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THE DRUG BARGAINING GAME: PHARMACEUTICAL REGULATION IN AUSTRALIA

Discussion Paper

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Abstract

Many countries, including Australia, regulate the price consumers pay for pharmaceuticals. In this paper, the Australian Pharmaceutical Benefits Scheme (PBS) is modelled as a multi-stage game played between the regulator and pharmaceutical firms. Conditions are derived under which vertically differentiated firms are regulated and a number of issues are discussed. These include efficiency, regulated firm profitability, leakage, and price discrimination. An extension examines the introduction of new drugs and concludes that if all the benefits of a new drug are to be realised, then existing agreements and transfers (per-unit subsidies) need to be renegotiated.

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1. Introduction

To ensure consumers equity of access, many countries regulate the price consumers pay for pharmaceuticals. The regulated price is normally well below the market price. Therefore, to induce participation by pharmaceutical firms in the regulatory regime, transfers are given by the government to the firms. These transfers are often implemented through a negotiated *agreed price* for producers. Willison *et al* (2001) document that Australia, Germany, the Netherlands, New Zealand, and the United Kingdom set a fixed consumer price with the difference between this price and the *agreed price* being the implied per-unit subsidy. In France and Sweden consumers pay a fixed proportion of the *agreed price*.

The literature on pharmaceutical regulation is mainly empirical with emphasis placed on measuring international price differences and seeing if they can be explained by the regulatory environment. Danzon and Chao (2000a) find that countries with strict price regulation (France, Italy, and Japan) have lower prices than the less regulated markets of the United States and the United Kingdom. However, Berndt (2000), provides a number of caveats about their interpretation of the data. In a related paper, Danzon and Chao (2000b), examine whether the extent of price competition between producers of generic drugs is affected by the regulatory environment in which they operate. They find that price competition is significant in less regulated markets (United States, Canada), but not in more regulated markets (France, Italy, and Japan).

Despite a substantial empirical literature, the theoretical literature on pharmaceutical regulation is rather scant. This paper endeavors to correct this situation by building a theoretical model of the Australian Pharmaceutical Benefits Scheme (PBS). The goal is to discover the implications of its design and suggest possible improvements. Although it is based on the Australian system, the model has wider appeal because similar schemes are in place in many European countries as well as Canada and New Zealand.

The PBS is modelled as a five stage game. In the first stage, pharmaceutical firms choose whether to enter the regulation process. In the second, the quality of the drug is determined and in the third, given the regulated price, the regulator chooses which firm/s to regulate. In the fourth stage, the regulator and the regulated firm bargain over a transfer which can be implemented via an agreed producer price and finally, in the fifth stage, pharmaceutical firms, with different quality drugs, compete with each other in the drug market.[1]

The main results are summarised in Propositions 1 and 2. Together they state that as long as the regulated price is less than the unregulated price of the high quality firm, then the high quality firm always enters the regulation process and is regulated. The negotiated *agreed price* is less than the unregulated price of the high quality firm. In some circumstances the low quality firm also enters the regulation process and is regulated. Since the regulated price is the same for high and low quality firms, a regulated low quality firm makes no sales. Essentially, the low quality firm is regulated to stop the low quality firm stealing consumers away from the high quality firm.

Once the model is outlined, a number of implications are drawn. The first is that a lowering of the regulated price for some drug classes can increase the regulator's payoff and reinforce equity of access. Therefore, the policy of having a single identical regulated price for all drug classes needs to be re-examined. Second, although the *agreed price* is below the unregulated price of the high quality firm, this does not mean the regulated high quality firm is worse off under regulation than without regulation. In fact, the bargaining process ensures it can not be made worse off. Third, the theory suggests that in the bargaining process the high quality uses of the drug should be specified and its subsidised use restricted to these uses. Failure to do so results in the subsidised use of the drug leaking out into low quality uses. Although this increases consumer surplus, it can reduce the regulator's payoff if the

[1] Anis and Wen (1998) develop a theoretical model of pharmaceutical regulation in Canada, but ignore strategic interactions between firms by assuming monopoly and ignore interactions between pharmaceutical firms and the regulator by modelling regulation as a price constraint.

induced unnegotiated transfers are large enough. In the absence of enforced use restrictions, solutions to the problem of unnegotiated transfers include the use of lump-sum transfers or price-volume contracts.

A feature of the Australian PBS is that there are two regulated prices. Concessional patients face a lower regulated price than general patients. Amending the analysis to incorporate a high and a low regulated price reveals that having two regulated prices can increase the regulator's payoff if in the presence of one regulated price (i) some consumers purchased the low quality drug or (ii) both high and low quality firms are regulated. If a single regulated price was chosen efficiently by the government, neither of these two cases would arise. Therefore, it is the arbitrariness of the setting of the regulated price that introduces situations in which having two regulated prices leads to greater regulator payoffs.

Finally, the model is amended to take exogenous innovation into account. First, a new lowest quality drug is introduced. It is shown that this can increase the payoff of the regulator even if the firm producing the new drug makes no sales. This follows because the presence of the new drug alters the disagreement payoffs in the absence of regulation in such a way that a smaller transfer is paid to the high quality regulated firm. It is also shown that no regulation might maximise the regulators payoff. In either of these cases, for all the benefits of the new drug to be realised, it is necessary for existing regulatory agreements to be renegotiated. This may entail drugs that were initially regulated being removed from regulation. Next, a new highest quality drug is introduced. The message is similar, to realise all the benefits from a new drug requires existing regulatory agreements to be renegotiated.

2. Australian Pharmaceutical Regulation - Institutional Detail and Procedures

Pharmaceutical patents provide their holders with monopoly power which allows them to charge monopoly prices. These prices can be such that an individual whose health outcome would be improved by taking the drug cannot afford to do so. To ensure equity of access to drugs, the Australian government has implemented a system of regulated prices and subsidies known as the Pharmaceutical Benefits Scheme (PBS).[2] The price a consumer pays for a drug appearing on the PBS list is either A$22.40 for a general patient or A$3.60 for a concessional patient (aged, disabled, unemployed etc.).

To ensure pharmaceutical firms participate in the scheme, the Pharmaceutical Benefits Pricing Authority (PBPA) determines a list of agreed prices which pharmacists (dispensers) pay the pharmaceutical firms for their drugs. If this price is above the price paid by consumers, then pharmacists claim the difference from the government, essentially, consumption of the drug is subsidized.

To be listed, a drug must meet efficacy, safety, and quality standards. In addition, it must undergo an economic evaluation. First, its quality relative to a comparator (the best existing treatment) is determined. Next, an agreed price, which ensures cost-effectiveness, is negotiated. To be cost-effective, an additional unit of health outcome must be attained at less cost with the drug being evaluated than the comparator. Generally, drugs that are cost-effective are listed at the agreed price. In determining the agreed price, the PBPA takes into account a number of factor. These include comments on the clinical and cost effectiveness aspects of the drug, prices of alternative brands, prices of drugs in the same therapeutic group, cost information, prescription volumes, and the prices of the drug in comparable overseas countries.

Two important characteristics of the pharmaceutical industry in Australia are (i) pharmaceutical firms are foreign owned and (ii) the pharmaceutical market is small relative to the world market. The first characteristic implies that the profits of pharmaceutical firms are not a component of Australian welfare and the second characteristic implies that the impact of Australian pharmaceutical regulation on pharmaceutical firm R&D is so small that it can be ignored.

[2] In PBPA (2000) the objective of the PBS scheme is given as ".... to secure a reliable supply of pharmaceutical products at the most reasonable cost to Australian taxpayers and consumers...."

3. Game Structure

Pharmaceutical regulation in Australia can be modelled as a stage game. In the first stage, a foreign owned pharmaceutical firm, at some cost, chooses whether or not to go through the drug evaluation, bargaining, and regulation process for a particular drug. If the firm decides to enter this process, then in the second stage the regulator evaluates the quality of the drug submitted for evaluation. In the third stage, the regulator decides which firms to regulate. The fourth stage involves bargaining (negotiation) between the regulator and the regulated firms over the transfer (subsidy) the firms are to receive in return for selling their drug at the regulated price to consumers. In the fifth stage, firms compete in the drug market. Those firms that have successfully gone through the evaluation process are constrained to charge the regulated price, other firms that have been unsuccessful in the evaluation process or did not enter it in the first place are free to charge any price they wish. The regulated price is not determined by the regulator, but is given to it by the government. As is usual, the game is solved backwards for the sub-game perfect Nash Equilibrium.

3.1. Stage Five - Drug Market Competition

The model used for drug market competition is a direct extension of the vertical differentiation model outlined in Tirole (1988, chpt 7). Mussa and Rosen (1978) preferences are assumed, so an individual with preference parameter θ obtains surplus

$$V = \theta s - p \tag{1}$$

when purchasing one unit of a drug of quality s at a price of p, and zero otherwise. The individual preference parameter, θ, is assumed to be uniformly distributed with density one across the population of consumers on the interval $[\underline{\theta}, \bar{\theta}]$, where $\bar{\theta} = \underline{\theta} + 1$.

It is assumed that there are two firms, 1 and 2, selling drugs within the same therapeutic class with qualities $s_1 < s_2$, respectively. These firms have identical and constant marginal production costs equal to c and choose prices, p_1 and p_2, to maximise profit. There are four cases to consider.

3.1.1. Neither Firm Regulated

The case of most interest is where both firms find it profitable to produce, so it is assumed that $\bar{\theta} > 2\underline{\theta}$. In addition, it is assumed that the market is covered, that is, all consumers buy one unit of one of the drugs. This requires that $p_1 \leq \underline{\theta}s_1$ in equilibrium.

Let $\tilde{\theta} = \frac{p_2 - p_1}{s_2 - s_1}$, it is straight-forward to show that individuals with preference parameter $\theta \geq \tilde{\theta}$ purchase from the high quality firm, firm 2, while the remaining individuals purchase from firm 1. The demands of each firm are, therefore, given by

$$D_1 = \frac{p_2 - p_1}{s_2 - s_1} - \underline{\theta}; \quad D_2 = \bar{\theta} - \frac{p_2 - p_1}{s_2 - s_1}. \tag{2}$$

The demand for the high quality drug falls with an increase in its price, because some consumers switch to the low quality drug. Substitution of this type is consistent with the findings of Pavcnik (2002). She found retail price falls of between 10-26% accompanied Germany's 1989 switch from a flat prescription fee to reference pricing.[3] Presumably, to reduce consumer substitution into competing drugs under reference pricing, pharmaceutical firms lowered retail prices so that the out-of-pocket expense to consumers increased by less than otherwise.

Firm profits are

$$\Pi_1 = (p_1 - c)D_1(p_1, p_2); \quad \Pi_2 = (p_2 - c)D_2(p_1, p_2) \tag{3}$$

and the best response functions of each firm are

$$p_1 = \frac{p_2 + c - (s_2 - s_1)\underline{\theta}}{2}; \quad p_2 = \frac{p_1 + c + (s_2 - s_1)\bar{\theta}}{2}. \tag{4}$$

Note that prices are strategic complements.

Solving (4) simultaneously for the Nash equilibrium prices yields

$$p_1^n = c + \frac{\bar{\theta} - 2\underline{\theta}}{3}(s_2 - s_1) > c \tag{5}$$

[3] If the retail price exceeds the reference price, then the consumer pays the difference.

and

$$p_2^n = c + \frac{2\bar{\theta} - \underline{\theta}}{3}(s_2 - s_1) > p_1^n. \tag{6}$$

These price equations are consistent with Lu and Comanor (1998) who found, for the United States, that the greater was the therapeutic difference (quality difference) between two drugs, the greater was the price differential. Denote Nash equilibrium profits by $\Pi_2^n > \Pi_1^n > 0$ and Nash equilibrium surpluses from each drug by

$$S_1^n = \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_1 - p_1^n) d\theta; \quad S_2^n = \int_{\tilde{\theta}}^{\bar{\theta}} (\theta s_2 - p_2^n) d\theta, \tag{7}$$

where $\tilde{\theta} = \frac{\underline{\theta} + \bar{\theta}}{3}$. Equilibrium prices, consumer surpluses, and profits are shown in Figure 1.

3.1.2. High Quality Firm Regulated - Low Quality Firm Unregulated

The effect of a regulated consumer price of $p_2 = \bar{p}_2$, depends on the size of $\bar{p}_2$. A number of cases are considered.

Case 1: $c < p_1^n < p_2^n < \bar{p}_2$

In this case, the regulated price is greater than the unregulated price of the high quality firm. Since (4) reveals that prices are strategic complements, the best response of firm 1 to regulation of firm 2 is to charge a price, $\hat{p}_1 > p_1^n$, where a hat signifies the value of a variable when the high quality firm is regulated. In the Appendix, it is shown that $\hat{S}_1 + \hat{S}_2$ is a decreasing function of $\bar{p}_2$, therefore

$$\hat{S}_1 + \hat{S}_2 < S_1^n + S_2^n. \tag{8}$$

It is not surprising that the sum of consumer surpluses decreases with an increase in the price of both drugs. Finally, note that

$$\hat{\Pi}_1 > \Pi_1^n; \quad \hat{\Pi}_2 > \Pi_2^n. \tag{9}$$

because $\bar{p}_2 > p_2^n$, $\hat{p}_1 > p_1^n$, and the best response functions are positively sloped.

Case 2a: $c < p_1^n < \alpha < \bar{p}_2 \leq p_2^n$

In this case, the regulated price is below the high quality firm's unregulated price, but above the low quality firm's unregulated price. The variable α is defined by $\alpha \equiv c + (s_2 - s_1)\underline{\theta}$. Calculation reveals that $p_1^n < \alpha$ if $5\underline{\theta} > \bar{\theta}$. This condition is assumed throughout the paper. Examining (4) reveals that if $\bar{p}_2 > \alpha$, then the best response of firm 1, $\hat{p}_1$, is such that $c < \hat{p}_1 \leq p_1^n$. At this price, firm 1 has positive sales. Using the fact that $\hat{S}_1 + \hat{S}_2$ is a decreasing function of $\bar{p}_2$ the following inequality holds

$$\hat{S}_1 + \hat{S}_2 \geq S_1^n + S_2^n. \tag{10}$$

It is not surprising that the sum of consumers surpluses increases with a decrease in both prices. Finally, note that

$$0 < \hat{\Pi}_1 < \Pi_1^n; \quad 0 < \hat{\Pi}_2 < \Pi_2^n. \tag{11}$$

because $\bar{p}_2 < p_2^n$, $\hat{p}_1 < p_1^n$, and the best response functions are positively sloped.

Case 2b: $c < p_1^n < \bar{p}_2 \leq \alpha < p_2^n$

Examining (4) reveals that if $\bar{p}_2 \leq \alpha$, then the best response of firm 1 is $\hat{p}_1 = c < p_1^n$. At this price, firm 1 has zero sales. The condition $\bar{p}_2 \leq \alpha$, can be rewritten as $\underline{\theta}s_2 - \bar{p}_2 \geq \underline{\theta}s_1 - c$ which implies there is no price at which firm 1's sales are positive. Inequality (10) still holds, but with $\hat{S}_1 = 0$. Profits are

$$0 = \hat{\Pi}_1 < \Pi_1^n; \quad 0 < \hat{\Pi}_2 < \Pi_2^n. \tag{12}$$

Case 3: $c < \bar{p}_2 \leq p_1^n < \alpha < p_2^n$

In this case, the regulated price is below the unregulated prices of both the high and low quality firms. As in case 2b, the best response of firm 1 is $\hat{p}_1 = c$. At this price firm 1 has zero sales. The relationships between consumer surpluses and profits are identical to case 2b above.

3.1.3. Low Quality Firm Regulated - High Quality Firm Unregulated

As in the preceding sub-section, the effect of a regulated consumer price of $p_1 = \bar{p}_1$ differs depending on the size of $\bar{p}_1$.

Case 4: $c < p_1^n < \bar{p}_1$

In this case, the regulated price is greater than the unregulated price of the low quality firm. Since prices are strategic complements, the best response of firm 2 to regulation of firm 1 is to charge a price, $\check{p}_2 > p_2^n$, where a check signifies the value of a variable when the low quality firm is regulated. In the Appendix, it is shown that $\check{S}_1 + \check{S}_2$ is a decreasing function of $\bar{p}_1$, therefore,

$$\check{S}_1 + \check{S}_2 < S_1^n + S_2^n. \tag{13}$$

Regulation has moved prices closer to the collusive outcome so

$$\check{\Pi}_1 > \Pi_1^n; \quad \check{\Pi}_2 > \Pi_2^n \tag{14}$$

Case 5: $c < \bar{p}_1 \leq p_1^n$

In this case, the regulated price is less than the unregulated price of the low quality firm. The best response of firm 2 is $\check{p}_2 < p_2^n$. It follows that

$$\check{S}_1 + \check{S}_2 \geq S_1^n + S_2^n \tag{15}$$

and that

$$\check{\Pi}_1 \leq \Pi_1^n; \quad \check{\Pi}_2 < \Pi_2^n \tag{16}$$

3.1.4. Both Firms Regulated

The effect of a regulated consumer price of $p_1 = p_2 = \bar{p}_1 = \bar{p}_2$ is for all consumers to buy the high quality drug if they buy at all. For the case where $\bar{p}_1 = \bar{p}_2 > \underline{\theta} s_2 > c$, the market is not covered. For $c \leq \bar{p}_1 = \bar{p}_2 < \underline{\theta} s_2$ the market is covered. Denote profits of the two firms and surpluses of the consumers where both firms are regulated by $\bar{\Pi}_1 = 0, \bar{\Pi}_2, \bar{S}_1 = 0$, and $\bar{S}_2$.

3.2. Stage Four - Bargaining Over the Transfer

In this stage, the regulator and the regulated firms bargain over the transfer, L, that is paid to the firm in return for it being constrained to charge the regulated price to consumers. A cooperative approach to the bargaining problem is assumed and a Nash bargaining solution is sought.

For expository reasons the case where only the high quality firm is regulated is developed. Given transfer L, the regulator achieves payoff $\hat{S}_1 + \hat{S}_2 - L$. The payoff of the regulator does not include the profits of firms 1 and 2, because they are foreign firms. The payoff of the high quality firm is its regulated profit plus the transfer it receives, that is, $\hat{\Pi}_2 + L$. If no agreement between the regulator and the firm is reached the regulator's and the firm's payoffs are $S_1^n + S_2^n$ and Π_2^n, respectively. The Nash bargaining solution for L is the solution to the following maximisation problem

$$\max_L \ NP \equiv \big(\hat{S}_1 + \hat{S}_2 - L - S_1^n - S_2^n\big) \times \big(\hat{\Pi}_2 + L - \Pi_2^n\big). \tag{17}$$

subject to

$$L \geq 0 \tag{18}$$

Constraint (18) is included as there is no mechanism in practice for firms to make transfers to the regulator. Rearranging the first order condition of this maximisation problem yields the interior solution

$$\hat{L}^* = \frac{(\hat{S}_1 + \hat{S}_2 - S_1^n - S_2^n) - (\hat{\Pi}_2 - \Pi_2^n)}{2}. \tag{19}$$

Note that $\hat{L}^*$ is a function of $(c, s_1, s_2, \hat{p}_1, \bar{p}_2, p_1^n, p_2^n)$. The size of the transfer depends on marginal cost, the qualities of the two drugs, the regulated price and firm 1's best response, and the unregulated prices. These are variables listed as factors in PBPA (2000), which are considered by the PBPA when deciding the size of the transfer it gives to firms with drugs listed on the PBS schedule. Constraint (18) is satisfied if

$$(\hat{S}_1 + \hat{S}_2) - (S_1^n + S_2^n) \geq (\hat{\Pi}_2 - \Pi_2^n). \tag{20}$$

Assuming (20) holds, the regulator obtains a payoff of

$$\hat{S}_1 + \hat{S}_2 - \hat{L}^* = \frac{\big(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2\big) - \big(S_1^n + S_2^n + \Pi_2^n\big)}{2} + S_1^n + S_2^n, \tag{21}$$

and the firm obtains a payoff of

$$\hat{\Pi}_2 + \hat{L}^* = \frac{\big(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2\big) - \big(S_1^n + S_2^n + \Pi_2^n\big)}{2} + \Pi_2^n. \tag{22}$$

The difference $(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2) - (S_1^n + S_2^n + \Pi_2^n)$ is shown in Figure 2.

The regulator's payoff is what it gets if there is no agreement plus half the additional total surplus generated by the agreement. Similarly the firm's payoff is what it gets if there is no agreement plus half the additional total surplus generated by the agreement.

In practice, the regulator and the firm do not explicitly bargain over a transfer L, but rather bargain over the size of a per-unit subsidy, ν. However, a bargain over ν is identical to the bargain over L, so in this case

$$\hat{\nu}^* = \frac{\hat{L}^*}{\hat{q}_2}, \tag{23}$$

where $\hat{q}_2$ is the quantity the regulated firm sells at the regulated price, $\bar{p}_2$. The price the regulated firm receives for each unit sold is $p_2^a = \bar{p}_2 + \hat{\nu}^*$ and in practice is known as the *agreed price*.

The case where only the low quality firm is regulated is identical to the above except $\hat{\Pi}_1$ and Π_1^n replace $\hat{\Pi}_2$ and Π_2^n in (17). The case where both firms are regulated is similar in structure to that above except now the regulator and the two firms bargain over transfers L_1 and L_2. This problem is just an extension of Nash's bilateral bargaining problem to multilateral bargaining and is given formally in the Appendix.[4]

3.3. Stage Three - Regulator Choice of Firm to Regulate

Given the regulated price, the regulator acts to maximise surplus net of the transfer and so chooses the regulation regime that gives it the greatest $S_1 + S_2 - L^*$. As the payoffs from regulation vary according to the value of $\bar{p}_1$ and/or $\bar{p}_2$, so will the choice of which firm to regulate. Therefore, the cases considered in the previous sections will each be analysed in turn.

Case 4: $c < p_1^n < \bar{p}_1$

[4] An alternating offer game that implements the multilateral extension of the Nash bargaining solution can be found in Krishna and Serrano (1996).

By result (13),

$$\check{S}_1 + \check{S}_2 - L^* < S_1^n + S_2^n \tag{24}$$

for all $L^* > 0$. Therefore, in this case, regulating neither firm dominates regulating the low quality firm.

Case 1: $c < p_1^n < p_2^n < \bar{p}_2$

By result (8),

$$\hat{S}_1 + \hat{S}_2 - L^* < S_1^n + S_2^n \tag{25}$$

for all $L^* > 0$. In addition, where both firms are regulated, $\bar{p}_1 = \bar{p}_2 \geq p_2^n$, it is shown in the Appendix that

$$\bar{S}_1 + \bar{S}_2 - L^* < S_1^n + S_2^n \tag{26}$$

for all $L^* \geq 0$. Therefore, in this case, regulating neither firm dominates regulating only the high quality firm or regulating both firms. Combining the results of Cases 4 and 1, yields the result that neither firm is regulated if the regulation price is greater than the unregulated price of the high quality firm. This has intuitive appeal. The inequalities in (24), (25), and (26) are confirmed in the first two rows of Table 1.

Case 2a: $c < p_1^n < \alpha < \bar{p}_2 = \bar{p}_1 \leq p_2^n$

Case 4 above applies, so the low quality firm is never regulated on its own. In the Appendix, it is shown that $\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2$ is a decreasing function of $\bar{p}_2$. Therefore, using (21)

$$\hat{S}_1 + \hat{S}_2 - \hat{L}^* > S_1^n + S_2^n. \tag{27}$$

As a result, regulating the high quality firm dominates regulating neither firm. However, it is possible that regulating both firms dominates regulating just the high quality firm.

Table 1 confirms, for a particular parameterisation of the model, that regulating both firms dominates regulating just the high quality firm. This occurs at a regulated price of $\bar{p}_1 = \bar{p}_2 = 1$. If only the high quality firm was regulated, then some consumers would purchase the low quality drug because this price is greater than $\alpha = .75$.

Regulating both drugs at a price of 1 ensures the market is covered and that only the high quality drug is purchased. Although total consumer surplus is lower, $\hat{S}_1 + \hat{S}_2 > \bar{S}_2$, the profits of the high quality firm have increased to such an extent that it is given no transfer and the transfer to the low quality firm is lower than what would be given to the high quality firm if it was the sole firm regulated. It is this reduction in the transfer that makes regulating both firms dominate regulating just the high quality firm. Essentially, the low quality firm is given a transfer so it does not steal consumers away from the high quality firm.

At a price of $\bar{p}_1 = \bar{p}_2 = .85$, Table 1 reveals that regulating just the high quality firm dominates regulating both firms. Unfortunately, whether regulating both firms dominates regulating just the high quality firm is not monotonic in the regulated price and so the analysis of this case, in general, is tedious and not done.[5] The important point to take from Table 1 is that in the case under consideration it is possible that regulating both firms dominates regulating just the high quality firm.

It should be noted, that where both firms are regulated, the low quality firm makes no sales. Therefore, any transfer it receives cannot be given as a per-unit subsidy, it must be given as a lump-sum. On the other hand, the transfer given to the high quality firm can be given as a per-unit subsidy and is determined as in (23) above.

Case 2b: $c < p_1^n < \bar{p}_2 = \bar{p}_1 \leq \alpha < p_2^n$

Once again, Case 4 above applies and the low quality firm is never regulated on its own. As in Case 2a, regulating just the high quality firm dominates regulating neither. However, unlike Case 2a, regulating both firms never dominates regulating just the high quality firm. This follows because consumer surplus and the profits of each firm are identical regardless of whether just the high quality firm is regulated or both firms are regulated. In particular,

$$\bar{\Pi}_1 = \hat{\Pi}_1 = 0; \bar{\Pi}_2 = \hat{\Pi}_2; \bar{S}_1 = \hat{S}_1 = 0; \bar{S}_2 = \hat{S}_2. \tag{28}$$

[5] The lack of monotonicity can be deduced from Table 1, where at a regulated price less than, but very close to p_2^n, regulating just the high quality firm dominates regulating both firms

However, having to ensure the low quality firm a payoff of at least Π_1^n, where both firms are regulated, increases the size of the transfer relative to where only the high quality firm is regulated. This bigger transfer ensures that regulating just the high quality firm dominates regulating both firms. This is confirmed in Table 1 at $\bar{p}_2 = \bar{p}_1 = \alpha = .75$ and at a regulated price of .6.

Case 3: $c < \bar{p}_2 = \bar{p}_1 \leq p_1^n < \alpha < p_2^n$

Case 2b above applies, so regulating the high quality firm dominates regulating neither firm and regulating both firms. In the Appendix, it is shown that $\check{S}_1+\check{S}_2+\check{\Pi}_1$ is a decreasing function of $\bar{p}_1$. Therefore, using the equivalent condition to (21) for regulating the low quality firm yields

$$\check{S}_1 + \check{S}_2 - \check{L}^* > S_1^n + S_2^n. \tag{29}$$

Therefore, unlike Case 2b, in this case, regulating the low quality firm dominates regulating neither firm. This is confirmed in the last row of Table 1. The choice the regulator faces is between regulating the low quality firm or regulating the high quality firm.

The regulator's payoffs from regulating the low and the high quality firms are $\hat{S}_1 + \hat{S}_2 - \hat{L}^*$ and $\check{S}_1 + \check{S}_2 - \check{L}^*$, respectively. Subtracting these two payoffs and substituting from (21) and its equivalent for regulating the low quality firm yields

$$\begin{aligned}&(\hat{S}_1 + \hat{S}_2 - \hat{L}^*) - (\check{S}_1 + \check{S}_2 - \check{L}^*) = \\ &\frac{\left((\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2) - (S_1^n + S_2^n + \Pi_2^n)\right) - \left((\check{S}_1 + \check{S}_2 + \check{\Pi}_1) - (S_1^n + S_2^n + \Pi_1^n)\right)}{2}.\end{aligned} \tag{30}$$

The regulator chooses to regulate the high quality firm if (30) is greater than zero and the low quality firm if it is less than zero. For the case in question, $(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2) - (S_1^n + S_2^n + \Pi_2^n)$ remains constant as the regulated price changes. However, as shown in the Appendix, $(\check{S}_1 + \check{S}_2 + \check{\Pi}_1) - (S_1^n + S_2^n + \Pi_1^n)$ is a decreasing function of $\bar{p}_1$ and so reaches a maximum at $\bar{p}_1 = c$. Therefore, (30) is greater than zero for all $\bar{p}_1 < p_1^n$ if it is greater than zero at $\bar{p}_1 = c$.

Tedious calculation reveals that the difference in (30) can be written as

$$\frac{(s_2 - s_1)(-3\underline{\theta}^2 + 2\underline{\theta} + 1)}{48} \tag{31}$$

which is strictly greater than zero on the interval $\underline{\theta} \in (0,1)$. The assumptions that $\bar{\theta} = \underline{\theta} + 1$ and $\bar{\theta} > 2\underline{\theta}$ ensure that $\underline{\theta}$ falls in this interval and so regulating the high quality firm dominates regulating the low quality firm. Once again this is confirmed in the last row of Table 1. Therefore, in this case, the regulator chooses to regulate the high quality firm.

The analysis of this subsection is summarized in the following proposition.

Proposition 1: *For $\bar{p}_1 = \bar{p}_2 > p_2^n$, neither drug is regulated. For $c < p_1^n < \alpha < \bar{p}_1 = \bar{p}_2 \leq p_2^n$, the high quality drug is regulated and for some parameterisations the low quality drug is also regulated. Finally, for $c < \bar{p}_1 = \bar{p}_2 \leq \alpha$, the high quality drug is regulated.*

This proposition requires many assumptions and a deal of effort to prove and yet the intuition is clear. If the regulated price is higher than the unregulated price of the high quality drug, then regulation pushes prices closer to their joint profit maximising level and reduces the regulator's payoff. In this case, no regulation is optimal. If the regulated price is below the unregulated price of the high quality drug, then regulating the high quality drug pushes prices away from their joint profit maximising level and increases the regulators payoff. If the regulated price is relatively high, then some consumers purchase the low quality drug. In this case, by regulating both drugs the regulator ensures that only the high quality drug is purchased. In essence, the low quality firm is bribed not to steal consumers away from the high quality firm.

3.4. Stage Two - Quality Evaluation

Drugs that are submitted for evaluation have their quality determined, either high or low, at a fixed cost of k. It is assumed that there is no error in this process.

3.5. Stage One - The Evaluation Decision

In this stage, the firms decide whether to enter the evaluation and negotiation stage of the game. The high quality firm knows that the evaluation process will reveal it to be high quality and that in Stage 3 the regulator will choose to regulate it as long as $\bar{p}_2 < p_2^n$. In the bargaining stage, it is guaranteed a payoff including the transfer which is strictly greater than its unregulated profit, therefore, for small k, the high quality firm chooses to enter the evaluation and negotiation stages of the game. For $p_2^n \leq \bar{p}_2$ and any positive k, the high quality firm chooses not to enter the evaluation stage of the game as it will not be regulated, and entering reduces its payoff by k.

The low quality firm knows that the evaluation process will reveal it to be low quality and that in Stage 3 the regulator will choose to regulate it only for some $\bar{p}_1 \in (\alpha, p_2^n)$. For these regulated prices, both firms are regulated and the bargaining process guarantees the low quality firm a payoff which is strictly greater than its unregulated profit. Therefore, for small k, the low quality firm chooses to enter the evaluation and negotiation stages of the game. For all other $\bar{p}_1$ and any positive k, the low quality firm chooses not to enter the evaluation stage of the game as it will not be regulated and entering reduces its payoff by k.

The equilibrium of the stage game is summarised in the following proposition.

Proposition 2: *The sub-game perfect Nash equilibrium of the PBS stage game is for neither firm to enter the evaluation stage of the game if the regulated price is greater than or equal to the unregulated price of the high quality firm. If the regulated price is below the unregulated price of the high quality firm and k is small, then the high quality firm enters the evaluation process and has its price regulated. It receives a transfer in the form of a per-unit subsidy. If the regulated price is below the unregulated price of the high quality firm, but above α, then, for some regulated prices, the low quality firm also enters the evaluation process and has its price regulated. The low quality firm sells no output and receives a lump-sum transfer. For all other regulated prices the low quality firm does not enter the evaluation stage of the game.*

4. Discussion

4.1. Efficient Price Regulation

Pharmaceutical firms are foreign owned, so a government solely concerned with efficiency would choose the regulated price to maximise $S_1 + S_2 - L$.

Proposition 3: *A regulated price is efficient if and only if it is in the interval* $c \leq \bar{p}_2 = \bar{p}_1 \leq \alpha$.

Proof: In the Appendix

The intuition is clear. Any regulated price in this interval has an equilibrium in which only the high quality firm is regulated and all consumers purchase the high quality drug. Therefore, any price in this interval maximises the total surplus, net of disagreement payoffs, which is available to be distributed between the regulator and the high quality firm.

The interval $[c, \alpha = c + (s_2 - s_1)\underline{\theta}]$ differs for different drugs and so efficient pricing would in general have different classes of drugs being regulated at different prices. However, in Australia, all drugs are regulated at the same price.[6] For those drug classes for which the single regulated price is above the α of that drug class, a lowering of the regulated price increases the regulator's payoff and reinforces equity of access. This suggest further thought needs to be given to the policy of having a single regulated price for all drug classes.[7]

Finally, it should be noted that although a lowering of the single regulated price increases the regulator's payoff for some drug classes, for those drug classes, where the regulated price is already below α, a lowering of the regulated price leaves both the regulator's and the firm's payoffs unchanged. This latter case highlights the distributional changes associated with changes in the regulated price. The lower

[6] Although the regulated price per prescription is identical for all drugs, the price of a course of treatment can vary if different conditions and treatments require different numbers of prescriptions. Therefore, although the price per prescription is fixed, the PBPA can get effective price differences by varying the number of doses in a script. There is no evidence to suggest that the PBPA does this.

[7] Perhaps, the information requirements of having different regulated prices for different drug classes are too high.

regulated price increases consumer surplus and increases the size of the transfer needed to compensate the pharmaceutical firm for lost profit. Income has been redistributed from taxpayers, who provide the revenue the government needs to implement transfers, to the consumers of drugs.

4.2. Firm Profitability

The assumed bargaining process ensures any regulated firm obtains a greater payoff under regulation than it would if it was not regulated. For example, where $c < \bar{p}_1 = \bar{p}_2 \leq \alpha$, only the high quality firm is regulated. Its payoff is $\hat{\Pi}_2 + \hat{L}^* > \Pi_2^n$ which is the payoff it obtains in the absence of an agreement, Π_2^n, plus half the additional surplus generated by the agreement. Clearly, in this case, the high quality firm likes the PBS system.

This is true for any regulated high quality firm despite the fact that the *agreed price* is less than the unregulated price, that is $p_2^a < p_2^n$.[8] This inequality is shown to hold in the Appendix. A lower price received by the regulated firm is no indication that it is worse off. This follows because consumers only pay $\bar{p}_2$ rather than p_2^a for the high quality drug and so the regulated firm receives p_2^a on a larger quantity than it would sell in the absence of regulation. It is this increase in quantity sold that makes the PBS system attractive to high quality regulated firms. This increase in quantity sold also makes it clear that the regulator is not exploiting any monopsony power. The price the pharmaceutical firm receives has not fallen below the unregulated price because of a movement down an upward sloping supply curve, but rather as the result of a bargaining process.

Regulated low quality firms have zero sales, but receive a lump-sum transfer to ensure they are better off being regulated compared to being unregulated. On the other hand, the payoff of an unregulated low quality firm decreases as a result of the regulation of the high quality firm, in fact, $\hat{\Pi}_1 = 0$.

[8] This is a within country price inequality that cannot be verified empirically because p_2^n is not observable. However, Danzon and Chao (2002a) found, across countries, that the agreed price in regulated markets was less than the market price in unregulated markets.

In the light of this discussion, what explains the pharmaceutical industry's hostility to the PBS system? One can understand why low quality firms might be hostile, but not general hostility.[9] As the negotiation process ensures that any regulated firm gets a payoff at least as large as if no regulation was in place, it would seem the industry postures hostility to do even better than this. The industry benefits from regulation, but like all industries would like to obtain an even greater payoff and so argues that the *agreed price* is too low. In doing this, it often compares the *agreed price* to prices in the US, which are higher.[10] However, this is not appropriate. Controlling for the size of the two markets, the quantity sold at the *agreed price* in Australia under regulation would be far greater than what would be sold in the US at this same price because consumers only pay $\bar{p}_2$ under regulation, not $p_2^a = \bar{p}_2 + \nu^*$. Given this argument, it is surprising that in Australia, the PBPA encourages pharmaceutical firms to make such comparisons by stating in PBPA (2000) that one of the factors it considers when determining the *agreed price* is "prices of the drug in reasonably comparable overseas countries." The analysis of this paper suggests that all that should be looked at when determining the *agreed price* is the additional surplus regulation generates and the quantity sold at the regulated price.

4.3. Leakage

So far it has been assumed that a drug has one use, but in reality drugs can have more than one use. This does not cause a problem for the analysis above for it can be repeated for each possible use. Let there be n uses for drug x. Index these uses so that in uses $1, ..., k$ the drug is high quality and assume the regulated price is such that the high quality use is always regulated.

For uses $i = 1, ..., k$, let $\hat{L}^{*i}$ be the transfer determined in the bargaining process,

[9] In fact, a pharmaceutical firm might be a low quality producer in one class of drug, but a high quality producer in another class. Overall, a firm is better off with regulation than without if the extra payoff it achieves from being the high quality regulated firm in one class of drug (class i) is greater than the payoff it loses by being the low quality unregulated firm in another class of drug (class j), that is, if $\hat{\Pi}_2^i + \hat{L}^{*i} - \Pi_2^{ni} > \Pi_1^{nj}$.

[10] Presumably, higher prices in the US are indicative of prices and profits being high in the absence of regulation, that is, indicative of high disagreement payoffs.

let $\hat{q}_2^i$ be sales at the regulated price, and let ν^{*i} be the implied per-unit subsidy. By definition, $\nu^{*i} = \frac{\hat{L}^{*i}}{\hat{q}_2^i}$ with *agreed price*, $p_2^{ai} = \bar{p}_2 + \nu^{*i}$. Note, each use has a different *agreed price*. Now as p_2^{ai} is just a device to make a transfer to the firm and effects no production or consumption decisions, the transfer could be implemented by having one per-unit subsidy $\nu^* = \frac{\sum_1^k \hat{L}^{*i}}{\sum_1^k \hat{q}_2^i}$ with one *agreed price*, $p_2^a = \bar{p}_2 + \nu^*$. Of course, paying this *agreed price* would be restricted to uses $1, ..., k$.

In reality, the PBPA can place restrictions on subsidised use, but they are not as widespread as theory would suggest. As a result, a problem known as leakage arises.[11] Assume there are no restrictions on the subsidised use of drug x, so regardless of use, consumers pay $\bar{p}_2 = \bar{p}_1$ and the producer receives p_2^a. Consider a use $j \in (k, n]$ for which there is a competitor of high quality, but this competitor is not regulated as it has chosen not to enter the costly evaluation process. It is possible that $\bar{p}_1 < p_2(\bar{p}_1) < p_2^n$ and by enough to ensure that some consumers purchase drug x in its low quality use. Drug x in its low quality use has been given the 1 subscript while the high quality competitor has been given the 2 subscript. Regulation and the failure to enforce restrictions on subsidised use, has resulted in drug x, which was regulated for high quality uses, leaking out into a low quality use.

Although leakage increases the total transfer paid to the producer of drug x above that determined in the bargaining process, (where only uses $1, ..., k$ were considered), it also increases consumer surplus because (i) the price of the high quality drug falls below what it would be in the absence of leakage and (ii) those consumers who purchase the drug in its low quality use only do so because they obtain more surplus through this action. Therefore, leakage does not necessarily reduce the regulator's payoff. For a big enough per-unit subsidy, leakage does reduce welfare, but what is big enough depends on the parameters of the model.

In the absence of enforced use restrictions, one way to avoid the unnegotiated transfers that result from leakage is to negotiate price-volume contracts. Consider

[11] This problem is informally discussed in Birkett, Mitchell, and McManus (2001). In Canada, this problem is known as prescription creep, Laupacis (2002)

the following price-volume contract

$$p_2^a \text{ for } \mathrm{q} \leq \sum_1^{\mathrm{k}} \hat{\mathrm{q}}_2^{\mathrm{i}}; \quad \bar{\mathrm{p}}_2 \text{ for } \mathrm{q} > \sum_1^{\mathrm{k}} \hat{\mathrm{q}}_2^{\mathrm{i}}, \tag{32}$$

that is, the firm is paid the agreed price for sales no greater than the aggregate quantity associated with the regulated price in its restricted uses and the regulated price for any additional sales. This contract avoids the problem of unnegotiated transfers and so ensures that leakage increases the payoff of the regulator.

Another method of avoiding unnegotiated transfers is to make a lump-sum transfer $\sum_1^k \hat{L}^{*i}$ and not calculate an implied subsidy and agreed price. $\sum_1^k \hat{L}^{*i}$, is transferred no matter what the drugs eventual uses. If a drug has many uses, then those that are regulated are determined in the choice of use to regulate stage of the game (Stage Three), taken into account in the bargaining process (Stage Four), and incorporated in the transfer $\sum_1^k \hat{L}^{*i}$.

A problem related to leakage is the failure to account for all high quality uses in the evaluation and negotiation stages of the regulation game. Let use $f \in [1, k]$ be a high quality use that is not included in the bargaining process. Assume that restrictions on subsidised use are not in place or not enforced. Therefore, consumers who purchase drug x for use f pay the regulated price, $\bar{p}_2$, and the producer of drug x receives the *agreed price*. By assumption, this use should be regulated. If $\nu^* = \frac{\sum_1^k \hat{L}^{*i}}{\sum_1^k \hat{q}_2^i} = \nu^{*f} = \frac{\hat{L}^{*f}}{\hat{q}_2^f}$, then failing to include use f in the bargaining process is of no consequence for it is regulated and the regulator's payoff from use f is the same as if it was included in the bargaining process. However, if $\nu^* < (>) \nu^{*f}$, then the regulator's payoff is less than (greater than) what it would be if use f was included in the bargaining process. This is not leakage, but there is a problem of unnegotiated transfers which may or may not reduce the regulator's payoff.

5. Two Regulated Prices

The analysis to date has been based on there being one regulated price. However, the Australian government sets two regulated prices, one significantly lower than the other. Consumers with a certain characteristic, eg a welfare recipient, are regarded as concessional patients and can purchase at the low price, other consumers are regarded as general patients and purchase at the high price. Resale is stopped by having consumers who are eligible for the low price present documentation to this effect.

The analysis is now amended to allow for two regulated prices. This is achieved by dividing the single market for a class of drugs into two separate markets. The consumers with $\underline{\theta} \leq \theta < \theta^c$ can purchase at the lower regulated price, $\underline{p}_1 = \underline{p}_2$, and consumers with $\theta^c \leq \theta < \bar{\theta}$ purchase at the higher regulated price. $\bar{p}_1 = \bar{p}_2$.[12] The number of cases to consider is large because in addition to the two regulated prices being exogenously given to the regulator, the θ at which the market is separated, θ^c, is also exogenously given to the regulator. Therefore, only the two most interesting cases are considered.

Case 5: $c < \underline{p}_2 < \bar{p}_2 \leq \alpha < p_2^n$

In this case, the higher regulated price is below α so in the absence of the lower regulated price only the high quality firm is regulated, the market is covered, and all consumers purchase the high quality drug. The addition of the lower price, $\underline{p}_2$, for consumers with $\theta < \theta^c$, does not alter the equilibrium payoffs of either the regulator or the firm from those that occur with only the one price, $\bar{p}_2$. This follows because the additional surplus ($\hat{S}_1 = 0 + \hat{S}_2 + \hat{\Pi}_2 - S_1^n - S_2^n - \Pi_2^n$) generated by regulation is the same whether there is one regulated price or two, so from (21) and (22) the payoffs are the same with one regulated price or two. However, the transfer is not the same as $\hat{S}_2$ increases and $\hat{\Pi}_2$ decreases with the addition of the lower regulated price. Therefore, from (19) the transfer, $\hat{L}^*$, increases. As a result, the per-unit subsidy and *agreed price* also increase with the addition of the lower regulated price. The intuition is clear. The addition of the lower regulated price has no effect on the number of consumers buying the high quality drug because all consumers are

[12]Tirole 1988 provides an interpretation of θ as the inverse of the marginal rate of substitution between income and quality. Wealthier consumers have a lower "marginal utility of income" or, equivalently, a higher θ. With this interpretation, wealthier consumers pay the high price.

buying the high quality drug in the absence of the lower regulated price. Therefore, the lower regulated price increases the consumer surplus of those purchasing at the lower price at the cost of reduced profit for the high quality firm.

Case 6: $c < \underline{p}_2 \leq \alpha < \bar{p}_2 < p_2^n$

In this case, the higher regulated price is above α so in the absence of the lower regulated price either (i) only the high quality drug is regulated and some consumers purchase the low quality drug (those with a relatively low θ), or (ii) both high and low quality drugs are regulated and some consumer might not purchase either drug

First, consider (i). The addition of the lower regulated price ensures all consumers with $\theta \leq \theta^c$ purchase the high quality drug. If θ^c is greater than or equal to the θ of the consumer who is indifferent between purchasing the high or low quality drug with just the higher regulated price, then the market is covered and all consumers purchase the high quality drug. If not, then some consumers would continue to purchase the low quality drug. For the market consisting of those consumers with $\theta \leq \theta^c$, the regulated price is below α. It was shown above, in Case 2b, that for a market in which this is true, regulating just the high quality firm dominates other regulatory regimes. Therefore, the addition of the lower regulated price increases the payoff of the regulator. Once again, the intuition is clear. The addition of the lower regulated price ensures that some consumers, who in its absence, purchased the low quality drug now purchase the high quality drug. This increases the additional surplus generated by regulation and so increases both the regulator's and the regulated firm's payoffs.

Secondly, consider (ii). Both firms are regulated to stop the low quality firm stealing consumers, with a low θ, from the high quality firm. As the lower regulated price is below α, all those consumers with $\theta \leq \theta^c$ purchase the high quality drug. Assuming that θ^c is such that the market is covered and all consumers purchase the high quality drug, having two regulated prices dispenses with the need to regulate both firms. This leaves $\bar{S}_2 + \bar{\Pi}_2$ unchanged, if the market was covered with just the higher regulated price, but increases it to $\hat{S}_2 + \hat{\Pi}_2$, if the market was uncovered with just the higher regulated price. With two regulated prices, there is no need to include the low quality firm in the bargaining process (no consumers are stolen by the low quality firm), so the regulator's payoff is greater with two regulated prices and just the high quality firm being regulated, than with one regulated price and both firms being regulated. It should be noted that the high quality firm's payoff is also greater with two regulated prices than one.

An implication of Cases 5 and 6 is that having two regulated prices only increases the regulator's payoff if the higher regulated price is above α. Two regulated prices would not be needed if one regulated price was in place and set below α. In fact, this follows directly from Proposition 3. The arbitrariness of the regulated price and the fact that it is the same for all drug classes is what introduces the possibility that two regulated prices might lead to a greater payoff for the regulator. Once again, equity of access seems to be the main driving force behind the setting of regulated prices rather than efficiency.

Equity of access and efficiency can both be achieved if regulated prices are set below the α of the relevant drug class. However, this may involve large transfers being paid to the regulated firm/s. Although these transfers have been accounted for in the regulator's payoff, the revenue that has to raised to implement these transfers may have political or deadweight loss costs that need to be taken into account. For a particular drug class, having one price below α and another price above α (that still leaves the market covered), reduces the size of the transfer and so can make regulation with two prices more attractive to the regulator than regulation with one price.

5.1. The Safety Net

To ensure equity of access, the PBS system includes general patient and concessional patient safety net thresholds.[13] When a general patient's and/or their family's expenditure on drugs in a calendar year reaches the threshold, they become concessional patients and pay the concessional regulated price. When a concessional patient's and/or their family's expenditure on drugs in a calendar year reaches the threshold they receive drugs free of charge.

Incorporating the safety net into the analysis is straighforward. For Cases 5 and 6 an additional regulated price of zero increases $\hat{S}_2$ and decreases $\hat{\Pi}_2$ by an equal amount. Therefore, $\hat{S}_2 + \hat{\Pi}_2$ is unchanged as are the regulator's and firm's payoffs. $\hat{L}^*$ increases so the zero price leads to a pure transfer from the regulator to those who consume at the zero price. For the case where $0 < \alpha < \underline{p}_2 < \bar{p}_2$, the introduction of a zero price for some consumers is qualitatively identical to Case 6 above and so increases the regulator's and the high quality firm's payoffs..

6. Exogenous Innovation and Regulation

To date it has been implicitly assumed that the stage game outlined in section 3 is repeated every period. If nothing in the environment changes, then the equilibrium of the game does not change either. In this section, it is assumed that a new drug exogenously becomes available. This changes the environment of the stage game and so can change which drug is regulated and the size of any transfer.

6.1. A New Low Quality (Generic) Drug

Assume firm 0 can produce a new drug of low quality, where $s_0 \leq s_1$. This firm will be called the generic firm and the drug it produces the generic drug.[14] The question to address is how the presence of this firm effects the equilibrium of the PBS stage

[13] Currently the general patient threshold is A\$686-40 and the concessional patient threshold is A\$187-20.

[14] The physical properties of the generic drug may be identical to those of the low quality drug, but might be perceived by consumers as of lower quality.

game?

6.1.1. Stage Five

No Firm Regulated

The demands of each firm are given by

$$D_0 = \frac{P_1 - P_0}{s_1 - s_0} - \underline{\theta}; \quad D_1 = \frac{P_2 - P_1}{s_2 - s_1} - \frac{P_1 - P_0}{s_1 - s_0}; \quad D_2 = \bar{\theta} - \frac{P_2 - P_1}{s_2 - s_1}. \tag{33}$$

The case of most interest is where it is profitable for the generic firm to produce. This requires that $\underline{\theta} \leq \frac{s_2 - s_1}{3(s_2 - s_0)}$ and is assumed.[15] The best response functions are

$$P_0 = \frac{P_1 + c - (s_1 - s_0)\underline{\theta}}{2}; \quad P_2 = \frac{P_1 + c + (s_2 - s_1)\bar{\theta}}{2} \tag{34}$$

and

$$P_1 = \frac{c}{2} + \frac{P_2(s_1 - s_0) + P_0(s_2 - s_1)}{2(s_2 - s_0)}. \tag{35}$$

The expressions for the Nash equilibrium prices are messy and are not given, however, they are denoted, P_0^n, P_1^n, and P_2^n. Not surprisingly, it can be shown that the introduction of the generic drug reduces the equilibrium prices of drugs 1 and 2 below what they would be in the absence of the generic, that is,

$$P_1^n < p_1^n \quad P_2^n < p_2^n. \tag{36}$$

The intuition is clear. The generic competes directly with the low quality firm, so in equilibrium the low quality firm's price is lower than in the absence of the generic. As the low quality firm's price is lower and prices are strategic complements, the equilibrium price of the high quality firm is also lower than in the absence of the generic.

High Quality Firm Regulated - Other Firms Unregulated

Let $\phi_0 = c + 2\underline{\theta}(s_2 - s_0)$, and the regulated price be $\bar{P}_2$. Note that $\phi_0 > \alpha$. At $\bar{P}_2 = \phi_0$, calculation reveals that in equilibrium $P_1(\bar{P}_2) = c + (s_1 - s_0)\underline{\theta} = \alpha_0$ and $P_0(\bar{P}_2) = c$. The equilibrium price of firm 1 is such that the generic firm prices at

[15] If this condition is satisfied, then the unregulated Nash equilibrium price of the generic firm is at least as large as marginal cost.

marginal cost and makes no sales. Note the similarity of α_0 to α. The following apply, (i) if $\bar{P}_2 > \phi_0$, then all three firms can profitably produce; (ii) if $\phi_0 \geq \bar{P}_2 > \alpha$, then firms 1 and 2 can profitably produce; and finally, (iii) if $\bar{P}_2 \leq \alpha$, then only firm 2 can profitably produce.

6.1.2. The Other Stages

To keep the effects of the introduction of a generic drug as transparent as possible only the more interesting cases are considered and the analysis is made less formal.

Case 7: $c < \bar{P}_2 \leq \phi_0 < P_2^n$

Although it is profitable for the generic firm to produce in the absence of regulation, in the presence of regulation, it is not. The analysis of the various stages of the game is identical to that in the previous sections except that the disagreement payoffs of firms 1 and 2 are lower. Therefore, the negotiated transfer/s to firm 2, if only the high quality firm is regulated, or firms 1 and 2, if both firms are regulated, is/are smaller and the regulator's payoff is larger than in the absence of the generic firm.

The mere presence of the generic firm has increased the payoff of the regulator even though the generic firm makes no sales. However, to realise this larger payoff requires the regulator to renegotiate the size of the transfer and the implied *agreed price* that is paid to the regulated firm/s. Failure to do so results in a failure to extract all the benefits that the presence of a generic drug can bring.

Case 8: $c < P_2^n < \bar{p}_2 = \bar{P}_2 = \bar{P}_1 = \bar{P}_0 < p_2^n$.

In this case, the regulated price is below the unregulated price of the high quality firm in the absence of the generic firm, but above the unregulated price of the high quality firm in the presence of the generic firm. In the absence of the generic firm, it was shown in the preceding sections, that either the high quality firm is regulated or both the high and low quality firms are regulated. However, in the presence of the generic firm, the regulator chooses not to regulate any firm in stage three. In this case, any regulated drug should be removed from the PBS list and have its per-unit subsidy removed. The extra competition generated by the generic firm results in equilibrium prices that are below the regulated level and so no regulation is necessary.

Failure to remove any regulated drug from the PBS list commits regulated firms to prices greater than the unregulated prices and so induces higher equilibrium prices from the unregulated firm/s.[16] This reduces the regulator's payoff below the case where regulated drugs are removed from the PBS lists, because (i) consumer surplus is lower and (ii) the per-unit subsidy results in the high quality firm receiving a transfer.

6.2. A New Higher Quality Drug

Assume firm 3 can produce a new drug of extra high quality $s_3 \geq s_2$. This firm will be called the best firm and the drug it produces the best drug.

6.2.1. Stage Five

With an appropriate relabelling, the analysis is identical to that in the previous subsection. Firm 0 is now firm 1, firm 1 is now firm 2, and firm 2 is now firm 3. Let $\phi_3 = c + 2\underline{\theta}(s_3 - s_1)$ and $\alpha_3 = c + (s_3 - s_2)\underline{\theta}$.

6.2.2. The Other Stages

Once again only a few cases are considered.

Case 7a: $c < \bar{P}_3 = \bar{P}_2 = \bar{P}_1 = \bar{p}_2 < \alpha$ *and* $\alpha_3 < \phi_3 < P_3^n < p_2^n$

In the absence of firm 3, firm 2 is regulated and firm 1 is not. In the presence of firm 3, this case is similar in structure to Case 7 above and the regulator chooses to regulate the best firm, firm 3. Firms 1 and 2 price equal to marginal cost and make no sales. The regulator's payoff has increased with the addition of the best firm because it produces the highest quality drug and yields the largest additional surplus from a regulation agreement. For small k, firm 3 enters the evaluation stage

[16] The failure to remove regulation in the presence of generic drugs provides another explanation for the finding of Danzon and Chao (2000b) that there is little price competition between generic drug producers in regulated markets.

as the bargaining process ensures it obtains a payoff larger than its disagreement payoff. In this case, it does not matter whether firm 2 is removed from the regulation list or not because under either scenario its makes no sales and receives no transfer.[17]

Case 8a: $c < P_3^n < \bar{p}_2 = \bar{P}_3 = \bar{P}_2 = \bar{P}_1 < \alpha < \phi_3 < p_2^n$

In the absence of firm 3, firm 2 is regulated and firm 1 is not. However, in the presence of firm 3, s_3 is such that P_3^n is less than the regulated price.[18] Therefore, in the presence of firm 3, the regulator chooses not to regulate any firm. Competition between firms 2 and 3 is so fierce that it is better to not regulate than regulate at the given regulation price. This case is identical in structure to Case 8 above and failure to remove firm 2 from the PBS list reduces the regulator's payoff.

7. Conclusion

Although the model of pharmaceutical regulation developed in this paper is relatively simple and based on the Australian Pharmaceutical Benefits Scheme, it is a very rich model with many implications for pharmaceutical regulation that extend beyond the Australian setting. The first is that although the regulated price is chosen to ensure equity of access, it also has efficiency implications that should be considered when its level is set. These efficiency consideration suggest the policy of having a single identical price for all drug classes needs to be re-examined. If the regulated price is the same for all drug classes, then having a different regulated price for different groups of consumers using a drug of a particular class, can increase the regulator's payoff. However, it should be noted that using two regulated prices within a drug class would not be needed if the regulated price differed between drug classes and was chosen with efficiency and equity in mind.

Secondly, although the negotiated *agreed price* is below the unregulated price of the high quality drug, high quality pharmaceutical firms that are regulated achieve

[17] Firm 2 receives no transfer if the transfer is made via a per-unit subsidy, but if it is made as a lump-sum firm 2 would have to be removed from the regulation list and its transfer reduced to zero.

[18] This can arise when the difference $s_3 - s_2$ is small, in fact, if $s_3 = s_2$, then $P_3^n = c$.

greater payoffs than they do in the absence of regulation. In this light, the hostility of the pharmaceutical industry to regulation and the claim that it reduces profit can be viewed as an attempt to extract more of the total additional surplus, generated by regulation, in the bargaining process.[19]

Thirdly, leakage does not necessarily reduce the regulator's payoff, because although it increases transfers above what are negotiated it also increases consumer surplus. Unnegotiated transfers arise because restrictions on subsidised use are not enforced. Methods to avoid unnegotiated transfers include, enforcement of restrictions, use of price-volume contracts, or the use of lump-sum transfers rather than per-unit transfers. Finally, the introduction of new drugs, of low or high quality, necessitates the renegotiation of existing regulatory arrangements including the removal of drugs from regulation if all the benefits from new drugs are to be realised.

In this paper, pharmaceutical regulation was modelled from the perspective of a small country so that regulatory decisions did not effect R&D. Future research will be aimed at extending the framework of this paper to the case of a large country, where firm payoffs have a significant effect on R&D expenditure.

[19]The same argument applies to the view that pharmaceutical regulation, along the lines of the Australian PBS, inhibits R&D by reducing firm payoffs.

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9. Appendix

Proof that $\hat{S}_1 + \hat{S}_2$, $\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2$, and $\check{S}_1 + \check{S}_2 + \check{\Pi}_1$ are decreasing functions of $\bar{p}_2 = \bar{p}_1$.

$$\hat{S}_1 + \hat{S}_2 = \int_{\underline{\theta}}^{\tilde{\theta}(p_1,p_2)} (\theta s_1 - p_1(p_2))d\theta + \int_{\tilde{\theta}(p_1,p_2)}^{\bar{\theta}} (\theta s_2 - p_2(p_1))d\theta \tag{37}$$

Differentiating (37) with respect to p_2 and using the fact that $\tilde{\theta}s_1 - p_1 = \tilde{\theta}s_2 - p_2$ at $\tilde{\theta}$ yields

$$\frac{\partial(\hat{S}_1 + \hat{S}_2)}{\partial p_2} = \tilde{\theta}(\cdot) - \bar{\theta} + \frac{\partial p_1}{\partial p_2}(\underline{\theta} - \tilde{\theta}(\cdot)) < 0 \tag{38}$$

because prices are strategic complements and $\underline{\theta} \leq \tilde{\theta} \leq \bar{\theta}$.

$$\hat{\Pi}_2 = (p_2(p_1) - c)(\bar{\theta} - \tilde{\theta}(p_1, p_2)) \tag{39}$$

Differentiating (39) with respect to p_2 yields

$$\frac{\partial\hat{\Pi}_2}{\partial p_2} = \bar{\theta} - \tilde{\theta}(\cdot) - (p_2 - c)\frac{\partial\tilde{\theta}}{\partial p_2} \tag{40}$$

Combining (38) and (40) yields

$$\frac{\partial(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2)}{\partial p_2} = \frac{\partial p_1}{\partial p_2}(\underline{\theta} - \tilde{\theta}(\cdot)) - (p_2 - c)\frac{\partial\tilde{\theta}}{\partial p_2} \leq 0 \tag{41}$$

because $\frac{\partial\tilde{\theta}}{\partial p_2} \geq 0$. For $p_2 \leq \alpha$, $\underline{\theta} = \tilde{\theta}$ and (41) equals zero while for $p_2 > \alpha$ (41) is strictly less than zero.

The proof that $\check{S}_1 + \check{S}_2 + \check{\Pi}_1$ is a decreasing function of $\bar{p}_2 = \bar{p}_1$ is identical to that above after relabelling.

The Bargaining Problem where Both Firms are Regulated

The bargaining solution for L_1 and L_2 is assumed to be the solution to the following problem

$$\max_{L_1,L_2} NP \equiv (\bar{S}_1+\bar{S}_2-L_1-L_2-S_1^n-S_2^n)\times(\bar{\Pi}_1+L_1-\Pi_1^n)\times(\bar{\Pi}_2+L_2-\Pi_2^n) \quad (42)$$

subject to

$$L_1 \geq 0; \quad L_2 \geq 0 \quad (43)$$

Assuming an interior solution, solving the first order conditions, and substituting into the regulator's payoff yields

$$\bar{S}_1+\bar{S}_2-\bar{L}_1^*-\bar{L}_2^* = \frac{(\bar{S}_1+\bar{S}_2+\bar{\Pi}_1+\bar{\Pi}_2)-(S_1^n+S_2^n+\Pi_1^n+\Pi_2^n)}{3}+S_1^n+S_2^n. \quad (44)$$

The regulator's payoff is the payoff it gets in the absence of an agreement plus one third of the additional surplus generated by the agreement. The same logic applies to the payoffs of the two firms.

Proof of (26) in the Text.

Where both firms are regulated at $\bar{p}_1=\bar{p}_2=p_2^n$, those consumers who purchased the low quality drug in the absence of regulation, consume the high quality drug or no drug under regulation. As these consumer could have done this in the absence of regulation, but chose not to, it follows that

$$\bar{S}_1(=0)+\bar{S}_2 < S_1^n+S_2^n \text{ at } \bar{\mathrm{p}}_1=\bar{\mathrm{p}}_2=\mathrm{p}_2^{\mathrm{n}}. \quad (45)$$

A similar argument establishes that

$$\bar{S}_2 < \hat{S}_1+\hat{S}_2 \quad \forall \quad \bar{p}_1=\bar{p}_2>p_2^n \quad (46)$$

which combined with (8) of the text yields

$$\bar{S}_2 < S_1^n+S_2^n \quad \forall \quad \bar{p}_1=\bar{p}_2\geq p_2^n. \quad (47)$$

Therefore,

$$\bar{S}_1(=0)+\bar{S}_2-L^* < S_1^n+S_2^n \quad \forall \quad L^*\geq 0. \quad (48)$$

Proof of Proposition 3: It suffices to show that any regulated price in the interval $\alpha < \bar{p}_2 = \bar{p}_1 \leq p_1^n$ has a smaller payoff than any price in the interval $c \leq \bar{p}_2 = \bar{p}_1 \leq \alpha$, and that all prices in the latter interval have the same payoff.

For a regulated price in the interval $c \leq \bar{p}_2 = \bar{p}_1 \leq \alpha$, the high quality firm enters, is regulated, and receives payoff

$$\hat{S}_1 + \hat{S}_2 - \hat{L}^* = \frac{\left(\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2\right) - \left(S_1^n + S_2^n + \Pi_2^n\right)}{2} + S_1^n + S_2^n, \tag{49}$$

Now $\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2$ is independent of $\bar{p}_2$ over this interval, therefore, all regulated prices in this interval have the same payoff. It was shown above that $\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2$ is a decreasing function of $\bar{p}_2$ over the interval $\alpha \leq \bar{p}_2 = \bar{p}_1 \leq p_1^n$. Therefore, $\hat{S}_1 + \hat{S}_2 + \hat{\Pi}_2$ reaches a maximum at $\bar{p}_2 = \alpha$, and any regulated price in the interval $\alpha < \bar{p}_2 = \bar{p}_1 \leq p_1^n$ has a smaller payoff than any price in the interval $c \leq \bar{p}_2 = \bar{p}_1 \leq \alpha$, for the case where the high quality firm is regulated.

What about where both firms are regulated? The regulator's payoff is

$$\bar{S}_2 + \bar{S}_1 - \bar{L}_1 - \bar{L}_2 = \frac{(\bar{S}_2 + \bar{S}_1 + \bar{\Pi}_1(= 0) + \bar{\Pi}_2) - (S_1^n + S_2^n + \Pi_1^n + \Pi_2^n)}{3} + S_1^n + S_2^n. \tag{50}$$

At $\bar{p}_2 = \bar{p}_1 = \alpha$, (50) is less than (49), because of the inclusion of Π_1^n and the division by 3. Now (50) is independent of $\bar{p}_2 = \bar{p}_1$ over the interval $[\alpha, 1]$ and decreasing over the interval $[1, p_2^n]$. Therefore, $\bar{S}_2 + \bar{S}_1 - \bar{L}_1 - \bar{L}_2$ reaches a maximum at $\bar{p}_2 = \bar{p}_1 = \alpha$, and any regulated price in the interval $\alpha < \bar{p}_2 = \bar{p}_1 \leq p_1^n$ has a smaller payoff, for the case where both firms are regulated, than any price in the interval $c \leq \bar{p}_2 = \bar{p}_1 \leq \alpha$, for the case where the high quality firm is regulated.

Proof that $p_2^a < p_2^n$.

Consider the case where $\bar{p}_2 \leq \alpha$, that is, only the high quality firm is regulated and it covers the market. *Suppose* $p_2^a \geq p_2^n$.

$$\begin{aligned}
\hat{S}_2 - S_2^n + \hat{S}_1(=0) - S_1^n &= \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_2 - \bar{p}_2) d\theta + \int_{\tilde{\theta}}^{\bar{\theta}} (p_2^n - \bar{p}_2) d\theta - \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_1 - p_1^n) d\theta \\
&= \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_2 - p_2^n) d\theta + \int_{\underline{\theta}}^{\tilde{\theta}} (p_2^n - \bar{p}_2) d\theta + \int_{\tilde{\theta}}^{\bar{\theta}} (p_2^n - \bar{p}_2) d\theta \\
&- \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_1 - p_1^n) d\theta \\
&= (p_2^n - \bar{p}_2) + \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_2 - p_2^n) d\theta - \int_{\underline{\theta}}^{\tilde{\theta}} (\theta s_1 - p_1^n) d\theta \\
&< (p_2^a - \bar{p}_2) \qquad (51)
\end{aligned}$$

The last inequality follows because, in the absence of regulation, consumers in the interval $[\underline{\theta}, \tilde{\theta}]$ purchase the low quality drug. Rearranging (51) yields

$$\hat{S}_1 + \hat{S}_2 - (p_2^a - \bar{p}_2) < S_1^n + S_2^n. \qquad (52)$$

Now $p_2^a - \bar{p}_2$ is the implied transfer under the agreed price and its size contradicts (27) of the text. Therefore, the supposition is incorrect. A similar proof can be constructed for the case where $\bar{p}_2 > \alpha$.

Table 1

c=.25, $\underline{\theta} = .5,\ \bar{\theta} = 1.5,\ s_1 = 1,\ s_2 = 2.$

$\bar{p}_2, \bar{p}_1$	$S_1^n + S_2^n$	$\hat{S}_1 + \hat{S}_2$	$\hat{L}^*$	$\hat{S}_1 + \hat{S}_2 - \hat{L}^*$	$\check{S}_1 + \check{S}_2$	$\check{L}^*$	$\check{S}_1 + \check{S}_2 - \check{L}^*$	$\bar{S}_2$	$\bar{L}_1$	$\bar{L}_2$	$\bar{S}_2 - \bar{L}_1 - \bar{L}_2$
1.2	.9306	.8253			.525			$.81^u$			.81
$p_2^n = 1.087$	.9306	.9306			.5833			$.9184^u$			.9184
1	.9306	1.0078	.0577	.9501	.625			1	.0486	0	.9514
.85	.9306	1.1512	.1726	.9787	.7			1.15	.0602	.1269	.963
$\alpha = .75$	.9306	1.25	.2569	.9931	.75			1.25	.0602	.2269	.963
.6	.9306	1.4	.4069	.9931	.8278			1.4	.0602	.3769	.963
$p_1^n = .41$	.9306	1.5833	.5903	.9931	.9306	0	.9306	1.6684	.0602	.5602	.963
.3	.9306	1.7	.7069	.9931	1.0003	.0431	.9571	1.8225	.0602	.6769	.963

A "u" superscript denotes a situation where the market is uncovered.

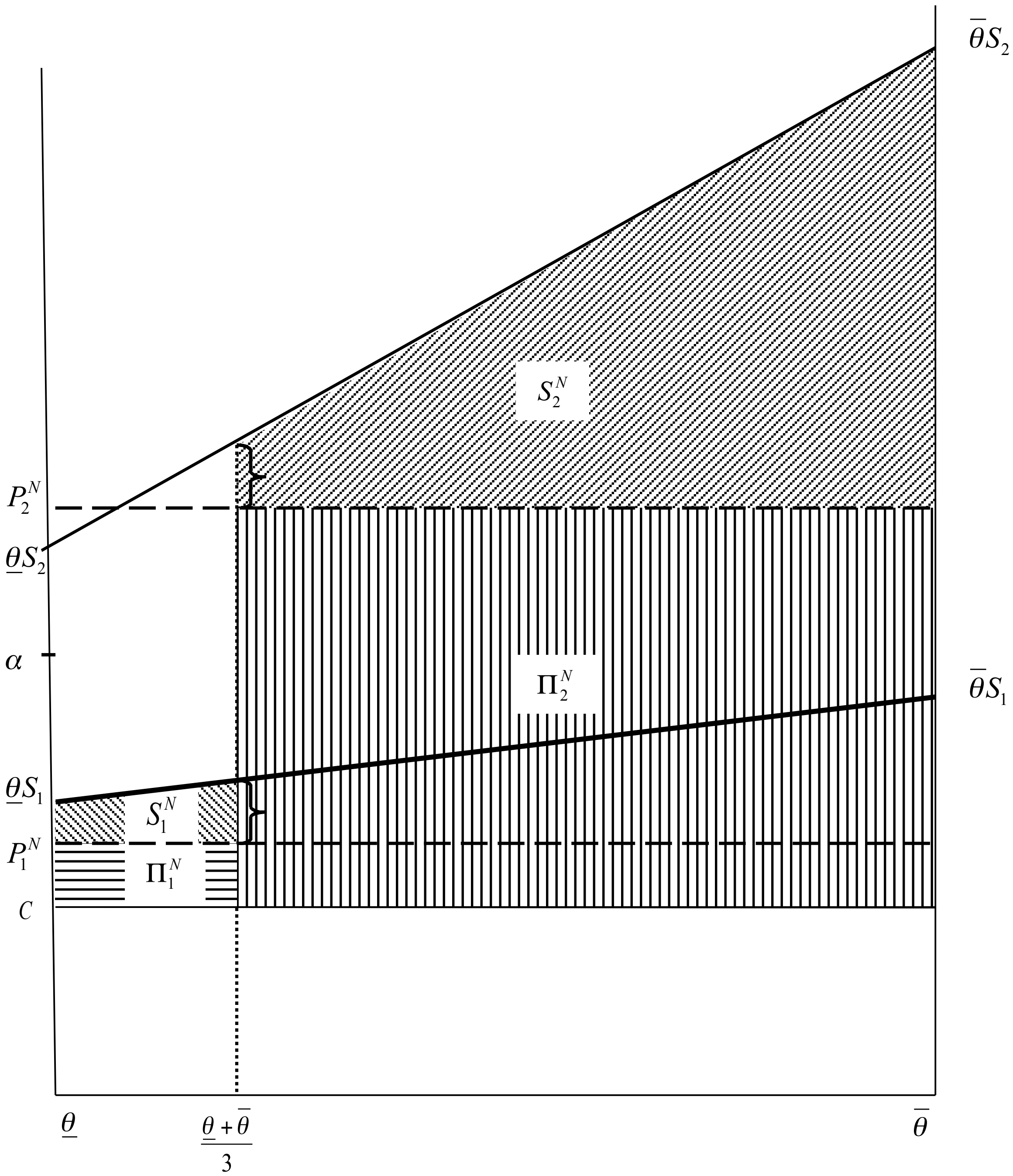
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Figure 1

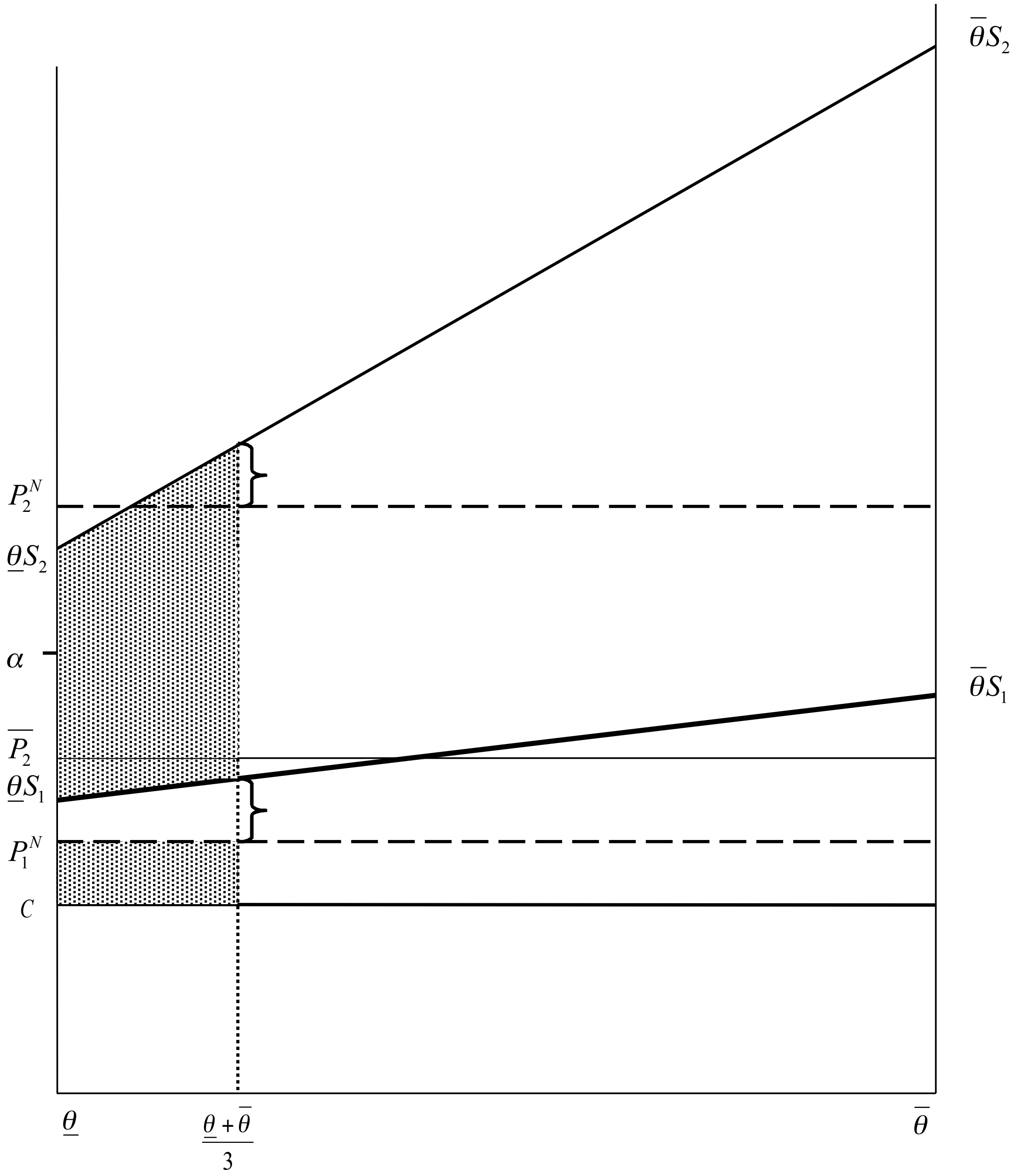
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Figure 2

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