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Products Liability and Prescription Drug Prices in Canada and the United States

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George J. Stigler Center
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the Economy and the State

The University of Chicago

WORKING PAPER SERIES NO. 123

**Products Liability and Prescription Drug Prices in Canada and the
United States**

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Products Liability and Prescription Drug Prices in Canada and the United States

Abstract

This paper investigates the degree to which products liability related costs explain differences in pharmaceutical prices between the United States and Canada. In a data set of identical products sold in both countries, the primary result is that both the litigation experience of specific pharmaceutical products and measures of product risk have substantial and strongly significant effects on the ratio of U.S. to Canadian prices. The observed distribution of price differences between the two countries has a mean of 69 percent higher in the U.S. and a median of 43 percent. Adjusting for the effects of liability risk reduces the predicted mean and median to 36 and 33 percent respectively. The principle effect of accounting for liability risk is to virtually eliminate the upper tail of the distribution of price differences. While 26 drugs in the sample are observed to have prices more than 100 percent higher in this country than in Canada, removing the effects of liability reduces the number in this range to five. This implies that efforts to explain international price differences in medical products which do not take account of the effects of differing legal systems are seriously flawed.

I. INTRODUCTION

Much of the recent debate on health care policy focused on international comparisons of the cost of health care provision. Of particular interest has been the comparison between the health care environment in the United States and Canada, especially focusing on the apparent lower cost of care in Canada. One of the important issues in such international comparisons has been the price of pharmaceutical drugs. Prescription drug expenditures make up a relatively small but highly visible part of total health expenditures and many policy makers have pointed to the high cost of pharmaceuticals as evidence for the need of health care reform. Numerous hearings on the high cost of prescription drugs have been convened by both Senate and House committees over the past several years.

At the request of Congress, the General Accounting Office conducted a study (GAO, 1992) showing large price differences for prescription drug products sold both in the United States and Canada. In a sample of 121 of the 200 most commonly prescribed pharmaceuticals in this country, sold by the same manufacturer under the same brand name in both countries, the GAO found that median price was approximately 43 percent higher in this country than in Canada. The methodology of the GAO report has been widely criticized, and there is good evidence that the methodology imparts a bias in favor of finding higher prices in the United States.¹ In addition, as pointed out by Danzon (1993) and Danzon and Kim (1993), the GAO

¹Among other problems, the US prices in the GAO data set are manufacturer's list prices, while Canadian prices are largely the "Best Available Price" published in the Ontario Drug Benefit Formulary. The former omits discounts available to many purchasers which are reflected in the later. As pointed out later, to the extent that this bias is not systematically related to liability risk, it does not affect the results of this paper. A discussion of the problems and biases in the GAO data set are found in the testimony of Ernst R. Berndt before the House Subcommittee on Health and the Environment (U.S. Congress, 1993), in Rozek (1995) and in Andersson (1995).

study, as do many other international drug price comparisons, ignores classical index number issues and thus, its results cannot be taken as an indication of the cross country differences in the cost of acquiring a certain level of drug therapy. Despite its shortcomings, the GAO report is consistent with other findings that observed prescription drug prices are commonly higher in this country than they are abroad.² To the extent that this general result is correct, it points to differences in market conditions which beg an explanation.

Several reasons for international price differentials have been suggested. Clearly, international differences in government regulations regarding prices, product approval and patent protection may affect price differentials, as may differences in production or distribution costs in different countries. It has also been suggested that the observed differences are attributable to variation in market power and price discrimination across countries.³

One component of international price differentials which is often mentioned⁴, but which has not yet been measured is the effect imposed by differing legal systems. It is to that issue that this paper is directed. Exploiting the difference in the legal systems of the United States and Canada, this article presents evidence of a strong link between the observed price differentials and various measures of expected liability cost, resulting in higher prices in the United States.

The legal systems of the United States and English speaking Canada share the common

²Examples of other studies with similar conclusions are Reekie (1984), Schut and Van Bergeijk (1986), and Szuba (1986).

³These arguments can be found to one degree or another in Reekie (1984), Schut and Van Bergeijk (1986), and Szuba (1986). Comanor (1986) provides a useful review of research into these and other issues in the pharmaceutical literature.

⁴The possible effect of liability costs on the prices of prescription drugs is discussed in Lasagna (1991) and in the testimony of Ernst R. Berndt before the House Subcommittee on Health and the Environment, (U.S. Congress, 1993, page 154).

heritage of the British legal system, but have drifted apart over time, particularly with respect to rules in tort law. The differences in law for prescription drug cases and the implied consequences for cross country drug pricing are discussed in Section II below.

Many medical products carry the potential for both cure and harm. To the extent that drugs vary in their harm causing potential, the differences in legal environments between the United States and Canada will give rise to differences in the cost of selling them. Specifically, litigation costs will be higher in this country for riskier drugs. To the extent that firms are able to identify and attribute these costs to particular products, market forces will cause prices to reflect these differences. Section III describes a set of variables which may serve as proxies for the relative risks of drug products and discusses the issues involved in their use for this purpose.

The estimated effects of product risk on price differentials are discussed in Section IV. The primary result is that both the litigation experience of a pharmaceutical as well as various measures of product risk are estimated to have substantial and strongly significant positive effects on the ratio of United States to Canadian prices. This implies that studies of international price differences which ignore differences in liability environments are missing an important effect and may suffer from serious omitted variable biases.

Using the model to predict what price differences would be in the absence of liability effects results in large reductions in the average price differential. In the GAO data set, the distribution of price differences has a mean of 69.2 percent and a median of 43.2 percent higher in the United States. Including all effects, the regression model reported in Table 4 predicts a mean difference of 69.7 percent and a median of 43.6 percent. Removing the effects of liability risk in this model reduces the mean and median to 35.5 and 32.6 percent respectively. The principal

effect of accounting for liability risk is to substantially diminish the upper tail of the price difference distribution. While 26 of the drugs in the sample are observed to have prices more than 100 percent higher in this country than in Canada, removing the effects of liability risk reduces the number in this range to five. The implications of these results are discussed in the conclusion, Section V.

II. THE LIABILITY ENVIRONMENT AND DRUG PRICE DIFFERENCES

A. Differences in the liability environments of the United States and Canada.

A substantial literature details the evolution of modern tort law in this country.⁵ The English Common Law forms the foundation for the rules of products liability law in both the United States and in English speaking Canada.⁶ While the past few decades have seen the law drift from its Common Law roots in both countries, it is generally recognized that the drift in the United States has been considerably larger.^{7,8} The most prominent distinction between the legal treatment of product accidents in these two countries is the evolution of strict products liability in the United States. In the case of prescription drugs however, strict liability is tempered in order to protect the market for socially valuable, yet “unavoidably unsafe products.” Comment k of the

⁵See, for example, Epstein (1980), Priest (1985), and Viscusi (1991).

⁶The law of Quebec is based on the French civil code which takes a much more conservative approach to products liability than modern American law. See for example, the ruling in *Lapierre v Attorney General for Quebec*, 16 DLR (4th) 554.

⁷See Linden (1977); Stikeman and Elliot (1993); and Howells (1993) for comparisons of the tort law principles the United States and Canada. Howells (1990) provides a detailed discussion of the issues related to pharmaceutical products liability in the United States and Canada.

⁸The change in the American products liability environment has had substantial effects on various markets as described by Chelius (1976), White (1989), Manning (1994) and others.

Second Restatement on Torts provides for an exemption from strict liability as long as such products are “properly prepared and accompanied by proper directions and warning.”⁹

Though comment k provides substantial protection for drug manufacturers, over the years, it has not proved airtight. First, the blanket application of this exemption for prescription drugs has been challenged in several cases.¹⁰ And second, many liability cases involving drug products have gone forward on the basis of negligence related issues not protected by comment k. Among these are claims that the warnings made by manufacturers were inadequate, and that the underlying design of the drug or medical device was defective. A few examples illustrate the limitations of comment k’s exemption.

In a famous case, a vaccine manufacturer was found liable because a warning supplied with a batch of polio vaccine sold to a public health clinic was not passed on to a plaintiff whose principal language was not English.¹¹ In another case, a manufacturer was held liable for damages from a stroke a patient suffered while taking a certain dosage of birth control pill. A lower dose was available, which purportedly carried a somewhat lower risk of stroke. Failure to communicate the apparently small difference in stroke likelihood to the patient’s doctor led to the manufacturer being found liable.¹² Finally, a drug company selling what was at the time the only FDA approved version of the DPT vaccine was found liable for injuries to a child because it had not sufficiently pursued development and government approval of an allegedly less risky form of

⁹Restatement (Second) of Torts, § 402 A, comment k. (1965).

¹⁰Among the cases which challenge the broad application of comment k to prescription drugs and medical devices are, *Kearl v. Lederle Laboratories*, 172 Cal. App. 3d 812, 218 Cal. Rptr. 453 (1985), (overturned in *Brown v. Superior Court*, 44 Cal.3d 1049, 751 P.2d 470 (1988)); *Shanks v. Upjohn*, 835 P.2d 1189 (1992); and *Hill v. Searle Laboratories*, 884 F.2d 1064 (1989).

¹¹*Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (1974).

¹²*Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1981).

the vaccine.¹³

In addition to decisions like these, the advent of market share liability,¹⁴ which is a distinctly American invention, increases the risks to manufacturers associated with inadequate warning and design defect cases. Thus, while the rules for pharmaceutical products liability in this country retain many of the properties of negligence, which is the prevailing rule in Canada, Canadian courts have been much less willing to hold manufactures to the standards of care which predominate in the United States courts.¹⁵

In addition to differences in legal doctrine, there are other differences in the legal systems of the two countries which result in higher product liability costs in the United States. Jury trials, for example, are the norm in the United States, while they are the exception in Canadian civil cases. Canadian litigants also have much more limited rights of appeal. Punitive damages are much rarer in Canadian cases than in the United States, and the level of damages, both punitive and compensatory are set by judges rather than juries. To the extent that juries are more willing than judges to favor plaintiffs at the expense of the deep pockets of a drug company, when damage awards are made, they will be higher in this country. Even if judges are not less willing to favor plaintiffs, the damages that Canadian judges are able to award are often subject to statutory limits in Canada. Other significant differences include the almost universal use of contingent fee arrangements in the United States, and the availability of class action suits. It has also been

¹³Jones v. Lederle Laboratories, 695 F. Supp. 700 (1988). This decision was ultimately overturned on appeal several years after the initial decision 982 F.2d 63 (1992).

¹⁴Sindell v. Abbot Laboratories, 607 P.2d 924, cert. denied. 449 US 912 (1980).

¹⁵Two important cases indicating the reluctance of Canadian judges to expand the liability of drug manufacturers in the ways American courts have are Rothwell v Raes, 54 DLR (4th) 193; and Lapierre v. Attorney General for Quebec, 16 DLR (4th) 554.

suggested that the smaller damage awards typical of Canadian cases reflect fundamental societal differences between the two countries and in particular, the existence of the broader social safety net in Canada.¹⁶

For the purposes of this study, it is not essential to precisely identify which of the preceding elements of law or society is accountable for the difference in the costs of the product liability environments in these two countries. I focus here on determining whether this difference has an observable effect on pharmaceutical prices. At present, I set aside both the search for the specific source of this difference and the broader question of the net welfare effects of the differences in the two countries' liability environments.

B. A simple model of price differences.

Given this focus, it is a simple matter to illustrate the mechanism through which differences in liability environments increase the cost of selling products with risky attributes in this country relative to Canada. It will be assumed that firms are risk neutral and that they maximize profits by choosing prices for their products which are a function of four variables. These are: manufacturing and marketing costs, the regulatory environment in which the firm's products are sold, the liability environment which prevails in the market and the structure of the market for each product. Under this assumption, the profit maximizing price set for good I in market j can be expressed as:

$$(1) \quad P_{ij} = f(C_{ij}, R_j, L_j(\pi_i), M_{ij})$$

¹⁶For discussions of these differences, see Howells (1990 and 1993), and Hutchinson and Hodgson (1990).

where each variable corresponds to the respective factor assumed to be part of the pricing decision. Thus, C_{ij} represents the direct manufacturing and marketing cost of good I in market j. R_j represents the regulatory environment in market j and M_{ij} , the structure of the market for good I in market j.

The expected liability cost in market j, L_j , depends both on the legal environment in market j as well as on π_j , the probability that the sale of a unit of good I will result in harm to the consumer.¹⁷ Under a simple negligence rule, if the court determines that the manufacturer has exercised due care, there is no liability for consumer injuries. Under ideal circumstances, then, manufacturers would choose to exercise due care and would not ever be found liable for damages. Firms in such a situation would incur only the costs of going to court and demonstrating their exercise of due care, though even this would not be frequent if plaintiffs knew they would not prevail in a liability claim.

However, errors in taking care or court errors in assessing the level of care taken relative to due care, can obviously result in manufacturers paying damages to injured consumers. Thus, in the presence of errors, expected liability costs will rise with the probability of consumer injury. Furthermore, if in one market, the court is more likely to make errors in favor of plaintiffs, or if damage awards when such mistakes are made are systematically higher than in another market, the expected damage payments will rise more rapidly with the probability of injury in the first market. In the presence of errors, not only do expected damages, but other litigation related costs

¹⁷For expositional ease, I write the model as though all drug products have the potential for inflicting a single level of harm on consumers, and that they differ only in the probability of inflicting this level of harm. Of course, this is not true, but since only expected damage matters, it is of no consequence at this level of abstraction to suppress the variation in damage potential.

rise with the probability of injury as well, as manufacturers are in court more often on cases having to do with more risky products.

One other element of cost that is affected by the prevalence of court errors is the effort the manufacturer would make to avoid accidents. In the case of pharmaceuticals it is unlikely that the fundamental nature of the product would be altered across markets, but increased effort may take the form of greater care in marketing or packaging a product, or in making investments in discovering the level of warning appropriate for a particular drug. While such costs are only indirectly related to expected litigation, they will be larger in a market where more court errors are made and will rise more rapidly with product risk.

The test of the proposition that liability differences matter then turns on whether there is a relationship between product risk and price differentials across markets with different legal environments. In implementing that test, the United States will be treated as a single market in which for the reasons discussed above, there is a relatively strong relationship between the probability of consumer injury and expected liability costs for goods sold within its borders. Canada will be treated as a single market in which traditional negligence rules prevail, and in which court errors are not sufficient to generate a strong relationship between the probability of consumer injury and expected litigation related costs.

III. EXPLAINING OBSERVED DRUG PRICE DIFFERENCES

The analysis employs the GAO data set containing factory price observations (the price charged by the manufacturer to wholesale distributors) on 121 of the 200 most commonly prescribed pharmaceutical preparations in this country. These 121 drugs are those for which the

GAO could identify factory prices and other data for identical products and packaging sold by the same manufacturer in each country.¹⁸ The products in this data set range from being 44 percent cheaper in the United States to being 967 percent more expensive, with the median product being 43 percent more expensive in the United States. There is good reason to suspect that the reported 967 percent price differential is an error,¹⁹ so the observation on that drug is dropped from the data set for the following analysis. The product with the greatest price differential in the remaining data set is 702 percent more expensive in this country than in Canada. Data on the patent status of one product is also missing in the GAO data set, reducing the useable sample size for this analysis to 119 products. Summary statistics for this data set are provided in Table 1.

As a partial explanation of the observed price differentials, the GAO study uses a linear regression model which has explanatory variables intended to control directly or indirectly for all the effects identified in equation (1) except for liability costs. A replication of the GAO results is provided in Table A.1 of the appendix. This paper modifies the GAO model to account for important missing variables and then proceeds with an estimate of liability effects.

¹⁸As discussed in the introduction, the US prices are factory list prices, while the Canadian prices are prices paid by a large government purchaser. Discounts in the latter source impart an upward bias to the US to Canadian price ratio. There is no reason to expect that such discounts are systematically related to liability risk, however, so this bias should not have an impact on the estimates of liability effects in price differences.

¹⁹The drug in this sample with the 967 percent price differential is Isordil, an antianginal drug. In all of the regression models done, this price differential was an extreme outlier, being, for example, more than four standard deviations outside the 95 percent confidence interval for the predicted values of the dependent variable in a regression analogous to that in Table 3. Investigating the possibility of an error, I phoned a pharmacy in Victoria, British Columbia and one in Provo, Utah to obtain a comparison price differential. After correcting for the exchange rate, the result was a differential of 254 percent at the retail level for the same dosage size and strength as reported in the GAO data set. Though this differential is not for factory prices, and was observed more than a year later than the GAO data set was gathered, the difference in the two differentials is large enough to raise serious doubts about the accuracy of this observation.

Separating the discussion of the explanatory variables into two groups is convenient at this point. The first group captures the effects of differences in regulation and markets between countries, and the second treats liability cost effects.

A. Market and regulatory effects.

To account for differences in regulatory environments between countries, the model includes dummy variables which identify patented drug products which were introduced to the market before or after two important pieces of price control and patent protection legislation in Canada. The critical years are 1988 and 1989 during which these changes occurred. The intended effect of these acts was to lower prices by placing drug prices under government scrutiny. The acts were structured so that drugs introduced prior to these acts are subject to more control than those introduced at later dates. To the extent that this regulation is effective, drugs introduced before 1988 should have higher prices in Canada, and therefore, a lower differential with that United States, than those introduced later. Also included is a dummy variable for drugs approved in the United States after 1984 to pick up the effect of the Waxman-Hatch act,²⁰ and a dummy for drugs listed on the Ontario Drug Board formulary, a body which through its buying power, exerts downward pressure on prices in Canada. Finally, a dummy variable is included which identifies drugs which are subject to federal reimbursement limits for drugs paid for under the Medicaid program in the United States. These limits are not particularly

²⁰The Waxman-Hatch act made it substantially easier for generic products to enter the US market in competition with pioneering products, effectively diminishing the market power of the pioneer product upon patent expiration. At the same time, patent life was extended for some products introduced after the passage of the act in order to compensate for time lost in the regulatory approval process. An analysis of the effects of this law is provided by Grabowski and Vernon (1992).

stringent,²¹ but to the extent that they are effective, they will exert downward pressure on U.S. prices and hence reduce the observed price differential.

Many of the regulatory variables are directly related to the length of time the drug has been on the market. This leaves open the possibility that age related effects may be inappropriately attributed to regulation. The number of years since drug introduction is included to capture any non-regulatory age effects which differ between countries.

Market effects are captured by several variables. The structure of the market for a drug in each market will be affected in part by whether a generic competitor exists for the good. In principle, it is not certain what the effect of generic competition will be on the price of branded drugs. On the one hand, it is possible that generics compete directly with brand name drugs, thus increasing the elasticity of demand for and reducing the price of branded products. On the other hand, it is possible that generic substitutes create segmented markets. The seller of a branded product may face a smaller but more inelastic demand. Consequently price may be higher than it would be in the absence of generic substitutes. Dummy variables which account for the availability of generics in each country separately and in both countries together are included to capture these effects. However, without knowing which of the competing models of generic competition is operative, it is not possible to predict what the direction of the effects will be. It is only possible to say that if a single model simultaneously explains the effect of generic availability in both countries, then the sign of the coefficient on generic availability in one country should be the opposite of that on generic availability in the other.

²¹Reimbursements to pharmacies for drugs designated by HCFA as subject to federal upper limits are limited to no more than 150 percent of the lowest published price of an equivalent product.

Identifying the specific therapeutic category to which a drug belongs accounts for market effects as well. Drugs used in similar or related therapies are likely to share many demand characteristics which will be reflected in prices. For example, a class of drugs which is not typically covered by an insurance policy in the US, such as contraceptives, may have a more elastic demand, and hence a lower price than drugs in a typically covered class. Differences in markets or insurance coverage for different classes of drugs between countries will show up in these variables. Seventeen drug category dummies are identified,²² sixteen of which are used in the regression analysis. Finally, the GAO study also includes a dummy for drugs sold by US manufacturers. To pick up possible country specific differences in production cost, this variable is retained in this model.

The regression in Table 2 includes the market and regulatory variables discussed to this point and serves as a benchmark from which to study the effect of liability. As a measure of the difference in the prices between the United States and Canada, the dependent variable is the natural log of the ratio of United States to Canadian prices. The regression represents a marked improvement in explanatory power over the GAO regression and has some interesting implications. Most of the estimated coefficients have signs consistent with expectations, however,

²²The Physician's Drug Handbook (Springhouse, 1991), provides a catalog of general and specific therapeutic categories for virtually all drugs in the US and Canadian markets. To generate the 17 drug category variables, each drug in the sample was classified into its more specific category when there were at least four products in the sample, and otherwise grouped with other drugs in its general category. For example, the sample includes 22 drugs under the general category of cardiovascular system drugs, of which ten are antihypertensives, eight are antianginals, two are antilipemics, one is a vasodilator and one is a cardiac glycoside. Dummy variables are defined for the specific categories antihypertensives and the antianginals, and the remaining four drugs are classified together under the general cardiovascular system drugs category. It would obviously be desirable to classify each drug according to its more specific category, but this sample is not complete enough to allow that.

many of the estimates are not statistically significant. Given the relative smallness of the data set, this is not surprising.

Unexpectedly, the regression implies that the presence of generic equivalents in each country increases the spread between US and Canadian prices. This result is not consistent with either single interpretation of the effect of generic availability discussed previously. It suggests that the market segmentation argument applies in the US, so that generics raise branded drug prices, but that in Canada, generic competition suppresses prices. It is not clear why different models would operate in each country, and it turns out that when liability variables are included, this result is modified.

Given the relatively small sample of drugs in each category, it is not surprising that only two of the therapeutic category dummies are significant at better than 10 percent. Nonetheless, the relatively large coefficient estimates on some of the categories indicates potentially large differences in the markets for these drugs. However, it should be emphasized that liability effects are likely to be related to therapeutic class, so that the proper estimation of the drug class effects requires specification of the liability environment as well.

Finally, it does appear that there is something in the age structure of prices in addition to the regulatory effects. Older drugs have significantly higher price differentials than do more recently introduced ones. Once again, however, it will be seen that the inclusion of liability effects changes this result.

B. Liability risk effects.

Incorporating the effects of product liability into the model requires a measure of such

risk. Such measures are not easy to come by. For obvious reasons, drug manufacturers are reluctant to discuss the risks of their products, and the information provided in package inserts is of little help for its general all inclusiveness. Every possible adverse effect is typically listed, without much information about the relative frequency of adverse outcomes. In an attempt to devise measures of pharmaceutical risk, several strategies were used, producing a handful of risk measures. Each measure is described below and regression results using each of them are found in Tables 3 through 6.

Litigation History

Perhaps the most appealing measure of expected liability cost available is a product's own litigation history. Lacking a complete history for each drug, useful summaries are provided in *Drugs in Litigation*, which is "a compilation of personal injury cases involving adverse reactions of prescription and nonprescription drugs." The intended audience for the book is attorneys representing both plaintiffs and defendants in drug litigation.²³ As such, this book summarizes case histories on a large number of prescription drug products, including descriptions of the important cases, trial verdicts and settlements where available.

From this source, several possible measures of risk could be identified; I focus on two. First is a measure of the volume of litigation for each drug, and second is the success rate of plaintiffs in litigation involving each drug. The first is chosen on the hypothesis that a history of litigation implies that future litigation is more likely and that regardless of outcome, litigation itself is costly enough to affect prices. Therefore, the more litigation there has been with respect to a

²³Patterson (1994), pp. v-viii.

particular product, the higher the cost of selling the product. The measure of litigation volume used is the total number of cases involving each drug before 1991 (the year in which the prices were observed) divided by a sales index for each drug from 1980 through 1990.²⁴

A history of litigation with outcomes favorable to the manufacturer may be a signal that there will be less future litigation, so that in addition to the total volume of litigation, the “success rate” of plaintiffs in past litigation may be an important determinant of expected future liability cost. Consequently, the second measure of risk chosen from this source is the proportion of total cases with outcomes favorable to the plaintiff. An outcome favorable to the plaintiff is defined as either a trial verdict for the plaintiff or a settlement that includes a payment to the plaintiff. Of course, having a measure of average awards paid to plaintiffs would be helpful, but unfortunately, complete enough information to calculate such a number is not available in this source.

Thirty-five of the drugs in the sample have case histories with unambiguous outcomes before 1991. Total cases prior to this year and the proportion of plaintiff “wins” are calculated for each of these drugs. The maximum number of cases listed for any of the drugs is 36, and the average number of cases is 7.9. Of these 35 drugs, the mean proportion of cases with outcomes favorable to the plaintiff is .413.

²⁴Actual aggregate sales data for this entire data set over a sufficiently long period are prohibitively expensive to acquire. As a substitute, I generated estimated sales over the period from 1980 through 1990 and used those as a measure of total sales. The estimation was done by using the ordinal ranking of each drug in each year’s American Druggist top 200 list for each year that a drug was on the market. In years that a drug was on the market, but not among the top 200, it was arbitrarily assigned a ranking of 250. Each year’s ranking was transformed into a sales estimate by applying an exponentially declining sales rate to the ordinal ranking. The rate of decline used for this estimation was calibrated from actual sales and rankings in the years 1990 and 1995. Though these estimates are only a rough estimation of total sales, the regression results on this point are not very sensitive to different methods of estimating sales or to different parameterizations of the exponential transformation.

It should be pointed out that litigation history as a measure of liability risk is not exhaustive. Certainly most claims against products are settled before a court case is filed, and some drugs that have not been on the market long enough for a litigation history to develop. Drugs for which a large proportion of claims are settled before litigation, and those with short market histories may not have litigation histories that accurately reflect future expected liability costs.

Significant Relationship to Vaccine Liability Cost

The second measure of risk comes from an examination of the recent price history of each product in the sample. Before the changes of the past two decades or so, the legal environment in this country was much more similar to that now prevailing in Canada than it is now. This implies that comparing the prices of drugs in the two countries over time would reveal the effect of liability cost as things changed only in this country. The absence of a history of Canadian prices, however, makes this experiment impossible. As a substitute for this, it is possible to compare the price histories of the drugs in the U.S. to known estimates of liability risk in other drug products.

I have elsewhere estimated the effect of liability cost on the prices of two common childhood vaccines, the Diphtheria-Pertussis-Tetanus (DPT) vaccine and the Oral Polio vaccine (OPV). Over the period from the early 1970's to the late 1980's the prices of these two vaccines increased by dramatic amounts, driven almost entirely by the costs associated with litigation (Manning, 1994). The estimates of litigation costs in these two vaccines can be taken as proxies for the costs of litigation in pharmaceuticals more generally over the time period when liability

rules were changing.²⁵ A significant relationship of a pharmaceutical's price history to the history of litigation cost in vaccines is evidence that the price of the pharmaceutical observed today includes a liability cost component.

Specifically, a relationship to vaccine liability cost is identified as follows. First, yearly observations from 1977 to 1993 on each drug's average wholesale price are obtained from the *American Druggist Blue Book*. For drugs introduced since 1977, prices are collected for as many years as they are listed in this source. Next, the prices of two pharmaceuticals sold in very competitive markets, and which are not substantially affected by liability costs, the DT vaccine, and a children's vitamin supplement, Tri-Vi-Sol,²⁶ are taken as proxies for manufacturing and marketing cost of all the prescription drugs in the sample over the same time period.²⁷

All prices are adjusted for inflation using the Consumer Price Index based in 1982-1984, and each of the 119 drug prices in the sample is regressed on each of the proxies for manufacturing cost and vaccine liability cost. Each pharmaceutical price history that shows a significant positive relationship (at the 5 percent level in a one-tailed test) to at least one of the cost proxies, and in the same regression, to at least one of the liability cost estimates is judged to contain a liability premium today. Thirty-one of the drugs in the sample satisfy these criteria and are identified with a dummy variable.

²⁵Briefly, the real litigation cost for DPT is essentially the difference in the inflation adjusted DPT price and the inflation adjusted price of the DT (the same vaccine without the Pertussis component) vaccine for any year. The real litigation cost component in OPV price is estimated to be the observed inflation adjusted OPV price less the equation: $-0.9549 + 3.6057 * (\text{inflation adjusted DT price})$. This equation is estimated from data pre-dating the change in liability rules in this country. The R^2 on this regression is .9879. See Manning (1994) for details.

²⁶Tri-Vi-Sol is a registered trademark of Mead Johnson Nutritionals.

²⁷Over the period from 1950 to 1990, the correlation of the DT price and the Tri-vi-sol price is .979. For further discussion of the use of the DT price as a proxy for cost, see Manning (1994).

Again, this procedure may not pick up all drugs with a liability component. On the one hand, if the liability risk for some drugs was revealed over a time period much different from that in the vaccine market, this test will not identify the risk component in those prices. On the other hand, recently introduced drugs have entered the current liability rule environment and missed the liability transition period that the vaccine prices cover. Once full liability effects are anticipated in the market and built into prices, there is little reason to expect the prices of risky drugs to follow significantly different paths than those of non-risky drugs.

Controlled Substance Designation

Certain pharmaceuticals have been identified as having high enough risk of addiction or other dangerous side effects that government controls are placed on their manufacture and distribution. Controlled drugs are listed on one of five schedules, I through V in order of decreasing control, corresponding to decreasing perceived risk. Compounds listed on schedule I are illicit narcotics, and the remaining schedules include drugs of differing levels of perceived risk.²⁸ This sample includes eight drugs on schedule IV and one on schedule II. Lacking more variety among the controlled substance categories, a dummy variable identifies all of the controlled substances as a single risk group.

While each measure discussed to this point bears a reasonable relationship to liability risk, they are apparently not redundant,²⁹ nor are they necessarily exhaustive. It is plausible that there

²⁸U.S. Department of Justice.

²⁹The degree of correlation among the four variables discussed to this point is not high. Pairwise correlations are provided in Table A.2 of the appendix. Two of the six unique correlations are statistically significant, one between the two measures of litigation volume and the other between the controlled substance designation and the variable for a significant relationship to vaccine liability.

are elements of risk that are not captured in any of them. In the empirical work that follows, these variables perform best and will be of primary interest, but other sources of information on product risk merit some attention. The first of these is information obtained directly from health care professionals.

Risk Assessment Surveys of Health Care Professionals

Various health care professionals are in a position to evaluate the relative safety of pharmaceutical products, either through their work experience with the products or through their education. In particular, physicians, professors of pharmacology and practicing pharmacists should all be able to evaluate the effects and risks of drug products. Surveys seeking information about perceived drug risk were sent to a sample of pharmacists, to a group of professors of pharmacology and to ten sets of physicians in the specialties most likely to prescribe each drug on the list. In each of these surveys, respondents were asked anonymously to rank each of the 121 drug products in the sample according to the risk they posed to consumers. Specifically, respondents were asked to "provide an indication of the likelihood that the use of each drug in the course of ordinary medical care would result in a severe adverse reaction or some other serious undesirable outcome." This was done by circling a number in the range from 1 to 4 on the survey sheet corresponding to an assessment that the likelihood was negligible, low, moderate or high.

The surveys, along with postage paid return envelopes, were sent to a random sample of 300 pharmacology professors; to 500 physicians practicing in the western United States; and to

50 pharmacists working at commercial pharmacies in the Provo and Salt Lake City, Utah areas.³⁰ Useable surveys were returned from, 32 pharmacology professors,³¹ 182 physicians, and 13 pharmacists.

To dampen the effect of variation across individual respondents, each individual's ranking of each product was transformed into the deviation from that individual's mean ranking for all the products in the sample. Thus, for a respondent whose average over the sample was, 2.5 and who ranked a particular drug as having low risk, or 2 on the scale from 1 to 4, the adjusted risk ranking would be -0.5. For each pharmaceutical, summary statistics were calculated within each survey class and are reported in Table 1.

As indicators of product liability risk, both the mean value and the standard deviation of the survey respondent's rankings are potentially useful. In principle, one would expect both of these statistics to be positively related to liability risk. The mean value is so related because higher mean risk may translate into a higher number of claims. The standard deviation of rankings should be positively related to liability risk because it corresponds to greater uncertainty about the filing of claims for a particular product. It may also be that greater variation in professional opinion about a particular product's riskiness increases the likelihood that its use will be questioned when an apparent undesirable consequence results from its use. This potentially

³⁰The 300 pharmacology professors were drawn from the faculty lists in *Peterson's Guide to Graduate Programs* (1993). The 500 physicians represented 50 each in the ten specialties identified as most likely to prescribe the drugs on the list. Physicians practicing in each of these specialties in the states of Utah, Arizona, Nevada, California, Oregon, and Washington were identified in the *1994 ABMS Directory of Board Certified Medical Specialists*. Matching drug products with physician specialties was accomplished with the assistance of a local physician. The pharmacists were identified through local phone books.

³¹Several pharmacology professors returned the survey because they did not feel their specialty qualified them to respond and others returned it saying that it was impossible to make judgments of the kind I had requested.

exposes the manufacturer of such a good to greater risk of losing a products liability claim in court.

Drug Reference Variables

Various reference sources describe pharmaceutical products for use by medical professionals. These descriptions contain data that may prove informative about liability risk. Seven variables that serve as potential measures of product risk are taken from the *Springhouse Drug Reference*,³² and from the *Physician's Drug Handbook*.³³ These variables are: pregnancy risk rating; an index of life threatening adverse reactions; the frequency of life threatening reactions; citation of mortality risk associated with the product; overdose and treatment danger; an index of contraindications to use; and an index of adverse interactions with other drugs. Descriptions of each measure are found in the appendix and summary statistics are reported in Table 1. In theory, all are positive measures of risk and to the extent that product risk translates into liability risk, they should be positively related to expected litigation cost.

IV. ESTIMATES OF LIABILITY EFFECTS

Adding measures of litigation risk to the baseline regression of Table 2 sheds light on several issues. As a first step, the variables for each drug's litigation history, the relationship to vaccine liability cost and the controlled substance designation are added and the effect is

³²Springhouse Corporation (1988).

³³Springhouse Corporation (1988). Springhouse advertises the information in its drug reference books as being "accurate and objective, contributed by independent clinical experts," with "absolutely no commercial bias."

substantial, as reported in Table 3. Again, the dependent variable is the log of the ratio of United States to Canadian prices.³⁴ The proportion of cases won by plaintiffs and the controlled substance designation have large and strongly significant effects on the price difference. Drugs with a significant relationship to vaccine liability costs also tend to be priced somewhat higher in the US than in Canada, but this difference is only weakly significant. Interestingly, after accounting for the proportion of plaintiff wins, the volume of cases filed is not a significant determinant of the price difference. If the proportion of plaintiff wins is dropped, the volume of cases becomes strongly significant, but it appears that all the relevant information about litigation history is contained in the proportion of plaintiff wins. When total cases and estimated sales are used separately in the regression, both are estimated to have coefficients very near zero and have t-statistics less than .70 in absolute value. Replacing the percentage of plaintiff wins with total cases and estimated sales has the same qualitative effect, though the parameter on total cases is now somewhat larger. In this last regression, coefficient on estimated total sales is $-8.958 \text{ E-}9$ with a t-statistic of $-.522$ and the coefficient on total cases is $.0096$ with a t-statistic of 1.42 , still far from significant.

The inclusion of liability variables also has substantial effects on several other parameter

³⁴The choice of this measure for the difference in prices provides the best fit to the data and given the skewed distribution of price differences, reduces the influence of extreme observations. However, the results in this and subsequent regressions are not greatly sensitive to other reasonable specifications of the dependent variable, particularly with respect to the liability effects. For example, using the percentage difference in prices as the dependent variable slightly reduces the r^2 , leaves the liability variables highly significant and results in predicted values and predicted liability effects which are nearly identical to those from the log specification. Using the simple price difference as the dependent variable does substantially reduce the significance of the coefficient on the proportion of cases won by plaintiffs, but also yields a regression with very large outliers which are not present otherwise. Removing the most outlying observations returns the estimate to high statistical significance.

estimates as well. The only two category variables that were significant without liability effects, antianxiety agents and general central nervous system drugs, are not significant and are greatly attenuated when liability effects are included. The age effect also seems to have been picking up liability effects, as that variable becomes small and insignificant with the inclusion of liability variables. A possible explanation for this result may be that newer products are less likely to be priced with liability premiums because the risks of liability for them have not yet been revealed. As time reveals this information, the price of riskier drugs rises in the United States relative to Canada.

Another place where including liability is important is the estimated effect of the availability of generics. The liability variables greatly reduce the estimated effect of generic availability in the United States and make it statistically insignificant. Rather than requiring a completely different story of generic competition in each country, as did the results of Table 2, these estimates are not wholly inconsistent with the claim that generic competition lowers prices of branded drugs in both countries. The generic only in Canada coefficient indicates that the price differential is significantly higher for those drugs facing generic competition only in Canada, implying that the generic tends to reduce prices of Canadian branded products. If generics reduced branded prices in the United States as well, the coefficient on generic only in the United States would be negative. While the estimate is positive, a 95% confidence interval around this estimate includes a wide range of negative values. Though an answer to the question of generic competition is not within the scope of this paper, the point is that when the liability effects were omitted, the results suggested a puzzle that in fact may not be a puzzle at all.

Given the uncertainty about the effect of generics, it may make sense to remove these

variables from the regression to see the effect this has on the liability variables, which are of most interest. Doing this has only minor impact on the parameter estimates. The general hormone category parameter rises to .54 from .35 and becomes statistically significant, and more interestingly, the parameter for drugs with a significant relationship to vaccine liability increases to .20 from .16 and becomes significant at less than 5%. Omitting the generic variables in the subsequent regressions has similar effects, none of which change the interpretation of the results.

Given that the total volume of litigation adds nothing to the liability risk assessment and that the age effect also appears to reflect liability effects, these variables are dropped from the regression equation to produce the model of Table 4. The primary result of doing so is to leave all the litigation history information in the proportion of plaintiff wins, and the estimate of that coefficient is correspondingly increased somewhat. The other variables remain little changed from their previous values. As discussed above, the regression results reported in Table 4 are very robust to alternative specifications and do not depend greatly on any small number of observations.³⁵

To this point two important conclusions are reached. The first is that a substantial premium exists in the US pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in the Canadian prices. The second is that ignoring this fact has an

³⁵Performing standard influence diagnostics on the model reveals that none of the parameter estimates is significantly sensitive to the deletion of any single observation from the data set. This analysis does reveal that nine observations have studentized residuals above 2 in absolute value. The primary effect of deleting these observations is to increase the significance of the liability indicators, particularly the relationship to vaccine liability costs, which becomes significant at less than 1%. A few of the other variables, such as the dummy for HCFA reimbursement limits, also become highly significant when these outlying observations are dropped, but the signs remain the same and nothing critical in the regression changes substantially.

important impact on the estimates of other variables and may lead one to draw errant conclusions about the workings of international markets for pharmaceuticals and other products with risk components. Having this result, the obvious next step is to ask how large the liability effect is. Before doing so, however, I turn briefly to the relationship of the price differences to measures of risk generated from health professional sources.

Table 5 report regressions in which the summary statistics from the health care professional surveys have been added to the risk variables of Table 4. Based on the prior belief that these professionals would have good information on product risk, and that product risk translates into liability risk, the results are somewhat surprising. Though only one of the estimates has statistical significance (and that at the 10 percent level), the effects of both mean and standard deviation for all survey groups are estimated to be negatively related to the drug price differential. This is not a result of the redundancy of these variables with the primary liability variables, as when these are dropped, not much changes. Rerunning the regressions without the three primary indicators of risk changes the signs of average pharmacist responses and the standard deviation of the physicians' responses, but only the pharmacists' average response is significant at the 10 percent level.

These results may be due to several factors. Perhaps the survey is not well designed for its purpose, or the group of health care professionals may not have a good sense of the kinds of risk that lead to litigation. Temin³⁶ suggests that physicians generally do not possess a great deal of detailed information about therapeutic or other differences among drugs, so perhaps it is also the case that they and other health care professionals do not possess detailed information about

³⁶Temin, Peter (1980) at chapter 5.

product risk as well.

Finally, the risk variables taken from medical reference sources also fail to explain liability risk. Table 6 reports the results of several alternative specifications of the regression model including the medical reference variables, where again, only the risk variables are reported. Across all alternative specifications, the primary indicators of risk remain quite stable and significant, while only one of the drug reference variables attains significance at the 10 percent level, and this is when the estimate is negative. Now it may be that prescribing physicians offset the risks mentioned in drug references through their prescribing behavior and other treatment, however, adverse drug reactions are often very hard to predict, and it seems unlikely that physicians would be able to so completely offset these risks while failing to offset the risks reflected by the set of primary liability indicators. It seems more likely that the data from medical references provide little information about the kinds of risk that result in litigation.

SIZE OF LIABILITY EFFECT

The predicted effect of liability on the price ratios is illustrated with the regression model in Table 4. These effects are visually represented in Figures 1 and 2, which are kernel estimates of the price differential distributions from the actual data and of predicted values from the regression model, both including and excluding the liability variables.

Figure 1 presents estimated frequency distributions of both the actual data and the predicted price differentials from the Table 4 regression. The two most interesting features of the actual data distribution are that the mean is substantially above zero and that it has a very pronounced upper tail. Although the model under predicts the frequency of drugs with lower

prices in the US and over predicts the frequency of drugs with moderately higher prices in the US, it does quite well at matching the upper tail of the distribution. In the actual data, the mean percentage price differential is 69.2 percent, and the mean differential predicted from the regression is 69.7 percent. The corresponding median values are 43.2 percent and 43.6 percent.

The consequence of removing the liability effects is illustrated in Figure 2 that compares the predicted distribution with the distribution predicted if the liability variables are removed. The principal result is that without liability effects, the distribution of price differentials becomes much more symmetric and retains a mean substantially above zero. The mean of the predicted “no liability” distribution is 35.5 percent and the median is 32.6 percent.

Given the discounting bias in the Canadian GAO prices, it is not surprising that the distribution retains a positive mean after liability effects are removed. If all other effects could be accounted for, it would be expected that this bias would leave the mean above zero, but unexplained differences around that mean would be symmetrically distributed. This is very close to what we have in Figure 2. That the liability effect is concentrated in the upper tail lends credence to the liability explanation. This is consistent with the prediction that liability costs are increasing in product risk. It would be far less convincing if, for example, the predicted liability effect simply shifted a skewed distribution to the left. The implication is that removing liability effects reduces the mean price differential in this data set by about half and the median by about one-fourth, but leaves both statistics substantially above zero.

Although without good time series data, one cannot make precise predictions about liability effects on specific drug products, it may be instructive to consider which drugs the model predicts to have liability components and which it does not. These are reported in the appendix,

Tables A.3 and A.4. Table A.3 lists the observed price differential as well as the differential predicted by the model and the differential after subtracting out the liability effect for the 48 products estimated to have such a component. Table A.4 lists the products with no estimated liability effect in descending order of predicted price differential.³⁷

V. CONCLUSION

This paper represents the first attempt to identify the role that products liability risk plays in international prescription drug price differentials. In the GAO data set used here, prices of identical products are, on average, reported to be sold at much lower prices in Canada than in this country, though there is reason to suspect these data contain a systematic bias in that direction. Taking a model of price differences that corrects for regulatory and market differences between these two countries as a baseline, this paper incorporates various measures of products liability risk faced by manufactures in this country, but either to a lesser extent, or not at all in Canada.

The results indicate strong and significant effects of liability risk in price differentials which is not related to the underlying bias in the GAO data set. A large part of the observed variation in the price differential is attributable to anticipated liability cost, and liability effects explain virtually

³⁷It may seem that the model misses in predicting no liability effect for Prozac because this drug has been the subject of several high profile cases in recent years. However, the Prozac litigation began only in July, 1990 with the case of Hala v. Eli Lilly & Co. (see Patterson (1994)), probably too late for the expected costs of litigation to be known by the manufacturer and incorporated into the May, 1991 price. Furthermore, it is interesting to consider what has happened to the price of Prozac since that time. The 1991 price differential for Prozac was about 8%. With the filing of several Prozac cases in recent years (to the knowledge of the author, several cases remain pending, but no rulings have yet been issued against the manufacturer) one would expect a price differential to develop for this drug, and in fact, this appears to be the case. A recent spot check of pharmacies in Chicago and Vancouver resulted in a retail price for Prozac about 58% higher in Chicago. Though this comparison is for retail and not manufacturer's prices, it lends support to the idea that litigation costs play a role in international price differences.

all of the very big price differences observed. The best prediction of the model is that in this data set, liability risk roughly doubles the average price differential and increases the median price differential by about one third.

The nature of this data set makes it impossible to extrapolate the magnitude of the liability effect to all drugs generally. It should be noted that the drugs in this sample are among the most popular sold in this country and all are made by major drug manufacturers. It certainly may be that for a broader sample, this result would be of different magnitude. However, this work indicates that liability costs must have a role in any complete explanation of international price differences. The fact that liability risk plays such a vital role in the model implies that any study of international drug pricing which ignores differences in legal environments across countries is seriously flawed. The size of these effects is simply too large to ignore.

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TABLE 1

Summary Statistics

Variable	N	Mean	Std Dev	Minimum	Maximum
Log of Ratio of US to Canadian Price	119	0.3861	0.4864	-0.5851	2.0820
Patented drugs introduced before 1988	119	0.3277	0.4714	0	1
Patented drugs introduced in 1988 or 1989	119	0.0672	0.2515	0	1
Patented drugs introduced after 1989	119	0.0588	0.2363	0	1
Listed on Ontario Drug Board formulary	119	0.8403	0.3678	0	1
Generic available only in US	119	0.1008	0.3024	0	1
Generic available only in Canada	119	0.1933	0.3965	0	1
Generic available in both US & Canada	119	0.3697	0.4848	0	1
Drug produced by US manufacturer	119	0.5966	0.4926	0	1
Approved in US after 1984	119	0.3277	0.4714	0	1
Subject to HCFA reimbursement limit	119	0.1765	0.3829	0	1
Number of years since introduction	119	14.6303	10.4742	3	54
General antimicrobial agents	119	0.0756	0.2655	0	1
Cephalosporins	119	0.0336	0.1810	0	1
Miscellaneous anti-infectives	119	0.0672	0.2515	0	1
General cardiovascular system drugs	119	0.0336	0.1810	0	1
Antianginals	119	0.0672	0.2515	0	1
Antihypertensives	119	0.0840	0.2786	0	1
General central nervous system drugs	119	0.0924	0.2909	0	1
Antianxiety agents	119	0.0420	0.2015	0	1
Nonsteriodal anti-inflammatory drugs	119	0.0840	0.2786	0	1
General hormonal agents	119	0.0336	0.1810	0	1
Estrogens and progestogens	119	0.0756	0.2655	0	1
Respiratory system drugs	119	0.0504	0.2197	0	1
Eye, ear, nose & throat drugs	119	0.0504	0.2197	0	1
Gastrointestinal tract drugs	119	0.0504	0.2197	0	1
Dermatomucosal agents	119	0.0504	0.2197	0	1
Agents for fluid and electrolyte balance	119	0.0420	0.2015	0	1
Total cases w/ unambiguous outcome	35	7.914	11.0304	1	36
Proportion cases w/ outcome for plaintiff	35	0.4134	0.3816	0	1
Total cases per thousand estimated sales	35	0.0148	0.0463	0.0001	0.2449
Sig. relationship to vaccine liability cost	119	0.2521	0.4361	0	1
Controlled substance drug	119	0.0756	0.2655	0	1
Pregnancy risk categories D or X	119	0.2521	0.4361	0	1
Index of life threatening adverse reactions	119	1.2521	1.4970	0	5
Index of frequency of adverse reactions	119	1.0840	0.9879	0	2
Drugs with cited mortality history	119	0.0504	0.2197	0	1
Index of overdose and treatment danger	119	1.3529	1.0544	0	3
Index of contraindications	119	1.7815	0.6129	0	3
Index of adverse drug interactions	119	1.4706	0.8216	0	3
Ave MD risk rating from survey	119	-0.0213	0.3412	-0.9557	1.3017
Std dev of MD risk rating from survey	119	0.5153	0.1194	0.2728	0.8872
Ave risk rating of drug, Rx survey	119	0.01114	0.3293	-0.7806	1.1425
Ave risk rating of drug, PhD survey	119	-0.004658	0.2538	-0.6242	0.9335
Std dev of risk rating, Rx survey	119	0.5021	0.1238	0.2459	0.9295
Std dev of risk rating, PhD survey	119	0.5596	0.1040	0.2791	0.9077

TABLE 2

Regression of US / Canadian Pharmaceutical Price Differential

Dependent Variable: Log of ratio of US to Canadian Price

Independent Variables	Parameter Estimate	Standard Error	T Value	Prob > T
Intercept	-0.2808	0.2062	-1.362	0.1765
Patented drugs introduced before 1988	0.1784	0.1002	1.781	0.0783
Patented drugs introduced in 1988 or 1989	0.2878	0.1782	1.615	0.1097
Patented drugs introduced after 1989	0.3001	0.2302	1.304	0.1956
Listed on Ontario Drug Board formulary	0.1565	0.1448	1.081	0.2827
Generic available only in US	0.2521	0.1474	1.711	0.0906
Generic available only in Canada	0.2544	0.1256	2.026	0.0457
Generic available in both US & Canada	0.4286	0.1224	3.502	0.0007
Drug produced by US manufacturer	0.0296	0.0797	0.372	0.7107
First approved in US after 1984	-0.1030	0.1032	-0.998	0.3210
Subject to HCFA reimbursement limit	-0.0744	0.1350	-0.551	0.5829
Number of years since introduction	0.0109	0.0048	2.285	0.0246
General antimicrobial agents	-0.0800	0.2121	-0.377	0.7069
Cephalosporins	0.4189	0.2701	1.551	0.1244
Miscellaneous anti-infectives	-0.2477	0.2187	-1.132	0.2604
General cardiovascular system drugs	-0.1406	0.2539	-0.554	0.5811
Antianginal agents	-0.1129	0.2063	-0.547	0.5855
Antihypertensive drugs	-0.1136	0.2034	-0.558	0.5780
General central nervous system drugs	0.3808	0.2014	1.891	0.0618
Antianxiety agents	0.6261	0.2312	2.708	0.0081
Non steroidal anti-inflammatory drugs	0.0151	0.2076	0.073	0.9422
General hormonal agents	0.3094	0.2657	1.164	0.2474
Estrogens and progestogens	0.1724	0.1990	0.866	0.3888
Respiratory system drugs	-0.1686	0.2353	-0.716	0.4756
Eye, ear, nose and throat drugs	0.0802	0.2313	0.347	0.7295
Gastrointestinal tract drugs	0.3713	0.2277	1.631	0.1064
Dermatomucosal agents	0.1254	0.2359	0.532	0.5963
Agents for fluid & electrolyte balance	0.0153	0.2418	0.063	0.9495
R-square	0.4790	F Value	3.099	
Adjusted R-square	0.3244	Prob. > F	0.0001	
Number of Observations	119			

TABLE 3

Regression of US / Canadian Pharmaceutical Price Differential

Dependent Variable: Log of ratio of US to Canadian Price

Independent Variables	Parameter Estimate	Standard Error	T Value	Prob. > T
Intercept	-0.1923	0.1902	-1.011	0.3149
Patented drugs introduced before 1988	0.0736	0.0932	0.789	0.4320
Patented drugs introduced in 1988 or 1989	0.1964	0.1592	1.233	0.2208
Patented drugs introduced after 1989	0.1604	0.2046	0.784	0.4351
Listed on Ontario Drug Board formulary	0.1511	0.1342	1.126	0.2632
Generic available only in US	0.1294	0.1361	0.951	0.3442
Generic available only in Canada	0.2729	0.1144	2.385	0.0192
Generic available in both US & Canada	0.3643	0.1133	3.214	0.0018
Drug produced by US manufacturer	0.0429	0.0709	0.606	0.5462
First approved in US after 1984	-0.0257	0.0949	-0.271	0.7869
Subject to HCFA reimbursement limit	-0.1678	0.1211	-1.385	0.1694
Number of years since introduction	0.0035	0.0050	0.694	0.4897
General antimicrobial agents	0.0107	0.1893	0.057	0.9550
Cephalosporins	0.3931	0.2427	1.620	0.1089
Miscellaneous anti-infectives	-0.2758	0.1978	-1.395	0.1667
General cardiovascular system drugs	-0.2695	0.2251	-1.197	0.2345
Antianginals	-0.2349	0.1848	-1.271	0.2072
Antihypertensives	-0.1057	0.1806	-0.585	0.5601
General central nervous system drugs	0.0653	0.2003	0.326	0.7451
Antianxiety agents	0.1967	0.2340	0.841	0.4029
Nonsteriodal anti-inflammatory drugs	-0.0552	0.1862	-0.296	0.7677
General hormonal agents	0.3494	0.2360	1.481	0.1422
Estrogens and progestogens	-0.0581	0.1886	-0.308	0.7590
Respiratory system drugs	-0.1364	0.2104	-0.648	0.5186
Eye, ear, nose & throat drugs	0.0977	0.2051	0.476	0.6351
Gastrointestinal tract drugs	0.2932	0.2031	1.444	0.1525
Dermatomucosal agents	0.1114	0.2096	0.531	0.5965
Agents for fluid and electrolyte balance	0.1031	0.2146	0.480	0.6322
Number of cases per thousand estimated sales	1.4974	1.5286	0.980	0.3300
Proportion of cases with outcome for plaintiff	0.5538	0.1662	3.333	0.0013
Controlled substance drug	0.6576	0.1939	3.391	0.0010
Significant relationship to vaccine liability cost	0.1623	0.0944	1.718	0.0893
R-square	0.6146	F Value	4.475	
Adjusted R-square	0.4773	Prob. > F	0.0001	
Number of Observations	119			

TABLE 4

Regression of US / Canadian Pharmaceutical Price Differential

Dependent Variable: Log of ratio of US to Canadian Price

Independent Variables	Parameter Estimate	Standard Error	T Value	Prob. > T
Intercept	-0.1055	0.1716	-0.615	0.5403
Patented drugs introduced before 1988	0.0492	0.0895	0.550	0.5839
Patented drugs introduced in 1988 or 1989	0.1594	0.1528	1.043	0.2997
Patented drugs introduced after 1989	0.1514	0.2036	0.744	0.4591
Listed on Ontario Drug Board formulary	0.1323	0.1277	1.036	0.3031
Generic available only in US	0.1078	0.1337	0.806	0.4223
Generic available only in Canada	0.2689	0.1108	2.426	0.0173
Generic available in both US & Canada	0.3517	0.1107	3.177	0.0020
Drug produced by US manufacturer	0.0396	0.0703	0.563	0.5749
Approved in US after 1984	-0.0577	0.0902	-0.640	0.5236
Subject to HCFA reimbursement limit	-0.1834	0.1198	-1.530	0.1296
General antimicrobial agents	0.0288	0.1873	0.154	0.8782
Cephalosporins	0.3743	0.2406	1.556	0.1233
Miscellaneous anti-infectives	-0.2541	0.1909	-1.331	0.1865
General cardiovascular system drugs	-0.2686	0.2242	-1.198	0.2340
Antianginals	-0.2474	0.1816	-1.363	0.1765
Antihypertensives	-0.0988	0.1787	-0.553	0.5819
General central nervous system drugs	0.0933	0.1977	0.472	0.6381
Antianxiety agents	0.1989	0.2330	0.854	0.3956
Nonsteroidal anti-inflammatory drugs	-0.0563	0.1823	-0.309	0.7580
General hormonal agents	0.3784	0.2337	1.619	0.1089
Estrogens and progestogens	-0.0184	0.1803	-0.102	0.9191
Respiratory system drugs	-0.1205	0.2080	-0.579	0.5640
Eye, ear, nose & throat drugs	0.1003	0.2013	0.498	0.6196
Gastrointestinal tract drugs	0.2816	0.1981	1.421	0.1588
Dermatomucosal agents	0.0906	0.2075	0.437	0.6633
Agents for fluid and electrolyte balance	0.1134	0.2123	0.534	0.5946
Proportion of cases w/ outcome for plaintiff	0.6316	0.1394	4.531	0.0001
Controlled Substance	0.6509	0.1907	3.412	0.0010
Significant relationship to vaccine liability cost	0.1727	0.0931	1.854	0.0670
R-square	0.6088	F Value	4.776	
Adjusted R-square	0.4813	Prob. > F	0.0001	
Number of Observations	119			

TABLE 5

Regressions of US / Canadian Pharmaceutical Price Differential
Survey Response Variables

Dependent variable: Log of ratio of US to Canadian Price

Independent variable	(1)	(2)	(3)	(4)	(5)	(6)
Proportion of cases w/outcome for plaintiff	.5925*** (.166)	.5931*** (.165)	.6085*** (.173)	.5886*** (.165)	.5972*** (.162)	.5988*** (.167)
Sig. relationship to vaccine liability cost	.1571 (.096)	.1698* (.095)	.1615* (.095)	.1652* (.095)	.1434 (.094)	.1594* (.095)
Controlled substance	.6663*** (.173)	.6285*** (.203)	.6999*** (.204)	.6896*** (.197)	.7555*** (.197)	.6574*** (.195)
Ave MD risk ranking from survey	-.0671 (.125)	-	-	-	-	-
Ave Ph.D. risk ranking from survey	-	-.1148 (.171)	-	-	-	-
Ave pharmacist risk ranking from survey	-	-	-.0917 (.178)	-	-	-
Std Dev MD risk ranking from survey	-	-	-	-.2282 (.372)	-	-
Std Dev Ph.D. risk ranking from survey	-	-	-	-	-.7647* (.427)	-
Std Dev pharmacist risk ranking from survey	-	-	-	-	-	-.2204 (.393)
R-square	.6116	.6123	.6115	.6120	.6242	.6117
Adjusted R-square	.4732	.4742	.4731	.4738	.4903	.4734
F Value	4.420	4.433	4.418	4.427	4.662	4.422

Note -- Market and regulatory variables remain as specified in Tables 3 and 4. Standard errors of parameter estimates are in parenthesis.

* Significant at .10

** Significant at .05

*** Significant at .01

TABLE 6

Regressions of US / Canadian Pharmaceutical Price Differential
Drug Handbook Risk Variables

Dependent variable: Log of ratio of US to Canadian Price

Independent variable	(1)	(2)	(3)	(4)	(5)
Proportion of cases w/outcome for plaintiff	.5576*** (.194)	-	.5934*** (.166)	.5088** (.195)	.5911*** (.165)
Significant relationship to vaccine liability cost	.1761* (.098)	-	.1766* (.096)	-	.1734* (.095)
Controlled substance	.6716*** (.176)	-	.6073*** (.210)	.6877*** (.183)	.6211*** (.205)
Pregnancy risk categories D or X	.0689 (.138)	0.0483 (.150)	.0619 (.129)	.0558 (.140)	-
# Life threatening adverse reactions listed	.0153 (.043)	.00590 (.045)	-.0173 (.027)	.0168 (.043)	-
Likelihood of life threatening reactions	-0.0394 (.075)	-.0605 (.072)	-	-.0415 (.076)	-
Mortality risk associated with use	-0.0221 (.223)	-.1687 (.245)	-.0924 (.207)	.0138 (.225)	-.1369 (.190)
Overdose and treatment danger level	-0.0254 (.067)	.0500 (.072)	-	-.0237 (.068)	-
Extremity and extent of contraindications	.00268 (.084)	.1242 (.089)	-	.0192 (.085)	-
Drug interaction severity	-0.0462 (.072)	-.1297* (.078)	-	-.0539 (.073)	-
R-square	.6241	.5168	.6157	.6091	.6126
Adjusted R-square	.4524	.3212	.4665	.4375	.4746
F Value	3.634	2.642	4.127	3.549	4.439

Note -- Market and regulatory variables remain as specified in Tables 3 and 4. Standard errors of parameter estimates are in parenthesis.

* Significant at .10

** Significant at .05

*** Significant at .01

Distribution of US/Canada Price Differentials

Table 4 Regression Model

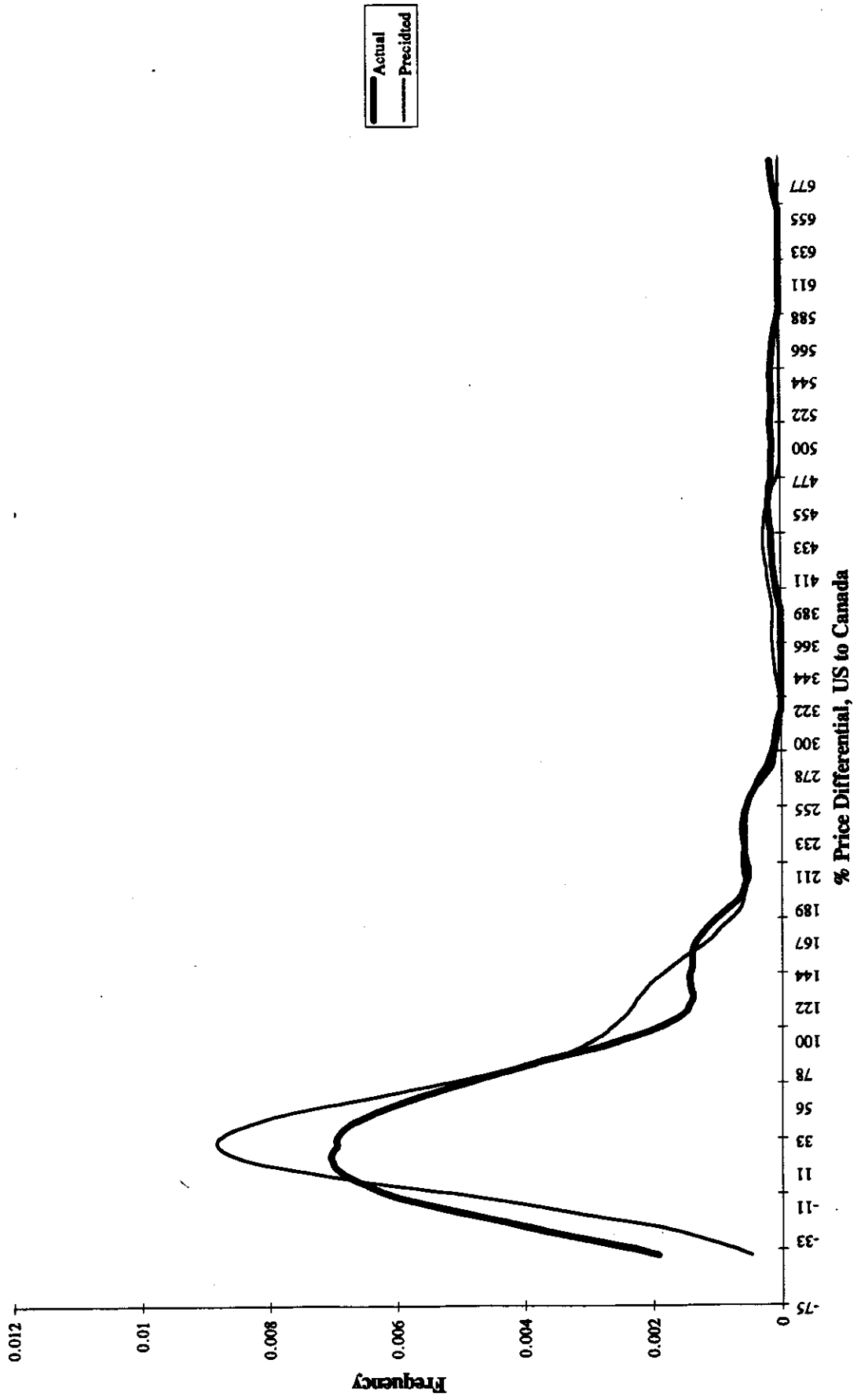


Figure 1

Distribution of US/Canada Price Differentials
Table 4 Regression Model

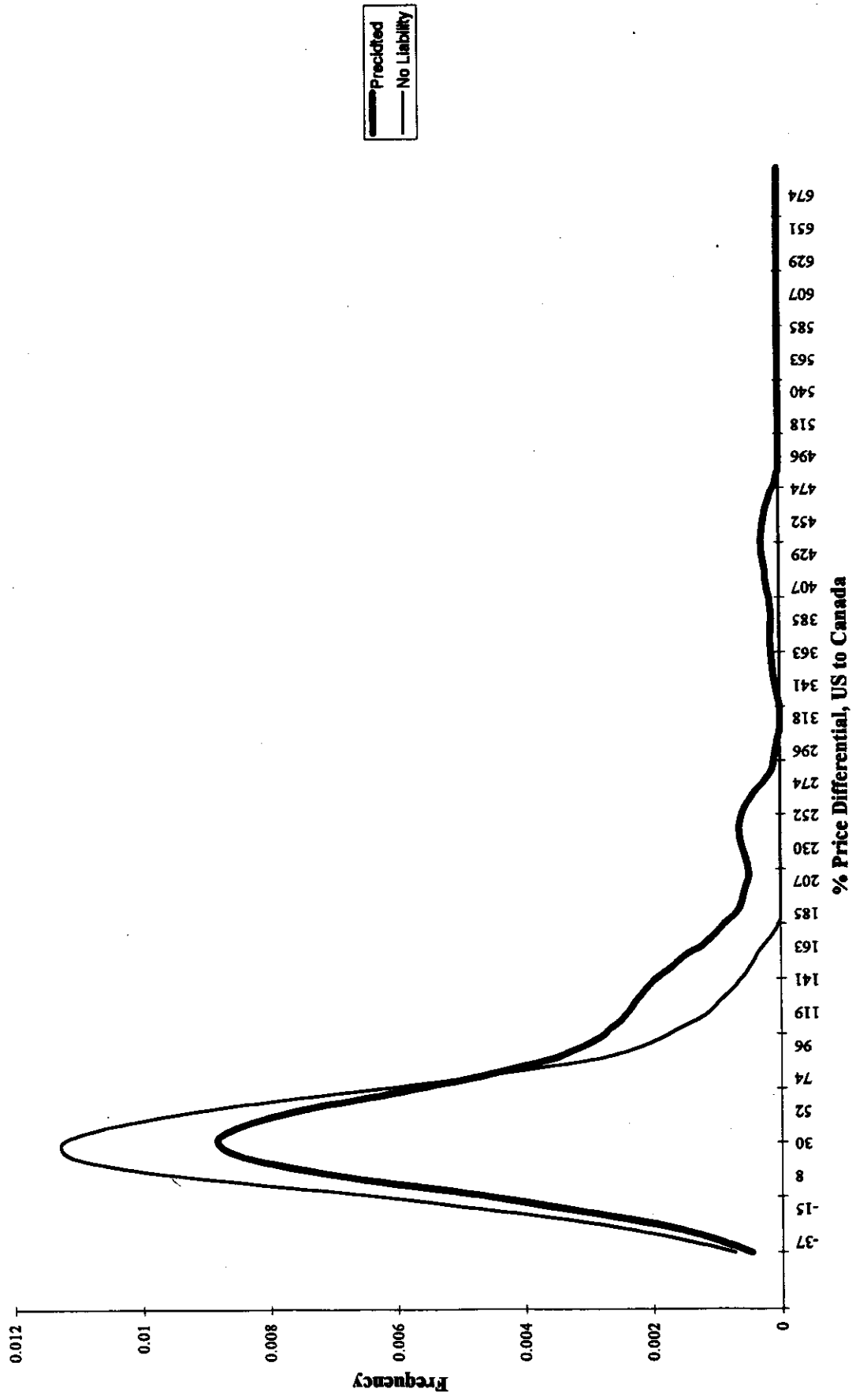


Figure 2

Appendix

Drug Reference Variables:

Following are seven potential measures of pharmaceutical risk as generated from product descriptions found in either the *Springhouse Drug Reference* (Springhouse Corp., 1988) or the *Physician's 1989 Drug Handbook* (Springhouse Corp., 1989).

1. *Pregnancy Risk*

Drugs are listed according to the risk their consumption imposes on the fetus of a pregnant woman according to a schedule of five categories, A, B, C, D, and X in increasing levels of risk. Drugs in categories D and X are associated with positive evidence of fetal risk and are contraindicated for virtually all pregnant women (Springhouse Corporation, 1989). A dummy variable for pregnancy risk takes the value 1 for drugs with ratings of D or X and takes the value 0 otherwise.

2. *Life Threatening Adverse Reactions*

The references list adverse reactions to each drug and identify certain reactions as life threatening, though no direct estimates of the expected frequency of such reactions is provided. A proxy for risk is the number of potentially life threatening adverse reactions identified for each drug product.

3. *Frequency of Life Threatening Reactions*

Though no explicit frequency of life threatening reactions is given in the reference sources, the descriptions often give some indication in the description. An index of this implied frequency is constructed for each drug, taking on the values 0 for no such reactions mentioned, 1 for reactions implied to be rare, and 2 for reactions which are indicated to be more than rare.

4. *Mortality Risk*

For some drugs, the references explicitly mention a history of mortality associated with consumption, though no explicit probability estimate is provided. A dummy variable indicates drugs for which mortality risk is cited.

5. *Overdose and Treatment Danger*

The references include sections detailing information about overdose dangers and the dangers associated with treating overdoses. From those sections, an index of danger, ranging from 0 to 3, is assigned to each drug according to the language of the reference as it appears that the drug imposes no danger (0) to severe danger (3).

6. *Contraindications*

An index ranging from 0 to 3 is assigned to each drug as the reference indicates the circumstances in which the drug is contraindicated. A rating of 0 indicates no contraindications listed, a rating of 3 indicates severe contraindications.

7. *Adverse Interactions*

Each reference includes information about interactions with other medications or drug products. Ranging from 0 to 3, this index corresponds to the severity of the listed interactions, with 3 being the most severe.

TABLE A.1

Original GAO Regression of US / Canadian Price Differential

Dependent Variable: Log of ratio of US to Canadian Price

Independent Variables	Parameter Estimate	Standard Error	T Value	Prob. > T
Intercept	-0.18833	0.18405	-1.023	0.3085
Patented drugs introduced before 1988	0.22771	0.10283	2.214	0.0289
Patented drugs introduced in 1988 or 1989	0.20585	0.19388	1.062	0.2908
Patented drugs introduced after 1989	0.41976	0.24036	1.746	0.0837
Listed on Ontario Drug Board formulary	0.26545	0.15113	1.756	0.0819
Generic available only in US	0.24692	0.16044	1.539	0.1268
Generic available only in Canada	0.12319	0.13124	0.939	0.3501
Generic available in both US & Canada	0.38913	0.11680	3.331	0.0012
Drug produced by US manufacturer	0.09210	0.08728	1.055	0.2938
Anti-inflammatory drug	-0.11017	0.13313	-0.828	0.4098
Cardiovascular drug	-0.03928	0.12701	-0.309	0.7577
Central nervous system drug	0.29416	0.12249	2.402	0.0181
Hormones and synthetic substitutes	0.27756	0.15567	1.783	0.0775
First approved in US after 1984	-0.18196	0.10114	-1.799	0.0749
R-square	0.3004	F Value	3.502	
Adjusted R-square	0.2147	Prob. > F	0.002	
Number of Observations	120			

Table A.2

Pairwise Correlations of the Four Principle Liability Variables

	Total cases divided by estimated sales	Proportion of cases won by plaintiffs	Controlled substance	Significant relationship to vaccine liability
Total cases divided by estimated sales	1.000 0.00	0.2382 0.009	-0.0426 0.645	-0.0796 0.390
Proportion of cases won by plaintiffs	0.2382 0.009	1.000 0.00	0.0308 0.7392	0.0416 0.654
Controlled substance	-0.0426 0.645	0.0308 0.7392	1.000 0.00	0.1999 0.029
Significant relationship to vaccine liability	-0.0796 0.390	0.0416 0.654	0.1999 0.029	1.000 0.00

Note -- The top entry in each cell is the Pearson Correlation Coefficient and beneath the coefficient is the P - level under the hypothesis that the correlation is actually zero.

Table A.3

Products with estimated liability effects in US/Canada price differential

Drug Name	Product Category	Observed % price differential	Predicted % price differential	Predicted differential without liability	Effect of liability on price differential
Tylenol w/ Codene	General central nervous system drugs	484.44	432.24	47.61	384.63
Valium	Antianxiety agents	433.86	443.04	89.42	353.62
Ativan	Antianxiety agents	702.02	371.68	107.01	264.67
Dalmane	General central nervous system drugs	236.45	239.59	49.04	190.55
Percoset	General central nervous system drugs	44.00	236.34	47.61	188.73
Xanax	Antianxiety agents	182.59	265.32	90.55	174.77
Halcion	General central nervous system drugs	196.49	228.70	71.45	157.25
Reglan	Gastrointestinal tract drugs	545.49	235.11	78.19	156.92
Restoril	General central nervous system drugs	150.62	166.08	16.78	149.30
Premarin	Estrogens and progestogens	162.20	164.32	45.97	118.35
Klonopin	General central nervous system drugs	171.79	141.46	25.94	115.52
Indocin	Nonsteroidal anti-inflammatory drugs	50.07	142.58	27.09	115.49
Coumadin	Miscellaneous drug categories	87.32	155.62	52.46	103.16
Lanoxin	General cardiovascular system drugs	15.94	86.61	-16.51	103.12
Orthonovum-135	Estrogens and progestogens	74.59	124.21	32.01	92.20
Norinyl	Estrogens and progestogens	83.53	115.50	26.89	88.61
Macrochantin	Miscellaneous anti-infectives	72.14	84.61	-1.84	86.45
Transderm-nitro	Antianginals	4.42	83.55	-2.40	85.95
Nitrostat	Antianginals	73.72	75.28	-6.80	82.08
Dilantin	General central nervous system drugs	221.83	118.15	38.94	79.21
Premarin-vaginal	Estrogens and progestogens	69.67	122.40	45.97	76.43
Orthonovum-777	Estrogens and progestogens	82.89	119.12	53.33	65.79
Phenergan	Respiratory system drugs	101.63	96.36	43.19	53.17
Inderal	Antianginals	250.60	54.02	4.99	49.03
Vanceril	General hormonal agents	142.80	180.26	135.81	44.45
Synthroid	General hormonal agents	277.60	169.37	126.66	42.71
Tri-norinyl	Estrogens and progestogens	85.14	34.24	-6.06	40.30
Achromycin-V	General antimicrobial agents	35.75	78.16	38.39	39.77
Zantac	Gastrointestinal tract drugs	30.42	136.42	98.93	37.49
Duricef	Cephalosporins	102.90	118.70	84.02	34.68
Slow-V	Agents for fluid and electrolyte balance	104.92	106.67	73.89	32.78
Ceclor	Cephalosporins	59.47	106.26	73.55	32.71
Elavil	General central nervous system drugs	154.45	102.55	70.43	32.12
Beconase-AQ	Eye, ear, nose & throat drugs	56.29	102.24	70.17	32.07
Provera	Estrogens and progestogens	74.60	43.62	11.56	32.06
Clinoril	Nonsteroidal anti-inflammatory drugs	47.81	90.60	60.37	30.23
Cleocin-T	Miscellaneous anti-infectives	9.40	17.76	-10.17	27.93
Naprosyn	Nonsteroidal anti-inflammatory drugs	69.70	68.63	41.89	26.74
Catapres	Antihypertensives	56.97	67.16	40.65	26.51
Deltasone	General hormonal agents	81.69	161.99	135.81	26.18
Lopressor	Antihypertensives	126.03	61.63	36.00	25.63
Topicort	Dermatomucosal agents	25.74	58.28	33.18	25.10
Flexeril	Miscellaneous drug categories	52.35	58.00	32.94	25.06
Dolobid	General central nervous system drugs	43.38	55.73	31.03	24.70
Monistat	Dermatomucosal agents	25.92	47.85	24.40	23.45
Corgard	Antianginals	63.74	44.93	21.95	22.98
Aldomet	Antihypertensives	81.97	44.78	21.82	22.96
Pediazole	General antimicrobial agents	31.80	28.87	8.43	20.44

Table A.4

Products with no estimated liability effects in US/Canada price differential

Drug Name	Product Category	Observed % price differential	Predicted % price differential	Predicted differential without liability
Diabeta	General hormonal agents	110.60	126.66	126.66
Tagamet	Gastrointestinal tract drugs	66.79	98.93	98.93
Timoptic	Eye, ear, nose & throat drugs	-5.94	72.65	72.65
Vancenase-AQ	Eye, ear, nose & throat drugs	162.10	68.54	68.54
Axid	Gastrointestinal tract drugs	69.09	66.70	66.70
Suprax	Cephalosporins	51.43	58.95	58.95
Triphasil	Estrogens and progestogens	64.87	58.58	58.58
Moduretic	Agents for fluid and electrolyte balance	24.14	58.20	58.20
Augmentin	General antimicrobial agents	64.19	54.49	54.49
Ceftin	Cephalosporins	74.96	52.78	52.78
Carafate	Gastrointestinal tract drugs	27.35	50.58	50.58
Pepcid	Gastrointestinal tract drugs	35.22	49.30	49.30
Lasix	Agents for fluid and electrolyte balance	48.71	44.76	44.76
Ventolin	Respiratory system drugs	51.61	44.57	44.57
Motrin	Nonsteroidal anti-inflammatory drugs	-13.05	44.10	44.10
Theo-Dur	Respiratory system drugs	-16.24	43.19	43.19
Nolvadex	Miscellaneous drug categories	4.05	42.90	42.90
Tegretol	General central nervous system drugs	21.27	41.88	41.88
Micro-K	Agents for fluid and electrolyte balance	49.56	41.76	41.76
Capoten	Antihypertensives	-3.76	41.49	41.49
Prinivil	Antihypertensives	-16.28	40.79	40.79
Feldene	Nonsteroidal anti-inflammatory drugs	35.54	40.53	40.53
Bactrim-DS	General antimicrobial agents	241.98	39.72	39.72
Ansaid	Nonsteroidal anti-inflammatory drugs	43.11	39.34	39.34
Sinemet	Antianxiety agents	2.45	38.63	38.63
Wymox	General antimicrobial agents	2.32	38.39	38.39
Prozac	General central nervous system drugs	8.31	38.09	38.09
Tobrex	Eye, ear, nose & throat drugs	58.63	34.48	34.48
Amoxil	General antimicrobial agents	4.93	33.01	33.01
Orudis	Nonsteroidal anti-inflammatory drugs	148.70	32.65	32.65
Propine	Eye, ear, nose & throat drugs	17.77	31.95	31.95
Retin-A	Miscellaneous drug categories	153.34	30.25	30.25
Slo-bid	Respiratory system drugs	20.79	29.91	29.91
Tenormin	Antihypertensives	30.28	28.37	28.37
PCE	Miscellaneous anti-infectives	43.56	27.66	27.66
Voltaren	Nonsteroidal anti-inflammatory drugs	24.33	27.50	27.50
Lotrisone	Dermatomucosal agents	47.55	26.80	26.80
Erythromycin-base	Miscellaneous anti-infectives	138.08	25.28	25.28
Cipro	General antimicrobial agents	3.87	24.44	24.44
Isoptin	Antianginals	-29.39	21.22	21.22
K-Dur	Agents for fluid and electrolyte balance	4.85	20.13	20.13
Betoptic	Eye, ear, nose & throat drugs	20.22	19.71	19.71
Terazol	Dermatomucosal agents	10.88	19.69	19.69
Zovirax-ointment	Dermatomucosal agents	-17.70	19.57	19.57
Procardia	Antianginals	-6.37	19.04	19.04
Bactroban	Dermatomucosal agents	63.48	18.56	18.56
Eryc	Miscellaneous anti-infectives	7.73	18.25	18.25

Table A.4 (Continued)

Products with no estimated liability effects in US/Canada price differential

Drug Name	Product Category	Observed % price differential	Predicted % price differential	Predicted differential without liability
Anaprox	Nonsteroidal anti-inflammatory drugs	20.24	17.33	17.33
Zestril	Antihypertensives	-16.28	16.31	16.31
Tenoretic	Antihypertensives	35.35	16.05	16.05
Noroxin	General antimicrobial agents	-1.81	15.95	15.95
Intal	Miscellaneous drug categories	19.76	14.72	14.72
Buspar	Antianxiety agents	-11.70	14.64	14.64
Hytrin	Antihypertensives	30.37	13.96	13.96
Trental	Miscellaneous drug categories	-34.36	9.21	9.21
Ventolin-syrup	Respiratory system drugs	-15.18	6.92	6.92
Nicorette	Miscellaneous drug categories	24.80	4.57	4.57
Erythrocin-sterate	Miscellaneous anti-infectives	11.16	4.29	4.29
EES	Miscellaneous anti-infectives	-44.29	4.29	4.29
Vasotec	Antihypertensives	-15.05	2.07	2.07
Anaprox-DS	Nonsteroidal anti-inflammatory drugs	-0.49	-0.68	-0.68
Rogaine	Miscellaneous drug categories	-19.34	-1.30	-1.30
Persantine	General cardiovascular system drugs	12.90	-1.86	-1.86
Zovirax	General antimicrobial agents	-32.71	-2.36	-2.36
Mevacor	General cardiovascular system drugs	3.88	-3.84	-3.84
Estraderm	Estrogens and progestogens	-26.52	-6.86	-6.86
E-mycin	Miscellaneous anti-infectives	-41.16	-7.73	-7.73
Atrovent	Respiratory system drugs	36.15	-8.61	-8.61
Questran	General cardiovascular system drugs	-11.96	-13.14	-13.14
Cardizem	Antianginals	-14.80	-16.25	-16.25
Calan	Antianginals	-25.96	-18.28	-18.28