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Divergent spender: State-societal and meso-organisational mechanisms in the containment of public spending on pharmaceuticals in a liberal capitalist democracy

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Abstract

For two decades, New Zealand has been placed consistently at the foot of OECD rankings for state expenditure on pharmaceuticals. In this article, we explore New Zealand's containment of pharmaceutical spending as a 'divergent' case of pharmaceutical policy in a liberal democracy. To elucidate the likely institutional mechanisms and interests behind this phenomenon, we conducted a case study of New Zealand's drug reimbursement policy. In doing so, we derived sensitising concepts from major accounts of pharmaceutical policymaking (Corporate Bias Theories and Reputational Theory) and theories of the western state (Historical Institutionalism and Corporate Domination Theory). Drawing on 28 expert interviews and documentary analysis, we identified three main mechanisms of spending containment. First, New Zealand's state bureaucracy use pricing strategies that rely on a spending containment strategy coordinated by bureaucratic managers. Second, these managers shape the policy preferences of expert committees involved in scientific drug assessment. Third, on a meta-level, conditions for spending containment are enabled by the judicial-legislative arena. As such, we find support for Historical Institutionalism and Reputational

Theory and more limited support for Corporate Bias Theory and Corporate Domination Theory. Our explanation posits further conceptual linkages between the macro/societal and meso-organisational theoretical levels.

KEYWORDS
bureaucracy, neo-liberal corporate bias, New Zealand, pharmaceutical expenditure, reputational theory, state theory

INTRODUCTION

Publicly funded pharmaceutical spending costs over 1 trillion USD globally (OECD, 2014), with the USA alone spending 2% of its GDP on government procured pharmaceuticals. This high arena of late capitalism (Daemmrich, 2004; Habermas, 1973) has generated a classic collective allocation problem for the 'state-capital relation' (Evans, 1995): the state's interest in allocating a collective good with finite resources—the pharmaceuticals necessary for citizens' health—and the pharmaceutical industry's interest in revenue maximisation. This dilemma has been studied chiefly with theories of pharmaceutical policy. These (meso level) organisational theories have included explanations of how state societal features shape lower-level organisations and policy making (Abraham, 1995). More recently, analyses of these relationships have seen scholars utilise the (state-societal level) theoretical framework of accounts of the western state (Ozieranski & King, 2016, 2017). Conceptual precision in understanding this dilemma can be promoted by combining theoretical traditions from these specific domains to elucidate how state-societal factors interact with organisational factors in determining pharmaceutical policy. Specifically, we assessed the relationship between potential drivers of public pharmaceutical spending: the interests of the state and state bureaucracy and the interests of the pharmaceutical industry.

We examined drug reimbursement policy in New Zealand, a capitalist liberal democracy with strong historical and political links with the UK as part of the Commonwealth. Despite greater health spending than the UK (OECD, 2014), New Zealand's public expenditure on pharmaceuticals represents 0.9% of its GDP, compared with the UK's 1.2%, and the OECD average of 1.5% (Cumming, 2010; OECD, 2014) placing it consistently in the OECD worldwide bottom five for public pharmaceutical spending. Pertinently, New Zealand's drug reimbursement spending levels have fallen from 15% annual average increases through the 1980s to 1% since the early 1990s (Barber & Sheehy, 2015). Coinciding with this was the introduction, in 1993, of the Pharmaceutical Management Agency (PHARMAC), the state bureaucracy responsible for health technology assessment and drug reimbursement policy. Notably, under PHARMAC estimated pharmaceutical expenditure rose more than 3.9 times between 2008 and 2018 but the actual expenditure only grew 1.6 times during the same period (PHARMAC, 2018:24).

We seek to understand the conditions underlying New Zealand's pharmaceutical spending containment diverging from the pattern observed in other OECD states. We identified two crucial themes namely, (1) the institutional mechanisms behind the spending policy outcomes, and (2) the consistency of these outcomes with the interests of the state or the interests of the pharmaceutical sector. To consider them, we compared the respective explanatory power of contrasting theories of the western state (Historical Institutionalism and Corporate Domination Theory) and, partially competing (Mulinari

& Davis, 2020), theories of pharmaceutical policymaking (Corporate Bias Theory and Reputational Theory).

Theories of the state and pharmaceutical policymaking

A central opposition among theories of the western state concerns the state's independence from 'external', non-state actors, or, conversely, their ability to control the state bureaucracy. This opposition has been best expressed in the debate between Corporate Domination Theory and Historical Institutionalism.

For Corporate Domination Theory, state policy in advanced capitalist countries, like the US, is decisively influenced by business and financial elites (Domhoff, 2006). This happens via policy-planning, lobbying, opinion-shaping, and candidate-selection mechanisms transferring both personnel and policy ideas from corporate-controlled organisations to state bureaucracy (Domhoff, 2006). These processes prevent the state from formulating and protecting its interests. The extent of corporate control is mitigated by state capacity, particularly the strength of state bureaucracy (Domhoff, 2006:219–220).

Contrastingly, Historical Institutionalism views state elites as actively competing with capitalists for vital resources (Skocpol, 1985). It emphasises that career bureaucrats and policy experts advising state bureaucracies enjoy 'potential autonomy' in pursuing state interests. These professionalised state elites have minimal ties to dominant socioeconomic interests and develop policy using 'stable office rules' (Skocpol, 1985) and strong internal agency culture. Their independence is further reinforced by institutional mechanisms establishing 'bureaucratic insulation' from non-state actors.

Broadly aligned with Corporate Domination Theory is Corporate Bias Theory of pharmaceutical policymaking, initially derived from extensive fieldwork focussing on pharmaceutical product regulatory agencies in Europe, especially the UK, the US and Canada (Abraham, 1995; Abraham & Lewis, 2000; Davis & Abraham, 2013; Lexchin, 2016) and, more recently, the price/cost (or health technology assessment) agency in England (Abraham, 2009). One key postulate of Corporate Bias Theory is that the pharmaceutical industry enjoys privileged access to government. Consequently, it can govern in partnership with other organised interests, systematically biasing the regulatory agenda 'in favour of these interests and at the expense of diverging or conflicting interests' (Davis & Abraham, 2013:33), for example, 'public interests' understood as policy alternatives that would maximise public health outcomes. Corporate Bias Theory was subsequently modified into 'Neo-Liberal' Corporate Bias Theory (hereafter, NLCB) (Abraham & Lewis, 2000) reflecting the political implementation of neoliberalism in the 1990s and its effect on legislative and regulatory institutions in Europe and North America (Davis & Abraham, 2013). Specifically, neo-liberal ideology—especially a deregulatory logic—in higher level spheres of governance has been linked to alterations in regulatory organisations' structures, personnel and decision-making (Davis & Abraham, 2013; Lexchin, 2016). Nevertheless, regulatory agencies may also initiate policy shifts more endogenously, responding to wider public-political culture (Mulinari & Davis, 2020).

Unlike Corporate Domination Theory, NLCB is consistent with 'structuralist' accounts claiming that state interests in the capitalist economy's long-term viability can override capitalist industry (Abraham, 1995; Abraham & Lewis, 2000). Typically, however, NLCB is empirically supported by policy mechanisms reflecting an 'instrumentalist' view of the state. This is, that capitalists need to establish their access to the policy process via formal consultative mechanisms between the state and industry trade bodies, widespread conflicts of interest of regulatory experts, and the revolving door syndrome involving state officials (Abraham, 1995, 2009). Drug regulatory agencies reviewing safety

and efficacy data upon advice from scientists and health professionals may also be vulnerable to conflicts of interests (Abraham & Davis, 2020).

Whereas Corporate Domination Theory stipulates that reduced state capacity creates space for corporate control, NLCB takes the view that the size of the neo-liberal regulatory state may in fact grow in conjunction with an increasingly pro-industry orientation capable of producing a strong, pro-business regulatory state (Abraham & Lewis, 2000). Corporate Domination theorists also premise the primacy of the expression of corporate interests in state policy on the way the corporate community controls key aspects of state governance. This potentially compromises the state's ability to manifest its independent interests via interlocking of state structures with the corporate community (Domhoff, 2006). Contrastingly, NLCB incorporates the idea that the state has its own interests—particularly in public health and financial management—which are held independently of the pharmaceutical industry (Abraham, 2007). NLCB, therefore, envisages that the state and industry are distinct entities—rather than the compromised, single entity of the Corporate Domination position—but whose interests nevertheless converge in processes of policy formulation via formal two-way bargaining.

NLCB has been supported empirically particularly by reduced drug approval times and the increasing proportion of unsafe drugs reaching the market (Abraham & Davis, 2005, 2020; Davis & Abraham, 2013) and rising drug reimbursement expenditure for branded pharmaceuticals (Abraham, 2009). While retrenchment in public pharmaceuticals spending in temporary macroeconomic contractions supports NLCB (Abraham, 2007), the theory is more difficult to uphold in scenarios where a long-term expression of the state's independent interest in savings results in prevailing harm to the industry's economic interests (Abraham, 2007) or where state institutions purposively reduce the industry's ability to maximise its interests.

A further theory of pharmaceutical policy which partially competes with NLCB is Carpenter's Reputational Theory of bureaucratic power (hereafter 'Reputational Theory'), derived primarily using material relating to the US pharmaceutical product regulatory agency (Carpenter, 2010). This account was initially built around the concept of 'bureaucratic autonomy', stressing that bureaucracies can display action which organised interests cannot counteract (Carpenter, 2001). Sharing with Historical Institutionalism the emphasis that the levels of professionalisation, esprit de corps and recruitment backgrounds in bureaucracies are protective factors, insulating state interests from external social actors, 'Carpentarian' bureaucracies are also capable of shifting electoral and representative opinion, a view acknowledging a more extensive role of infrastructural power in executing state interests than the classical Weberian view of bureaucracy. Carpenter also distinguishes between three potentially overlapping varieties of 'bureaucratic power' derived from the agency's reputation and legitimacy with various audiences, such as politicians, physicians and citizens (Carpenter, 2010). Agency 'directive power' stands for the formal power to change the behaviour of pharmaceutical companies and can be generated from a reputation for irreversible decision-making and commercial awareness. The Agency's 'gatekeeping power' stands for formal control over access to the national market, while 'conceptual power', denotes its ability to shape the behaviour of 'audiences' by moulding the concepts and methods they use (Carpenter, 2010).

Reputational Theory can align with NLCB. For example, agency acquiescence to industry's regulatory demands may be a self-interested attempt to maintain agency reputation, and equally predicted by 'corporate bias' (Mulinari & Davis, 2020). Nevertheless, Reputational Theory has been primarily associated with industry-independent bureaucracy and a theorisation of agency power over the pharmaceutical marketplace (Carpenter, 2010).

Fieldwork supporting the theories of pharmaceutical policy has prioritised product regulatory agencies, leaving health technology assessment, pricing and costing bodies (such as PHARMAC) as somewhat neglected institutional players. The applicability of the Neo-Liberal Corporate Bias and

Reputational Theories—which were theoretically derived in Europe and North America—is also largely untested outside these areas.

Theoretical expectations

We generate the theoretical expectations based around the *interests* behind the spending containment policy and the expectations of the *mechanisms* that lead to the achievement of those interests. For state theories:

Historical Institutionalism views the spending containment policy as an expression of an independent state interest which can diverge from the interests of industry. These interests are reinforced by, for example, professionalised state employees' insulation from external actors.

Corporate Domination Theory envisages that the spending containment policy is aligned with corporate interests. Policy mechanisms include the 'revolving door' of private sector employees into the agency which reduces the ability of the state to express independent interests.

For pharmaceutical policy theories:

Reputational Theory claims that the spending containment policy can be linked to autonomous, insulated bureaucracies protecting state interests, including those of fiscal management. This will be consistent with mechanisms such as 'projections of power' to audiences shaping the achievement of the policy.

Neo-Liberal Corporate Bias Theory (NLCB) would predict that the spending containment policy is consistent with an outcome in the state interest—such as the long-term capitalist viability of the economy—but that this should not harm the long-term economic interests of industry. It can also predict that in containing spending, agency managers bias reimbursement policy away from 'public interests in health' and towards state or industry economic interests. The underlying mechanisms can include industry's privileged access to policy making.

In what follows, we first introduce New Zealand's drug reimbursement policy. We then outline our methods. Turning to our findings, we begin with the judicial-legislative context as an important cross section of New Zealand's state societal relationship with—and reaction to—industry. Subsequently, we examine PHARMAC's pricing strategies for newer, branded pharmaceuticals and then consider PHARMAC's relationship with New Zealand's political state. Following this is an analysis of PHARMAC's bureaucratic processes—particularly its health technology assessment body. Finally, we summarise our theoretical conclusions.

PHARMAC and drug reimbursement in New Zealand

In New Zealand, the drug reimbursement process for branded medicines begins with PHARMAC receiving a company's health technology assessment (HTA) submission either as part of an application to amend the pharmaceutical schedule in respect of a new listing or amending a current listing. An overall dossier including HTA information is then sent to PHARMAC's Pharmacology and Therapeutics Advisory Committee' (PTAC), which assesses each pharmaceutical using a decision-making framework before making a prioritisation decision (PHARMAC, 2017). Decision-making involves the 'statutory objective', including PHARMAC's mission statement to make the best use of resources for the greatest number of New Zealand's citizens. Criteria for reimbursement decisions include clinical effectiveness and cost-effectiveness (PHARMAC, 2017).

Following the PTAC process, PHARMAC's in-house health economists undertake further cost-utility analysis and a budget-utility analysis (PHARMAC, 2017). The recommendations for priority level made by PTAC committees and the health economists are then submitted to the PHARMAC board. Unlike HTA agencies typically found in Europe, PHARMAC is involved in economic evaluations but also taking reimbursement decisions (Ozieranski & King, 2016). Several alternative actions are possible for the PHARMAC board, including a reimbursement decision, negotiations with companies, a request for further information from suppliers, a further PTAC or PTAC subcommittee appraisal, or a further economic assessment. The final reimbursement decision is made by PHARMAC's executive committee and all stages of the process are also subject to its general discretion, with PTAC recommendations not binding (PHARMAC, 2017).

Regarding PHARMAC's structure, PTAC is normally formed by medical professionals and arranged into around 16 committees organised by medical speciality, comprising 3–5 members each (PHARMAC, 2017). PHARMAC also has a Board comprising 5–6 members appointed for a fixed term by New Zealand's Ministry of Health. The 'Board' is collectively responsible for PHARMAC's strategic direction but it delegates all day-to-day tasks to PHARMAC's executive committee (PHARMAC, 2017), comprising a CEO and 4 or 5 further executive members, which attend price negotiations and manage further teams of employees in individual departments, including health economists (PHARMAC, 2017). Recruitment to PHARMAC's board, executive committee and PTAC committees is the responsibility of the Ministry of Health. Board members can serve 10-year maximum terms (PHARMAC, 2017).

METHODS

BM conducted 28 interviews of which 22 took place face to face and were tape-recorded, with the remainder undertaken by video-link from the UK. Of the 28 interviews, six interviewees were re-interviewed. All interviewees gave informed consent. The sampling approach was broadly successful, with 60 interviews being sought in total; the non-responses were related primarily to multinational drug companies. The interviews were combined with documents, including court files and policies. PHARMAC's (anonymised) conflict of interest data was also obtained following a freedom of information request and totalled a breakdown of 18 months of reported conflicts of interest between 2016 and 2018 (Table 1).

Qualitative data was analysed in NVivo using 'sensitising concepts' derived from pharmaceutical policy and theories of the western state (e.g. 'privileged access' 'policy insulation'). Initially, data were arranged into general codes informed by research questions and the tripartite structure of 'macro', 'meso' and 'micro' levels of operation/analysis—drawn from a prominent pharmaceutical policy analyst (Abraham, 1995)—was used as the thematic framework. The analysis followed a deductive-inductive technique involving an iterative, constant comparison of emerging codes with theoretical and sensitising concepts. In constructing our arguments, we integrated multiple voices and data sources using 'thick description'.

Key imitations are the sample size and composition, including the low representation of multinationals, and the inherent difficulty in drawing conclusions from conflicts of interest data. We could not access details of recruitment to PHARMAC's executive committee and departmental teams under the CEO and board member level. We were also unable to incorporate analysis of the intellectual property regulations context due to resource constraints.

TABLE 1 Composition of the purposive sample of expert interviewees.

Interview number	Sector and position held	No. of interviews
1	Industry, chief executive	1
2	Industry, senior lawyer	1
3	Industry, chief executive	1
4	Journalist, editor	1
5	Journalist, staff writer	1
6	PTAC, subcommittee member	1
7	Industry, consultant	1
8	Industry, consultant	1
9	Academic, Full professor	1
10	Academic, Full professor	1
11	Industry, chief executive	1
12, 13	Medicine, General Practitioner	2
14	Industry, consultant	1
15	PHARMAC, board level	1
16, 17	Consultant to industry[a]	2
18	Industry, association, senior	1
19	Politics, cabinet	1
20	Patient association, senior official	1
21	Patient association, senior official	1
22	Academic, Assistant Professor	1
23	Academic, post-doc	1
24	Industry, board member	1
25, 26	Medicine, Hospital Consultant	2
27, 28	Academic, Professor	2
Total		28

Note: The interview numbers correspond to the numbers in circular brackets which follow the quoted material from interviews.
aAnd formerly a PHARMAC employee in a senior advisory role.

Institutional mechanisms and interests behind spending containment

PHARMAC's legislative—judicial environment

We now consider PHARMAC in its wider legislative context regarding, first, anti-competition litigation and, second, a supranational trade treaty.

In the late 1970s, New Zealand's economy was characterised by heavy government involvement through price controls, state-run monopolies, and tariff and licensing requirements (Blacktop, 2016), with no right of private action on competition grounds for private parties against 'the crown'. This was altered in New Zealand's 1980s economic reform period, particularly the Commerce Act of 1986, opening the economy up to imports by removing licensing requirements and introducing market mechanisms into many sectors (Adhar, 2020; Blacktop, 2016).

Out of this context came a direct test of PHARMAC's position as a crown corporation under the Commerce Act in the shape of *Glaxo NZ Limited v Attorney-General [*1991*] 3NZLR 129 (CA) ("Glaxo")*. The pharmaceutical company initiated litigation alleging that PHARMAC had shared confidential information with another pharmaceutical company in breach of anti-competition law. PHARMAC claimed that it was not captured by the act because as 'a 'crown corporation' PHARMAC was not 'engaging in trade'—the legal concept that brought the agency within the parameters of the act—but 'regulating social welfare' (*Glaxo NZ Limited v Attorney-General [1991] 3NZLR 129 (CA) ("Glaxo")*. Nevertheless, PHARMAC's argument was rejected in New Zealand's Court of Appeal, which stipulated:

> It could be said that the defendant trades off its advantage in one area in order to ensure advantages in another and (…) They involve financial advantage to the defendant even if that is ultimately for the National good.
>
> (Glaxo NZ Limited v Attorney-General (1991 3 NZLR 129 (CA) at 139)

Subsequently, the New Zealand government passed legislation directly on this issue, in the form of *Section 53 of the New Zealand Public Health and Disability Act 2000 9 ("s53")*:

> It is declared that nothing in Part 2 of the Commerce Act 1986 applies to any agreement to which PHARMAC is a party and that relates to pharmaceuticals for which full or part-payments may be made from money appropriated under the Public Finance Act 1989. (Parliamentary Counsel Office, 2000, Part 4, section 53)

The rationale of s53 contrasts with NLCB's expectations given the outcomes of s53 disfavour industry interests. The rationale of the policy may, however, be compatible with the operation of NLCB given that potentially s53 has a 'deregulatory logic' reflecting a corporatist approach to pharmaceutical spending in both the state's and industry interests.

Prolonged litigation—from 1999 to 2009[1]—concerned how PHARMAC, while negotiating an agreement for the supply of a drug coming off patent, alleged that AstraZeneca threatened to withdraw the supply of another product. PHARMAC's argued that the effect of this was to produce a monopolistic 'tying in' arrangement forcing it into a further agreement with AstraZeneca. PHARMAC made a complaint based on anti-competition grounds to New Zealand's Commerce Commission. AstraZeneca then challenged the Commission's jurisdiction on this issue. As Ahdar (2020) notes, in the subsequent decision, 's53 [was given] an asymmetric application. It was there to exempt Pharmac, and only Pharmac, in its activities (immunizing the purchaser's "demand-side" market power), but not to protect those with whom Pharmac dealt, that is, a pharmaceutical vendor in the potential exercise of its "supply-side" market power'. Initially, New Zealand's High Court and the Court of Appeal agreed with the Commerce Commission's argument by acknowledging that the object of s53 was to protect PHARMAC as a Crown entity regarding striking pharmaceutical arrangements that were for the public benefit and, correspondingly, did not exist to enable a supplier with market power to engage in anti-competitive behaviour (Ahdar, 2020). Yet, New Zealand's Supreme Court later overturned this decision arguing that AstraZeneca's conduct was exempted by s53 and hence rejecting the asymmetric application of s53 in the previous judgements. The reasoning of the Supreme Court judged that a s53 exemption,

> might sometimes work to the ultimate disadvantage of the public by restricting the flexibility of the process and possibly frustrating the objective of better health outcomes from

> the funding available to Pharmac (…) it might very well be difficult in some cases to determine the legitimacy of a negotiating tactic in response to an anticompetitive exercise of market power by Pharmac, the lawfulness of which is itself an abnormal feature of a commercial negotiation in this country (….) the exemption applies to any anti-competitive behaviour (…) during the negotiating process (Astrazeneca Ltd v Commerce Commission (2009) NZSC 92 at 17).

One possible interpretation of the Supreme Court judgement in '*AstraZeneca'* is that in overturning the decisions, it has reduced the immunisation of PHARMAC's 'demand side power', reaching a pro-industry decision seeking to prevent 'stultifying company negotiations' (Ahdar, 2020). The outcome corresponds with balancing the desirability of the exemption for both the New Zealand state and capital or, more structurally, New Zealand's capitalist state for drug reimbursement. An opposing Historical Institutionalist view, however, follows the AstraZeneca case's central mechanism (the structural dynamics that account for whose interest is being expressed in the case)—the judgement expresses the state's interpretation of the interests of public health given their finite resources and—ipso facto—that the state is expressing—and reaching—this view independently. The decision reflects that this approach to the public interest in health is the rationale for the anti-competitive exemption: the s53 exemption from anti-competition challenges aims to protect PHARMAC's 'abnormal' bargaining and negotiation practises from litigation that would challenge these practices on the grounds that they were anti-competitive. Contrasting with the NLCB view, s53 constitutes a regulatory rather than a deregulatory response to *"Glaxo"* that reinforces state support for PHARMAC's containment processes.

While remaining at the macrosocietal level of executive and legislative policymaking, we consider the 'Trans-Pacific Partnership Treaty'. By 2012, the special 301 watch report of the United States Trade Representative report raised concerns with New Zealand's reimbursement policy:

> The industry continues to express concerns regarding, among other things, the lack of transparency, fairness, and predictability of the PHARMAC pricing and reimbursement regime, as well as the negative aspects of the overall climate for innovative medicines in New Zealand (United states trade representative report 2012)

That same year the Trans-Pacific Partnership treaty (TPP) was in the early phase of further negotiations. The TPP envisaged general changes to trading conditions in the Asia Pacific, including agreements on tariffs and market access and more favourable access to US pharmaceutical companies (Lopert & Gleeson, 2013). An officially unavailable draft text proposed by the US in 2011 for an 'Annex on Transparency and Procedural Fairness for Healthcare Technologies'—reportedly rejected by all TPP parties—was subsequently published on 'wikileaks' in 2012 (Citizentrade, 2012). Pertinent factors included the introduction of an appeals process potentially allowing challenges to PHARMAC's decisions. Specifically, 'Transparency and disclosure requirements' could undermine PHARMAC and industry price negotiations by requiring PHARMAC to identify and disclose price information, or reasons for selecting a specific supplier.

Throughout 2012–2018, the TPP raised disquiet in New Zealand's society with the clandestine negotiations seemingly repeatedly failing. Subsequently, the TPP became the Comprehensive and Progressive Trans-Pacific Trade Treaty (CPPTP) between New Zealand and 8 other countries. Documentary sources claimed consistently that the CPPTP would not affect PHARMAC, corroborated by the final reading of the treaty by New Zealand's Members of Parliament (New Zealand Parliament, 2018). Further analysis shows that New Zealand has suspended the application of procedural rules for PHARMAC that form the treaty's text (Box 1).

BOX 1 Summary of New Zealand's suspended procedural rules under the Comprehensive and Progressive Trans-Pacific Trade Treaty (CPPTP)

In the event of non-suspension of procedural rules specific to reimbursement decision-making signatory countries to the CPPTP would have been required to apply the following:

- Complete assessment of applications within a specified time-period,
- Disclose "procedural rules, methodologies, principles and guidelines" used for their assessment,
- Provide "timely" opportunities for applicants to comment during decision-making,
- Provide written information about the reasons for decisions.
- Provide a review process for negative listing decisions, which may be invoked at the request of an affected applicant.

Note: Based on Gleeson et al. (2019:4).

Thus, little evidence existed for 'corporate bias' operating in the treaty agreement *for pharmaceuticals* as indicated by, first, the length of the legislative 'struggle' in repackaging the TPP into the CPPTP. Second, the suspension of procedural rules. Third, the framing of CPPTP as a legislative success by legislators. Overall, these factors suggest substantial pushback from New Zealand elites over the treaty, contrary to the expectations around class elites in the statal space in Corporate Domination Theory and more supportive of historical institutionalists' view of independent state actors. However, NLCB theorists might claim that elite pushback reflects New Zealand's corporatist, especially an existing directorate of state–corporate partnerships who favour a national-level status quo given New Zealand's highly concentrated economy of manufacturers, indicative of 'small economy capitalism' (Ahdar, 2020; chapter 8).

Pricing and spending strategies for branded pharmaceuticals

In commenting on PHARMAC's internal operation, our interviewees commonly saw it as unresponsive to considerable media and political pressure for increased funding for novel drugs.

> PHARMAC refused to fund EPIPEN [an injectable anaphylactic drug] arguing that needle injector drugs were more cost-effective despite the cost per patient only being an increase of $60 (…) it's farcical (…) (4)

Another interviewee suggested that the rationale for such cases reflected PHARMAC's negotiation position:

> PHARMAC sticks rigidly to its budget, because they know if they budge an inch, some pharmaceutical company can come along and say "me-too! (25)

Additionally, PHARMAC used the interplay of reduced patent protection and the generic market to identify branded drugs appropriate for reimbursement without escalating costs. Notably, PHARMAC might delay decisions on applications to improve its subsequent bargaining position in negotiations for

branded drugs with expiring patents. Tenders were distributed by PHARMAC to companies which were then asked to submit proposals. An industry employee alluded to this aspect of the tender strategy:

> We have a lot of companies that don't patent drugs in the Asian-Pacific-Region, so there is only the five years data exclusivity for registration. So PHARMAC are always keen on these medications because they can easily delay five years and wait for a generic. (14)

Further, PHARMAC might delay reimbursement decisions to increase the chances of reaching negotiated agreements. An industry board member explained how PHARMAC applied pressure to companies by combining price negotiation and further tenders:

> (There is) a strategy of delays so long as it's reasonably possible, then they narrow down the patient base and then they have a competitive process for trading companies who are desperate to get their medication funded. PHARMAC go back and forth from negotiations to the market and if they are not satisfied they will do another tender and at that stage they see what price they can get (from negotiations). (24)

Requests for proposals (RFPs) set up a tender process and price negotiations. RFPs were published on the PHARMAC website and invite proposals for treatment areas it wishes to supply. A key rationale for RFPs was to 'smoke out' the companies that PHARMAC could negotiate with. An industry executive argued:

> The initial methodology is open consultation, (PHARMAC) do this to find out which company is interested. Then they put up a proper tender, and then they'll do their cost-effectiveness (…) it is like a cycle and they know they get known for running a tight process (…) they're (PHARMAC) smart people (16)

RFPs could lead to offers whereby PHARMAC and industry reach agreements without competitive tender and sometimes without—or at least before—formal applications. This was indicated by the industry's willingness to reduce prices without the need for further commercial negotiations. An industry consultant and former PHARMAC employee described one RFP:

> PHARMAC issued an RFP regarding the supply of a medication to New Zealand and before that medication was even registered, the company dropped their price (by) 30% just to tie-up the deal. (17)

PHARMAC's competitive tender processes encouraged price competition among multiple companies. This process—which involved the submission of bids—could then lead to further negotiations. PHARMAC might negotiate both before, during and after their multistage tender process. Negotiation took place between PHARMAC and multiple actors in some examples of drugs tender that function like 'play-offs'. A PHARMAC employee explained:

> If we do an RFP we can have some discussions. We see what comes in and then we go back to each of the suppliers (…) and then maybe we will run a more competitive process as a result of what comes out of this first step. (15)

Deal-making between PHARMAC and industry over reimbursement decisions happened outside the procedural process listed in PHARMAC's operating procedure. A consultant suggested: 'PHARMAC appears willing to strike deals at any time' (8). An NLCB theorist can analyse this as evidence of industry having 'privileged access.' However, despite this access, the industry's position was often portrayed as weak. A chief executive of a pharmaceutical company acknowledged:

> I think most of the research companies see it (dealing with PHARMAC) as a commercial necessity. (…) So a lot of their interest is in maintaining their commercial operation and their job in New Zealand. So they will do whatever deal they see maintains the business. (3).

These relationships created an opportunity for PHARMAC to listen to deal-making offers. A PHARMAC employee said:

> Some companies will be coming to us with innovative proposals all the time. And, you know, they are the companies that will get things over the line. It's a guaranteed market (…) we (PHARMAC) might award somebody a contract and we guarantee (…) that product won't be delisted or the access won't change. So if they (industry) negotiate well, they can do quite well after that. (15).

Furthermore, commercial agreements reached under conditions of lobbying were perceived to prioritise PHARMAC's interests, demonstrating that its collaboration with industry over prices remained 'institutionally insulated'. A former consultant noted:

> [for an expensive leukemia drug] PHARMAC did quite well on the commercial settlements despite the lobbying. I mean the price they've secured was significantly lower than the rest of the world. (8).

A further pricing strategy for branded pharmaceuticals involved 'bundling', namely agreements on one drug being combined with other drugs from the same pharmaceutical company for other areas of pharmaceutical need. A senior hospital consultant and PTAC member described how negotiation underpinned 'bundling':

> (PHARMAC) go to a company and say this new drug is not going to make it, plus you're not getting any priority for funding. But if you can reduce that price, or if you can offer us a (…) package of drugs we can buy to offset prices, then we will consider making it a higher priority for funding (…) the new drugs have been allowed into the country when they would not have been based on pure hard-nosed technology assessment. So their great strength, is not ultra-clever HTA's but in doing very good negotiating with drug companies. (26).

Overall, the 'two-way bargaining' reflected by negotiated bundles was consistent with NLCB. But the strategies did not fit the view that interests 'converge' outlined in NLCB, with their use aligning more to tactical pressure imposed by the bureaucracy to drive agreements on the state bureaucracy's terms.

PHARMAC and the New Zealand state

One Journalist noted:

> On Herceptin, PHARMAC stood up to the prime minister, refusing to fund it. (4)

In 2006, PHARMAC decided against spending $30 million a year for a 12-month Herceptin programme for women patients with the HER2 positive form of breast cancer. By 2010, 5 years into the controversy, an individual affected by the decision took the case to the High Court, which rejected their appeal for funding. Later, in 2012, the incoming Labour government overrode PHARMAC and ordered special funding for long regimen Herceptin (Manning, 2012).

In the Herceptin case, PHARMAC seemingly ignored both the 'audience' of society and the 'audience' of politicians, contrasting with the view that these audiences constrain policy and promote agency responses to reduce reputational damage (Carpenter, 2010:730). As such, although the Herceptin case heightened pressure to fund, the social visibility of the funding decision also increased the risk that a capitulation over Herceptin would damage PHARMAC's reputation for fiscal management. One implication of this is that PHARMAC reinforced (or compensated) other aspects of their reputation in the Herceptin process—for example, for policy irreversibility and strict cost-effectiveness assessments—for their other competing audiences (e.g., industry, the medical milieu) (Carpenter, 2010).

However, extensive communications material on the PHARMAC website appealed to values such as fairness and national interests. This promotion of a public profile corresponded with a 'projection' of reputation to a key audience (Carpenter, 2010). An industry consultant remarked:

> PHARMAC are very good at public relations, they make an effort to be in front of the public with messages (…) they are very aware of the need to dominate the public pressure space. (8).

Many interviewees credited PHARMAC with having political and social support. One crucial reason for political popularity was that PHARMAC's handling of policy de-politicised drug reimbursement for successive governments. PHARMAC's agency reputation was derived not primarily from patient consumers but consumers understood more broadly as taxpayers (cf Carpenter, 2010:730). An academic observed:

> PHARMAC is like a "commitment device" whereby broad-level political settings (are) established and then the technocrats and bureaucrats are allowed to get on with implementing those settings insulated from interference. (28)

PHARMAC's published operating procedures showed only limited consultations with consumers and patient groups in the form of consumer advisory council (CAC) to once yearly meetings. However, this gap may be being filled by PHARMAC's cultivation of wider societal popularity, with their public relations efforts seeking to shield it from sources of potential unpopularity. A consultant to industry suggested:

> PHARMAC's whole machine is designed to insulate New Zealanders from knowledge about the benefits of innovative drugs. (7)

Nevertheless, the relative exclusion of civil society groups from the policy process may hamper PHARMAC's ability to balance competing public interests in their decision making, consistent with NLCB.

We now consider how bureaucratic and corporate relations played out in HTA.

Conflicts of interests in PHARMAC's Health Technology System

The categories and distribution of financial conflicts of interest (COIs) involving PHARMAC employees in the PTAC and PTAC subcommittees (Table 2) may ostensibly support Corporate Domination Theory and NLCB. Although it was unclear how far they represented a 'co-optation' of PTAC members (cf, Abraham, 2009), the COIs resembled how risks of financial incentivisation, including involvement in lucrative clinical trials, might diminish the experts' independence, as documented elsewhere (Ozieranski & King, 2016, 2017). However, the proportion of 'employment based' COIs was noticeably higher, with PTAC members reporting conflicts between their multiple roles across other public sector bodies. This is inconsistent with the 'revolving door' expected by the Corporate Domination Theory, and instead supports Historical Institutionalism, with HTA members moving freely around other positions within the public sector and not between public and private industry roles (Ozieranski & King, 2016, 2017).

Table 3 shows that PHARMAC board members' career backgrounds are consistent with historical institutionalists' predictions that career bureaucrats are drawn primarily from the public sector. We also found that PHARMAC's CEO position has had four incumbents since 1993, of which two were

TABLE 2 Conflicts of interest reported by PTAC committees 2016–2018[a].

Categories of conflict of interest[a]	Number of conflict of interest (%)
Honorarium	10 (4)
Involvement in clinical trials	47 (19.1)
Sponsored travel, accommodation and expenses	39 (16)
Consultancy to industry	26 (10.6)
Shareholdings	7 (2.9)
Personal contacts	12 (4.9)
Unsponsored attendance at industry organised events	17 (7)
Private medical practice	3 (1.2)
Membership and employment in government committee/ public sector	46 (18.8)
Research grants	17 (7)
Lectureships	11 (4.5)
Other	10 (4)
Total	245 (100)

[a]PTAC committees correspond to an area of medical speciality. PTAC also has one central committee which sits above the subcommittees. The total COIs in this table refer to those in both PTAC sub committees and the central PTAC committee for the period 2016–2018

[b]The categories used in the table are inductive. The table is based on reported conflicts of interest recorded in PHARMAC's internal conflict of interest register 2016–2018 and presented to us in a spreadsheet. This was obtained via a freedom of information request submitted to PHARMAC in 02/2018 and received in 07/2018.

TABLE 3 PHARMAC Board member's post- and pre-PHARMAC employment by sector 1993–2020[a]

	Private sector health	Public sector/government ministry	Academic/university	Private business sector	Medicine	Total[a]
Post-PHARMAC employment	4 (13%)	15 (48%)	4 (13%)	8 (26%)	0 (0%)	31 (100%)
Pre-PHARMAC employment	3 (18%)	7 (41%)	1 (6%)	2 (12%)	4 (23%)	17 (100%)

[a]The categories used in the table are inductive. The table draws on Internet-based searches of Pharmac's board members (by name) involving, in particular, social networking websites such as Linkedin. The table does not include employment data on PHARMAC's executive committee. The names of PHARMAC's board members were taken from PHARMAC's annual reports 1993–2020 (PHARMAC, 2021) which are available on Pharmac's website (pharmac.govt.nz).

[b]The total numbers and percentages listed in the table were aggregated using available employment data for each board member between 1993 and 2020. Each employment position noted from an Internet search is counted as 1; for example, where one board member leaving post, for example, in 2003 had six positions listed while another board member leaving post, for example, in 2015 only two, each of these positions were allocated to one of the inductive categories and totalled. The post-PHARMAC employment data excludes the board in place at the time of writing.

promotions of long-term PHARMAC employees. The stability of the board and CEO position in low total numbers also supported Historical Institutionalism.

Contrastingly, a consultant to industry mentioned his part in negotiations which involved PTAC committee members triggering the tender process for a therapeutic area which then led to reimbursement decision:

> I did a lot of negotiations for one of the research companies for an oral Hep-C [hepatitis C] drug putting pressure on PTAC and externally from commissions. That led to them [Pharmac] issuing a tender for the supply of oral Hep-C medications and because they are the only two researchers in New Zealand one of them got the deal. (8)

Although this apparently indicates a lack of 'policy insulation', consistency also existed with a form of 'bureaucratic autonomy'. The relevant protective factor consisted in decision-making being concentrated in 'the contracting stage', namely in formal negotiations between PHARMAC and industry representatives. Indeed, a common critique associates a lack of formal policy transparency with industry's weakened interests. This contrasted with the established interpretation of drug regulatory transparency put forward by NLCB where decreased transparency is consistent with corporate bias (Abraham, 1995; Abraham & Davis, 2020). An academic said:

> The pressure point [in drug reimbursement] *is 'PHARMAC's executive committee* (…) The reason why companies want more transparency is to provide them with more potential pressure points in the decision-making process to reduce the leverage that PHARMAC has in the drugs market. (28)

Rather than generating 'policy access' for industry, the dynamics of negotiation contrastingly concentrated the impact that the PHARMAC's executive could have on deal making. Thus, one distinguishing feature of PHARMAC's HTA is how HTA's overall impact on drug reimbursement was mediated by an executive committee.

We also investigated the distribution of COIs within the PTAC committee structure, demonstrating that industry prioritised developing financial relationships with influential PTAC committee members (Table 4).

Mitigating this, COIs were likely diffused by informational asymmetries. A PTAC member and hospital consultant explained:

> with PTAC subcommittees (…) it's a little bit like leaving "the rabbits in charge of the lettuce" because they all have an interest (…) in things being available to our specialty but we don't have an insight into what other people are doing [in other subcommittees]. The cancer specialist will look at studies that will show some small advantage of their drug but at quite high costs (…) Meanwhile there are specialties out there that are $20,000 extra [to that] and they are getting funding decisions based on that. So, they can't really see that. (25).

Overall, PHARMAC 'policed' the effect of COIs by concentrating decisive power over reimbursement decision-making in formal negotiations with industry. A final issue is the relationship between PHARMAC's executive committee and PTAC itself.

TABLE 4 Reported conflicts of interest by PTAC committee[a]

HTA committee where conflicts of interest reported	Total number of COIs reported in the committee
PTAC[b]	55 (32%)
Cardiovascular	28 (16)
Respiratory	18 (10.5)
Cancer	16 (9)
Neurological	16 (9)
Immunisation	15 (8.5)
Haematology	13 (7.5)
Endocrinology	13 (7.5)
Total	174 (100)

[a]The committee categories are non-inductive and are based on reported conflicts of interest recorded in PHARMAC's internal conflict of interest register 2016–2018. This was obtained via a freedom of information request submitted to PHARMAC in 02/2018 and received in 07/2018. Table 4 presents COIs for the PTAC central committee and the top 7 PTAC subcommittees for numbers of COIs. This represented 8 out of a total 16 PTAC committees. On that basis, the total COIs for each committee is calculated as a percentage of COIs of the top 8 subcommittees (including the PTAC central committee).

[b]PTAC's central committee.

Spending containment and internal bureaucratic management

PHARMAC's concern with spending containment was filtering into the PTAC subcommittees. A chief executive reflected:

> PTAC are making recommendations based wholly on price. They have knowledge of price because they can see how much a drug costs in the documents supplied to them by the therapeutic group manager. (3).

For others, PHARMAC's executive committee overrode PTAC's decisions on clinical effectiveness and cost-effectiveness, with evidence that PTAC might take independent decisions which were then ignored or potentially edited from the published minutes of PTAC meetings. Others suggested that PHARMAC used PTAC's HTA to legitimise cost-effectiveness arguments in negotiations. An industry expert noted:

> PTAC will say this product is not cost-effective on price effectively setting up a negotiation position for PHARMAC. (8).

Consistent with Carpenter's (2010) notion that bureaucracies stabilise internal policy drift was evidence PHARMAC had disbanded PTAC committees to promote support for the spending strategy. One industry consultant said:

> (…) where there has been very strong data to suggest a drug should be available and commercially there hasn't been a large impact PTAC subcommittees which have provided a certain direction of information with a positive view to funding, have found themselves disbanded and replaced with new people. (14).

Control by the PHARMAC executive committee was indicated by other practices. One consultant explained:

> There are increasingly tight confidentiality requirements for PTAC members (…) Minutes of the PTAC meetings are managed and edited by PHARMAC and not produced by an independent committee. (8).

Drugs were returned for consideration by PTAC, ostensibly to pressurise negotiations with industry, particularly for pharmaceuticals with expiring patents that PHARMAC had targeted. Two industry consultants said:

> Registrations take awhile (…) then PHARMAC create delays (…) time kills, it's about patents and their negotiation strategy. (7).

> PHARMAC does it just to delay, to frustrate the company. The company gets so frustrated that they enter into a commercial arrangement. (8)

Finally, at least some agreements between PHARMAC and drug manufacturers were struck before concluding the formal drug registration process. In influencing Medicines and Medical Devices Safety Authority (MEDSAFE), formally part of New Zealand's Ministry of Health and responsible for drug registration, PHARMAC can be said to have 'gatekeeping' power formally out of their purview. This also reflected NCLB as industry and state interests seem to be driving the processes. An industry consultant and an interviewee with a background in private and public sectors concurred:

> I've done it myself (on behalf of a company) (…) we say this is the price we'd likely go to in the New Zealand market, and it's going to save you 4 Million Dollars (…) Pharmac would say (to MEDSAFE):'can you please expedite this product. (14).

> (MEDSAFE) will be on the phone to Pharmac and they have regular meetings with Pharmac, and Pharmac will say for instance: 'this area, this area and this area. (7).

CONCLUSION

In explaining New Zealand's apparent exceptionality for public spending on pharmaceuticals, we sought to advance the debate between the two sets of theories, while also expanding the home domain of explanation of the theories of pharmaceutical policy in North America and Europe. Our explanation follows the analytical framework of Abraham (1995, 2007, 2009) and his collaborators (Abraham & Lewis, 2000; Davis & Abraham, 2013) positing that the characteristics of pharmaceutical policy phenomena operate across the state-societal (macro level), the meso-organisational (meso level) and the microsociological level (micro level) of regulatory decision-making.

PHARMAC's practices have been secured by legislative interventions *at the state societal level*. This involved state elites re-negotiating and suspending PHARMAC treaty obligations. Additionally, the *AstraZeneca* litigation reflects the dynamics of the state–capital relation for drug reimbursement policy by highlighting the rationale for PHARMAC's exemption from anti-competition laws. The social welfare function (and potentially the public interest) is secured by anti-competition laws because

anti-competitive practices reinforce PHARMAC's containment strategies. Indeed, the struggle over the TPP and CPPTP mirrors our interpretation of the competition case law; the opacity of price negotiations is targeted by industry and protected by the judicial–legislative sphere. These features may constrain industry's ability to maximise its interests and, contrastingly, enable PHARMAC and New Zealand's state (including bureaucracy) to pursue their interests. This indicates that PHARMAC's bargaining power—and their 'demand side power'—may be structurally leveraged.

Similarly, at the *meso-organisational level* PHARMAC coordinates many pricing strategies which challenge market prices or seek better reimbursement deals. The prevalence of these pricing negotiations has centralised executive managerial influence. Negotiations are arenas which are 'policed' by price 'bottom lines' as opposed to acting as secure, vertical access points to further industry interests (cf Ozieranski & King, 2016). At the HTA level, PHARMAC's executive committee wields power over PTAC's HTA system.

More indirectly, we have considered the *micro-sociological level of decision making*. Decision making is characterised by technocratic principles (e.g. the respective roles that cost-effectiveness and efficacy take in decisions) and price considerations (e.g. negotiations, HTA). Contrasting with findings from Europe (Ozieranski & King, 2017), one further characteristic is that the bureaucracy is formally open about being informally open (rather than having formal closedness and often clandestine informality) as reflected in the same procedural guidelines for applications for funding alluding to maximum executive manager discretion over decision making. Pharmaceutical scholarship has emphasised pressures on policy makers (Abraham, 2009; Ozieranski & King, 2016, 2017). But the PHARMAC case demonstrates that reimbursement policy, including price negotiations, involve deal making pressure on industry.

Specifically, New Zealand's high arena of pharmaceutical policy operates so as to erode industry power at (and with) what Weber might call the rational limits of capitalism. Industry can escape 'zero-sum games' with one another—competing for finite, exclusive contracts—because PHARMAC simultaneously offers 'non zero-sum games' in the shape of informal deal-making. As such, containment is a function of the interaction of rational games played around formal reimbursement and informal deal making.

Containment also combines complementary features at macrosocietal, meso and micro levels. PHARMAC realizes a form of infrastructural state power over external capital which is inherent in the institutional and formal features of social democratic capitalism. The containment phenomena is affected by pricing strategies but they are protectively nested in a legal-societal intervention into the structure of competition, a state-societal diffusion of a public political ideology of distributional fairness and the impact both have on the social bases of pharmaceutical products commodification (Offe, 1974).

Our data are largely inconsistent with the Corporate Domination position. Although access to PHARMAC is informal, extensive opposing data indicated high levels of autonomy in decision making in, for instance, multiple rounds of negotiations and 'play offs' in tenders. The judicial–legislative sphere also appeared strongly insulated. On balance, our data, unsurprisingly, supports Historical Institutionalism. PHARMAC displays classically Weberian features including 'stable office rules'—for example, commitment to the 'statutory objective' and an institutional containment culture—and has strong levels of employee continuity as evidenced in low executive manager and board level turnover. There are strong indicators of 'policy insulation.' In PHARMAC's HTA, we also found cost-utility analysis at higher, bureaucratic levels.

We identified some inconsistency with the NLCB expectations, including little evidence of a 'revolving door' at the board level, with board members predominantly drawn from—and exiting to—public positions. A 'deregulatory logic' at the political level that could shape PHARMAC's practices

was not supported, placing New Zealand at odds with the overwhelming evidence to the contrary found in the US drug regulation (Abraham & Davis, 2020; Davis & Abraham, 2013). Instead, the themes of 'statutory exemption' 'asymmetric application' and legislative 'suspension' were prominent. Counterintuitively, PHARMAC used 'privileged access' afforded to industry to reproduce spending containment. This was the crucible of its "directive power" and targeted as such by multinationals in the TPP negotiations.

The opaqueness of the negotiation fora means that NLCB cannot be decisively ruled out (Abraham, 1995; Abraham & Davis, 2020). There is potential for 'bundling' deals for industry to secure its economic interests at the expense of public interest; for example, through agreements which combine riskier combinations of newer products and older discounted products. This analysis also supports the rival analysis of PHARMAC's utilisation of a power of override over the HTA system as essentially prioritising deal making over public interests. However, key inconsistency with NLCB exists in two dimensions. First, there is long-term fiscal retrenchment in the New Zealand state's interest. How far industry interests are harmed is unclear but the policy mechanisms that would improve the achievement of these interests are mirrored by the suspended changes of TPP/CPPTP. Second, the mechanisms—for example, legislative intervention in competition law—attributable to these policy outcomes reflect ways that institutional and statal independence is being secured and do not evidence dominant corporate or capitalist power at any decision-making level.

Our data largely supports reputational theory. PHARMAC seeks to enhance its public relations profile, reducing the potential impact of media pressure and pressure from 'assimilated allies' such as patient organisations coopted by drug companies to influence political decision-makers (Abraham, 2009; Davis & Abraham, 2013). Further, the more offensive, protective features of PHARMAC's pricing strategies go further than the 'Weberian' characterisation of bureaucracy—with professional elites primarily defending the rational independence of state decisions—in having a 'neo-Weberian' character with an active role shaping the achievable parameters of other organised interests. A core feature of this was that a close-knit group of agency managers and health economists formed PHARMAC's strategic centre.

NLCB theorists may argue that mutual and converging interests in the 'capitalist state' explain the spending containment policy. However, our data supports an explanation whereby the state–industry relationship is a version of 'tutelage and authoritative supervision' by the state (Offe, 1974:37); rather than a long-term compact structured by the exigencies of the macro-economy, the containment strategy authorises the achievable parameters of capitalist interests. To do this, the state must violate interests that exceed this supervision in order to maintain it (Offe, 1974). An NLCB argument can also be weakened at the meso-organisational level. Contrary to NLCB's view that state–industry relations influence other levels of policy making, the direction of travel in the spending containment policy flows from the meso to the macro level. PHARMAC's success has garnered a political consensus which has depoliticised drug reimbursement at the state societal level. This echoes Carpenter's view (2001) that 'bureaucratic autonomy' can set representative opinion. Thus, rather than neo-liberal political will (Mulinari & Davis, 2020) or consumerist individualism shaping regulatory culture (Daemmrich, 2004; Davis & Abraham, 2013: chapter 2), the regulators' appeal to public-political concepts, such as utility, fairness and economic security. NLCB theorists may additionally claim that containment does not require the support of instrumental mechanisms—for example, widespread conflict of interests, policy access—and is initiated endogenously by bureaucrats on behalf of the capitalist class. The net policy outcome of spending containment would then be empirically consistent with structuralist NLCB because policy has been 'biased away from' alternatives in the public interests of health. To counter this fully, future research should investigate how individual reimbursement decisions are taken, linking HTA and the negotiations themselves.

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BM and PO report no conflicts of interest.

AUTHOR CONTRIBUTION

Ben Main: Conceptualization (lead); Formal analysis (lead); Writing-original draft (lead). **Piotr Ozieranski:** Conceptualization (supporting); Writing-original draft (supporting).

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