The Right to Health: Implications for the funding of medicines in Australia


ABSTRACT

Australia’s health system is characterised by an ongoing tension between a commitment to utility and a commitment to individual rights. This tension is particularly problematic for the Australian Government when deciding which cancer medicines to add to the Pharmaceutical Benefits Scheme to make cheaper for patients. This paper investigates how the right to the highest attainable standard of health has influenced decisions about funding high cost cancer medicines in Australia. We then consider the value of the right to health for funders and conclude that resource allocation decisions should not be entirely informed by the right to health. We maintain that instead, regard should be had to the cost-effectiveness and affordability of cancer treatments before they are subsidised.

INTRODUCTION

In Australia, two decision-making bodies control access to medicines. The first is the Therapeutic Goods Administration, which determine whether medicines are sufficiently safe.
and efficacious to be given marketing approval.\(^2\) Next is the Pharmaceutical Benefits Advisory Committee (PBAC), which assesses the economics of introducing new medicines into the health system.\(^3\) If both bodies are satisfied, the government will then negotiate prices for new medicines with drug sponsors and then list the drugs on the Pharmaceutical Benefits Scheme (PBS).

If medicines are not included on the PBS, patients in the community have to seek access through other avenues. Other avenues include access through hospitals, pharmaceutical industry compassionate access schemes and self-funding. All of these mechanisms have their problems, particularly when medicines are very expensive, as is the case for many new-targeted therapies that have entered the market. For instance, prior to the listing of Keytruda for metastatic melanoma on the PBS, it cost patients $156,130 per year of treatment.\(^4\)

While there is a strong ethical imperative to add drugs outside the financial reach of the average Australian onto the PBS, doing so is a major contributor to increases in PBS spending. The National Commission of Audit has stated that PBS spending has increased in recent years, particularly because of a growing demand for pharmaceuticals, an aging population, and the increasing incidence of chronic disease.\(^5\) The Commission of Audit predicts that PBS spending will increase from approximately $9 billion to more than $15 billion by 2023\(^6\) - this is in addition to the 13 per cent yearly growth of the PBS since 2005.\(^7\)

These challenges have led to numerous debates about access to high cost medicines in Australia. For example, on 3 December 2014, the Australian Senate commissioned the Senate Community Affairs References Committee to report on the ‘availability of new, innovative and specialist cancer drugs in Australia.’\(^8\) In particular, the Committee was charged with focusing on issues related to: (a) timing of access and affordability for patients; (b) how the PBAC and PBS handles these medicines, and the impact of delays in approval on patients; and (c) the impact of the quality of care to cancer patients.\(^9\)

The Committee received over 200 submissions from individual consumers, pharmaceutical companies, research collaboratives, patient advocacy groups, physicians and special interest groups. A public hearing was also held in Canberra. In order to address inefficiencies associated with the processes that evaluate new cancer medicines, the Senate report arising


\(^6\) Australian Government National Commission of Audit, n 5.


\(^9\) Parliament of Australia, n 8.
from the inquiry recommended a comprehensive review of current systems for registration and subsidisation of medicines.\textsuperscript{10}

It is clear from the Senate report that there is a strong belief that patients ought to be able to access medicines that relieve their suffering and prolong their lives, and it is the government’s responsibility to find solutions to ensure that medicines remain accessible to all. This view is akin to the basic tenet of the right to the highest attainable standard of health – an internationally recognised human right owed to all peoples. This right to health obliges states to provide basic medical services for their entire population, including those who suffer from chronic diseases.

The general public seems to be alert to the existence of such a right. For example, some patients submitted to the Senate inquiry that being denied access to medicines because of affordability was unfair. One individual stated about another;

"On top of the extreme suffering he has endured fighting this wretched disease, the added torment of knowing there is a drug which could help him, but at a huge cost is very unfair.”\textsuperscript{11}

Nonetheless, despite the right to health potentially being relevant to discussions about high cost drug funding, it was not explicitly consider at any point in the Community Affairs References Committee report. From this finding, one might hypothesise that the right to health is not explicitly present in Australian health policy, but rather, is only used for rhetorical purposes.

The aim of this paper is to investigate whether this is in fact accurate – that is, whether the right to health plays any explicit, or implicit, role in Australian health policy. More specifically, we will assess the role that the right to health might play in decisions about the funding of high cost medicines.

We begin by describing international and national laws that mention to right to health or a right to access medicines. We then present the results of a systematic search we conducted of Australian laws and health policies, looking for either explicit references to the right to health, or policy assumptions that imply that such a right to health might exist.

The results of this investigation are then used to make an informed assessment about whether, and to what extent, the right to health influences the Australian health system. Further, we consider the potential value of the right to health for those policymakers tasked with the duty of ensuring fair and equitable access to high cost medicines in Australia.

**MATERIALS AND METHODS**

The international laws relevant to this subject were located using the World Health Organisation website and the Officer of the High Commissioner for Human Rights website. In the search bar of both websites, appropriate terms were searched for that included: “right to health,” “right to health care,” “right to the highest attainable standard of health,” “access to health*,” “right to medicine*,” “right to pharmaceutical*,” “right to drug*,” “access to medicine*,” “access to pharmaceutical*,” “access to drug*,” “right to essential


\textsuperscript{11} Parliament of Australia, n 10, 62.
medicine*,” and “access to essential medicine*.”

Relevant domestic laws were located using the Commonwealth Department of Health website, and the ComLaw website. Each law was searched for any mention of the word or words: “right,” “access,” “equit*,” “fair*,” “just*,” “right to health*” and “essential medicine*.” Further, the second reading speech for each of the relevant domestic laws was located using the Parliament of Australia website. Each second reading speech was searched for any mention of the word/s: “right,” “access,” “equit*,” “fair*,” “just*,” “right to health*” and “essential medicine*.”

Domestic policies relevant to this paper were located using the Department of Health website and the Parliament of Australia website. The same searching process above was employed.

To locate relevant academic literature on the right to health, Google Scholar, Global Health, Informit Online, Embase.com, and AGIS Plus Text were searched. Key words that were used when searching in these databases included “human rights health”, “right to health”, “right to cancer”, “access* cancer”, “health* access*” and “health* equity”. No date or other limits were placed on the search. All articles and websites were accessed between August and November 2015.

RESULTS

We identified 13 relevant international laws, 16 relevant domestic laws, and 3 relevant domestic policies.

International ‘right to health’ laws

According to international law, every person has a right to the highest attainable standard of health.12 Like all human rights, the right to health is owed to all human beings, irrespective of their race, gender, place of residence, or other status.13

The first formal international document to recognise the right to health was the Constitution of the World Health Organisation 1946.14 It alludes to the right to health in both its preamble, and in Article 1. Article 1 of the Constitution of the World Health Organisation 1946 states that:

“The objective of the World Health Organisation shall be the attainment by all peoples of the highest possible level of health.”15

The Universal Declaration of Human Rights 1948,16 which was drafted just two years later, also recognises the right to health in Article 25(1). It states that:

“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services...”17

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14 World Health Organization Constitution 1946.
16 Universal Declaration of Human Rights 1948.
Both the Constitution of the World Health Organisation 1946 and the Universal Declaration of Human Rights 1948 drew attention to health at the global level. Nonetheless, neither law enforces countries to provide adequate health care within their borders. This is because neither is binding on states – a state is able to choose whether they wish to meet the standards set out in both laws, and very few states have done so. Thus, to actualise positive health outcomes for people in nation states, enforceable human rights laws were required.

The first international document to make the right to health enforceable in international law was the International Covenant on Economic and Social Rights 1976 (ICESCR). The ICESCR is a multilateral treaty that requires states to take steps, including legislative measures, to realise the rights listed within it. The right to health is one of the listed rights - it is protected in Article 12, which states that:

"The State Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."

Article 12 of the ICESCR also sets out four steps to be taken by the State parties to the ICESCR to achieve the full realisation of the right to health. These are:

“(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;  
(b) The improvement of all aspects of environmental and industrial hygiene;  
(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;  
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”

Article 12 of the ICESCR is the most comprehensive statement on the right to health in international law. It has transformed health from a national concern, into a global priority. Nonetheless, Article 12 of the ICESCR does not give any indication of how far the right to health is intended to extend, nor does it specify how, or to what extent, states are expected to achieve the four steps outlined.

To address this issue the United Nations’ Committee on Economic, Social and Cultural Rights issued General Comment No. 14: The right to the highest attainable standard of health 2000 (General Comment No. 14). General Comment No. 14 provides more explicit direction on the right to health than does Article 12 of the ICESCR, and has therefore assisted policy-makers translate the right to health into domestic laws.

Notable provisions in General Comment No.14 include:

"4. …the highest attainable standard of physical and mental health is not confined to the right to health care.  
7. The right to health is not to be understood as a right to be healthy…[the right to

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22 General Comment No. 14: The right to the highest attainable standard of health 2000.  
23 General Comment No. 14: The right to the highest attainable standard of health 2000.
health] include[s] the right to a system of health protection[, which provides equality of opportunity for people to enjoy the highest attainable level of health.

12. The right to health in all its forms and at all levels contains the following interrelated and essential elements... (a) Availability... (b) Accessibility... (c) Acceptability... (d) Quality...

Importantly, General Comment No. 14 clarifies that the right to health is a ‘progressively realisable’ right. This means that States must meet the provisions in Article 12 of the ICESCR as closely as possible, but are not expected to provide health care measures that they cannot afford. However, General Comment No. 14 does emphasise that the ‘progressively realisable’ nature of the right to health should not be “interpreted as depriving States parties’ obligations of all meaningful content.” All states are still required to employ appropriate means at all levels of government to realise the right to the extent that they can afford. However, because General Comment No. 14 does not specify how much a state should expend on health, in practice it has been difficult for states to define and meet their obligations.

Despite this shortcoming, all states are required to effect a number of provisions, called ‘core obligations.’ These obligations are non-negotiable. General Comment No. 14 states that these core obligations include: “

(a) To ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
(b) To ensure access to the minimum essential food which is nutritionally adequate and safe, to ensure freedom from hunger to everyone;
(c) To ensure access to basic shelter, housing and sanitation, and an adequate supply of safe and potable water;
(d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;”


Every state in the world is a signatory to at least one international human rights treaty that addresses health-related rights. This suggests that the basic premise of the right to health is widely, if not universally, supported.

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24 General Comment No. 14: The right to the highest attainable standard of heath 2000.
25 General Comment No. 14: The right to the highest attainable standard of heath 2000, Art 30.
26 General Comment No. 14: The right to the highest attainable standard of heath 2000, Art 31.
27 General Comment No. 14: The right to the highest attainable standard of heath 2000, Art 43.
International ‘right to medicines’ laws

According to General Comment No. 14, states must take positive steps to ensure that essential medicines are accessible to all. The World Health Organisation defines essential medicines as “those [medicines] that satisfy the priority health care needs of the population.”

Essential medicines are selected with regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. The World Health Organisation’s Essential Medicines List is a catalog of medicines that the World Health Organisation believe satisfy the aforementioned criterion, and thus need to be accessible to all people.

More specifically, General Comment No. 14 stipulates that states must ensure:

“(a) The availability of essential medications in sufficient quantity;
(b) The accessibility of the medication to everybody (including physical and economic accessibility);
(c) The acceptability of the treatment with respect to the culture and ethics of the individual; and
(d) An appropriate quality of the medication.”

While these objectives are admirable, they are unfeasible for a number of developing countries. The World Health Organisation recognises this, and instead encourages these states to prepare their own national essential medicines lists. States are then required to make available and accessible the essential medicines on their national list. Four out of five countries globally now have national essential medicines lists.

International ‘right to high-cost medicines’ laws

If a high cost medicine is listed on the World Health Organisation Essential Medicine List or an applicable National Essential Medicine List, then, as with any other essential medicine, states must ensure that it the medicine is economically accessible to all people in the relevant jurisdiction.

For the most part, high-cost medicines have been absent from the World Health Organisation Essential Medicines List and from the majority of national lists around the world. This is due to fact that, until recently, a medicine needed to be considered cost-effective and affordable in order for it to be listed as essential.

This changed in 2001, when the WHO’s Executive Board reviewed methods for the selection of essential medicines. The Executive Board noted that absolute treatment cost should not be a reason to reject a proposed addition to the model list if criteria for benefit and public

29 General Comment No. 14: The right to the highest attainable standard of health 2000, Art 12.
31 Essential Medicines and Health Products Information Portal, n 30.
32 Essential Medicines and Health Products Information Portal, n 30.
health relevance are met. In doing so, affordability changed from a precondition for listing an essential medicine to a consequence that must be managed after the decision to list.\textsuperscript{36}

The implementation of the concept of essential medicines still, however, remains flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.\textsuperscript{37} Nonetheless, this change has resulted in a number of high-cost medicines since being added to the WHO Essential Medicines List, including medicines for cancer, hepatitis C, multidrug-resistant tuberculosis and new oral anticoagulants.\textsuperscript{38} For example, 16 new cancer medicines were added to the WHO Essential Medicines List in 2015.\textsuperscript{39} The addition of these 16 cancer agents to the WHO Essential Medicines List has extended the chapter of cancer medicines from 30 to 46. Notably, three of the new drugs – imatinib (\textit{Gleevec}, Novartis), rituximab (\textit{Rituxan}, Genentech), and trastuzumab (\textit{Herceptin}, Genentech) are expensive ‘targeted’ cancer therapies (for instance imatinib costs $4,500 per month of treatment in the United States).\textsuperscript{40}

It is arguable that, with removal of its cost-effectiveness criterion, the Essential Medicines List is now more aspirational than it is practical. This is because nation states have limited funds for health, and using these funds on expensive medicines may create massive disparities in health care spending, and create inequities in other areas of the health system. However, the addition of high cost medicines to the WHO Essential Medicines List may inspire developed countries, who can afford these high-cost medicines, to consider adding similar medicines to their own national lists, or consider taking further actions, such as issuing compulsory licenses, to make expensive medicines more affordable.\textsuperscript{41}

\textbf{Australian human rights laws}

Australia is a party to seven of the major international human rights treaties\textsuperscript{42} including the ICESCR – the ‘right to health’ law. However, because international law is not automatically enforceable in Australia (domestic enabling legislation is needed), the international right to health is not justiciable in Australia. No domestic legislation that explicitly protects the right to health has been passed to date.

Despite this, the Australian Government has consistently stated that it supports the right to health described in the ICESCR,\textsuperscript{43} and has admitted that Australia has the resources to adopt legislative, budgetary, judicial and administrative measures that effectively realise the right

\textsuperscript{36} World Health Organization, n 35.
\textsuperscript{39} Union for International Cancer Control, \textit{EML Phase 1}, http://www.uicc.org/advocacy/our-campaigns/essential-medicines.
\textsuperscript{40} Memorial Sloan Kettering Cancer Center, \textit{US Medicare Monthly Drug Prices at Launch (2014 dollars)}, http://app.drugabacus.org/abacus-mskcc.
to health.\textsuperscript{44} What Australia does have is a health rights charter – a summary of the health related rights recognised in Australia. This summary is called \textit{The Australian Charter of Healthcare Rights 2008} (Charter).\textsuperscript{45} The Charter has three guiding principles, one of which is, ‘everyone has a right to the highest possible standard of physical and mental health [in Australia].’\textsuperscript{46} Notably, this is the same right as that protected by the ICESCR.

The Charter is, however, not based in legislation, and as such, has no legal influence. While some domestic health policies such as \textit{PD2011.022 Your Rights and Responsibilities 2011} (NSW) do mandate that, ‘All health professionals delivering healthcare services within NSW Health must be made aware of the detailed rights and responsibilities outlined in [\textit{The Australian Charter of Healthcare Rights}]\textsuperscript{47} these rights have never been the subject of litigation in Australia.

\textbf{State and territory human rights laws}

At the State level, only the Australian Capital Territory and Victoria have human rights charters that protect and enforce a variety of human rights in their jurisdictions – the \textit{Human Rights Act 2004} (ACT) and the \textit{Charter of Human Rights and Responsibilities 2006} (VIC). Both laws explicitly protect civil and political rights only.\textsuperscript{48} Thus, the right to health, a ‘social’ right, is not particularised in either law.

However, this does not mean that the right to health can be freely violated. In Section 7 of the \textit{Human Rights Act 2004} (ACT), it is stated that:

\begin{quote}
“Rights apart from Act
This Act is not exhaustive of the rights an individual may have under domestic or international law.
Examples of other rights
... rights under the ICESCR [\textit{International Covenant on Economic, Social and Cultural Rights (1966)}] not listed in this Act.”\textsuperscript{49}
\end{quote}

Similarly, in Section 5 of the \textit{Charter of Human Rights and Responsibilities Act 2006} (VIC) it is stated that:

\begin{quote}
“A right or freedom not included in this Charter that arises or is recognised under any other law (including international law...) must not be taken to be abrogated or limited only because the right or freedom is not included in this Charter.”\textsuperscript{50}
\end{quote}

Both sections ensure that an individual’s right to health, as provided for in international law, cannot be discredited by virtue of the aforementioned sections.\textsuperscript{51}

\textsuperscript{45}Australian Commission on Safety and Quality in Healthcare, n 43.
\textsuperscript{46}Australian Commission on Safety and Quality in Healthcare, n 43.
\textsuperscript{47}PD2011.022 \textit{Your Rights and Responsibilities 2011} (NSW).
\textsuperscript{49}\textit{Human Rights Act 2004} (ACT) s 7.
\textsuperscript{50}\textit{Charter of Human Rights and Responsibilities Act 2006} (VIC) s 5.
\textsuperscript{51}\textit{Human Rights Act 2004} (ACT) s 28 and \textit{Charter of Human Rights and Responsibilities Act 2006} (VIC) s 7(2) can limit the application of human rights in the respective jurisdictions.
Further, the civil and political rights contained in both Acts can occasionally be used to indirectly protect the right to health. For example, in *Castles v The Secretary to the Department of Justice* [2010] VSC 310, a prisoner sought a declaration that they were entitled to continue the IVF treatment that they were receiving prior to being imprisoned. They argued that the decision not to allow her to access IVF was a breach of her rights to family life and privacy under the *Charter of Human Rights and Responsibilities Act 2006* (VIC). Emerton J found that the *Corrections Act 1986* (VIC) s 47(1)(f) conferred on Castles the right to continue to undergo IVF treatment.

**Other Australian laws that allude to a ‘right to health’**

Responsibility for health care in Australia is split between the Commonwealth and State Governments. At both the Commonwealth and State levels, there are a number of health-related laws that implicitly suggest that there might be such a thing as a (limited) right to health in Australia.

The Commonwealth government has the power to legislate on pharmaceutical, sickness and hospital benefits, as well as medical and dental services. A number of Commonwealth laws deal with subjects relevant to the right to health, including the *Health Insurance Act 1973* (Cth) and the *National Health Act 1953* (Cth).

**Health Insurance Act 1973 (Cth)**

The *Health Insurance Act 1973* (Cth) introduced Medicare (Medibank at the time) in 1975—a Commonwealth funded healthcare scheme that enables all residents of Australia to be automatically covered by medical and hospital benefits.

Prior to 1975, most Australians had private health insurance, but some remained uninsured. The government sought to remove this disparity by introducing a universal health insurance that could be accessed by all Australians. In the Second Reading Speech for the *Health Insurance Bill `1973* (Cth), Mr Hayden MP stated that Medibank sought to establish ‘social equity in health insurance’ and that his government believed that this task was ‘an obligation.’

“Out our program gives true freedom. It gives freedom from fear of the financial consequences of illness, it gives freedom of choice of doctor and hospital and it does this in a way which does not levy a penalty on the sick and the economically less fortunate members of the community...Our program is not one which stems from doctrinaire beliefs but it is one which flows from a sense of social justice. It is a program which rejects the belief that health care is a commodity to be traded rather than a social utility to be used to improve the quality of living...It is indeed a program which must cause this Parliament to decide whether health care is to be a privilege

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52 Commonwealth of Australia Constitution Act 1900 (Cth).
53 Commonwealth of Australia Constitution Act 1900 (Cth) s 51, 81 and 96.
54 There were several accompanying bills including the *Health Insurance Commission Bill 1973* (Cth).
57 Commonwealth of Australia, n 55, 5.
58 Commonwealth of Australia, n 55.
to be purchased or a right to be enjoyed equally by every Australian." 59

Here, Mr Hayden MP lucidly characterises health as a ‘right’; a ‘right’ that is owed to all Australians without economic or health-related discrimination. Thus, it appears that Medicare is, at its core, a fundamentally human rights based program.

The use of rights language to describe Medicare has continued in more recent years. For example, Mr Blewett MP (Health Minister 1983-1987) described the underpinning attributes of Medicare as:

- Simplicity: “the simpler we made a health scheme the more chance it has of delivering the services to those who need them most”
- Affordability: “everyone will contribute towards the nation’s health costs according to his or her ability to pay”
- Universality: “Medicare will provide the same entitlement to basic medical benefits, and treatments in a public hospital to every Australian resident regardless of income”
- Efficiency: “Having the maximum number of health dollars spent on delivering health services rather than administering them” 60

These attributes are remarkably similar to the core principles of the right to health as outlined in Article 12 of the ICESCR. For example ‘universality’ is similar to Part (d) of Article 12 of the ICESCR: ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness.’ 61

Further, rights language is used throughout the Health Insurance Act 1973 (Cth). For example, the Act refers to a ‘right to use [medical] equipment’ 62 and a ‘right to payment of benefits.’ 63 Further, the Health Insurance Act 1973 (Cth) lists the ‘Rights of persons under review at hearings [relating to health].’ 64

It is noteworthy, however, that while Section 26 of the Health Insurance Act 1973 (Cth) used to recognise the rights of patients to treatment, this provision has since been removed. So too have the Medicare Commitments that the Commonwealth, States and Territories were once expected to follow. 65

**National Health Act 1953 (Cth)**

The National Health Act 1953 (Cth) makes provision for pharmaceutical, sickness and hospital benefits. Today, the National Health Act 1953 (Cth) underpins the Pharmaceutical Benefits Scheme – a program that provides subsidised prescription drugs to Australian residents. 66 It also contains extensive provisions about the operation of nursing homes.

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59 Commonwealth of Australia, n 55.
62 Health Insurance Act 1973 (Cth) s 23DZR(1)(f).
63 Health Insurance Act 1973 (Cth) s 80A(1).
64 Health Insurance Act 1973 (Cth) s 103.
66 Australian Government Department of Health, n 7.
Although the National Health Act 1953 (Cth) does not explicitly use rights language, it does require that essential medicines be economically accessible in Australia, which is a key objective of the international right to health. In Australia, essential medicines are defined as medicines that are necessary to maintain the health of the community in a way that is cost-effective to the public.67

Other relevant laws include the Aged Care Act 1997 (Cth), the Disability Services Act 1986 (Cth), the Veterans’ Entitlements Act 1986 (Cth), the Military Rehabilitation and Compensation Act 2004 (Cth) and the Australian Institute of Health and Welfare Act 1987 (Cth) - all of which focus on various health-related entitlements.

Domestic ‘right to medicines’ policies

National Medicines Policy

The National Medicines Policy, introduced in 1999, is a framework designed to ensure that all Australians have access to quality medicines.68 It is the primary authority on how medications are to be handled in Australia, both through the PBS and alternate access schemes. The National Medicines Policy has four central objectives:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines; and
- Maintaining a responsible and viable medicines industry69

Whilst these objectives had already been implied in Medicare and PBS purpose statements prior to 1999 (for example, Medicare and the PBS both protect ‘access’ for all Australians), the National Medicines Policy satisfies the World Health Organisation’s desire for Australia to have a clear therapeutic drug strategy.70 Further, since its inception in 1999, lawmakers have had to ensure that new health laws support the four objectives of the National Medicines Policy.

In 2014, Tim Watts MP criticised the National Health Amendment (Pharmaceutical Benefits) Bill 2014 (Cth), which proposed to increase the PBS safety net, because, “The National Medicines Policy aims to achieve positive health outcomes for all Australian through access to and wise use of medicines. It is difficult to see how the bill before the House conforms to these objectives [“timely access to the medicines that Australians need, at a cost individuals and the community can afford”].”71 This suggests that the National Medicines Policy does inform domestic health laws, and ensures that potential health laws do not disadvantage the (sick) individual.

67 Australian Government Department of Health, n 7.
70 Australian Government Department of Health, n 68.
Pharmaceutical Benefits Scheme

The principal mechanism for ensuring access to medicines in Australia is the Pharmaceutical Benefits Scheme (PBS). The PBS provides Australians with affordable access to necessary medicines.  

It does this by subsiding the cost of approximately 80% of the medications dispensed in Australia.

The first attempt to legislate for the provision of free pharmaceuticals came in 1944 in the Pharmaceutical Benefits Act 1944 (Cth). In the Second Reading Speech for the Pharmaceutical Benefits Act 1944 (Cth), the government stated:

“Any man, who is honest and thrifty can, so long as he remains well, provide to some degree against the economic accidents of life, but he cannot foresee an illness which may disable him...the Government, therefore, intends to relieve the citizen, as far as possible, from the economic burdens of illness...this must, necessarily, involve the provision of medicine.”

This statement suggests that the PBS sought to eliminate economic discrimination against the sick, and to ensure that all Australians can access medicinal remedies for their illnesses. However, the High Court of Australia, with only one dissentient, shortly after declared the Act unconstitutional because the Commonwealth did not have the power to spend money on the provision of medicines. In response, the Government held a national referendum in 1946 to extend the powers of government over a range of social services, including pharmaceutical benefits. Dr Evatt, who introduced the referendum bill to Parliament, stated, “Not only in Australia, but also throughout the world, it is the community’s duty to provide for its members benefits of a social service character.”

The referendum was successful - a majority (54.39%) of the Australian public agreed that the government had a ‘duty’ to provide social service benefits to them. The referendum amendment introduced Section 51 (xxiiiA) into the Constitution of Australia 1901 (Cth), which reads:

“The provision of maternity allowances, widows’ pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances.”

After the amendment, the Pharmaceutical Benefits Bill 1947 (Cth) was reintroduced to the Commonwealth Parliament. In the Second Reading Speech, Senator McKenna stated that the “scheme is designed to lessen the economic barrier between the patient and efficient

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72 Parliament of Australia, n 10 . 7.
74 Commonwealth of Australia, n 71.
75 Constitution Alteration (Social Services) Bill 1946 (Cth).
77 Commonwealth of Australia, n 77.
78 Australian Constitution 1901 (Cth).
treatment for his illness or incapacity.”

Equal access to medicines, without regard to wealth, appeared to be the key philosophy of the early Pharmaceutical Benefits Scheme. Notable however is that relatively few prescriptions were covered under it because of opposition from the medical profession.

With the election of the Liberal government in 1949, the comprehensive scheme proposed under the 1947 Labor legislation was altered. Concerned about the expense of the scheme, the new government introduced a limited scheme in 1950 to provide a list of 139 ‘life saving and disease preventing drugs’ free of charge to the whole community.

The Pharmaceutical Benefits Scheme as we know it today, was introduced in 1960 following the passage of the National Health Act No. 72 1959 (Cth). In the new scheme, there was an expanded range of subsidised drugs for the general public and the introduction of a patient contribution of 5 shillings to provide some control on volumes and expenditure.

In the Bill’s Second Reading Speech, Pr Cameron MP stated that the reason for a co-payment was because, “the cost of pharmaceutical benefits could soon exceed £30,000,000 a year, and would dominate the entire national health service, leaving correspondingly less room for manoeuvre for improvements and operations in any other direction…it is not in the interests of the public that a scheme of social benefit should be unstable and uncontrolled in the amount it costs.”

However, many politicians at the time were opposed to this change, arguing, as Mr Clarey MP did, “We say that education is essential for the progress of the nation, and education is free. Two things are necessary for the progress of the nation – education and health. Both should be free. Both should be the right of every member of the community, and Opposition members will never be satisfied until a health scheme is introduced here that entitles everybody from the day of their birth to the day of their death to the fullest measure of treatment in respect of their health, so as to build and maintain a healthy and strong nation.”

Despite such opposition, the new scheme passed and was introduced in 1960.

Notwithstanding the introduction of the co-payments, prescription volumes increased from 24.6 million in 1959 to 60, to 60.4 million in 1968 to 69, and Commonwealth expenditure rose from $43 million to $100 million at the end of the decade.

Issues of affordability and sustainability still plague the Pharmaceutical Benefits Scheme. To limit the cost to the public of listing particular medicines, medicines are listed on the PBS only if they satisfy two main criteria – community need and cost effectiveness. A medicine meets the ‘community need’ criterion if it is necessary to maintain the health of the community. A medicine is considered to be ‘cost effective’ if its cost can be justified by

82 Parliament of Australia, n 75.
83 Parliament of Australia, n 75.
84 Parliament of Australia, n 75.
85 Parliament of Australia, n 75.
87 Parliament of Australia, n 75.
88 Australian Government Department of Health, n 7.
89 Australian Government Department of Health, n 7.
the improved health outcomes it brings. The later criterion is non-negotiable - the National Health Act 1953 (Cth) requires the Pharmaceutical Benefits Advisory Committee to assess cost-effectiveness. If the Pharmaceutical Benefits Advisory Committee is satisfied that a medicine meets both criteria, then the Department of Health negotiates its price with the supplier.

Other strategies employed to ensure the PBS is affordable, and continues to ensure accessibility to medicines, include specifying a maximum number of repeat prescriptions an individual can have subsidised, and restricting subsidised medicines to specific therapeutic uses only.

This year, the Department of Health unveiled the Pharmaceutical Benefits Scheme Access and Sustainability Package 2015 – an amalgamation of 20 measures which together are intended to ensure that high cost medicines will be accessible to more people over the next 5 years. In particular, the Sixth Community Pharmacy Agreement 2015, which is a part of the Package, will provide $18.9 billion over five years to 5400 community pharmacies to support subsidisation of high cost medicines.

Alternate Access Schemes: Section 100 Programs

In addition to the medicines subsidised through the Pharmaceutical Benefits Scheme, there are a number of other drugs that are subsidised, but are distributed under alternative arrangements. These alternative arrangements are provided for under Section 100 of the National Health Act 1953 (Cth):

“(1) The Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:
(a) who are living in isolated areas; or
(b) who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment”

There are a number of Section 100 programs, all of which are designed to ensure that patients are able to access the medicines they require.

The largest Section 100 program is the Highly Specialised Drugs Program (HSDP). The HSDP subsides high cost drugs that treat complex conditions that require hospital supervision.

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90 Australian Government Department of Health, n 7.
92 Australian Government Department of Health, n 7.
93 Australian Government Department of Health, n 7.
95 Australian Government Department of Health, n 94.
97 National Health Act 1952 (Cth), s 100.
98 Parliament of Australia, n 73.
Conditions covered on the scheme include cancers, and hepatitis.\textsuperscript{99} The average annual growth in the HSDP has been around 6.38\% from 2009 to 2014.\textsuperscript{100}

The Efficient Funding of Chemotherapy Program, an initiative of the Section 100 Program that provides chemotherapy at an accessible price, has had an average annual growth rate of 62\% since its inception in 2009.\textsuperscript{101}

The Life Saving Drugs Programme\textsuperscript{102} is a separate scheme that provides eligible patients with subsidised access to ten expensive drugs.\textsuperscript{103} The ten drugs currently listed all treat serious medical conditions that are: rare, identifiable with reasonable diagnostic precision, and sufficiently debilitating.\textsuperscript{104} Among other criteria, the drug must be economically burdensome for patients.\textsuperscript{105} Currently, 268 patients are being treated on the Life Saving Drugs Programme.\textsuperscript{106} On average, each patient costs the Australian Government over $300 000 a year\textsuperscript{107} even though none of the LSDP drugs cure diseases.\textsuperscript{108}

The Orphan Drugs Program is a scheme designed to encourage drug manufacturers to develop and market ‘orphan drugs.’\textsuperscript{109} An ‘orphan drug’ is defined in Regulation 16 H (2) of the \textit{Therapeutic Goods Regulation 1990} (Cth) as a drug that:

\begin{quote}
“(a) [is] intended to treat, prevent or diagnose a rare disease; or
(b) [is] not commercially viable to supply to treat, prevent or diagnose another disease or condition.”\textsuperscript{110}
\end{quote}

Regulation 45(12) of the \textit{Therapeutic Goods Regulation 1990} (Cth) provides that companies do not have to pay to have ‘orphan drugs’ considered by the Pharmaceutical Benefits Advisory Committee for listing on the Pharmaceutical Benefits Scheme.\textsuperscript{111}

Since the introduction of the Orphan Drug Program, the annual number of orphan drug designations has increased from an average of 13 in the first few years of the program to 20 approvals in 2009.\textsuperscript{112} 42\% of all the drugs covered by the Orphan Drug Program have been for cancer.\textsuperscript{113}

\textsuperscript{99} Parliament of Australia, n 73.
\textsuperscript{100} Parliament of Australia, n 73.
\textsuperscript{103} Australian Government Department of Health, Other supply arrangements outside the Pharmaceutical Benefits Scheme (PBS), http://www.health.gov.au/LSDP.
\textsuperscript{104} Australian Government Department of Health, n 91, 7.
\textsuperscript{105} Australian Government Department of Health, n 91.
\textsuperscript{107} Australian Government Department of Health, n 106, 7.
\textsuperscript{108} Australian Government Department of Health, n 106, 12.
\textsuperscript{110} Therapeutic Goods Regulation 1990 (Cth) Reg 16 H(2).
\textsuperscript{111} Therapeutic Goods Regulation 1990 (Cth) Reg 45(12).
\textsuperscript{113} Australian Government Department of Health, n 112, 6.
While increasing the range of drugs is beneficial for recovery, particularly to those suffering from rare diseases, the Orphan Drugs Program does not ensure that they are economically accessible. Thus, patients might still have to forego treatment due to price.

**Other avenues to access medicines**

Evidently, not all high cost medicines are subsidised through the PBS, and even those that are may not be subsidised for all the types of cancers for which it may prove beneficial. Patients that need access to a high-cost medicine that is not subsidised by the PBS do have alternative, although ad hoc, avenues for access. At the discretion of a pharmaceutical company, access to a drug may be granted to a patient for free, at a significant discount, or free of charge after an initial commitment to buy the first courses of treatment. Another option is for patients to seek treatment through the public hospital system. Public hospitals are funded by a separate budget, and are autonomous with regards to decisions about what drugs they buy, to whom they dispense drugs, and for what reasons. This is typically managed through the Drug and Therapeutics Committee that has governance over the hospital formulary. Access to free medicines may also be granted via clinical trials (if one exists), but being accepted into these trials is not straightforward and access may be limited by eligibility criteria, size of the trial, and location of the trial. In rare instances, the government may also be pressured to create special funding streams, outside of the PBS, for specific expensive medicines such as the Herceptin Program to fund transtuzumab for breast cancer patients.\(^\text{114}\)

All of these approaches can lead to inconsistent decisions, as neither pharmaceutical companies nor hospitals are obliged to provide access to medicines, and are not governed by a central decision making body. Access to clinical trials can be limited for the reasons already stated, while the creation of special funding streams for particular diseases by governments can also be criticised for discriminating against patients suffering from other life-threatening diseases for which expensive medicines may help, yet remain unfunded. In all cases the unpredictability and financial pressures that result when patients must raise the money for treatment themselves, and are faced with the prospect of forgoing treatment only because they cannot afford it, are highlighted in the Senate Inquiry as major stressors for already vulnerable patients.

**DISCUSSION**

**Value of the right to health**

This analysis has demonstrated that there is no broad common law or legislative right to health in Australia because the right to the highest attainable standard of health, as outlined in Article 12 of the *International Covenant on Economic, Social and Cultural Rights 1976*, has not been ratified into domestic law. This has been the case for over 50 years, and is unlikely to change. Unfortunately for patients, this means that the Australian Government is under no legal duty to ensure that they are able to access medicines-including those that might extend their lives. Further, no domestic legal action can be brought against a pharmaceutical company for not providing the medicines they produce at affordable prices. Thus, the international right to health ensures no legal benefit in Australian courts. This is true even for disadvantaged parties such as those with rare diseases for whom there are limited therapeutic options, or diseases that can only be treated using very expensive medicines.

While this situation may appear unjust, there are very strong arguments for the right to health to remain absent from Australian law. The primary argument against ratifying rights in Australia is; if the right to health were justiciable via legislation, courts would have the power to make resource allocation decisions if the right to health is activated in a case. Because the public does not elect judges, there are legitimate concerns that judges should not be given the power to make decisions that affect all citizens. At least in theory, government bodies, such as the various Departments of Health and their nominated committees such as PBAC, are better suited to be making resource allocation decisions because they are answerable to citizens by way of elections.

Further, some claim that Australia already does enough to protect the right to health, namely via Medicare and the PBS; an explicit right to health is therefore unnecessary. Others propose that characterising health, as a ‘right,’ would place an undue financial burden on the government to provide everyone with adequate healthcare, which is impossible in a resource-limited society.

This does not mean that the notion of a right to health is irrelevant in Australia - it does serve a rhetorical purpose. Dworkin claimed that categorising something as a right makes that ‘good’ more important than other ‘goods.’ In Australia, health has undeniably become more important since the right to health was incorporated into international law in 1966. In 1981-82, 6.3% of GDP (10.8 billion dollars) was spent on health care, whereas, in 2013-2014, 9.8% of GDP (154.6 billion dollars) was spent on health measures. Evidently, health care has become increasingly important to the Australian Government, as it has for international law making bodies. While Australian Governments have not necessarily been motivated to increase their expenditure on health because of international law, it seems likely that they would have been influenced by the plethora of international commentary on the right to health, and changing public perceptions about the importance of health.

The significance of rights as a rhetorical device is also evident in our finding that human rights language is employed in the purpose statements of many, if not all, domestic access policies. As we have shown, Medicare, the PBS and other health access schemes are explicitly underpinned by principles such as equity, social justice and universality, which focus on the rights of (disadvantaged) individuals rather than only the good of the collective.

We have also shown that there are programs in place, such as the Highly Specialised Drugs Program and the Life Saving Drugs Program, which provide concrete examples of Australia’s commitment to the rights of at least some individuals, irrespective of cost. These programs exist because the patients with the highest medical need are often the patients with the least capacity to fund their own treatment. Proponents of the right to health argue that these patients should not be denied treatment simply because the medicines they need are incredibly expensive. The existence, and rapid growth, of these programs shows that society is generally unable to tolerate denying life-saving or life-sustaining treatment to patients, particularly where those patients are recognisable and where there is a clear person responsible for making the allocation decision. Philosopher Albert Johnson described this phenomenon as ‘the rule of rescue’ – an innate human impulse to save identifiable 

118 Parliament of Australia, n 10, 62.
individuals at risk of imminent death no matter how great the cost or small the likelihood of benefit.\textsuperscript{119}

**Implications for health resource allocation in Australia**

While it is understandable that people in need of healthcare would use whatever rhetorical devices they can, and while the rule of rescue describes an admirable human reaction, these arguments can also confound resource allocation decisions. Clearly, in a resource limited health system, ignoring the cost of treatments altogether is impractical, and some regard must be had to the cost-effectiveness and affordability of treatments before they are subsidised. For this reason, those making resource allocation decisions inevitably have to balance their commitment to addressing the needs of individuals against the need to ensure the greatest good for the greatest number of people. Australia’s health system is, therefore, characterised by an ongoing tension between a commitment to utility and a commitment to individual rights.

In spite of the impracticalities of making resource allocation decisions based solely on the right to health, there does appear to be an international and domestic shift towards providing more patients with higher cost drugs. Nonetheless, ways of minimising the cost of providing high-cost medicines to the population at subsidised rates are necessary for this shift to be sustainable. Some commentators have recommended integrating the Section 100 Programs into the Pharmaceutical Benefits Scheme to minimise unnecessary administration fees. Others have recommended negotiating new arrangements with Australian pharmaceutical companies. Ultimately, a solution needs to be found if right to health premised programs are to remain cost-effective and affordable.

**CONCLUSION**

As Justice Kirby stated in his Inaugural Lecture to the Australian Institute of Health Law and Ethics, ‘it is possible for us to recognise, in recent years, a growing understanding that the allocation of healthcare resources has an ethical dimension.’\textsuperscript{120} However, as this analysis makes clear, there is no universal model for resolving the ethical problems of resource allocation. While the right to health model serves an important rhetorical function, and encourages governments to ensure that medicines—including high cost medicines—are accessible to all patients who need or want them, this is clearly unfeasible in a resource-limited system.
