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Prescriptions from Down Under: Can Canada Import Australia's Pharmaceutical Benefits Scheme?

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Toward A National Strategy on Drug Insurance: Challenges and Priorities

I. Introduction

There is no provision in the *Canada Health Act* or in other legislation for a national prescription drug insurance plan. As a consequence although all provinces provide some coverage for seniors and social assistance recipients, 10 percent of Canadians are completely uninsured and a further 10 percent are under-insured.ⁱⁱ Canada's failure to provide a national plan for its citizens puts it in the odd company of United States and Mexico amongst OECD countries.ⁱⁱⁱ

There have been numerous calls to establish a national plan providing insurance for prescription drugs. But what should be the hallmarks of such a plan? How should it be funded? What should be the respective roles of federal and provincial governments in funding and/or managing such a scheme? Should there be an outright prohibition on user charges as there is for "medically necessary" hospital and physician services? To answer these questions it is useful to consider the experience of a similar jurisdiction with a national drug insurance scheme. Canada and Australia share institutional, demographic and geographic features that make comparison worthwhile.^{iv} Australia's Pharmaceutical Benefits Scheme ("PBS") is a popular program, ensuring subsidized access for all Australians to a comprehensive range of medically necessary, cost-effective drugs.^v As Canada considers what shape a national pharmaceutical plan could take Australia's PBS is worthy of study. If Australians can do it why can't we?

The present Canadian system differs from Australia's system^{vi} in five significant respects. First, the PBS covers all Australian citizens whereas in Canada at least 10% of Canadians do not have the security of prescription drugs coverage.^{vii} Secondly, the PBS is a national program and the Commonwealth

(equivalent to Federal) government funds and administers the PBS. The Commonwealth government has constitutional responsibility for the insurance of prescription drugs.^{viii} The Canadian constitution (at least insofar as it has been interpreted by the courts to date) does not empower the federal government to regulate the insurance of prescription drugs although, as discussed further below it may achieve the same goal indirectly through use of its spending powers. The federal government does have constitutional jurisdiction over patents and thus is able to regulate a maximum price for patent drugs through the Patented Medicine Prices Review Board. Third, the PBS has monopsony power in negotiating with drug companies, as there is one single purchaser of publicly funded drugs in Australia. By comparison, in Canada there are a multiplicity of provincial insurers and private insurance plans which each negotiates price and volume arrangements with drug companies. Fourth, Australia has one central process for determining which drugs receive public subsidization; despite efforts at inter-provincial co-ordination on this issue in Canada this has yet to occur in Canada. And finally, as will be discussed in greater detail, the mix of funding for pharmaceuticals differs significantly as between Australia and Canada with a much greater proportion of spending on pharmaceuticals coming from public funds in Australia than is the case in Canada.

In this paper I will first examine the sources of funding for the PBS. Then I will turn to examine the management of the PBS and the process for inclusion of a new prescription drug into the PBS scheme. I will then turn to discuss the various advantages and disadvantages of the PBS scheme and, finally, the prospects for adopting the PBS model in Canada.

II. Funding of the PBS

Although the PBS covers all Australians (universal access) this does not mean that all prescription drugs attract full public funding and a significant component of spending on prescription drugs comes from out-of-pocket payments. Thus Australia's PBS scheme is a national system of **subsidies** for prescription drugs with safety nets ensuring free medicines for the chronically ill. There are three sources of funds for prescription drugs: the PBS (government subsidies), out-of-pocket payments by patients (co-payments/user charges), and private insurance. As Graph 1 illustrates, on average 41.5 percent of total spending on pharmaceuticals is paid out-of-pocket by patients, 58 percent by subsidies from the Commonwealth government (the PBS), and 0.5% percent by private health insurance.^{ix} By comparison in

Canada, 39.5 percent of total spending on pharmaceuticals is paid out-of-pocket by patients, 30.8 percent by subsidies from provincial governments and 24.6 percent by private health insurance.

A. Co-payments/User Charges

The PBS provides for a significant role for out-of-pocket payments on the part of patients. As Table 1 indicates, on average 41.5 percent of total spending on all pharmaceuticals is paid out-of-pocket by patients. But the amount patients pay out of pocket is much less if we consider only prescription drugs that are **listed** on the PBS (i.e. to which some form of PBS subsidy applies). PBS subsidies covering 83 percent, or approximately \$3.24 billion, of the total \$3.9 billion value of PBS-listed medicines issued from community pharmacies.^x Patients pay from their own pockets, on average, 17 percent of the total spent on PBS-listed medications.^{xi}

The amounts that patients must pay out-of-pocket for prescription drugs varies depending on whether he/she is classified as "General" or a "Concession" patient.^{xii} General patients are required to pay a flat amount of \$22.40 per prescription (unless the actual cost of the prescription is less).^{xiii} If a General patient spends more than \$686.40 in any year on PBS pharmaceuticals then the maximum amount payable per prescription falls to \$4.60. Concession patients are required to pay \$3.60 per prescription up to a maximum of \$187.20.^{xiv} General and Concession patients only pay above the standard co-payments if they and their doctor choose higher cost drugs that have a therapeutic equivalent at the base price ("therapeutic premiums").

Patients entitled to hold a concession card include pensioners, seniors, veterans and social security recipients.^{xv} Approximately one-third of the Australian population is covered by a concession card of some kind^{xvi} and 80 percent of the Commonwealth government's PBS spending in 1997-1998 served to subsidize pharmaceutical purchases for Concession patients.^{xvii}

This year the Commonwealth government proposed a sizeable increase in the size of patient co-payments for drugs: an increase in payments for General patients to \$28.60 per prescription and for Concession patients to \$4.60 with the safety-net threshold increasing, respectively to \$874.90 per annum for General patients and \$239.20 for Concession patients.^{xviii} However, the Australian Senate (which unlike the Canadian Senate is an elected body) has moved to strike down this legislation. Critics suggested the

Government rethink its recent decision to cut taxes for the wealthy if it is having difficulty paying for the PBS.^{xix}

B. Government Subsidies

When we look at the total amount spent per capita on pharmaceuticals, Australia spends less per capita in total on pharmaceuticals than Canada does. OECD data for 1996 (calculated in US\$ at current exchange rates and then expressed in constant 1996 US\$) records Australia as spending \$202 per capita compared with \$258 per capita in Canada.^{xx} More recent data (not adjusted, see Graph 3) records \$377.80 per capita (in Australian dollars) compared with \$465.15 per capita (Canadian dollars) in Canada.

However, unfortunately, both the federal and provincial governments in Canada may be more interested in the size of the Australian *government's* share of spending on the PBS and increases in this share over time rather than the overall (public and private) performance of the system. OECD data for 1996 (calculated in US\$ at current exchange rates and then expressed in constant 1996 US\$) records the Australia government as spending \$93 per capita compared with expenditure of \$100 per capita on the part of Canadian governments.^{xxi} In 2000/2001 Australian government spent \$219.10 (Australian) per capita^{xxii} compared to \$152.07 (Canadian) per capita on the part of Canadian governments.^{xxiii} Thus Australian governments do pay more per capita than Canadian governments but in total (public and private) Australia spends less on prescription drugs than Canada does.

Of course, as with all OECD countries, the PBS must wrestle with issues of cost increases in drug spending. Although Australian expenditures on pharmaceuticals compares well with other OECD countries, like every other country has had to battle increasing costs as a result of inflation, population growth, an aging population^{xxiv}, technological growth, and a greater reliance on drug therapies.^{xxv} In recent years, PBS expenditures have increased at an average rate of 9.7% per year, almost twice the 4.8% at which spending on the entire health system increases yearly.^{xxvi} The Commonwealth claims that these increases in spending are due, in large part, to the high cost of innovative new therapies^{xxvii} but there are also concerns that irresponsible prescribing is leading to wastage. Nonetheless, the general philosophical underpinnings of the Commonwealth's continued spending are that prescribing in accordance with cost-effectiveness guidelines serves to cut costs in other areas of the health system.^{xxviii} Thus although there are concerns

about the rate at of growth in PBS costs there is no cap under which the Commonwealth government is committed to keeping PBS spending.^{xxix}

C. Private Insurance

The role of private health insurance in funding pharmaceuticals in Australia is very low -- only \$35 million of the \$7,242 million spent on pharmaceuticals in 2000/01 (0.5%). By comparison, in Canada 24.6% of total funding for pharmaceutical was sourced from private insurance funds in 2000/01 (see Graph 1).

Why does private insurance not play a larger role in funding pharmaceuticals in Australia? This is a particularly interesting question given that that there are no restrictions on private insurance for pharmaceutical expenses and the Australian Commonwealth government has an explicit policy of supporting the role of private health insurers in the Australian system and subsidizes their activities. The reason for the small role for private insurance for pharmaceutical expenses is due to lack of demand. The PBS provides for maximum co-payments and a safety net if annual costs exceed certain ceilings (\$686.40 for General patients and \$187.20 for Concession patients). With this level of security provided for in the public plan, Australian citizens have no need to purchase private insurance

III. Management of the PBS

Australia and Canada differ in terms of the sources of funding for prescription drugs. Australia relies to a much greater extent than Canada does on public funding and Canada relies to a much greater extent than Australia does on private insurance. Because of the level of public funding there is a strong incentive for the Australian Commonwealth government to efficiently regulate and manage the marketing of drugs and the prices and utilization of pharmaceuticals.^{xxx} For example, Australia was an early pioneer in the use of cost-effectiveness criteria, requiring pharmaceutical companies to demonstrate that, comparatively, the drug for which PBS listing is being sought offers superior monetary value.^{xxxi} In general, Australia takes a significantly more centralized approach to managing prices, utilization and total spending on pharmaceuticals than Canada does.

For a drug to be listed with the PBS (and thus attract government subsidies), a pharmaceutical company must first register that drug with the Therapeutic Goods Administration (TGA).^{xxxii} The TGA reviews the application and then passes it along to the Australian Drug Evaluation Committee (ADEC) for a review of

the particular drug's clinical merits.^{xxxiii} Following consultation with ADEC, the TGA makes its final decision on the application.^{xxxiv} The three major criteria cited by the TGA in this process are safety, efficacy, and quality.^{xxxv} Once a particular drug has been registered, the sponsor pharmaceutical company may, theoretically, price the product as it pleases.^{xxxvi}

Failure to achieve registration with the TGA bars any chance of success in applying for PBS subsidization.^{xxxvii} Following registry with the TGA, a sponsor pharmaceutical manufacturer may then apply for listing under the PBS. This stage involves the Pharmaceutical Benefits Advisory Committee (PBAC), which is comprised of independent (no government affiliation) members of expert clinical and pharmaceutical backgrounds.^{xxxviii} The Minister of Health appoints the members of PBAC.^{xxxix} PBAC advises the Minister for Health which pharmaceuticals the PBS should provide subsidies for.^{xl} PBAC's recommendations exert great influence upon the Commonwealth government's final PBS listing decision.^{xli}

The *National Health Act* also empowers PBAC to establish expert subcommittees.^{xlii} There are currently two subcommittees: the Drug Utilization Sub-Committee (DUSC), which "monitors the patterns and trends of drug use and makes such utilization data available publicly," and the Economics Sub-Committee (ESC), which "advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to the PBAC."^{xliii} The PBAC compares the effectiveness, safety, and cost of a pharmaceutical with products of a similar nature.^{xliv} Some applications to the PBS are for subsidization of innovative drugs, but many applications seek PBS subsidization of "me-too" drugs, i.e. a company's own particular brand of a therapy already listed under the PBS scheme.^{xlv}

In determining cost-effectiveness, the PBAC follows the Australian Guidelines.^{xlvi} The Guidelines require companies to provide the results of clinical trials demonstrating the relative effectiveness of the drug in question and to justify their decision to select a particular drug against which to compare its product during clinical trials.^{xlvii} The Guidelines also require that the clinical and economic analyses conducted by the sponsor pharmaceutical company be sufficiently thorough to pass muster with the PBAC.^{xlviii} The PBAC also considers the price that the sponsor wishes to charge for its product.^{xlix} Though there is no formal cap on total PBS spending, the PBAC must take care to ensure that any new additions to the scheme are valuable enough to warrant budgetary increases.^l

Pharmaceutical companies have three basic options in offering an economic analysis of their product as follows:

1. they may claim that it is the equivalent of another currently listed product, and has a cost minimizing effect;
2. they may claim superiority, in which case they would argue their product's cost effectiveness;
3. or, in rare circumstances, they may claim that their product is inferior, but is available at a lower price and thus it is cost-effective to fund it.^{li}

The methodological ideal is randomized, controlled clinical trials pitting the sponsor's product against the drug to which the sponsor claims equivalence or superiority.^{lii} However, in certain cases, such as that of an especially innovative therapy, the lack of an appropriate comparator medicine necessitates a deviation from the standard.^{liii} Though indirect outcomes, such as improvements in patient productivity, are not strictly barred from the analysis, only the projected effects on direct costs, such as the cost of pharmaceuticals, hospitalization, and other medical care concerns, are compulsory.^{liv}

Following a positive outcome at the PBAC level, the Pharmaceutical Benefits Pricing Authority (PBPA), a separate committee composed of independent industry and consumer members, enters negotiations with the sponsor to determine the price at which the product is to be marketed.^{lv} The Minister for Health considers the recommendations from the PBAC and the PBPA and then (normally) approves the listing. Upon the Minister's approval, the product becomes subsidized under the PBS.^{lvi} Once listed, the process engaged by everyday Australian consumers and pharmacists is simple and efficient. The consumer simply presents her prescription for a listed pharmaceutical to an authorized pharmacist, makes her co-payment, and the Commonwealth government reimburses the pharmacist the difference between the user charge and the price listed under the PBS.^{lvii}

IV. Advantages and Disadvantages of the PBS model

Not surprisingly, evaluations of the efficiency of the PBS listing process vary according to perspective. A recent government audit of the PBAC was generally positive.^{lviii} And the PBAC has been praised for processing listing applications under the PBS within eleven weeks of their initial submission.^{lix} However, the pharmaceutical industry claims that the effect of the PBS is to suppress drug prices thus forcing drug companies to absorb the real costs of developing, manufacturing and marketing drugs and obscuring the

true cost thereof from patients.^{lx} On the other hand, critics have charged the Commonwealth government with being too ready to list new medications on the PBS^{lxi} particularly “me-too” drugs that represent only a slight or marginal improvement over their predecessors but are more expensive.^{lxii}

No system is without its difficulties but a national plan, administered by a single agency like the PBAC, offers the prospect of:

- (A) equitable access for all citizens to needed prescription drugs;
- (B) moderating growth in spending on pharmaceuticals to efficient level by (1) using PBAC’s market power as a monopsony purchaser to negotiate optimal prices with multinational drug companies and (2) taking a centralized and coordinated approach to ensuring rational utilization of pharmaceuticals; and
- (C) integrating the drug approval, patenting and purchasing process.

Let me discuss each of these possible advantages in turn.

A. Equitable Access For All Citizens To Needed Prescription Drugs

Given the social justice values that underpin Canada’s Medicare program and the growing importance of drug therapies in the treatment of health care needs, it is of great concern that at least 10 percent of Canadians have no prescription drug insurance. The majority of Canadians have coverage through private employment-based extended health benefit plans albeit with a variety of different co-payment requirements. Provincial drug benefit plans insure the elderly and those on social assistance, although each province covers different drugs and there are significant (up to 10-fold) variations in co-payment requirements. The people who don’t fall into these categories are at risk of either being completely uninsured (roughly ten percent of Canadians), or being under-insured (another ten percent).^{lxiii} A national pharmacare plan, like Australia’s PBS, would reduce this inequity.

In terms of equitable access it is notable that the Australian scheme allows for the payment of user charges for prescription drugs. Various studies have demonstrated that the corollary effect of whatever impact user charges has on suppressing demand for pharmaceuticals is that some people may not access the pharmaceutical drugs they need.^{lxiv} A recent study in Australia revealed that 14% of Australians of below-average income had not filled a prescription at sometime during 1997-1998 because of the drug’s cost, as opposed to only 7% of Australians of above-average income.^{lxv}

Thus user charges may affect the willingness of patients to acquire needed drugs and must, if used, be fairly targeted at those who are most able to pay. However, if user charges were allowed in a Canadian national plan for prescription drugs this still would be far preferable to the status quo. In the context of a national plan, there could be at least minimum *national* standards with regard to out-of-pocket payments for prescription pharmaceuticals. The provision of national standard regarding maximum out-of-pocket payments (annual safety nets as in the PBS) would be essential to ensure fair access to necessary health care across Canada and to maintain the integrity of Medicare.

B. Moderating Growth In Spending On Pharmaceuticals To An Efficient Level

(1) Monopsony Purchaser

The PBS has proved relatively effective in controlling increases in total spending on drugs (a function of prices and utilization).^{lxvi} In 1998, Australia devoted 11.4 percent of total health expenditures to pharmaceuticals (a 44.3% increase since 1980) whereas Canada devoted 15 percent (a 76.5% increase since 1980).^{lxvii} Australian pharmaceuticals are priced at approximately 60 percent of what other developed nations pay,^{lxviii} with little difference in the price paid for brand names and their generic equivalents.^{lxix}

The ability to keep prices and total costs *relatively* low has been attributed to PBS' monopsony power which allows it to have much greater power in negotiations with pharmaceutical companies. The deflating effect of PBS' monopsony power on prices appears most effective where pharmaceutical companies are in competition with one another, for instance in the case of me-too drugs where multiple products have similar therapeutic properties. Where the PBS is negotiating over the price of a unique drug, the pharmaceutical company also has market power, lessening the PBS advantage.^{lxx} Notwithstanding this limitation, the lesson seems to be that a single agency can use its monopsony power to negotiate favorable price and volume arrangements with multi-national pharmaceutical companies. By comparison, in Canada there are at least 14 governments (10 provincial, 3 territorial and 1 federal (purchasing for Aboriginal needs)) and dozens of private insurers each negotiating price and volume arrangements with large pharmaceutical companies. There is a one central body, the Patented Medicines Prices Review Board (PMPRB), which regulates the maximum factory-gate prices of patented drugs. The evidence is that the PMPRB has been able to control relative increases in prices for patented drugs at or near something approximating what the Australian system is able to achieve.^{lxxi} However, the PMPRB only has jurisdiction over patented drugs and the prices of non-patented drugs have increased significantly. Moreover, the PMPRB has no jurisdiction to

regulate utilization whereas, of course, total spending is a product of both the price of pharmaceuticals and utilization.

The PBS hasn't relied only alone on its monopsony bargaining power to contain costs. Targeted user charges were introduced in 1960 in an attempt to control utilization.^{lxxii} There are no studies that aware of that have isolated the impact of user charges in Australia from other measures that may have a moderating effect on growth on total pharmaceutical expenditures. In Australia, user charges are a flat fee of (for general patients) \$24.60 unless, of course, the drug is in fact cheaper. A flat fee would not seem to provide relative pricing signals (e.g. the relative cost of one drug compared to another). User fees based on a percentage of total costs (with the annual safety-net ceilings still in place) would *prima facie* seem a better vehicle for ensuring relative pricing signals.

(2) A Centralized And Coordinated Approach to Ensuring Rational Utilization Of Pharmaceuticals

It has become clear in the operation of the PBS that focusing on price-restraint alone will not result in effective control of costs and that trying to moderate utilization through the imposition of user charges has adverse distributional effects. Thus various policies are now being implemented that seek to control utilization of pharmaceuticals through incentives and efforts targeted at the supply-side, i.e. physician prescribing habits. For example, the PBS scheme requires physicians to obtain PBS approval before prescribing certain high-cost drugs. The current multiplicity of federal, provincial, territorial and private plans operating in Canada means that there is no national approach to initiatives aimed at rationalizing utilization of pharmaceuticals.

A national pharmacare plan, like the PBS, promotes the rational use of pharmaceuticals. Pharmacoeconomic analysis is a key component of the decision to include pharmaceuticals on the publicly funded list in Australia.^{lxxiii} This is not a simple cost-control measure. In Australia, spending on the PBS rose faster *after* the introduction of cost-effectiveness analysis.^{lxxiv} In other words, cost-effectiveness analysis speaks to a goal of efficiency and not cost-containment. Thus such a process may require public funding for very expensive drugs provided the additional cost is measured as relatively worthwhile compared to alternative treatments in terms of health outcomes (e.g. life-years gained, reductions in diastolic blood pressure, etc). Economic evaluations have become a common feature of formulary decisions in most OECD countries and are widely used in Canada, both within provincial formulary

committees^{lxxv,lxxvi} and in evaluations conducted by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA).^{lxxvii} The CCOHTA, a national assessment organization funded by the federal, provincial, and territorial health ministries, claims that “the majority of [its] pharmaceutical evaluations have direct input into provincial formulary decisions within a year of publication.”^{lxxviii} Despite the work of the CCOHTA and the sharing of information between provincial formulary committees, the pharmaceuticals listed in provincial formularies vary widely.^{lxxix} A national pharmacare plan would improve upon the current system by eliminating the duplication of (expensive) pharmacoeconomic evaluation in the various provincial committees. Moreover, presently in Canada individuals who are covered by private insurance have coverage for drugs that are not considered cost-effective enough to be listed in provincial formularies. A national plan would extend the rational use of pharmaceuticals by all Canadians and not simply those covered by provincial insurance plans.

C. Streamlining the Pharmaceutical Approval and Listing Process

The federal government regulates the approval of new pharmaceutical products for sale in Canada, through the Therapeutic Products Program (TPP) of Health Canada. This branch oversees clinical trials to ensure the safety, quality and efficacy of new drugs. After successfully passing these hurdles – which often takes longer than a year,^{lxxx} pharmaceutical companies must then approach ten different provincial drug benefit plans to get the drug on the provincial formulary, which can take upwards of two years to accomplish.^{lxxxi} Coordinating the two steps within one central organization would result in significant time and information savings, thus getting beneficial drugs into the Medicare system sooner.

In summary, then, a national pharmacare program, similar to Australia’s PBS, has the potential to be better able to contain increases in total costs, promote fairer and better use of drugs, and streamline the drug approval and purchasing process. So why hasn’t it happened?

V. Impediments to Adoption of the PBS

A. Changes in the Funding Mix, Political and Public Support, Interest Groups

If we look at aggregate spending on all health care goods and services, Australian and Canada have a similar split of 70% public funding and 30% private funding (private insurance and out-of-pocket payments). However, there are significant differences in the sources of funding for pharmaceuticals. In Australia, total public funding accounts for approximately 58% of total spending on pharmaceuticals whereas in Canada

total public funding accounts for 39% of the total spent on pharmaceuticals (Table 1 – 2000/01). In Australia, private funding for approximately 42% of the total spent on pharmaceuticals whereas in Canada, total private funding accounts for approximately 61%. Moreover, of the private funding that is spent on pharmaceuticals in Australia, most of it is in the form of out-of-pocket payments on the part of patients (comprising 41.5% of total spending on pharmaceuticals). By comparison, the private monies that are spent on pharmaceuticals in Canada are split between out-of-pocket payments (comprising 37.4% of total spending on pharmaceuticals) and private insurance (23.7% of total spending on pharmaceuticals). In Australia, private insurers play virtually no role in the funding of pharmaceuticals (0.5% of total spending on pharmaceuticals).

Australia and Canada fund pharmaceuticals in very different ways. This fact means that adoption of the PBS model would result in at least three dramatic changes to the Canada system:

- a. A significant increase in government funding and in particular of federal funding if the scheme were to regulated and managed at a central level;
- b. An increase in out-of-pocket payments for some groups of Canadians (particularly those Canadians who are relatively well-off and have private insurance covering pharmaceutical costs)
- c. A substantial decrease in the role of private insurers

The radical shifts in funding entailed in adoption of a PBS model highlight the impediments there would be to such adoption. First, looking at the role of governments, Australia's PBS has demonstrated a better overall capacity to control cost increases than the Canadian model of multiple provincial and private purchasers. But governments (whether federal or provincial) are nervous about commitments to expansion of public funding *even if greater public spending is the key to optimal cost control in the longer term*. This reluctance is likely to be particularly strong in the case of a prescription drug program, where technological developments and patient demand are likely to necessitate rates of increases in spending above rates in increases on other areas of health care or social programs. Only a government with a very strong commitment to leadership in social justice issues, long-range vision and a healthy budget surplus will venture to make the commitment of public funding required.

To the extent that adoption of the PBS model would result in a greater *capacity* to control increases in spending on pharmaceuticals (through moderating both price and utilization) then pharmaceutical

companies (who obviously wish to retain their profit margins) will strongly oppose such reform and lobby governments accordingly. Apart from pharmaceutical companies the private insurance industry will also strongly oppose this kind of reform. Private insurers' primary role in the present Canadian health care system is insuring prescription drugs, home care, and services not covered by public plans. If Canada adopted the PBS model, this would significantly impact upon private insurers' market share. Moreover, there could be claims by US-based private insurers for expropriation payments under NAFTA.^{lxxxii}

Government reluctance to commit to a new public program could be overcome by a groundswell of public support for a national drug plan. But the political dynamics of the existing system mean this is unlikely to happen. Those Canadians who are well insured for prescription drugs, primarily the 68% of full time workers who receive supplemental insurance packages through their employer, have little or no personal incentive to support a new national drug insurance program. Private insurance provision by employers attracts a significant tax subsidy that is not reflected in the proportion of public spending devoted to health care.^{lxxxiii} Adoption of the PBS model would likely result in a redistribution of resources away from wealthier to poorer Canadians, with the former having to contribute a larger share in the form of out-of-pocket payments and user charges.

The political dynamics of Canada's existing system of insurance for prescription drugs are somewhat similar to that which exists in the US for all health care services. In both, the wealthier and much of the middle-class have insurance through employer-sponsored plans; government has programs providing some coverage for the very poor and relatively generous programs for the elderly; and there remains a small but significant proportion of the population without any insurance (10% of Canadians without prescription drug insurance; 15% of Americans without any form of health insurance). Any momentum for change in this kind of system is stymied by lack of political will, lack of a strong public mandate for change and the resistance of interest groups like private insurance and pharmaceutical companies.

B. Constitutional Barriers

A further barrier to adoption of the PBS model in Canada is the *Constitution*.^{lxxxiv} The courts, to date, have largely interpreted the *Constitution* as empowering the provinces with primary jurisdiction over both health insurance and health care services, making unilateral federal action difficult.^{lxxxv}

In 1945, the High Court of Australia disallowed the Commonwealth government's attempt to use its spending power to create the PBS.^{lxxxvi} This prompted the Labour government of the day to initiate a referendum seeking a constitutional amendment to give the federal government concurrent jurisdiction over health in order to enact the PBS – a referendum that was successful.^{lxxxvii} In Canada, the federal government's spending power has been interpreted more broadly than was the case in Australia and federal spending statutes, like the *Canada Health Act*, have survived constitutional challenge.^{lxxxviii} Indeed the main source of federal power in health insurance and health care delivery is the "spending power" which enables the federal government to indirectly ensure national standards in areas of provincial jurisdiction by virtue of its ability to finance (and threaten to withdraw financing from) provincial programs.^{lxxxix} The *Canada Health Act* is premised on this power.

It is possible that the federal government could implement another spending statute, similar to the *Canada Health Act*, providing financial incentives to the provinces to comply with national standards in providing public insurance for prescription drugs. These standards should include that provinces provide coverage to all residents; maximum amounts able to be charged as user charges for different groups (elderly, poor, etc.) and safety-net limits (annual limits beyond which citizens are not required to pay any further sums out of pocket for prescription drugs).

But although there is an established precedent for the federal government to use its spending power to establish national standards in access and entitlements any national program must speak also to issues of management and cost control. As discussed earlier, total spending on drugs is a function of both price and utilization. Thus to ensure the long-term sustainability of a drug insurance program it is essential that there be a coordinated approach to regulation/setting of prices and utilization. With respect to prices, significant federal funding would be required to facilitate the implementation of a national drug plan and this fact alone should provide the impetus for negotiations by the federal government as a central payer (with monopsony powers) of prices for pharmaceuticals that are publicly funded. In addition to the activities of the Patented Medicines Review Board in regulating maximum factory-gate prices for patented drugs, the federal government could through use of its spending power require provinces to ensure public subsidies only for those drugs that have been vetted through a national formulary process.

Ensuring cost-effective utilization across the country is, however, a more difficult problem than regulating prices. A national formulary will mean that in general only cost-effective pharmaceuticals are publicly funded. But of course, as has been demonstrated in Australia, that does not mean that there will still not be waste or inefficient under or over utilization of drugs. Utilization can, to some degree be regulated through requiring payment of user charges. However, most policy-makers agree that to have an appropriate effect on utilization it is necessary (and preferable because of the distributional issues associated with user charges) to focus incentives on the supply side, i.e. at physicians who prescribe drugs to patients. As mentioned above, the PBS in Australia is seeking to put in place several initiatives to convince doctors to be more careful in their prescribing habits. The difficulty in Canada is that the provinces have clear jurisdiction with regard to regulation of physicians. By comparison, the Australian Commonwealth government funds the bulk of physician services and has constitutional jurisdiction to directly regulate the activity of physicians. In Canada it would be difficult for the federal government through a spending statute to require the provinces to regulate physicians' prescribing habits primarily because of the multiplicity of approaches that could be taken and that there is no one national standard that could be articulated in this regard. Moreover, in all likelihood to get a national pharmacare plan launched would take a significant injection of federal funds and unless the provinces were paying a significant share of the total bill for pharmaceuticals they would have little incentive to actively regulate and/or physicians' prescribing habits.

Of course there is no constitutional bar to the provinces creating a pan-provincial pharmacare plan. Indeed over the course of the last year the provinces have taken some steps to rationalize their respective formulary committees and prevent duplication in commissioning cost-effectiveness studies and there is a joint federal-provincial initiative to share information across the country with respect to existing public prescription drug insurance plans.^{xc} As commendable as these initiatives are, however, they do not solve the problem of insuring those Canadians without prescription drug insurance nor do these initiatives speak to national standards for out-of-pocket payments required of patients.

VI. Conclusion

In not ensuring access for all citizens to the security of prescription drug insurance, an increasingly important component of effective health care, Canada stands in the odd company of Mexico, Turkey and the US amongst OECD countries. Calls for a national drug insurance plan in Canada are not new. The 1964 Royal Commission, headed by Justice Emmett Hall, recommended a national drug insurance plan.^{xcii}

In 1997, the National Forum on Health advocated extending Medicare to prescription drugs. And, even more recently different commissions and policy analysts have added their voices to a call for a national plan.^{xcii} Despite various promises on the part of the Federal government no concrete reform proposals have been put forward. But the prospects of reform at a national level seem more promising in recent times with a flurry of provincial reports over the last year and the Kirby and Romanow Commissions due to report by November 2002. Both reports are tipped to recommend some form of national drug insurance plan, even if it is but a basic plan protecting all Canadians against catastrophic drug costs across the country. With the impetus of these reports will there be the necessary convergence of political forces over the next 12 months to provide what Carolyn Tuohy would describe as a “window of opportunity”^{xciii} for reform and, in particular, enough momentum for the establishment of national standards in prescription drug insurance?

A significant impediment to the adoption of a PBS model in Canada is that constitutionally the federal government does not have the capacity to directly regulate the insurance of pharmaceuticals nor the insurance or activities of physicians. It is possible to surmount these constitutional impediments but these impediments mean that the federal government will have to bring more funds to the table to ensure national standards across the provinces.

Reluctance on the part of the federal and provincial governments to commit to an expensive program could be overcome by a groundswell of public support for a national drug plan. However, this groundswell of pressure is unlikely to occur. The political dynamics of Canada’s existing system of insurance for prescription drugs are somewhat similar to that which exists in the US for all health care services. In both, the wealthier and much of the middle-class have insurance through employer-sponsored plans; government has programs providing some coverage for the very poor and the elderly; and there remains a small but significant proportion of the population without any insurance.

Momentum for change of the existing status quo is stymied by lack of political will, lack of a strong public mandate for change and the resistance of interest groups like private insurers and pharmaceutical companies. Indeed, the biggest impediment to adoption of a PBS model in Canada is likely to be the opposition of pharmaceutical companies and private insurance companies. Given the existence of private insurers in Canada’s health care system and that their primary role is insurance of pharmaceuticals it is not, very likely, that this insurance role will be outright nationalized. This is also the prospect of claims under

NAFTA by US based insurers for expropriation. As a consequence of this the prospects for importing Australia's PBS model are slim, despite its clear appeal in terms of equity and efficiency. The kind of reform that will be possible in Canada is one that makes some accommodation for existing interest groups like private insurers. For example, the province of Quebec has been able to establish a drug insurance program covering all citizens through regulation of existing private insurers (limiting risk-rating activities), employer-mandates and expansion of government programs. This kind of reform, in effect what is known as a managed competition model, harnesses the energy of private insurers in a compulsory insurance plan. The Quebec reforms have been heavily criticized for a number of reasons including the imposition of higher user charges on the poor in order to help fund extension of coverage to all;^{xciv} its reliance on private insurers as opposed to a model of public insurance;^{xcv} and because the costs of the plan have been increasing rapidly.^{xcvi} Clearly the Quebec plan has many difficulties that need to be addressed (although some of its detractors, for ideological reasons, will never be satisfied). Nonetheless politically and pragmatically it is this model that is the most likely path forward in Canada to a universal system. Although the Quebec model may not have the potential to be as efficient as the Australian PBS model it does at least begin to speak to the issue of equity by ensuring a basic level of coverage for all its citizens.

ⁱ. R.S.C. 1985, c. C-6, (“CHA”). The CHA ensures close to 100% public funding for "medically necessary" hospital services and "medically required" physician services but does not protect pharmaceuticals needed outside of a hospital.

ⁱⁱ. Applied Management, Fraser Group, Tristat Resources. *Canadians' Access to Insurance for Prescription Medicines*. Ottawa: Health Transitions Fund, Health Canada, 2000.

ⁱⁱⁱ. Jacobzone, S. *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*. Paris: OECD, 2000. Labour Market and Social Policy - OECD Occasional Papers #40.

^{iv}. Gray G. *Federalism and Health Policy: The Development of Health Systems in Canada and Australia*. Toronto: University of Toronto Press; 1991.

^v. Australian National Audit Office. *Pharmaceutical Benefits Scheme: Audit Report No. 12*. Canberra: Department of Health and Family Services; 1997.

^{vi}See Part VII of the *National Health Act 1953* together with the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.

^{vii} <http://www.health.gov.au/pbs/aboutus.htm>; date of access May 2002.

^{viii} <http://www.parl.gc.ca/37/1/parlbus/commbus/senate/Com-e/SOCI-E/rep-e/repjan01vol3-e.htm#1.1%20Government%20Responsibility> at para 1.1; J. Hall, “Incremental change in the Australian health care system” (1999) 18(3) *Health Affairs* 95 at 96 [hereinafter *J-Hall*]; A.S. Mitchell, “Current Experience in Australia” (1996) 30 *Drug Information Journal* 495 at 495 [hereinafter *Mitch*]; S.R. Hill, A.S. Mitchell & D.A. Henry, “Problems With the Interpretation of Pharmacoeconomic Analyses: A Review of Submissions to the Australian Pharmaceutical Benefits Scheme” (2000) 283 *JAMA* 2116 (I do not have a precise page number for this citation as I obtained this article on-line and there were no page numbers listed; date of access May 2002) [hereinafter *Review of*

Submissions]; <http://www.australianprescriber.com/magazines/vol18no2/benefits.htm> “The Australian Pharmaceutical Benefits Scheme” by David Graham, date of access May 2002 [hereinafter *Graham*]. Australia’s six state and two territorial governments retain constitutional jurisdiction over public hospitals and community health centres -- See, e.g., *Mitch*, *ibid.* at 495; *Review of Submissions*, *supra* note 2; <http://www.parl.gc.ca/37/1/parlbus/commbus/senate/Com-e/SOCI-E/rep-e/repjan01vol3-e.htm#1.1%20Government%20Responsibility> at para 1.1 (date of access: May 2002).

^{ix}See Table 1. Also see *J-Hall*, *ibid.*, “Exhibit 1” at 98 for a very helpful table of information – a similar chart may also be obtained online at <http://www.aihw.gov.au/publications/health/ah98/ah98-x01.pdf> at p. 41 of the pdf file. The PBS “has evolved from supplying drugs in the British Pharmacopoeia to pensioners and 139 life saving and disease preventing drugs for others, into a scheme which from 1 May 2002 covers 593 drug substances (generic drugs), available in 1,461 forms and strengths (items) and marketed as 2,506 different drug products (brands). Restrictions apply to 785 of the items, 286 of which require an authority prescription” – see <http://www.health.gov.au/pbs/aboutus.htm> (date of access: July 2002).

^x Financing and Analysis Branch, Commonwealth Department of Health and Aged Care, “The Australian Health Care System: An Outline” (2000) available online at <http://www.health.gov.au/haf/ozhealth/ozhealth.pdf> at p. 13 (date of access: July 2002).

^{xi} *Ibid.*

^{xii} See, e.g., <http://www1.health.gov.au/pbs/contents/explain4.htm#establish>; *J-Hall*, *supra* note 8 at 104; *Graham*, *supra* note 8 for a discussion of copayments.

^{xiii} <http://www.health.gov.au/pbs/budget/consumer/consumer.htm>.

^{xiv} <http://www.health.gov.au/pbs/budget/consumer/consumer.htm>; see also

<http://www.health.gov.au/pbs/budget/professional/professional.htm> for a table with similar information.

^{xv} Concessional patient qualifications are listed directly in the National Health Act, 1953, s.84 – Interpretation. The entire act is available at: <http://scaleplus.law.gov.au/html/pasteact/0/173/top.htm> or a direct link to s.84 is available at: <http://scaleplus.law.gov.au/html/pasteact/0/173/0/PA004650.htm> See also Commonwealth Department of Health and Ageing, “Schedule of Pharmaceutical Benefits” (2002) available online at <http://www1.health.gov.au/pbs/contents/explain4.htm#establish> (date of access: September 2002).

^{xvi} Walker, A., Percival, R., & Fischer, S., “A Microsimulation Model of Australia’s Pharmaceutical Benefits Scheme” (1998) at p. 3, available online at <http://www.natsem.canberra.edu.au/pubs/tps/tp15/tp15.pdf> (date of access: September 2002). [this figure is from 1995 and needs to be updated if possible]

^{xvii} Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation at p.19, para. 78 online at <http://www.health.gov.au/pbs/pubs/commons.pdf> (accessed June 2002) [hereinafter *Policy Review*].

^{xviii} <http://www.health.gov.au/pbs/budget/consumer/consumer.htm>; see also

<http://www.health.gov.au/pbs/budget/professional/professional.htm> for a table with similar information; also,

http://www.apf.gov.au/budget/2002-03/budget_overview/html/overview-009.html.

^{xix} See Australian Broadcasting Corporation, “Senate to Reject PBS Changes” (2002) available online at <http://www.abc.net.au/worldtoday/s585524.htm> (date of access: July 2002).

^{xx} See S. Jacobzone, *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*, Labour Market and Social Policy – Occasional Papers No. 40 OECD, Table 3, p. 65.

^{xxi} See S. Jacobzone, *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*, Labour Market and Social Policy – Occasional Papers No. 40 OECD, Table 3, p. 65.

^{xxii} Organization for Economic Cooperation and Development (OECD), July 2001. (www.oecd.org) (Date accessed: September 18, 2002). 2001 Australian Population is listed as: 19,357,594. Total Commonwealth government expenditure of \$4 049 554 733 divided by 2001 population figure provides a per capita expenditure of \$209.20. See also “Table 1: PBS Prescription Volume and Government Cost, year ending December 2001” at <http://www.health.gov.au/pbs/pubs/pbbexp/pbdec/bookp01.htm>.

^{xxiii} Drug Expenditure in Canada 1985-2001. Canadian Institute for Health Information, p.46. Published: 2002.

^{xxiv} Parliament of Australia, “2002-03 Budget Overview” (2002); full report available online at http://www.apf.gov.au/budget/2002-03/budget_overview/html/overview.html (date of access; July 2002); for this particular citation see http://www.apf.gov.au/budget/2002-03/budget_overview/html/overview-003.html.

^{xxv} See, e.g., *HI*, *supra* note 42; *J-Hall*, *supra* note 8 at 104.

^{xxvi} Commonwealth Submission to National Competition Policy Review of Pharmacy Regulation at p.19, para. 76 online at <http://www.health.gov.au/pbs/pubs/commons.pdf> (accessed June 2002) [hereinafter *Policy Review*].

^{xxvii} Rickard, M., “The Pharmaceutical Benefits Scheme: Options for Cost Control” (2002) available online at <http://www.apf.gov.au/senate> at i (date of access: July 2002).

^{xxviii} *Ibid.*

^{xxix} See, e.g., *Mitch*, *supra* note 8 at 497; *Graham*, *supra* note 8.

^{xxx} See, e.g., *J-Hall*, *supra* note 8 at 104.

^{xxxi} See, e.g., *Mitch*, *supra* note 8 at 495: “Since 1990, Australia has required that before granting a subsidy for a new drug, consideration must be given to its comparative cost-effectiveness or value for money. The basis for this requirement is a set of guidelines originally released in draft form in 1990, and revised in 1992. Until the end of 1994, Australia was the only country which had such a requirement.”; *J-Hall*, *supra* note 8 at 104: “Australia is the first country to include cost-effectiveness as a criterion in decisions on the reimbursement of pharmaceuticals. It is certainly not the first to attempt to incorporate economic evaluation in decision making about health care resource allocation. The approach is somewhat different that the use of economic studies by purchases of health care, because the PBS does not work within a fixed budget.”; M.F. Drummond, “Basing Prescription Drug Payment On Economic Analysis: The Case of Australia” (1992) 11 *Health Affairs* 191 at 191 [hereinafter *Case of Australia*]: “Cost-effectiveness guidelines may represent the ‘thin end of the wedge’ for pharmaceutical companies, who fear that other major buyers of drugs will take Australia’s lead”, and at p. 192: “Australia is ... the first country to propose mandatory guidelines for economic analysis prior to reimbursement of medicines.”; S. Hill, D. Henry, B. Pekarsky & A. Mitchell, “Economic evaluation of pharmaceuticals: what are reasonable standards for clinical evidence – the Australian experience” (1997) 44 *British Journal of Clinical Pharmacology* 421 at 421 [hereinafter *Economic Evaluation*]: “Australia was the first country to introduce an explicit requirement for economic data in relation to subsidization of pharmaceuticals, beyond the normal regulatory requirements of quality, efficacy and safety.”; D.A. Henry & S.R. Hill, “Assessing new health technologies: lessons to be learned from drugs” (1999) 171 *Medical Journal of Australia* 554 at 554 [hereinafter *Assessing*]: “The Australian Pharmaceutical Benefits Scheme (PBS) and processes used for evaluating drugs are internationally regarded as sophisticated because of the use of explicit cost-effectiveness methods”; see also D. Hailey, “Australian Economic Evaluation and Government Decisions on Pharmaceuticals, Compared to Assessment of Other Health Technologies” (1997) 45(4) *Social Science and Medicine* 563 at 577; A. Mitchell, “Update and Evaluation of Australian Guidelines” (1996) 34(12 Supplement) *Medical Care* DS216 at DS224; D.A. Freund, “Initial Development of the Australian Guidelines” (1996) 34(12 Supplement) *Medical Care* DS211 at DS212 [hereinafter *Freund*]; (though the latter three are not on point to the extent of the previously noted sources).

^{xxxii} See *Economic Evaluation*, *ibid* at 421; *Freund*, *ibid* at DS212; *Mitch*, *supra* note 8 at 496. The TGA is the branch of the Commonwealth Department of Health and Aged Care responsible for administering the *Therapeutic Goods Act 1989* which ensures the “quality, safety, efficacy, and timely availability” of therapeutic goods in Australia (see TGA, “Medicines Regulation and the TGA (December 1999)” available online at <http://www.health.gov.au/tga/docs/pdf/medregs.pdf> at 2 (date of access: July 2002). The TGA is comprised of more than 400 staff members, including “scientific staff in a wide range of disciplines including medicine, toxicology, pharmacy, pharmacology, microbiology, virology, biomedical engineering, veterinary, and biochemistry. Other staff include clerical staff, laboratory technicians, surveillance investigators, Good Manufacturing Practice (GMP) auditors, technical reviews and librarians ... many with post graduate qualifications” (this information is available online in the TGA recruitment document at <http://www.health.gov.au/tga/docs/pdf/recruit/infosheet.pdf> (date of access: July 2002).

^{xxxiii} See *Economic Evaluation*, *supra* note 24 at 421. For more information on ADEC, see TGA, “Australian Drug Evaluation Committee” (2001) available online at <http://www.health.gov.au/tga/docs/html/adec/adec.htm#mship> (date of access: July 2002): “The Australian Drug Evaluation Committee (ADEC) was formed in 1963 and given the role of providing independent, scientific advice on new drugs, within the policy framework of the time, to the Federal Government ... The committee has continued to meet regularly since it came into being and when the *Therapeutic Goods Act 1989*(the Act) came into force, the committee's establishment was carried forward under Regulation 36 (1) of regulations to the Act (the Therapeutic Goods Regulations).” ADEC’s membership includes medical practitioners and people with a background in pharmacology/pharmaceuticals.

^{xxxiv} *Ibid.* at 421.

^{xxxv} See, e.g., *Freund*, *supra* note 24 at DS212; *Mitch*, *supra* note 8 at 496; *Graham*, *supra* note 8 at Fig. 1.

^{xxxvi} *Mitch*, *supra* note 8 at 496.

^{xxxvii} *Graham*, *supra* note 8.

^{xxxviii} See, e.g., *Freund*, *supra* note 24 at DS212; *Mitch*, *supra* note 8 at 496.

^{xxxix} Access and Financing Division, Commonwealth Department of Health and Aged Care, “Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC: Part I – Roles and Responsibilities of the

PBAC” (1999) available online at <http://www.health.gov.au/pbs/pubs/pharmpac/part1.htm> (date of access: July 2002) [hereinafter *Roles and Responsibilities*].

^{xi} *Graham*, *supra* note 8

^{xli} *Graham*, *supra* note 8.

^{xlii} *Roles and Responsibilities*, *supra* note 32.

^{xliii} *Ibid.* See also Pharmaceutical Benefits Scheme, “Pharmaceutical Benefits Advisory Committee (PBAC)” (2001) available online at <http://www.health.gov.au/pbs/listing/committee.htm> (date of access: July 2002) which states that “The Pharmaceutical Benefits Advisory Committee (PBAC) established the DUSC in 1988 under section 101A of the National Health Act 1953 to: collect and analyse data on drug utilization in Australia for use by the PBAC; make inter country comparisons of drug utilization statistics; and to assist in generating information relating to rational use and prescribing of medicines”, and that “The Pharmaceutical Benefits Advisory Committee (PBAC) established the ESC in December 1993 under section 101A of the National Health Act 1953 to: review and interpret economic analyses of drugs submitted to the PBAC; advise the PBAC on these analyses; and to advise the PBAC on technical aspects of requiring and using economic evaluations.”

^{xliiv} See, e.g., *Economic Evaluation*, *supra* note 24 at 422; *Freund*, *supra* note 24 at DS212; *Mitch*, *supra* note 8 at 496-497; *J-Hall*, *supra* note 8 at 104.

^{xliiv} *Graham*, *supra* note 8.

^{xliiv} *Freund*, *supra* note 24 at DS212.

^{xliiv} *Ibid.* at DS213.

^{xliiv} *Ibid.* at DS214.

^{xliiv} *Ibid.* at DS212.

ⁱ *Mitch*, *supra* note 8 at 497.

^{li} See, e.g., *Economic Evaluation*, *supra* note 24 at 422; *Hailey*, *supra* note 24 at 565.

^{lii} See, e.g., *Assessing*, *supra* note 24 at 554; *Hailey*, *supra* note 24 at 565.

^{liii} *Case of Australia*, *supra* note 24 at 192. Note that this particular citation comes from a paper discussing a *draft* version of the then (1992) new Australian Guidelines.

^{liiv} See, e.g., *Hailey*, *supra* note 24 at 565; *J-Hall*, *supra* note 8 at 105. PBS policy is that equally efficacious medicines should be equally priced (for this point, see *Assessing*, *supra* note 24 at 555). The Commonwealth defines cost-effectiveness analysis as “[a]n economic evaluation that compares therapy involving the proposed drug with therapy involving its main comparator(s) having common clinical outcome(s) in which costs are measured in monetary terms and outcomes are measured in natural units”

[<http://www.health.gov.au/pbs/pubs/pharmpac/glossary/glossc.htm#cost-effective> (date of access: July 2002)].

^{liv} See, e.g., *Economic Evaluation*, *supra* note 24 at 422; *Graham*, *supra* note 8; *Mitch*, *supra* note 8 at 498.

^{lvi} See, e.g., *Mitch*, *supra* note 8 at 498.

^{lvii} *Ibid.*, at 496.

^{lviii} *GA-PBAC*, *supra* note 42 at para. 8????????????????

^{lix} *Mitch*, *supra* note 8 at 498.

^{lx} See, e.g., *Hailey*, *supra* note 24 at 566.

^{lxi} See, e.g., *HI*, *supra* note 42????? ; *Graham*, *supra* note 8.

^{lxii} See, e.g., *Assessing*, *supra* note 24 at 555.

^{lxiii} Applied Management, Fraser Group, Tristat Resources. *Canadians' Access to Insurance for Prescription Medicines*. Ottawa: Health Transitions Fund, Health Canada, 2000.

^{lxiv} Robyn Tamblyn’s work has amply demonstrated there are significant concerns about the impact of user charges in deterring patients from obtaining the drugs they need -- R. Tamblyn, et al., “Adverse Events Associated With Prescription Drug Cost-Sharing Among Poor and Elderly Persons,” (2001) 285 *Journal of the American Medical Association* 421 (accessed online June 2002).

^{lxv} C. Schoen, “Equity in Health Care Across Five Nations: Summary Findings from an International Health Policy Survey,” (2000) online at http://www.cmwf.org/programs/international/schoen_5nat_ib_388.asp at Exhibit 3.

^{lxvi} See, e.g., K. Harvey, “The Australian Pharmaceutical Benefits Scheme: Background Paper” (2001) at <http://mirror.squidly.org/Medreach/Background.htm> (accessed June 2002) [hereinafter *HI*]; B. Loff, & S. Corder, “Australian Government Loosens Its Grip on the Pharmaceutical Industry,” at <http://mirror.squidly.org/Medreach/Loff.htm> (accessed May 2002) [hereinafter *L&C*]; “Government Audit of PBAC,” at <http://www.anao.gov.au/> at para. 8 [hereinafter *GA-PBAC*]; *Freund*, *supra* note 24 at DS211; *Case of Australia*, *supra* note 24 at 191 .

^{lxvii} (footnote to table by Joanne)

- ^{lxviii} See, e.g., *HI*, *supra* note 42; K. Harvey, "The Australian Pharmaceutical Benefits Scheme (PBS) and the Pharmaceutical Benefits Advisory Committee (PBAC) controversy," (2001) at http://mirror.squidly.org/Medreach/PBS_Q&A.doc (accessed June 2002) [hereinafter *H3*]; *J-Hall*, *supra* note 8 at 104.
- ^{lxix} *HI*, *supra* note 42.
- ^{lxx} Industry Commission. *The Pharmaceutical Industry: Report No. 51*. Canberra: Australian Government Publishing Service; 1996.
- ^{lxxi} For a discussion of the PMPRB see D. Menon, "Pharmaceutical Cost Control in Canada: Does it Work?" (2001 May/June) 20: 3 *Health Affairs* 92. Refer also to the report produced at the PMPRB showing differences in increases in spending on patents and generics.
- ^{lxxii} Harvey K. Medicinal Drug Policy. In: Harvey K, Murray M, editors. *The Politics of Health*. Melbourne: Churchill Livingstone; 1995:238-283
- ^{lxxiii} Commonwealth of Australia. Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee including major submissions involving economic analysis. Canberra: Australian Government Publishing Service; 1995.
- ^{lxxiv} Cookson. ASTEC Non-EU Case Study on Australia. London: LSE Health, 2000; Birkett DJ, Mitchell AS, McManus P. A cost-effectiveness approach to drug subsidy and pricing in Australia. *Health Affairs* 2001;20(3):104-114
- ^{lxxv} Applied Management, Fraser Group, and Tristat Resources. *Canadians' Access to Insurance for Prescription Medicines*. Ottawa: Health Transitions Fund, Health Canada; 2000.
- ^{lxxvi} Ministry of Health and Long-Term Care. Ontario Guidelines for Economic Analysis of Pharmaceutical Products. Toronto: Queen's Printer for Ontario; 1994.
- ^{lxxvii} CCOHTA. Guidelines for Economic Evaluation of Pharmaceuticals: Canada. 2nd ed. Ottawa: CCOHTA; 1997.
- ^{lxxviii} CCOHTA. *Health Technology Assessment ... a basis for informed health care decisions*. Ottawa: CCOHTA Publications. Online: http://www.ccohta.ca/newweb/pubapp/pdf/ccohta_e.pdf
- ^{lxxix} Anis A, Guh D, Wang X. A dog's breakfast: prescription drug coverage varies widely across Canada. *Med Care* 2001;39(4):312-4.
- ^{lxxx} Rawson N. Approval of new drugs. *CMAJ* 2000;162(4):501-4.
- ^{lxxxi} Pharmaceutical Researchers and Manufacturers of America, *Why the Canadian System Isn't the Answer* (9 Nov. 1999) online: <www.phrma.org/facts/bkgrndr/canada.html>
- ^{lxxxii} (reference Epps & Flood, forthcoming McGill Law Jnl.)
- ^{lxxxiii} Footnote Mark Stabile; David Duff, tax consultant info on the provisions providing for tax breaks.
- ^{lxxxiv} Reference the Constitution Act.
- ^{lxxxv} Arguably a case could be made for federal jurisdiction over pharmaceuticals, using the peace, order and good government (POGG) power. This power gives the federal government the power to legislate with regard to matters of 'national concern.' In order to qualify for federal intervention under the national concern doctrine the issue "...must have a singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern and a scale of impact on provincial jurisdiction that is reconcilable with the fundamental distribution of legislative power under the Constitution." (*R. v. Crown Zellerbach Canada*, [1988] 1 S.C.R. 401 at 432; 49 DLR (4th) 161) To justify use of the POGG power the federal government would argue that its use is legitimate in order to achieve a national pharmaceutical plan with all its attendant benefits (ensuring national standards of access, the benefits of one single purchaser in dealing with large multinational drug companies, and the benefits of integrating safety evaluations and listing decisions) and it is not feasible to achieve this through 10 separate provincial initiatives. But the prospects for this argument succeeding are uncertain given cautionary statements by Justice La Forest of the Supreme Court in too readily relying on the POGG power (*R. v. Hydro Quebec* [1977] 3 S.C.R. 213 at 244-266.) Indeed the Federal government has treaded gingerly in this area, preferring to invoke its criminal law powers rather than attempting to rely on POGG when intervening in the health care sector (Jackman, M. 2000. Constitutional Jurisdiction Over Health in Canada. *Health L. J.*, 8: 95.)
- ^{lxxxvi} *Attorney General (Vict.) v. Commonwealth of Australia* (1945), 71 CLR 237.
- ^{lxxxvii} After the Referendum on 28 September 1946, the Constitution Alteration (Social Services) Act 1946 (enacted on 19 December 1946) altered the Constitutional powers of the Parliament by adding clause xxiiiA to section 51 [outlining federal powers]: (xxiiiA) **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.**

^{lxxxviii} *Winterhaven Stables v. Canada (A.G)* (1988) 53 D.L.R. (4th) 413 (Alta. C.A.) (leave to appeal to S.C.C. refused 55 D.L.R. (4th) viii).

^{lxxxix} Flood C., *The Structure and Dynamics of Canada's Health Care System*. In: Downie J, Caulfield T, editors. *Introduction to Health Law*: Butterworths; 2000.; Jackman M. *Constitutional Jurisdiction over Health in Canada*. *Health Law J*. 2000;8:95.; Choudhry S. *Bill 11, The Canada Health Act and the Social Union: the Need for Institutions*. *Osgoode Hall LJ* 2000;38:39-99.; Battle K, Torjman S. *Can We Have National Standards?* Ottawa: Caledon Institute for Public Policy, 1995.

^{xc}NEED TO CITE THIS – CIHR involvement...

^{xc}i. Canada. *Royal Commission on Health Services*. Ottawa: Queen's Printer, 1964.

^{xcii}. Decter, M. et. al. *IRPP Task Force on Health Policy: Recommendations to First Ministers*. Ottawa: Institute for Research on Public Policy; 1999; National Forum on Health *Canada Health Action: Building on the Legacy*. Sainte-Foy, Québec: Éditions MultiMondes; 1998; Blomqvist Å, Xu J. *Pharmacare in Canada: Issues and Options* (unpublished mimeo, copy on file with author) 2001.

^{xciii}Carolyn Hughes Tuohy, *Accidental Logics*...cite.

^{xciv}R. Tamblyn, et al., "Adverse Events Associated With Prescription Drug Cost-Sharing Among Poor and Elderly Persons," (2001) 285 *Journal of the American Medical Association* 421 (accessed online June 2002).

^{xcv} Marie-Claude Premont – Romanow paper

^{xcvi} Claude Forget