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Harmacy: The Political Economy of Community Pharmacy in Australia

David Gadiel

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The Centre for Independent Studies (CIS)
PO Box 92, St Leonards, NSW 1590
Level 4, 38 Oxley St, St Leonards, NSW 2065
Phone: +61 2 9438 4377



David Gadiel is an independent economist who has worked in many areas to do with the economics of health. He contributed to the Pharmacy Guild's cost-benefit study of S2 and S3 medicines (reference 57) but disagreed with some of its methods and conclusions.

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Executive summary

The regulatory environment that governs community pharmacy has created one of Australia's most protected industries. It is a beneficiary of government largesse and central regulation and control in state, territory, and commonwealth jurisdictions. Entry barriers, ownership restrictions, exclusive rights to sell certain types of medicine scheduled as 'poisons,' and an exclusive agency relationship in distributing pharmaceuticals listed on the Pharmaceutical Benefits Scheme, have led to community pharmacy acquiring considerable market power..

During the term of the National Competition Plan (1995–2005), Australia's pharmacy network attracted the scrutiny of three major reviews initiated by the Council of Australian Governments. These were the Wilkinson Review on ownership, location, and entry restrictions; the Galbally Report on poison scheduling; and a cost–benefit analysis, conducted by the Pharmacy Guild, on pharmacy's control of non-prescription 'poisons' sold as 'over-the-counter' medicines.

With skilful networking and political lobbying, however, community pharmacy has proved resilient to change. The welfare loss from restrictions on where consumers may shop, the inflated prices they consequently pay, and the inefficient use of labour and capital associated with local or quasi-monopoly profits are likely to be a considerable economic burden. By contrast, pharmacy deregulation has delivered considerable benefits to consumers in the United Kingdom and uncompetitive pharmacy arrangements in continental Europe are being reviewed.

Whilst there may be benefits in regulating pharmacy quality standards, there can be none for restricting entry and ownership. The cost of reform, however, would weigh on what is a small but well-organised industry, and gains would be diffuse. One option could be to facilitate adjustment with the aid of compensation arrangements. The commonwealth will have the opportunity of reassessing the value of privileges enjoyed by community pharmacy when in 2009 it commences negotiations on a new Community Pharmacy Agreement with the Pharmacy Guild of Australia.

Harmacy: The Political Economy of Community Pharmacy in Australia

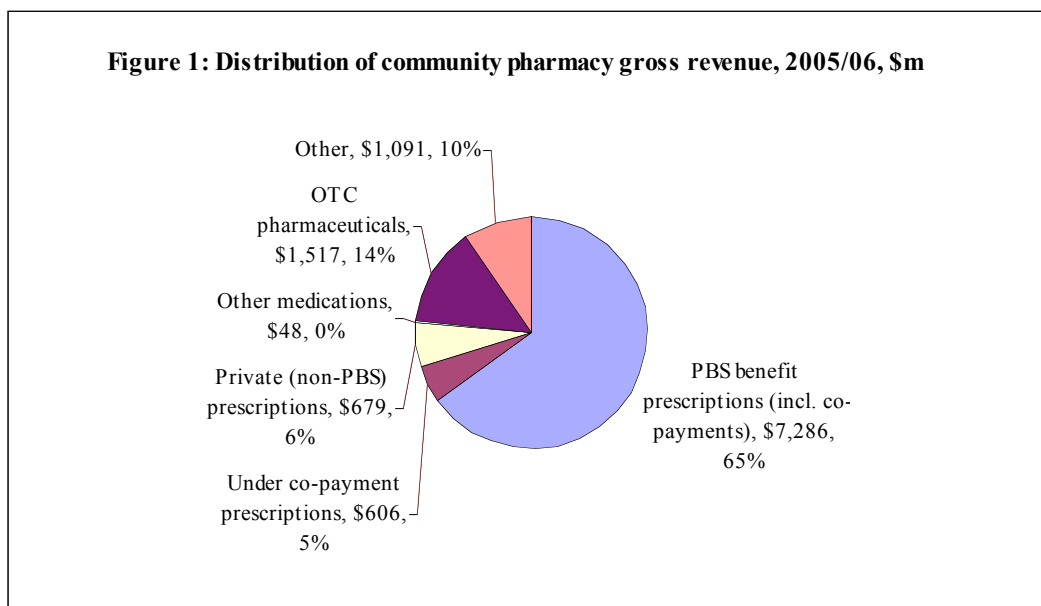
‘Monopoly ... is a great enemy to good management.’
—Adam Smith¹

Background: Pharmacies and pharmacists

Pharmacists and doctors can trace a common lineage, in part, to apothecaries who combined the roles of prescribing and dispensing drugs for their clients. In mid-nineteenth-century England, these roles became more defined and specific, when registered pharmacists began to concentrate on compounding and dispensing. In Australia, initially mostly for practical reasons, there has been a historical separation between responsibility for prescribing and dispensing. The *National Health Act* now restricts to pharmacists the dispensing of almost all prescriptions that attract a benefit under the Pharmaceutical Benefits Scheme (PBS). NSW also prohibits doctors from dispensing ‘for profit.’

This demarcation is characteristic of the rigidity that permeates most health labour markets in Australia.² The logic of limiting dispensing to pharmacists is that by avoiding possible conflicts of interest if doctors were directly exposed to the blandishments and favours of pharmaceutical companies, the risk of excessive prescribing is minimised.³ Evidence of this dichotomy does not appear to have a discernible impact, however, upon either of these phenomena in Australia, or upon morbidity and mortality specifically attributable to lack of prescription supervision by pharmacists in countries such as Singapore and Japan where demarcation is not the law.⁴

Figure 1: Distribution of community pharmacy gross revenue 2005–06, \$ million



Source: Australian Institute of Health and Welfare (AIHW).⁵

Note: PBS benefit prescriptions include *National Health Act* s85 benefits, RPBS benefits and s100 pharmaceuticals other than ‘Highly Specialised Drugs’ dispensed through hospitals. The figure for the ‘other’ category is the author’s estimate.

Community pharmacy is the business environment in which pharmacists undertake professional dispensing, but pharmacies essentially are retail establishments selling health, professional services, and non-health merchandise. Their locations include shopping strips, shopping malls, medical centres, and some private hospitals. Pharmacies differ from other retailers in that some 65% of their gross revenue derives from prescriptions pharmacists dispense under the PBS. The balance derives from non-PBS prescriptions, ‘over-the-counter’ (OTC) pharmaceuticals, professional services, and other goods (mostly ‘health and beauty’ merchandise). The total value of all types of medication sold in pharmacies during 2005–06 was some \$10.1 billion, representing 90% of their gross revenue (figure 1). Pharmacies pay GST on the cost of the goods they sell, but reclaim some 85% as an input credit—predominantly in respect of most pharmaceuticals.

To be viable, a community pharmacy must possess approval to dispense pharmaceuticals under Australia’s PBS. While it is technically possible to freely operate a non-PBS pharmacy, almost all community

pharmacies are approved to dispense PBS pharmaceuticals, which remain the backbone of their business.

Since 1990, dependence on government payments has been assured with a series of five-year Community Pharmacy Agreements between the commonwealth and the Pharmacy Guild of Australia (Government–Guild Agreements). These agreements embody high levels of commercial protection and public funding that have profoundly insulated community pharmacy from competition.

Community pharmacy's business environment

The community pharmacy industry is subject to multiple tiers of intervention, often involving complex overlapping of jurisdictional authority, consisting of barriers to entry, ownership criteria and restrictions, monopoly over selling certain classes of medication, and exclusive access to certain types of public funding. The nature of these restrictions, involving price and quantity, and the jurisdictions in which they derive, may be summarised as follows:

- specific restrictions on who may own a pharmacy (states and territories, commonwealth)
- specific restrictions preventing supermarket ownership or management (Government–Guild Agreements, states and territories)
- entry barriers to pharmacies with PBS dispensing approval (Australian Community Pharmacy Authority—Commonwealth)
- location restrictions (Government–Guild Agreements, Australian Community Pharmacy Authority—commonwealth)
- restrictions upon advertising pharmaceutical prices (prior to 2007—commonwealth)
- exclusive statutory rights to sell certain classes of OTC pharmaceuticals (poison scheduling—states and territories, commonwealth)
- sole rights to dispense and sell prescription pharmaceuticals (poison scheduling—states and territories, commonwealth)
- exclusive access to PBS payments as well as access to other government funding, including support for accreditation, quality of

care initiatives, training, professional services, electronic lodgement of claims, rural workforce support, and so on
(Government–Guild Agreements—commonwealth)

By any standards, the retail pharmaceutical distribution chain in Australia is thus a highly protected and regulated activity. It is nevertheless a regime the Pharmacy Guild of Australia (the Guild) claims to yield a variety of public benefits.⁶ Yet, as will be shown, there has been little serious economic evaluation of this regime's impact on economic welfare.

Market intervention is also *prima facie* evidence, given own-price elasticity for medicines sold in pharmacies is likely to be less than unity, that Australians may be paying more for many goods sold by pharmacies than if barriers to entry and ownership and other anticompetitive interferences were removed. If this were to happen, it would oblige pharmacies to compete more effectively with each other as well as with alternative points of sale, such as supermarkets and convenience stores.

Pharmacy ownership restrictions

All states and territories impose conditions on the ownership and control of pharmacies.⁷ This accords with the view of the Pharmacy Guild of Australia, which advocates professional ownership, claiming 'outside commercial interests would, ultimately, consume and compromise the pharmacist.' They also claim non-pharmacist ownership would interfere with customer access to dispassionate professional advice, and compromise pharmacy operators' duty of care to consumers.⁸

Ownership restrictions were precipitated originally when the UK pharmacy chain, Boots the Chemist, attempted to open a chain of retail pharmacies in NSW in 1939. Their entry was thwarted by NSW legislating to restrict pharmacy ownership to individuals. Since then, pharmacy ownership has become subject to progressively more stringent criteria.

The *NSW Pharmacy Practice Act*, for instance, now stipulates that only pharmacists may have pecuniary interests in pharmacy businesses. It also limits them to owning five pharmacies. Similar ownership limitations are inherent in the legislation of other states (but not territories). Companies may be permitted to have interests in pharmacies, but typically only where each of their members and directors are registered pharmacists.⁹

State legislation restricting the scale of pharmacy ownership perpetuates a small pharmacy business model in which pharmacist owners depend upon the Guild for support and backup. The larger the scale of a pharmacy or a pharmacy group, the more likely they are to acquire independence and self-reliance. State ownership arrangements hence support the Guild's *raison d'être*. As we show below, however, ownership restrictions have limited the access of pharmacies to external entrepreneurial capital, and inhibited their ability and incentive to innovate and make efficiency gains.

A possible unintended consequence of ownership restrictions is the emergence of pharmacy chains administered by manager-pharmacists under established brand names, owned by jigsaws of partnerships either within or across states and territories.¹⁰ These include central management companies to reduce individual pharmacy overheads. They are retailer-driven and differ from wholesaler 'banner groups' (see below). Ownership of each pharmacy or group of pharmacies rests with the original pharmacist shareholders, each of whom may own shares in the management company.¹¹ There is scope for external, non-pharmacist finance in this model—one has been publicly listed.¹² There is also scope for blurring the operational and management aspects of community pharmacy, which in turn could ultimately defeat the purpose of pharmacy ownership restrictions.

National competition policy and pharmacy

As will be shown, the commonwealth's policy towards pharmacy is caught between competing objectives. For instance, between 1995 and 2005, during the term of the National Competition Plan, the Council of Australian Governments (COAG) charged the National Competition Council (NCC), pursuant to its National Competition Policy, to assess the performance of Australian governments in meeting their commitments to lower business costs and remove restrictions to competition, except where there was a demonstrable public benefit.¹³ National Competition Plan incentive payments were available to complying states and territories.

COAG accordingly initiated its National Competition Review of Pharmacy (the Wilkinson Review) in 1999.¹⁴ This included consideration of the costs and benefits of pharmacist ownership, based on a joint submission of the Guild and the Pharmaceutical Society as well as its own commissioned research. The former claimed pharmacist ownership conferred annual net benefits of the order of \$550 million to \$1,270 million, from reduced hospital costs and superior care, based upon consumer 'willingness to pay' to have prescriptions dispensed in phar-

macist-owned pharmacies. The Wilkinson Review's own commissioned research considered these claims to be markedly exaggerated.

To the extent there are inherent net benefits from professional care delivered by pharmacists—and, as we discuss below, there is controversy on this—neither the Guild nor the Wilkinson Review explored whether standards of professionalism could better be secured by regulatory avenues other than general restrictions on ownership. The Wilkinson Review, however, did recommend lifting restrictions on the number of pharmacies a pharmacist could own and relaxing restrictions on friendly-society ownership of pharmacies (subsequently foiled by the Guild).¹⁵

In assessing Australia's overall progress towards realising National Competition Policy reforms, the NCC concluded that 'the retention of competition restrictions (in pharmacy) had no parallel in other professions and for which no public interest justification could be established.'¹⁶ The capacity of community pharmacy to resist competition reform without apparent public benefit has nevertheless proved remarkably durable.¹⁷

Continued retention of state and territory restrictions on pharmacy ownership, moreover, contradicts the joint commitment of the Third Government–Guild Agreement (2000–2005) to the 'continued development of an effective, efficient and well-distributed community pharmacy service in Australia which takes account of ... the objectives of National Competition Policy.'¹⁸

The Fourth Government–Guild Agreement (November 2005) reaffirms a pharmacist ownership philosophy by prohibiting a pharmacy being publicly accessible within or partly within a supermarket or adjacent or connected to a supermarket.¹⁹ In the face of a spirited campaign waged by the Guild, Woolworths had sought unsuccessfully to enter the community pharmacy business, commencing with an eighteen-month trial of five in-store pharmacies.²⁰

There have been attempts to implicate Woolworths, as a part of a grocery oligopoly, as ill-suited to operating pharmacies²¹. Nevertheless, following an inquiry on grocery prices in Australia, in July 2008 the ACCC found that the grocery market was 'workably competitive,' that firms do not collude, and that incumbent firms do not face substantial long-run cost advantages.²² On the other hand, consumers are able and willing to switch between alternative suppliers. One factor that was found could limit competition were barriers to entry and expansion because of difficulties in finding new sites for development—analogue in

their impact to pharmacy location restrictions in thwarting local competition (see below).

PBS cost

Pharmacy is insulated from enhanced competition and efficiency that comes with reform, and this creates a dilemma for the commonwealth. Community pharmacy is critical to the administration of Australia's PBS—responsibility for whose funding rests with government.

The cost of the PBS to government amounted to \$6.4 billion during 2006–07, representing nearly 12% of total recurrent government expenditure on health.²³ Because expenditure on the PBS until recently has been one of the fastest growing elements of the commonwealth's health expenditure, government should be concerned to secure value for money from the Scheme.

Although some 20% of the PBS cost to government relates to retail distribution, most initiatives taken by government to preserve the sustainability of the PBS have been directed less at community pharmacy than at other players. Prices received by pharmaceutical manufactures for products that attract a PBS benefit, administered by the Pharmaceutical Benefits Pricing Authority (PBPA), for instance, are constrained by the so-called 'minimum pricing policy' and its variants; and the Fourth Government–Guild Agreement seeks to curtail allowable pharmacy wholesaler markups on generic pharmaceuticals with effect from August 2008. The government is nevertheless compensating pharmacies for the flow-on effect of the latter.²⁴

The pharmacy 'restructuring' program

The entry of new businesses represents an avenue to real productivity growth in retailing.²⁵ However, since 1990 the commonwealth's quest to encourage efficiency as best it can, without causing disharmony with Guild, has focussed upon 'restructuring' community pharmacy by limiting new entrants. The Guild describes this initiative as 'widely acknowledged as one of the shining models of successful microeconomic reform of the past decade.'²⁶

To safeguard community pharmacy against fragmentation of its retail distribution base, the commonwealth's 'restructuring' program restricts the number of pharmacies approved to dispense PBS prescriptions—the presumption being that viability of dispensing could be subject to economies of scale. The First Government–Guild Agreement (1990–1995) included a 'buyout' package that encouraged pharmacies to close

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or amalgamate. During its term, there were 630 pharmacy closures and 64 amalgamations, costing \$42 million and \$4 million respectively.²⁷

Nearly 5,000 pharmacies remain approved to dispense PBS prescriptions by the Australian Community Pharmacy Authority under s90 of the *National Health Act*. New approvals are subject to narrow criteria, and for all practical purposes, entrants must purchase an existing approved pharmacy (or a PBS approval number). The commonwealth claimed that pharmacy restructuring would achieve ‘savings to the taxpayer and encourage a competitive, streamlined pharmaceutical [sic] industry’²⁸.

Between 1989–90 and 2006–07, PBS benefit prescriptions dispensed per pharmacy increased from some 19,000 to about 34,000. The use of entry barriers to achieve scale in dispensing as an end in itself, however, offers no warranty as to efficiency in the absence of competition driving innovation and technical change. In any case, there is evidence that with current dispensing technology, marginal costs in dispensing are constant, and that there is no difference between the economies of operating the prescription departments of small pharmacies and larger ones.²⁹

Also in the name of viability, to prevent pharmacies that relocate from trading in proximity to a competitor, they must be at least 1.5 kilometres ‘in a straight line’ from the nearest pharmacy (reduced from 2 kilometres in July 2002 under terms of the Third Government–Guild Agreement). There are also special distance rules for ‘short relocations.’ In July 2006, further to recommendations in the Wilkinson Review and the terms of the Fourth Government–Guild Agreement, relocations to ‘large’ medical centres and ‘small’ shopping centres without a pharmacy were allowed, provided there was no existing pharmacy within 500 metres.³⁰

Although it is claimed that location rules help ensure an equitable national distribution of pharmacies,³¹ they have been no panacea. In rural areas especially, location restrictions could be conducive to local monopolies because they may limit the chances that pharmacies will compete with one another.³² In some instances, location restrictions have actually prevented small rural communities from having their own pharmacy—because they have been too close to another town with a pharmacy.³³ In reality, an ‘equitable distribution’ may be frustrated simply because distance and isolation may necessarily attenuate pharmacy control. Some small communities without pharmacies must rely on dispensing doctor services.³⁴ Needy, isolated communities (including Aboriginal Medical Services) are obliged to obtain medicines

through pharmacist or prescriber dispensing under s100 of the *National Health Act*.³⁵

Usurping the role of the price system in providing signals as to costs and benefits to incumbent and new entrant firms may be prima facie evidence of too few firms in an industry.³⁶ By inhibiting access to external capital and competition, pharmacy entry barriers are likely to discourage the adoption of new technology in retail formats, in information systems, and in the organisation of work, which in most countries, including Australia, has been the mainspring of retail productivity gain.³⁷

PBS pricing arrangements

In some respects, the heart of the public policy dilemma in pharmacy is a product of the PBS that provides insurance cover to Australians for many pharmaceuticals through a pharmacy payments system—the cost of which for political reasons, Government is bound under Medicare to largely underwrite.

In the face of entry barriers in community pharmacy and enforced economies of scale, the Commonwealth seeks to constrain PBS prices at the retail level, where possible, by means of periodic, centralised collective bargaining arrangements structured into the Government–Guild Agreements.

Rather than embodying principles that would facilitate competitive pricing, these agreements nominate prices paid to pharmacies for each of 2,000-odd items that attract a PBS benefit. When they supply pharmaceuticals to PBS claimants, pharmacies are paid a ‘PBS Dispensed Price’ listed in the Schedule of Pharmaceutical Benefits.³⁸ The PBS Dispensed Price derives from the price obtained by the manufacturer set by the PBPA, a wholesaler markup of 7.52% (the so-called Approved Price to Pharmacist), and, at the time of writing, a pharmacy dispensing fee of \$5.44 per item (indexed) and a variable markup—for example, 10% on drugs whose Price to Pharmacy exceeds \$45.00.³⁹

Within this centrally controlled environment, government aims to limit consumer demand, subject to Safety Net thresholds, with a series of mandatory and indexed copayments—at the time of writing, \$31.30 per item for ‘general’ PBS claimants and \$5.00 for ‘concessional’ claimants.⁴⁰ More than 80% of the PBS’s cost to government, however, derives from concessional prescriptions.⁴¹

Because of significant public insurance available from the PBS, many consumers make little or no copayment towards the true cost of their

prescriptions. This may encourage them to incur willingly pharmaceutical expenditures they would not otherwise have considered reasonable. The existence of insurance cannot bid up prices charged by pharmacies, since prices of items attracting benefit are held at the PBS Dispensed Price. Nevertheless, because consumers are shielded from price, the existence of insurance can contribute to distortions in consumption expenditure and thereby cause a potential ‘excess’ cost to government.

In partly or wholly suppressing the price variable, the PBS underwriting experience on concessional prescriptions effectively exposes the government to considerable involuntary moral hazard. The latter may cause the people who are insured to behave less prudently than if they were responsible for the full cost of their PBS pharmaceuticals.⁴² There are thus economic imperatives for ensuring that community pharmacy, which is an important beneficiary of the insurance system, does not in other ways add to the risks the government is exposed to in maintaining a sustainable PBS.

Pharmacy charging practices—prescriptions with no PBS benefit

While government influences prices of pharmaceuticals on which it pays a benefit, the community pharmacy network exerts a quasi-monopoly power over prices it charges consumers for other prescription and non-prescription pharmaceuticals.

Because it does not pay a benefit on them, the commonwealth does not collect data on prescriptions for items listed on the PBS with a PBS Dispensed Price below the applicable copayment—so-called ‘under copayment’ prescriptions. In 2005–06, estimated expenditure on these was about \$606 million (figure 1). Pharmacies can set their own prices here, provided they do not exceed the relevant copayment (for example, \$31.30 for general claimants in 2008, except where a brand premium applies).

For under copayment prescriptions, pharmacies generally charge prices that deviate from the PBS Dispensed Price. Few consumers are likely to be aware of this.⁴³ There is also no evidence of price competition on under copayment prescriptions, even though (after considerable debate) pharmacies have been permitted to advertise these prices since January 2007.⁴⁴

Under the Third Government–Guild Agreement (effective until November 2005), pharmacies had been restricted in the case of under

copayment prescriptions to charging an allowable extra fee of up to 10% of the copayment, plus 50 cents per item in excess of the PBS Dispensed Price.⁴⁵ Lack of data prevented verifying compliance with this guideline. Under the current Fourth Government–Guild Agreement, the Guild and the government instead have agreed they will ‘make reasonable efforts to facilitate the online collection and recording of relevant data on PBS prescriptions supplied by community pharmacy that are priced below the patient copayment’⁴⁶. The Pharmaceutical Benefits Advisory Council (which is responsible for recommendations to government on pharmaceuticals to be listed on the PBS) considers that collection of under copayment data to be ‘critical,’ because generic pharmaceuticals that are out of patent are now increasingly causing PBS Dispensed Prices to fall below the \$31.30 general copayment.⁴⁷ In the meantime, pharmacies apparently charge what the market will bear on under co-payment prescriptions.

Pharmacies also sell prescription pharmaceuticals not listed on the PBS, but that, like PBS prescriptions, only they may sell. In 2005–06, estimated expenditure on these was \$670 million (figure 1). Non-PBS prescriptions also include ‘off label’ prescribing (items prescribed for a reason other than specified as attracting a PBS benefit). These ‘private prescriptions’ are not subject to a commonwealth-administered Dispensed Price.

Although pharmacies can compete on the pricing of private prescriptions, as to some extent occurs with mail-order and warehouse-type pharmacies (see below), they can also attract considerably higher dispensing fees and markup than PBS items. Suppliers of pharmacy software, for instance (including one program part owned and distributed by the Guild) had been accustomed to inserting a default markup of 75% on private prescriptions, until representations from the Australian Consumers Association to the ACCC halted the practice.⁴⁸

Poison scheduling restrictions

Prescription pharmaceuticals, whether PBS, under copayment or private, mostly belong to poison schedule category S4 ‘prescription only’ (a few narcotics and the like belong to an S8 category, covering ‘controlled drugs’). Some pharmaceuticals scheduled as poisons are also classified as Schedule 3 ‘pharmacist only’ and Schedule 2 ‘pharmacy only’; others not classified default to an ‘open seller’ category. Items classified below S4 are generally OTC pharmaceuticals for self-medication. Only pharmacies may sell S2 and S3 items subject, in addition in the case of S3 items, to customers being served by a pharmacist. Pharmacies also sell ‘open sellers’ but non-pharmacy retail outlets, principally supermarkets, also sell them. Unlike S2 and S3 items (and

prescription medicines and certain other pharmacy goods and services), ‘open sellers’ are subject to GST at point of retail sale.

Figure 2: Summary of pharmaceutical poison scheduling in Australia

	Schedule	Outlet
Prescription	S8	Pharmacy
	S4	
OTC	S3	
(non-prescription)	S2	
	Open seller	Pharmacy and other retail

In 2005–06, estimated expenditure on scheduled pharmaceuticals below S4 and on ‘open sellers’ was about \$2.9 billion, consisting of \$1.5 billion of sales in pharmacies (covering ‘open seller,’ S2, and S3 products) (figure 1), and \$1.4 billion of sales in non-pharmacy outlets (covering just ‘open sellers’).⁴⁹

Scheduling of pharmaceuticals in Australia is administered in the interests of public health and safety at state and territory level, on the *Standard for the Uniform Scheduling of Drugs and Poisons* developed by the National Drugs and Poisons Schedule Committee (NDPSC) within the commonwealth Department of Health and Ageing’s Therapeutic Goods Administration (TGA). States and territories maintain their own poisons lists or codes, which are uniformly based on the national standard but rely on state and territory ‘poisons’ legislation.⁵⁰

In the case of the market for S2 and S3 medicines, pharmacies operate in a quasi-monopoly environment, free of GST. There is a fringe of mail-order and warehouse-type pharmacies that compete on S2 and S3 prices among themselves and with mainstream pharmacies. Notwithstanding the introduction of s45(A)(1) of the *Trade Practices Act* (pursuant to the *Competition Policy Reform Act*), prohibiting behaviour that could be deemed to lessen price competition, the majority of pharmacies set S2 and S3 prices in a closed environment, frequently (because of location restrictions) in local monopoly situations.⁵¹ The Guild vigorously opposed the *Trade Practices Act* amendment.⁵² Aware that price-cutters supply a small fraction of the total market, mainstream pharmacies appear reluctant to retaliate,⁵³ either because it is

unnecessary, since they enjoy a local monopoly, or else in fear that a price war could cause more damage than their forbearance.⁵⁴

NSW Health has produced an indicative ‘cost–benefit’ analysis claiming Australia’s scheduling regime works well and yields a ‘large positive’ in NSW. Various categories of unit costs are explored, including those to consumers; but as no comprehensive price and quantity data are assembled, no modelling is possible.⁵⁵

While it may be broadly argued that Australia should set its own policies according to its own needs and priorities,⁵⁶ few countries possess pharmaceutical scheduling arrangements for non-prescription pharmaceuticals as complex and restrictive as in Australia. The United Kingdom and France, for instance, simply use a Pharmacy Medicine classification for their scheduled pharmaceuticals.⁵⁷ The Netherlands and the United States restrict only the sale of prescription medicines (for safety or therapeutic reasons). Based on the experience of ten countries and the EU, the United States General Accounting Office found no evidence to support the alleged benefits of pharmacist counselling or in retaining a pharmacy-controlled class of OTC pharmaceuticals⁵⁸.

Comparative effects of re-scheduling from ‘prescription’ to ‘non-prescription’

There has been a long-term trend, encouraged by an interest in promoting greater consumer self-care and accountability, to switch pharmaceuticals in the United States, as in many countries, from prescription to non-prescription (non-prescription being equivalent to ‘OTC’ in the United States and all of S3, S2 and ‘open seller’ items in Australia). Many of these switches have been ‘blockbusters.’⁵⁹ In Australia, there has been an analogous switch from S4, ‘prescription only,’ to S3, ‘pharmacist only’ medicines.⁶⁰

It is argued that Australia’s S3 classification has facilitated a larger switch from prescription medicines than would otherwise have been possible. For instance, a study based on a limited number of products claimed to be directly comparable seeks to argue that the existence of the S3 ‘pharmacist only’ classification has yielded a periphery of more potent medicines ‘off prescription’ in Australia than in the United States.⁶¹ Such studies cannot, however, be interpreted as evidence that Australia’s poison schedule is ‘less regulated,’ with easier consumer access than in the United States, as some writers claim.⁶²

A proper evaluation would first require enumeration of any additional pharmaceuticals ‘off prescription’ in Australia and expenditure on them—were it not for its S3 ‘pharmacist only’ classification—representing more Australian access to pharmaceuticals via pharmacies. These would then need to be compared with the much larger number of pharmaceuticals and the associated expenditure that would be OTC in the United States and classified as S2, ‘pharmacy only,’ in Australia—representing less Australian access via general retail. Access via pharmacies, by itself, is clearly not an indication of overall consumer accessibility.

In general, scheduling arrangements in the United States relative to Australia have been found to offer benefits that include ‘better consumer access, with medicines available at a wider range of outlets ... (and) lower medicine costs, due to competition and availability of medicines in stores with lower overhead structures.’⁶³

The study on a limited number of comparable medicines found considerably more of them were OTC in United States than were ‘open seller’ in Australia.⁶⁴ Examples meeting the ‘blockbuster’ criteria would include antihistamines for hay fever, such as cetirizine and loratadine; antifungals used to treat athlete’s foot and other tinea, such as clotrimazole; H₂-receptor antagonists, such as famotidine, for heartburn and acidity; synthetic corticosteroid nasal sprays, such as fluticasone, for allergic rhinitis, and so on. All of these, sold under various well-known brand names, are S2, ‘pharmacy only,’ in Australia but classified as OTC and available in supermarkets in the United States.

The antihistamine loratadine is an interesting case study: its sole metabolite, desloratadine, which has the same (if faster) pharmacological effect,⁶⁵ is a prescription item in the United States but an S2 ‘pharmacy only’ item in Australia.⁶⁶ Such apparent anomalies only further illuminate the fallacy of comparing, without qualification, items that are ‘on prescription’ in the United States and ‘off prescription’ (yet pharmacy controlled) in Australia, without recognising the availability of a parallel OTC parent drug in the United States.⁶⁷ When United States prescription items shift to OTC, it can encourage pharmaceutical companies to register their active metabolites (and the like) still under patent as prescription items (for example, desloratadine) and (by differentiating them for marketing purposes) charge a higher price for which there is an insurance rebate. Unlike in Australia, prescription prices are not there held by the equivalent of a PBS. Even so, by contrast with Australia, informed consumers in the United States can continue to benefit from supermarket access (free of time cost) if they switch to substitute, low-cost OTC parent compounds (as in the case of loratadine).⁶⁸

Australian scheduling anomalies

Australia's pharmacy-controlled non-prescription scheduling arrangements especially discriminate against small rural towns that are unable to support pharmacies. In contrast to comparable situations in other countries, such communities in Australia can be denied reasonable access to commonly purchased non-prescription medicines that are restricted to pharmacies. It is sometimes possible for local stores to obtain a 'Schedule 2 licence,' but this provides access only to a limited range of pharmaceuticals.⁶⁹ In any case, it defeats the general principle of limiting access to medicines that are 'poisons' and not supposed to be sold without professional supervision.

There are 'grey' areas in Australia's scheduling arrangements. Some S3 items may be sold on prescription (principally to facilitate payment of a PBS benefit to the concessional population),⁷⁰ and the dichotomy between an S2 and an 'open seller' often depends on pack size rather than chemical entity. Larger packs of analgesics (the most commonly sold non-prescription product group), for instance, are classified as S2, 'pharmacy only,' and smaller packs as 'open seller'—with consumers at liberty to purchase unlimited quantities of smaller packs from general retail outlets. A significant fringe of S2s and 'open sellers' may hence be substitutes for each other.

The appendix to this monograph provides a descriptive tabulation of the types of non-prescription pharmaceuticals that the NDPSC has scheduled as either S3 or S2 poisons in Australia. Generally, medicines classified as S3 are versions of those classified as S2 that are more potent. Examples would include antihistamines that may cause drowsiness, or analgesics or cough mixtures that are compounded with larger concentrations of codeine. Medicines may be similar, but sold as S3s in larger pack sizes or with labelling recommending larger doses. All paediatric syrups for children older than two years of age are classified as S3. Many less potent medicines classified as S2 might be considered candidates for open sale in the event of a rationalisation of poison scheduling in Australia. As discussed below, the NDPSC contemplated this in 2005.

Poison scheduling for S2 and S3 products and National Competition Policy

Poison scheduling is an area of pharmacy's market power where concerted efforts to question it precipitated a public economic evaluation in which the Guild itself became a participant.

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In recognition of anomalies apparent in Australia's poison scheduling, the Australian Health Ministers Conference (AHMC) was requested by COAG in July 1999, under the National Competition agenda, to review it against National Competition principles. This included an interest in simplifying Australia's OTC scheduling under the umbrella of an Australia New Zealand Therapeutic Products Authority. The AHMC commissioned a comprehensive review of drugs and poisons, the Galbally Report, which among other things recommended that evidence should be assembled and evaluated to test whether health outcomes had improved because of

- S2 and S3 pharmacy scheduling, and
- the effectiveness of professional standards for counselling pharmacy customers on the appropriate selection and purchase of scheduled OTC products.⁷¹

Professional standards for pharmacy counselling had originally been introduced in handling S2 and S3 pharmaceuticals in response to an Industry Commission review in 1996.⁷² Failing evidence of net benefits associated with retention of the S2/S3 regime, Galbally favoured simplification and amalgamation of Australia's OTC poisons into a single schedule with effective 'risk-based professional standards.'⁷³

Although OTC sales represent about 14% of pharmacy gross revenue (figure 1), they contribute nearly 20% of gross profit.⁷⁴ Any deregulation of S2 and S3 products that increased competition could prove disproportionately injurious to pharmacy profit. Because of Galbally's recommendations, many OTC products were at risk of being deregulated. Different scenarios were possible. For instance, with an S3 'pharmacist only'-type schedule, S2 'pharmacy only' products could migrate to 'open seller' status. Pharmacies would then lose not only the equivalent of their GST-free margin on these deregulated items; they could also become immediate prey to price competition from supermarkets and general retail outlets. Supermarkets had foreshadowed the likelihood of considerable consumer savings if they were to sell deregulated scheduled products.⁷⁵

Alternatively, with an S2-type amalgamated schedule, the more potent S3 products could shift to the S4 schedule where, if not sold as under copayment or private prescriptions, they could become subject to a controlled PBS Dispensed Price. Not surprisingly, on what were purported to be public health grounds, the Guild opposed OTC deregulation.

There are individual examples of deregulation that the Guild has since opposed. In June 2003, when the NDPSC decided to remove the NSAID ibuprofen (in packs of less than twenty-six doses of 200 mg or less)⁷⁶ from the S2 ‘pharmacy only’ schedule and give it ‘open seller’ status, the Guild proclaimed ‘grave concerns for public safety.’⁷⁷ In May 2004, the NDPSC did the same for nicotine-replacement therapies, where the Guild alleged their re-scheduling to ‘open seller’ was based upon ‘flawed criteria.’⁷⁸ In June 2007, phenylephrine and paracetamol combinations moved to ‘open seller’, whereupon the Guild claimed it would ‘confuse’ consumers.⁷⁹ There were claims too, that it would ‘devalue the role of pharmacy’.⁸⁰ Whilst assertions about safety have never been substantiated in these instances with systematic evidence from high-quality studies, the products concerned are now widely sold in supermarkets at considerable savings to consumers.⁸¹

Evaluation of S2 and S3 poison scheduling

Pursuant to Galbally’s recommendations, the commonwealth funded the Guild under terms of the Third Government–Guild Agreement, to evaluate the costs and benefits of amalgamating the S2 and S3 OTC schedules in conjunction with effective risk-based pharmacy counselling.

The ensuing study, supervised by the Guild, was further evidence of government’s capture by the Guild. It used an epidemiological model to estimate the costs of any illnesses avoided because of professional counselling at points of sale for S2 and S3 pharmaceuticals in pharmacies.⁸² It extrapolated the experience of a sample of so-called professional interventions (episodes of patient counselling) to all interventions in a year associated with the sale of S2 and S3 pharmaceuticals. Illnesses and adverse drug interactions so avoided were clinically assessed and suitably coded. Most interventions were appropriate, but some were found to be of poor quality and unlikely to contribute to health gain.

Gross benefits were measured in healthy life years saved, with assumptions about the statistical value of a life and expected survival. *Only the producer costs of the interventions were considered* (professional time, training, labelling, pharmacy layout, and so on).⁸³ The central estimate of annual net benefits at 2000–01 prices attributed to the current dual S2/S3 scheduling arrangements was \$2.7 billion.⁸⁴ The Guild publicised this finding as evidence of ‘how pharmacy teams manage the potential risk of harm to the consumer.’⁸⁵ The inappropriateness of the Guild’s epidemiological model used to obtain this false result is considered below.

Roughly comparable savings were claimed in scenarios with an amalgamated schedule—except it was unrealistically assumed that if the S2 schedule were abolished, all S2 products would migrate to the more restrictive S3 classification rather than to ‘open seller’ status. Similarly, if the S3 schedule were abolished it was assumed all products would shift to S2 status, rather than that many would become S4 prescription pharmaceuticals.

The TGA’s National Co-ordinating Committee on Therapeutic Goods was dubious about the Guild’s findings (for reasons other than the shortcomings of the economic model used), but decided to maintain existing S2 and S3 scheduling for at least the term of the current Community Pharmacy Agreement expiring in mid-2010.⁸⁶

Options for pharmacy deregulation

The Fourth Community Pharmacy Agreement extends community pharmacy businesses a lease of life under stringent entry and regulatory barriers until 2010, but various layers of deregulation could theoretically occur after that, including:

- A shift towards a fully competitive market in pharmacy products, with all prices deregulated, state and commonwealth entry barriers removed, and poison scheduling confined to S4 prescription products (some S3s would shift to S4). Thus, if it wished, government could set a notional Dispensed Price for PBS benefit without limiting the ability of pharmacies to set their own prices—as occurs in the case of medical services covered by Medicare (for which government sets a Schedule Fee). Price competition would then prevail (with retail rivalry and advertising of prices) without necessarily prejudicing consumers. Government could continue to exercise its monopsony power in setting manufacturer prices through the PBPA (if manufacturer prices were thought to be uncompetitive) and there would be a transfer to government of the pharmacy GST margin on deregulated S2s and S3s.
- Retention of the current regime but with a relaxation of entry barriers, easing ownership restrictions and barriers to PBS s90 approvals, enabling supermarkets and other retail outlets to establish pharmacy departments, under the supervision of registered pharmacists, as in other countries.
- Retention of entry barriers, but with either total or partial deregulation of non-prescription poison scheduling.

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- Alternatively, a partial deregulation involving at least some relaxation of state or Commonwealth entry barriers in conjunction with some relaxation of scheduling.

The first option is an ideal scenario; the others are examples of stages that could be implemented separately. Each would deliver considerable gains to consumers and taxpayers while losses imposed on pharmacy owners would be considerably smaller. For the moment, we concentrate on the former.

In the event of at least partial deregulation, work undertaken for Woolworths suggested that there could be reductions in the price of pharmaceuticals.⁸⁷ There could also be gains from economies of scope in supermarkets and the convenience of a one-stop shop and longer trading hours.

If just ownership restrictions were relaxed, entrepreneurial capital would be released into the pharmacy industry, supermarkets could open their own pharmacy departments, and price reductions would extend to PBS under copayment prescriptions, private prescriptions, and to S2 and S3 pharmaceuticals. If S2 and S3 scheduling only were abolished (with some S3 items moving to S4), the scope for price reductions would be smaller. Supermarkets would sell these items from 'health and beauty' shelves rather than in their pharmacy departments. In either case, a quasi-monopoly would be vitiated, accompanied by erosion of the 'rentals' or producer surpluses currently appropriated by community pharmacies.

Greater price competition associated with deregulation would not destroy the community pharmacy industry, although it might change the way community pharmacies operate. Nevertheless, it would offer consumers greater choice over where they could purchase their prescriptions and OTC medicines. We show below that the experience of parallel markets under the status quo for 'open sellers,' which are currently sold in both pharmacies and supermarkets, is instructive.

Assessing 'willingness to pay' for pharmacy-based professional services

As remarked above, many 'open sellers' and S2, 'pharmacy only,' products are differentiated only by pack size. Pharmacy transactions involving small packs of 'open seller' analgesics, for example, may be accompanied by professional advice and recommendations typically given with larger (S2, 'pharmacy only') packs of their similarly formulated counterparts. Pharmacies claim that as this service is not offered

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by other outlets, they should be entitled to recoup its cost.⁸⁸ Since not all consumers may value this advice, not all of them may be willing to pay for it. Some industry advocates regard professional interventions as part of a new category of ‘cognitive’ services for which pharmacies should be entitled to charge. Supermarket prices for ‘open sellers’ are thus substantially lower than pharmacy prices.⁸⁹

In the parallel, unregulated environment, consumers are evidently more conscious of price than any possible risk of buying an ‘open seller’ analgesic without a professional intervention. Indeed, some 79% of ‘open seller’ sales occur in general retail outlets, mainly supermarkets (worth about \$1.4 billion in 2005–06).⁹⁰

The experience with ‘open seller’ products illustrates the existence of two classes of health consumers: the risk-conscious and the price-conscious. Risk-conscious consumers are evidently willing to pay for higher levels of service they perceive to be available from community pharmacies, while the price-conscious buy largely on price, and their demand is price elastic. Because the demand of the risk-averse clientele attracted to pharmacies is relatively price inelastic,⁹¹ pharmacies maintain their prices, and some seek to compete on service by offering professional advice. The risk-averse minority who are prepared to pay for these services in the unregulated ‘open seller’ market throws an important light on the revealed preferences of health consumers.

It is plausible that patterns of business behaviour and consumer risk behaviour inherent in the different markets for ‘open seller’ medicines could replicate themselves if S2 and S3 medicines were deregulated or if pharmacies in supermarkets were permitted to sell S4 prescription medicines.⁹² Lower prices would be complemented by the greater availability afforded by longer supermarket hours. Unlike large supermarkets, few pharmacies trade out of hours or on Sundays.

With information about prospective price differentials, and some plausible assumptions about the variance in own-price elasticity in each of these two markets, the extent of ‘willingness to pay’ for professional advice could be tested. The evidence with respect to ‘open sellers’ suggests there would be a switch in demand, if S2 and S3 schedules were deregulated, to points of sale with lowest prices. Because demand would be highly price elastic in deregulated settings, lower prices could also increase consumption to meet legitimate needs that would have otherwise remained untreated. The Consumers’ Health Forum of Australia believes that pharmaceutical costs are a key issue causing needy consumers to delay or avoid purchase of necessary medication.⁹³

The potential lower prices and consumption gains that have hitherto eluded Australian OTC customers are a marker for large welfare losses on the \$1.5 billion annual expenditure (on 2005–06 figures) on pharmacy sales of regulated S2 and S3 items.⁹⁴ These losses are associated with an erosion of consumer surplus and the accrual of supernormal profit being now harboured within the current regulated community pharmacy industry—precisely the opposite of the \$2.7 billion net benefit the Guild’s S2/S3 cost–benefit study attributed to regulation and precisely the opposite of the Guild’s representations in 2000 to the Wilkinson Review.

The Guild’s study⁹⁵ was defective because it considered only the producer costs of poisons schedule deregulation; it neglected the considerable cost burden imposed upon consumers. It neglected to consider how consumers might reveal their preferences in the event of deregulation and whether they would be willing to pay for professional interventions associated with scheduling—to which the Guild had attributed an unqualified benefit. It implicitly assumed all consumers were risk-averse and that professional interventions were likely to be universally valued, and it dismissed the burden of the excess cost of pharmaceuticals and the restrictions in accessing them. The TGA’s National Co-ordinating Committee on Therapeutic Goods failed to recognise or address these issues.⁹⁶

The Guild’s coercive model fails to consider the right of individuals to exercise personal responsibility and to make legitimate self-care choices for themselves in a market setting.⁹⁷ Their model would be more relevant to evaluating costs and benefits for ‘public goods’ for which there were no market (for example, in the health sector, herd immunity from immunisation or fluoridated water).⁹⁸ By contrast, in the case of closed schedule pharmaceuticals, market prices of substitutes are available and could be usefully employed as markers in a counterfactual scenario.

Consumer safety

A revealed preference approach might be criticised because consumer perception of the risk of potentially toxic medications may be imperfect, hence a ‘willingness to pay’ may undervalue the gain from mitigating risk. For example, because market failure is supposed to be inexorable,⁹⁹ ‘consumers may be unaware of being a danger to themselves.’ If, however, consumer perceptions were incorrect, the best solution would be to provide everyone with adequate facts through product labelling and warnings and adequate access to CMI (consumer medical information) on the internet and through other sources, so that they could then make their own choices. Experience to date sug-

gests CMI has not always been readily available.¹⁰⁰ In many instances, past experience with a particular medicine, in conjunction with professional advice already received, is likely to assist in fashioning consumer choice.¹⁰¹

The correct starting point for analysing these choices is to comprehend the value that properly informed individuals place upon incremental safety, and how their attitudes to risk exposure are likely to vary from one to another.¹⁰² In a revealed preference model, consumer behaviour is explained less by the intrinsic risk of chemical entities or the way in which they are formulated, or the indications, dosages, or types of patients to be treated—criteria now underlying scheduling in Australia. It is, rather, governed by the spectrum of consumer attitudes to unintended incremental risk¹⁰³—as manifest in the actual risk–price trade-offs they make as to where and for which medicines they shop.¹⁰⁴

In any case, despite anecdotal claims to the contrary,¹⁰⁵ there are no systematic epidemiological data to show that morbidity and mortality attributable to analgesics and the like are significantly different between Australia and countries that use less restrictive poison scheduling.¹⁰⁶ Furthermore, there is doubt as to whether professional intervention and guidance are always needed,¹⁰⁷ and even if justified, their quality has been called into question. It is reported that many pharmacists simply ‘do not get involved in OTC medication sales.’¹⁰⁸ Data on S3 and S2 interventions from mystery-shopper surveys undertaken as part of the Guild’s Quality Care Pharmacy Program (QCPP) are equivocal,¹⁰⁹ and poor pharmacy staff training has become a significant failing.¹¹⁰ Besides, the quality of advice from registered health professionals ought to meet absolute standards without the inducement of artificially inflated markups made possible by barriers to competition that masquerade as a ‘safety issue.’

Efficiency consequences of quasi-monopoly in pharmacy

A rich economic literature has developed around social losses attributable to excessive market power and rent-seeking behaviour that is now so characteristic of community pharmacy in Australia. Tullock and others have argued the supernormal profit created by monopoly encourages expenditure on lobbyists to secure, maintain, and augment market power.¹¹¹ A corollary is that ‘rent’ created by monopoly or government regulation may be shared by various groups, whether bureaucrats, politicians, or owners of capital and labour. Hence, a beneficiary of regulation may be members of the workforce of a (regulated) firm such as a pharmacy, whose jobs and careers may owe their

existence to the demarcations and work practices associated with the regulated framework.¹¹²

Inflated, less-than-competitive pricing by community pharmacies has engendered profit horizons enabling them to bid for professional labour at the expense of public hospitals,¹¹³ despite clinical work in hospitals being more challenging and demanding of skills and professional training than the community sector.¹¹⁴

Concentrating highly trained pharmacists into community pharmacy has discouraged the substitution of pharmacy technicians for many less demanding administrative tasks that have become the dominant routine in day-to-day operations of community pharmacy.

Although trained pharmacy assistants are employed in pharmacies, this has not released pharmacists from the onerous requirement of personally handling all sales of OTC S3 products (for no properly measurable public benefit), and the obligation for a pharmacist to remain at a pharmacy whenever it is open. Such rigidities have stifled technical change and the cost-effective deployment of pharmacist labour into proper clinical settings where pharmacists would collaborate with other health professionals.¹¹⁵ The rigid retail model of resident owner-managers has thus contributed to an artificial scarcity of pharmacists, arising from the protection and maintenance of specific roles for pharmacists that could easily be delegated to others.¹¹⁶ The latter has occurred, for example, in the Netherlands.¹¹⁷

Exclusive authority to dispense under the PBS has become associated with an inflated amount of goodwill written into the balance sheets of PBS-approved pharmacies—analogueous to premiums, for example, that must be paid to acquire a taxi plate. Asking prices for leasehold community pharmacies in capital cities are usually in the range of \$1 million to \$1.8 million, depending upon location, the volume of prescriptions, trading hours per week, and so on.¹¹⁸ When community pharmacies change hands, reports of goodwill of at least \$1 million are commonplace.¹¹⁹ Relocatable PBS approval provider numbers alone are typically advertised in the region of \$350,000, but for up to \$650,000 in the Sydney CBD.¹²⁰

The capitalisation of economic rent into the value of a pharmacy reinforces the difficulty of pharmacy deregulation because pharmacy owners could readily misconstrue it as an acquired property right with a potential to become part of their superannuation. There is a capital gains exemption available on sale proceeds up to \$1 million (indexed from May 2006) for the active assets of eligible small businesses such as community pharmacies.¹²¹ This concession represents a significant

element in the retirement planning of ageing owner-pharmacists who could construe any dilution of their quasi-monopoly as unjust interference by government with their alleged property rights. As we discuss below, pharmacy owners may seek to interpret deregulation as grounds for a legal claim to compensation.

Commercial business lenders regard pharmacy goodwill as an acceptable security in arranging funding for purchasing a pharmacy. Indeed, until global financial uncertainty began to unfold in 2008, the ready availability of mortgage and mezzanine finance or guarantees from Australia's three full-line pharmacy wholesalers—competing to add mortgagor pharmacies to their respective 'banner group' buying cooperatives (Priceline, Chemmart, and so on)—had served only to add to the inflated entry costs into community pharmacy.¹²²

This has helped sustain the distortions and inefficiencies of the current regulatory environment, with mortgagees disinclined to scrutinise too closely the internal business plans and work practices that community pharmacies adopt.¹²³ The comfortable relationship between wholesalers and community pharmacy has also encouraged other areas of unsustainable wholesaler support that potentiate deadweight economic loss. For example, full-line wholesalers routinely provide almost every pharmacy in Australia with daily, and frequently twice-daily, deliveries.¹²⁴ This is an ill-disciplined and costly method of maintaining a pharmacy's inventory, especially in the case of non-emergency supplies. Such archaic work practices may partly reflect that two of Australia's full line wholesalers originated as community-pharmacy-controlled cooperatives.

The wholesaler guarantee model of funding is effectively a product of pharmacy ownership restrictions that have denied the pharmacy industry access to genuinely entrepreneurial capital from external investors that could challenge the culture of the industry.

Intensive concentration of highly trained labour and the excessive and inefficient application of capital that has been a corollary of market power are contrary to efficiency in resource allocation. Nor is this a spur to the adoption of sound business models in community pharmacy. A more competitive market in a retail setting in community pharmacy could expect to be associated with waves of innovation. This could include the adoption of automated dispensing and new workflow management strategies that reduce patient waiting times and dispensing errors,¹²⁵ the use of pharmacy nurses to sharpen the clinical focus of pharmacies,¹²⁶ and so on, as new entrants created avenues for technical change and shared the benefits with consumers.¹²⁷

Avenues of pharmacy influence

The community pharmacy business has become a significant beneficiary of government payments, regulation, and control in state, territory, and commonwealth jurisdictions. Entry barriers, ownership restrictions, exclusive statutory rights to sell certain classes of poisons, and an exclusive agency relationship in distributing PBS pharmaceuticals have all served a part in creating a business conditions consistent with excessive arrogation of market power by community pharmacy.

The origin of the influence associated with such protection derives from a variety of avenues, but in particular, from

- grass roots advocacy through day-to-day personal contact by pharmacists with their customers
- organised, high level political lobbying and professional advocacy, and
- patronage available to Australian academic pharmacists.

Risk-averse consumers who frequently shop at pharmacies are a primary constituency of grassroots advocacy. Pharmacists are convenient points of first contact with the health system without a formal appointment.¹²⁸ They are people-oriented communicators, well practised at engaging customers, especially vulnerable and elderly people most likely to be willing to pay extra to shop in pharmacies. Where information asymmetries between pharmacists and such clients occur, moreover, pharmacists may be susceptible to developing 'agency' relationships with them.

Agency relationships are prevalent in health settings where, for lack of information, principals delegate authority to another party who then becomes the agent to help them make decisions.¹²⁹

Grassroots support engendered by pharmacists offers an efficient platform as a 'natural community hub' to cultivate perceptions of credibility and reliability amongst community groups,¹³⁰ as well as to respond effectively to initiatives such as a national petition that substantially foiled the Wilkinson Review's recommendation relaxing restrictions on friendly society pharmacy ownership.¹³¹

The appeal of local pharmacies to the 'small business' sentiment is another species of grass roots advocacy. It exploits a romantic attachment to local 'corner store' philosophies and anxieties about retail concentration in the hands of supermarkets.¹³² Those so inclined might claim to

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be willing to pay 'to keep competition in the market' and to plead the cause of 'battlers.' It remains unclear whether these evocations are authentically consumer-driven or a manifestation of small business pressure by another name.¹³³ As remarked above, it also an area in which the ACCC is displaying an increasing interest.¹³⁴

Community pharmacy's high-level political lobbying has been effective and diligent. Most pharmacists are members of the Pharmaceutical Society of Australia (PSA), which is the professional organisation of pharmacists. Although technically separate from the Guild, the PSA and the Guild have historically complemented one another well, despite differences about representation in negotiations with government.¹³⁵ The PSA tends to concentrate on peak professional matters and the Guild on business affairs. Senior office bearers, 'wearing different hats,' are often common to both organisations at both state and territory and national levels.

This facilitates efficient networking within the bureaucracy, among politicians, and with other peak bodies in health. Even if differences occur, they have reinforced each other's point of view in entrenching anticompetitive arrangements to their mutual benefit. They have always attracted bipartisan political support.¹³⁶

The culmination of the Guild's achievements has been in successfully resisting pharmacies in supermarkets and its leadership and inspiration since 1990 in negotiating successive five-year Government-Guild Agreements. Apart from securing community pharmacy's contract for administering the PBS, these agreements also guarantee a flow of largesse under what are described as 'professional pharmacy programs and services.' Under the Fourth Agreement, the amount of funding so allocated over the period 2005-2010 is some \$570 million. This includes \$260 million funding for activities described as 'Better Community Health,' covering the QCPP and 'research and development.'

The budget for research and development is some \$20 million, with the Guild itself fundholder and administrator. Because other areas of Better Community Health also include 'evaluation' and 'pilot projects,' the amount effectively available for research and development is much larger than the \$20 million earmarked. This may be small compared with sums handled by the NHMRC and the like, but a large amount to be allocated to the exclusive discretion of an industry whose dominant source of revenue is government payments.

The Guild's control over publicly funded research, with the assistance, in the case of individual projects, of steering committees comprising

members with an affiliation or membership, in one capacity or another, to one or more of the Guild itself, the PSA, university pharmacy departments or government, assists it in setting public policy agendas.

Compensated deregulation

Because they have much to lose from deregulation, community pharmacy owners through the Guild have devoted considerable energy to insulating themselves from change. Government's fears of medicine-related misadventure in the event of deregulation, its rigid adherence to the precautionary principle, and its anxiety about the risk of consequential litigation may, too, have assisted the Guild in its work. Evidence of the Guild's success is that debate concerning inefficiency and consumer costs in the retail distribution of prescription and pharmacy OTC medicines attracts only modest recognition and carries little weight in guiding public policy.

For example, during the term of the National Competition Plan, at the bidding of the Guild, the commonwealth went so far as to persuade states to withdraw their impending NCC-compliant reforms that would have relaxed pharmacy ownership restrictions.¹³⁷ This must invite consideration of whether a more pragmatic approach to pharmacy deregulation should explicitly acknowledge artificial asset values acquired by community pharmacy owners.

Any relaxation of entry barriers and rationalisation of poison schedules would be associated with windfall losses. In reality, these would not be economic losses, but rather transfers from pharmacies to consumers. They could also be more than offset by the gains to consumers and taxpayers. Nevertheless, pharmacy owners could conceivably interpret an erosion of asset values occasioned by a change in the conditions under which government grants PBS approval as creating a legal right to compensation. It is doubtful, however, whether a legal right to compensation would be upheld, since PBS approval is not subject to payment of a fee to government.¹³⁸

If no compensation were paid, the loss of value would represent a transfer from current pharmacy owners to health consumers. On the other hand, if government were to meet the full cost of compensation, it would mean the whole cost would be transferred to taxpayers. Some pharmacy owners might consider this equitable insofar as taxpayers are also health consumers who may benefit from lower prices, more choice, and more competition (contrary, of course, to rhetoric concerning gains alleged from regulation).

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Various compensation strategies have been considered as an avenue to reform (in slightly different circumstances) in other industries.¹³⁹ In the context of community pharmacy, the most practical might be the immediate payment of compensation to pharmacy owners from general budget revenue, in place of removing ownership restrictions, and barriers and relocation restrictions in connection with PBS approval. This could be offset over time by an associated stream of ‘productivity savings’ in the retail distribution of PBS benefit prescriptions. It is likely that government would want to control any such exposure by limiting individual payments to some fraction of the actual erosion in asset values.

Payments could vary depending on individual circumstances—for example, a pharmacy recently acquired with significant capital improvements might embody entry costs and hence attract compensation exceeding that for a pharmacy that had long been in the same hands and was in disrepair. Differential criteria could hence be employed to justify payments as *ex gratia* (made due to moral obligation rather than in consideration of a legal claim).

Having regard to volatility inherent in sovereign risk as well as varying individual pharmacy circumstances, if average compensation were notionally set at say, \$0.3 million per pharmacy—equivalent to a third of average goodwill at 2005–06 prices,¹⁴⁰ the immediate total payout could amount to some \$1.5 billion (5000 pharmacies × \$0.3 million).

As remarked above, it would be ideal if there were a shift towards a more competitive model for PBS pricing. Assuming, however, that the government retains for the moment the current PBS remuneration structure for pharmacies, a stream of ‘productivity savings’ could be assessed and deducted from the markup and dispensing fees to pharmacies from when compensation commenced.

For illustrative purposes, if ‘productivity savings’ were treated at say, a one-off 15% in year 1, the cost of the annual compensation payout on constant 2006–07 pharmacy remuneration of \$1.3 billion¹⁴¹ could be amortised over roughly nine years at a discount rate of 5%. If allowance (say 2%) were made for annual growth in the number of prescriptions, the payout could be amortised in a little over seven years. If there were follow-on productivity improvements after the first year, the payback period would be commensurately shorter.

There would be an associated restructure of the community pharmacy industry, with hastened retirements, occupational separations, and re-deployment of some labour to other sectors. Some firms would cease operating; others would amalgamate or become takeovers. New, more

productive firms would enter, more efficiently re-employing some of the labour released by exiting firms.¹⁴² Eventually, a new equilibrium population of pharmacies would be achieved in varying retail formats.

Greater competition from supply chain management by supermarkets would change the work practices of pharmacy wholesalers. Supermarkets would integrate wholesale and retail inventory management, as they now do for most supermarket merchandise. Woolworths estimated that its additional cost in providing a pharmacy wholesale service would be half that of using the services available through existing pharmacy wholesale arrangements.¹⁴³ If gains from such efficiencies were passed on to consumers, it could contribute to a more competitive retail environment.

Any adjustment in Australia would occur over time, and not necessarily uniformly. Remote localities may experience considerably less change than large retail concentrations in metropolitan areas. Genuine structural adjustment would nevertheless offer significant potential welfare gain. Nobody would be worse off, while compensated pharmacy owners and consumers of medicines would be better off.

Deregulation in other countries

There are international precedents for securing structural adjustment in community pharmacy in Australia. Supermarkets in the United Kingdom have been involved in retail pharmacy since 1991. In 2003, the UK Office of Fair Trading (OFT) found supermarkets had contributed to price decreases of the order of 30% on OTC items.¹⁴⁴ This led the OFT to recommend the abolition of all entry regulations into community pharmacy, since they ‘inhibit price competition ... they stifle efficiency improvements and innovation ... [and] they limit the availability of pharmacy services.’¹⁴⁵ Deregulation in the United Kingdom has not affected the number of pharmacies. Patient choice remains uncompromised, but pharmacies are obliged to compete.¹⁴⁶

Pharmacy deregulation is now starting to occur in some highly regulated continental European markets, including Italy and Germany.¹⁴⁷ The European Union contends that national laws that restrict pharmacy ownership and barriers to new entrants— analogous to those in Australia—violate European law. The European Commission is accordingly bringing infringement actions against seven EU member states over their restrictive pharmacy ownership rules.¹⁴⁸ Proceedings are also before the European Court of Justice in a test case on the right of the Netherlands-based DocMorris mail-order pharmacy to operate a discount, non-pharmacy-owned supermarket-type pharmacy in the German town of Saarbrücken.¹⁴⁹ In April 2007, Celsio AG, Europe’s

largest pharmaceutical wholesaler, acquired control of DocMorris and plans to develop partnerships with owner-managed pharmacies based on the DocMorris philosophy throughout Germany.¹⁵⁰

DocMorris's business model is being contested by incumbent pharmacy interests who are challenging EU laws that guarantee the right of any European citizen to set up business anywhere in the Union. The outcome of this case, expected in 2009, could have profound implications for European competition policy on pharmacy.¹⁵¹

Concluding comments

Effective political lobbying and professional advocacy have successfully communicated a 'pharmocentric' vision of the health system to governments in Australia, in which community pharmacy, as a first point of contact, appears to have acquired a pivotal role in the wellness quest.¹⁵² This is ironic because the role of community pharmacists has evolved in small retail settings where they are isolated from other health professionals. Although there may be theoretical benefits in protecting quality standards, the cognitive work of community pharmacists as clinicians has failed to materialise effectively in Australia¹⁵³. In their role, conceived by the Guild, as resident owner-managers, they have never properly integrated with other health disciplines in the wider health system.

Even so, the needs and interests of pharmacies have exerted a powerful influence upon their retail clientele. Moreover, public policy on pharmacy has been reinforced by publicly funded research under control of the Guild.

Although monopolies that rely on professional licensure occur elsewhere in health, there are special doubts as to whether the privileges perpetually conferred upon community pharmacy have contributed to consumer welfare or to efficient business practice. Competition reform seems likely to have been impeded, because without compensation, the cost of adjustment would bear on a small, extremely well-organised industry, whereas the benefits would be diffuse and fully captured only over time.

Community pharmacy remains as a standout candidate for microeconomic reform. Experience in the UK suggests that this would not destroy the industry. Removal of ownership restrictions would create significant opportunities for injections of entrepreneurial capital. Wherever they were located, pharmacists would continue to supervise the dispensing of prescription pharmaceuticals and to offer professional advice if consumers sought it or if clinical imperatives dictated.

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Consumers would be able to exercise greater choice, however, over where this advice was offered, and over the retail format in which they purchased their medicines.

An opportunity for government to reconsider its options on community pharmacy will present in 2009, when negotiations are due to commence on the new 2010–15 Government–Guild Agreement.

Appendix: Examples of non-prescription pharmaceuticals scheduled as S2 and S3 poisons

S2 'Pharmacy only'	S3 'Pharmacist only'
Analgesics with a single therapeutically active ingredient, such as aspirin or paracetamol, in packs of >25 tablets or capsules; codeine <10 mg, if compounded with other non-opiate analgesics; dihydrocodeine <5mg, if compounded with aspirin in packs <26, etc. [§]	Analgesics with codeine <12 mg, when formulated with paracetamol and/or sedative antihistamines, etc.
NSAIDS (non-steroidal anti-inflammatory drugs) such as diclofenac <12 mg in packs <21; ibuprofen <201 mg in packs <101; naproxen <251 mg in packs <31; topical NSAIDS such as etofenamate and indomethacin.	NSAIDS such as diclofenac <26 mg in packs <31; ibuprofen <401 mg in packs of <51, etc.
Cough medicines including codeine and its semi-synthetic derivatives; bronchodilators; decongestants such as promethazine and pheniramine, etc.; anaesthetic lozenges.	Cough medicines, etc., with pseudoephedrine; cough medicines with higher concentrations of codeine and its semi-synthetic derivatives; paediatric liquid formulations of analgesics, antihistamines, decongestants, cough suppressants, etc., for treating children over two years of age;* bronchodilators containing aminophylline.
Nasal decongestants that constrict blood vessels; synthetic corticosteroid and other sprays for allergic rhinitis (e.g. fluticasone).	Pseudoephedrine (in small quantities eg <71 mg per pack of tablets); salbutamol, and terbutaline in metered aerosol packs for asthma.
Non-sedating antihistamines such as cetirizine and desloratadine; others, such as chlorpheniramine, trimetopazine, when combined with other therapies such as decongestants, etc.	Antihistamines such as trimetopazine in solid oral preparations; more potent antihistamines such as buclizine, clemastine, and mepyramine, which may cause drowsiness; or larger pack sizes of others.
Dermatologicals, including acne preparations, topical anaesthetics, antibacterial creams, and ointments; steroid creams and ointments to relieve itching; anti-fungals for ailments such as athlete's foot (e.g. nystatin); wart remedies; herpes remedies, burn	More potent dermatologicals, including those for psoriasis (e.g. dithranol); antifungals such as butoconazole, miconazole, and amorolfine; topical steroids such as alclometasone.

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remedies, etc.	
Travel sickness remedies such as diphenhydramine and promethazine.	
Eye drops, including astringents, decongestants, anti-infectives, etc.	More potent eye drops, including anti-infectives and anaesthetics.
Antispasmodics; anticholinergics.	Cleansing laxatives.
H ₂ -receptor antagonists for heartburn and acidity, such as ranitidine >150 mg and famotidine.	Some proton pump inhibitors for treating gastroesophageal reflux.
Fluoride drops.	Topical fluorides for dental use.
Certain vitamins, such as folic acid	
Disinfectants and antiseptics, such as glutaraldehyde & hexachlorophane.	
Tobacco withdrawal remedies containing nicotine in transdermal patches or chewing gum.	Tobacco withdrawal remedies containing nicotine in inhaler cartridges.
Anti-diarrhoeals.	Anti-diarrhoeals containing opioids.
Insect repellents, >10% pyrethrins.	
Anthelmintics (worm remedies)	
Anti-dandruff shampoos, <3.5% selenium sulfide.	
	Other medicines, including anti-obesity preparations; organic nitrates for heart conditions such as angina; vasodilators.

§ Aspirin and paracetamol in blister strips or childproof containers in packs <26 are 'open sellers.'

* In September 2008, paediatric formulations with sedating antihistamines for children under two years of age were moved from the S3 to the S4 'prescription only' schedule.

Source: NSW Department of Health¹⁵⁴

Endnotes

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- ⁴⁰ Except where a 'special patient contribution,' a 'brand premium,' or a 'therapeutic group premium' may apply.
- ⁴¹ AIHW, *Health Expenditure Australia, 2006–07*, table C2. This includes the cost of drugs prescribed under s100 of the *National Health Act*, other than 'Highly Specialised Drugs,' and it includes prescriptions dispensed to those in the general population who were covered by the Safety Net.
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