



# Drug Re-importation in North America and Europe: An Overview



**Brian Ferguson**

**September 2007**

## Atlantic Institute for Market Studies

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# EXECUTIVE SUMMARY

In recent years there has been a considerable amount of discussion regarding Americans buying lower-priced prescription drugs from Canada. These sales are referred to as “re-importation” because in most cases the drugs in question were originally manufactured in the United States. A 2003 study estimated the annual value of this trade at more than \$1 billion.

The U.S. Food and Drug Administration (FDA) has objected to such imports, not so much because of concerns over Canadian safety standards, but rather over the potential for drug counterfeiters who falsely claim to be Canadian – and hence subject to Canadian regulation and quality control – selling dangerous products to unsuspecting American consumers over the Web or through the mail.

Drug prices tend to differ between Canada and the United States not due to Canadian price controls, as some would argue, but rather because the regulated separation between the two markets makes price discrimination possible. It also should be noted that drug prices vary considerably within each country for different market segments.

Generally high levels of insurance coverage tend to make American consumers insensitive to drug prices, and hence these prices tend to be higher south of the border. However, there are significant insurance coverage gaps in the U.S. and these customers are the ones who look north for access to cheaper medicines.

The European experience with drug re-importation (or more correctly in the European context, parallel trade in drugs) shows that due to the nature of European drug licensing, regulatory regimes, and insurance plans, the benefits of such trade accrue to importers and pharmacists, rather than to consumers or the original manufacturers of the drugs.

There is little to worry about in the case of individual Americans driving across the border to fill prescriptions at reputable pharmacies in Canada. However, large-scale purchases of Canadian drugs by American institutions should sound alarms about disruptions to the Canadian domestic market. As well, such a move will not solve the basic problem that America faces: a large segment of the population with insufficient insurance coverage.

# INTRODUCTION

Things have quieted down on the Canada-U.S. drug re-importation front. Therefore, this is an opportune time to take a look back at some of the issues raised in the debate, and also to think about whether the issue is likely to reappear. While we are looking back, it also seems useful to look across the Atlantic, since drug re-importation, or parallel trade in drugs, as it is known in the European Union, is a more active policy issue in the EU than it is in North America, at least for now.

The debate was, of course, extremely active in North America recently, in particular, during the 2004 U.S. presidential election. Partly that was political: scenes of congressmen organizing bus tours to Canada of constituents looking for cheap medication made for good TV news, and press releases from various city and state governments saying that they would be arranging for their employees, and often others as well, to order from Canadian Internet pharmacies received much press attention. Partly, too, it was economic: it was estimated<sup>1</sup> that in 2003 the value (at full U.S. retail price) of drugs re-imported from Canada into the United States was over a billion dollars, a small figure relative to total U.S. spending on drugs, but still one likely to capture the attention of the press.

Interest in re-importation has died down since 2004 for a number of reasons. One factor is undoubtedly that many Americans have realized that re-importing drugs from a market one tenth the size of their own is unlikely to have much impact on U.S. prices. The rise in the value of the Canadian dollar relative to the U.S. dollar has undoubtedly also damped enthusiasm for the Canadian solution. Most important, though, will have been the introduction of prescription drug coverage under Medicare Part D, which has caused many elderly Americans who did not have retiree drug coverage through their former employers to hope that they will finally be able to afford prescription drugs.

Lately, however, interest in re-importation seems to be recovering. Governor Schwarzenegger of California, who had previously vetoed three bills intended to permit Californians to buy drugs from Canada, recently wrote to the White House asking that the federal government take steps to permit re-importation. Last year (in one of those episodes which helps explain why Canadians do not understand American politics) language was added to a bill dealing with the funding of food and farm programs which would, according to an Associated Press report on Forbes magazine's website,

*... block the Food and Drug Administration from enforcing regulations prohibiting the re-importation of prescription drugs that are typically sold for a lower price abroad than they are in the United States.*

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<sup>1</sup> See Hollis and Anis (2004).



The appearance of such language in a bill which also deals with the Milk Income Loss Contract program, the peanut storage program, the proposed livestock tracking program and funding for research on hydroponic tomato farming, not to mention funding for the Food Stamp program, is a regular occurrence, and that language is, equally regularly, dropped from the legislation when it reaches the House-Senate conference stage.

More seriously, the state of Nevada has recently introduced legislation designed to overcome the FDA's safety objections to individual American consumers making purchases from Canadian pharmacies. According to a Kaiser Daily Health Policy Report item<sup>2</sup> from April of 2006:

Under the legislation, pharmacists in Canada that have been approved by the Pharmacy Board can fill and mail prescriptions to Nevada residents that are in the Orange Book, a list of U.S.-approved drugs, and in Canada's drug product database, HC-DPD; have been manufactured in accordance with standards under FDA and the Therapeutic Products Directorate of Health Canada; in a strength that appears in the Orange Book and the HC-DPD; and are drawn from a pharmacy's on-site inventory system. Canadian pharmacists cannot dispense a drug that is liquid, injectable or in intravenous form, nor can the drug require refrigeration or other special handling during shipment.... Supporters of the bill said it will prevent Nevada residents from ordering unsafe prescription drugs from an estimated 11,000 unregulated Web sites that offer cheaper drugs. The board said it will conduct undercover purchases to ensure pharmacists are abiding by regulations among other safety actions.

Effectively, then, Nevada is offering Canadian pharmacies an opportunity to become licensed Nevada pharmacies. As of June 8, 2006, four Canadian pharmacies had met the state's requirements<sup>3</sup>. The Nevada approach is more serious than most because it tackles the FDA's safety concerns head on. Whether the FDA will permit the Nevada bill to go ahead is a question, but it is worth noting that, until very recently, American authorities made no serious effort to enforce the laws restricting re-importation of drugs by individuals.

The FDA has taken much criticism for its claim that it refuses to permit re-importation because it cannot guarantee the safety of the drugs involved. Supporters of re-importation make the point that Canadian drugs do not seem to be killing Canadians in large numbers, and often make the argument that the drugs in Canadian drugstores are produced in the same factories which produce the drugs in U.S. drugstores.

This is an unfair characterization of the FDA's concern. The FDA's concern is not with the safety of drugs that are sold in Canada, but rather with the issue of counterfeit drugs. Counterfeit

<sup>2</sup> Kaiser Daily Health Policy Report, April 24, 2006: *Nevada Pharmacy Board Approves Regulation Allowing Residents To Purchase Medications From Canada* on line at [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=36799](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=36799)

<sup>3</sup> Kaiser Daily Health Policy Report, June 8, 2006: *Canadian Pharmacies Receive 30 Calls Daily for Nevada Prescription Rx Reimportation Program* [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=3&DR\\_ID=37793](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=37793)

drugs represent a growing problem even in the absence of parallel trade,<sup>4</sup> but there is reason to argue that the problem of counterfeiting may be exacerbated by parallel imports, with what are nominally identical drugs entering a country from various parts of the world. The FDA's concern is that many on-line pharmacies which label themselves as Canadian and have Canadian websites have no physical location in Canada, so that there is no guarantee that drugs purchased over the Internet are actually coming from Canadian suppliers. Even if the pharmacy has a physical operation in Canada, there is no guarantee that the drugs that it sends to the United States are genuine. Health Canada, while responsible for ensuring the safety of drugs sold to Canadian consumers, has, and takes, no responsibility for monitoring the safety of drugs shipped to the United States, whether they originate in Canada or whether they are simply transshipped through Canada for the sake of being postmarked Canada.

In a libertarian world one might simply say caveat emptor, and note that this problem would largely be resolved if Americans were to buy only from Internet sites that could be verified as belonging to large Canadian drugstores, for whom reputation would be a valuable product (see the Nevada legislation referred to above). In the real world, though, a bad reaction to a counterfeit drug apparently imported to the United States from Canada would prompt lawsuits. Even if there was no drug importer within reach of American courts it would bring the wrath of all kinds of people down on the heads of FDA officials, on the argument that they had been derelict in their duty to protect American consumers. The real world is definitely a have-your-cake-and-eat-it-too world.

The rational bureaucratic response to this kind of incentive structure is to block all parallel imports rather than risk being blamed when consumers fall prey to the pharmaceutical equivalent of a Nigerian scam. (This would also help explain why the FDA has generally not enforced restrictions on Americans buying drugs in Canada for their own use – if people in Detroit go across the border to Windsor to buy drugs, they will probably be buying from a large Canadian chain. Similarly, in the case of Maine and New Brunswick, many doctors in border communities of Maine are also licensed to practice in New Brunswick, so there are no concerns about the validity of the prescription being filled.)

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<sup>4</sup> On counterfeits, see Stephens, Harper, Pitts, Taylor, Satchwell, and Tremblay, (2006).

One factor underlying the resurgence of interest in re-importation is that same Medicare Part D program which was in part responsible for the issue fading away. Specifically, it is the very odd design of Part D. Part D is a government-designed program run by private insurance carriers, which sets conditions on the type of coverage that an insurer can offer and still be eligible for inclusion in the Medicare plan. In structure it is, as Kaplan (2005) noted,<sup>5</sup> like no other insurance program in the world. It involves a regular monthly premium plus an annual deductible of (in 2006) \$250. Beyond the \$250 there is a 25 per cent co-insurance rate on the next \$2000 in annual drug expenditure. This brings total expenditure to \$2250. For the next \$2850 of annual coverage, from \$2250 to \$5100 in annual expenditure, the co-insurance rate is 100 per cent, meaning that the insured individual is responsible for the whole of that \$2850. Beyond \$5100 in total expenditure there is a five per cent coinsurance rate on all further drug expenditure.

That \$2850 between \$2250 and \$5100 is what has come to be called the “Medicare doughnut hole,” and it is that hole that is responsible for the revived interest in drug re-importation. It has been estimated that 7 to 10 million Medicare beneficiaries will fall into the doughnut hole, but the ones who really matter, from the point of view of the re-importation debate, are the low income elderly with chronic illness.

In most years the healthy elderly, whose drug costs generally do not exceed \$2250 annually, will not fall into the doughnut hole. It might happen occasionally, to the occasional individual, but for that particular group, it probably will not happen that often. The hole is much more likely to swallow the seriously chronically ill, whose costs will push them into it on an annual basis. While it is possible to buy plans with extra coverage, those who do so are signalling that they expect to have to use it: that they have a chronic illness. In insurance theory, that kind of signal is the basis for differentiation in rates, and reports suggest that the monthly cost of insurance with supplemental coverage for the doughnut hole can be many times higher than the monthly cost of standard plans which leave the hole uncovered, depending on the availability of generic drugs. That is not because the extra expenditure is so much greater than the average expenditure, rather it is because those who buy that coverage are signalling that they have a high probability of having to use it, and insurance premiums reflect the probability that an individual will make a claim on the plan. While the more affluent elderly can cover the hole either out of their savings or because they can afford the extra premiums for supplemental coverage, the low income elderly will find themselves in trouble. They are the ones who will be looking to Canada for cheap drugs, and since their plight will make good TV news, we can expect it to spur a revival of interest in re-importation, especially among politicians who are up for re-election.

That being the likely case, this is probably not a bad time to be looking at some definitions and issues surrounding re-importation.

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<sup>5</sup> Robert L. Kaplan (2005).

## The North American Case

We have been talking here about “re-importation”, but when the debate was at its hottest, the headlines were about letting Americans import Canadian drugs, when in fact there were virtually no Canadian drugs involved. Nonetheless, Americans referred to Canadian drugs in the same way as they might refer to Canadian softwood lumber, as a product which was produced in Canada and which would, were it not being kept out of the U.S. market by domestic interests, lower the price Americans had to pay for that product. (Sadly, Americans enthusiasm for free trade did not pass over from pharmaceuticals to softwood lumber.) It was not even a matter of Canadians having access to drugs produced in some other part of the world, by some non-American drug companies, which might, if permitted into the United States, create price competition in the American domestic market. The drugs involved were American-made drugs<sup>6</sup> which had been sold to distributors in Canada who could, under re-importation, sell those drugs back into the American market.

Many people, noting the difference in the price of drugs across the border, assumed that that difference was due to the activities of Canada’s Patent Medicines Price Review Board (PMPRB), which, they assume, imposes tight controls on the price of drugs. In fact, there is reason to debate whether the PMPRB’s ceilings are binding, and whether prices would be any higher in the absence of regulation. More important, many commentators fail to realize that the PMPRB does not control the retail price of drugs. Rather, it regulates what has been called “the factory gate price of drugs”,<sup>7</sup> the price that the manufacturer charges the wholesaler at the first stage of the marketing chain. The wholesale and retail mark-ups are left to the market<sup>8</sup>. There is no hard evidence on the point, but it’s quite likely that the major reason for the difference in Canadian and American prices for brand-name prescription drugs is simple price discrimination or, as the marketing literature knows it, pricing to market.

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<sup>6</sup> Even the term “American drugs” is somewhat misleading. The drugs are American in the sense that the companies which made them happen, at the moment, to be headquartered in the United States. The pharmaceutical industry is the quintessential multinational industry. In the 1960s and 70s, it was predominantly a European industry, and drugs tended to be released to market first in Europe. At that time there was concern in the United States about American drug firms moving to Europe. After the 1980s, though, as a result of changes in taxation and regulation on both sides of the Atlantic, the tide turned, and drug companies started moving from Europe to the United States. The current dominance of the U.S. industry is a consequence of that migration of firms, which is why so many American drug companies have names which once were associated with the European industry. The tendency to think in nationalistic terms about economic matters is usually unfortunate, and particularly so in this case.

<sup>7</sup> <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=272#9>

<sup>8</sup> When drugs are being paid for by provincial government plans, the allowable mark-up and dispensing fee will be specified.

Americans have higher incomes and, in all probability, more generous health insurance. There is a standard result in economic theory which holds that when two markets can be strictly separated from each other, the way re-importation rules separate the Canadian and American markets for drugs, a firm which is selling in both markets can increase its total profits by setting its prices independently in the two markets, in each market setting the price which will maximize the profit obtained from that market. That might result in its setting the same price in both markets, if market conditions happened to be identical, but it could also result in its setting a higher price in one market than in the other. Drug companies certainly take advantage of market segmentation when it occurs, so that there is no reason to think that Canadian and American prescription drug prices would be identical in the absence of the PMPRB. This means, among other things, that those opponents of re-importation who argue that it would amount to importing Canadian price controls<sup>9</sup>, and who argue that Canadians are free-riding on American research funded by American consumers, are on somewhat shaky ground. Americans, by dint of their higher incomes and more generous insurance coverage would tend to face higher drug prices even in a world with no government interference in the market, so long as drug companies could price discriminate. (It is worth remembering, too, that the research is only labelled “American” because the drug companies happen, at the moment, for profit-maximization purposes, to be headquartered in the United States.)

This is not to say that government regulation is never the determining factor behind drug prices. It is widely accepted that Canadian pricing rules are the reason that the prices of generic drugs are noticeably higher in Canada than they are in the United States, where competition in the market sets a limit on them<sup>10</sup>. Canada is not unique in this. Both the Dutch<sup>11</sup> and Australian public drug coverage systems are set up in such a way (we presume unintentionally) as to discourage the sort of price competition that would drive down the price of generic drugs. While the price of patented drugs is higher in the United States than in the rest of the world, once drugs come off patent, American consumers generally do better than the rest of us, at least from the perspective of the market price of drugs.

In speaking of differences in the prices of drugs, we should note that, despite what the news reports suggest, there is really no such thing as the “American” or the “Canadian” price of a drug. Not only are there differences in the prices across national borders, there are also significant differences within each country. Within the U.S., for example, various groups, most notably government agencies, have negotiated discounted prices with drug companies. Government pricing rules sometimes have unintended consequences. For example, Mark Duggan

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<sup>9</sup> Blocking re-importation because of price controls elsewhere would not be without precedent. According to Maskus (2000), Japan blocks parallel imports of patented or trademarked goods if the original sale (i.e., in another country) has been subject to price control.

<sup>10</sup> See, Anis, Guh, and Woolcott (2003). See also: *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada* PMPRB November 2002, on line at <http://www.pmprb-cepmb.gc.ca/CMFiles/study-e22SHF-8292005-2710.pdf>

<sup>11</sup> See Windmeijer, deLaat, Douven and Mot (2004).

and Fiona Scott Morton (2006)<sup>12</sup> consider the effects of the US Medicaid program's drug-pricing rule. Medicaid bases the price that it will pay for a drug on the average private-sector prices for that drug. Those private sector prices will have been set at profit-maximizing levels, but when Medicaid is a large purchaser of a drug, drug companies have an incentive to raise the prices that they charge private-sector purchasers, even if that means losing some profit from those markets, in order to keep the Medicaid price high. The effect of the rule, then, is not to lower the price that Medicaid pays, but rather to drive up the prices that other purchasers pay.

Even when we are looking at market-determined prices of drugs, we cannot really talk about a single "American" or "Canadian" price. It is often said that American prices are 100 per cent higher than Canadian ones. As a recent report from the U.S. Department of Health and Human Services shows,<sup>13</sup> the actual overall price difference depends very much on how drug prices are calculated and averaged<sup>14</sup>. Even if we accept the larger figures, however, there are significant differences between market prices charged for the same drug by different suppliers even within the United States. For example, Alan Sorensen (2000)<sup>15</sup> reports on the dispersion of drugstore prices of over 100 prescription drugs in two communities in upstate New York. (Pharmacies in New York State are required to post their prices for 152 top-selling prescriptions, so that information on competing prices is easy to obtain.) He finds that, on average, the highest posted price for a given prescription is over 50 per cent above the lowest price. This was among pharmacies so close together that, in one of the communities investigated; each of the town's ten pharmacies was within a five minute drive of all of the others. Some U.S. states are setting up Web pages on which are posted the prices of drugs in different pharmacies. Taking advantage of that information, and buying more generic drugs, would go a long way towards cutting the costs of American health care.

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<sup>12</sup> Duggan and Morton (2006).

<sup>13</sup> HHS Task Force on Drug Importation, December 2004: Report on Prescription Drug Importation Department of Health and Human Services, Washington D.C.

<sup>14</sup> Looking at some of the differences calculated in the HHS report makes it clear just how sensitive the differential will be to increases in the value of the Canadian dollar.

<sup>15</sup> Sorensen, Alan T. (2000).

Our understanding of the pharmaceuticals market world wide is muddled by the very complicated structures on both the demand and supply sides. For example, odd though it might sound, the main reason that prices of patent medicines in the United States are as high as they are is the completeness of the U.S. insurance system. Because people who have good insurance frequently pay very little out of pocket for drugs, they are insensitive to changes in the price of drugs, either up or down. When one only pays a few dollars for a prescription, regardless of what the full price of the drug might happen to be, one has no particular incentive to shop around, and suppliers have no competitive incentive to keep prices low. As Nina Pavcnik (2002)<sup>16</sup> has shown, drug companies do respond to consumer demand in setting prices, but that will only happen if consumers have an incentive to respond to prices. If that is taken away, consumers have no incentive to pay much attention to price and certainly no reason to shop around for a better deal (even if that just involves making a five-minute drive). Without a consumer response to worry about, suppliers are free to raise the price of their product well above the level which they might otherwise be able to reach. Eventually, of course, those high prices and the consequent high drug expenditures will be passed back to consumers in the form of higher insurance premiums, but in the absence of a direct link between their drug usage and what they pay for insurance, this in itself will not create an incentive for the individual consumer to keep an eye on the full prices of the prescriptions that he has filled.

This, then, is the source of much of the trouble in the U.S. market for prescription drugs. Drug companies set their prices at levels appropriate to markets in which the bulk of the consumers have insurance generous enough to make them insensitive to the full retail prices of their drugs. Those levels tend to be high. Insured consumers do not worry about this: the amount that they will pay out of pocket will be well below the full retail price of the drugs. People covered by government plans will also be protected, and probably will not be paying much out of pocket. The uninsured, including those who are in jobs which pay too much for them to be eligible for a government program but do not provide private drug insurance, not only have to pay out of pocket but have to pay the full market price. The full retail price, in other words, tends to be paid out of pocket only by those consumers who do not have insurance. These, for the most part, are the people looking to parallel imports from Canada as a source of (probably barely) affordable drugs.

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<sup>16</sup> Pavcnik, (2002).

## The European Union Case

The point has sometimes been made in the North American debate over re-importation that re-importation, or, more correctly, parallel trade in pharmaceuticals, is widespread in the European Union. There are limits to what we can learn from the European experience, though, because the structure of the EU market differs considerably from that of the North American market<sup>17</sup>.

The issue at hand, in both the North American and European cases, can be characterized in a number of different ways. One is to ask whether the original manufacturer can grant exclusive territories to the various national distributors of its product. This is the market segmentation necessary for price discrimination, or pricing to market. The issue is also often framed in terms of the property rights retained by the original manufacturer when the goods are sold to a wholesaler or retailer. In formal terms, at what point are the original manufacturer's property rights exhausted? In most cases, the original seller loses all claim to property rights as soon as the product is sold: property rights transfer completely to the buyer. When one buys a book or a car, one is perfectly free to re-sell it at some point in the future – that is why markets for used car and used books exist – and the original seller cannot prevent one from doing so. Nor should he want to: in the case of a durable good such as a book or a car, knowledge that one will be able to recover part of the purchase cost by re-selling it later on makes one more willing to buy the product in the first place. If used car markets were to be banned, demand for new cars would fall (people who might have traded in their car after a couple of years would now hold on to it much longer) and the price of new cars would fall<sup>18</sup>. In the case of drugs there are considerable differences in practice as to when the original seller's property rights are exhausted, and those differences underlie the differences in parallel importation rules across countries. The European Union has adopted a community exhaustion principle, meaning that as soon as a drug is sold anywhere in Europe, the buyer is free to do with it what he will, including re-selling it, so long as he satisfies the drug safety regulators.

The United States generally works on the basis of exhaustion of property rights at first sale of the product, although there are many exceptions to the rule. There is also a twist; the establishment of exclusive territories for wholesalers or retailers can be made a matter of contract, with no need for government to intervene except to provide a mechanism for enforcing or, if the loss of social welfare associated with the establishment of local monopolies is thought sufficiently severe, to void the original contract. Broadly speaking, though, a good purchased in one part of the United

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<sup>17</sup> On the structure of the European market, see Arfwedson (2003).. Also, Kanavos, Gross and Taylor, (2005). Also see, Szymanski and Valletti (2005) and Kanavos and Costa-Font (2005). We draw from all of these in what follows.

<sup>18</sup> The same holds for books. It is not easy, though, for an economist to convince either a book publisher's rep. or the author of a sociology textbook that the fact that students know that they will be able to sell the book at the end of the year makes them more willing to buy rather than borrow and photocopy, and that props up the price of new textbooks.



States can be resold in another. The United States has had a free market internally for most of its history, thanks to the interpretation an early Supreme Court put on the commerce clause in the American constitution, and American economic growth and general prosperity has benefited greatly from that decision.

A few points of detail might help to clarify these statements. First, when we talk about the European case, we shift from using the term “re-importation” to using the term “parallel imports”, because there are typically several countries involved. A Swedish drug company might, for example, sell its product into both Greece and the United Kingdom. In part because of drug pricing regulations in the two countries, Greece is a low-price country and the United Kingdom is a high-price one. A parallel importer would buy the original drugs in Greece and sell them in the United Kingdom in competition with drugs sold into the British market by the original manufacturer. They might even be sold back into Sweden, since it too is a high-price country. A significant portion of the European drugs which are targets for parallel trade within the EU are made by the Anglo-Swedish, drug firm AstraZeneca, putting AstraZeneca in the position in which some American-based drug firms would be were Canada-U.S. re-importation permitted. According to Arfwedson (2003)<sup>19</sup>, in the case of at least one product, AstraZeneca lost virtually all of its domestic Swedish market to parallel imports of its own products.

The parallel importer is essentially acting as an arbitrageur, profiting on the difference in prices charged for exactly the same product in two different countries<sup>20</sup>. Normally, as economists, we welcome arbitrage, but in this case there are problems which have to be considered and to which we shall return later.

Exhaustion of property rights is not always an unmixed blessing. According to Szymanski and Valletti (2005), a few years ago<sup>21</sup>, Glaxo Smith Klein sold at cost price three AIDS drugs to buyers in France, on the understanding that they would be used for humanitarian purposes. The buyers, however, re-sold the drugs to a Swiss firm<sup>22</sup> which in turn re-sold them to a British wholesaler who then sold them to NHS hospitals. It created something of a fuss in the newspapers when it was learned that low-cost drugs intended for Africa had wound up in a British hospital, but as of the 2004, the only legal action which had been taken was by Glaxo against the British wholesaler, Dowelhurst, arguing that by re-selling the drugs in the United Kingdom Dowelhurst had violated GSK’s trademark. In that case the British courts ruled that Glaxo Smith Klein had no further property rights over the drugs after it had sold them – once

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<sup>19</sup> Arfwedson (2003).

<sup>20</sup> We should note here that parallel trade does not refer to trade in generic copies of drugs. In general, once a drug is off patent, it will not be a target for parallel trade for the simple reason that there will be no profit in it. Profit will be squeezed out by generic competition.

<sup>21</sup> Szymanski and Valletti (2005).

<sup>22</sup> An interesting twist, since Switzerland is not an EU member.

one buys a good one owns it and can do what one likes with it. (In May, 2005, GSK and Dowelhurst settled their dispute out of court, with each side still expressing the view that they were in the right.)

Parallel importation (PI) is big business in Europe, although the extent of it varies across countries. Most Parallel Imports (PIs) go to high-priced countries, with the market share of PIs having risen<sup>23</sup> from 1.9 per cent to 10.1 per cent between 1997 and 2002 in Sweden (Kanavos and Costa-Font, 2005), and from 9.5 per cent to 19.8 per cent between 1998 and 2002 in the UK. In Greece parallel trade has gone from 0.9 per cent of the market in 1997 to 22 per cent in 2002, but in the case of Greece the numbers refer to parallel exports. Greece and Spain are probably the major sources of supply of parallel drugs to Sweden and the United Kingdom.

Even those figures are somewhat misleading, however, since parallel trade is only profitable for (and therefore is limited to) a handful of drugs for which the price differentials are very large. For many drugs, then, there are no parallel imports, while for a handful of drugs PIs are a very significant part of the market.

We should note that the system of parallel importing differs significantly between North America and Europe. It is not, as is presently the North American concept, a matter of buying drugs in Greece and setting up a website offering to sell them to consumers in Sweden. Parallel importers are regulated middlemen between pharmacists. They must obtain a license for each drug which they want to tranship, and if they make more than minor changes to packaging (including moving blister packs of drugs from one type of box to another)<sup>24</sup> they have to hold a license as a drug manufacturer (Kanavos, Gross, Taylor, 2005). If the original manufacturer sells the same drug under different names in different EU countries, the parallel importer has to obtain a separate transshipment license for each named version.

Most importantly for purposes of drawing North American lessons from the European experience, because of the way the European drug insurance system is set up, parallel trade has virtually no scope for saving consumers money, because in some countries consumers pay nothing out of pocket, while in others, which use reference pricing, consumers pay only the difference between the reference price and the list price of the drug. In those countries, most consumers buy drugs whose list price is at the reference level<sup>25</sup>.

While neither the United States nor Canada have European-type universal drug insurance systems, the design of most private drug insurance in both countries is such that, as we noted earlier, insured consumers are insensitive to the full price of the drugs which they buy, so that there is virtually no price competition among insured drugs at the consumer level. Under this set-up, we would expect an outcome rather similar to the European one, with re-importation not

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<sup>23</sup> Kanavos and Costa-Font (2005).

<sup>24</sup> Kanavos, Gross, Taylor (2005).

<sup>25</sup> Pavcnik (2002)

affecting the price paid by insured consumers. Uninsured consumers are a different matter, to which we shall return below.

The benefits of parallel importation in Europe, then, go to the parallel importer and the pharmacist who buys drugs from a PI source rather than from the original manufacturer. How the profits are divided is a matter for bargaining, but in the AstraZeneca case mentioned above, the drug company will have received only the profit that it made on the original, non-Swedish sale, while the profit that it would have made on the Swedish sale will have gone to the druggists and the parallel importer. If the original sale was into Greece, which has, until recently, had laws effectively requiring that drug prices there be no higher than the lowest in Europe, AstraZeneca's margins would probably have been quite tightly squeezed.

In some countries the government cuts itself in on the deal, by funding the drug insurance system on the assumption that pharmacists will be buying some parallel imports. In the United Kingdom, for example, the NHS claws back part of the payment due to pharmacists (for drugs covered by the NHS) to reflect the level of parallel import products which it assumes that the pharmacist has bought. In Germany, pharmacies are required to buy a certain minimum percentage of parallel imported drugs, at a given price differential relative to the price set by the original manufacturer, which probably sets a floor under the price of the PI product.

There is disagreement among analysis about the impact of parallel imports in Europe over the price of drugs at the wholesale level. Ganslund and Maskus (2004) find evidence of a significant effect<sup>26</sup> on the Swedish market, while Kanavos, Costa-Font, Merkur and Gemil (2004)<sup>27</sup>, using a broader set of countries but a more restricted set of products, argue that virtually all of the benefit goes to the middleman with, in particular, very little going to the national health insurance system. Their result has been disputed on the argument that competition between parallel importers should at least mean that most of the benefit goes to the pharmacists, but it may be that, given the regulatory structure surrounding parallel importing in the EU, the appropriate economic model is that of a dominant large firm with a competitive fringe consisting of a small number of smaller firms, in which case the smaller firms will set a price very close to that charged by the dominant firm.

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<sup>26</sup> Ganslandt and Maskus (2004).

<sup>27</sup> Kanavos, Costa-Fonte, Merkur and Gemil (2004).

We noted above that parallel exports now amount to about 22 percent of the Greek pharmaceutical market<sup>28</sup>. This has raised concerns about shortages in Greece (just as there is concern that re-importation to the United States on a scale sufficient to make an impact on that market would result in shortages in the Canadian market). Swedish pharmacists also complain of shortages of PI drugs and unreliability of supply, giving some credence to the “competitive fringe” view of the market. Evidence on shortages is to date anecdotal, but some drug companies have become sufficiently concerned that they have implemented restrictions on the quantity of drugs that they will supply to countries which are sources of parallel exports<sup>29</sup>. The European courts have ruled that, while a complete halt to supplies would be grounds for compulsory licensing of the drug in question, drug companies are free to restrict supply to an amount consistent with the size of a country’s domestic market, so that any parallel exports would reduce the quantity of drugs available for consumption in the exporting country.

American drug companies have moved to restrict re-importation from Canada by refusing to supply any wholesaler who has sold to re-importers. Tight inventory control methods make it likely that, even if a complete cut-off of supply were not feasible<sup>30</sup>, oversupply would not be necessary, so that if a significant quantity of drugs was being re-exported from Canada, Canadians could reasonably expect to experience shortages in the domestic market. Since wholesale and retail margins are not subject to price controls, competition among retailers for the reduced supply of drugs could be expected to raise the price of drugs to Canadian consumers. Because the amount involved would be small relative to the total U.S. market (and because even if there were retail price controls in Canada, they would not apply in the United States any more than Greek pricing regulations apply in Sweden) there would be no significant reduction in the American price.

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<sup>28</sup> For a summary of the institutional structure of the Greek pharmaceutical market, see Kontozamanis, Mantzouneas and Stoforos (2003).

<sup>29</sup> They already restrict supplies to low price countries when other countries use those low prices as the basis for setting their own reference prices. See Danzon (1998).

<sup>30</sup> Some of the U.S. legislation intended to legalize re-importation includes restrictions on restriction of supply. It is not easy to see how that sort of requirement could actually be enforced.

# Policy Issues

Economists tend, for the most part, to support free trade and oppose barriers to trade. It seems unlikely that many economists took the side of the publishers and recording companies when Australia and New Zealand opened their book and record markets to parallel imports. Even though, technically, much of the higher price that goes along with monopoly power in a market is simply a transfer from consumers to producers, and therefore does not represent a loss of social welfare, it is fairly safe to say that most economists are to some degree Smithian<sup>31</sup>, taking the view that the sole purpose of production is consumption, and have, at least in the back of their minds, a social welfare function that places greatest weight on consumer benefit. Contrary to the conventional wisdom, market-oriented economists are not automatically pro-firm, nor pro-profit.

In the case of the pharmaceutical sector, however, there are a few additional factors to be considered. One is that, to the extent that private American insurance replicates the effect which public European insurance has in making consumers almost completely insensitive to price, it seems unlikely that insured consumers will realize any significant benefit from re-importation. Even in the case of public sector insurance plans, it is not clear that there would be any significant effect beyond a reallocation of the profits between firms. Economists frequently find themselves in the minority, defending the social benefit which follows from the activities of middlemen against those who assume that all that middlemen do is leech off revenue without adding social benefit<sup>32</sup>. In this case, while the arbitrage activities of European parallel importers benefits European pharmacists, the lack of direct benefit to consumers lessens the tendency to defend the middleman.

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<sup>31</sup> Adam Smith, author of *The Wealth of Nations*.

<sup>32</sup> This unfavourable view of middlemen and arbitrageurs goes at least back to the medieval period, when the profit which they made was termed “profit from alienation”, and it was assumed that they made that profit by “forestalling and engrossing”, meaning, essentially, by cornering the market and creating monopolies for their own benefit. It is a view which was, for the most part, wrong then and is wrong now.

There is an additional factor, which would tend to make many – though not all – economists prefer the present distribution of revenues, at least as a second best solution to certain problems<sup>33</sup>. Pharmaceutical companies fall into a category of enterprise whose production processes are characterized by large fixed costs and low variable costs. In the case of drugs, the fixed costs are primarily the up-front research costs necessary to bring a drug to market, and the variable costs are the actual production costs – the costs of physically assembling pills. While the picture may change if some of the newer biologicals live up to their promise, historically the costs of assembling pills has been a very small part of the total cost of producing medication. The R&D costs which must be borne up front are much larger. Further, a significant cost must be incurred before a drug company has real evidence as to whether a research direction is going to bear fruit. This is the reason why drug companies need patent protection – without it they would not be able to recover their research costs, not only on successful drugs, but also on ideas which looked promising but never panned out.

As economist Peter Temin (1980) has pointed out<sup>34</sup>, before the U.S. courts ruled that pharmaceuticals were patentable, drug companies were essentially identical to today's manufacturers of generics, that is, they did very little research but rather waited for someone else to prove that a drug was valuable, then took the idea and assembled pills. The process by which drugs were brought to market in the 1950s would not work well today, in part because nobody was undertaking the type of clinical trials required today to demonstrate both efficacy and safety. In the early days of the modern pharmaceutical industry, the initial research stage was far more expensive than the development stage. Today, even though the cost of research has not fallen, that relation has been reversed. Most of the \$800 million that it costs to bring a new drug to market is now attributable to the development and testing stage rather than the pure research stage<sup>35</sup>.

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<sup>33</sup> Some free-traders do tend to support re-importation quite strongly. The Globalisation Institute, for example (<http://www.globalisationinstitute.org>) in general supports re-importation.

<sup>34</sup> Temin, (1980).

<sup>35</sup> For a low-tech discussion of the process of calculating the cost of bringing a new drug to market, see Adams and Brantner (2006).

It is important, also, to remember that the handful of drugs which do successfully reach the market have to cover the costs of all of the promising but ultimately blind alleys down which researchers went. Looking only at the costs directly attributable to a drug which has reached the market overlooks that need. Finally, recall that only a handful of drugs are really successful: no more than a third of drugs on the market cover the industry average cost, when that cost is correctly calculated to include a share of the cost of all research efforts. The rest of the drugs on the market cover their production costs and make some contribution towards industry research costs, but are not profitable when equal shares of the sunk costs of the industry's research enterprise are attributed to them. It is also important to remember that, while a patent's life (and therefore monopoly status) is for twenty years, that is twenty years from the date at which the patent was filed, and filing comes early in the drug development process. Typically a drug will have about seven years of patent protection left when it comes to market. The pharmaceutical industry is, therefore, very dependent on a handful of high-profit drugs for its profitability<sup>36</sup>. Parallel importers, by focusing on the most profitable drugs, cut into that revenue.

Drug industry research is funded to a very significant degree by retained earnings. The long development period necessary before a drug reaches market and the low probability of any given single drug actually making it to market, let alone being highly profitable, makes an investment in a single research line a very risky investment. If drug companies had to fund their research entirely from the financial markets<sup>37</sup>, the rate of interest that the markets would demand in order to compensate for the riskiness of the investment would probably exceed the rate used to value internal funds in cost-of-development studies. As a result, it makes sense for drug companies to fund their research internally. Consistent with this, F.M. Scherer (2000) has shown<sup>38</sup> that drug company R&D spending appears to be driven very much by fluctuations in their gross profitability. Looking at drug prices in a dynamic framework, then, there is much validity to the claim that parallel importation, focused as it would be on the most profitable drugs, could do serious damage to drug research<sup>39</sup>. While nobody would want to claim that the drug companies are populated by angels, parallel importation on European lines, where much of the return from arbitrage stays with the parallel importer, would seem to put research at risk without even the short-term benefit of lower prices to consumers.

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<sup>36</sup> Contrary to what's often stated, this isn't new: only the drugs have changed. In the earlier years of the modern pharmaceutical industry, profitability also depended on a handful of blockbuster drugs. In those days, the blockbusters were new antibiotics.

<sup>37</sup> If, for example, they paid all of their retained earnings to shareholders as dividends and borrowed to finance research lines.

<sup>38</sup> Scherer (2001).

<sup>39</sup> Now that India has signed on to TRIPS, and implemented product patents as opposed to the process patents which it recognized in the past, drug companies might be tempted to take advantage of the high quality of the scientific human capital available there to move some of their R&D activity to that country. There might also be cost savings associated with moving more of their operations to those Eastern European countries which have shown an ability to adapt to a market economy. As we noted earlier, the multinational drug industry has no significant problem relocating geographically when the incentives are right.

Drug re-importation between Canada and the United States along European lines would not be a particularly good idea. Still, there is an argument for it as a second best solution to some American policy problems, and, among second best solutions, one which drug companies would probably not object to, although it would not be particularly politic for them to come out in favour of it. The most pressing health care problem which the United States faces is the problem of the uninsured. In many cases the importance of no insurance is overestimated. Lack of insurance is not the same as lack of care when it comes to access to certain kinds of care, most notably hospital emergency room and clinic care, but it is true that in the case of pharmaceuticals, lack of insurance is likely to mean lack of care<sup>40</sup>. While there are some programs aimed at giving low-income groups access to expensive drugs, there is no national program<sup>41</sup>, so the uninsured frequently end up being the only group actually paying full price for prescription drugs. Since many of the uninsured are low-income individuals, it is not unusual to find them priced out of the market. From the perspective of the drug companies, this is not a profit-maximizing state of affairs.

From the drug companies' perspective, of course, the ideal situation in the United States would be for everyone to have private health insurance along the lines of General Motors' plan. Unfortunately, given that even GM cannot afford a GM style plan any more<sup>42</sup>, that option would not appear to be viable. A second best solution would be to extend price discrimination to the poor and uninsured, looking in particular for a way to move the most disadvantaged of them from zero drug consumption to positive consumption at a price which at least covers the costs of physically assembling the pills<sup>43</sup>.

Unfortunately, this is not an easy thing to do. Drug companies cannot simply announce low prices for the uninsured, for two reasons: First, it creates a tremendous incentive for insured individuals to drop their coverage. At the very least, the price charged to the uninsured would have to exceed the co-payment or co-insurance charge faced by the insured, to lessen the immediate incentive to drop coverage. Second, as soon as a low price plan was announced, other groups, notably the government plans, would be demanding that they too pay the lower prices,

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<sup>40</sup> We should qualify that statement by pointing out that about half of drug company marketing expenses is accounted for by the value of detailing - of free samples given to doctors. Most of those drugs will wind up being given to people without good drug coverage. Critics of drug industry advertising expenses should note that drug companies could slash their advertising expenses simply by not giving drugs away.

<sup>41</sup> It often comes as a surprise to Americans to discover that the same is true of Canada - many Americans, including American health economists and policy analysts, don't realize that Medicare doesn't cover prescription drugs and that we basically get our drugs the same way they do - through employer-based insurance topped off by a patchwork of special programs for individual diseases or groups.

<sup>42</sup> Strictly speaking it's not that GM can't afford a GM style plan, it's that GM and its unions never faced up to the true costs of a GM style plan and therefore didn't fund it properly. Had they, and other major corporations with generous health insurance plans, faced up to the true cost of those plans some time ago (not just making vacuous statements about how they spent more on health care than on steel - raising the question of just how much steel goes into the modern car - and demanding that the US government bail them out), the US might have made rather more progress towards a sensible, private health insurance system than it actually has.

<sup>43</sup> Leaving R&D costs to be covered by those higher income, better insured groups, who are already paying for it anyway.





and while the cut in price would save both private and public insurers money in the short run, it would also cut into the retained earnings of the drug companies, which fund their research.

A similar problem would arise with price discrimination aimed at charging lower prices to lower-income (as opposed to uninsured)<sup>44</sup> individuals. This sort of plan would be complicated by the need to verify income, and would tend to work best in conjunction with a government program, bringing us back to the problem of its impact on prices paid by government programs. Under these circumstances, re-importation by individual Americans from Canada might be a second best policy solution<sup>45</sup>. If we consider which individuals are likely to take advantage of such an option, it is fairly safe to conclude that they will generally not be the well insured. They are much more likely to be the uninsured or older individuals who have Medicare drug coverage, but who have hit the “doughnut hole” in their coverage<sup>46</sup>. Some of them are likely to be voluntarily uninsured individuals who are still able to pay full U.S. list price for drugs, but the bulk are likely to be individuals who cannot afford<sup>47</sup> to do so, at least on any kind of a regular basis (individuals with chronic conditions, for example). So long as the Canadian on-line price is high enough above the co-payment on most insurance plans that the insured are unlikely to take advantage of direct re-importation, but low enough to bring those who had been priced out of the U.S. market into the Canadian market, re-importation represents sales that would not otherwise be made. It would, in effect, act as a form of price discrimination which, by creating sales which would not otherwise have been made, would bring revenue to the pharmaceutical companies which they would not otherwise have received<sup>48</sup>. From that point of view, drug companies would probably welcome a situation in which the FDA did not enforce restrictions on individual import, and where competition among on-line retailers was sufficient to bring a significant portion of the uninsured into the market. What they would not welcome would be the situation with which they were threatened during the last U.S. presidential election cycle, where cities and states were demanding the right to re-import drugs under their own programs.

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<sup>44</sup> The two groups are often assumed to be identical, but as the developers of Massachusetts’ new health insurance program realized, a significant portion of the uninsured could afford insurance but prefer not to buy it. In Massachusetts many of them assume that being able to receive publicly funded care at the Massachusetts General Hospital is all the coverage that they need. The bulk of these individuals are young and tend to assume that they are invulnerable. In addition, another significant segment of people working in low-paying jobs which do not provide insurance are young people in part-time jobs, who still have coverage through their families. Sorting out the composition of the uninsured is a useful first step in working out how to make coverage available for the involuntarily uninsured.

<sup>45</sup> I am indebted to Pierre-Thomas Leger of HEC Montréal for observations on this point.

<sup>46</sup> For many in this group, re-importation will not be an option. Anyone who expects that their drug costs will be so high that they come out the other side of the doughnut hole need to be sure that their insurer will recognize the uncovered expenditures they make as legitimate ones. If insurers do not accept re-importation expenses as legitimate, even for purposes of adding up someone’s total drug spending, using even a legitimate Canadian internet pharmacy would simply increase the effective size of the doughnut hole. That fact will tend to set a limit on demand for re-imported drugs.

<sup>47</sup> In economic jargon these are individuals whose choke price is below the market price for the drugs.

<sup>48</sup> Obviously the on-line price would have to be above the cost of manufacturing the pills.

# CONCLUSIONS

## Canadian Perspective on an American Policy Mess

How should Canadians react to the idea of being used as a mechanism for enabling some Americans to buy drugs more cheaply than they can at home? To the extent that it involves Americans driving across the border to have their prescriptions filled at Canadian pharmacies, neither we nor the drug companies should worry about it. The same applies to individual Americans making purchases from the websites of legitimate Canadian pharmacies, since the number of individuals whose insurance status makes that their best option for having their prescriptions filled will probably not be large enough to disrupt the Canadian market. Nor should the FDA worry about either of those types of re-importation, since the value which legitimate Canadian pharmacies place on their reputations should serve as a guarantor of quality.

However, when American politicians start proposing that government plans make large-scale purchases in Canada, we should be concerned about disruption to our market.

We should also be concerned when American politicians start using re-importation of Canadian drugs as a political smokescreen. A policy of controlling US drug costs by shipping drugs north to Canada and hoping that they will still be cheap when they come back into the United States is on a par with asking the tooth fairy to provide a national dental service on the grounds that it will be self-financing. Not only would it disrupt our market, but by going along with it we would be abetting a fraud perpetrated on American consumers by American politicians.

Re-importation is not a solution to the American no-insurance problem, and our government should make it quite clear that, while we are quite happy to sell them softwood lumber, and to let individual Americans buy drugs here, the costs to Canadian consumers of large scale re-importation of pharmaceuticals by local and state government plans would far outweigh the benefits to American consumers.

The United States needs to take serious steps to sort out its health insurance mess, and drug re-importation is not a serious step.

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## **Other AIMS work on health care:**

*A Finger on the Pulse* by Julia Witt

*The Good News: Pharmaceuticals and the Cost of Health Care* by Julia Witt

*Going Public on What is Private* – the Canadian Health Care Consensus Group

*A First Look at the Numbers* – the Canadian Health Care Consensus Group

*Definitely NOT the Romanow Report*, by Brian Lee Crowley, Brian Ferguson, David Zitner, and Brett J. Skinner

*Payment Is Powerful: Overcoming Canada's Shortage of GPs by Increasing Family Practice Compensation*, by Ida Rayson

*Operating in the Dark: The Gathering Crisis in Canada's Public Health Care System*, by Brian Lee Crowley, Dr. David Zitner, and Nancy Faraday-Smith

*Expenditure on Medical Care in Canada*, by Brian Ferguson

*The Non-Sustainability of Health Care Financing under the Medicare Model*, by Brett J. Skinner

*Medicare and User Fees: Unsafe at Any Price?* by Carl Irvine and Dr. David Gratzner

*Alice in Borderland: Why Canadians Cannot Afford to Be Complacent about US Drug Re-importation*, by Brian Ferguson

*This Won't Hurt a Bit: Why the Vaccine Crisis Shows We Shouldn't Believe What Health "Planners" Tell Us about How to Reform Drug Policy*, by Brian Ferguson and Julia Witt

*Why Not "Europeanize" Health Care? AIMS in The National Post*, by Brian Lee Crowley and Johan Hjertqvist

*Issues in the Demand for Medical Care: Can Consumers and Doctors Be Trusted to Make the Right Choices?* By Brian Ferguson

*Better Medicine*, by David Gratzner

*How Should We Decide What to Cover under Medicare?* by Julia Witt

*Profits and the Hospital Sector: What Does the Literature Really Say?* by Brian Ferguson

*Improving Canadian Health Care: Better Ways to Finance Medicare*, by Brett J. Skinner

*Public Health, State Secret*, by Dr. David Zitner and Brian Lee Crowley

## **AIMS Books**

*Retreat from Growth: Atlantic Canada and the Negative-Sum Economy*, by Fred McMahon

*Road to Growth: How Lagging Economies Become Prosperous*, by Fred McMahon

*Looking the Gift Horse in the Mouth: The Impact of Federal Transfers on Atlantic Canada*, by Fred McMahon (photocopies only)

## **Commentaries**

*Defining Atlantica: Bridges to Prosperity* by Charles Cirtwill

*Still More Equal than Others: Capped Equalization is still too much* by Bobby O'Keefe

*Health Care: Towards significant changes* by Claude Castonguay

*Moving on Up: The transition from poverty to prosperity* by Charles Cirtwill

*Taking the caller off hold: Move forward with telecom deregulation* by Ian Munro

*A new Golden Rule: The three Cs of local government* by Charles Cirtwill

*Taxing Incentives: How Equalization Distorts Tax Policy in Recipient Provinces*, by Kenneth J. Boessenkool

*Fiscal Equalization Revisited*, by Professor James M. Buchanan, Nobel Laureate

*Testing & Accountability: The Keys to Educational Excellence in Atlantic Canada* by Charles Cirtwill, Rod Clifton, and John D'Orsay



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