordability. These values are described in the New Zealand Medicine Strategy (Minister of Health, 2007) as values which must be considered in decision making. This process eventually develops a lexicographical ordering of priorities based on each panel member's preferred selections.

Such frameworks require at some point the ranking of priorities of moral and ethical judgments. The research has demonstrated that approaches to carrying out such judgments are morally disputed. The data from the OIA requests to PHARMAC showed that doctors on the panels are there to rule on clinical matters. PHARMAC does not explain how these panellists are qualified (or entitled), more than any other citizen, to impress their own moral judgments on the outcomes of PHARMAC's decisions. However, moral sensitivity and ethical reflection should be an integral part of the allocative decision making process (UNESCO, 2005). This is affected by the wider community, not just the expert medical practitioners chosen by PHARMAC to populate the various panels. Consequently, Gillon asserts that in the absence of a stated philosophical basis for PHARMAC's decision making, Hansen's system is undermined.

Hadorn (2006) submitted to the Review of High-Cost Medicines that PHARMAC lacked the ability to introduce discussions about fairness into the decision making processes, particularly decisions about providing (or not providing) subsidies for high-cost medicines for individuals. He appealed to the distributive justice principles of Rawls and suggested that PHARMAC introduce a "Rawlsian Wrinkle" into the decision making process (Hadorn 2006). He described this wrinkle as aligned to Rawls' difference principle, where the needs of the least well off are considered before the needs of the most well off. This suggestion was not meant to undermine the clinical effectiveness or value for money assessments already carried out by PHARMAC. The wrinkle was suggested to add an assessment of fairness and equity into the wider utilitarian processes.

This suggestion was not taken up by McCormack in the final review report. This was primarily because PHARMAC's decision making clinical panels had no expertise in assessing such a determination and the boundaries of the 'most well off' and 'least well off' could not be satisfactorily defined by PHARMAC.

Gillon (2006) proposed an alternative to Hadorn and Hansen's propositions. He suggested that PHARMAC should institute three mechanisms to ensure that its decisions, as far as is practicable, comply with the principles of distributive justice. Firstly, he suggested that PHARMAC should develop an 'allocation committee' drawing on the models of ethics committees and the NICE's Citizen Council. Gillon suggested that the allocation committee should be advisory to the PHARMAC Board and it should review contentious decisions or make recommendations on potentially contentious allocation issues. He suggested the committee examine Hope, Reynolds and Griffith's four step process where conflicting values are used in explicit cases (Hope, Reynolds, & Griffiths, 2002).

Secondly, Gillon (2006) suggested that PHARMAC should make more explicit the ethical framework within which PHARMAC, and its decision making panels, make distributions of various kinds. Gillon suggested PHARMAC adopt Daniels and Sabin's 'Accountability for Reasonableness', which is discussed several times in this thesis. He stated that PHARMAC should purposefully put in place the capability and processes to develop transparency about reasoning that all can eventually agree is relevant. Such a capability would assist the decision making panels to locate their thinking and decision making in this ethical framework. This would help claimants, particularly unsuccessful claimants, to know the ethical basis for PHARMAC's decisions.

Finally, Gillon (2006) recommended that PHARMAC develop an external appeal process to review decisions made by either the panels of experts or the PHARMAC staff and Board. The evidence gathered in this research from the OIA requests showed that the processes PHARMAC used for reviewing

Community Exceptional Circumstances decisions are all managed by PHARMAC and are finally arbitrated by the PHARMAC board.

For this reason, PHARMAC was found to be placed in a conflicted interest in any review or investigation of its own actions. These conflicts (or even apparent conflicts) were described as PHARMAC being the arbiter on its own processes, particularly because cost containment is the strong mandate in all decision making. External review of the decisions would give unsuccessful claimants an opportunity to argue for the reversal of PHARMAC's decisions. This proposal was strongly rejected by PHARMAC for two reasons. Firstly, PHARMAC stated that their Board was equivalent to a Citizens Council because it was appointed by the Minister of Health. Secondly, PHARMAC stated that it could not tolerate external review of its decisions because such a review (even advisory) would put at risk its financial performance for which it was accountable to Parliament.

The NZORD interviewee suggested that PHARMAC should significantly increase the budget for Community Exceptional Circumstances. They suggested that the budget should be increased from \$3 million to \$8 million to position New Zealand's scheme in line with the funding levels available for rare diseases to the Australian Benefits Scheme. PHARMAC has accepted this advice and announced an increase in funding for the new Exceptional Circumstances scheme by increasing the available funding to \$8 million.

The PHARMAC announcement of increased funding may not necessarily assist NZORDs members to get access to the medicines they are applying for. This is because the increase in funding also comes with a loosening of the decision making criteria under the Named Patient Pharmaceutical Assessment scheme, and it is probable that many more applications will now be received and approved for non-NZORDs members increasing the competition for the larger amount of funding.

In summary, test-question 4 has drawn out considerable debate about the components of fairness as they are consequential to the lives of the claimants. The discussion has explored many elements of the fairness of PHARMAC's management of the Community Pharmaceutical Schedules but concentrated more intensely on the management of Community Exceptional Circumstances policy. The discussion about deciding on a person's capability has also developed some normative options suggested by participants in the rationing debate.

In my view PHARMAC does not meet the requirements of test-question 4 given -the things he/she has reason to value is not considered in the Community Exceptional Circumstances decision making process.

Discussion of Theme 5 from the Research

Ministers of Health (King and Ryall) have intervened in PHARMAC's decision making process by directing that selected drugs be made available when PHARMAC had decided against the subsidisation of these drugs.

As stated in the introduction to this chapter, this theme is presented on its own because it is somewhat different to the four other regularly occurring themes. It is different because the theme describes the behaviour of Ministers. PHARMAC had no control over the inputs or the outcomes of this phenomenon which was shown from the research.

The actions of both Ministers King and Ryall, have on these occasions ignored the rational analysis and advice provided by PHARMAC. Decisions made by PHARMAC not to fund Beta Interferon, a drug for MS, and to only fund Herceptin for nine weeks and not twelve months were decisions overruled by the Ministers.

In the first case in 1999, Health Minister Annette King was persuaded by the Multiple Sclerosis Society of New Zealand, who applied considerable political pressure on the Minister, to direct the PHARMAC Board to make Beta

Interferon available to a limited number of MS patients on the Community Pharmaceutical Schedule. This decision was taken against the advice of officials and against the cost-utility analysis indicating an unaffordable cost of the benefits of the drug.

Wayne McNee, PHARMAC's general manager at the time, stated that PHARMAC had twice turned down funding for Beta-Interferon because the benefit for most patients was low relative to the cost. He stated that it was beneficial for some patients but it was very difficult to know which patients (McNaughton, Kayes, & McPherson, 2006). Research had shown that the majority of people taking Beta-Interferon would not have benefitted significantly. Finally, McNee stated that PHARMAC believed that at \$20,000 per patient per year, the drug was simply too expensive (NZ Herald, 1999). The Minister nevertheless was persuaded by the Multiple Sclerosis Society as to the basic unfairness of PHARMAC's approach and she directed PHARMAC to subsidise the medicine for a specific number of MS sufferers. Subsequently, in 2002 the funding cap on the numbers of patients who could be treated with Beta-Interferon was removed.

The Hon. Annette King made an election pledge in the 1999 election campaign that if the Labour Party won the election, the government would direct PHARMAC to fund the drug. She stated that the Labour Party had taken this stand because, as the Opposition Health Spokesperson, she had heard compelling evidence from MS sufferers and their doctors that MS sufferers would benefit from Beta-Interferon (King, 1999). King believed that the previous National government chose not to intervene in PHARMAC's decision making. Labour won the election and Minister King directed the PHARMAC Board to fund the drug under her stated conditions.

The second example of political overriding of PHARMAC's meso-level rationing processes occurred following the public controversy about PHARMAC's refusal to fund Herceptin for more than nine weeks for sufferers of breast cancer. The

details of this case are explained in Chapter 5 in the examination of the Walsh vs PHARMAC case. The Opposition Health Spokesperson, Hon. Tony Ryall also made an election promise in the 2008 election campaign as to override the decision making processes of PHARMAC. He promised to provide extra funding to the Ministry of Health for twelve month courses of Herceptin for approximately 300 women with breast cancer. After the 2008 election, Hon. Tony Ryall became Health Minister and implemented his election promise.

In a complicated deal changing PHARMAC's 2008 Output Agreement with the government, PHARMAC paid back the Ministry of Health \$9 million for being relieved of the duty to fund 9weekcourses of treatment of Herceptin. Hon. Tony Ryall then directed the Ministry of Health to pay PHARMAC \$12 million to provide Herceptin treatment for twelve month courses via the DHBs. The Minister also provided the DHBs with an extra \$3 million to cover the associated costs of assessments, monitoring and investigations that were a necessary adjunct to providing the treatment for twelve month periods (Scoop, 2008).

These two occurrences of political interference in PHARMAC's rationing decisions raise the question of where scientific evidence and economic evaluations sit in the policymaking process in New Zealand. It is true that New Zealand has democratically elected governments, in the Westminster parliamentary system. The parliaments elected in this system have an unfettered right to enact any laws and regulations they feel necessary to enact. They cannot be bound by previous laws made by previous parliaments, and in turn they cannot restrain future parliaments from making any law (Jackson, 2006). Inherent in this system of democracy is also the right of politicians to make social contracts with the electorate to enact policy settings they believe are necessary.

However, Professor Peter Gluckman, New Zealand's Chief Science Advisor, has given advice about the desirable relationship between evidence and policy.

“One of the key challenges for all governments is how to make the best use of evidence in both policy formation and policy evaluation. The

challenges are multiple: to identify what research and knowledge is needed; to identify appropriate sources of that knowledge; to ascertain the validity, quality and relevance of the knowledge obtained; and to understand how that knowledge informs a range of potential policy options. As science has become more complex and impacts on every aspect of our lives, offering solutions to many of the problems the world confronts, these issues become more urgent". (Gluckman, 2011)

The problem with Gluckman's approach to policy making is deciding which knowledge base should be used. It cannot simply be assumed that, as is often suggested in science, there is a clear, commanding and reproducibly derived evidence base for the knowledge required to solve social problems. My research has given two examples (those concerning King and Ryall) demonstrating that Gluckman's suggested approach is not universally accepted. There are other characteristics to policy formation and decision making such as societal values, financial constraints, public opinion and the all important process of elections (and election manifestos) which are the centre of New Zealand's democracy and constitutional arrangements⁷⁷.

When politicians react to intense lobbying and lay aside the analytical approach to which PHARMAC's utilitarian model appeals, they undermine the cost containing processes of their own agent. Gillon (2006) suggests that under these conditions Ministers who override PHARMAC's decision making have a concomitant responsibility to provide PHARMAC with extra resources to meet the election promises which were made (R Gillon, 2006). Minister Annette King directed PHARMAC to fund Beta-Interferon out of its resources and did not provide extra funding for the commitment. Minister Tony Ryall funded the Herceptin election promise with extra funding provided through the Ministry of Health to PHARMAC and the DHBs.

In this chapter, I have used the test-questions as a framework for examining the results of the thematic analysis of PHARMAC's operation of the Community

⁷⁷ New Zealand does not have a written constitution. New Zealand's legal and democratic framework is considered to be the existence of a collection of statutes and regulations passed by the Parliament (including the Constitution Act 1986, The Bill of Rights 1990 and The Electoral Act 1993), signed treaties including the Treaty of Waitangi, Orders in Council, International Treaties and Charters, Letters Patent, the Royal Assent for new legislation. The Cabinet Manual and the common law made by decisions of the Courts. Taken together, all these laws and constitutional traditions are described as New Zealand's 'constitutional arrangements'.

Exceptional Circumstances policy. I have also drawn on literature to support the examination of PHARMAC's performance.

As discussed, these results show that PHARMAC stands up well to the principles of distributive justice in relation to its role as a national drug subsidising agency. It meets the needs of the wider population under the principle of distributive justice described by Rawls and Sen. However, in relation to the second purpose of PHARMAC, to manage the Community Exceptional Circumstances policy, the results are mixed. PHARMAC does not always meet the needs of the 'exceptional' under the principles of distributive justice described by Rawls and Sen and has been twice overridden by political fiat.

The Use of Intuition in Decision Making

The discussion on the test-questions presented above does not attempt to illicit definitive answers, however PHARMAC decision makers do have to arrive at definitive answers. If decision makers were armed to make decisions with knowledge about clinical effectiveness, cost utility (in terms of costs and benefits) and fairness to all, under the constraints of limited funding, this raises the question, what part should intuition play in such determinations?

Rawls deals with the use of intuition in his discourse on reasonably held opposing points of view (presented on p.57 of this thesis) and how these conflicts might be managed. He suggests that this be done by reference to the two Rawlsian principles. The first is that each person is entitled to the most extensive basic liberty compatible with the liberty of others. The second is that where inequalities are to be organised, that this organisation should be done by meeting the needs of the least advantaged first. At some point intuition is needed to order or rank these priorities and in New Zealand, particularly in distributing public money, this has the potential for considerable political impact.

The data from the research showed how the two Rawlsian principles do not closely align with PHARMAC's decision making processes. Much of the reason for this is the political unacceptability of actors in the process (Ministers of Health, PHARMAC officials, decision making panels and administrators) being explicit about why decisions are made. Such actions encase the political and administrative arms of government in controversy. Lindblom (1958) and Daniels and Sabin (1998) have drawn on the use of intuition and described the process of muddling through. Together they describe how this form of intuition can produce morally defensible decisions. However this does not solve the problem of political acceptability of either the process or in some cases the decisions. This would particularly be the case if such decisions were explicitly aiming to meet the needs for the most disadvantaged first; however that might be determined.

From PHARMAC's point of view, being explicit about the use of intuition in decision making is perfectly reasonable. However this approach would somewhat undermine the use of their nine decision making criteria and the use of cost benefit analysis as decision making instruments. The data from my research suggests that this is the case. What has not been explored here is the appropriate level of weighting of intuition against the stated criteria, how this might be done and what measures might inform such weighting. Otago University Professor Paul Hansen's "1000 Minds" multi-criteria decision making software (outlined on page 236 of this thesis) goes some way to achieving these objectives. This could be an interesting area of subsequent research testing how such inequalities might be weighted.

What New PHARMAC System Could Emerge?

This research has demonstrated that three basic principles should determine PHARMAC's decision making system for people whose need for pharmaceuticals is considered exceptional and fall outside the ability of general medicine provisions. PHARMAC could institute mechanisms which ensure

decisions on such claims, as far as is practicable, comply with the requirements of distributive justice and these could be based on the following principles:

1. Decisions are informed by an analysis of the likely clinical effectiveness of the proposed medicine;
2. Decisions are informed by a costs and benefits analysis of substantive opportunities for spending the PHARMAC budget and
3. Decisions are informed on the basis of fairness to the applicants.

One suggested system for PHARMAC could be to ensure that panels of decision makers are constituted to draw on the models of New Zealand ethics committees and the NICE's Citizen Council in the United Kingdom. The panels might be advisory to the PHARMAC Board who will make final decisions on such claims. The panel could examine either Hope, Reynolds and Griffith's four step process where conflicting values are used in explicit cases (Hope, Reynolds, & Griffiths, 2002) and Daniels and Sabin's 'Accountability for Reasonableness' framework. Such a capability would assist the panels to locate their thinking and decision making in an ethical framework.

Under this suggested system, the first criterion for payment by PHARMAC in deciding on provision of medicines under such conditions might be that PHARMAC can demonstrate that the medicines are affordable on an ongoing basis. This system should not undermine the provision of an adequate range, quality and quantity of medicines for the general New Zealand population. The material received under the Official Information Act requests (outlined in Appendix 9) indicated that PHARMAC has both the capability and processes for making such determinations. Where medicines cannot be afforded on an ongoing basis, given the government's health priorities and funding allocations,

PHARMAC could be more open about stating this is the reason for their decision not to fund an applicant.

The second payment criterion in this system might be that PHARMAC can demonstrate that the medicines are likely to be effective in controlling symptoms where other medicines cannot. This criterion is likely to require an understanding of the medical literature and a reasonable and pragmatic view of the clinical circumstances of each case. My research has showed how wide the divide can be on opinions about clinical effectiveness by medical experts. Consequently, at times there may be reasonably held differing opinions supported by adequate research on clinical effectiveness and consequently unanimous decisions may not be possible. At such times the unresolved case might be referred to an External Review Council.

Such an External Review Council (akin to the NICE Citizen's Council in the UK) could be independent of PHARMAC Board and staff, made up entirely of non-medically qualified citizens appointed by the Minister of Health. The Council in such cases could be asked to review PHARMAC decisions where there is dissatisfaction or political controversy about the decisions. The PHARMAC decision makers would need to be aware that their decisions may be subject to review by citizens and consequently be required to contain robust arguments and understandable information which support such decisions. The External Review Council might be required to make recommendations to the PHARMAC Board who will make all final determinations. This is necessary because it is the PHARMAC Board who must ensure the pharmaceutical needs of both the community and individuals are met under its governing legislation.

The third criterion under this suggested system might be that PHARMAC can demonstrate that the decision makers have received and considered relevant information about the personal circumstances of the applicant. This is likely to be the most contentious of the proposed criteria. It would be contentious because there will be varying sets of morals and values genuinely held by decision makers. This may create dilemmas, even conflict, among decision makers to

propose or not to propose a subsidy for the medicine based on information about the claimant and that which they have reason to value in their lives.

Gillon (2006) has suggested that these moral dilemmas, created by the need to limit the supply of health care, should be handled exercising sound judgment by decision makers who must do the best they can. In cases where decisions cannot be reached by this method, cases should be referred to the External Review Council to make recommendations to the PHARMAC Board.

Finally, to complete the requirements of fairness (aligned to Rawls and Sen's principles of distributive justice), PHARMAC could be required to effectively communicate the reasons for their decisions to claimants and the public. The example of the New Zealand Health and Disability Commissioner's⁷⁸ case notes of decisions in respect of complaints made by members of the public regarding inadequate health care is an excellent example. The health and disability commissioners have achieved the highest levels of detailed public communication on such cases publicly describing decisions without impugning the confidentiality of natural persons. This is a New Zealand public health agency which communicates its decision making process, the decisions which it makes, the reasons for the decisions and the recommended actions to remedy complaints. PHARMAC could follow this example.

Under these conditions and criteria described above, claimants would know that their cases had been heard, assessed by experts, fairly considered, open to scrutiny and, where necessary, reviewed by an impartial and independent review body.

⁷⁸ <http://www.hdc.org.nz/decisions--case-notes>

Chapter 8: Conclusions

Introduction

This research has examined five emergent themes about PHARMAC's Community Exceptional Circumstances policy by utilising test-questions which were developed in the philosophical framework in Chapter four.

There are a number of elements where this work has made a contribution to health research in New Zealand (and possibly internationally) that are worth noting. This study is the first time a distributive justice template has been used to assess the practice of a New Zealand government funded health agency. Indeed, this is the first time triangulated research on PHARMAC has fully engaged the distributive justice principles of fairness and equity. Other 'firsts' are the interviewing of present or past Ministers of Health who have had a significant engagement with PHARMAC and provided astute and discerning views of the agency. This is the first time OIA requests to multiple government agencies have been extensively used in a thesis on PHARMAC. Such a gathering of official documents, examining both the policy and operational activities of a government agency, has shown that research can be enhanced using this data procurement method.

This chapter contains a discussion on my research findings and the use of the test-questions, based on Rawls' and Sen's principles, to examine these findings. I include a discussion about the limitations of the research and a section on further research which could be undertaken to develop the content and usability of the test-questions.

In this chapter I summarise the contribution I consider this research has made to our understanding of distributive justice and public policy and make closing comments about the thesis question. Finally, there have also been some political developments relating to PHARMAC which have occurred since the research

was completed in February 2011 and these are presented as postscripts in this chapter.

What has this Research Discovered About Distributive Justice?

The elements of Rawls' and Sen's view of distributive justice have been identified in Chapter 4 and developed in the Socratic tradition into questions which assist the exploration of the principles of distributive justice. Through this research I have taken the principles which satisfy their requirements of fairness and equity and examined how a public health agency has applied them.

Using the exemplar of PHARMAC's Community Exceptional Circumstances policy I have shown how the principles of distributive justice urge public institutions to;

- consider the needs of the least advantaged before the needs of the most advantaged;
- avoid making biased decisions by removing the influence of vested interests, personal priorities and the prejudices of their chosen decision makers;
- be open about the decision making process and accountable for decisions;
- ensure that they engage in some form of rational analysis to determine the best use of resources and agree about the process for doing this and
- be aware of the consequences on people affected by decisions and be aware of the capacity of those affected to do the things they have good reason to value.

Limitations to the Research

The iterative public policy research approach taken here has drawn on data from PHARMAC, the arms of government and parliament, the literature on the subject, the media reports and key informants. When I set out to gather the policy data, I intended to interview patients who had been affected by PHARMAC's Community Exceptional Circumstances policy. However, after informally meeting some patients who might have been interview subjects, I discovered that their level of knowledge of the Community Exceptional Circumstances policy and their understanding the reasons behind decisions was very low. This was particularly the case for patients who had, for one reason or another, been denied access to medicines under PHARMAC's policy. The patients' doctors primarily made the decision to claim, and it was the patients' doctors who were required by PHARMAC to manage the claims for them. Consequently, I interviewed the patients' representatives and professional advocates who were familiar with the operation of the PHARMAC's policy. The lack of a case study research methodology of patients was an unavoidable limitation to my research.

The thematic analysis was greatly assisted by NVivo 8 computer software programme. After collecting and organising all the data and completing the search functions for interrogated the data, I used NVivo 8 to extract the most commonly used words and sets of words. This was an important step in identifying the building blocks of the emergent themes. However, NVivo 8 was unable to decipher the magnitude or importance of participant contributions from both the media stories and some key informant interviews. Several complaints about PHARMAC were made in exaggerated terms and conversely, some interviewees made insightful comments using reserved and quiet language. Future users of NVivo 8 would be assisted by being aware that the programme has this limitation.

Development of Alternative Themes from the Data

The Braun and Clark (2006) system of thematic analysis which was used required a discipline of reporting the regularly occurring themes which emerged from the data. However, other themes which were not reported but were important themes are also worthy of mentioning. Patton (1990) recognises that there can be a balance between description of emergent themes from qualitative research and interpretation of the themes. Decisions must be made about what to leave out, described by Patton as “the agony of omitting” (p429). The following alternate presentation of themes is consequently recorded here:

- Individuals from PHARMAC exert considerable pressure and influence over the Community Exceptional Circumstances decision making process;
- The Community Exceptional Circumstances decision making process is highly variable and contested;
- How Community Exceptional Circumstances claims are made, has a positive or negative bearing on the outcome of the claim and
- PHARMAC’s arbitrary thresholds for Community Exceptional Circumstances decision making demonstrate that applicants are unlikely to be successful.

These alternate themes do not change the conclusions of the research; rather they amplify the outcome as the themes relate to the test-questions which have been presented.

The Use of the Test-Questions

The test-questions which I have developed have provided a starting point for the discussion about the themes which emerged from the data and demonstrated their value in analysing the selected constructs of distributive justice.

There is no one set of infeasible answers to the test-questions. This is because there is no single agreed set of values which underpin the process of rationing health resources. However, the greatest value of the test-questions has been to provide decision makers with a framework to analyse the content of fairness and equity of their decisions.

Having utilised the test-questions in this research, it has become clear that the questions would not greatly assist decision makers deciding on state distributions at the macro-rationing level. This is because governments do not set their allocative priorities based solely on set theory or fixed policy statements. Governments' allocative practices evolve and continue to evolve (Jackson, 2006) to meet complex political arrangements and responsibilities. This is particularly so under Mixed Member Proportional (MMP) coalition governments which have dominated in New Zealand parliaments since 1996. The Finance Minister prepares a budget based on these MMP political arrangements and responsibilities (particularly statutory requirements) in discussion with other Ministers, assessments of funding levels by Heads of Government Departments, Chief Executives of Crown Agencies and Treasury officials. At this level, Sen's and Rawls' conversations about fairness and equity would play very little part in directing macro-level decisions.

Once a government's budget is presented to Parliament, the estimates of income and expenditure for the government programme (department by department) are debated. In reality, there is little chance for MPs to change the estimates by proposing amendments. This is because such changes will alter the confidence and supply arrangements⁷⁹ of the government. However, MPs of all parties may find the test-questions useful to provide a general examination of the fairness and equity of certain elements of the budget.

⁷⁹In the New Zealand parliament the term 'confidence and supply' refers to the ruling party's holding of power. This is assured for the term of a parliament by the governing party signing agreements with selected minor parties on motions of confidence in the government and on budget appropriation votes which supply funding to the government departments and agencies.

A section of the New Zealand Ministry of Health is the Health Impact Assessment (HIA) unit which is a New Zealand wide service responsible to the Office of the Director of Public Health. This unit attempts to measure and report the potential long-term policy impacts on health indicators and determinants of wellbeing. The unit was established in 2010 as part of a wider strategy to improve health and reduce inequalities in New Zealand. One of the tools used by the HIA is the Health Equity Indicator Tool⁸⁰. The tool estimates potential policy impacts on social, economic, cultural, psychosocial, behavioral and historical factors that fundamentally determine health. It examines the pathways of these factors that lie as root causes of health inequalities. The test-questions would be useful tools for this unit to use in considering fair and equitable access to cost effective health distributions across the country.

At the meso-level, it is doubtful that the test-questions would be used by DHB Board members and managers when they are deciding on regional allocations of funding. This is because the DHBs are constrained by the size of their budgets. The budget levels are determined on a population basis and DHBs are often put in the position of deciding which services to discontinue and which services to persist with. The financial resource available to DHBs to make allocative decisions each year on new projects is remarkably small⁸¹. As in macro-level allocative decisions, the test-questions might only provide assistance to DHB board members to reflect on and discuss the fairness and equity of providing or not providing services to certain groups in their districts.

However, the test-questions have proved most useful in generating significant debate about distributive justice at the micro-level of service. The test-questions are suggested to decision makers as an opportunity to assess the elements of fairness and equity for an individual person against other criteria required to be satisfied before a decision is made. This process could equally be applied to decisions about the approval of elective surgery for claimants, a person's access

⁸⁰ The details of this Health Equity Assessment Tool are provided on the Ministry of Health website. See: <http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/523077dddeed012dcc256c550003938b?OpenDocument>
⁸¹ I asked this question of Dr. Karen Poutasi, the Director General of Health, at an event to mark her retirement, at the Alexander Turnbull Library, Wellington in May 2006.

to alcohol and drug treatment or the long term care and support of people suffering mental illness and physical disability. The questions could even be used at a service level. For example managers and clinical staff may be able to use the questions to discuss what a fair and equitable waiting time is for a person sitting in a public hospital Accident and Emergency Department. These micro-level allocations contain elements of distributive justice such as equity, openness, the analysis of substantive opportunities and consequences on peoples' lives. Those who must decide on these matters at this level of decision making could use the test-questions to generate a discussion about acting fairly and equitably.

Further Research

The test-questions which were developed in this thesis have tested these requirements of distributive justice in the chosen PHARMAC example. Further research utilising the test-questions in other OECD countries with different social welfare institutions would develop comparative studies on the operational aspects of distributive justice.

My research could also be advanced by studying PHARMAC decision makers themselves. If they would agree to participate, it would be interesting to see if the test-questions provided any opportunity for them to consider if they would have made different decisions or if they would more clearly be able to articulate the reasons for decisions they have made.

The allocation of other state distributions such as social housing by Territorial Local Authorities and the Housing Corporation New Zealand also provides an opportunity for decision makers to reflect on the fairness and equity of their allocative decisions. Research into decision makers using the test-questions in this context would be interesting. It would also be enlightening to compare decision makers experiences of distributive justice between health and non-health social distributions.

The test-questions now need to be published and introduced to the health policy readership. In doing so, such publications may encourage some collaborative research on the use of the questions by other researchers in both health and non-health decision making jurisdictions.

There are many actors and institutions that rely on PHARMAC contracts and appointments to committees and panels to gain access to information or to engage in decision making. Further research utilising critical social theory raises the possibility of discovering the power interests being served by the awarding of contracts and the appointments to these actors and institutions. Such research touches on distributive justice by examining the functional relationships between PHARMAC and DHBs, hospitals, pharmaceutical companies, medical academics, medical professional associations and colleges, and other professional interests (e.g., pharmacists, nurses, midwives).

Similarly, further research into the economic efficiency of PHARMAC and its outputs would develop knowledge about what is implied (or generally believed) about PHARMAC's performance. This research might look into how the principles of economic welfare and Pareto efficiency can be applied to PHARMAC's subsidising decisions. This would include an examination of PHARMAC's use of the exemption from Part 2 of the Commerce Act. This exemption plays a large part in the economic performance being achieved by PHARMAC's current policy settings. This kind of research would offer another way of looking at the 'value for money' equation other than the much discussed cost-utility analysis.

Finally, PHARMAC's governing legislation (the NZPHDA 2000) recognises and respects the principles of the Treaty of Waitangi. It does so in response to the Crown's desire to improve the health status of Maori and reducing health disparities between Maori and non-Maori. However, income disparities and social inequalities have been discussed in this thesis as possibly more powerful drivers of ill health than access to health services and medicines. PHARMAC would be

well placed to lead further research into the question: is it better to try to improve the health status of Maori by improving access to medicines or by trying to reduce both social and income inequalities for Maori.

Closing Comments on the Thesis Question

“How does the operation of PHARMAC’s Community Exceptional Circumstances policy align with the distributive justice principles of fairness and equity as described by John Rawls and Amartya Sen?”

This research has produced five emergent themes which paint a picture of PHARMAC making rational allocative decisions about the provision of subsidies for medicines for the general public. The themes have also demonstrated PHARMAC’s performance in relation to the management of individuals whose pharmaceutical needs were described as exceptional.

The arms length relationship between PHARMAC and government has provided successive Health Ministers with the opportunity to avoid being involved with claims made by groups or individuals lobbying for access to publicly subsidised pharmaceuticals. This relationship has also provided PHARMAC the clear space to make unpalatable decisions which ensure the budgets are achieved. This is PHARMAC’s statutory purpose.

Consequently, there has been little complaint from governments about PHARMAC and very few examples where governments have reversed PHARMAC’s decision making. When the Hon. Annette King intervened to instruct PHARMAC to fund Interferon for MS sufferers, the Minister claimed to do so both on the evidence put before her about the effectiveness of the drug (although PHARMAC experts disputed this evidence), and based on her notion of fairness and equity to this patient group.

However, my research showed that PHARMAC was seen by some members of the public (and sometimes their doctors) in a very different light. There was a view of PHARMAC which was expressed as harsh, bureaucratic and somewhat

impenetrable and decisions were dominated by PHARMAC's view of financial value.

In the case of Community Exceptional Circumstances policy, PHARMAC did not demonstrate that decisions were made primarily in consideration of a person's capacity to live a life they might value, but rather to ensure its own budget levels were not breached. Making these allocative decisions is consistent with PHARMAC's statutory purpose and, given this set of circumstances, the gained reputation is understandable.

Equally, PHARMAC has gained a national and international reputation of excellence in public health rationing practice and is well regarded among New Zealand senior government health officials. PHARMAC's practices are now being promoted as appropriate methods for analytically prioritising (rationing) other health service spending and procurement. Whilst there may be challenges to the fairness and equity considerations of implementing this idea, this research has shown that PHARMAC is the clear leader among OECD countries for procurement in terms of value for money.

The research has also shown how PHARMAC has achieved budget control in operating the Community Exceptional Circumstances policy by managing the budget and when required, giving greater weighting to the affordability decision making criteria above the other criteria it promulgates. The research has demonstrated that some allocative committees, for example the Community Exceptional Circumstances Panel, did not record their reasons for making their decisions. Again this is understandable from their point of view, however not advising claimants of the reason for decisions is inherently unfair and provides no level of procedural justice to claimants who are declined their claims.

The research also discovered that there is no clear set of values which have been promulgated by PHARMAC to indicate which values guide PHARMAC's decision making, other than the desire to achieve budget (which is not a value but an outcome). PHARMAC achieves this outcome by generally following the

utilitarian principles of attempting to provide the greatest quality and range of pharmaceuticals for the greatest number. This utilitarian approach does not provide for people whose genuine needs are found at the margins.

In recent years, PHARMAC has been funding, when it can afford to do so, greater numbers of treatments on the Community and Hospital Pharmaceutical Schedules for rare disorders suffered by fewer people. However, not all can be accommodated in this manner and there are still cases, many presented in the media, who cannot receive treatment because the cost is demonstrated by cost-benefit analyses to be too high. This will continue, due to the increased funding being applied to the new NPPA scheme as a result of the PHARMAC review of its own policy. However, not all can be accommodated in this manner and there will still be cases who cannot receive treatment because the cost as demonstrated by a cost-utility analysis is considered too high for the system to bear. As PHARMAC concluded in its own review of the Community Exceptional Circumstances schemes, there is no purpose that it could propose that would alter the harsh reality that all treatments cannot be provided for all people who need them.

Finally, this research has demonstrated that PHARMAC's general allocative policies align with the utilitarian efficiency, accountability and equality principles of distributive justice described by Rawls and Sen, because PHARMAC is able to use government resources to great advantage on behalf of the general public. Of this there can be little doubt. This is because of the high regard in which PHARMAC is held for achieving impressive cost savings on the price of medicines for New Zealanders. This ensures that more people can be provided for than otherwise would have been the case if PHARMAC did not exist.

The research has clearly shown that PHARMAC, and its allocative committees, has achieved this success in part by managing the Community Exceptional Circumstances policy for many individual claimants in a way that has been dominated by its need to control its budget. This has been PHARMAC's most

important decision making criterion. In doing so PHARMAC's operation of the community Exceptional Circumstances policy has not closely aligned with Rawls' and Sen's principles of distributive justice such as openness, equality and fairness to all.

Postscripts

During the reading of the 2011 Government Budget the Minister of Finance, Hon. Bill English announced the government's intention to stop funding certain pharmaceuticals and alternative health treatments. These are currently being supplied under a Disability Allowance provided by the Work and Income section of the Ministry of Social Development (MSD). In 2009–2010 there were 24,000 people who accessed MSD subsidies for alternative health treatments such as acupuncture, homeopathy, osteopathy, vitamins and gym memberships (English, 2011).

The Minister stated that this situation undermines the status of PHARMAC and effectively has both PHARMAC and MSD subsidising pharmaceuticals. Interviewee 'C' referred to this practice in his/her interview. The government is preparing new subsidy rules to manage the payment of Disability Benefits for pharmaceuticals and alternative health treatments which can be paid out by MSD. In future, they must be approved by PHARMAC before the funding can be provided. It is suggested that PHARMAC will carry out a cost-benefit analysis and examine the clinical evidence before the subsidy is approved.

The implementation of this policy puts PHARMACs advisory panels, particularly PTAC, in a position to approve or deny payments of public health subsidies for alternative health treatments. The PTAC members are all leaders and academics connected to traditional medical professions. Taken as a general rule, these professions have not enthusiastically embraced such alternative health treatments. Patients tend not to tell doctors about their use of alternative treatments (Ernts E., 2006) for fear of a negative reaction. This is largely because such medicines are not subjected to rigorous clinical trials and do not

stand up to the same rigorous clinical trials (particularly double-blinded clinical trials) as other more conventional medicines. This will change under the new regime because PTAC will require both clinical evidence of effectiveness and evidence that the alternative medicines are meeting satisfactory cost-utility analyses.

Also at the end of the writing of this thesis, New Zealand's has been engaged in attempts to negotiate a trading partnership with nine other countries including the United States and Australia. The agreement, known as the Trans Pacific Partnership Agreement (TPPA) is by another name a free trade agreement with the other Pacific nations. PHARMAC's aggressive anti-competitive procurement practices and the assessment process for examining the cost-utility and the comparative clinical effectiveness of new medicines has been criticised by 28 USA Senators as an issue in the negotiations for a TPPA.

A letter signed by the 28 senators lobbying President Obama, urged him not to sign a TPPA with New Zealand, if such an agreement includes the current PHARMAC policy of not purchasing what they referred to as 'innovative medicines'. Other issues raised by the lobbyists on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) were the assessment process used by PHARMAC, the lack of clinician involvement in decision making and the lack of new medicines being made available to the New Zealand people.

Allan Clarke, Chief Executive of Medicines New Zealand represents the international drug companies in New Zealand. He has accused PHARMAC of being a closed shop, of not letting drug companies present their experts to give submissions on the applicant medicines and falling short of international best practice in its decision making (Morning Report, 2011).

The irony of this situation is that New Zealanders, thanks to PHARMAC, pay approximately one-third the price of medicines per drug category as that paid by citizens of the USA. PHARMAC's allocative practices are already being used in

several Medicaid State funded public health insurance schemes in the USA and, as previously mentioned, in some Veterans Administration Hospitals.

In August 2011, PHARMAC's Chief Executive Officer, Matthew Brougham took up a position as head of PHARMAC's equivalent in Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH). It is probable that Brougham's expertise in managing down New Zealand's medicines bill will be utilised in his new position at CADTH.

Undoubtedly PhRMA's greater concern about New Zealand's entry into the TPPA is less about the rules of engagement in negotiating drug contracts (of which New Zealand must be a tiny market compared to other OECD countries) and more about limiting a contagion of PHARMAC's very effective price reducing practices. Such practices are obviously attractive to the Canadian government and must be alluring to other Pacific Partners and OECD governments struggling with rising medicine costs.

Both New Zealand's major political parties, National and the Labour Opposition have declared their support for PHARMAC and have given assurances that the agency will not be compromised (Morning Report, 2011) in its ability to control pharmaceutical prices as a result of any TPPA. No final decisions have been made at the time of writing.

Appendices:

Appendix 1: Ethics Approval



MEMORANDUM

Auckland University of Technology Ethics Committee (AUTEC)

To: Marilyn Waring

From: **Madeline Banda** Executive Secretary, AUTEC

Date: 24 January 2008

Subject: Ethics Application Number 07/196 Research into how PHARMAC's 'exceptional circumstances' policy is applied.

Dear Marilyn

Thank you for providing written evidence as requested. I am pleased to advise that it satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC) at their meeting on 12 November 2007 and that the Chair of AUTEC has approved your ethics application. This delegated approval is made in accordance with section 5.3.2.3 of AUTEC's *Applying for Ethics Approval: Guidelines and Procedures* and is subject to endorsement at AUTEC's meeting on 11 February 2008.

Your ethics application is approved for a period of three years until 24 January 2011.

I advise that as part of the ethics approval process, you are required to submit the following to AUTEC:

A brief annual progress report using form EA2, which is available online through <http://www.aut.ac.nz/about/ethics>. When necessary this form may also be used to request an extension of the approval at least one month prior to its expiry on 24 January 2011;

A brief report on the status of the project using form EA3, which is available online through <http://www.aut.ac.nz/about/ethics>. This report is to be submitted either when the approval expires on 24 January 2011 or on completion of the project, whichever comes sooner;

It is a condition of approval that AUTEK is notified of any adverse events or if the research does not commence. AUTEK approval needs to be sought for any alteration to the research, including any alteration of or addition to any documents that are provided to participants. You are reminded that, as applicant, you are responsible for ensuring that research undertaken under this approval occurs within the parameters outlined in the approved application.

Please note that AUTEK grants ethical approval only. If you require management approval from an institution or organisation for your research, then you will need to make the arrangements necessary to obtain this.

When communicating with us about this application, we ask that you use the application number and study title to enable us to provide you with prompt service. Should you have any further enquiries regarding this matter, you are welcome to contact Charles Grinter, Ethics Coordinator, by email at charles.grinter@aut.ac.nz or by telephone on 921 9999 at extension 8860.

On behalf of the AUTEK and myself, I wish you success with your research and look forward to reading about it in your reports.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Madeline Banda', with a small flourish at the end.

Madeline Banda

Executive Secretary

Auckland University of Technology Ethics Committee

Cc: Greg Coyle greg.coyle@tec.govt.nz

Appendix 2: Key Informant Participant Information Sheet



28 April 2010

Research into how PHARMAC's 'Community Exceptional Circumstances' policy is applied.

My name is Greg Coyle and I am an Auckland University of Technology PhD student. I am writing to you to ask you if you would be prepared to take part in a research project I am conducting as part of my PhD study. The topic of the research is an examination of how the PHARMAC policy of 'Community Exceptional Circumstances' has worked for individual citizens and the community in New Zealand.

I am asking you to contribute to this study because you have has experience of this PHARMAC policy and I am asking a variety of people to give there perspectives from their experience. I plan to talk to PHARMAC managers, politicians, members of the pharmaceutical industry, and members of the medical profession, academics and patient advocate groups who have all experienced the policy in some way or another. I am also conducting a media study of some stories about Community Exceptional Circumstances which have been reported in the New Zealand media.

In the case that you would have liked to participate but for one reason or another you cannot participate, I would be grateful if you would suggest an alternate whom I could approach to be interviewed.

Your agreement to participate would mean that I would conduct a one hour interview in relation to the PHARMAC policy. This will be a face to face interview which can take place either in your home, office or any other convenient place. The interview will be recorded. This research will benefit future patients who will apply for subsidy for pharmaceutical treatment under the Community Exceptional Circumstances policy by examining the way in which PHARMAC applies this policy and identifying if there are any areas where the policy and application can be improved. Politicians and health administrators will also benefit because my study will highlight the pressures on the individuals who apply for Community Exceptional Circumstances and the pressure on the national pharmaceutical budget.

The privacy of all the participants in the study will be protected and the comments made in the interviews will remain anonymous. Should you wish your comments to be attributed to you, this will be done.

No fees will be paid to you for your contribution.

I would be grateful to you if you could indicate your agreement to participate in the study or indicate if you decline the offer to participate in the study by returning the enclosed consent form to me within 14 days.

If you decide to participate you will receive a copy of a transcript of your tape recorded interview either by mail or e-mail which ever you would prefer. The transcript will be prepared by a paid transcriber who will sign a confidentiality agreement binding that person to treat the names or any of the details of the interviews with the strictest confidentiality.

If you would like to make any corrections to the transcript or you would like to add any reflections which might have occurred to you since the interview you will have an opportunity to do this before the final transcript is verified by you.

A copy of the results of the study will be sent to you when the data is analysed and reported in the thesis. If you wish to read either an executive summary or the whole thesis when it is completed, an electronic version of the thesis and /or the executive summary will be made available to you.

Should you have any concerns about the nature of this research you should make these concerns known to my PhD supervisor, Professor Marilyn Waring, Professor of Public Policy at Auckland University of Technology. You can do this by phone (09) 921-9999 or by mail to AUT, 90 Akoranga Drive, Northcote, Auckland or by email marilyn.waring@aut.ac.nz .

If you have any concerns regarding the conduct of the research these should be notified to the Executive Secretary, AUTEK, Madeline Banda, madeline.banda@aut.ac.nz , 921 9999 ext 8044.

Researcher Contact Details:

The best way to contact me is by e-mail gregjo@clear.net.nz or alternatively my phone numbers are (0275) 110-353 or (04) 977-5333.

Approved by the Auckland University of Technology Ethics Committee Ethics Application Number 07/196



Project title: Research into how PHARMAC's 'Community Exceptional Circumstances' policy is applied.

Project Supervisor: Professor Marilyn Waring

Researcher: Greg Coyle

- I have read and understood the information provided about this research project in the Information Sheet dated 2nd September 2007.
- I have had an opportunity to ask questions and to have them answered.
- I understand that notes will be taken during the interviews and that they will also be audio-taped and transcribed.
- I understand that I may withdraw myself or any information that I have provided for this project at any time prior to completion of data collection, without being disadvantaged in any way.
- If I withdraw, I understand that all relevant information including tapes and transcripts, or parts thereof, will be destroyed.
- I agree to take part in this research (please tick one); Yes or No
- I wish to receive a copy of the report from the research (please tick one): Yes or No
- Please sign both copies of this form and retain one copy for your records and
- Please return the other copy of this form in the stamped addressed envelope provided. Thank you.**

Participant - Signature:.....

Participant - Name:

Participant - Email

Date:

Approved by the Auckland University of Technology Ethics Committee Ethics Application Number 07/196

Appendix 4: Sample Interview Questions

Sample Interview Questions (Key Informants)



Project title: Research into how PHARMAC's 'exceptional circumstances' policy is applied.

Project Supervisor: Professor Marilyn Waring

Researcher: Greg Coyle

These questions will be used to prompt discussion.

1. What was your involvement with PHARMAC's Community Exceptional Circumstances policy?
2. Can you describe to me your actions and activities in relation to this policy?
3. What do you think of PHARMAC's definition of 'Exceptional'?
4. Were you aware of the criteria which guided PHARMAC in its "Exceptional Circumstances" decisions?
5. What experiences can you tell me about PHARMAC's application of the nine decision making criteria?
6. Do you think PHARMAC uses the decision making criteria consistently? criteria
7. What does fairness mean to you?
8. How would you know if PHARMAC was acting fairly or unfairly?
9. What do you think about PHARMAC's analysis of financial efficiency, the Cost Utility Analysis?
10. Thinking more widely about rationing health services in the publicly funded service, what principles come to your mind which would describe fair and equitable distributions?
11. How would you describe the effectiveness of PHARMAC?

12. What improvements could be made to PHARMAC's policies or operations to ensure the interests of the patients or the interests of the health service are better served?

(Approved by the Auckland University of Technology Ethics Committee Ethics Application Number 07/196.)

Appendix 5: OIA Request

Greg Coyle
142 Upland Rd
Kelburn
Wellington
gregjo@clear.net.nz
ph. (04) 977 5333

Matthew Brougham
Chief Executive
PHARMAC
P.O. Box 10-254
Wellington

Dear Mr. Brougham,

Request under the Official Information Act 1982

I am a PhD student studying at the Auckland University of Technology writing a thesis on the rationing of health services.

My OIA request is for the following information;

1. Policy documents PHARMAC has on the preparation and implementation of the 'Exceptional Circumstances' policy. This includes Community EC, Hospital EC and Cancer EC
2. PHARMAC Board minutes which are available to the public which discuss Exceptional Circumstances policy or cases. This includes Community EC, Hospital EC and Cancer EC
3. Any papers or articles published by PHARMAC on Exceptional Circumstances. This includes Community EC, Hospital EC and Cancer EC

My contact details are:

Home Address 143 Upland Rd., Kelburn, Wellington

Home Phone (04) 977-5333

Cell Phone (021) 413-354

Email gregjo@clear.net.nz

Thank you for your assistance,

Yours sincerely,

Greg Coyle

Appendix 6: OIA Response from PHARMAC

PHARMAC
Pharmaceutical Management Agency

Level 14, Cigna House,
40 Mercer Street, PO Box 10-254,
Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
www.pharmac.govt.nz

16 September 2008

Greg Coyle
143 Upland Road
Kelburn
Wellington

BY EMAIL: gregio@clear.net.nz

Dear Greg

REQUEST FOR INFORMATION RELATING TO EXCEPTIONAL CIRCUMSTANCES POLICY - OFFICIAL INFORMATION ACT 1982 (OIA)

We refer to your letter received on 8 August 2008 in which you request information held by PHARMAC in respect of:

1. Policy documents PHARMAC has on the preparation and implementation of the 'Exceptional Circumstances' (EC) policy. This includes Community EC, Hospital EC and Cancer EC.
2. PHARMAC Board minutes which are available to the public which discuss EC policy or cases. This includes Community EC, Hospital EC and Cancer EC.
3. Any papers or articles published by PHARMAC on EC. This includes Community EC, Hospital EC and Cancer EC.

As discussed with Jan Quin on 14th August, the request is very broad and I understand you limited your request to documents relating to policy around the setting up of EC, specifically community EC.

Further you have asked for any documents specifically relating to how we balanced the needs of the individual against the needs of many.

Lastly, we agreed that documents relating to the decisions on actual cases should not be released as these documents could result in patients being known even if names were withheld, given the rarity of some of the conditions being considered.

Documents provided

Enclosed are a number of documents including draft papers, papers, letters, emails and file notes that we hold on file.

You will notice that a number of documents have information withheld. Some of the information was withheld because it related to issues other than Exceptional Circumstances and so is beyond the scope of your request.

We are withholding the other information under the OIA as we consider this is necessary to:

A221994 -

- protect the privacy of natural persons (section 9(2)(a));
- maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to members of an organisation in the course of their duty (section 9(2)(g)(i); and
- maintain legal professional privilege (section 9(2)(j)).

As required under the OIA, we also considered whether, in the circumstances, the withholding of this information was outweighed by other considerations which render it desirable, in the public interest, to make this information available. In this case we did not consider that the public interest outweighed the reasons for withholding the information. Please note you have the right, by way of complaint under section 28(3) of the OIA to an Ombudsman, to seek an investigation and review of our decision.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M Brougham', with a long horizontal flourish extending to the right.

Matthew Brougham
Chief Executive

Appendix 7: Community Exceptional Circumstances Buprenorphine / Naloxone Application

PHARMAC

Pharmaceutical Management Agency

Community Exceptional Circumstances
Panel Co-ordinator
PHARMAC
PO Box 10-254
Wellington 6143
Phone (04) 916 7553
Fax (09) 523 6870 (redirects to Wgtn)
Email ecpanel@pharmac.govt.nz

Dear Dr

NHI:

Patient:

D.O.B.:

Medication: **buprenorphine/naloxone (suboxone) 8mg (16-24mg daily sublingual)**

Application for supplies of buprenorphine/naloxone (Suboxone) 8mg (16-24mg daily sublingual) for the above patient has been approved for a period of 52 weeks, based on the information you supplied.

The Ministry of Health, Sector Support Services will notify you with the approval number. The patient will be able to obtain funded supplies from the pharmacy nominated on the application form, in this case . . .

Please note that all renewal applications should be on the appropriate form which can be downloaded from <http://www.pharmac.govt.nz/healthpros/EC/ECForms>

The form can be either faxed to the number on the form or posted to:

PHARMAC
PO Box 10-254
Wellington

Yours sincerely



p.p. Jayne Watkins
Signed on behalf of:
Exceptional Circumstances Panel

Investing in Health

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Application Form for Community Exceptional Circumstances Approval

Return completed form to:

Exceptional Circumstances
Panel Co-ordinator
PHARMAC
PO Box 10-254, Wellington
Phone: 04-916-7553
Facsimile: 09-523-6870
Email: ecpanel@pharmac.govt.nz

Please refer to information sheet if necessary. Complete ALL relevant details. Please type or print CLEARLY.
For a renewal complete this page and sections 7 and 8 only

Patient Det:

Last Name:	
First Name:	
Address:	
Gender:	
Date of Birth:	
NHI No:	

Details of

Last Name:	
First Name:	
Address:	
Phone:	
Facsimile:	
Email:	
Are you	

Disease/Condition

*attach further information if appropriate, a clinical report is useful, be specific.

a-t prolongation
→ Torsade de Pointes
→ cardiac arrest (VF)

Medicine/treatment sought:

Complete fully, attach additional information as necessary to cover all strengths required.

Brand Name:	Suboxone
Chemical Name:	Buprenorphine/Naloxone
Manufacturer:	Reckitt Benckiser
Form and Strength:	8mg
Dosage to be used:	1 16-24mg
Dosage regimen: (where applicable)	daily, sub ling
Extemporaneously compound?:	Yes <input type="checkbox"/> No <input type="checkbox"/>
(If Yes, attach a full list of ingredients)	

Note that if this is not completed an approval cannot be issued

Nominat

Name:	
Address:	
Phone:	09

Where can the medicine be obtained? This will generally NOT be a hospital pharmacy.)

1. ENTRY CRITERIA

Complete the criteria to which this application applies.

- (a) Rare condition (rare is considered to be a prevalence of <10 nationally)

What is the prevalence (not incidence) of the condition in NZ?

- (b) Reaction to alternative treatment unusual (unusual is considered to be <10 nationally)

List all treatments trialled, patient response to each treatment and how often this response to this treatment occurs in NZ. (Note that failure to respond to funded treatments is not generally exceptional. In order to obtain funding through Exceptional Circumstances the nature of the response would need to be considered exceptional).

Treatment	Response of this patient	Rarity (how often would you expect this to occur)
methadone.	Q-T. prolongation (490. usec)	1:500 treated patients

- (c) Unusual combination of clinical circumstance applies

Describe the unusual combination of clinical circumstances and how often this combination occurs in NZ. (Note that end of spectrum treatments are not necessarily approved; patients must be clearly distinct):

(L.A.)
 Has had oral morphine as substitute medication.
 Has persistently diverted this and injected intravenously.
 - Requests to go back on methadone.
 - We, (medical officers) consider this contra-indicated

2. CLINICAL BENEFIT AND SUITABILITY

(a) attach evidence that it is a safe and efficacious treatment (e.g. full journal articles, not just references, conference proceedings or abstracts). Note that a higher degree of proof will be required for unregistered medications or registered medications for non-registered indications.

(b) Is the pharmaceutical registered for this indication in NZ? Yes No

If not, has patient consent been obtained for this use as a non-registered medicine? Yes No

(c) Attach specialist opinion (if available) or provide contact details of the specialist the patient has seen and who can be con

Name of specialist: -

Address: -

(Note: the Exceptional Clr

Specialist: _____

 (appropriate opinion)

3. OTHER MEDICATIONS

Provide a full list of treatments for this condition that have been tried or considered.

Pharmaceutical	Unsuitable due to:
Long acting morphine (M-Estla)	- divided and injected intravenously.

Please list any other relevant medications that the patient is currently taking:

Diazepam 15g daily

4. OTHER ISSUES

Is there any other relevant information that should be considered?

note of septicemia / antibodies continues
& habitual I.V. use.

5. ATTACHMENTS

Please attach any additional information which may help the Panel in assessing this application, such as relevant clinic letters, supporting references, lab results, hospital admissions record/s, management plan, and any other information which may be relevant. Please list in the table below the information which you are attaching to this application:

Additional information which is attached to this application
 (to be completed by applicant):

1.	Clinical Summary - discharge 27/02/2008.
2.	
3.	
4.	
5.	

(Please continue this list on an additional page if there is more information than the space provided here.)

6. COST ESTIMATE

(As this is an application for funding a cost estimate must be included. Failure to give a cost estimate may delay processing of the application. Note that applications in excess of \$15,000 for the duration of treatment may undergo a cost utility analysis and will require PHARMAC approval).

Cost per year (quoted by nominated pharmacy, based on dosage requested. Cost must be COST BRAND SOURCE without mark-ups or dispensing fees)	\$ 3790 - 5685
Anticipated duration of requested treatment: <small>(Note that approval will generally be given for only 1 year, renewal would then have to be sought)</small>	indefinite

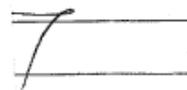
7. RENEWAL (COMPLETE FOR RENEWALS ONLY)

If this is an application for renewal please attach the following:

1. a **full report** including details of the patient's clinical progress, the continuing need for the medication and the short and long term future management of this patient.
2. append any relevant and recent **specialist review**.
3. append any relevant investigations eg laboratory tests, radiology.

8. SIGNATURES

Signature of Medical Practitioner



Date of Request: _____

9. PATIENT CONSENT

Patient details

Last Name

First Name

CONSENT BY PATIENT

For the purposes of this application form I consent to:

information concerning my medical conditions being given to the Exceptional Circumstances Panel (and if required, to PHARMAC); and

the Exceptional Circumstances Panel seeking further information from medical care providers or seeking further medical opinion as may be necessary for the consideration of my application.

X

Date: _____

Patient Copy

Referral Reason
CARDIAC ARREST

Diagnoses

Primary Diagnosis

• VF cardiac arrest w success resuscitation

Secondary Diagnoses

- Acute QT prolongation likely due to methadone
- Methadone program for benzodiazepine dependency

Procedures

Primary Procedure

• Diagnostic Coronary study +/- LV, 26/02/2008, Dr P Nakpathomkun

Discharge Medications

- Diazepam, po 7mg, mane, 2 weeks (script given)
- Diazepam, po 8mg, nocte, 2 weeks (script given)
- Paracetamol, po 1g, qid/prn, 100 tabs (script given)
- M-eslon, po 120mg, bd, 10 days (script given)
- M-eslon, po 60mg, od/prn to top up for withdrawal symptoms, 10 days (script given)
- Lactulose, po 10-20ml, bd/prn, 3 months (script given)
- Coloxyl with senna, po 2 tabs, bd/prn, 3 months (script given)
- Ibuprofen, po 400mg, tds/prn, 2 weeks (script given)
- Omeprazole, po 20mg, od, 3 months (script given)
- Aspirin EC, po 100mg, od, 3 months (script given)

Allergies

NKDA

Clinical Management

Background:

Benzodiazepene dependency (known to ██████████ - on methadone programme)

Opioid dependency

Previous IV drug use.

Nicotine dependency

Previous hx of seizure-type activity - ?absence seizure/petit mal (not documented)

Hep B +ve

42 y.o. lady BIBA following cardiac arrest in community.

Witnessed loss of consciousness by partner. ? Had convulsion in front of partner (became stiff and unresponsive). Ambulance called 06:28.

On ambulance arrival (06:33), was unconscious/unresponsive with agonal respirations and no palpable pulses. She was pulled off bed onto floor and CPR initiated. Initial trace showed VF.

ROSC after 2 min CPR and DC shock 360J.

Initially intubated and ventilatory effort assisted, then spontaneous resp shortly after.

On arrival at ACH,

O/E - GCS 5/15 (E1 V1 M3), T 35.4, BP 142/72, P 86, O2 sats 100%, spontaneous resp, pupils 4mm, PEARL

31/03/2010

Page 1 of 3

Appendix 8: Community Exceptional Circumstances Applications Approved Between 2001–2009 (Provided on CD ROM)

Appendix 9: Analysis of Material Received Under the Official Information Act Requests (Provided on CD ROM)

Appendix 10: Seven further cases of Community Exceptional Circumstances Applications Released under the Official Information Act (Provided as PDF Files on CD ROM)

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