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INSURANCE AGENCIES: WHAT IMPACT ON PATIENTS?**

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The Use of Secret Rebates by Provincial Drug Insurance Agencies: What impact on patients?

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1. Introduction

British Columbia's provincial drug insurance plan, PharmaCare, has recently introduced a novel mechanism to obtain price reductions for PharmaCare. It has instituted a sole-sourcing arrangement for a generically available drug in which a single firm is contracted to be the only listed supplier for all of British Columbia (BC). The single supplier may charge a high price but must pay a rebate to PharmaCare for every sale made which is fully or partly insured by PharmaCare. The rebate amount is confidential under the agreement.

This mechanism is now in use for one product – olanzapine, which is used to treat schizophrenia and other mental disorders. Olanzapine is generically available everywhere else in Canada, but in BC, only the branded product, known as “Zyprexa” and made by Eli Lilly, is available, because Lilly was awarded the sole-sourcing arrangement with the province.¹

This short paper assesses this mechanism. It first demonstrates that the approach to sole-sourcing used by BC results in substantially higher prices for consumers whose purchases are not 100% insured by PharmaCare. While the sole-sourcing has been defended as being similar to that employed in New Zealand, this paper shows that in fact the approach employed in BC, with its secret rebates to the province, is completely different from that used in New Zealand. Finally, the paper discusses the effects of sole-sourcing with secret rebates on competition in generic drug markets. There are reasons for concern that sole-sourcing combined with secret rebates may undermine competition in generic drug markets and ultimately result in higher costs to patients and insurers.

2. How does PharmaCare's sole-sourcing mechanism work?

Eli Lilly has been selling olanzapine under the tradename “Zyprexa” for many years. Novopharm, a generic drug manufacturer, challenged Lilly's patents on the grounds of invalidity under the special regulations created for pharmaceuticals under the Patent Act.

¹ The province has not been willing to state whether such a sole-sourcing contract was awarded; however, Zyprexa is the only brand of olanzapine listed on the PharmaCare formulary, so I assume that it was awarded.

Lilly abandoned one infringement claim and a second patent was declared invalid, and Novopharm was granted a “Notice of Compliance” by Health Canada to sell a generic form of the drug. A Notice of Compliance was subsequently given to another generic drug manufacturer, Pharmascience. Other provinces have listed Novo-olanzapine and PMS-olanzapine in their formularies at substantial discounts to Zyprexa.

The BC government, alone among provinces, issued a “request for proposals” in December 2007, asking firms to bid for the right to be the sole supplier of olanzapine to be listed on the provincial formulary, or list of drugs covered by PharmaCare. Firms were required to include two prices in their proposal: a list price, at which the drug would actually be listed and sold to consumers; and a “cost recovery amount” or rebate which was to be paid by the firm to the provincial government for each pill insured in whole or in part by PharmaCare.

Ultimately, Lilly was awarded the sole-sourcing contract, with a list price for Zyprexa under the contract that was 6% higher than before. The rebate paid to PharmaCare is confidential under the terms of the contract.

The sole-sourcing contract provides that only one firm’s olanzapine will be listed on the BC formulary, but it does not bar other manufacturers from selling olanzapine in British Columbia provided they have obtained a Notice of Compliance from Health Canada. However, in practice, the sole-sourcing contract means that there cannot be meaningful sales of olanzapine made by any competing firm. Those consumers whose purchases of olanzapine are insured by PharmaCare will certainly prefer to buy the sole-sourced item, since any other form of olanzapine would not be covered by PharmaCare; those consumers whose purchases are covered by private insurance will prefer the sole-sourced product, since typically third-party insurers harmonize their product list with that of PharmaCare; and those consumers who are uninsured will prefer to purchase the sole-source olanzapine since that brings them closer to their deductible limit, while competitive olanzapine would not bring them closer to their deductible limit.² In these circumstances, since demand for competitive, lower-priced olanzapine would be so small, pharmacies are unlikely to stock it.

3. The effect of sole-sourcing with secret rebates on prices and consumer welfare

A starting point for analyzing the impact of the sole-sourcing agreement for olanzapine is an examination of prices. PharmaCare has defended its sole-sourcing strategy on the basis that “the province is acting in the public interest to achieve the lowest drug prices possible for the people of British Columbia.” In fact, the “people” of British Columbia are paying the *highest* prices for olanzapine in Canada.

The table below shows the current wholesale prices of olanzapine in BC and Alberta. (In each case, the lowest priced brand is shown.)

² I confirmed this with a call to the PharmaCare help desk on May 15, 2008, 11:11am. I was informed that any drug that was a non-benefit would not count as an eligible expense.

	BC (\$)	Alberta (\$)	% price difference
2.5mg	1.92	1.18	63%
5mg	3.85	2.36	63%
7.5mg	5.77	3.54	63%
10mg	7.69	4.73	63%
15mg	11.54	7.09	63%

Many patients in BC have 100% coverage of their purchases of olanzapine, under PharmaCare’s Plan G, and those patients are of course indifferent to the nominal price. However, for all other patients, either they or their insurers (if they have private insurance through work or some other plan) must pay 63% more than they would in the absence of the sole-sourcing agreement.

PharmaCare has reason to be pleased with the outcome, since it is receiving its secret rebate. A reasonable assumption is that the secret rebate is sufficiently large to lower the net price of olanzapine, when insured by PharmaCare, below the generic price available in the rest of Canada. Note that PharmaCare is only able to get this low price by allowing Lilly to charge more for olanzapine to those consumers who are not fully insured by PharmaCare. It is instructive to see exactly how this works, using examples relating to patients whose purchases of olanzapine are not 100% covered by PharmaCare.

Example 1: Mary V.

Mary V. suffers from schizophrenia. Her doctor has prescribed 10mg of olanzapine daily, and she stays on it for six months. Zyprexa 10mg pills are priced in BC at \$7.69 each, so for 180 days, the total cost will be \$1384. Mary’s family income is \$55,000 a year. This means, under BC’s “Fair PharmaCare” plan, that her family deductible is \$1650 (= 3% × \$55,000), and she must pay the full cost of all drugs until her expenses exceed that amount.³ The rules mean that Mary doesn’t benefit from PharmaCare at all, and she pays far more than without the sole-sourcing arrangement. If Mary had purchased her pills in Alberta, she could have purchased the generic version and saved \$533.

Example 2: Bob L.

Bob L. suffers from bipolar disorder. Unlike Mary, he has already reached his deductible limit, so for every tablet of olanzapine, he is supposed to pay only 30% of the price of the medicine, while PharmaCare picks up 70%. Bob pays 30% of \$7.69 per pill, or \$2.31. PharmaCare pays the rest (\$5.38 per pill) but receives a secret rebate. We don’t know how large this rebate is: a conservative assumption is that the rebate is \$3.00 per tablet, bringing the cost to PharmaCare slightly below what it would pay for a generic. Now PharmaCare’s net cost is only \$2.38 each. Notice that, even though he is only supposed to be paying 30%, Bob is actually paying almost 50% of the net cost of the medicine.

³ British Columbia has a special “No-Charge Psychiatric Medication Plan” (Plan G) which is available to individuals who are registered with a mental health service centre and who demonstrate clinical and financial need. Under that plan, Zyprexa is listed as limited coverage with special authority approval required. (See <http://www.health.gov.bc.ca/pharme/outgoing/plangtable.html>, last accessed May 22 2008.) Persons without financial need, such as Mary, would not be eligible.

It is apparent why PharmaCare finds this an attractive solution. Without sole sourcing, the generic price would have been \$4.73 per pill. PharmaCare would have paid 70%, or \$3.31, and Bob would have paid the other 30%, or \$1.42. With sole-sourcing, Bob pays more, since he is paying 30% of a higher price. So the province saves both ways: it makes the patient pay more, and it benefits from a lower net price from the seller. (However, it is important to recall that the province is only able to get this lower net price from the seller because the seller is permitted to charge a much higher price to other patients, such as Mary V., whose purchases are not insured by the province.)

The situation of Bob and Mary with and without sole-sourcing is shown in the table below:

	Mary V.		Bob L.	
	Competitive Market	Sole-sourcing	Competitive Market	Sole-sourcing
Price for 10mg tablet	\$4.73	\$7.69	\$4.73	\$7.69
PharmaCare contribution	\$0.00	\$0.00	\$3.31	\$5.38
Assumed secret rebate	\$0.00	\$0.00	\$0.00	\$3.00
Net cost to PharmaCare	\$0.00	\$0.00	\$3.31	\$2.38
Net cost to patient	\$4.73	\$7.69	\$1.42	\$2.31
Revenue of seller	\$4.73	\$7.69	\$4.73	\$4.69

As this table shows, for patients whose drugs are covered by PharmaCare (at least in part), the total price paid to the seller may in fact be lower than with competitive sales; however, the seller is compensated by being able to charge higher prices for those purchases which are not covered by PharmaCare. So while PharmaCare’s costs are reduced, the “people” of British Columbia, whether covered or not covered, end up paying more for their drugs when they are sick. Thus, sole-sourcing is almost exactly like the reverse of insurance: normally insurance reduces the net price the patient pays for a drug. Sole-sourcing increases the price.

It is possible for the rebate to PharmaCare to be larger than the amount that it pays, so that PharmaCare could even make profits from “insuring” certain drugs. For example, suppose in the above example that the rebate to PharmaCare was \$5.50 per 10mg tablet. The seller could be willing to pay a large rebate, if it received the right to charge a high price on all purchases, including those not covered by PharmaCare. In this case, PharmaCare’s contribution to the cost of the drug would be only \$5.38, so for every pill consumed, PharmaCare would make a *profit* of \$0.12.

An analogy

It is possible to get a clearer perspective on the real point of sole-sourcing with secret rebates by putting it in a totally different context. Suppose the government established a sole-sourcing agreement with a car manufacturer, whereby that firm would be the only authorized seller of vehicles in the province, and could charge monopoly prices to consumers. The firm would however be required to supply all vehicles required by the government at an undisclosed low price. It is obvious what would happen: the government would save money – perhaps it would even be able to get all its vehicles for free – but it would be able to do so only at a cost to consumers, since they would have to pay monopoly prices.

The car example, as far-fetched as it seems, is perfectly analogous to PharmaCare’s agreement with Lilly. The government, in order to get a good deal on its purchases of olanzapine, is giving one firm the right to be the only authorized seller and to charge monopoly prices to patients.

The sole-sourcing approach is problematic in a number of ways. First, it can be seen simply as a tax on those individuals whose purchases of olanzapine are either not covered by PharmaCare or are only partly covered by PharmaCare. These patients pay more so that PharmaCare can save. But such a tax is inconsistent with the principle of tax equity, since it specifically targets sick people to raise revenues.⁴ (Note that patients like Mary V. are being taxed without receiving any compensating benefit.) Second, the tax is inefficient since some patients will inevitably be deterred from taking their medicines because of the high prices the sole-sourcing arrangement enables. Failure to be effectively treated may lead to higher healthcare costs in the long run. Third, the sole-sourcing arrangement means that PharmaCare does not actually pay for the percentage of drug it claims to. Evidently, from a patient perspective, sole-sourcing combined with secret rebates is undesirable.

4. The BC and NZ approaches to sole-sourcing

According to a recent article in the Vancouver Sun, BC Health Minister George Abbott explained that the tendering concept came from New Zealand, and justified its use on the basis that it had been successful there.

New Zealand has for several years used sole-sourcing of generically available medicines to achieve lower prices. However, the New Zealand approach is in fact quite different from BC PharmaCare arrangement for olanzapine. I confirmed with officials at New Zealand’s pharmaceutical agency, Pharmac, that they award tenders on the basis of the lowest price actually charged. There is no mention in the 84 pages of the most recent Pharmac invitation to tender of any rebates to be paid to Pharmac.⁵ Since most products are fully subsidized, with patients responsible only for a fixed prescription charge (e.g.

⁴ Tax equity is commonly defined as the equal treatment of individuals with comparable income and social circumstances. See, for example, the definition provided by the federal government’s “School of Public Service” at http://www.cspc-efpc.gc.ca/services/thesaurus/thes8_e.html.

⁵ The invitation to tender is available from the author upon request.

NZ\$15), Pharmac's only incentive in New Zealand's tendering contracts is to look for the lowest list price.⁶

In BC, in contrast, the chief criterion is not the price paid by the patient, but the net price paid by PharmaCare. The Request for Proposals issued by the BC government explicitly requests potential suppliers to detail the "list price" of the drug and the "net price" to PharmaCare (which is equal to the list price less the secret rebate). It then states that the proponent "with the lowest Total Net Price will be the successful Proponent." (p. 7) In other words, the list price which is actually paid by uninsured patients is not a meaningful factor in the decision as to which firm will be awarded the sole-sourcing contract.⁷ In these circumstances, the obvious strategy is to charge a very high list price with a large rebate. The firm following this strategy will be awarded the monopoly and will be enabled to charge high prices, but PharmaCare will pay low net prices.

The sole-sourcing approach in BC is therefore not comparable to that in New Zealand. If PharmaCare wanted to emulate the strategy of New Zealand, it would tender for a sole-sourced product on the basis of the list price.⁸ Even then, PharmaCare would face a possible drop-off in generic participation; indeed, Saskatchewan's move to a list-price-based tender system has caused all of Canada's major generic suppliers to abandon the Saskatchewan market.⁹

5. The effect on competition

Just as BC PharmaCare's secret rebate arrangement is not good for patients, it is not good for competition. The problem is that the sole-sourcing arrangement with secret rebates is likely to favour the brand name seller, as opposed to generic sellers. This in turn will reduce the incentives for generic firms to challenge patents which are invalid, which is typically the condition for there to be generic competition at all.

The first question to ask is whether the sole-source tender contracts are really on a level-playing field. Normally, the firm that has lower costs will win tender contracts: certainly that would be a desirable outcome from the perspective of efficiency. The sole-sourcing contract with secret rebates, however, distorts the outcome so that what matters is not so much how low the firm's costs are, but how high a list price the firm can charge. There are some reasons to be concerned that generics will tend to find it difficult to compete effectively on this basis, which are discussed below.

First, as shown above, the way to win these contracts is to offer the lowest net price to PharmaCare. The winner can afford to offer a lower net price to PharmaCare if it also sets a higher list price, on which it will make more money from all the sales not insured

⁶ See <http://www.pharmac.govt.nz/healthpros/Schedule/charges>

⁷ The request for proposals specifically states that the list price will only be relevant in determining the winner if the net prices offered by two proponents are identical.

⁸ Saskatchewan in fact uses a process similar to that of New Zealand called Standing Offer Contracts. There are no secret rebates and the tender to supply the province is awarded on the basis of the list price.

⁹ Only 2 small generic companies, Nu-Pharm and Dominion Pharmacal, typically participate in Saskatchewan's standing offer contract system.

by PharmaCare. Thus, in the case of olanzapine, Lilly, the winner of the contract, set a list price for PharmaCare which was even higher than before generic competition arrived. For a generic firm to have been competitive, it would have had to offer the same net price. But for it to have earned the same profits as Lilly is earning, it would have had to set the same high list price. One can see immediately why this is problematic. Patients, whether insured by PharmaCare or not, would certainly have been resistant to being switched to a generic as expensive as (or even more expensive than) the brand name product to which they were accustomed. In addition, generic olanzapine is available elsewhere in Canada at much lower prices, so any generic firm that tried to sell at a very high list price in British Columbia would have to sell the same product elsewhere at much lower prices. (The same is not true for the brand name product, which maintains high prices everywhere in Canada.) I expect that patients would have objected to a situation in which the brand product became unavailable, replaced by a more expensive generic.

Second, generic companies may face greater pressure from pharmacies to include a rebate to the pharmacy in their product pricing, because that has been a traditional part of relationships between pharmacies and generic manufacturers. In contrast, brand name manufacturers typically do not pay such rebates. In effect, such a rebate would increase the cost to the generic, and make it less competitive. (These rebates, unlike the rebate paid under sole-sourcing, do not permit the firm to charge higher prices to uninsured patients and hence do not affect pricing in the same way.)

Thus, generic manufacturers are likely to be at a disadvantage in competing for sole source contracts if they are structured with secret rebates, as in BC. This leads to two possible inefficiencies. First, a firm with higher costs may end up winning the contract, inefficiently displacing a firm with lower costs. Second, generic competition itself may be damaged, as I explain below. This in turn may end up delaying the arrival of generic competition.

A common but erroneous belief is that generic competitors enter when “the patent” on a product expires. This is not how it usually works. Typically, brand name companies legitimately obtain several patents on their products over a period of years.¹⁰ The patents permit them to apply to the courts (or to Health Canada) to block generic entry. Generally, only a subset of the patents will be found valid and infringed by the generic entrant (in which case generic entry must wait for expiry of the patent), and the remainder will be found invalid and/or not infringed. Generic entry occurs, then, when the last patent still standing is shown to be either invalid or not infringed, or expires.¹¹

¹⁰ For example, Pfizer owns 43 patents in Canada which mention “atorvastatin” or Lipitor. Of those, 17 are listed in the Health Canada Patent Register. Any generic firm wishing to sell generic atorvastatin in Canada is required to address all the listed patents. The earliest patents in the Health Canada register were filed in 1990 and will expire in 2010. The latest ones were filed in 2002 and will not expire until 2022. While it is possible that some of the later filed patents would be found invalid in court, no one will know unless a generic company invests in challenging their validity. In the absence of such challenges, the monopoly will last until at least 2022.

¹¹ This is exactly what has happened with olanzapine. Novopharm challenged the validity of the patents held by Lilly. Lilly abandoned its claims under patent 2,214,005, and patent 2,041,113 was found invalid.

Unfortunately, the process of litigation is tremendously expensive and risky. The generic firm which challenges patent validity in court will sometimes be unsuccessful, and it will have to suffer the costs. Even when successful, however, the generic company hardly wins if its success in court does not give it any advantage over other generic firms which did not bear the costs and risks of litigation. The advantage obtained by the generic firm's investment in litigation is normally that it has the opportunity to be for some period the only generic in the market, or at least one of the first two generics.

Now consider what happens if there is a practice of sole-sourcing as described above, in which the generic firm is disadvantaged against the brand. The outcome is that a generic firm invests heavily into risky litigation and successfully shows patent invalidity. It is given approval to sell its product by Health Canada, and then finds that in the sole-sourcing competition, it loses against the brand name firm. By the time the next request for proposals is issued in two or three years, there are five generic companies with a Notice of Compliance from Health Canada, and the litigating company finds that it obtained no benefit at all from having invested in litigation, relative to the other generic firms that did not. If all generic companies decide to wait for some other firm to challenge the outstanding patents, no one will make this risky but socially important investment, and this may lead to the extension of monopolies on the basis of patents which, if they were challenged in court, would be determined to be invalid or not infringed.

Thus, even if sole-sourcing had other attractive properties – such as a reduction in prices for consumers of medicines which are generically available – it is important to consider its effects on the availability of generic products. If generic firms are deterred from challenging patents which are in fact invalid or not infringed, Canadian consumers and payers – including PharmaCare – will be much worse off.

6. Summary

The use of sole-sourcing by British Columbia, paired with secret rebates to PharmaCare, is causing higher drug prices for patients and private insurers. While PharmaCare may be able to reduce its short-term drug costs through this approach, it is doing so by increasing costs for other payers, including uninsured and partly insured patients. The April 2008 Report of the Pharmaceutical Task Force to the Minister of Health noted that if tendering was to be used, it should be both transparent and fair.¹² Evidently, a tendering process with secret rebates is not transparent, nor is it fair to impose high costs on those patients whose purchases are not covered by PharmaCare. Despite claims that the tendering approach has been successfully used in New Zealand, the pharmaceutical management agency in that country does not use secret rebates in its tender process for generic drugs. Finally, the sole-source approach with secret rebates is likely to harm incentives for generic drug companies to challenge patents, which could ultimately lead

¹² Report of the Pharmaceutical Task Force to the Minister of Health, April 10 2008, available at www.health.gov.bc.ca/library/publications/year/2008/PharmaceuticalTaskForceReport.pdf, last accessed May 25, 2008.

to higher prices for Canadian consumers and insurers if drug monopolies are sustained by invalid patents.