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# What Is Fair? Choice, Fairness, and Transparency in Access to Prescription Medicines in the United States and Australia

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## Introduction

The role of government in assuring population access to affordable and appropriate health care represents a central question for any nation. Of particular concern is access to prescription drug coverage, not only because of the vital role played by drugs in modern medicine, but also because of their high costs. This article examines the sharply contrasting prescription drug coverage and payment policies found in Australia and the U.S. – strong political allies and international trading partners – and describes how key U.S. interests have sought, through an aggressive trade agenda, to expand markets for U.S. goods and services, even when market expansions clash with other nations' contrasting emphasis on social equity and fairness. Indeed, the nation's bilateral free trade negotiations have brought the contours of this policy schism into sharp relief.

We begin with an overview of Australia's approach to prescription drug coverage. We then examine U.S. policy, and in particular, its policy approach under Medicare, the nation's only universal health care financing system. We also provide a summary table of key features, which can be found at the end of this article. In examining Medicare prescription drug coverage policy, we pay special attention to two aspects of policy design: (1) beneficiaries' right to choose among plans and (2) the right to challenge the benefit design (that is, the design of drug plan formularies). Both of these policy devices touch deep chords in U.S. society regarding notions of fundamental fairness; the question is whether, compared to the Australian system, these two legal dimensions of the U.S. system create fairness that is more illusory than real.

We conclude with a brief discussion of the ways in which the U.S. vision of the role of government in advancing markets, along with its desire to safeguard its own industries, has resonated in bilateral trade agreements, and briefly consider the resulting impacts on the Australian system.

## The Australian Approach to Prescription Drug Coverage: The Pharmaceutical Benefits Scheme (PBS)

Australians have benefited from comprehensive outpatient prescription drug coverage for over 50 years. In establishing the Pharmaceutical Benefits Scheme

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(PBS) following the end of World War II, Australia signaled affordable access to essential prescription medicines as a national health policy priority. The objective of the PBS is to “to provide timely access to the medicines that Australians need, at a cost individuals and the community can afford.”<sup>1</sup> As a key component of a broader, single payer, health insurance system, the program reimburses community pharmacists for the costs of dispensing outpatient prescription medicines that are prescribed in accordance with a comprehensive formulary, or “positive list.”

At its inception, the PBS offered free access to every drug in the British Pharmacopoeia for pensioners, and 139 “life-saving and disease-preventing” drugs for everyone else.<sup>2</sup> Since that time, the PBS has evolved into a formulary of more than 2,500 different items covering most medical conditions for which drug

For many years, the addition of new drugs to the PBS formulary was based primarily on a consideration of clinical need. In the late 1980s, however, the Australian Government took the unprecedented step of introducing an explicit consideration of “value for money” as a prerequisite for formulary listing. The economic evaluation requirement is not, as is often claimed, intended primarily as a mechanism of cost containment, but rather as a means of ensuring that the addition of each new drug to the formulary represents reasonable value for money for Australian taxpayers.<sup>5</sup>

Although Australia was the first country to introduce economic evaluation to support decision-making for its national formulary, pharmacoeconomic evaluation to inform drug reimbursement and coverage decisions is used in Canada (originally at provincial level

**One of the effects of the reference pricing system is that the prices of drugs may be linked irrespective of patent status. Although the pharmaceutical industry perceives this as undermining the value of the patent, from the payer’s perspective, however, it may be argued that it is neither rational nor efficient to pay more for a drug just because it is patented if it confers no additional health benefit, than a drug whose patent has expired and is cheaper.**

therapy is appropriate. The program covers all Australian residents who are citizens, as well as visitors and temporary residents from countries with which Australia has reciprocal health care agreements.<sup>3</sup> Funded through federal taxation revenue, the PBS is essentially a demand-driven program with an uncapped appropriation. Beneficiaries do not pay premiums, but contribute to the costs of their medicines through flat co-payments set at two levels determined by income. Importantly, the co-payment does not vary with the cost of a drug, and caps on annual out-of-pocket expenditures protect against catastrophic costs.

Consideration of whether, and under what conditions, a drug should be subsidized is the responsibility of the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is a statutory independent expert committee established under the National Health Act 1953 to make recommendations to the Minister for Health and Ageing on which medicines should be included on the PBS formulary, and any listing conditions that should apply. The legislation makes clear that the PBAC is the “gatekeeper” to the formulary; though the Minister is the final decision-maker, he may not add a drug to the formulary unless he has first received a positive recommendation from the PBAC.<sup>4</sup>

in British Columbia and Ontario and later centrally through the Common Drug Review), in the U.K. by the National Institute for Health and Clinical Excellence (NICE), and the Scottish Medicines Consortium, and to varying degrees in a number of European countries including France, the Netherlands, and Sweden.<sup>6</sup> This form of evaluation is sometimes referred to as a “fourth hurdle,” reflecting the additional obstacle to be overcome by a drug company (over and above the requirement to demonstrate safety, efficacy, and quality for marketing approval) before funding of a new product within a public program. Although it is applied to only a very limited extent within U.S. federal programs, it is reportedly used by a number of large private insurers and managed care organizations.<sup>7</sup> Recently, there has also been growing interest in the establishment of a mechanism for the centralized evaluation of comparative effectiveness in the U.S., as a way to support a more value-based health care system.<sup>8</sup>

Pharmaceutical companies seeking to add a drug to the PBS formulary must present a detailed submission according to a comprehensive set of guidelines, which describe how to identify, collate, and present the necessary clinical and economic evidence.<sup>9</sup> Under the legislation, the PBAC may only recommend the listing of a

medicine after an explicit consideration of evidence of its comparative clinical effectiveness and cost relative to alternatives (which may be drug or non-drug therapies).<sup>10</sup> Where a drug is substantially more costly than available alternatives, it may only be listed if it offers, for some patients at least, a clinical advantage.<sup>11</sup> Put simply, this means that unless a new drug offers an additional clinical benefit over an appropriate comparator, it may be added to the formulary, but cannot receive a higher price for subsidy purposes. A drug listed on this basis is subject to reference pricing – that is, it is linked by a “therapeutic relativity” to its comparator, either joining an existing reference pricing group or forming a new one. The price the government pays for any drug in a reference group is then set by the lowest price (known as the benchmark), which has been secured for any drug in the group. One of the effects of the reference pricing system is that the prices of drugs may be linked irrespective of patent status. Although the pharmaceutical industry perceives this as undermining the value of the patent, from the payer’s perspective, however, it may be argued that it is neither rational nor efficient to pay more for a drug just because it is patented if it confers no additional health benefit, than a drug whose patent has expired and is cheaper.

Where a sponsor presents evidence that a new drug offers a clinical advantage over its comparator, the additional benefits are weighed against the additional costs in a cost-effectiveness or (preferably) a cost-utility analysis, and a determination is made as to whether the drug is acceptably cost effective at the price proposed by the drug’s sponsor. In this respect, the PBS operates as a therapeutic-value based pricing system: it may be thought of as “purchasing outcomes” rather than drugs.

If a drug is not considered acceptably cost effective, then the sponsor may make a resubmission in which it could (1) present further evidence of incremental benefit over the comparator; (2) offer a reduction in the proposed price; or (3) try to identify an indication or patient population in which the drug is more cost effective. As a result, a drug may be listed on the PBS but with its subsidized use limited to certain indications, patient groups, or clinical settings in which it is determined to be both clinically and cost effective.<sup>12</sup> Cost effectiveness is context dependent, and a drug may be acceptably cost effective when used for one indication or patient group, but not cost effective when used in other circumstances.

While the deliberations of the PBAC are held *in camera*, detailed information on the committee’s recommendations and reasoning are made public after each meeting. Importantly, decision-making is at population level, and the PBS processes provide no

mechanism for considering individual circumstances or accommodating individual needs and preferences, or for allowing an individual to challenge a coverage decision that he believes may affect him adversely. If a patient does not meet the listed criteria for subsidy, then there is no mechanism to consider an exception. The only mechanism for reconsidering a coverage decision is at the level of the decision to add a drug to the formulary.

As the PBS accounts for around 80 percent of prescriptions dispensed in Australia, and more than 90 percent of those dispensed in the community,<sup>13</sup> the government wields significant monopsony power, and medicines which are not listed on the PBS generally have a limited market. To the pharmaceutical industry, the PBS processes are seen as a mechanism for price suppression.<sup>14</sup> This has been reinforced by studies that have highlighted, at times inappropriately, differences in pharmaceutical prices between Australia and other OECD countries, particularly the U.S.,<sup>15</sup> but without taking sufficient account of the benefits of an assured market with a high penetration of patented products.<sup>16</sup> Price comparisons are not straightforward and depend on a range of factors including treatment patterns and the basket of drugs compared. Comparisons with the U.S. are the most compelling but also the most likely to mislead. Prices paid for PBS-listed medicines are publicly available, but those paid by major third-party payers in the U.S. are not. In fact, some evidence suggests that for drugs that represent significant advances in therapy – true therapeutic innovations – the prices paid in Australia are as high as in the U.S., and sometimes even higher, for biologics, in particular.<sup>17</sup>

Australians have an expectation that prescription medicines will be both accessible and affordable. In terms of its reach and impact, the PBS has been successful in ensuring that all residents have access to a comprehensive range of prescription medicines drugs at prices that are affordable not only to individuals, but also to the government and the community as a whole.

### **The U.S. Approach to Prescription Drug Coverage: The Case of Medicare**

In contrast to Australia, the U.S. has no national mechanism for ensuring prescription drug coverage for the population. As with other essential health care services (other than, perhaps, hospital care to screen and stabilize emergency medical conditions), the U.S. approach to health care is market based, meaning that, by and large, health care is dealt with as a commodity. Of course, affordability is a recognized barrier, but no national financing mechanism exists to make health care affordable to the population. Instead, health insurance for the under-65 population is a voluntarily con-

ferred dimension of employee compensation.<sup>18</sup> The federal and state governments jointly operate Medicaid, an essential public financing scheme for certain indigent populations such as low-income children, pregnant women, impoverished elderly, and disabled persons.<sup>19</sup> Only in the case of elderly persons and certain persons with disabilities does the U.S., through Medicare, offer universal coverage and financing. Not until 2003, nearly 40 years after prescription drug coverage was first recommended, and 15 years after an initial Medicare prescription drug law was enacted and quickly repealed,<sup>20</sup> did Congress add outpatient prescription drug benefits through enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (known as Medicare Modernization [MMA]).<sup>21</sup>

The MMA added a new section, Part D, to Medicare, which had previously consisted of three parts: A (hospital insurance), B (supplemental medical insurance), and C (offering various forms of private health insurance coverage as a Medicare coverage option and renamed Medicare Advantage as part of the MMA). Although Part D is a complex law, it can basically be summarized as follows: the legislation entitles individuals who qualify for Medicare Parts A and B coverage to voluntary, subsidized enrollment in a participating, commercially sponsored prescription drug plan. Prescription drug plans are sold in decentralized, federally defined regional markets, and the public enrollment subsidy is adjusted by family income, with low income Medicare beneficiaries fully subsidized for covered benefits.

Under the standard benefit, Part D enrollees are entitled to covered plan benefits following satisfaction of an initial plan deductible. Initially, covered benefits are payable at a 75 percent rate up to an expenditure threshold; at this point, enrollees fall into what is known as a “doughnut hole” and must incur thousands of dollars in direct financial obligation for uncovered costs until they reach a second, catastrophic threshold. At this point, plan coverage resumes, with payment for 95 percent of the recognized costs of covered benefits. The value of both the subsidy and the doughnut hole are pegged to an annual inflation rate, which means that the costs beneficiaries must incur continue to rise with time, along with the program’s financial protections. Low-income Medicare beneficiaries receive additional help through a special “low income subsidy” program, but this assistance phases out at 150 percent of the U.S. federal poverty level and contains strict asset and complex enrollment requirements.

Prior to 2003, no Medicare prescription drug market existed. Thus, in order to create a market for outpatient prescription drug coverage, the law incentivizes companies in several ways: indirectly, by creating a

pool of “customers” who can afford their products, and directly through generous payments, “stop loss” protections against the risks of entering the market, and wide latitude within broad statutory rules to design their products. Thus, the U.S. has chosen to use its resources to stimulate a market both directly and indirectly.

The tortured structure of the legislation – and the high level of financial exposure enrollees continue to face – are the result of its design. Because the law relies exclusively on a heavily subsidized commercial market willed into being by the legislation, the nation must pay for private services including enrollment, coverage design, price negotiation and payment, program operations, and bill payment. Furthermore, because these tasks are the purview of market suppliers, data on their operations are considered proprietary and thus enjoy considerable public shield. Under these circumstances (as well as the right to exit the market whenever conditions go south), it comes as little surprise that a robust prescription drug market quickly emerged.<sup>22</sup>

Part D plans come in two basic forms. Some offer coverage only for prescription drugs and are known as prescription drug plans (PDPs). Others are Medicare Advantage plans that offer coverage for all Medicare benefits (i.e., A, B, and D coverage) for a comprehensive fixed monthly premium and are known as Medicare Advantage – Prescription Drug Plans (MA-PD plans).

The existence of multiple providers was intended to support a key objective of Part D: to deliver a high degree of choice for beneficiaries. In some respects, it may be argued that in providing choice, Part D has been unexpectedly successful: the number of “stand-alone” prescription drug plans (PDPs) and Medicare Advantage plans with prescription drug coverage (MA-PDs) exceeds predictions.<sup>23</sup> The federal investment is estimated at \$395 billion over ten years.<sup>24</sup>

Because Medicare Part D involves federal governmental financing for voluntary private health insurance, the cost of the coverage is high in relation to the benefits conferred. One prominent U.S. economist has estimated, for example, that citizens of France, the U.K., and Canada pay 34 to 59 percent of what it costs Americans for the same prescription drug market basket.<sup>25</sup> Had Part D legislation mirrored Medicare’s initial design structure – that is, had the law relied on direct government financing for covered services at publicly negotiated rates – the coverage lapse confronting beneficiaries with high health needs (i.e., the doughnut hole) might have been substantially eliminated. However, because eliminating the doughnut hole would have lowered the price of prescription drugs by an estimated 45 percent (along with creating direct government control),<sup>26</sup> the approach was politically unthinkable. (As it was, nearly super-

human political effort was required to pass any government-financed prescription drug coverage scheme under Medicare, reflecting overwhelming industry resistance to *any* role for government in prescription drug financing and the memory on the part of many lawmakers of the Medicare prescription drug debacle of 1988.)<sup>27</sup> Indeed, so closely did the 2003 battle resemble the politics surrounding the passage of the original 1965 Medicare statute, that, as with the 1965 law, the 2003 legislation famously contains a statutory non-interference clause prohibiting the Secretary of Health and Human Services from engaging in direct price negotiation.<sup>28</sup> (The 1965 non-interference clause prohibited interference in the practice of medicine; overt statutory prohibition against interfering in price negotiations was unnecessary since the original legislation was structured to effectively pay physicians what they charged.)<sup>29</sup>

Medicare PDPs and MA-PD plans compete over a range of plan characteristics; in theory at least, plans use this competition to drive drug price discounts. Enrollees may choose among plans offering different premiums, formularies, number of cost-sharing tiers, degrees of cost sharing, utilization management tools and extent, if any, of gap coverage. In 2007, the number of PDP choices ranges from 45 in Alaska to 66 in Pennsylvania and West Virginia; even greater numbers of MA-PD plans are available in each region, with nearly 4,000 across the country.<sup>30</sup> So complex is the choice that both the government and private organizations have created online tools that allow both enrollment (in the case of the government) and comparison shopping by price and coverage characteristics.<sup>31</sup>

Participating plans have a degree of autonomy in constructing their coverage design, which is presumed to operate on the basis of a formulary (as would any modern drug coverage scheme). The law specifies that if a participating provider uses a formulary, it must appoint a Pharmacy and Therapeutics committee to develop and review the formulary according to Model Guidelines developed by the U.S. Pharmacopoeia (USP).<sup>32</sup> Moreover, if the formulary conforms to the Model Guidelines, then the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, must approve it. The USP Model Guidelines require each formulary to include at least two drugs within each pharmacologic class (as defined by USP) of covered Part D drugs, except for the so-called protected classes, for which the plans must cover “all or substantially all” drugs.<sup>33</sup> In addition,

each pharmacologic class is made up of a number of formulary key drug types (FKDTs), and plans must cover at least one drug in each FKDT.

**In view of the highly risk-averse nature of the insurance industry, decision-makers concluded that only relatively robust federal regulation could avert the complete avoidance of certain beneficiaries and conditions through the use of exclusionary design principles. But as each layer of design regulation is added, the ability to negotiate deep discounts is weakened.**

Although “free market competition” and “choice” are words commonly used in describing Part D, the rules established by CMS on participating drug plans impose not inconsiderable constraints, with the result that the benefit more closely reflects a regulated industry than an unfettered, market-driven program. For example, the degree of granularity of both the pharmacologic classes and the FKDTs has increased with each of the three iterations of the Model Guidelines to date. For those subclasses containing only a single drug, plans that wish to comply with the Model Guidelines have no choice but to add the drug to the formulary – irrespective of the clinical place of the drug, the therapeutic benefit it confers, or the cost of its acquisition – and thus have little or no leverage in the price negotiation. Regulatory constraints tend to support the multiple-tiered benefit design that most providers have opted for. Some plans have as many as eight tiers, but most have three or four, with co-payments increasing with each subsequent tier, and higher tiers typically requiring enrollees to contribute a 25 or 33 percent co-insurance amount rather than a fixed co-payment. In addition, providers have considerable autonomy in the application of utilization management tools: prior authorization, quantity limits, and step therapy requirements.

In sum, the theoretical long-term financial advantages to be gained by stimulating robust market development and entry through very high payments at the outset have been blunted by the realities of this particular type of market, which focuses on vulnerable populations, and a pharmaceutical industry with surpassing political power. The extent of the federal coverage design standards ultimately included in the law are in part a testament to an industry whose overarching goal was to ensure the strongest possible strategic

position in relation to a heavily subsidized Medicare market. At the same time, the regulatory standards underscore the inherent asymmetry of information in U.S. health care purchasing, especially when the product to be purchased is as complex as prescription drug coverage, and the consumers are elderly and disabled. Even the most intrepid Medicare beneficiaries would have difficulty navigating the plan choice comparison gauntlet (either the paper or online version). Furthermore, more than a quarter of all beneficiaries are estimated to have a degree of cognitive impairment.<sup>34</sup> Thus, the goal of a truly competitive purchasing environment has had to give way to market realities and concerns. These concerns are, of course, not irrational. In view of the highly risk-averse nature of the insurance industry, decision-makers concluded that only relatively robust federal regulation could avert the complete avoidance of certain beneficiaries and conditions through the use of exclusionary design principles.<sup>35</sup> But as each layer of design regulation is added, the ability to negotiate deep discounts is weakened.

Of course, it would have been unimaginable for Congress and the President to say to Americans, "We are paying a king's ransom to get private companies to do what we could do for you for half the price and more coverage." Therefore, in the tradition of any political undertaking whose goal is to make a major change attractive to politicians and the general population alike, lawmakers stressed not only the additional benefits (and indeed, prescription drug coverage has grown significantly since the law was enacted, from a quarter of seniors aged 65 or older without any form of drug coverage in 2003 to over 90 percent of the 44 million Medicare beneficiaries covered in 2007),<sup>36</sup> but also the fact that the benefits would be consistent with American values: the right to choose and the right to all medically necessary care recommended by a physician.

Choice is a value that ostensibly permeates American society and culture, although the extent to which this emphasis on choice is a reflection of efforts on the part of the market to insist that people want choice above all, cannot be known. Studies of choice suggest, in fact, that having too many choices creates both confusion and inefficiency.<sup>37</sup> Therefore, whether people would have traded a degree of choice for the simplicity and stability of traditional Medicare – especially had they understood how the program would work and had been told that they could get a good deal of more coverage through an approach that mirrored traditional Medicare – cannot be known. Since government administered coverage and pricing could not possibly have been enacted given the politics of the White House and Congress in 2003, such a dialogue would have been moot.

Americans' belief in the right (at least among affluent and insured persons) to all medically necessary care is so pervasive that most policymakers appear to consider it a policy canon that the electorate simply will not tolerate a public, transparent discussion concerning the tradeoff between ensuring decent coverage for all persons, and allowing some individuals to have access to virtually everything that is available, even as others have virtually nothing. (A version of this was tried in the U.S. in Oregon in 1993, when then-Governor John Kitzhaber held a series of statewide discussions about rationing. In that case, however, the only individuals who were asked to give up coverage to aid the uninsured were the state's poorest Medicaid-enrolled women and children).<sup>38</sup> This inability to have a public discussion about national health policy choices in modern society was a strong undercurrent in the collapse of the Clinton health reform plan, and generally reflects a broader failure on the part of American society to be able to grapple with the notion of a collective, public decision to curb individual freedoms in the name of a social good. So ingrained is this individualism aspect of the American psyche that the policymaking process, ever eager to succeed politically, simply concludes that individual freedom is an essential dimension of any broad policy solution, regardless of need or topic.

The Medicare prescription drug legislation tips its hat to the American psyche not only through its provisions guaranteeing a choice of plans, but also through the coverage appeals process. In American law, it is a generally accepted aspect of fair process that insured individuals should have a means of challenging a denial of payment for a covered benefit on medical necessity grounds.<sup>39</sup> But what is *not* legally accepted is the notion that Americans should have the right to challenge the design of the coverage itself.<sup>40</sup> Indeed, where privately sponsored or purchased coverage and Medicaid are concerned, challenges to coverage design are dismissed as being without legal remedy, in deference to the discretion of payers in determining what will be covered.

Medicare is profoundly different. Since 1999, the law has allowed beneficiaries to challenge coverage determinations under the traditional program. Medicare coverage determinations, like Australia's PBS listing recommendations, consist of a structured technical and deliberative assessment of the evidentiary appropriateness of altering Medicare coverage design by recognizing a new technology or procedure. Part D follows suit, permitting enrollees to challenge not only the denial of a covered benefit, but also the design of coverage itself. This right to challenge population-wide design limits included in any particular Part D plan is accomplished through a special appeals proce-

dures known as the “exceptions” process. The process covers not only tiering design, but also the presence, in either a general or a particular form, of a specific drug on the formulary.<sup>41</sup> As one might imagine, support for an exceptions process is politically strong; but even if public-coverage determinations were open to individual challenges, how would it be possible *not* to allow coverage-design challenges when the decision-maker is a private company?

In truth, however, the Part D exceptions process is structured so as to create a nearly conclusive presumption against design modification. The regulations that establish the exception process grant nearly total discretion to plans by providing that a plan “must” grant an exception “whenever it determines that the drug is medically necessary consistent with the physician’s [submission of proof].”<sup>42</sup> However, within Medicare’s broad medical necessity standard,<sup>43</sup> the plan’s precise medical necessity protocol, and the evidence that it may consider, are left entirely to the plan – hence, the legal legerdemain (the plan “must” grant the exception whenever the plan concludes, totally without regulatory encumbrance, that the exception is necessary).

As if a nearly unfettered grant of discretion were not sufficient, the regulations also impose a heavy evidentiary burden on requesting physicians and patients. Under the exceptions rules, plans are empowered to require physicians to provide supporting documentation demonstrating: the ineffectiveness of the drug on the formulary tier; or the *likelihood* of ineffectiveness “based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee and known characteristics of the drug regimen; or an actual or likely adverse reaction “based on sound clinical evidence and medical and scientific evidence;” or the drug’s ineffectiveness or potential for adverse impact based on “sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the enrollee.”<sup>44</sup> In other words, clinical *judgment* alone does not suffice; in the absence of scientific evidence the rule is constructed so as to allow the plan to deny the request, even when there is no scientific evidence to be had.

This legal allocation of the burden of proof in relation to the design of a formulary runs contrary to the expectation that the burden should fall on the entity with preferred knowledge position (in this case, the plan itself, which presumably would know why a drug was either wholly excluded or limited to restrictive terms of coverage). Furthermore, many physicians would find meeting this burden of proof challenging in all but a few clinical circumstances. Other than excluding the use of a particular drug because of

documented prior subjective treatment failure, previous or predictable adverse reactions on the part of the patient, or known drug-drug interaction, physicians would find that the necessary evidence regarding the effects of alternative drugs may be scarce, particularly so in the case of newer drugs. And if it is difficult for physicians to meet the evidentiary standard, then clearly it is impossible for enrollees.

Federal public reporting requirements are so limited that the number of requested and granted exceptions is not known. One legal commentator who has written extensively on Medicare appeals procedures has reported that enrollees and those acting on their behalf have encountered significant problems both in requesting exceptions and in pursuing other coverage determinations and prosecuting appeals.<sup>45</sup>

In sum, while the architects of Part D have highlighted the unalloyed benefits of freedom of choice for Part D enrollees and have developed a paper system for challenging design limits, the reality is quite different. Many important characteristics of the program are involuntary, inequitable, and highly opaque. Enrollees are required to choose their plan on the basis of premiums, drug price, and prescription regimens at the time that the law’s annual enrolment window is open. Not only does this have the effect of institutionalizing risk selection, but an objectively sensible and rational choice of plan can prove to be a costly mistake as prices rise throughout the year, new drugs are prescribed, or formularies are varied. Other than complying with the CMS regulations, plans are not required to disclose why certain drugs are, or are not, covered, nor in the majority of cases are the processes of formulary decision-making or benefit design transparent.

This gap between the illusion of fairness and the reality for Medicare beneficiaries carries over into the appeals process. Enrollees are given the legal right to challenge plan design, a right that possibly might counterbalance some of the (potential) problems that can arise if the patient has a rare condition or encounters a changing health need during an enrollment period. Yet, as we have shown, the burden of proof is extremely high in an exceptions challenge, and the plan has virtually complete discretion to control the terms of the challenge, the methods used to evaluate the evidence, and the detailed standard of necessity itself. Even if the enrollee somehow enters the exceptions process, the time period for resolving the appeal can take years.<sup>46</sup>

Thus, in one sense at least, a tradeoff exists between transparency and opacity, certainty and flexibility. Part D enrollees may find that CMS rules are inconsistently applied and that formularies change over time, and that the reasons why particular drugs are, or are not covered, are obscure. They have the right to

appeal, given sufficient effort and determination to do so, but with an outcome that is by no means certain. The complexity and multiple levels of appeal in Part D thus serve to encourage the belief that no decision is final – that there is always a further avenue of appeal – but the tradeoff is a lot of secrecy that precedes it.

### **The U.S. Trade Agenda and the Australia U.S. Free Trade Agreement**

To the U.S. pharmaceutical industry and its peak body, the Pharmaceutical Research and Manufacturers of America (PhRMA), “fourth hurdle” systems like the Australian Pharmaceutical Benefits Scheme represent non-tariff barriers to overseas markets.<sup>47</sup> This view is complemented by rhetoric intended to deflect criticism over the high prices of medicines in the U.S. – namely, that countries like Australia that impose “price controls” are “free-riding” on the R&D investment of U.S.-based companies, gaining access to innovative medicines without contributing substantively to the costs of their discovery and development.<sup>48</sup>

In November 2001, WTO Members adopted the Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement and Public Health, which said that the TRIPs Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all.”<sup>49</sup> But within a few months, the U.S. government had embarked on a bilateral and regional trade negotiation agenda incorporating TRIPs-plus intellectual property standards that would appear to be at odds with the intent of the declaration. The pursuit of higher standards of IP protection for pharmaceuticals, to prolong monopoly prices and delay the market entry of generic medicines, suggests a willingness to further the interests of an industry sector even where the consequences might undermine the public health objectives of trading partners and their efforts to facilitate access to essential medicines.<sup>50</sup>

But this is not the only dimension of U.S. efforts to export its particular value system through the trade agenda. In 2002, Congress’ Trade Promotion Authority mandate directed the United States Trade Representative (USTR) to seek “the elimination of government measures such as price controls and reference pricing which deny full market access for United States products” in markets abroad.<sup>51</sup> The Australia U.S. Free Trade Agreement (AUSFTA), which entered into force in January 2005, was the United States’ first attempt to test whether a trade agreement could be used to bind another government with respect to policies for subsidizing prescription medicines for its citizens. A further attempt

was made in the recent Korea U.S. Free Trade Agreement (KORUS) negotiation.

Both the Australian (AUSFTA) and Korean (KORUS) Agreements contain provisions by which the U.S. has tried – arguably without success in Australia’s case – to limit the autonomy of its trading partners in evaluating, selecting, valuing, and reimbursing medicines on their national formularies, to allow the market a greater role in determining the demand for, and prices of reimbursed medicines. In Korea’s case, this followed a controversial 1999 medicine pricing agreement in which the country agreed to set the prices of new medicines at the average G7 price – all countries with much higher per capita GDP.<sup>52</sup>

While it is clearly too soon to determine the effect of the KORUS provisions on the Korean system, the issue of whether, and to what extent, the U.S. succeeded in its objectives is still being debated in Australia, more than two years after entry into force of the AUSFTA. The release of the AUSFTA text was met with claims that the obligations of the Pharmaceuticals Annex of the Agreement would undermine the fundamental listing and pricing processes of the PBS, and drive increases in the prices paid for PBS medicines. However, the specific (and it should be noted, reciprocal) obligations of the text, in fact refer only to timeliness, transparency, and consultation in formulary listing processes, and make no reference to pricing.<sup>53</sup>

Two issues continue to draw scrutiny. Agreement to the establishment of an independent review mechanism for the PBS listing process, to be made available to sponsors of unsuccessful PBS listing applications, led to claims that this would threaten PBAC’s gatekeeper role and lead to the listing of less cost-effective medicines at higher prices than would have previously been the case.<sup>54</sup> However, the independent review is not an appeal mechanism with the capacity to remake the Committee’s decision to recommend or reject a listing application; the outcome of any review, which is limited to a re-evaluation of issues in dispute and not of the recommendation itself, is a report back to the PBAC. The PBAC is then required to consider the reviewer’s findings, and determine whether they warrant a reconsideration of its conclusions in respect to the issues in dispute, and if so, whether any change in its views concerning those issues would cause it to reconsider its original recommendation.<sup>55</sup> The review therefore functions as quality assurance process, rather than a mechanism of appeal.

The other key area of concern stems from certain “Agreed Principles” contained in the opening paragraph of the Pharmaceuticals Annex. These state that the Parties are committed *inter alia* to “the need to promote timely and affordable access to innovative phar-

maceuticals... (and) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.<sup>56</sup> Despite the fact that the Agreed Principles are not couched in treaty-level language and confer no specific obligations on the parties, various commentators have argued that these, together with an obligation to participate in an AUSFTA Medicines Working Group with the U.S. – an annual bilateral discussion forum of health and trade officials – would be a mechanism by which the U.S. would continue to pressure Australia on its PBS listing and pricing policies and drive increases in the prices of PBS medicines.<sup>57</sup> In fact, the prices of PBS medicines have not risen since the inception of the AUSFTA and under administrative arrangements introduced in August 2005 to reduce generics prices, the prices of many still-patented PBS medicines have been reduced through the flow-on effects of reference pricing.<sup>58</sup>

Nevertheless, renewed concern has been expressed since the recent announcement of modifications to the PBS known as “PBS Reform.”<sup>59</sup> On August 1, 2007, the PBS was separated into two formularies – in simple terms, separating single and multi-source medicines – and various levers applied to reduce the prices of multi-source medicines. Reference-pricing mechanisms will continue to apply to some extent within each formulary but not between them, and the flow-on of any price reductions – which would previously have been applied to any drug considered “equivalent at the population level” – will be largely limited to drugs considered either bioequivalent or “interchangeable at the patient level.”<sup>60</sup> Predictably perhaps, it has been claimed that the changes are evidence that the Australian Government has bowed to pressure from the U.S. in the AUSFTA Medicines Working Group to dismantle reference pricing.<sup>61</sup> This would imply that the U.S. could succeed – in a forum without any reporting or decision-making role – in convincing the Australian Government to agree to changes to PBS listing and pricing policies that it had failed to gain agreement to within the treaty negotiations. In reality, the changes are clearly a domestic response to longstanding concern over the need to find ways to reduce generics prices (as evidenced by the administrative changes introduced in 2005), and to take advantage of a large number of major patent expiries to generate savings to the PBS that may be used to offset some of the costs of new listings.<sup>62</sup> Importantly, while the changes limit the scope of reference pricing once drugs are subject to generic competition, they do not alter the application of therapeutic value-based pricing at the point at which

a drug is added to the PBS. A new, patented medicine may still be listed at the price of an appropriate off-patent comparator at the time of listing, if it fails to demonstrate superior efficacy or safety over the older drug.

## Conclusion

The U.S. has permitted those political interests steeped in a market ethos not only to control the domestic approach to health care financing (with results now approaching 17 percent of GDP) but also to dominate the nation’s position with trading partners. The result has been attempts to undermine other nations’ efforts to manage the impact of market failure and pursue population equity. Ironically, this driving emphasis on “open” markets comes at a time when the administration is promoting the concept of value-driven health care at home, through a heightened interest in comparative effectiveness.<sup>63</sup> Yet in its bilateral trade agenda, the U.S. is trying not merely to undermine the pursuit of value-driven health care by its trading partners; in essence, it is attempting to remake other nations’ health systems in its own image.

These actions also suggest that in a global economy, the political interests that resist government pricing structures in the U.S. view as equally essential the elimination of such constraints abroad. Together with the “free rider” myth – the notion that U.S. prices are high because other nations benefit from the innovations of an industry without contributing to the costs of its R&D – these interests stress choice and freedom from design limits as fundamental values that must be advanced both here and throughout the world, even when the price of advancement may be financial jeopardy to the social fairness that other nations value.

Of course, what Americans would think if they knew how political and economic interests of a powerful industry articulated their “values” cannot really be known, especially since framing the question itself introduces the questioner’s underlying values.<sup>64</sup> One way to pose the question might be: should the people of all nations be able to benefit from the innovation of the American pharmaceutical industry, and should the very cost of innovation itself be protected as a matter of international policy that aims to eliminate “free riders”? However, another approach might be: how much value is gained by Americans and the world when U.S. lawmakers pursue the costliest policies under a guise of rights and fairness for U.S. citizens while characterizing other nations as “free riders” that attempt to maximize health outcomes and ensure fairness and equity for their own? In a world in which transparency of information about public policy has become the exception rather than the norm, we doubt that the American public will ever be given the opportunity to hear all sides.

Table 1  
**Comparison of Key Elements of the Australian Pharmaceutical Benefits Scheme (PBS) and Medicare Part D**

|                        | <b>Pharmaceutical Benefits Scheme</b>   | <b>U.S. Medicare Part D Drug Benefit</b>   |
|------------------------|---|--|
| Coverage               | All Australian citizens who are residents, and visitors from countries with which Australia has a Reciprocal Health Care Agreement – currently Italy, New Zealand, Ireland, Finland, Malta, the Netherlands, Sweden, Norway, and the U.K. | Medicare eligible citizens aged 65 and over, disabled, ESRD patients.  |
| Rationale and emphasis | Equity, timely access, affordability (both to individuals and the community), universality.   | Choice, market-based competition, individual rights.   |
| Financing              | Single-payer funding through federal income tax revenue and Medicare levy.  | Federal income tax revenue (74.5% of premiums); individual premiums (25.5%).   |
| Structure of program   | Centralized, uniform national reimbursement program providing reimbursement to community pharmacies for costs of dispensing medicines prescribed according to a national formulary, less applicable co-payment paid by the patient.       | Distributed, regional insurance program; voluntary enrollment; multiple private providers; competition-based model. Coverage determined by providers (within CMS regulations). |
| Structure of benefit   | Stable coverage throughout year; fixed co-payments according to patient income, no variation with cost of drug. Absolute limit on annual out-of-pocket expenditure.   | Variable coverage through calendar year. Co-payments and co-insurance variable with drug and year-to-date expenditure. No cap on annual out-of-pocket expenditure.             |
| Negotiating power      | Drug cannot be listed on the formulary without positive recommendation expert advisory committee. Strong negotiating power derives from size of PBS market.   | Limited. Plan may negotiate individually or through a PBM, but must cover at least two drugs in each USP drug class, all drugs in protected classes and one drug in each FKDT. |
| Excluded drugs         | Available on private prescription at cost to patient (cost may be partly offset by optional private health insurance). No individual coverage determinations.   | Available on private prescription at cost to patient. Patient may seek individual coverage determination for non-covered drug.   |

|                                      |   |  |
|--------------------------------------|---|--|
| Formulary structure and cost sharing | Single national positive list. Fixed co-payments according to income, no variation with cost of drug. \$4.06/USD 25.44 per item. Annual out-of-pocket expenditure cap: USD 227.35/USD 1104.78.*   | Determined by individual providers. Most plans have multiple tiers with different co-payment and co-insurance levels. Standard benefit in 2007: average monthly premium \$27.35, deductible \$265, co-insurance 25% up to \$2400 pa; 100% up to out-of-pocket expenditure of \$3850 (excl premiums), thereafter 5% co-insurance. No annual out-of-pocket expenditure cap. Enrollees qualifying for the Part D low-income subsidy pay reduced premium and cost-sharing amounts. |
| Formulary decision-making            | Expert committee recommends listing and conditions of access based on assessment of evidence of comparative effectiveness and cost against therapy most likely to be replaced in practice. Decision-making at population level; no mechanism for individual coverage determinations.  | Individual plan providers establish own P&TC to determine formularies and access arrangements; formularies are set at plan level. Formularies adherent to USP Model Guidelines must be approved by CMS.  |
| Transparency of process              | Procedural rules, guidelines, detailed information about coverage/non-coverage decisions in public domain. Publicly available formulary includes prices, conditions of listing.   | Most providers consider the process to be commercially confidential; beyond CMS regulations no rationale for coverage or utilization management is required. Formularies are subject to change.  |
| Pricing                              | No price control, but cost-effectiveness evaluation indirectly impacts pricing – a more costly drug cannot be listed unless it offers a meaningful increment in clinical benefit. Therapeutic reference pricing used extensively.   | Price negotiated by individual providers or their PBMs. Tier placement and UM tools are used to influence negotiation, but capacity to negotiate limited by CMS regulations and USP Model Guidelines. Prices significantly higher than Medicaid and VA.  |
| Reviews and appeals                  | No appeal on formulary listing decisions; judicial appeal on process of decision-making under Administrative Decisions (Judicial Review) Act 1997. Sponsors of formulary listing applications may seek independent review of issues in dispute, but not of the overall listing recommendation. No individual coverage determination, no individual appeals. | Exception request may be made for off-formulary drugs or to reduce co-payment or co-insurance amount for on-formulary drugs. If denied, may proceed to a 5-level appeal process – re-determination by the drug plan; reconsideration by the independent review entity (IRE); hearing before an administrative law judge; Medicare Appeals Council review; and appeal to federal court.   |
| Government expenditure per capita    | In 2005-06: \$1023* concessional (low income beneficiaries); \$528* general beneficiaries.  | \$1,690** in fiscal year 2006.   |

\*Department of Health and Ageing, Canberra, based on exchange rate of USD \$1.00 = AUD 1.20694 on May 1, 2007.

\*\* Average benefit per enrollee as reported in 2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Available at the U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services Web site <<http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2007.pdf>>.

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