Cover page

Limits to neo-liberal reforms in the health sector: the case of pharmaceutical management in New Zealand

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Acknowledgements: Amy Davis received a Victoria University of Wellington Summer Research Scholarship in support of this research. We would like to thank Josh Barton and the anonymous review for their helpful comments.

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Date of submission: 6/7/2012

Title page

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Biographical Sketch

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Biographical Sketch

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Abstract

In New Zealand in 1993 a pharmaceutical management agency (PHARMAC) was established during the height of neo-liberal reforms in the health sector. The agency's relationship with pharmaceutical companies, patient lobby groups and health professionals has been hostile at times, but despite this hostility PHARMAC has remained substantially independent from political interference. This paper draws on critical theory and Durkheimian perspectives to explain how such a strong regulatory organization was established during a time when attempts were made to re-shape the health sector to conform to a neo-liberal agenda. An analysis of historical and contemporary issues demonstrates the contradictory position of the state in relation to the regulation and subsidization of pharmaceuticals, with conflicting demands to retain popular support, restrain state expenditure and respond to expectations to provide pharmaceuticals to its citizens. This paper demonstrates how the establishment of PHARMAC reconciles these contradictory demands, arguing that it removes decision-making from political control and has been able to sustain its place by appealing to objective assessment criteria. This case signals limits of the neo-liberal agenda.

Keywords: New Zealand; Pharmaceutical regulation; neo-liberalism; critical theory; Durkheim

Introduction

In 1993 the New Zealand government introduced a radical shake up of the health sector grounded in neo-liberal ideology, pursuing market mechanisms to stimulate competition at purchaser and provider levels [1]. But there was a seemingly paradoxical outcome of these reforms, the establishment of the Pharmaceutical Management Agency (PHARMAC). PHARMAC manages the list of prescription pharmaceutical products which are subsidized by the state. It has a monopsonist position in the pharmaceutical market place being the only agency (with some rare exceptions) responsible for the purchasing of state-subsidized medications. PHARMAC's primary functions have been retained, extended, and remain relatively free from direct government control, despite being seen as reducing consumer choice. In addition, the agency can be seen as having a passion and devotion to the public good.

This paper draws on two theoretical traditions to provide insights into this paradox arguing that PHARMAC acts as an institution that tempers particular moral forces in society between the state, capital and the individual. Critical-theoretical concepts in relation to the contradictions in capital provide insight into why a government committed to free market principles supported an agency that constrains the pharmaceutical market. Durkheimian concerns with the balance of opposing moral forces and the need for intermediary institutions are invoked to explain the role of PHARMAC and the enthusiastic support from its workforce.

PHARMAC currently operates as a stand-alone Crown entity, accountable to the Minister of Health. It has four main roles:

- Managing the Pharmaceutical Schedule of roughly 2000 government-subsidized medicines.

- managing the subsidy of some medicines for public hospitals
- promoting the 'optimal' use of medicines
- managing special access programmes and funding medicines for people with rare conditions [2].

After a pharmaceutical's efficacy and safety has been assessed by Medsafe's Medicines Assessment Advisory Committee (MAAC), PHARMAC considers proposals from pharmaceutical companies, health professionals, consumer groups, and individuals for new drugs to be subsidized. If successful, a drug prescribed for any eligible person in New Zealand can then be dispensed at a subsidized price from a pharmacy. PHARMAC (and its delegated committees) assesses subsidy proposals through nine broad criteria, including the health needs of New Zealanders, the clinical risks and benefits of pharmaceutical intervention, the availability of pharmaceutical products, and cost-effectiveness, which relies on quality-adjusted life years (QALYs) [3]. Medicines are assessed and weighted according to an economic evaluation and pharmacoeconomic model. For a new drug to be subsidized, it usually needs to meet a QALY threshold that is lower than other similar pharmaceutical interventions[4]. To enhance cost-effectiveness PHARMAC enters into negotiation with pharmaceutical companies. As only one drug within a therapeutic sub-group is usually fully subsidized, pharmaceutical manufacturers compete to place their product on the Schedule to gain market share.

In short, pharmaceuticals are heavily regulated in New Zealand with a major advance in that regulation occurring during efforts to introduce a neo-liberal influence on the health sector. This paper is organised into the following sections: a history of state subsidization of pharmaceuticals in New Zealand and the attempts by the state to control the costs of this activity; a brief outline of the 1993 health reforms and the establishment of PHARMAC; a

discussion of some of the challenges that PHARMAC has faced; and a theoretical conclusion on the role of PHARMAC and its ambiguous position.

Various sources of data have been systematically analysed. Archival material from the New Zealand government, held at Archives New Zealand, provided information and correspondence from the former Department of Health, responsible for organising and administering New Zealand's Pharmaceuticals Benefit Scheme (PBS) between 1941 and 1993. Published documents and reports from PHARMAC have been used to determine how PHARMAC and the New Zealand government interpret PHARMAC's role in the New Zealand health system. These sources also provide insight into the official discourses of PHARMAC and the rationale behind its establishment. Newspaper reports on PHARMAC-related issues and criticisms of funding decisions were accessed.

History of state subsidization of drugs

An understanding of the history of pharmaceutical subsidization allows us to discern the continuities and the development of concerns that led to the establishment of PHARMAC. The regulation of pharmaceuticals by the New Zealand state dates back to at least 1936 when pharmacies applied for licenses from the Bureau of Industry (and later – the Department of Trade and Industry). Most pharmacies were owner-operated compounding their own drugs, and the establishment of British 'company' pharmacies was viewed as a serious threat to the viability of local pharmacies [5]. The Bureau of Industry's Pharmacy Plan Industrial Committee (PPIC) developed a schedule of standard prices for drugs for all pharmacies therefore removing price competition [6].

In 1941 the first Labour government passed legislation providing medicines free to patients on the prescription of any registered medical practitioner. The 'Pharmaceutical Benefits Scheme' adopted the rules and schedule of prices developed by the PPIC [7]. The range of free pharmaceuticals to be subsidized was defined in a 'drug tariff'. The Pharmacology and Therapeutics Advisory Committee (PTAC) was the major driver in pharmaceutical management from this time. PTAC's decisions focussed primarily on the clinical need for the drug, and PTAC members did not generally have the expertise to evaluate the fiscal impact their recommendation had on overall pharmaceutical expenditure [8]. The Department of Health negotiated the price of drugs with pharmaceutical companies. While in theory the government was in strong bargaining position through its control of access to the New Zealand market, in practice the Department of Health saw its role as an efficient administrator, rather than a tough commercial negotiator [9]. Relatively few barriers prevented the inclusion of high cost, brand-name drugs on the drug tariff, which pushed up the cost of the PBS [9]. As doctors were not constrained by cost restrictions they had no need to be concerned with drug prices in deciding on which medicines to prescribe from the 'free list' [9].

Before the 1940s there were few demonstrably effective therapeutic drugs of wide application [10]. Mixtures compounded in the pharmacy made up almost 60% of the prescription items dispensed in 1941, but they became increasingly displaced by mass-produced, trade-name products [11]. Effective advertising (under current New Zealand law direct-to-consumer advertising of prescription medications is legal) and the increased availability and accessibility of a broad range of medicines at little or no cost rapidly drove up pharmaceutical use and cost to the government. The pharmaceutical industry justified high prices for new medicines by claiming that new chemical and biological entities incurred very large research and development costs [12]. The commitment of successive government to supply as wide a range

of new pharmaceutical products as possible to New Zealanders also proved to be a major cost-driver [9].

By the mid-1960s, the Department of Health used a form of reference pricing where competing brands of drug existed, basing payments to pharmacists on the lowest priced brand of the drug in the group, which became the 'bench-mark' or maximum acceptable price [9]. However, a lack of tight budgetary constraints and clear negotiating objectives meant that the Department of Health had few incentives to drive bargains with suppliers, and in addition it lacked information on actual prescribing data and international price comparisons [13]. Once a drug was placed on the tariff, manufacturers had little incentive to provide a discounted price.

The notion of 'free medicine' rapidly became a right and expectation of the New Zealand health system, with expenditure on the PBS steadily rising as a consequence. Between 1950 and 1980 the number of prescriptions per head of population increased from 2.8. to 7.7 and the average cost of pharmaceuticals per head of population rose three fold over the same period [14]. In 1982 more than 60 % of consultations with general practitioners involved a prescription [13]. During the 1980s expenditure on non-hospital pharmaceuticals grew by 15% a year [15].

The establishment of PHARMAC

From the 1980s reforms were undertaken in a determined effort to decentralise the control of health and restrict expenditure [16]. Reforms started by the Fourth Labour Government elected in 1984, and extended by the later National government, attempted to tackle the problem of

pharmaceutical benefits and find alternate ways for the Department of Health to negotiate prices [16].

Pharmaceutical policy reviews argued that the state's pharmaceutical expenditure could be controlled by better use of the tools the Department of Health had available to it, such as removing from the tariff drugs that offered poor value for money, bargaining over price [17] and varying the level of part charges for a drug [13]. Similarly, pharmaceuticals also featured in the core health services debate of the early 1990s, with suggestions for a basic list indicating which medicines should be used in 'most' situations [18].

In addition, PTAC's decisions were perceived to be closed, contradictory and subject to lobbying. To illustrate, after four unsuccessful attempts to get Xanax (alprazolam), an anti-anxiety medication, on the drug tariff between 1986 and 1989 the manufacturer was successful in 1990.[1] Although PTAC rejected the application in 1989 due to concerns about its expense and the issue of drug dependency[2], the decision was reversed in 1990. In Xanax's application to PTAC in 1990, a number of general practitioners, hospital doctors, and a psychiatrist supplied manufacturer-supported testimony as to Xanax's effectiveness for their patients. [3]

The neo-liberal vision of health sector reform became manifest in the Health and Disability Services Act 1993, which introduced a competitive approach to the provision of health services. Four Regional Health Authorities (RHAs) were created to purchase services for the population

[1] Pharmacology and Therapeutics Advisory Committee, 'Extract from Minutes', 22 August 1990, Pharmaceutical Benefits – Pharmacology and Therapeutics Advisory Committee – General, 1993-1993, ABQU W4452 632 1322 208-2-3-2 79652, ANZ. Available at Archives New Zealand.
[2] Pharmacology and Therapeutics Advisory Committee, 'August 1990 Agenda – Drug Tariff Application', 142/701/3375, Pharmaceutical Benefits – Pharmacology and Therapeutics Advisory Committee – General, 1993-1993, ABQU W4452 632 1322 208-2-3-2 79652, ANZ. Available at Archives New Zealand.
[3] 'Petition to Drug Tariff', assorted letters to Lenore Jansen, Benefits and Subsidies, Department of Health, Wellington, 25 June 1990 to 9 July 1990, Pharmaceutical Benefits – Pharmacology and Therapeutics Advisory Committee – General, 1993-1993, ABQU W4452 632 1322 208-2-3-2 79652, ANZ. Available at Archives New Zealand.

in its area from a range of providers in a competitive health market. A Ministry of Health was to replace the existing Department of Health [16]. Hospitals became Crown Health Enterprises based on business models [1].

However, the 1993 Act did not contain any statutory provisions to establish a pharmaceutical benefits system and the drug tariff. The purchase of community pharmaceuticals was viewed to be a task most appropriately undertaken by the new RHAs and so the system of administering the drug tariff by the Department of Health was abolished. In a Department of Health memorandum, four options were proposed for reform of the PBS: the establishment of a Ministerial Advisory Committee, a State-Owned Enterprise, a quasi-government organisation, or a joint-venture company [8]. The establishment of a joint-venture company to manage pharmaceuticals was seen as consistent with the general thrust of the health reforms and gave the RHAs control over the drug tariff in line with their responsibility to manage the drug budget. In terms of minimising litigation risk, this option was viewed as the most desirable as the Minister of Health would have the greatest amount of distance from pharmaceutical decision-making [8]. PHARMAC was established as a non-profit joint-venture company to negotiate supplies for pharmaceuticals, largely independent of government and under the four RHAs, with each having a 25% share in the company. PHARMAC took over the functions of the drug tariff section of the Department of Health with the drug tariff itself converted to the Pharmaceutical Schedule [19]. In 2001 PHARMAC became a stand-alone Crown Entity, accountable directly to the Minister of Health [16]. Its primary objective was ‘to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided’[20].The establishment of PHARMAC as a separate business unit, outside the Ministry of Health, meant that placing an item on the Pharmaceutical Schedule was no longer a

Ministerial decision subject to considerable lobbying and PTAC's advisory capacity was absorbed into PHARMAC's structure.

Since its establishment, PHARMAC has adopted a broad range of strategies to achieve pharmaceutical cost savings. Foremost among PHARMAC's strategies are supply side interventions aimed at lessening the drug bill. Broadly, PHARMAC uses the threat of loss of market share to force the suppliers of products in each cluster of medicines judged to be interchangeable to compete on price [21]. Products not listed on the Pharmaceutical Schedule gain little market share as historically sales have reduced if a pharmaceutical has carried a surcharge [19]. Doctors have been highly sensitive to the imposition of charges to their patients, changing their prescribing patterns to avoid increasing direct patient costs [19]. Pharmaceutical companies may be deterred from licensing a medicine with MAAC if they think a listing on the Schedule is unlikely, thereby reducing the range of drugs available in New Zealand [12].

Reference pricing has been one of the most controversial market control policies utilised by PHARMAC. Although forms of reference pricing have been long used in New Zealand, PHARMAC used the policy more intensively. Formal reference pricing was introduced in July 1993 with the intent to 'reduce the excessive market segmentation based on brand marketing, which previously allowed suppliers to establish markets that were free from price competition' [22]. The majority of the products listed on the Pharmaceutical Schedule are covered by reference pricing, divided into therapeutic sub-groups of pharmaceuticals that produce the 'same or similar' effect in treating a condition [23]. New products to the Schedule are generally subsidized only if they join an existing sub-group, which requires offering a price below the prevailing reference price [22]. PHARMAC's particular form of reference pricing is broader

than that used in many other states. Some states define their therapeutic groups narrowly, essentially meaning they have to be interchangeable medicines [24]. Unlike some European systems which determine the level of subsidy based on the average cost of the drug in the therapeutic group, PHARMAC determines subsidy from the lowest cost at which there is willingness to supply the drug [25]. One fully subsidized pharmaceutical is in each therapeutic sub-group [24]. PHARMAC considers reference pricing to have been a highly effective and powerful tool because pharmaceutical suppliers have tended to lower their prices to the subsidy level.

PHARMAC also utilises contracts, fixed expenditure caps, and tendering for sole or preferred supply. Tendering allows PHARMAC to choose the lowest tendered price to become the subsidy level for all drugs in a group, and fixed expenditure caps can fiscally cover abrupt demand-side changes if a new drug is subsidized [22]. Innovatively, PHARMAC may also accept a package deal across a range of therapeutic groups to lower pharmaceutical costs. A manufacturer may prefer to give a large price cut on an old product with a small market share rather than accept a low launch price on a new product that it hopes will gain significant volume. For example, in 1996, a 40% price cut on Tagamet (cimetidine) was offered in return for a listing on the Schedule for Famvir (famciclovir), thereby reducing the reference price for drugs in Tagamet's reference group by the same amount [22].

Drug companies complain that reference pricing pushes pharmaceutical prices down to the bare minimum, and does not leave them with the resources to develop new drugs. While New Zealand benefits from its 'tough' stance, 'other countries are paying for it' [26]. Merck Sharp and Dohme believed the price negotiated for simvastatin had reached such a low level in New Zealand that it changed its brand name from Zocor to Lipex because there was a perceived risk

of parallel importing from New Zealand to other less regulated countries [27]. Although the criteria for entry to the New Zealand Pharmaceutical Schedule tightened over the five years to June 1998, PHARMAC was able to list 363 new drugs, widen access to 67, and yield cumulative savings of $284 million [28].

While the majority of OECD and other countries use remarkably similar price controls to contain medicine costs, the range of methods PHARMAC uses, and the aggressive implementation of their bargaining is somewhat unusual [12, 22]. This monopsony power has allowed PHARMAC to negotiate prices on new products which then apply to all other products in the reference group. This strategy is not deployed in other countries where reference pricing is used, such as in Germany or the Netherlands [22]. PHARMAC's reference pricing system and other strategies is regarded as more comprehensive that other countries [22]. For example, a number of European reference pricing systems fix reference prices at the average or median price in the category, or the minimum price for drugs off patent. However, PHARMAC sets the reference price at the price of the lowest priced medicine within a therapeutic category regardless of patent status [29-30]. In the UK. drug prices are set by manufacturers under the Pharmaceutical Price Regulation Scheme, with the National Institute of Clinical Excellence (NICE) evaluating and providing advice on a limited number of medicines. Primary Care Trusts make local decisions about medication funding [31]. As such the monopsony power used by PHARMAC does not apply in the UK. In the US Pharmacy Benefit Managers (PBMs) use tiered formularies where products that are considered to be most cost-effective carry a lower copayment than non-preferred products [22]. Tiered formularies apply to compounds that are generically equivalent – that is – the molecule in the product is generic and patients would pay more for the brand price over the generic price [22]. In reference pricing systems products are classified into groups assessed as having similar therapeutic effects [22] so the

therapeutic agents included in the group is much wider than generic classifications. In addition, PBMs in the US are not in a monopsony situation [22].

Challenges to PHARMAC

New Zealand's comparatively low pharmaceutical spend is seen as resulting from its strong regulatory system. It has been estimated that between 1994 and 2008 the drug budget increased at an annual rate of 2%, compared with a 15% annual rate of increase prior to that period, additionally in other OECD countries drug expenditure rose in relation to total health services expenditure but fell in New Zealand [15]. However, PHARMAC's decisions have led it into conflict with patient groups, medical professionals and pharmaceutical companies. It has been subject to intense lobbying, media scrutiny and litigation [32].

Litigation and long, drawn-out court cases marked PHARMAC's first years controlling the Pharmaceutical Schedule. Between 1993 and 1998 about 18% of PHARMAC's operating costs was spent on legal fees [28], but PHARMAC's processes withstood multiple bouts of litigation. In 1998 alone PHARMAC won a judicial review test case concerning therapeutic sub-group and reference price decisions and had a favourable ruling that it had statutory exemption from the Commerce Act [28].Drug companies did not rely on the courts to secure support but also made direct approaches to the public. For example, in 1997 the Researched Medicines Industry launched a May Day campaign using full-page advertisements in major daily newspapers questioning PHARMAC's plan to reduce the cost of a range of drugs [28].

The use of cost utility analysis as the principle tool in decision-making led to some tough decisions. Medical professionals contested PHARMAC's reference pricing policy on the basis

that a single drug may have several uses, diseases require more than one therapeutic approach, and concerns over adverse effects, all necessitating more choice within subsidized medications [33]. This is an argument against the concept of therapeutic equivalence between drugs that was used by PHARMAC.

Funding of the statin group of drugs has been particularly controversial and is illustrative of the tensions that arise from PHARMAC decisions [27]. Cardiologists claimed that PHARMAC's decision "caused more harm and premature death to New Zealand patients than any of their other manoeuvres" [34]. Lipid-modifying drugs were released into the New Zealand market in the late 1980s and statins became a focus for PHARMAC as future expenditure on this group of drugs was predicted to be extremely high [25]. Between 1989 and 1997 three statins, fluvastatin, pravastatin and simvastatin, were all fully subsidized and available to New Zealand patients on a specialist prescription [25]. But in 1997 PHARMAC funded fluvastatin. Although PHARMAC argued that it had consulted with the National Heart Foundation, cardiologists and other specialists, and the Royal College of General Practitioners, many doctors and patients criticised the decision seeing fluvastatin as an enforced patient switch resulting in less control over cholesterol levels and increasing in patient cardiovascular events. Although simvastatin was still available to patients, it was referenced-priced to fluvastatin, and as the more expensive pharmaceutical, many were reluctant to pay the patient co-payment. After significant pressure, and a new round of negotiations with manufacturers, atorvastatin, a more potent statin, was given full funding from June 1998, but was subject to Special Authority approval and to be used only if cholesterol levels were not being controlled on fluvastatin. In 2002, simvastatin was again available without additional patient cost or special approval after a commercial arrangement between Merck, Sharp and Dohme and PHARMAC. In an attempt to streamline statin prescribing decisions, PHARMAC proposed simvastatin as the primary statin drug,

switching approximately 39,000 patients off alternative fully-funded statins. Many patients had initially been treated with simvastatin before being switched to fluvastatin in 1997, then changed to the stronger atorvastatin and then switched back to simvastatin. Pfizer discussed the possibility of the company leaving New Zealand, taking with them atorvastatin and other medications. PHARMAC re-evaluated and decided to continue to fund patients on atorvastatin. It has been claimed that this episode led Pfizer to withdraw $40 million annual medical research funding from New Zealand [34].

PHARMAC's Chairman responded to concerns over statins by explaining that

> The patients who get the greatest benefit from statins are those with established heart disease. Previously, only about half of eligible high-risk patients were in fact getting statin treatment. Yet the dissent over our statin decision has focussed on marginal differences between brands of statins, rather than on overall patient benefit [35].

PHARMAC further responded in *The New Zealand Medical Journal* pointing out that advocating for individual patients so that "other patients [miss] out altogether" is an important ethical issue that clinicians need to reconsider [36]. PHARMAC here invoked a utilitarian argument based on what was best for the population in defence against the lobbying of health professionals for their individual patients.

Funding decisions in relation to Interferon Beta, used for multiple sclerosis, also gained intense media coverage. Before 1999, New Zealand patients could receive Interferon Beta if they were prepared to pay for it themselves. PHARMAC had twice declined to fund Interferon Beta because, in line with the assessment made by the UK's National Institute for Health and

Clinical Excellence (NICE), the benefit for most patients was deemed to be low relative to the cost. In 1999, after extensive lobbying from neurologists and the MS Society, the Minister of Health directed PHARMAC to make Interferon Beta available to a limited number of patients based on screening by a panel of neurologists. The funding cap was set at 180 people with that cap being later removed in 2002.

As the issues over statins and Interferon Beta have illustrated there was opposition to the utilitarian focus of PHARMAC and its use of particular economic evaluations. The potential for a free-trade agreement between New Zealand and the United States has provoked recent debate over the continuation of PHARMAC's role as a monopoly purchaser of pharmaceuticals in New Zealand. The release of confidential American Embassy diplomatic cables by WikiLeaks in late 2010 led to a flurry of public discussion around the activities of PHARMAC. The cables illustrated frustration from international pharmaceutical companies with New Zealand pharmaceutical management. [4] American pharmaceutical companies consider New Zealand to be hostile ground and one of the most restrictive markets in the world. Unable to meet their sales and profit targets, they argue it was becoming increasingly difficult to keep investments or even a presence in New Zealand. Like similar arguments in Australia, major pharmaceutical manufactures aimed to place pharmaceuticals on the agenda of free-trade negotiations [37]. The monopsonist position of PHARMAC goes against the aims of free-trade, and major drug companies hold out hope that a New Zealand-United States free-trade agreement could be a lever for improving their access to New Zealand's pharmaceutical market.

[4] 'WikiLeaks Cable: No Quick Fix for Pharmaceutical Market', *The New Zealand Herald*, 19 December 2010.

PHARMAC is a small organisation (having around 60 staff) created to fulfil a specific function within New Zealand's public health system, and has had significant impact on the availability of pharmaceutical products in New Zealand [38]. PHARMAC workers describe their organisation as a "passionate" one [4]. In 1996 PHARMAC's General Manager described reference pricing as the 'government's slingshot' in its David and Goliath battle with pharmaceutical companies [24]. He argued that international manufactures do not have New Zealand's best interests at heart, with most of the money in pharmaceuticals in New Zealand going into marketing, sales teams, glossy brochures, and 'flying doctors to attractive facilities for ski weekends', rather than health research and development [26]. Moore argues:

> New Zealand is a small country, vulnerable to and a target for some of the overseas giants who could buy the islands outright with just the money they spend on marketing. It is reference pricing which the government uses to keep the drug barons at bay. …there is an elite, powerful, rich little group into whose hands one must play in order to buy pharmaceuticals [24].

Publicly, PHARMAC's publishing and writing activities have effectively presented its views to a wide domestic and international audience. PHARMAC has been quick to provide rebuttal arguments in *The New Zealand Medical Journal* when its methods have been questioned [3, 36]. Its senior managers and health economists also regularly contribute to international journal publications, openly provide information to academic researchers and comment on contemporary pharmaceutical issues in the media.

PHARMAC initially welcomed dialogue with the pharmaceutical industry. It hoped to avoid contentious issues with the industry, and at the time, the strength of feeling against PHARMAC's cost-saving policies was unexpected [39]. The resulting years of litigation and

media campaigns launched by the industry and RMI rapidly changed this opinion.

PHARMAC often presents itself as a small organisation fighting for the best outcomes for New Zealand against the might of the international pharmaceutical industry. Throughout these controversies and tensions, PHARMAC has retained its functions within the New Zealand health system and there has been a notable lack of political interference through changes of government. In only two instances in nearly 20 years has the government overruled PHARMAC decisions [15]. In 2009, Cabinet agreed in principle to expand PHARMAC's role into hospital medicines and a limited range of medical devices. No country apart from New Zealand appears to have delegated the management of both community and hospital pharmaceuticals to one government agency [12].

Although the importance of regulatory bodies is well recognised, and most studies have largely been positive about PHARMAC's role in controlling drug costs, a number have highlighted some concerns for the future [12]. In a 2005 study of pharmaceutical price regulation New Zealand had one of the lowest new product launch rates [40]. A 2010 study also highlighted that drugs subsidized in New Zealand were predominantly older medicines first registered in the 1970s or earlier [41].

Discussion – the regulation of neo-liberalism

It is clear from this description that PHARMAC has become a powerful agent of regulation in New Zealand limiting the market activities of pharmaceutical companies and being targeted by them, health professionals and lobby groups as PHARMAC's activities interfere with values prized by supporters of neo-liberalism – personal freedom, unhindered markets and consumer choice. How are we to explain the birth of such an organization at a time when efforts were made to ground health sector reforms in a neo-liberal ideology?

At the time the New Zealand state introduced subsidized access to doctor-prescribed pharmaceuticals there were few pharmaceutical agents that were effective and the manufacture of these was primarily locally-based and small scale. However, over time the shifting of manufacture offshore and the huge expansion in the availability and consumption of pharmaceuticals became a major problem for the state.

The health reforms that led to PHARMAC can be seen in relation to Habermas's discussion of crises of legitimation. Habermas identifies two crises for states exercising power in capitalism. One is an output crisis which results from running fiscal deficits. The state pharmaceutical budget can contribute to this deficit. The other is a potential input crisis, or a crisis of legitimacy, where the maintenance of popular support for the arrangements of the capitalist state could be undermined [42]. The electorate's expectations in relation to health care provision and access to pharmaceuticals require the state to subsidise pharmaceuticals in order to maintain popular support. In Western Capitalist societies the allocation of health resources is seen as a public responsibility [43]. That is, there is a moral imperative to support citizens in relation to matters of sickness and disease. The playing out of the health reforms and the establishment of PHARMAC can be seen in relation to these contradictory functions. The state-subsidization of pharmaceuticals led to a vast increase in state expenditure. One impact of this, through the requirement to gain the revenues to cover this cost, is that money is drawn away from other spheres of investment. For this reason capitalists call on the state to restrict state expenditure. There is a tension between particular capitals with pharmaceutical capitalist enterprises attempting to maintain state subsidies of their products and other capitalist enterprises making demands on the state to reduce expenditure. In addition the state is caught in a bind between public payment and the private appropriation of profit. The establishment of PHARMAC can be seen as an elegant way for the state to stay at arm's-length from this

tension and conflict. Drug companies employ the rhetoric of a right to health care and draw on humanitarianism to protect their position. PHARMAC draw on notions of the collective good and utilitarianism to legitimate their activities, positioned within a legal-rational mode of legitimacy. As such PHARMAC can reconcile the contradictory demands of a particular grouping of capitalists (pharmaceutical companies to maximise profit) and capitalists in general (to reduce state expenditure). A neo-liberal government is particularly caught in these contradictions as a result of a primary goal being a reliance on market mechanisms. An unfettered market with no state subsidy is likely to bring about a crisis of legitimacy for the state and a loss of popular support. The creation of PHARMAC enables a resolution to this controversy as regulatory 'decision-making' is no longer driven by elected governments.

PHARMAC does not at heart challenge the capitalist production of pharmaceuticals but supports it. It supports the reductionist positioning of biomedicine, and in fact, through the concept of therapeutic equivalence, takes this further, removing the assessments of medical practitioners from the equation. It challenges individual capitalist enterprises, and some lose out in this challenge, but overall it cements the place of the capitalist production of pharmaceuticals as having a central place in the delivery of health care.

PHARMAC workers appear to have a passion for its activities, beyond the usual responses of government agencies. Again the distance from government no doubt allows PHARMAC latitude to express itself without having to have sign-off from ministries looking to protect their government minister. A perhaps complementary reading to the one above draws on a Durkheimian analysis. Here we can similarly consider PHARMAC as an institutional means to contest capital and the promises of the market. PHARMAC is an institutional means to balance the anomic desiring of the population for a pill for every ill with the anomic desiring of drug companies to maximise profits. Durkheim was concerned that in contemporary society there

was a lack of regulation of our desires that would lead to anomic states. Without regulation unfettered desires can lead to pathological outcomes. Durkheim most famously articulated this position is his book *Suicide* where institutional forms of moral authority found in different religions could influence levels of anomie in a community, which could in turn lead to different suicide rates. Durkheim saw the need for new institutional groupings to foster social cohesion by countering anomic currents with altruistic or even fatalistic forces. The former refers to a commitment to a higher order beyond one's self interests and the latter refers to inescapable limits on human action [44]. The new institutional or social groupings provide checks and balances on individuals and other institutions [45]. We can consider PHARMAC as acting in this capacity as a source of social cohesion through proffering a new morality based on utilitarianism. For Durkheim, a cohesive moral force that would replace traditional religion would be based on science but go beyond science [46]. PHARMAC relies on particular scientific calculations, but as has been noted, has a passionate commitment to the public good, as such exhibiting altruistic tendencies in Durkheimian terms. PHARMAC functions as a moral force that tempers both consumer consumption of medications, requiring a level of fatalism from patients about what is available to them, and the multinational companies' desires to extract maximum profit on their activities. The state itself recognised its limitations in the face of these forces and the delegation to an agency making decisions independent of elected officials provides a solution to its dilemma. PHARMAC's passion is based on its view of itself as working on behalf of New Zealanders, against hostile opposition from those who would profit from illness. Its public health perspective aligns it with Durkheim's concept of a cult of humanity. Elsewhere it has been argued that public health itself fulfils this function of a moral force in society [47-48] and PHARMAC can be seen as taking on that public health function of facilitating processes that temper the desires of commerce and of the individual.

So drawing on critical theoretical analyses complemented with a Durkheimian framing our puzzle can be 'solved', and this has implications for how public good, private profit and electoral demand contradictions can be resolved. We would argue that one of the crucial elements in allowing PHARMAC to maintain its role is a reliance on what can be argued as an 'objective' assessment process. Maor argues that PHARMAC's funding decisions, and PHARMAC itself, are less susceptible to political moves than agencies in other countries because it utilises techniques that are 'best practice' [49]. The use of QALYs and cost-utility analysis allows for a population perspective to be applied to the consumption of pharmaceuticals. Although using these economic tools is open to contestation relatively few decisions have been successfully challenged by the medical profession, the pharmaceutical industry, politicians, or the public [49]. We can consider an analogy here with medicine itself. Over the period of the nineteenth and twentieth centuries medicine became increasingly technical and there was a shift from diagnosis and treatment plans relying on the subjective symptoms provided by patients to relying on objective signs detected through instrumentation [50]. This has an effect of empowering the medical practitioner and disempowering the patient. With PHARMAC's use of 'objective' economic assessments of pharmaceuticals, patients and drug manufacturers are disempowered in relation to this standard.

Another crucial element of PHARMAC's success is its distance from patient lobbying. Lessing contends that PHARMAC's continued independence provides the government with a means of containing the pharmaceutical budget while at the same time shielding the Minister from much of the 'heat' of contentious decision-making [32]. However, there have been two instances where intense lobbying has led to the undermining of PHARMAC decisions, the case of Interferon Beta discussed above and the case of Herceptin. In the latter case an elected government met its election promises by funding Herceptin through the Ministry of Health and

so circumventing PHARMAC. These exceptions can be seen as a form of 'pressure release' for PHARMAC whilst at the same time providing a form of electoral legitimacy for the government. These cases place politicians in a positive light and shore up electoral support but also take pressure off PHARMAC's general activities.

PHARMAC was established in circumstances of pressure on state expenditure and governments seeking to buffer themselves from electoral demands. It has been sustained by purporting to follow 'objective' protocols that have withstood legal challenges from the pharmaceutical industry and lobbying demands from patient groups. This is a case of neo-liberal governments putting in place institutional barriers to neo-liberal agendas.

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