Statement on Importation of Prescription Drugs
by
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Senate Subcommittee on Investigations
"Drug Importation"

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Mr. Chairman and members of the committee, I appreciate the invitation and opportunity to testify on issues relating to importation of prescription drugs. My name is Marv Shepherd, and I am the Director of the Center for Pharmacoeconomic Studies, College of Pharmacy, The University of Texas at Austin. I have studied the issues surrounding drug importation since 1994.

Several congressional bills have been introduced to make drug importation a safe practice and make drug importation a cost-effective alternative for Americans. In addition to these legislative efforts, the Medicare Prescription Drug Improvement and Modernization Act of 2003, Public Law 108-173 (MMA) has directed the Secretary of Health and Human Services (HHS) to make a thorough examination of drug importation.

One method of prescription drug importation is importation by individuals. I stand opposed to this type of methodology because it puts Americans at tremendous risk. It bypasses professional medical supervision and safe medication use procedures and protocols. There are no double checks on prescription drug accuracy, no checks on drug-drug, or drug-disease interactions, there is virtually no counseling, and patients do not have access to professionals to get critical drug questions answered.

The potential for problems is particular serious for those who obtain their prescription drugs via the internet because of the many fraudulent internet pharmacy sites located outside of the U.S. For example, prescriptions ordered via the internet from what are purportedly to be Canadian pharmacies may in fact not be located in Canada and many times drug products are supplied by a pharmacy providers outside of the Canada. Recent news stories have revealed that one Canadian company is now forwarding the prescriptions on to a British pharmacy.[1] I am also aware of situations in which Americans believe they are receiving American made prescription drugs from Canada when in reality these drugs are coming from a variety of other countries. For example, a recent article in *Scrip* reports that one Canadian Internet Pharmacy Provider

(Canadapharmacytrust.com) is shipping pharmaceuticals which were made in Mexico to U.S. residents. The article goes on to say that the drug products were not approved by Health Canada nor the FDA.[2]

Furthermore, my research shows that in 2003 Canada imported pharmaceuticals from over 80 countries. Canada does have federally negotiated mutual recognition agreements with 18 Western European countries on Pharmaceutical GMPs (Good Manufacturing Practices). But as noted, Canada is importing drugs from more than just these countries including Ecuador, Mexico, Brazil, and China. From 2002 to 2003, Canadian imports from India have increase 109%, Singapore 72%, Mexico 50%, Italy 282%. Even though U.S. pharmaceutical exports to Canada have increased nearly one billion dollars since 1999, as a proportion of all Canadian imports, U.S exports to Canada have been decreasing. In 2000, U.S. drugs comprised 55% of all Canadian drug imports, but in 2003 it has dropped to 43%. Drug importation to Canada is now greater than what Canada manufactures.

The personal importation of pharmaceuticals is growing enormously and, in my opinion, is out of control. There are no guarantees that legislators, regulators and pharmacists can provide the information necessary to consumers on whether the imported prescription drugs they are receiving are adulterated, counterfeit, or approved for use in the United States. There is also no way for local pharmacists to determine whether the medication is safe and effective.

I understand the plight of individuals unable to afford much needed prescription drugs and support the goal of lowering drug costs for the American consumer. However, the anticipated savings importation programs may generate is uncertain because of factors such as price differentials for specific drugs in and out of the United States, the availability of product for importation, the additional importation overhead costs required, plus the profit taking by the intermediaries in the importation process.

One of the potential negative consequences of a program that permits pharmacies and wholesalers to import prescription drugs is the development of a two-tiered drug system of drugs based on product cost and source. If states base their reimbursement to pharmacies on an importation-based acquisition cost, pharmacies would have to establish a dual inventory system, one system for U.S. made drugs and another system for imported drugs. More importantly, drug importation is a direct threat to our generic drug industry. Drug importation may destroy the incentive for generic drug development.

All of us are aware of the potential for drug counterfeiting. Drug counterfeiting is a world-wide problem. No country is immune from this threat. However, drug importation, especially personal importation, only opens this door wider. Counterfeiters go where the money is and the U.S. is an excellent target for pharmaceutical fraud, deception and counterfeiting. We have been fortunate that more people haven't been hurt or killed by these products. I have said and continue to say it is only a matter of time before some horrific tragedy involving imported pharmaceuticals occurs.

I believe that until more data are available as to the likely impact of importation on the cost of drugs, the impact on our drug distribution system and the risks posed to American citizens, I am opposed to proposals which allow for the importation of prescription drugs. The Health and Human Services is now intensively investigating this issue; I urge you and others to let these professionals do their work, receive and study their report and then make the right decisions. To develop a drug importation scheme in haste without the input from their report may be more costly than any of us in this room want to expend or face.

Thank you again for this opportunity and I look forward to answering any questions that you may have.

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[1] Associated Press, "U.K. Pharmacy Filling U.S. Prescriptions," *New York Times*, May 2, 2004.
[2] "Mexican Drugs Shipped to US via Canada, say Consumers," *Scrip: World Pharmaceutical News*, No 2942, April 9, 2004, p 17.

Drug Importation Analysis: Comparison of the Canadian Pharmaceutical Market Size with the U.S. and Implications for Drug Importations

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Submitted to:
Representative John D. Dingell
Ranking Member
House Committee on Energy and Commerce

And

Senator Norm Coleman
Chairman
Senate Permanent Select Committee on Investigations

Submitted to the
Senate Subcommittee on Investigations
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Introduction

This report was written in response to a request from the Ranking Member of the House Committee on Energy and Commerce, John Dingell and Chairman of the Senate Permanent Select Committee on Investigations, Norma Coleman. The letter request was written March 5, 2004. The request asked for descriptive information about the size of the Canadian pharmaceutical market. Specifically, the requests were:

1. How large roughly is the Canadian pharmaceutical market and how does it compare to the U.S. market?
2. What percentage of the drugs used in Canada are made in the U.S. (or is a U.S. form located overseas)? Of this figure, what percent of these drugs are consumed by Canadians, and thus what percent are theoretically available for the purpose of re-importation?
3. To the extent determinable, what is the status of this residual supply? Is it approaching exhaustion? Or is it already exhausted? If demand in this area ultimately exceeds supply, what are the implications of this situation?

In examining the questions, one can see that all three are interrelated. In fact, to determine the size of the pharmaceutical market, the amount of pharmaceuticals imported needs to be determined which to some extent addresses the second question, which is: what is the percentage of drugs used by Canada made in the U.S. In essence the general formula to calculate the size of the Canadian pharmaceutical market is as follows:

Canadian Drug Supply = (Amount of Drugs Manufactured in Canada) - Amount of Drugs Exported which were made in Canada) + (Amount of Drugs Imported – Drug Imports that were Exported) + Amount of Drugs Exported but were Re-imported

For this report, this formula was simplified to the following:

Apparent Domestic Canadian Drug Market = Manufacturing Drug Shipments + Total Drug Imports – Total Drug Exports

Data Sources, Commodity/Industry Codes and Exchange Rates

A variety of data sources were used for this report. However, the primary sources for Canada were obtained from Statistics Canada's Survey of Manufacturing (ASM) for Canada's Pharmaceutical and Medicine Manufacturing (NAICS 3254).[1] In addition, Canadian pharmaceutical manufacturing statistics were obtained from Canada's Business and Consumer site strategies.gc.ca. This site is produced by Industry Canada which is a Department of the Canadian Federal Government.[2] The primary source for U.S. data was the Foreign Trade Division of the U.S. Census Bureau[3] and the United States

[1] http://www.ic.gc.ca/canadian_industry_statisitics/cis.nsf/idE/cis3254datE.html
[2] http://www.strategis.ic.gc.ca/
[3] http://www.ita.doc/gov/td/industry/otea/industry_sector/tables_naics/325412.htm

International Trade Commission.[4] As mentioned many data sources were also utilized and they will be referenced appropriately in the report.

Pharmaceutical manufacturing, import and export commodity codes were used to specify commodity and industry identification.[5] The designated commodity code used most often in this report was HS 3004 and is titled: "medicaments-put up in measured doses or packed for retail use." This designation was used because it was believed that this would accurately reflect drug products for consumer use rather than using an overall pharmaceuticals and medicines product code which may cover bulk pharmaceuticals. However, at times an industry code was used and when this was done the NAICS (North American Industry Classification System) code was employed. The NAICS code used for pharmaceutical and medicine manufacturing was NAICS 325410.

The financial amounts expressed in the report will be in U.S. dollars, unless otherwise specified. When converting Canadian dollars to U.S. dollars, Table 1 denotes the exchange rates employed for each year. At times, it is difficult to determine if over-the-counter drug (OTC) products are included in the amounts provided by Canada or the U.S. Plus, in Canada some products sold as OTCs are prescription drugs in the U.S. Also, for the analyses on pharmaceutical manufacturing output, importation and exportation, the analyses were conducted for products designated in measured dosing units or packaged for retail use (Code HS3004).

Table 1
Canadian to U.S. Dollar Exchange Rates

Year	Exchange Rate
1997	1.38
1998	1.48
1999	1.49
2000	1.49
2001	1.55
2002	1.57
2003	1.40

Source:http://www.bankofcanada.ca/en/exchange.htm

Methods Employed to Determine the Size of the Canadian Pharmaceutical Market

Three approaches were used to determine the size of the Canadian pharmaceutical market. The first approach was to determine the dollar value of drug products manufactured by pharmaceutical manufacturers (brand and generic drugs manufactured) add the amount of drug products imported, and subtract the amount of Canadian drugs exported. The second approach was to determine the number of prescriptions filled in Canada and the third approach was to determine the total amount of drug expenditures in

[4] http://dataweb.usitc.gov/scripts/user_set.asp
[5] http://strategis.ic.gc.ca/sc_mrkti/tdst/tdo/tdoDefinitions_30.php accessed March 5, 2004.

Canada. The latter approach is commonly referred to as the market size because it reflects retail, clinic and hospital expenditures or the total amount expended on pharmaceuticals in Canada by public and private payers. However, the number of prescriptions dispensed approach does offer an insightful method because it eliminates drug price differences between countries.

The differences between these approaches are distinctive. As mentioned, the drug expenditure approach does include markups on the drug product from the retail pharmacies, wholesalers and other outlets. Thus, this method provides the total dollar volume expended on drug therapies in Canada. The first method provides drug costs from the manufacturer or drug cost as reported upon importation or exportation (FOB value). Both methods are relevant for a comparative analysis with the U.S.

Canadian Pharmaceutical Manufacturing

Table 2 denotes the annual pharmaceutical and medicine manufacturing reported by the Strategis web site. Manufacturing data were only available through 2001.

Table 2
Canadian Pharmaceutical and Medicine Manufacturing (NAICS 3254)
(Value in Billions of U.S. Dollars)

Year	Value ($billions)
1997	3.529
1998	3.219
1999	3.319
2000	3.670
2001	4.387

http://strategis.ic.gc.ca/sc_mrkt/tdst/tdo/tdo.php#tag accessed March 11, 2004.

Using the data provided by Statistics Canada from their Annual Survey of Manufacturers (ASM), Table 3 presents pharmaceutical and medicines manufacturing (NAICS 325410). These statistics are the total value of drug manufacturing shipments of the industry. This is the value of the goods produced by pharmaceutical manufacturers in Canada. **In using Table 3 the values within the column labeled manufacturing shipments is the one used to represent the drug shipments from the facility.** Also, the data sites do not provide a breakdown by drug name; this information is considered proprietary and not for distribution. Nor does the ASM information breakdown the product as to whether or not the product was manufactured in measured dosage units or packaged for retail use. This information can be very useful because one can determine to what extent products are bulk pharmaceuticals or products in measured dosage forms or packaged for retail use. The site provides a total dollar amount of the drug shipments from Canadian drug manufacturing facilities.

Table 3
Annual Pharmaceutical and Medicine Manufacturing Output and Revenues (Value in Billions U.S. Dollars)

Year	Manufacturing Shipments	Value Added*	Total Revenues
1997	$3.529	$2.557	$4.347
1998	$3.219	$1.824	$4.122
1999	$3.319	$1.812	$4.563
2000	$3.670	$1.946	$4.966
2001	$4.387	$2.258	$6.258

Source: http://www.ic.gc.ca/canadian_industry_statistics/cis.nsf/idE/cis3254datE.html accessed March 11, 2004.

*Value-added is the measure of net output. Value-added is the gross outputs less the inputs such as cost of materials and supplies, fuel, electricity) which have been used to develop the product.

Exportation of Pharmaceuticals Manufactured in Canada

As expected not all drugs manufactured in Canada, stay in Canada for Canadian use. Some drug products are exported. Table 4 depicts the amount of pharmaceuticals in measured dosage forms or packaged for retail use which were exported to the U.S. or other countries. (Note Canadian drug import and export data can be categorized into products in measured dosage forms or products packaged for retail use).

The results in Table 4 show that vast majority of drug products exported from Canada were shipped to the U.S. Also, the proportion of drug exports to the U.S. has more than tripled since 1999. Pharmaceuticals made in Canada and exported to "other countries" has been under $300 million since 1999 and when compared to those products exported to the U.S. are relatively small.

Lastly, based on the dollar amounts of drugs manufactured in Canada (Table 3), 19.5%, 20.0% and 23.0% of the pharmaceuticals manufactured in Canada were exported in 1999, 2000, and 2001 respectively. To summarize, approximately one-fifth of the drugs manufactured in Canada were exported and U.S. received approximately 80% of these exports. ***Please note that these export figures do NOT include pharmaceuticals obtain via pharmacy internet providers and shipped to U.S. residents.***

Table 4
Trend in Canadian Drug Exports to the U.S. and Other Countries for Pharmaceuticals in Measured Dosage Forms or Packaged for Retail Use Which Were Manufactured in Canada
1999-2003
(Value in Thousands of U.S. Dollars)

Year Exported to	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
U.S.	$411,595 (63.4%)	$544,347 (72.4%)	$853,909 (84.6%)	$904,392 (81.8%)	$1,456,495 (84.4%)
Other Countries	$237,241 (36.6%)	$207,019 (27.6%)	$155,914 (15.4%)	$200,848 (18.2%)	$269,427 (15.6%)
Total	$648,836 (100.0%)	$751,366 (100.0%)	$1,009,823 (100.0%)	$1,105,240 (100.0%)	$1,725,921 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/tdst/tdo/tdo/.php

Canadian Drug Importation

The next step in this process is to determine the amount of pharmaceuticals Canada imports. Table 5 shows the dollar amount and proportion of Canadian drug imports which were packaged for retail use or in measured dosage forms from the U.S. and "other countries" from 1999 through 2003.

Since 1999, total pharmaceutical imports by Canada have increased 101.6% from $2.347 billion to $4.732 billion. U.S. drug imports to Canada have increased 67.2% from $1.254 billion to $2.097 billion and Canadian imports from all other countries have increased 141.1% from $1.093 billion to $2.635 billion from 1999 to 2003.

Even though the U.S. drug exports to Canada have increased nearly a billion dollars since 1999 (Table 5), the percentage of U.S. made drugs being imported by Canada has been decreasing. In 2001, the U.S. proportion of Canadian imports was nearly 56%, but in 2003 it declined to 44.3%. It needs to be noted that not all U.S. made pharmaceuticals exported to Canada are FDA approved. Also information provided by the U.S. government on U.S. exports does NOT include product name nor does it include whether or not the product is FDA approved. Both the Canadian and U.S. government authorities will not release specific product names; they are classified as proprietary information.

The trend depicted in Table 5 indicates that Canada is importing more drugs and since 2000 more and more drugs are non-U.S. made pharmaceuticals. Figure 1.0 graphically depicts the shift in the proportion of Canadian drug imports from the U.S. and other countries. Later in this report, a more detailed analysis will be presented on what countries are exporting drug products to Canada.

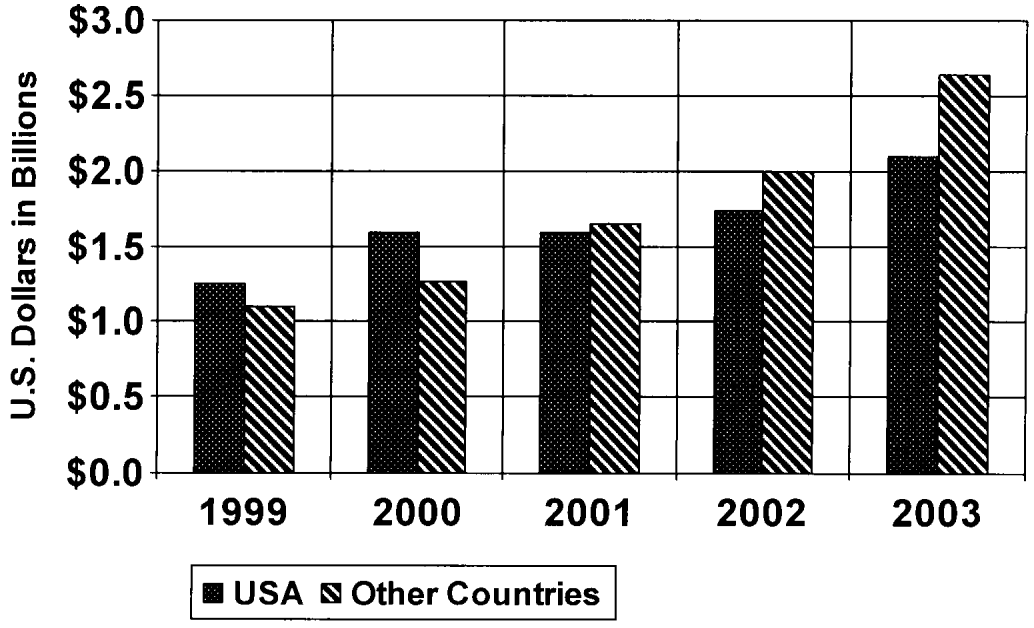
As stated, it needs to be reiterated that both U.S. and Canadian importation and exportation information sources will not reveal pharmaceutical product names and the quantity by product names. This information is considered proprietary by the company and is to be protected by the governmental agencies. This limitation certainly weakens this section of the analysis in that it makes the analysis less definitive. One will not be able to determine Canadian product surpluses or shortages by product name.

Table 5
Trend in Canadian Drug Imports from the U.S. and Other Countries for Pharmaceuticals in Measured Doses or Packaged for Retail Use
1999-2003
(Value in Billions of U.S. Dollars)

Year Exporting Source	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
U.S.	$1.254 (53.4%)	$1.602 (55.9%)	$1.598 (55.7%)	$1.733 (49.2%)	$2.097 (44.3%)
Other Countries	$1.093 (46.6%)	1.265 (44.1%)	$1.646 (44.3%)	$2.000 (50.8%)	$2.635 (55.7%)
Total	$2.347 (100.0%)	$2.867 (100.0%)	$3.245 (100.0%)	$3.733 (100.0%)	$4.732 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004.

Figure 1.0 Trend in Canadian Drug Imports for Drugs Packaged for Retail Use 1999-2003
U.S. Dollars



Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004.

Total Drugs Exported from Canada

Like Canadian manufactured pharmaceuticals, not all drug products imported by Canada remain in Canada. Some Canadian imported pharmaceuticals are exported. The term "re-exports" (The U.S. term is "foreign exports") is used to designate drug products which were imported by Canada, but latter were exported. ***Please note that re-exports do not include drugs purchased by U.S. residents from Canadian internet pharmacy providers. Also none of the export data from Canada include drugs shipped by Canadian internet pharmacy providers to U.S. residents nor does the export data include drugs purchased by U.S. residents who drive to Canada and return to the U.S. with pharmaceuticals.***

Table 6 depicts the total amount of pharmaceuticals exported from Canada from 1999 through 2003. This total includes the total dollar amount of drugs exported which are manufactured in Canada, plus the Canadian exports from drugs which have been imported into Canada. Table 6 depicts products which are in measured dosage forms and drug products packaged for retail use. It does not include bulk pharmaceuticals.

Table 6
Trend in Total Canadian Drug Exports* for Pharmaceuticals in Measured Dosage Forms or Packed for Retail Use
1999-2003**
(Values in Thousands of U.S. Dollars)

Year Country	1999 (%)	2000 (%)	2001 (%)	2002 (%)	2003 (%)
To U.S.	$428,064 (64.0%)	$592,708 (73.8%)	$902,531 (85.0%)	$967,492 (81.9%)	$1,541,163 (84.5%)
To Other Countries	$240,738 (36.0%)	$210,796 (26.2%)	$159,625 (15.0%)	$214,221 (18.15)	$282,970 (15.5%)
Total Canadian Exported Drugs	$668,802 (100.0%)	$803,505 (100.0%)	$1,062,156 (100.0%)	$1,181,713 (100.0%)	$1,824,133 (100.0%)

Source: http://strategis.gc.ca/sc_mrkti/ accessed March 12, 2004
* Total drug exports from Canada include the pharmaceutical exports from drugs manufactured in Canada plus Canadian drug imports which have been exported.
** Table does NOT include drugs shipped from Canada to the U.S. via Canadian internet pharmacy operations nor does it include drugs purchased by U.S. residents in Canada and brought back to the U.S.

In 2003, Canada exported $1.824 billion of pharmaceutical products. This is an increase of 172.7% since 1999. The majority of drugs exported from Canada were shipped to the U.S. In 2003, $1.541 billion of the Canadian exports came to the U.S, whereas only $285 million went to other countries. Close to 85% of the Canadian drug exports come to the U.S. ***Again it must be emphasized that that none of these export figures include pharmaceuticals shipped to U.S. residents from Canadian internet pharmacy***

operations nor drugs purchased in Canada by U.S. residents and brought back to the U.S.

Estimates of U.S. Resident Purchases of Canadian Drugs

Dollar estimates as to the extent Canada provides drugs to U.S. residents vary. For 2003, IMS has estimated that U.S. residents purchased $1.1 billion of drugs last year from Canada.[6] But, in another analysis, IMS estimates drug sales from Canadian internet sites and foot-traffic at $700 million.[7] Canadian internet pharmacy providers are the primary sources, but do not under estimate of number of U.S. residents traveling to Canada to purchase drugs. One indicator of the growth of Canada supplying drugs to U.S. residents is the growth in the number of Canadian internet pharmacy providers. In 1999, there were10 Canadian internet providers, now the estimate ranges from 120 to130 Canadian internet operations supplying drugs to U.S. residents.[8]

Apparent Domestic Canadian Market

As noted earlier, the apparent Canadian domestic market for drug products is calculated by summing the manufacturing shipments and total drug imports and subtracting total Canadian drug exports. The formula is as follows:

Apparent Domestic Market = Manufacturing Shipments + Total Imports – Total Exports

Please interpret this value with caution, because the "apparent market" and real domestic market are different. The value placed on products at the border and at the manufacturer's level may be different than the domestic market value. Plus, various other factors play a role in this difference including freight handling charges, and mark-ups from various handlers of the product.

Also, this calculation does not take into account the amount of drugs being supplied by Canada to U.S. residents via the Canadian internet pharmacy providers or by U.S. residents traveling to Canada to purchase drug products. Without this deduction, the figure from the above formula will give a market size, but it may not reflect the amount of drugs used primarily by Canadians.

Another problem in determining apparent market size is that the Canadian pharmaceutical manufacturing data has all shipments from the manufacturing facilities. This includes bulk pharmaceuticals, chemicals, along with products in measured doses. This means that other product forms such as bulk pharmaceuticals manufactured are included in the data with the finished drug products (products in measured dosage forms and packaged for retail use). Thus, to make the variables uniform, information on drug

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[6] "Rx Sales Jump 11%, Top $200Billion", *America's Pharmacist*, April 2004, 10.

[7] Saatsoglou Paul "Pharmaceutical Reimportation: magnitude, Trends and Consumers," Supplement to *Managed Care*, Vol.13. No. 3, March 2004.

[8] Carlisle, Tamsin, "What's Left for Canadians If Americans Buy Their Drugs" *Wall Street Journal*, November 4, 2003.

imports and drug exports must also include these "other products" or bulk pharmaceuticals along with the prepared dosage form drugs and pharmaceuticals packaged for retail use. The previous import and export tables only had data on pharmaceuticals which were in measured dosage units or packaged for retail use. Table 7 presents the information on Canadian manufactured shipments, pharmaceuticals imported and drugs exported with "bulk" pharmaceuticals added to the drugs in measured dosage forms or packaged for retail use.

Table 7
Canadian Pharmaceutical Manufacturers' Production, Amount of Pharmaceutical Imports and Exports and the Apparent Market Size
1999 through 2003
(Value in Billions of U.S Dollars)

Canadian Product Source and Exports	1999	2000	2001	2002	2003
Manufacturer Shipments	$3.319	$3.670	$4.387	Not Available	Not Available
Total Imports	$3.423	$4.014	$4.546	$5.116	6.399
Total Exports	$1.131	$1.248	$1.490	$1.625	$2.400
Apparent Market Size	$5.611	$6.436	$7.443	----------	----------

Source: http://strategis.ic.gc.ca/sc_mrkti/

Using the above formula and the most recent pharmaceutical manufacturing data available from Canada Statistics depicted in Table 6, the Canadian apparent domestic market for 2001 was $7.443 billion ($4.387 + $4.546 – 1.248 = $7.443). However, remember this figure includes some bulk pharmaceuticals. Also remember, this figure does not include distribution charges, wholesaler charges and mark-ups at the retail or hospital level. Theoretically, this figure represents the ingredient costs of drugs to be distributed to various health care provider outlets in Canada including internet pharmacies and other pharmacies providing drugs to the U.S. residents. Thus, this figure cannot be considered as only meeting the needs of Canada. Canadian drug products which are being shipped to U.S. residents need to be subtracted.

Deduction of Canadian Drugs Being Purchased by U.S. Residents

As mentioned, the estimations for U.S residents obtaining drug products from Canada through Canadian internet pharmacy providers and other Canadian retail outlets range from $700 million to $1.1 billion. If it is assumed that markups through the distribution chain range from 18% to 25%,[9] then the amount of drug costs shipped to U.S. residents

[9] "Trend 2002: The Pharmacy Report" Analysis of Canadian community pharmacies produced by Taro Pharmaceuticals and McKesson Canada, 2002, p 38.

runs from $525 million (.75 x $700 million) to $902 million (0.82 x 1.1 billion). When you subtract this figure from the apparent domestic market of $7.443 billion it leaves an estimated Canadian market size range of $6.541 billion to $6.918 billion. **Thus, when you take into account the Canadian drugs being purchased by U.S. residents, the Canadian drug market approaches $7 billion.** Remember, this does not include markups or dispensing fees throughout the Canadian drug distribution chain.

The $7.443 billion dollar figure represents pharmaceuticals available for sale in Canada, including products distributed to hospitals. Even though hospitals may not be a source of pharmaceuticals for U.S. residents, hospital purchases were not deducted from the $7.443 billion calculated market size because hospitals represent a portion of the Canadian pharmaceutical market. For informational purposes only, Canadian hospitals purchased $1.16 billion of drugs in 2000, $1.34 billion in 2001 and $1.49 billion in 2002. These figures are in Canadian dollars;[10] the U.S. dollar equivalent amounts are: $779 million in 2000, $865 million in 2001 and $949 million in 2002.

Separation of Bulk from Retail Packaged or Drugs in Measured Doses

When you subtract the import figures from Table 6 from the total import figures in Table 7 you will obtain the amount of bulk pharmaceuticals imported or pharmaceuticals not in measured dosage units or packaged for retail use. This same methodology can be used for calculating Canadian bulk exports of pharmaceuticals (subtract figures of total exports, found in Table 6, from total exports reported in Table 7). The results show that in 2003 there was a total of $1.667 billion of imported bulk pharmaceuticals ($6.399 - $4.732 = $1.667). A total of 69.26% (4.732/6.399) of the Canadian drugs imported were in measured dosage forms or packaged for retail use in 2003. For pharmaceuticals exported by Canada in 2003, the amount for bulk pharmaceuticals is estimated to be $576 million ($2.4 billion – $1.824 billion = $576 million). Pharmaceuticals in measured doses or packaged for retail use represent 76.0% of the Canadian pharmaceutical exports. This the analysis shows that drug products imported by Canada and exported by Canada are primarily products in measured dosage units or products packaged for retail use.

Comparison to the U.S. Pharmaceutical Market

In comparison to the U.S. pharmaceutical market, the Canadian market is relatively small. Using U.S. Department of Commerce, Bureau of Census data, Table 8 presents U.S. pharmaceutical manufacturers' production, U.S. imports and U.S. exports of pharmaceuticals. Table 8 also includes the U.S. apparent pharmaceutical market size employing the same formula as previously used.

[10] "The Canadian Pharmaceutical Market," IMS Report, IMS Health Incorporated, 2003, p 13.

Table 8
U.S. Pharmaceutical Manufacturers' Production, Amount of Pharmaceutical Imports and Exports and the Apparent Market Size
1999 through 2003
(Value in Billions of U.S Dollars)

U.S. Product Source and Exports	1999	2000	2001	2002	2003
Manufacturer Shipments	$72.751	$80.038	$93.779	Not Available	Not Available
Total Imports	$9.801	$10.131	$13.506	$19.368	Not Available
Total Exports	$7.662	$9.175	$11.375	$11.220	Not Available
Apparent Market Size	$74.89	$80.994	$95.910	----------	----------

Source: U.S. Department of Commerce: Bureau of the Census; International Trade Administration http://www.ita.doc.gov/td/industry/otea/industry_sector/tables_naics/325412.htm accessed March 29, 2004

The latest data available from the U.S. Department of Commerce for pharmaceutical manufacturing was 2001 and it shows that U.S. pharmaceutical manufacturers produced $93.779 billion dollars of pharmaceutical products. However, in reality, the pharmaceutical manufacturing industry produced a total of $100.068 billion worth of shipments, but the Department of Commerce did not classify all shipments as pharmaceutical shipments. Some of these other shipments may have been diagnostic testing supplies, other chemicals or products not classified as pharmaceuticals.

U.S. drug imports were $13.506 billion and of this total, $12.447 billion was for pharmaceuticals packaged for retail use or in measured dosage forms. The U.S. pharmaceutical industry exported $11.377 billion worth of pharmaceutical products. Using these figures and the apparent market formula, the apparent U.S. market size was found to be $95.910 billion in 2001.

The Canadian apparent pharmaceutical market size (Table 7) in comparison with the U.S. apparent market size (Table 8) is much smaller than the U.S. In 2001, the U.S. market size was $95.910 billion whereas the Canadian market size was $7.443 billion. Based on this approach, the U.S. pharmaceutical market size is approximately 13 times larger ($95.910 billion/ $7.443billion = 12.89) than the Canadian. As a matter of interest, the U.S. pharmaceutical exports are greater than the total Canadian market size in 2001.

Other Comparative Methods

Another approach to compare Canadian pharmaceutical market size to the U.S. is to examine the amount each country spends on pharmaceuticals annually. But, before this

analysis it was decided to compare the number of prescription filled annually for each country. Of course there is huge difference in the population of Canada when compared to the U.S. and thus the number of prescriptions will be reflective of the population differences. In Canada, the 2003 population was 31,629,700.[11] For the U.S., the population in 2003 was 290,810,000.[12] Thus, one can expect a large difference in number of prescriptions dispensed between the countries.

Number of Prescriptions Comparison

This approach on comparing the number of prescriptions does assume that the quantity of the drug per prescription (Number of dosage units per prescription) is the same for each country. Table 9 presents the total number of prescription dispensed per year from 1999 through 2002 for Canada and U.S. In examining the results it can be seen that the U.S. prescription drug market is approximately 10 times larger than the Canadian market based on the number of prescriptions dispensed. It is unknown if the number of prescriptions dispensed by Canadian internet pharmacies to U.S. residents is included in these figures.

Table 9
Number of Prescriptions for U.S. and Canada from 1999 trough 2002
(Numbers is Thousands)

Country	1999	2000	2001	2002
Canada*	**264,376,000**	**285,530,000**	**306, 184,000**	**326,219,000**
U.S.	**2,707,000,000**	**2,865,000,000**	**3,009,000,000**	**3,138,000,000**

* Source: IMS Health
**IMS Health and National Association of Chain Drug Stores Economics Department http://www.nacds.org/user-assets/PDF_files/dollar-Sales.pdf

On average, in 2002 there were approximately 8,590,260 prescription drugs in the U.S. dispensed per day (3.138 billion/365). When you divide the total number of prescription drugs dispensed in Canada, 326,219,000, by 8,590,000 prescriptions per day, **the results show that if U.S. residents were to purchase all their prescription drugs in Canada, the annual supply of Canadian drugs would be exhausted in 38 days (37.94 days)** and this assumes no drug supply for the Canadians. Of course, this assumes that the quantities of the drug per prescription are equal between countries and prescribing patterns are similar.

When you calculate the number of prescriptions dispensed per person for 2002, the results show 10.4 prescriptions per person were dispensed for Canada (326.219 million Rxs/31.361 million people) and 10.9 prescriptions per person were dispensed for the U.S.

[11] http://www.statcan.ca/english/Pgdb/demo02.htm accessed March 23, 2004.
[12] http://eire.census.gov/popest/data/states/tables/NST-EST2003-01.php accessed May 5, 2004.

(3.138 million Rxs/287.973 million people). Thus, both countries utilize approximately the same number of prescriptions per capita.

Canadian Drug Expenditures

In regard to prescription drug expenditures, Table 10 depicts the annual dollar expenditures for prescription drugs for Canada and the U.S. These data reflect public funded programs and private expenditures for drug products from both countries. The data in Table 10 are expressed in U.S. dollars. In Canadian dollars, the annual expenditures for Canada were as follows: $10.239 billion for 1999, $11.728 billion in 2000, $13.297 billion for 2001 and $14.572 billion for 2002.[13] The Canadian expenditures for 2001 and 2002 were forecasted. It must be mentioned that various estimates exist for the size the of the Canadian retail pharmacy market. It was decided to use information from the Canadian Institute of Health Information because of its completeness.

Table 10
Trends in Canadian and U.S. Drug Expenditures
1999-2002
(Volume in Billions of U.S. Dollars)

Country	1999	2000	2001	2002
Canada*	$6.871	$7.871	$8.643 (forecast)	$9.282 (forecast)
U.S.**	$125.758	$145.611	$164.143	$182.712

*Source: "Drug Expenditures in Canada 1985 – 2002," Canadian Institute for Health Information, 2003, 66.
**Source: IMS Health and National Association of Chain Drug Stores Economics Department http://www.nacds.org/user-assets/PDF_files/dollar-Sales.pdf

The comparisons in Table 10 reflect not only the difference in size of the populations and drug markets, but they also reflect the difference in drug prices at the retail level between the countries. Thus, the comparisons show a larger difference in market size than the previous analyses.

Summary of Comparative Analysis

The results show that the U.S. pharmaceutical market is much larger than the Canadian market. The Canadian drug market which is used by the Canadians is approximately $7.0 billion whereas the U.S. market is approximately $95 billion when using governmental data on product costs from manufacturer and importation evaluations. This is a 13 fold difference. Based on the number of prescription filled, the Canadian annual prescription

[13] "Drug Expenditures in Canada 1985 – 2002," Canadian Institute for Health Information, 2003, 66.

drug supply would only last 38 days in the U.S. This is a nine fold difference and based on the pharmaceutical expenditures there is a 19 fold difference.

Extrapolation of Older U.S. Residents Drug Use and the Canadian Drug Supply

In the United States, people 65 years of age or older have approximately 28 prescriptions dispensed per year in the U.S.[14] This 28 days may seem like a lot, but this number is heavily dependent on quantity of the medication dispensed for each prescription. If a prescription is written for a 90-day supply then only four prescriptions are needed per year. Thus, and person on five chronic medications and each prescription was written for a 90-supply, the total number of prescription dispensed per year would be 20. Most medications for the treatment of chronic conditions are written for 90-day quantities. Thus the average of 28 prescriptions pre year sounds reasonable for people 65 years of age or greater.

In 2001, people 65 years of age or greater accounted for 30.352 million people in the U.S.[15] Using the 28 prescriptions per year average, the estimated number of prescriptions annually to serve this population is approximately 979.776 million (28Rxs/year x 30.352 million). As documented earlier, Canadian pharmacies dispensed 306 million prescriptions in 2001. Based on these facts, to supply just half of the U.S. elderly population and provide enough pharmaceuticals to take care of the Canadian needs, Canada will need to increase their total drug supply by 2.5 times. Notice that this estimate does not account for other population groups which may want to obtain their pharmaceuticals from Canada and only includes half of the U.S. elderly.

Other Issues Canadian Drug Importation

As noted earlier in Table 5, the U.S. provides 44.3% of Canadian imported pharmaceutical products. The remaining come from a variety of countries. Canada does have mutual pharmaceutical manufacturing agreements with 18 countries which are primarily located in Western Europe. And in fact, Canada does import a large amount of pharmaceuticals from these countries. However, in examining the importation data, Canada is also importing pharmaceuticals from over 100 countries some of which include China, Mexico, Ecuador, Brazil, India, and Hong Kong and Singapore.[16] Table 10 depicts the dollar amounts of Canadian imported pharmaceuticals, the exporting country and the year.

From 2002 to 2003, there was a 26.1% increase in drug imports for Canada. For the previous two years, annual increases have been around 13%. One item of interest in looking at Table 10 is the fluctuations in the amount of drug imports by year for some countries. There have been major changes in sources of pharmaceutical products by year.

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[14] "Cost Overdose: Growth in Drug Spending for the Elderly 1992-2010," Families USA, July 2000, 6.
[15] http://www.census.gov/statab/www/poppart.html accessed May 4, 2004.
[16] http://strtegis.ic.gc.ca/sc_mrkti/tdst//tdo/tdo.php accessed March 28, 2004.

For example, Ireland exported close to $200 million in 1999, but decreased exports to $41 million the following year and in 2003 it was approaching $700 million.
It is also worth noting that some of these countries have had a tremendous increase in the amount of pharmaceuticals being exported to Canada in recent years. It can be hypothesized that this is most likely a response to the increase demand from U.S. residents and perhaps supply shortages in Canada. For example, since 2001 Canadian imports from the U.S. have increased 31.2%, from Ireland 231%, Italy 282%, Mexico 50%, Singapore 72%, and India 109%. Recently, *Script* reported that a Vancouver internet pharmacy provider is "openly selling U.S. citizens prescription medicines that allegedly come from Mexico and are not approved by either Health Canada or the U.S. FDA." [17] Some Canadian internet providers are on record of stating that they will find creative ways of obtaining drug products to meet U.S. demands, if U.S companies will not meet their needs. It is this type of information that has many U.S. authorities worried about the quality of imported drug products.

Table 10 Trend in Imported Canadian Pharmaceuticals in Measured Doses or Packed for Retail Use by Country by Country 1999-2003

	1999	2000	2001	2002	2003
United States (U.S.)	1,254,311,235	1,592,006,336	1,598,438,598	1,793,060,587	2,097,199,943
Ireland	199,447,738	41,383,925	206,071,951	438,393,420	682,506,549
United Kingdom (U.K.)	147,666,168	162,892,340	257,198,969	311,383,991	406,414,553
Germany	92,112,130	324,150,542	356,652,961	250,232,330	340,642,981
Sweden	159,062,746	224,440,239	262,215,121	336,302,276	305,074,422
France (incl. Monaco, French Antilles)	101,646,463	305,826,201	114,740,886	154,766,473	260,583,813
Switzerland	171,650,097	185,639,599	165,800,110	171,872,184	163,654,400
Italy (includes Vatican City State)	16,858,740	23,555,031	26,806,935	42,065,631	102,533,237
Denmark	56,155,279	48,998,111	52,488,721	66,472,723	82,957,897
Belgium	26,455,563	33,723,466	40,465,406	39,711,486	60,140,262
Netherlands	39,107,967	44,550,164	50,122,282	56,355,308	57,979,106
Australia	14,953,982	14,939,756	36,394,430	39,151,382	35,165,129
Spain	13,091,102	10,416,576	14,910,734	17,416,756	30,416,629
Mexico	9,439,259	9,968,995	16,814,478	15,857,350	25,276,253
Japan	17,903,970	4,943,088	1,875,572	10,922,853	20,125,762
Israel	6,756,619	9,339,424	14,500,995	16,724,536	18,014,407
Austria	1,749,807	4,422,486	4,270,600	7,632,486	13,673,762
Singapore	1,821,849	907,911	2,767,210	1,492,824	4,904,130
Finland	1,830,886	2,137,776	2,302,451	2,932,492	3,571,742
India	3,857,686	5,929,390	1,583,930	5,324,872	3,316,641
China	2,701,437	4,013,760	7,203,586	2,314,027	2,972,456
Ecuador	238,567	[illegible]	--	1,516,374	2,687,887
Norway	12,286	27,310	269,611	411,624	1,884,032
Hungary	2,907,423	4,892,093	4,084,945	3,089,287	1,869,047
Slovenia	1,127,537	665,901	918,000	1,341,694	1,770,403

[17] Mexican Drugs Shipped to US via Canada, say Consumers," *Scrip World Pharmaceutical News*, No 2942, April9, 2004, 17

Hong Kong	957,953	1,566,652	1,496,071	908,142	1,341,165
Brazil	5,820	462	1,157,341	4,516,057	1,123,451
Thailand	145,345	213,159	615,460	498,154	929,496
New Zealand	1,209,685	596,133	929,712	632,210	918,626
Portugal	45,594	25,158	77,360	614,000	615,668
Re-Imports (Canada)	722,391	4,453,656	303,333	1,253,378	610,008
South Africa	181,974	354,573	228,272	328,501	314,778
Malta	--	--	185,703	280,136	279,898
Taiwan (Taipei)	37,770	371,060	52,462	196,594	255,240
Korea, South	109,533	122,401	505,488	151,167	149,042
Cuba	--	136,648	176,682	120,583	139,486
Argentina	50,424	64,011	36	3,586	75,480
Colombia	137	24	5	13,847	73,936
Luxembourg	8,175	36,509	146,136	--	59,934
Poland	273	8,084	--	12,472	41,396
Guyana	1,921	6,341	29,607	29,826	41,115
Czech Republic	954	3,369	625	205	40,005
Greece	321,373	29,639	29,923	31,248	19,220
Bolivia	--	--	--	--	12,324
Costa Rica	1,309	634	--	82,058	6,965
Philippines	2,080	58,749	777	1,003	4,151
Iceland	--	361,463	2,758	--	3,572
Panama	2,920	29,919	--	30	2,582
Iran	23,682	49,288	--	--	2,355
Niger	--	10,946	--	--	2,101
United Arab Emirates	2,206	1,313	1,852	4,788	2,032
Sri Lanka	79	407	120	675	1,886
Guatemala	--	--	10	--	1,871
Pakistan	2,759	4,788	482	1,806	1,682
Malaysia	1,875	2,128	8,352	32,560	1,655
Macau (Macao)	--	--	--	--	1,100
Vietnam	--	--	147	190	564
Indonesia (includes East Timor)	10,823	--	76	420	507
Jamaica	--	21	2,069	1,084	480
Uruguay	--	86,449	--	1,975	417
Tunisia	--	--	--	31	332
Slovakia	92,671	284,569	10	2	331
Lebanon	--	--	--	--	326
Kenya	--	--	307	26	288
Paraguay	--	--	--	--	257
Saudi Arabia	9	--	--	415	233
Russia	73	66	63	24	222
Trinidad and Tobago	457	695	9,222	3,586	213
Albania	--	--	--	--	171
American Samoa	--	--	--	--	170
Fiji	--	--	--	360	156
Venezuela	349	--	--	19	143
Nigeria	--	--	2	787	128
Bahamas	229	32	--	631,477	124
Chile	66,101	4,370	2,805	191,537	122
Turkey	5,095	14,848	--	125	113

Ukraine	--	50	246	2,874	110
Bermuda	--	74	141	1,207	108
Ghana	--	--	136	146	51
Barbados	14,216	15	4,184	6,848	49
Jordan	202	100	170	40	49
Morocco	--	--	--	44	16
Saint Lucia	--	--	--	--	14
Romania	--	--	--	81	13
Dominica	--	--	--	--	10
Côte-D'Ivoire (Ivory Coast)	17	--	1	--	7
Peru	1,141	2,583	962	62	3
Bulgaria	20	12,867	10	80	1
Egypt	--	1,322	--	--	1
Grenada	--	--	--	383,306	--
Croatia	214,731	73,630	77	20,504	--
Yugoslavia - Serbia and Montenegro	--	--	--	2,499	--
Seychelles	--	--	--	836	--
British Virgin Islands	--	--	--	108	--
Dominican Republic	61	--	--	61	--
Nepal	--	--	--	20	--
Kuwait	--	--	--	10	--
Syria	--	--	32	2	--
El Salvador	--	--	56	1	--
Georgia	--	844	56,631	--	--
Cameroon	21	--	5,634	--	--
Latvia	--	--	1,691	--	--
Guinea	--	--	1,093	--	--
Netherlands Antilles	--	--	552	--	--
Honduras	--	60	46	--	--
Brunei Darussalam	--	--	14	--	--
Belize	344	14,084	--	--	--
Central African Republic	--	1,663	--	--	--
Cyprus	--	24	--	--	--
St. Helena	20	20	--	--	--
Gabon	--	19	--	--	--
Sudan	1,112	--	--	--	--
Sierra Leone	874	--	--	--	--
Qatar	75	--	--	--	--
Mali	18	--	--	--	--
TOTAL (ALL COUNTRIES)	2,347,111,427	2,866,966,530	3,244,933,426	3,733,187,909	4,732,413,392

Source of data: Statistics Canada
Report Date: 04-May-2004
http://strategis.gc.ca/sc_mrkti/tdst/tdo/tdo.php?headFootDir=%2Fsc_mrkti%2Ftdst%2Fheadfoot&naArea=9999&lang=30&searchType=BL&toFromCount
OUPED#tag

Conclusion

Using today's realities and from a practical perspective, it does not appear reasonable for Canada to meet the drug needs for many in the U.S. This is especially true if U.S. pharmaceutical manufacturers limit their shipments of pharmaceuticals to Canada and the demand for Canadian continues to escalate. It seems reasonable to project that a shortage of prescription drugs will occur in Canada with the rising demand from U.S. residents. Evidence of this has already appeared in many newspapers across the country. To meet the demand of U.S. residents, Canada will have to either expand their manufacturing capabilities or import more pharmaceuticals. And, it appears that the latter approach appears to be the strategy in place.

Even if pharmaceutical manufacturers were to continue their drug shipments to Canada, the drug distribution infrastructure of Canada needs to be developed to handle the expected increased volume. Innovative methods are available to mediate the logistical supply chain issues and the drug control concerns, but the cost of developing such systems may offset the savings generated. Just the logistical development for a drug recall protocol and the re-labeling of drug products which do not meet FDA labeling standards will add costs to the system. Canadian and U.S. firms along with governmental agencies will probably have to invest heavily in their infrastructure and personnel if they were to assume such a venture.

In writing this report other questions have arisen that need to be addressed in regard to importing pharmaceuticals from Canada. These include:

- What are the most popular drugs being imported from Canada?
- Who is purchasing drug products from Canada? In other words, what are the demographic characteristics of people now obtaining drug products from Canada?
- What are the top 20 drug products used by Americans 65 years of age or older? Are these available in Canada and are these products being imported?
- What drug products are being imported by Canada and what country and what firm is supplying the product? Are these products approved by the Health Canada or the U.S. FDA?
- To what extent do U.S. residents travel to Canada to purchase pharmaceuticals? What is the demographic profile of these customers? Are products purchased by traveling to Canada different than products purchased through Canadian internet providers?
- Are Canadian internet pharmacy providers by-passing the Canadian importation declaration process and obtaining drug products which are not approved by Health Canada nor reported?
- How many Canadian internet providers have facilities working "off-shore" and providing drugs to U.S. residents?
- What changes in the drug distribution infrastructure need to be made to accommodate Canadian drug importation?
- How could products be directly shipped from U.S. manufacturers to U.S. wholesalers or warehouses while the purchasing agreements pass through

Canadian firms? This would eliminate distribution, storage and drug custody problems.

- Will cost savings be captured by middlemen in the distribution or will they passed on to consumers or buyers?