PHARMACEUTICALS AND PUBLIC POLICY:

An Assessment of the Productivity Commission Draft Report

A Submission to the Productivity Commission

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1. Overall Conclusions

In August 2002 the Australian Government requested the Productivity Commission to undertake an evaluation of the Pharmaceutical Industry Investment Program (PIIP), directing it to produce an interim report by November 2002 and a final report by January 2003. While focused on PIIP, the Commission's terms of reference are broad, and include requiring the Commission to determine whether there is economic justification for intervention in the pharmaceutical industry and, if so, to identify and assess possible policies and programs to undertake such intervention.

The Draft Report represents a serious attempt to undertake a rigorous assessment of the PIIP program, and of other issues related to policy for the industry, in the context of drug pricing systems and industry developments, both in Australia and overseas. The terms of reference request, and the Commission attempts to deliver, a much more ambitious and rigorous analysis than was, for example, asked for or delivered in the Commission's 30 August 2002 report *Review of Automotive Assistance* (PC 2002). This ambitious target has made it more difficult for the Commission to deliver a high quality outcome in the time available.

Globally the pharmaceutical industry is in the midst of fundamental change, and both the strategies of firms and the policies of governments are changing rapidly. The industry is one of great importance to Australia, given our level of professional and scientific expertise, our heavy investment in health sector R&D and the continuing erosion of high quality jobs throughout the economy. It was always unlikely that, even in spite of the efforts of highly skilled and dedicated personnel, the Commission could produce an adequate response to these terms of reference, for such a complex and changing industry, in this timeframe. Certainly the Draft Report does not constitute such an adequate response, nor does it suggest that one can be produced in the limited further time available.

In my assessment, many of the central propositions of the Draft Report are wrong. However, these personal assessments are of limited importance. Much more important is the fact that the Commission does not succeed, for many of these central propositions, in

[1] The author is also Director of the *Pharmaceutical Industry Project: Equity, Sustainability and Industry Development* at the Centre for Strategic Economic Studies. This paper is not an official output of this project, but draws on work done within the project. The project is overseen by a steering committee comprising representatives from Merck Sharp and Dohme (Australia), CSL, Eli Lilly (Australia), the Department of Industry, Tourism and Resources, the Department of Health and Ageing and Medicines Australia, and receives financial support from the Merck Foundation, from Merck Sharp and Dohme (Australia) and from Eli Lilly (Australia). None of these parties is in any way committed by any of the views expressed in this paper.

providing a coherent argument or a plausible body of evidence. As a result, the draft report will be an instrument of discord rather than consensus within the concerned community, and does not provide a sound basis for public policy in Australia.

Some further process is needed to provide a sounder analytical basis for national debate and government policy. One option would be for the Commission to seek more time to produce, after further consultation with those involved in preparing the Pharmaceutical Industry Action Agenda and with other interested parties, a more considered and definitive document. But other options should also be considered.

2. The Context of the Report

Partly because of the limited time available, the context in which the Commission places its report is in my view quite inadequate. Four matters are particularly relevant here. First, while the Commission's analysis proceeds mainly in the context of a standard neoclassical model, it is not explicit about the theoretical framework it is adopting. Nor does it refer to the wide range of literature produced over the past two decades that provides alternative perspectives for its analysis, some of which is noted below. More generally, the Commission has not had the opportunity to review adequately the international literature in many of the areas that it touches upon.

Theoretical Models for Knowledge Intensive Economies

For example, several strands of the contemporary literature explore mechanisms whereby technological, policy or other differences between countries and regions can lead to multiple equilibria, in some cases involving diverging growth paths. These strands include aspects of new growth theory (eg Murphy, Shleifer and Vishny 1989; Azariadis and Drazen 1990; Romer 1994); elements of the so-called new development economics and new economic geography models (eg Krugman 1991, 1992; Krugman and Venables 1995; Baldwin and Forslid 1999), and recent literature on general purpose technologies (eg Bresnahan and Trajtenberg 1995; Helpman 1998). Using various combinations of economies of scale, externalities and highly elastic factors supplies, modeled in a framework of imperfect competition, these models generate multiple equilibrium paths in which economies increasingly diverge. They thus suggest that, through coordination failures and in other ways, adverse features of an economy's technological base or economic structure can have persistent and cumulative effects. As a result, policies that successfully address these features can have persistent and cumulative positive effects.

In another vein, the evolutionary economics literature (eg Nelson and Winter 1982; see also Bryant 1998) also stresses, from a quite different theoretical base, the way in which path dependent processes can generate large divergences in economic outcomes between nations or regions, as a result of relatively small divergences in economic conditions or policies. Within that broad tradition, the innovation systems literature (eg Lundvall 1992) emphasises the systemic linkages between the organisations and institutions that comprise a national or regional innovation system, and the importance of the innovation system in influencing long run growth potential. Finally, on quite another tack, there has

been an extensive literature (eg McCombie and Thirlwall 1994) on growth constrained by the balance of payments, and this literature seems to have some relevance to Australia.

It is accepted that there is a need for the Commission to determine a single coherent framework for any such analysis. But the choice of the theoretical framework is so central to the results that it is necessary to address this issue explicitly, having regards to the rich menu of alternatives now available. Adoption of some of these other approaches would have had a fundamental impact on the argument of the Draft Report.

The Global Pharmaceutical Industry

Second, there is no discussion of the global pharmaceutical industry, of the nature and extent of change taking place in the industry, and of the opportunities and challenges that this might present for Australia. At the present time, the biomedical industries are probably the main focus of global technological change. Progress in basic science and in the application of new technologies – from high throughput screening and computational chemistry to genomics and proteomics – offers a wide array of new drugs and treatments. Massive resources are being devoted to these new technologies and products, especially in the centre of this revolution, the USA, and firm strategies are being adjusted significantly. (For a review of some of these issues, see Rasmussen 2002a, 2002b, and Sweeny 2002) Many governments are considering how their economies are best positioned to participate in these emerging industries, that will be so central to the advanced economies of the present century.

The Changing Nature of Drug Price Regulation

Third, there is little recognition in the report of the changing nature of drug price regulation in Australia. Over the past five years or so, and partly in response to the emergence of new, high cost drugs, the PBS pricing regime has been tightened significantly. Indeed, there are signs that Australia could be moving towards a variant of the New Zealand system, with reference pricing based on therapeutic groups, with both within patent and generic drugs included in the reference groups, and with an aggressive approach to generics (see, for example, Lofgren 2002 and Sheehan and Sweeny 2002). The New Zealand experience suggests that such a system may have a dramatic impact on industry development.

The Position of the Australian Economy

Finally, there is no discussion of the current position of the Australian economy, and of the relevance of the pharmaceutical industry to that position. Here I refer, for example, to the slow growth in the demand for labour (only 0.6% growth in total hours worked in the market sector between 1989-90 and 2001-02) in the context of rapid productivity growth, the absolute decline in the number of full-time permanent jobs in the 1990s (Borland, Gregory and Sheehan 2001), the continued erosion of Australia's relative position in knowledge intensive industries, and the impact of that erosion in terms of the balance of payments and the level of foreign debt. These and other matters would seem to be very relevant to the Commission's analysis, especially if some of the alternative models noted

above (such as those involving economies of scale and an elastic supply of labour (Krugman 1992) or balance of payments constraints on growth) were considered.

In my view, these deficiencies in its contextual setting make the report seem mechanistic and devoid of relevance to the real issues facing Australia at this time. The report does not address the technological revolution in the industry, the response of governments and firms to that revolution, nor the Australian response in terms of the changing nature of the PBS. It does not address the many new strands of theoretical and empirical literature explicitly developed to interpret knowledge intensive economies and industries, and shows limited coverage of the international literature generally. The report reads as if a formula is being applied, which could be run equally well, and with similar results, to the clothing industry in the 1960s or to the pharmaceutical industry in the 21st century. Again, this is perhaps inevitable given the timeframes with which the Commission was presented.

3. Price Suppression and Its Implications

In terms of price suppression and its implications (Chapter 3), the Draft Report puts forward three main propositions: that price suppression is only one of several factors contributing to lower pharmaceutical prices in Australia than in developed countries generally; that volume effects are likely to significantly counter the impact of price suppression on prices, and that there is little evidence that pharmaceutical pricing effects activity. As a result it finds that the rationale for an industry policy based on price suppression is weak.

In my judgment each of these three propositions are wrong, and they are supported in the Draft Report by arguments of very dubious quality. In the context of the Draft Report, price suppression may mean one of two things: the suppression of prices by the PBS relative to those that would prevail if free market pricing prevailed in Australia, or relative to the average level applying in the developed countries. These two would be the same if average developed country prices could be taken as a reasonable proxy for Australian free market prices, as is often done in analyses of other industries. But many countries undertake price suppression (in either sense), and also use industry policies to support the pharmaceutical industry. So these two meanings are not the same, and the Commission generates considerable confusion by swinging from one to the other.

Many of the Commission's arguments suggest that it has the free market price meaning in mind. But the closest it comes to a definition of price suppression is 'the effect of cost containment and bargaining arrangements under the PBS in lowering the (wholesale) prices of pharmaceuticals below that applying in many other countries' (p 3.1). But it immediately goes on to cite an official statement of the rationale for PIIP, which implicitly defines price suppression as the impact on prices from 'the Government exercising its monopsony (sole purchaser) purchasing power under the Pharmaceutical Benefits Scheme' (p 3.1). That is, as the impact on prices relative to what would otherwise have been the case in the absence of the PBS, rather than to the level of prices in other countries.

Two other considerations seem to me to be important in considering the argument of this chapter. First, there is no general presumption that, given free and open markets, prices for traded manufactured goods (converted at current exchange rates) would be lower in Australia than in other developed countries. Economic theory predicts that such prices should equalize, and prices for cars, clothes, computers or phones do not seem to be lower in Australia than in, say, the USA. The recent Commission report on automotive assistance (PC 2002) demonstrates broad equalization for car prices. Thus there would need to very strong grounds for a presumption to the contrary in the case of pharmaceuticals.

Second, the PBS sits as part of a complex set of historical relationships and institutions controlling pharmaceutical practice in Australia. As the Commission is aware, the counterfactual case – that the PBS does not control drug prices, and hence does not practice price suppression – is not at all simple to specify. For example, while the US system is the clearest example of free drug pricing, one is forced to presume that the bipartisan support for low drug prices to consumers in Australia is so strong that it would be preserved in any decontrolled system for wholesale drug pricing. Thus it may be more reasonable to see the Australian counterfactual not in terms of a full free market on the US model, but as one in which drug companies are free to sell their drugs at prices they determine, and with a bigger contribution from the taxpayer. But many questions would remain, such as how drugs are marketed, and this again links to the issue of what price suppression means.

The Extent of Price Suppression

The conceptual confusions about price suppression are evident in Preliminary Finding 3.1: *Australia's PBS arrangements constitute only one of several factors contributing to lower pharmaceutical prices relative to other countries*. As it stands, this means that if Australia dismantled the apparatus of the PBS, Australian prices would still be lower than the average of developed countries, including all of those that continue to practice price suppression. This seems to me to be a most implausible claim, and almost certainly wrong. It is also one that the Commission has done nothing to establish. On the other hand, if the claim had been that the PBS arrangements constitute only one of several factors contributing to lower prices than in countries, such as the USA, where free markets prevail, this would be a more plausible one.

In pursuing its argument about the extent of price suppression (section 3.3), the Commission makes four main points, which I discuss briefly below:

(i) *Industry views about price rises*. A central piece of evidence on which the Commission relies in its assessment of the extent of price suppression is two surveys of firms undertaken by the BIE, in 1991 and 1995. In the 1991 surveys firms were asked to estimate the impact on prices if 'the Government did not control pharmaceutical prices either to pharmaceutical suppliers or to consumers' (BIE 1991). In the 1995 survey they were asked 'if there were no Factor (f) scheme but the Government did not control pharmaceutical prices – either to suppliers or to consumers – how different would you expect your operations (average local prices for your products) to be in 1999 compared to

1993' (BIE 1995). In both years firms on average thought that prices would rise modestly, of the order of 20%.

Given the complexities in specifying the precise meaning of the counterfactual already noted, these seem to me to be close to meaningless questions. What did company executives assume in answer them – that they were being asked to suppose that a free market system like the USA were in place in Australia, or that the apparatus of the PBS remained in place but they could nominate their own price? Even if they had a clear meaning in 1991/1995 their relevance to 2002 is highly questionable, given the major changes in the PBS and in global pharmaceutical markets and products since that time.

(ii) *Marketing costs*. Of the factors that play a substantial role in the differences between Australian and overseas drug prices, the Commission puts most emphasis on two: marketing costs and national income differences. It cites US data suggesting that, for US companies, marketing and related costs accounted for 27% of drug sales revenue, and that marketing personnel accounted for 35% of US drug company personnel. It also notes that many countries, with the exception of USA and New Zealand, do not allow direct marketing of prescription drugs to consumers.

This is another example of the confusion about the meaning of price suppression. Marketing costs are indeed a major cost difference between free market and controlled systems, and hence between Australian and US prices. But they have little role in explaining price differences across the majority of regulated systems, and if Australia moved to a full free market the issue of marketing would re-emerge.

(iii) *The influence of relative national incomes on drug prices*. Using a simple analysis, the Commission points out that a strong correlation exists for seven developed countries between income levels and drug price levels, and suggests that income level may be a factor independent of price suppression in determining relative drug prices (p 3.12 to 3.14). But, as previously noted, strong reasons are needed to override the normal presumption that goods traded in open markets tend to price equalization, and hence that the most obvious explanation of this correlation is that price suppression is greater in lower income countries. The correlation itself does nothing to establish income level as a independent factor on pricing decisions.

(iv) *International differences in generics prices*. The Commission sees further evidence for its view that powerful forces other than price regulation are at work in international drug prices in the variations across nations in generics prices (p 3.14 and box 3.1). 'Generic drugs are apparently supplied by a competitive market – where the potential for price suppression should be close to zero – yet there remains a substantial degree of variation in international prices' (p 3.14). But in many countries, such as Australia, generic drugs are not priced in competitive markets, and a whole host of regulations and restrictions apply to them. These factors, rather than some mysterious 'powerful forces', are surely the main reasons for differences in generics prices.

Much of the literature presumes that the main reason for price differences across developed countries are the systems of price regulation, but there has been little sophisticated testing of this proposition, to my knowledge. In one recent econometric analysis, Danzon and Chao (2002) find that 'strict price regulation systematically lowers prices for older molecules and globally diffused molecules' (p 159) and conclude:

> The main factors tending to lower prices in other countries, relative to the US, are lower prices for older molecules and for therapeutic value, as measured by global penetration. These negative returns to age and therapeutic value are particularly strong in the countries with strict price regulation – France, Italy and Japan – and are consistent with the structure of their regulatory systems. (p 192)

For the Commission to take, on the basis of a cursory analysis, a contrary view – that price regulation is only one of many factors, and probably a minor one at that – is quite unsatisfactory.

Volume Offsets to the Effect of Price Suppression on Profits

In considering volume offsets the Commission argues that, if prices were not suppressed, drug firms would experience declines in sales volume that would significantly offset the profit effect of higher prices. But this argument ignores the central fact that neither doctors nor consumers face price signals in Australia. The bipartisan commitment to unfettered prescribing practices by doctors and to subsidised charges to consumers suggests that this would continue to be the case even if wholesale drug prices were higher. Recognition of this fact would seem to invalidate the argument used. Nor is it apparent that these arrangements have led to higher than average use of drugs in Australia – by OECD measures Australia appears to be in the middle rank in terms of drug usage.

The Commission might argue, of course, that the proper counterfactual for considering price suppression is the case in which all of the arrangements surrounding the current PBS are done away with, to be replaced by free market price US style. But, apart from their being no apparent reason why this is the case, such a position would seem to imply that the base for measuring price suppression is also free market pricing US style, rather than the average of developed countries.

The Effect of Price Suppression on Domestic Activity

In terms of the effect of price suppression on domestic activity, the Commission is faced with the fact that 'almost all pharmaceutical firms visited by the Commission were of the strong view that price suppression, price-volume agreements and other features of the PBS made Australia a 'hostile' location for new investment in pharmaceutical production or R&D' (p 3.20). The Draft Report also notes the survey data collected by the Lewin Group for firms in Australia in 2001 (Lewin Group 2001), which provides detailed documentation of this view. However, the Commission cannot accept this view, and spends many pages worrying about how such a view can be incorporated into conventional economic models and what additional evidence can be provided. This response to the industry's views is very different from the Commission's unquestioning

use, in Section 3.3 of the Draft Report, of industry views about the even more complex question of changes in drug prices if price regulation were to be removed.

Much of this analysis is, in my view, wrong-headed or simplistic. It is quite possible to develop models according to which this view is rational and consistent with the fact that 'large MNEs are deliberative and hardheaded in their investment allocation decisions' (p 3.29). If this fact cannot be understood within conventional models, this is most likely a commentary on their inadequacy. An example of simplistic analysis is the cross-country analysis of links between prices and activity in Appendix B. Inter alia, this analysis ignores the fact that many countries have industry policies to offset some of the effects of price suppression. Thus the high value of export growth for Australia over 1980-95, relative to the level of prices, is more an indication of the success of the Factor (f) program than a sign that there is no link between pricing and activity.

4. Other Rationales for an Industry Policy

In Chapter 4 the Commission considers other rationales for an industry policy in pharmaceuticals other than price suppression, and in effect argues that there is no such rationale. Such a rationale may be independent of price suppression in the PBS, or it might be seen as a rationale for policies to offset the domestic activity implications of price suppression. For example, the DITR website states the government 'aims to stimulate investment in pharmaceutical activity and to develop Australia as a regional centre of excellence in both R&D and manufacturing' through the PIIP program.

My perception is that many of those who support industry policies for pharmaceuticals in Australia argue along the following lines. The pharmaceutical industry, and the technologies and industries that underpin it, are in the process of dramatic change, and will be major players in the economies of the future. Australia has some of the attributes to participate in these industries, in terms of scientific and economic characteristics, but has major limitations – for example, small scale, lack of critical mass in key technologies, lack of ready access to both large global firms and to small specialist ones. Effective industry policies – that can help local firms to grow, that can strengthen the presence of large MNEs in Australia and that can develop links with the smaller firms that are proliferating around the world in these industries – can help to build important industries for the future, and hence have major long term effects on Australian welfare.

The Commission's main focus in this chapter is on spillovers that may lead to less than optimal activity within the industry, and its main argument is that there is no evidence that such spillovers are greater in the pharmaceutical industry than in others. The Commission does not come to grips with the industry policy argument sketched above. Indeed, that argument makes no sense within a standard neoclassical model, where firm structures are given, resources are fully employed and externalities are at the margin. Its home is within models emphasizing systemic linkages, pervasive complementarities, path dependent processes involving the creation of capability and critical mass, and innovation systems models. In such models, effective policies that lead to firm creation and enhancement, and hence industry development, can have social benefits far beyond the spillover effects of R&D much discussed in the literature. To come to grips with the

industry policy argument for Australia, the Commission needs to address the reality, or otherwise, of this prospect, and of the theoretical frameworks in which it can be set.

5. The Effectiveness of PIIP

In Chapter 5 the Commission considers the effectiveness of PIIP, and in particular whether it has led to increased activity levels in the participating firms relative to what would otherwise have been the case. Given the many influences on firm outcomes, estimating such effects is inherently difficult, and the Commission addresses many of these difficulties in a serious and systematic fashion. The Commission finds that PIIP probably has quite high inducement rates[2] for value added and R&D (base case estimates of 55% and 45% respectively are carried forward into the analysis of Chapter 6), but does not appear to have induced additional employment, investment and exports.

Overall, I have no reason to quarrel with these appropriately qualified conclusions, although some of the findings are surprising. However, one issue that is not adequately considered in this chapter is that of lags arising from the long-term nature of commitments in this industry. Firms that are induced by an industry program to build a factory, undertake a cooperative R&D program or enter into a corporate alliance with an Australian company set in motion processes, and undertake commitments, that are likely to extend long beyond the life of the government support.

This fact has two implications for the analysis of Chapter 5. First, as foreshadowed in the Commission's Figure 5.1 but not incorporated into the analysis, the inducement effects from a given program are the sum of those during the program period and those that continue beyond the period. By including only the first of these, the Commission probably underestimates inducement rates. Second, this fact raises issues about using the activity of non-PIIP firms as the base for assessing activity induced by PIIP, as the levels of activity of some non-PIIP firms may be influenced by the Factor (f) program. While the Commission notes various ways in which the Factor (f) program might influence estimates of PIIP inducement rates, it does this specific impact of the long lags involved.

Some illustration of these issues can be provided by the experience of Merck, Sharp and Dohme (MSD). MSD is a company whose Australian activities are large by the scale of the domestic industry. For example, it exported medicines valued at $406 million in 2000 (DITR 2002). MSD was a participant in the Factor (f) program but was an unsuccessful applicant for the PIIP program. Nevertheless, MSD experienced big increases in physical investment, value added and exports between 1998-99 (the last year of Factor (f)) and the average level for the first three years of PIIP (1999-00 to 2001-02). According to the company, virtually all of these increases were due either to Factor (f) or to the anticipation of a successful PIIP application. Thus Merck's factor (f) induced activities may substantially bias the non-PIIP firm aggregates as a base measure.

[2] The inducement rate is the amount of activity induced by the program, divided by the amount of activity that is eligible for subsidy.

6. The Cost-Benefit Analysis of PIIP

In Chapter 6 the Commission applies a variant of the cost-benefit analysis framework deriving from the Bureau of Industry Economics to the PIIP program. This framework has been used on many occasions over the past decade or more to analyse R&D and related programs (BIE 1991, 1993, 1994, 1995; Lattimore 1996). But, to my knowledge, no detailed documentation and analysis of this framework has been provided, and there are many questions outstanding about both its theoretical presuppositions and about the details of its application.

There are, in my view, four major issues to be addressed about the application of this framework to the pharmaceutical industry in Australia at this time. The issues are largely about the framework of analysis rather than the specific values of the parameters used, and the Commission adequately addresses none of these issues. While the Commission seeks input on the values of the specific parameters used, the more significant issues relate to the structure of the analysis.

The Displacement of Existing Activity

First, the use of cost-benefit analysis within an implicit general equilibrium, full employment framework implies that all of the activities induced by PIIP have displaced activities that would have occurred in other areas. For the pharmaceutical industry in Australia in the 1990s this assumption cannot be justified, in my view, and the Commission makes no attempt to justify it. For example, given the slow growth in the demand for labour over the past decade or more, and the concentration of that growth in low value jobs, it is likely that the induced activities would have added to labour demand, rather than simply rearranged the use of labour. Including social benefits from induced activities, rather than only from the spillovers from induced activities, would change the Commission's analysis fundamentally.

Long Term Commitments in the Pharmaceutical Industry

Second, given the substantive, long term commitments required in this industry, some activities induced by PIIP will continue beyond well the cessation of funding. As previously noted, this is implicitly acknowledged by the Commission but is not taken account of in the cost-benefit calculations. Given delays in getting activities underway, the induced activities beyond the period of program funding may be equal to, or even greater than, those within the funding period. Thus, proper recognition of long-term commitments would also have a major impact on the Commission's analysis.

Spillovers from Induced Activities other than R&D

Third, the particular approach that the Commission adopts leads to the conclusion that there are social benefits via spillovers only for induced R&D, and not for induced value added activities (and no other induced activities are detected). This important proposition is not argued for, being only mentioned in a footnote on p 6.7, and could be challenged in

the context of a broader concept of the systemic linkages within the economy and of the objectives of policy. It is also a key assumption in terms of the quantitative results.

Leakage and the Social Cost of Taxation in Programs Based on Price Suppression

Fourth, there are difficult questions about whether the leakage of program funds overseas and the marginal social cost of taxation should be included as social costs in the evaluation of a program designed to offset price suppression. For in the Australian case, price suppression means reduced payments to foreigners and lower taxation – given the commitment of successive Australian Governments to limited prices to consumers, the main effect of higher drug prices would be higher levels of taxation. Thus PIIP payments partly offset these social benefits of price suppression, and probably should not be included as a program cost in this case.

The Efficiency of PIIP

The bottom line is that there are major issues that the Commission needs to address about the application of this methodology to the PIIP program, and hence to this industry in Australia at this time. My own assessment is that a pharmaceutical industry program with the relatively high 'bang for the buck' (induced activity per dollar of subsidy cost) that the Commission finds for PIIP will almost certainly have strong net social benefits in Australia's current circumstances. Without these and other issues being addressed much more fully, the Commission's Preliminary Finding 6.1: *The most likely (base case) estimate of the impact of the PIIP is a net social cost of about $40 million for the first three years of PIIP…..'* (p 6.18), has no credibility.

Application of the Commission's Methodology to the Automotive Industry

In terms of the consistency of the approach taken by the Commission to program assessment, it is interesting to compare methodology used in the Draft Report to that used in the *Review of Automotive Assistance* (PC 2002). In the latter report, the Commission was neither asked to provide, nor did it undertake, a detailed social cost benefit analysis of the Automotive Competitiveness and Assessment Scheme (ACIS). Yet it recommended an extension of ACIS for five years beyond 2005, at a cost of $2 billion, a recommendation that has subsequently been accepted by the Government. As far as I can see, if the methodology applied by the Commission in the Draft Report had been applied to ACIS say over 2001-2005 (with social benefits arising only from R&D spillovers and social costs arising mainly from the marginal social cost of taxation and from foreign leakage), the net social cost of ACIS would inevitably be very high indeed. This is not intended as a criticism of either the ACIS report or of the Government's subsequent decision, but as again highlighting the potential unreality of the Commission's methodology.

Other Matters

There are many other issues addressed by the Commission in this important report that should be discussed. But given the time available, in this brief paper I can only provide a few additional comments on some of the key points.

In Chapter 7 the Commission considers the desirable characteristics of any modified PIIP program, were the Government to take the view that such a program were desirable. Inter alia, the Commission recommends that any further program should be limited to payments for induced R&D. I do not support this proposal, and argue elsewhere in this paper about the limitations of the Commission's approach to an industry policy for pharmaceuticals. The content and scale of such a policy can only be determined after a much more thorough specification of its objectives and of the theoretical basis on which it would be supported.

Clause (f) of the PBPA's guidelines requires it to take the level of activity being undertaken in Australia, including new investment, production and research and development, in determining drug prices. In practice the PBPA has ignored this clause, and has looked to the Factor (f) and PIIP programs as justification for this course of action. The Commission suggests that the clause should be dropped, on the grounds that it is currently being ignored and that there is no appropriate way of giving effect to it. Again, I do not support the Commission's proposal. There are various ways of giving effect to this clause, such as the UK rate of return pricing guidelines. The clause should be dropped, if at all, only after a serious consideration of Australia's industry and health objectives in relation to drugs, and of the best ways of achieving these objectives. It should not be allowed to drift away just because the issues are too difficult.

In Chapter 8 the Commission raises the important issue of access by MNEs, in the pharmaceutical industry as elsewhere, to the general R&D tax concession. Rightly, in my view, it queries whether it should continue to be a condition of access to the concession that the ownership of the intellectual property generated by the R&D should be held in Australia. This issue goes to the heart of the rationale for public support for business R&D in Australia – whether it lies in the social benefits arising from spillovers from R&D undertaken within Australia, or whether it aims to support the development of new products and processes that can be owned and commercialized by Australian-owned firms. While not entirely discounting the second rationale, I believe that policy should primarily focus on the former, and hence allow MNEs access to the concession for R&D undertaken in Australia.

Finally, the Commission recommends that Australia's intellectual property legislation should be amended to allow generic drug manufacturers to export to countries where patents have expired, even if a patent is still in force in Australia. I can see no valid objections to this proposal, provided that proper safeguards are in place, and it should assist in the development of Australia's generics industry.

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