

6. Prescription Piracy:

The Black Market in Foreign Drugs Will Not Reduce U.S. Health Care Costs

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Key Points

- Foreign countries will not permit U.S. politicians to siphon off medicines their citizens need by means of a black market.
- Policies that allow this practice effectively steal intellectual property from innovative companies that operate legally in the United States.
- Many Canadian Internet pharmacies appear to be selling generic versions of medicines that are still patented in the United States.
- States should not encourage the illegal practice of “re-importing” prescription medicines.

Introduction: A Borderline Issue

Some politicians in the United States are well known for supporting the so-called “re-importation” of foreign medicines through the black market from countries such as Canada, as a way to reduce health care costs for Americans. Unfortunately for them, this black-market trade in prescription drugs will not achieve the expected outcomes.

First, it is impossible to supply the demands of American patients through the cross-border drug trade without simultaneously reducing access to

medicines for patients in the source countries. Foreign governments will ban the export of drugs to Americans before allowing American cross-border consumers to jeopardize the supply of retail drugs for their citizens. This chapter presents Canada as a case study of a major source country that has supplied the black-market trade in prescription drugs to the United States. Further, it explains the basic economic reasons why Americans will not be able to rely on foreign pharmacies to supply their medications.

Second, the black-market drug trade depends on unfair trade practices that are often illegal under international law. Many of the drugs being traded are unauthorized copies of medicines that are still under patent protection in the United States. Foreign cross-border drug retailers are engaged in the massive theft of intellectual property, because they are copy-pirating the latest drug inventions. This violation of the property rights of global drug makers could potentially reduce economic growth in the U.S. pharmaceutical industry, resulting in job loss. The violation also might discourage investment in the development of new medicines, which means that patients in the United States and around the world will not realize the benefits of future pharmaceutical improvements. This chapter discusses the role that Canadian-based cross-border Internet pharmacies are playing in the black-market copy piracy of American drug inventions.

Canadian vs. U.S. Demand for Canada's Drug Supply

The notion that the cross-border drug trade can be relied upon to supply medicines to Americans assumes that foreign sources of supply will remain adequate to meet U.S. demand. Both the evidence and the economics of the cross-border drug trade show that this assumption is false.

The basic economic fact driving the cross-border drug trade is price differences between the United States and countries like Canada. Previous research has shown that after adjusting for currency value, prices for the 100 top-selling brand-name drugs in Canada are on average 43 percent below U.S. prices for the same drugs (Figure 1). By contrast, the 100 top-selling generic drugs are on average priced 78 percent higher in Canada than the same drugs in the United States.ⁱ In fact brand-name products account for about 72 percent of the value of all cross-border Internet sales to Americans.ⁱⁱ

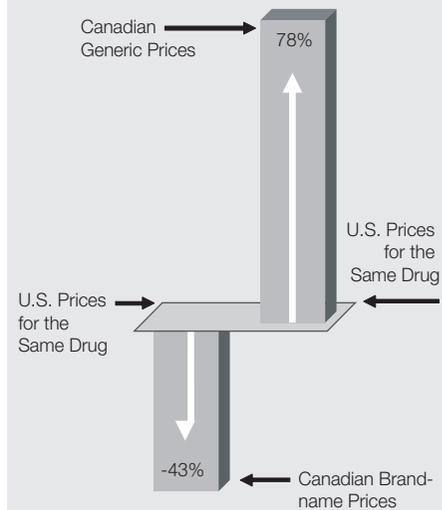
This pattern of cross-border sales is consistent with the fact that 92 percent of the top-selling brand-name products are priced *lower* in Canada than in the United States, while nearly 75 percent of top-selling generic products are priced *higher* in Canada than in the United States.ⁱⁱⁱ The higher relative price of most Canadian generic drugs explains why a smaller percentage of such drugs are resold to Americans through Internet pharmacies. U.S. consumers are simply able to buy most of these drugs more cheaply at home.

It is important to recognize that lower prices on Canadian brand-name drugs are not simply due to Canadian price controls, but are also the normal result of market economics. There is evidence that even in the absence of price controls, the normal Canadian free-market price for drugs would probably remain much lower than U.S. prices.^{iv}

There are valid economic reasons why drug companies charge lower prices in Canada than in the United States, and why they cannot afford to allow lower Canadian prices to be imported into the American market through the cross-border drug trade. Previous research indicates that across segmented free markets the prices of drugs should be positively correlated to the average incomes in each market. That is, drug prices should be higher in wealthier markets and lower in poorer markets – a pricing relationship that is consistent for many non-pharmaceutical products as well.^v

Differential pricing between markets occurs because sellers find that the profit-maximizing price in a market depends on the level and distribution of income among buyers. A positive relationship between price and average

Figure 1. Average Canadian Price Differences From U.S. Prices for the Same Drugs Over the Top 100 Brand-name and Top 100 Generic Drug Products Sold in Canada in 2003 (at Purchasing Power Parity)



Source: Skinner (2005); IMS Health Inc. (2004).

income in a market usually occurs because average income is an important factor in determining consumers' willingness to pay in a market.^{vi} For the seller, the best price is the one that maximizes profits through an optimal combination of supply and demand within each market. The optimal price is usually higher in markets with higher incomes.^{vii}

Drug manufacturers can charge lower prices in Canada relative to the United States only when the two markets are segmented; that is, price differentiation is possible when vendors can prevent customers who enjoy lower prices (Canadians) from reselling their goods to customers who pay higher prices (Americans).^{viii} If the cross-border drug trade undermines North American market segmentation, Canadian prices would adjust naturally in response to the increased market demand from the growing wave of American consumers and converge toward higher American prices.

Aside from normal demand-driven price increases, the growth of the cross-border trade should create upward pressure on Canadian prices. Drug manufacturers want to prevent Canadian prices from being "imported" to the United States, thus undermining global pharmaceutical pricing strategies. Therefore, drug companies would also have an incentive to raise the price in Canada to eliminate any artificial cost savings that are driving cross-border sales. Federal Canadian drug-price controls prevent natural price movement above the status quo. As such, existing Canadian pharmaceutical policies prevent normal price adjustments from taking effect. The difference between Canadian and U.S. prices for brand-name (mostly patented) drugs has created an incentive for Canadian Internet pharmacies to buy up the Canadian drug supply at prices fixed by law in Canada. They then resell the same drugs to American consumers at a premium over the Canadian price, but still sufficiently below the U.S. market price to attract American consumers.

Those consumers represent an opportunity to capture a higher price and sell a larger quantity of drugs, thus creating a powerful profit incentive for Internet pharmacies to engage in reselling the Canadian drug supply to Americans. However, the growth in the cross-border drug trade encourages drug makers to restrict their supply of medicines in Canada to normal domestic consumption levels in order to prevent Canadian prices from being brought into the United States.

Drug Makers Choose How to Respond

Research-based drug companies cannot afford to have Canadian prices prevail in the American market because their global price differentiation strategies are designed to recover the significant research and development costs associated with bringing new drugs to market. Research indicates that on a risk-adjusted basis, inventing and developing a new drug costs on average \$800 million to \$900 million in U.S. dollars.^{ix} The cost of this process is recovered through differential pricing strategies that match prices with demand and income conditions in each market.

In this context, drug manufacturers have only a few options with which to deal with increasing volumes of cross-border resale drugs. First, in a free market, drug makers would simply adjust Canadian prices toward the U.S. price level to eliminate the savings that are driving consumer demand for cross-border drugs. This is the easiest, most effective, and the least costly strategy. However, federal drug price controls in Canada preclude drug companies from exercising this option.

Another option is to minimize cross-border sales of drugs. Drug companies would supply the Canadian market at levels that are consistent with normal Canadian demand. The cross-border trade would become a zero-sum game: if pharmacies were to redirect substantial portions of the Canadian drug supply to American consumers, it would result in equivalent shortages for Canadian consumers. Such a strategy limits the damage that can be done to international pricing structures in pharmaceutical markets, and puts the onus for action on the Canadian government to protect its domestic drug supply. Given that price controls are the cause of the cross-border drug trade, this would seem appropriate.

In fact, evidence shows that as of June 2005 at least 10 of the largest brand-name pharmaceutical companies supplying the Canadian market have implemented policies to restrict sales of drugs in Canada to normal domestic consumption levels. These companies include Abbott Laboratories, AstraZeneca, Boehringer-Ingelheim, GlaxoSmithKline, Lilly, Merck Frosst, Novartis, Pfizer, Sanofi Aventis, and Wyeth.^x

In fact, even under the current volume of black-market cross-border drug trade, shortages are occurring in Canada, and the Canadian government has signaled that it intends to ban the export of the domestic drug supply

to Americans. In late 2005, Canada's federal health minister introduced legislation that would allow Canada to enforce an export ban on the cross-border drug trade in the event that a drug shortage materializes. The move followed a November 2004 Canadian Pharmacists' Association report that found that 80 percent of pharmacists in Canada were experiencing one or more drug shortages weekly, and that shortages were becoming more frequent.^{xi} Such shortages are not surprising when one considers the relative size of the American and Canadian consumer segments currently competing for access to Canada's retail supply of drugs.

The cross-border Internet pharmacy industry is represented by a number of trade associations, the most prominent of which is the Canadian International Pharmacy Association (CIPA). Importantly, CIPA officials identify U.S. *seniors and Americans without health insurance* as the specific target markets for its members. Based on this claim, we can estimate the size of the cross-border drug trade's target market and compare it to Canada's own population of consumers.^{xii}

American seniors numbered about 36 million in 2004.^{xiii} By comparison, Canada's total population is roughly 32 million and its current population of seniors about four million.^{xiv} This means that there are approximately nine times as many American seniors as there are Canadian seniors in the competition for a limited Canadian drug supply. In fact, there are more U.S. seniors competing for Canada's drug supply than there are Canadians as a whole.

Some claim that the recent implementation of the Medicare Modernization Act (MMA), which extended publicly-subsidized drug benefits to most American seniors, may reduce the need for many American seniors to shop for drugs in Canada. The act created a Medicare drug benefit for seniors, beginning in 2006. The drug benefit is available on a voluntary basis to all Medicare beneficiaries. Perhaps surprisingly, eligibility for the Medicare drug benefit is more universal than existing Canadian programs for seniors, despite Canada's government health-run care system.

However, the standard drug benefit specified by the act for calendar year 2006 has a \$250 annual deductible; pays 75 percent of covered drug costs between \$250 and \$2,250; provides no further coverage until an enrollee has incurred \$3,600 in out-of-pocket drug costs for the year; and pays about 95 percent of covered drug costs beyond that catastrophic

threshold. The catastrophic threshold is defined in terms of the actual out-of-pocket costs that enrollees incur.^{xv} (CBO 2004: viii)

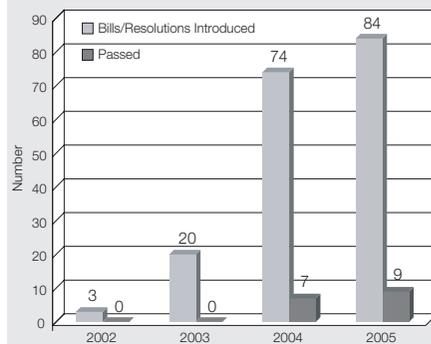
The deductible structure of the benefit and the fact that some seniors are not eligible for coverage at all under the act mean that seniors as a whole will still face significant out-of-pocket drug costs. As a result, American seniors may still demand drugs that are sold through Canadian-based Internet pharmacies. Also, as discussed later in this paper, there are accelerating legislative efforts under way in the United States to allow Medicare recipients to obtain retail drugs from Canadian pharmacies.

The other stated target market for Canadian Internet pharmacies is Americans without health insurance. According to the United States Census Bureau's *Current Population Survey* (CPS), nearly 46 million Americans lacked health insurance in 2004.^{xvi} However, estimating the number of people without health insurance is the subject of much debate because of the way that the Census Bureau collects data on the issue. Government survey questionnaires overstate the uninsured population – possibly counting many responses twice.^{xvii} Based on the characteristics of the individual in the uninsured survey population, the best estimate of the actual long-term uninsured population in the United States is 23 million.^{xviii} Nevertheless, this group alone equals two-thirds of Canada's population.^{xix}

The total current U.S. population competing with Canadians for access to their drug supply is between 59 million and 82 million people, a consumer group roughly 85 to 160 percent larger than the entire population of Canada. It is no wonder Canadian pharmacists are reporting shortages. But Canadian drug shortages would worsen dramatically if U.S. demand for Canadian medicines were to undergo an “official” expansion of the kind recommended by some American politicians.

The cross-border resale drug trade is currently illegal in the

Figure 2. Number of U.S. State and Federal Bills and Resolutions Introduced and Passed that Favored Legalizing the Cross-border Drug Trade, January 2002 to September 2005



Source: National Conference of State Legislatures (2005).

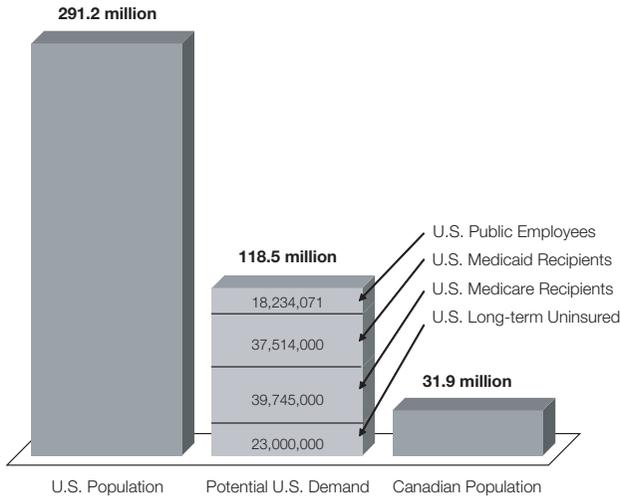
United States. Yet, since the trade began in 2002, many federal, state, and local American politicians have been attempting to legalize the purchase of resale drugs from Canadian Internet pharmacies. The number of attempts to pass legislation at the federal and state level has grown from three per year in 2002 to 84 per year by September 2005 (Figure 2). Many of the proposals allow the bulk buying of drugs from Canadian Internet pharmacies to supply federal, state, and local government employees in the United States, as well as recipients of U.S. government programs like Medicaid and Medicare.^{xx}

The total scope of potential U.S. demand for foreign-sourced retail drugs under these proposals is enormous when compared to the total populations of the source countries themselves. For instance, the U.S. Census Bureau reports that the total number of full-time equivalent, federal, state, and local civilian employees of the U.S. government is approximately 18.2 million people, or approximately 57 percent of the entire Canadian population.^{xxi} It is probable that the family members of these employees would be eligible to make cross-border purchases. The 2004 U.S. census reports that the average American family size was 3.18 people.^{xxii} Therefore, the potential consumer segment represented by government employees and their families in the United States could be as high as 58 million, or nearly twice as large as Canada's entire population.

Additionally, the number of people enrolled in state Medicaid programs alone (37.5 million: mainly social assistance recipients) is 17 percent larger than the entire Canadian population. The number of Medicare beneficiaries (39.7 million: mainly seniors and the disabled) is 24 percent larger than the Canada's 32 million.^{xxiii}

A conservative estimate of the potential individual and bulk demand for cross-border drugs shows that the number of American consumers that might compete for access to the Canadian drug supply is nearly four times the size of Canada's entire population. The enormous size of the potential American consumer demand relative to Canada's population is shown in Figure 3, and indicates that it is clearly not feasible for cross-border pharmacies to supply either their target markets (approximately 63 million customers between Medicare seniors and the uninsured populations), or potential bulk buyers (approximately 56 million customers between Medicaid and U.S. public employees, excluding family members).^{xxiv}

Figure 3. Estimated Size of U.S. Consumer Groups Competing for Access to Canada's Drug Supply



Source: U.S. Census Bureau (2005); American Blue Cross-Blue Shield Association (2005); Statistics Canada (2005). To be conservative, this analysis only includes the direct employee population of 18.2 million.

This Is Not Free Trade

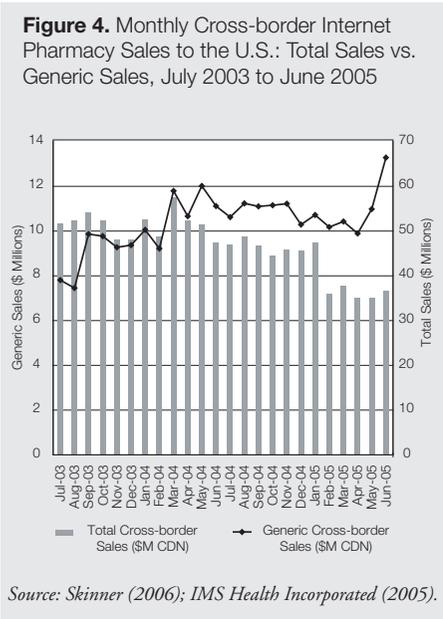
No matter what some might think, the cross-border drug trade is not free trade, which is based on respect for property rights. Yet, the evidence suggests that Canadian-based Internet pharmacies are profiting from the theft of U.S. intellectual property on a massive scale by selling to American consumers generic versions of drugs still patented in the United States.

According to the best data available there are at least 278 Canadian-based Internet pharmacies that are “confirmed or suspected” of primarily selling drugs to Americans. As of June 2005, the annualized value of drug sales to the United States through these pharmacies was an estimated \$456 million (measured at manufacturer-level prices). This is down 18 percent from the previous 12 months ending June 2004 (IMS Health Inc. 2005: allowing 90 U.S. cents to the Canadian dollar). The value of sales measured at the final U.S. retail prices charged to American consumers by Canadian Internet pharmacies are certainly much higher than the figures reported above and do not include “foot traffic” sales to American consumers through regular “brick-and-mortar” border pharmacies.

What explains the recent leveling off of Canadian-based cross-border Internet drug sales to the United States? Of the 500 top-selling cross-border drugs between July 2004 and June 2005, 302 (60 percent) were brand-name products representing 72 percent of the total value of Internet sales and 198 (40 percent) were generic products representing 28 percent of the total value of Internet sales. A closer look at data on annual sales for the 500 top-selling cross-border drug products between July 2003 and June 2005 shows that relatively less expensive generic products are displacing brand-name products in the volume of drugs being traded over the Internet to Americans, thus largely explaining the drop in the overall value of sales.^{xxiii}

Figure 4 shows how the monthly value of all cross-border Internet drug sales declined between April 2004 and June 2005. At the same time, the monthly value of cross-border sales in specifically generic products has steadily increased. Therefore, the shrinking value of cross-border sales is not solely reflective of declining unit volumes of the drugs being traded. These data indicate that relatively lower priced generics (relative to brand drugs) have accounted for a greater share of the cross-border product mix since April of 2004, thus largely explaining the drop in the overall dollar value of sales over time.

Figure 4. Monthly Cross-border Internet Pharmacy Sales to the U.S.: Total Sales vs. Generic Sales, July 2003 to June 2005



Source: Skinner (2006); IMS Health Incorporated (2005).

The large and rising proportion of Canadian cross-border drugs accounted for by generic products is very surprising. As mentioned earlier, nearly three-quarters of the 100 most commonly prescribed generic products available in both Canada and the United States in 2003 were priced higher in Canada. The average price difference for the group of high-priced generics was 116 percent greater in Canada, while the top 100 generics as a whole were priced 78 percent higher, after adjusting for currency differences.^{xxvi}

Why would Americans be buying so much of Canada’s generic drug supply if these kinds of drugs were almost always cheaper in the United States? The answer is found in an analysis of the Canada-U.S. patent status of cross-border drug products. Of the top 500 drugs sold by suspected cross-border pharmacies, 198 are generic in Canada. However, 50 of these are still patent-protected in the United States. Table 1 shows that nearly half (47 percent) the value of generic sales through cross-border Internet pharmacies to Americans was accounted for by products that were not yet generic in the United States. In almost all cases, the lack of a generic equivalent in the United States means that these drugs were still under active U.S. patent protection (Table 2). The data suggest that Canadian-based Internet pharmacies are engaged in a massive theft of U.S. intellectual property, by selling drugs to Americans in violation of active U.S. patent rights.

Table 1. Distribution of Prescription Drug Sales to Americans Through 278 Identified Canadian Cross-Border Internet Pharmacies, July 2004 to June 2005, (C\$, manufacturer-level prices)

Total Canadian Cross-border Internet Pharmacy Sales to U.S.	\$506,642,793
Top 500 Drugs (Incl. brand and generic products) Sold Through Canadian Cross-border Internet Pharmacies to U.S.	\$468,235,940
198 Canadian Generics in top 500	\$131,130,748
50 of 198 Canadian Generics, Non-Genericized In U.S.	\$61,203,561
Percentage of Generic Sales Violating U.S. Patents	46.7%

Source: Skinner (2006) using IMS Health Incorporated (2005) data.

Table 2. Drugs that are not genericized in the United States (grouped by therapeutic category and active ingredient) that are being sold in generic versions (across 50 products) from Canadian-based Internet pharmacies to Americans

Therapeutic Category*	Generic Active Ingredient	U.S. Patented Brand Name Version
Antiarthritics	Leflunomide	Arava
Antiarthritics	Meloxicam	Mobic
antihistamines, systemic	Cetirizine	Zyrtec
antihyperlipidemic agent	Fenofibrate micro	(various: Tricor, Triglide, Lofibra, etc.)
antihyperlipidemic agent	Simvastatin	Zocor

Therapeutic Category*	Generic Active Ingredient	U.S. Patented Brand Name Version
antihyperlipidemic agent	Pravastatin	Pravachol
anti-infectives	Levofloxacin	Levaquin
anti-infectives	Terbinafine	Lamisil
antispasmodic/antisecretory	Domperidone	(No equivalent brand or generic)
bronchial therapy antispasmodic/antisecretory	salvent (CFC free) domperidone	(various: similar to Albuterol) (no available product)
bronchial therapy antispasmodic/antisecretory	salbutamol hfa domperidone	(various.: similar to Albuterol) (no available product)
cardiovascular bronchial therapy	carvedilol salvent (CFC free)	Coreg (various: similar to Albuterol)
hormones bronchial therapy	desmopressin salbutamol hfa	(various: DDAVP, Stimate, Minirin, etc.) (various: similar to Albuterol)
hormones cardiovascular	alendronate carvedilol	Fosamax Coreg
neurological disorders, hormones	lamotrigine desmopressin	Lamictal (Various: DDAVP Stimate, Minirin, etc.)
psychotherapeutics hormones	sertraline alendronate	Zoloft Fosamax
neurological disorders	lamotrigine	Lamictal
Psychotherapeutics	sertraline	Zoloft

*Source: Skinner (2006); IMS Health Incorporated (2005) Notes: *USC2 description.*

These findings make it highly probable that American patent holders have legal recourse in U.S. courts to stop the cross-border trade. The federal government certainly has the legal and moral authority to ban imports of these generic drugs in order to enforce its own laws on property rights. The findings also imply that American politicians who promote the legalization of the cross-border resale drug trade are inadvertently encouraging an enormous rip-off of their own nation's intellectual property and leaves open the question of whether they might be legally liable for the losses suffered by patent holders.

Canadian-based Internet pharmacies are trading in stolen goods. The cross-border drug trade simply cannot be justified using free-market arguments, unless one uses Tony Soprano's definition of free trade.

Endnotes

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- ii Brett J. Skinner, *Price Controls, Patents, and Cross-border Internet Pharmacies: Risks to Canada's Drug Supply and International Trading Relations*, (Vancouver and Toronto: The Fraser Institute, 2006).
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- vi However, higher prices may sometimes be observed in poorer markets if a very wide income range characterizes the market. This is because average incomes are affected by the distribution of wealth in the market. For instance, a poor country may have a small minority of its population that is extremely wealthy while the bulk of the population is extremely poor. This will lower the average income (total income divided by population). If the domestic market cannot be segmented between consumer groups based on income or if the incomes of the poor are not high enough to buy at the lowest possible price, then it will only be profitable to sell to the smaller but wealthier population whose average incomes, if considered as a separate consumer group, are much higher. Furthermore, the profit-maximizing price will be set at the equilibrium of the wealthier consumer group. If this small group of consumers has higher average incomes than the average incomes in foreign markets, then its prices will be higher as well. (Skinner 2004)
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- x ii Canadian International Pharmacy Association (CIPA) News release, "CIPA discusses consequences of changes to Canadian Food and Drug Act," *CNW Group*, (November 15, 2005).
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- x iv Statistics Canada, CANSIM, table (for fee) 051-0001, Last modified: (October 27, 2005).
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