

Canada / US Cross Border Trade

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Montreal*

Outline

- Overview of Cross Border Trade in North America
- Learning from the European Experience
- Why Canadian Prices are lower than US prices
 - Is this changing? Why?
- Legal / Regulatory Aspects of Cross Border Trade
 - Canadian and US laws
- Reaction of Canadian Industry
 - Price increases, differential pricing, supply limits/controls
- Reaction of Canadian Government Agencies
 - Health Canada, Drug Plans, PMPRB, Bureau of Competition Policy
- Outlook

Overview of Cross Border Trade

- Background
- Types of Cross Border Trade
 - Foot Traffic
 - Internet Pharmacies
 - “Bulk” re-importation

Look Who's Running Drugs

TIME Magazine July 29, 2002

Americans are going to Canada — and Canadian websites — for cut-rate prescriptions. Bad idea?

By CHRISTINE GORMAN

For years, U.S. citizens living in northern border states from Maine to Washington have been slipping into Canada to pick up prescription drugs at cut-rate prices. The Senate passed a proposal last week that would make it easier to ship Canadian drugs directly to the U.S. But opposition from the drug industry is fierce, and Washington handicappers give the measure little chance of becoming law. So where does that leave price-conscious consumers — especially those senior citizens whose drug costs are not covered by Medicare? On the Internet, of course. In the past two years, online providers in..

Drug Costs: The Canadian Cure

TIME Magazine Nov. 24, 2003

By NATHAN THORNBURGH

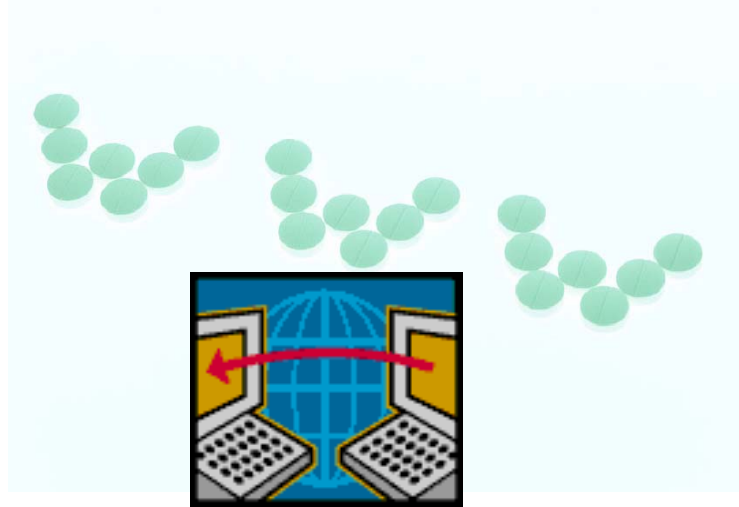
Springfield, Mass. looked north for a solution..

At home he faced rising costs for his diabetic son's insulin. At work he was forced to lay off teachers, policemen and fire fighters in part because of skyrocketing drug prices. So Michael Albano, the colorful mayor of Springfield, Mass., looked north for a solution. Starting in July, Springfield became the first city in the nation to officially encourage its employees to buy prescription drugs from Canada. City workers fax or mail their prescriptions to a company in Canada; the prescriptions are filled there, and the drugs are mailed to the patients' homes. The workers get a reduced copay, and...

"Foot-traffic"

- Americans visit Canada on their own or as part of an organized "tour"
- US patients will usually will have their US prescriptions countersigned by a Canadian physician and dispensed at a Canadian pharmacy
- Sales volume unknown
- Likely legal, but raises important ethical issues
 - e.g., does Canadian M.D. examine patient, is he/she available to provide advice to patient

Internet Pharmacy



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Internet Pharmacies - how it works...

- US patient faxes prescription to Canadian Internet Pharmacy
 - Brokers are springing up in some US locations to facilitate the process for seniors (are these legal?)
- Patient must sign power of attorney allowing the pharmacy to act on his/her behalf and to absolve the IP of all responsibility
- Patient must provide medical information and name / contact info of U.S. M.D.
- Canadian M.D. reviews file and counter-signs the U.S. Rx which is then filled and couriered to the U.S. patient
- Rx size is generally limited to 90 days and may require new prescription for repeats
 - but there are no mechanisms to prevent Rxs from being filled by multiple internet pharmacies
- No provisions to ensure that Rxs are not subject to unsuitable climatic conditions in transit

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Canadian Internet Pharmacies

- Based primarily in Manitoba, Sales volume: \$650 million?
- Internet Pharmacies employ Canadian MDs to counter-sign prescriptions
 - Cdn Professional associations have warned MDs that this practice is unethical
 - MDs must examine patients, be available to provide advice
 - Cdn malpractice insurer has warned MDs that they will not be covered for incidents that occur as a result of Internet prescription
 - IPs have probably provided alternate coverage or guarantees
- Pharmacist licensing bodies are concerned about the growth of internet pharmacies and are monitoring for un-ethical / inappropriate practices
 - Also concerns about shortages of pharmacists
- the larger Internet Pharmacies have become adept at following the letter (if not the spirit/intent) of Canadian regulations and legislation
- Illegal in the US but US Customs/FDA not enforcing
 - Proposed legislation would make it legal

Canadian Internet pharmacies

- 100 or more now operating
- Most located in Manitoba, Alberta and BC
- Mediplan Pharmacy (www.RxNorth.com) in Minnedosa, Manitoba filled its first cross-border Rx in March 2001
 - Now fills 2,000 prescriptions per day
 - 2003 annual sales of \$71 million US, up from \$31 million in 2002
 - 197 employees incl. 17 pharmacists and still expanding
- Organized “Canadian Internet Pharmacy Association” to lobby governments

CIPARx Website...

The screenshot shows the CIPARx website homepage. At the top left is a red maple leaf logo with 'CIPARx' written on it. To its right is the text 'CIPARx Canadian International Pharmacy Association'. On the top right is a circular logo that says 'CERTIFIED CANADIAN CIPARx INTERNATIONAL PHARMACY'. Below the header is a 'Welcome to CIPA' message. The main content area contains a paragraph about CIPA's creation in November 2002 and its mission. Below this is a link to a video of Andy Troszok's testimony to the US Congress. On the left side, there is a vertical menu with links: 'CIPA HOME', 'ABOUT CIPA', 'MISSION', 'FAQ'S', 'WHAT'S NEW', 'MEMBER'S PAGE', 'LINKS', and 'CONTACT CIPA'. On the right side, there are several circular buttons: 'How do I Join CIPA?', 'Benefits of Membership', 'Resources for Members', 'Information for Consumers', and 'Med Alert!'. At the bottom left, it says 'February 2004'. At the bottom center, it says '© Palmer D'Angelo Consulting Inc'. At the bottom right, it says '11'.

Member's Web Mail

CIPARx Canadian International Pharmacy Association

WELCOME TO CIPA

The Canadian International Pharmacy Association (CIPA) created in November, 2002, is an organization who represents the Canadian International Pharmacy Industry. Our presence is to represent and support the ethical and professional practice of International Pharmacy, and to ensure the highest standards of practice are carried out by its members. CIPA promotes the growth and viability of the Canadian pharmacies that provide international services, as well as to provide a unified voice to address the challenges facing the industry at large.

At present, CIPA is working to provide an insurance package for it's Pharmacies, and Physicians. Please see the ["How do I join"](#) link or see the contact information below to address any questions, comments or concerns on becoming a member or CIPA's upcoming insurance benefits.

View the video of [Andy Troszok's Testimony to the US Congress Safety of Canadian Medications for US Consumers](#)
(Click the link to view the video, or right-click and choose "Save As" to download.)

*Please note: CIPA does not stock, supply or distribute any form of

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Canadian Internet Pharmacy Association

- Lobbying governments in Canada and building public support in the US
- Claims that safety issue is really a smokescreen and they are willing to submit to any and all regulatory scrutiny to ensure patient safety
- Have reacted to industry measures in Canada to limit supplies.
 - Full page advertisement in the New Times ...

CIPA Advertisement in New York Times



Glaxo is
taking away
your right to
affordable
prescription

The world's second largest drug maker, GlaxoSmithKline, has stopped providing its drugs to Canadian pharmacies and wholesalers who supply an estimated one million uninsured and underinsured American seniors with affordable, high quality medications. If Glaxo gets its way, all drug makers will likely follow its lead and eventually strip seniors of their well-established right to access affordable drugs from alternative sources.

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Canadian Internet Pharmacies Stress patient care...



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But the real motivation is profit...



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And the profits are significant...

- Analysis of top selling Canadian drugs available on internet pharmacy prices indicate that they are marked up an average of 38%
- Assuming annual ex-factory internet pharmacy sales of \$650 million, the mark up represents almost \$250 million
 - Some of this represents additional costs but most is profit!

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Bulk importation

- Bulk importation (as proposed in U.S. legislation) is parallel trade of prescription drugs with an important distinction:
 - the drugs in question are (ostensibly) manufactured in the United States or at FDA approved facilities, imported from Canada, where they are sold at significantly lower prices than in the United States
 - The objective is to provide US consumers with Canadian prices for US manufactured / FDA approved drugs
- Pharmacies, wholesalers or distributors in Canada would export Canadian labeled drugs to the US where they are inspected, tested and re-labeled by “importers” and distributed to US retail pharmacies
 - The expectation is that US pharmacies will pass savings on to US cash paying consumers
 - Note: these are the same pharmacies that are currently marking-up prescription drugs by 30% to their cash paying customers

Bulk Importation Not Feasible: Lack of Supply

- Canadian companies/affiliates control supply into distributors / wholesalers
- US manufacturers will not export more than Canadian companies/affiliates require to meet Canadian domestic demand
- Manufacturers are adopting counter measures
- Some products cannot be “re-imported” (e.g., certain injectables, narcotics)
- If 10% of Canadian drugs were diverted to the US this would supply less than $\frac{1}{4}$ of 1% of US market

Importation: Profit Seeking will limit savings

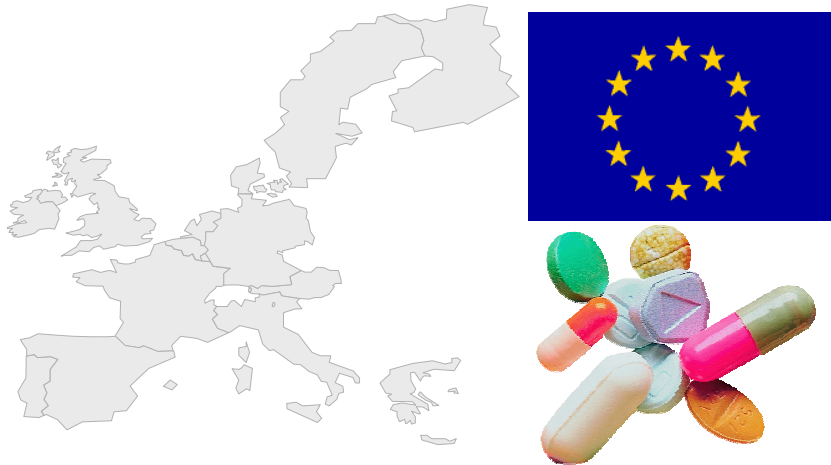
- Canadian exporters will seek profits from drugs they export
- Importers will seek to maximize profits (after absorbing regulatory compliance and other costs)
- Existing discounts/rebates make it difficult to compete in managed care market
- Limited supply imported drugs will bid up the price to pharmacies and consumers
- US cash prices already include significant mark-ups (WAC + 30%)
 - No reason to believe that pharmacies will pass along savings from re-imported drugs

Conclusion: Re-importation will not provide savings to American consumers

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Parallel Trade: The European Perspective



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How does parallel trade work in Europe?

- Parallel trade in Europe is based on and protected by fundamental principles of the EU
- The principle of free movement of goods:
 - Quantity restrictions on imports/exports are prohibited between member states
- The exhaustion principle of intellectual property rights:
 - Once trademark holders have sold a product they cannot prohibit subsequent resale; their rights in respect of that market are 'exhausted' by the act of selling it
 - Consequently they cannot prevent resale by prohibiting use of their trademark
 - But, recent European court rulings have upheld the right of manufacturers to limit supplies to domestic demand

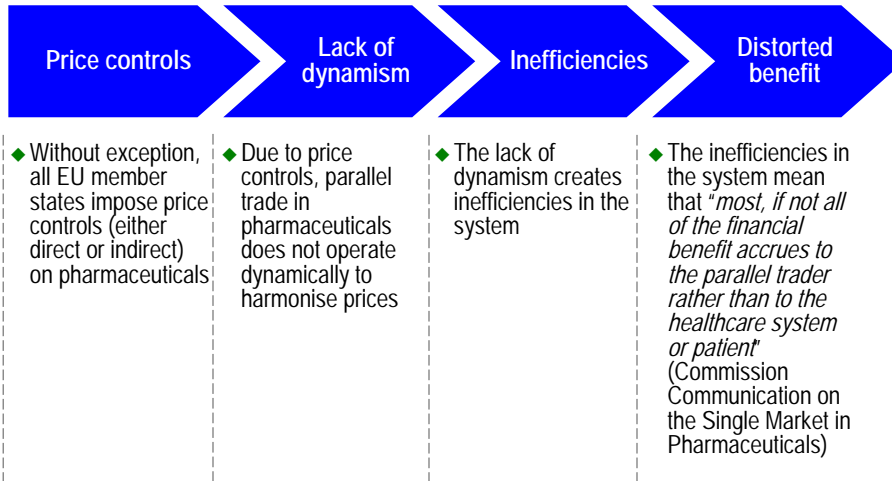
Source Furniss J, Cambridge Pharma Consulting

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Price controls make parallel trade of pharmaceuticals different from other goods



Source Furniss J, Cambridge Pharma Consulting

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Parallel trade in Europe: Negative impact on patients

- Compliance with Therapy
 - Inconsistency of presentation
 - Foreign language labeling
- Quality/Integrity of Products
 - Risks associated with repackaging
 - Risks of Counterfeiting
 - No medical information systems
- Patient Access in "exporting" countries
 - Shortages of innovative products
 - Delayed launches for new products
- Other impacts
 - Limited (if any) financial benefits / savings to patients
 - Risk to patient support / education programs
 - Risk to R&D opportunities for patients (clinical trials etc)

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Source: Furniss J, Cambridge Pharma Consulting

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Governments and public authorities gain very little from parallel trade in Europe

Top-line fiscal savings are minimal:

- Almost all the price differential is absorbed into the traders' operating margins
- For every \$6 lost by manufacturers due to parallel trade only \$1 accrues to payers – the other \$5 is go to costs and profits of the parallel trader
- Limited savings to payers are usually mandated by regulations / laws (e.g., "clawback" provisions)



In Europe, Parallel Trade is about Profit not savings

Source: Decision Resources Inc, Cambridge Pharma Consulting

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Parallel Trade: Summary of European experience

- Euro parallel trade in pharmaceuticals is a legal artifact of the single European market
 - it is not a government policy intended to deliver savings
- Minimal fiscal benefit: Savings are not passed on to consumers and payers
 - profit opportunity for trades, distributors, wholesaler, pharmacists
- Patient care is jeopardized: quality/integrity and compliance issues in importing markets, product shortages in exporting countries
- Decreased competitiveness of the Pharma industry in local markets
 - Profits of traders are not invested into R&D - opportunity loss for patients, health care system, economy

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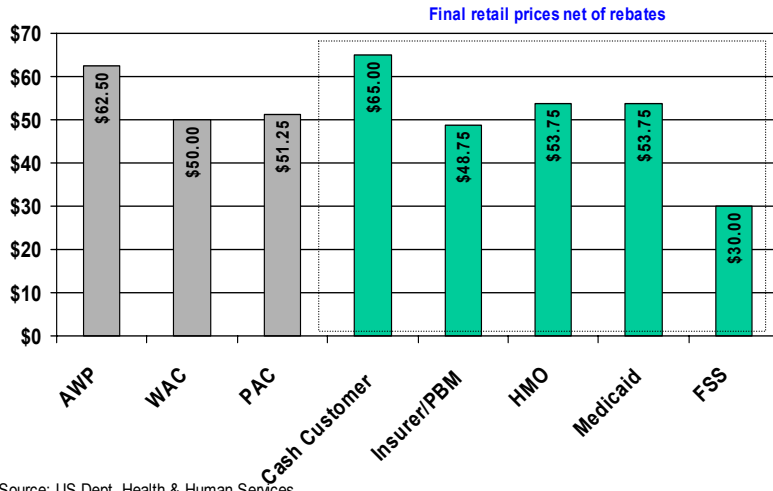
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US has price differentiation based on buying power..

- In the US, the market is fragmented between powerful buying groups – large employers, unions, PBM's, HMO's, insurers, Medicaid, Dept of Veterans Affairs – and uninsured cash paying customers (including many seniors)
- There is **no single "US Price"**. Prices vary depending on buying power. Confidential rebates and discounts make it hard to know actual prices paid.

Drug Prices in the United States

Example of a typical prescription



Source: US Dept. Health & Human Services

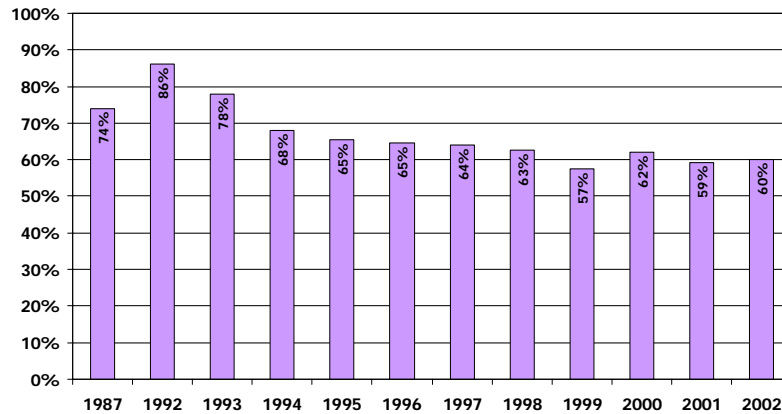
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Canadian Ex-factory Prices as % of US Prices

(Source: PMPRB)



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Single Pricing in Canada

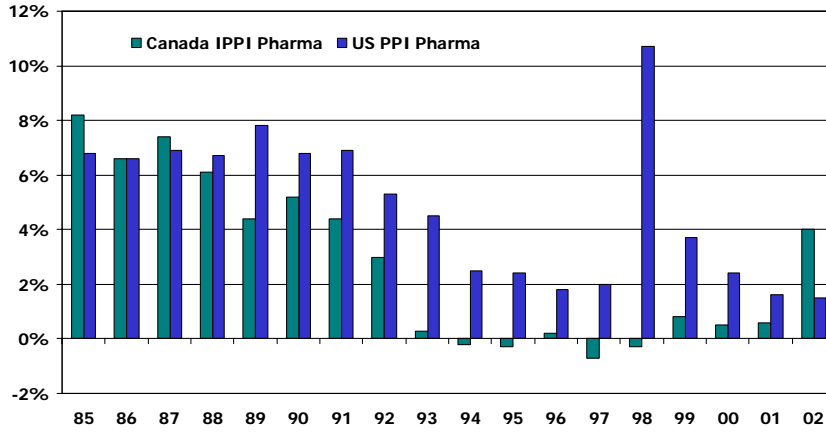
- Unlike the US, most customers and payers (outside of hospital) in Canada pay the same ex-factory price
 - Wholesale/Retail mark-ups are limited to 10% above ex-factory prices
- No comprehensive managed care structure that can deliver market share in return for discounted prices or rebates.
- The distribution system makes differential pricing by “payer of benefit” difficult.
- Centralized price controls and government reimbursement policies discourage differential pricing.
- As a result, pharmaceutical companies in Canada are using a single price policy
 - But this may be changing – manufacturers are actively looking at mechanisms to implement differential pricing using adjudication, rebates, etc..

Price Controls / Reimbursement

- Patented Medicine Prices Review Board (PMPRB)
 - Limits introductory prices
 - Therapeutic class, international price referencing
 - Limits price increases to CPI
- Government Reimbursement Policies
 - Cost minimization / Budget impact focus
 - Best available price policies
 - No price increases allowed in Ontario and Quebec
 - But this is changing – as many as two dozen companies have taken increases (3% to 4%) on many of their products in 2003 with the exception of Quebec where negotiations are ongoing
 - Price increases are the maximum allowed by PMPRB

Annual Pharma Price Increases: Canada vs US

(Source: Statistics Canada, US Bureau of Labor Statistics, PMPRB)



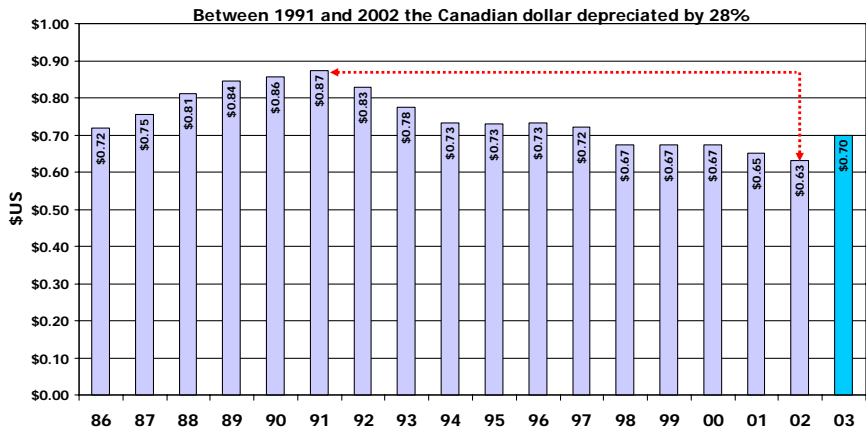
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Value of Canadian Dollar (vs \$US)

(Source: Bank of Canada)



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Canadian Legal Regulatory Environment

- Canadian legislation does not authorize bulk exports without an export certificate however there is no clear prohibition
- But, without an export certificate it may be difficult for Canadian exporters to respect Canadian regulations
 - e.g., recalls

Canadian Competition (anti-trust) Law

- Canadian Competition Bureau ruled in March that GSK was not contravening civil or criminal provisions of the *Competition Act* by implementing supply limits
 - “...the fact that these cross-border sales violate US law supports the position that GSK has a reasonable business justification for blocking the exports, while continuing to supply the Canadian market.”
 - “...there is no appreciable impact on Canadian consumers resulting from GSK’s actions...”
- Ruling does not prevent complainants pursuing private legal action

US Law: Consumer Practices and the Internet

- FDA/U.S. Customs allow a 90-day “personal use” supply of medications for people returning from abroad.
- Mail-order shipments from Canada do not result in prosecution of American consumers.
- FDA warning on facilitators of practice (aiding and abetting) are criminally liable.
 - HUMANA
 - United Health Care
 - Anthem
 - Premera Blue Cross

US Legal/Regulatory Environment

- Imports to the US are illegal without the manufacturer's consent (but the FDA is not enforcing this law if for personal use)
 - Bulk imports are clearly illegal
- FDA concerned about safety of distribution system, potential for counterfeiting
- Most states do not allow Rx sales to their residents if pharmacy is not licensed in their state.
- FDA and state regulators are trying to shut down storefront operations (e.g Rx Depot) that are acting as intermediaries by helping consumers make purchases from Canada.

US Legal Regulatory Environment (cont'd)

- Medicare law signed in December 2003 will provide a prescription drug benefit for US seniors and disabled starting in January 2006. Until that time, discount cards will be provided to assist seniors with prescription costs (up to 15% discount).
- Expected this benefit Rx benefit will reduce some of the demand for lower priced imports.
- State and municipal governments (eg Minnesota, Illinois, Boston, Springfield) are pressuring federal government to legalize imports. Looking for ways to reduce drug plan costs and to gain support of constituents. Minnesota has set up a web site to help residents purchase drugs from Canadian pharmacies.

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What is industry doing?

- Many companies are raising prices
 - Respecting PMPRB guidelines for patented medicines (2% to 4%)
 - Higher increases for non-patented medicines
 - Challenging provincial government policies (including price freezes)
 - Negotiations ongoing in Quebec
- Differential pricing / high list prices
 - May be possible to set list prices higher and offset them with rebates and discounts to lower average selling price.
 - Particularly for hospital drugs
 - Will provincial drug plans allow differential pricing or a system of rebates
- Manufacturers opting to limit supply to control parallel trade...

Manufacturers have implemented supply limits

- GSK, Wyeth, AstraZeneca Lilly and Pfizer are all monitoring supplies to pharmacies selling across the border
 - Pfizer has told 46 pharmacies they must buy directly from manufacturer.
- Makes it more difficult for pharmacies to obtain extra supply for US customers – some are insisting they will not sign Pfizer's directive and will look for alternative sources of supply.
 - Average Internet price for GSK products up 22% since supply limits introduced.
- Rationale for supply limits:
 - Must ensure that supply to Canadians is not jeopardized or may lead government to take action against the manufacturers.

- What's been the response of US Industry...?

Pharma focuses on patient safety, price controls



1100 Fifteenth Street, NW Washington, DC 20005

Imports carry risks

The health care status quo indeed must change. Our health system has not kept up with dramatic advances in pharmaceutical research, leaving too many patients

- “[Re-importation] exposes Americans to dangerous imports”
- “It also imports foreign governments' price controls” – “[that] are drying up the discovery of new medicines in Europe”

passing a meaningful Medicare prescription drug bill this year. It's time seniors and disabled persons got coverage and the discounts that come with it.

The bill passed by the House to allow imports of medicines from more than 20 foreign countries is the wrong type of change. The bill prohibits the Food and Drug Administration (FDA) from barring such imports even if it determines it can't be done safely. The FDA has consistently opposed this idea because it evnnses

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Similarly, Glaxo is stressing safety...



GlaxoSmithKline

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IMPORTING MEDICINES INTO THE UNITED STATES

- Late
- New
- Imp
- into
- Key
- Press
- Other
- Photo
- Med
- Fina
- Fina
- Shar
- Pres
- Proc

- “The medicines patients get through cross-border Internet sales may not always be what they expect, raising the very real issue of patient safety. Exporting prescription medicines to the US over the Internet essentially short-circuits the chain of accountability that is intended to help ensure drug safety”

safety systems that protect consumers of medicines bought and sold domestically in the US are not in place to regulate cross-border sales. While medicines sold in Canada and the US may bear the same tradename, may contain the same active

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The traditional Canada / US relationship

“When the U.S. sneezes, Canada catches a cold.”

Health Minister Anne McLellan

New release 18Nov03

- "... the [FDA] Commissioner may have left the impression that unsafe Canadian drugs are going across the border to the United States as a result of the practice of internet pharmacy. Let me assure all Canadians that drugs approved for use in Canada are safe."
- "... there is no evidence that any of the [FDA] allegations [of unsafe drugs from Canada] are substantiated. Health Canada actively investigates any information brought to our attention. If any Canadian laws have been violated, Health Canada will take necessary measures to protect the health and safety of Canadians. The US FDA has an obligation to enforce its own laws."
- "As recently as yesterday, no jurisdiction had reported drug shortages as a result of the practice of internet pharmacy."

Canadian Finance Minister John Manley

"Canada Will Keep Drug Price Controls", Manley Says

- Price controls are "Canadian domestic policy intended to support Canadian consumers," Manley said in an interview with Bloomberg News. "I don't think that we have any intention of changing that policy."
- "to ensure that proper professional practices for prescribing and dispensing pharmaceutical products are being complied with, and that's something on which we are cooperating with U.S. authorities"
- "To the extent we assist in limiting (access to price-controlled drugs) to Canadians, I don't think that our government should have a problem" with U.S. relations, he said.
- "That's our principal preoccupation, to make sure the Canadians have access to pharmaceutical products," Manley said. "There is no sign at the moment of chronic shortages, but that could change."

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Cdn Industry Response-Expected 2003/2004

- Limit wholesaler supply of products systematically to cap exports while preventing Canadian market shortages.
- Guard against counterfeits, raise issues on safety.
- Raise prices (many already have, others will follow)
 - Prices of new products will be as high as possible – global pricing strategies are more important than ever
 - Single global price the new norm
- Movement to “US style pricing”:
 - Greater reliance on differential pricing mechanisms, rebates, discounts to offset high list prices
- Lobbying governments to stop cross border trade

US Outlook

- US Congress has passed Medicare legislation
 - Includes a drug benefit that starts in 2006 and discount cards in 2004 – this may reduce cross border demand for some products
- US Industry (*PhRMA*) will continue to lobby US & Canadian governments to limit cross border trade & internet pharmacy and eliminate price controls
 - Pressure on Canadian affiliates to establish US prices
- US States continue pressure for imports – unlikely in the near term but could change after 2004 US elections

US states continue pressure for Canadian drugs

- State and municipal governments (eg Minnesota, Illinois, Boston, Springfield) are pressuring federal government to legalize imports. Looking for ways to reduce drug plan costs and to gain support of constituents.
- Minnesota has set up a web site to help residents purchase drugs from Canadian pharmacies.
- “The Governor of Illinois has ordered 12 state health care programs to look for alternatives to medicines on their preferred drug lists that are made by five companies limiting Canadian drug supplies, news sources report.” (Source: FirstWord P/S/L Group November 27, 2003)

The issue will remain on the front page...



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Palmer D'Angelo Consulting Inc.(PDCI) is Canada's leading pricing and reimbursement consultancy. Established in 1996, the firm has extensive expertise and experience in price regulation (PMPRB), public and private reimbursement strategies, submissions, global pricing strategies not to mention pharmaceutical policy and economic research projects. PDCI also maintains extensive databases of international pharmaceutical prices, and provincial drug plan claims and costs.

www.pdci.ca

Palmer D'Angelo Consulting Inc. (PDCI)



W. Neil Palmer, Principal Consultant

Mr. Palmer is responsible for leading PDCI's pricing, reimbursement and policy research assignments. Before founding PDCI, he worked with the Canadian Patented Medicine Prices Review Board (PMPRB) where his responsibilities included policy development, overseeing the price review of patented medicines and conducting economic research. Prior to the PMPRB, he worked with the Health Division of Statistics Canada where he was responsible for economic and statistical analysis of health care costs and utilization. He has written extensively on pharmaceutical pricing and reimbursement issues and is a frequent speaker at pharmaceutical conferences in North America and Europe.

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