The economic crisis, the Pharmaceutical Benefits Scheme, and the dilemmas of medicines policy

AS THIS SPECIAL ISSUE of *Australian Health Review* was finalised, the media reported daily on the global financial debacle and its deepening into a crisis in the real economy. The causes of the crisis are hazy — but its impact, across the globe, on people's lives is real and distressing. Many people are affected by worsening poverty and deteriorating access to health services and medicinal drugs. In the United States, unemployment often means the loss of health insurance, reinforcing risks of financial and social disaster for many families who would have previously considered themselves comfortable middle class. For those lucky enough to retain jobs, the cost of health insurance may rapidly become unaffordable; "Healthcare a Budget-Buster for Families; Even County's Middle Class Can't Afford It", ran a typical recent headline in a non-metropolitan newspaper.[1]

Even before the present crisis, tens of millions of Americans were excluded from health insurance. Those not excluded pay premiums to insurance companies that spend vast resources trying to insure the healthy, avoid the sick, and deny payment for claims wherever possible. Gaining power partly on a wave of resentment against the excesses of neo-liberalism, President Barak Obama has promised public health insurance for those not otherwise covered. Should this reform be successfully implemented, it will belatedly bring to US citizens a level of security approximating what Australians, and many Europeans, have had for decades.

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The Obama proposal is not for a truly universal, single-payer system, and there are signs that the administration's political resolve is weakening as the economic crisis worsens. But as argued by Nobel prize-winning economist Paul Krugman,

> helping families purchase health insurance as part of a universal coverage plan would be at least as effective a way of boosting the economy as the tax breaks that make up roughly a third of the stimulus plan [approved by Congress in February] — and it would have the added benefit of directly helping families get through the crisis, ending one of the major sources of Americans' current anxiety.[2]

Amartya Sen, another Nobel prize-winning economist, makes the same point, noting that the present downturn is fiercer, affecting more people more dramatically, where health care "is not guaranteed for all".

> The US has a 7.6 percent rate of unemployment now, which is beginning to cause huge deprivation. It is worth asking how the European countries, including France, Italy, and Spain, that lived with much higher levels of unemployment for decades, managed to avoid a total collapse of their quality of life. The answer is partly the way the European welfare state operates, with much stronger unemployment insurance than in America and, even more importantly, with basic medical services provided to all by the state.[3]

It is a truism that the US health system needs fundamental reform to address long-neglected irrationality and wastefulness. More is spent on health — if not on health services directly, then on administration and other transaction costs — in the US than in any other country: well beyond 15% of gross domestic product, compared with about 9% in Australia. According to Organisation

for Economic Co-operation and Development (OECD) data, total per capita expenditure on health and pharmaceuticals in the US in 2006 was more than twice that in Australia.[4] Yet key outcomes (such as infant mortality rates) are notoriously worse in the US than in many OECD countries, and even some developing countries.

This is the system within which the pharmaceutical industry, including companies with a European origin (many of which have relocated research and development [R&D] functions to the US) is deeply embedded. There are obvious incompatibilities between the values underpinning this system, and the public policy philosophy which sustains the Pharmaceutical Benefits Scheme (PBS) and similar programs in many other countries. In the US, there has long been "overwhelming [pharmaceutical] industry resistance to any role of government in prescription drug financing"; when in 2003 Congress legislated for outpatient prescription drug benefits under Medicare for elderly persons and some categories of people with disabilities, a statutory non-interference clause was included to prohibit the Secretary of Health and Human Services from engaging in direct price negotiation with suppliers.[5] (p. 647)

In recognition of escalating pressures for health reform, the industry and its lobbying organisation Pharmaceutical Research and Manufacturers of America (PhRMA) has recently modified its public position, expressing conditional support for the health policy objectives of the new administration and the Democratic Congress. According to Billy Tauzin, the head of PhRMA, "PhRMA had been isolated into a one-party camp ... We're trying to reposition as less of a partisan player."[6]

Public policy in the US was always free-market oriented, notwithstanding the Keynesian economic stabilisation function of its vast military expenditures in the past half century. Government in other countries, including Australia's, moved in the same direction from the 1980s, as the finance sector expanded, and ideas of deregulation, privatisation, and the "freeing-up" of markets came to be accepted as common sense. These are the ideas and policies which now stand accused as contributing to the current dire social and economic crisis. In the words of the Australian Prime Minister, Kevin Rudd, "extreme capitalism" — the notion that role of markets should be maximised, and the public sector minimised — must be abandoned both as a way of organising the economy and as a way of thinking about society.

Neo-liberal ideology has, however, never been implemented fully and consistently. In many sectors, health in particular, governments continue to play a major and sometimes expanding role. In Australia, Medicare (established in 1984) and the PBS (since the early 1950s) have weathered many political storms and pressures. Indeed, medicines policy in Australia was never strongly infused by free-market ideology. This was partly as a consequence of the economically marginal role of foreign multinational drug companies, which established only minor R&D and manufacturing activities in Australia. The Department of Health was able to bargain from a position of strength with peak associations representing the pharmaceutical industry, retail pharmacy, and the medical profession. More recently, other interests, including consumer organisations, patient support groups, public health academics and advocates, and groups representing the R&D community, gained admittance to the policy network, albeit at the margin.[7]

In medicines, policy tensions are inevitably played out, subtly or not so subtly, between different perspectives and interests. The research literature on Australian medicines policy is extensive, and there have been innumerable public inquiries and reviews; most recently the pharmaceutical sector figured centrally in the Review of the National Innovation System.[8] Assessments of policy trends differ in emphasis. Some analysts have discerned an expanding influence of neoliberal ideas, and a growing propensity on the part of policy makers and regulators to accommodate commercial interests, with detrimental effects on regulatory practices.[9,10]

In contrast, the Productivity Commission and the pharmaceutical industry argue that some regulatory requirements, particularly the PBS list-

ing system, are excessively costly and complex. Particular concerns are expressed about the time taken from Therapeutic Goods Administration (TGA) registration to eventual PBS listing, and about constraints on direct access to Pharmaceutical Benefits Advisory Committee (PBAC) officials.[11] To address such concerns, the Department of Health and Ageing in November 2006 announced the establishment of an Access to Medicines Working Group, jointly with Medicines Australia, to explore "the capacity to further streamline and coordinate regulatory approval, reimbursement and pricing processes to reduce the time it takes to list a medicine on the PBS".[12] (p. 79) It is well known that the industry considers "reward for innovation" (code for critique of PBS pricing arrangements) to be inadequate. In essence, firms steeped in the US healthy policy environment find the PBS less than hospitable, and have voiced this critique for decades.

If it is the case that what industry proponents, and US parent companies of many members of Medicines Australia (represented by PhRMA and the US Trade Representative), claim are low PBS prices have contributed to Australia's increasingly marginal position within global innovation and production networks, this can be only one of many factors, and probably a minor one at that.[13] In the tussling over policy, this aspect is, however, consistently emphasised, as in several submissions to the Innovation Review. Two of the largest companies make broader claims:

> Pfizer Australia does not see substantial opportunities to expand our own manufacturing in Australia — particularly in high value-add activities, such as the manufacture of active ingredients. Because of past decisions by Australian governments and disunity within the Federation, this country has lost a $15 billion manufacturing industry to Singapore. [14] (p. 3)

> While the pharmaceutical sector in Australia has been growing, its rate of growth has failed to keep pace with countries such as Korea, India, China and Singapore, who are key competitors. If Australia does nothing to stimulate the growth of this sector, the country will increasingly lose investment from global companies such as Merck Sharpe and Dohme.[11] (p. 1)

As noted, the PBS is criticised for not rewarding "innovation" adequately, compared with the US market where consumers for many patented drugs pay prices that vastly exceed their cost of production. But in contrast to the US system the PBS "operates as a therapeutic-value based pricing system: it may be thought of as 'purchasing outcomes' rather than drugs".[5] (p. 645) Innovation in the Australian context refers not to patents, which do not necessarily entail therapeutic advancements, but to added therapeutic value, and prices are intended to reflect this reality.

Notwithstanding these differences, Australia's National Medicines Policy, referred to frequently in the following articles, has provided a means of managing tensions between different perspectives within a partnership framework. The strength of partnerships was evident in Medicines Australia hosting the dinner which celebrated 60 years of the PBS at the Second Medicines Joint Policy Conference (Canberra 25–26 November 2008).

The global financial and economic crisis has demonstrated once again that effective government regulation is indispensable in modern societies. In the period of neo-liberal dominance, the market mechanism came to be accepted as efficient and desirable in most domains, including, to a degree, in health and social policy. To the extent that such thinking put medicines regulators under pressure to be overly responsive to commercial imperatives, the new context should make it possible for public health and social objectives to be pursued more confidently.

Australian Health Review in this issue provides a vista on Australian medicines policy, with a particular focus on the PBS. The TGA does not figure centrally in most of the following articles, which is consistent with its low public profile and the perception among many stakeholders that its performance is of a very high standard. The major recent example of the TGA appearing in the media spotlight was its 2003 intervention against the complementary medicines manufacturer Pan Pharmaceuticals, which in 2008 resulted in $50

million in payments for damages, and an extra $5 million for legal costs, being awarded against the agency. Regulation of complementary medicines remains a vexed issue and is explored in this issue by Harvey (*page 279*) and in a comment on his article by Bollen and Whicker (*page 288*).

It may be useful to remind readers that relations between the industry and the TGA were for decades characterised by a high degree of mutual suspicion. Concerted efforts from 1991, at the high-point of neo-liberal influence, resulted in the TGA being redefined as a "business unit" managing industry-responsive and market-oriented regulatory arrangements, including full cost recovery through fees paid by the industry, the agency's primary "clients". Whereas the PBAC, the gatekeeper to the PBS, retains arms-length relations with the industry, the TGA provides an Industry Consultative Committee as "a forum to exchange information on industry trends and regulatory expectations, to discuss the development of the TGA's corporate plan, annual business plans and budget".[12] (p. 70) Pfizer expresses the following appraisal:

> the TGA's assessment of the medicines quality, safety and efficacy is of the highest order. The advice that our Australian manufacturing staff receive from the TGA following audits is also excellent. The TGA's policy work has been very good.[12] (p. 69)

There are TGA critics pointing to, for example, the rofecoxib (Vioxx) debacle as suggestive of excessive secrecy and inappropriately close relations between the agency and its clients.[15] But these are weak voices in the context of medicines policy deliberations within committees and working groups where key stakeholders interact. That TGA issues, most of time, are being discussed within relatively closed networks of experts and insiders is also explained by the highly technical nature of its activities, which are typically difficult to understand for even well-informed members of the general public.

In contrast, it is not difficult to understand the policy dilemmas involved in providing "timely and affordable access", the role of the PBS. Most of the articles which follow revolve around PBS pricing and economic issues and the central role of cost-effectiveness analyses in the listing process. de Boer explores the complex reforms of 2007 — the bifurcation of the single PBS formulary into F1 and F2, and associated changes (*page 176*). Searles considers the significance in this context of the Australia–US Free Trade Agreement (*page 186*). It would seem, at the very least, that the AUSFTA has had the effect of increasing pressures for the industry's perspective to be given a significant hearing in the PBS listing process, as acknowledged obliquely by the Department of Health and Ageing:

> the sponsor of a major submission can also request a hearing at the PBAC meeting. The scope and duration of the hearing before the PBAC have been *extensively discussed … as part of the implementation of the Australia United States Free Trade Agreement*.[12] (p. 74, emphasis added)

PBS pricing issues are analysed further in articles by Robertson et al (*page 192*) and by Bulfone (*page 200*), who proposes an alternative model of generics pricing. It is likely that the information and arguments relating to the role of copayments in the PBS system presented by Sweeny (*page 215*) and by Doran and Robertson (*page 231*), with a comment by Lopert (*page 241*), will remain a standard resource on this topic for some years to come. Faunce introduces the challenges for regulators of a new category of nanomedicines (*page 258*), and Liaw and Peterson explore the vexed issue of doctor–pharmacist relations (*page 268*). The article on pharmaceutical innovation in South Korea, Singapore and Taiwan should remind readers interested in Australian medicines policy of the regional and global context of developments in this industry (Hsieh and Löfgren, *page 245*). The final texts in the block of articles on medicines policy commissioned for this issue of *Australian Health Review* introduce important books on pharmaceutical policy in Ireland and the global bio-economy.

When at some point the next collection of articles appears on Australian medicines policy

the emphasis will perhaps have shifted back to the safety regulation system and the role of the TGA. But, on the other hand, there is little doubt that the "therapeutic value" and welfare state design of the PBS will continue to generate intense discussions for years to come.

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