Before the
Department of Health and Human Services
Food and Drug Administration
Washington, D.C.

In Re: Petition to Provide Certification	)
to Congress Under Section 804(*l*) of	)
Chapter VIII of the Federal Food,	)
Drug and Cosmetics Act, and to	)
Authorize a Pilot Program for	)
Importation of Prescription Drugs	)
in the State of Illinois	)

AFFIDAVIT OF ALAN SAGER, Ph.D.

Professor Alan Sager, Ph.D., being duly sworn, hereby deposes and states:

QUALIFICATIONS

I am a professor of health services at the Boston University School of Public Health, where I have taught health care finance, administration, and policy to public health students since 1983. I serve as one of the two directors of the Health Reform Program, and direct the master of public health degree program in health services. I have a B.A. in economics from Brandeis University, and a Ph.D. in city and regional planning, specializing in health care, from the Massachusetts Institute of Technology.

I have served on the Massachusetts Health Finance Working Group, on the Massachusetts Attorney General's Advisory Group on Health Care Reform, and as a hospital trustee. I have testified six times before U.S. House and Senate committees (four times on prescription drug issues and twice on hospital survival problems), and before eight states' legislative committees (on prescription drug pricing, health care costs, physician balance billing, improving health care coverage, and hospital survival).

Since 1993, the Health Reform Program has been investigating methods of obtaining affordable medications for all Americans while protecting and enhancing breakthrough pharmaceutical research. The evidence and analysis offered in this affidavit rest on work performed jointly over the past fifteen years with my fellow director, Deborah Socolar, M.P.H.

I am over the age of 18, and a citizen and resident of the United States of America and the State of Massachusetts. I have personal knowledge of all the facts and opinions set forth in this Affidavit, and I would be competent to testify thereto if called upon to do so as a witness. The opinions expressed in this Affidavit are my own, and are not presented on behalf of Boston University.

INTRODUCTION

Governor Blagojevich's petition on behalf of the State of Illinois requests that the Commissioner of the United States Food and Drug Administration (FDA) certify to Congress that importing prescription drugs from Canada is safe and will result in a significant reduction in the cost of prescription drugs to the American consumer. The State of Illinois asks the FDA to promulgate regulations authorizing pharmacists and wholesalers to import prescription drugs from Canada into the United States on a nationwide, statewide, or pilot program basis. Alternatively, the State of Illinois asks the FDA to grant waivers to residents nationwide, statewide, or on a pilot program basis so that residents may import prescription drugs from Canada into the United States for personal use. In my opinion, importing prescription drugs from Canada is safe, and accomplishes the essential goal of lowering drug prices.

Higher drug prices hurt American patients and penalize American employers, workers, and taxpayers. Prescription drug prices in the United States are the highest in the world, with patients and payers in the United States providing the world's drug makers with about one-half of their world-wide revenue. The gap between U.S. prices and those in other wealthy nations is rising, and the U.S. share of drug makers' revenue is also increasing. This is not a stable or sustainable arrangement.

Importing prescription drugs from Canada offers a safe and effective way to lower prescription drug prices in the United States. There is little evidence of any genuine health threat arising from the importation of prescription drugs from Canada, which has stringent regulatory protections in place to ensure safety. Whatever health risks have been identified are largely attributable to the current FDA opposition to imports, which has resulted in an unregulated prescription drug black market. By allowing imports from Canada, the FDA could establish a regulatory framework that would eliminate the health risks arising from the prescription drug black market. American consumers would save billions of dollars importing Canadian prescription drugs, and the lower prices would enable individuals who presently cannot afford prescription drugs to obtain needed medical treatments.

This affidavit is divided into three main sections. The first identifies and describes the unsustainable price levels of prescription drugs in the United States. The second sets out reasons why importing prescription drugs from Canada is safe, and why it will enhance the health of the citizens of the United States and the residents of Illinois. The third describes why importing prescription drugs from Canada would result in a significant reduction in drug costs for American consumers.

In this affidavit, the word "importing," and its variants, will be used to describe the activity of bringing prescription drugs from Canada into the United States. Another term, "reimporting," refers to bringing back into the United States drugs manufactured here but then exported for use in another nation. For purposes of this Affidavit, the word "importing," and its variants, includes "reimporting."

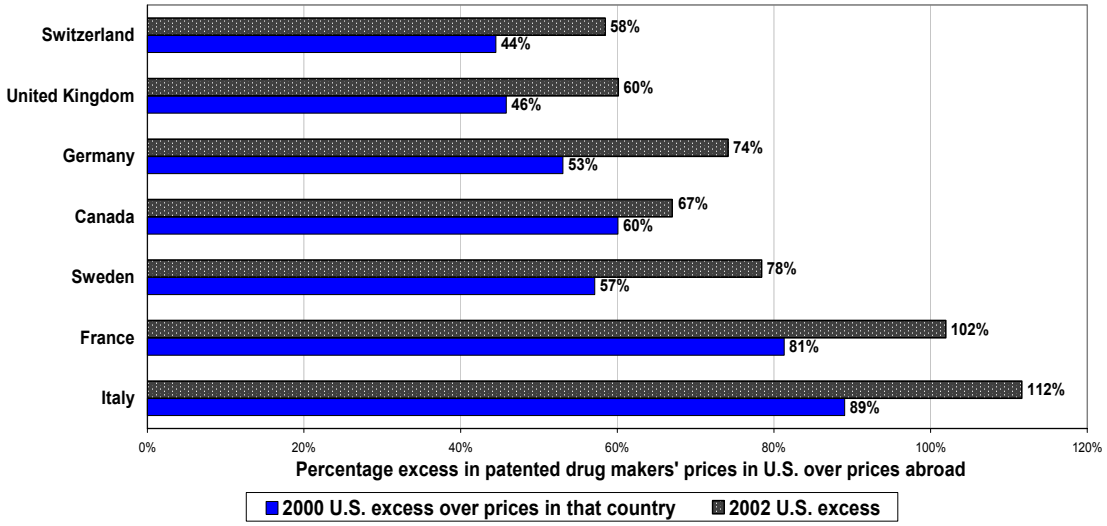
I. UNITED STATES DRUG PRICES ARE RISING AND UNSUSTAINABLE

1. The world's highest prices—and rising. Prescription drug prices in the United States are the highest in the world. The evidence in Exhibit 1, calculated from data compiled by the Canadian Patented Medicine Prices Review Board, shows that U.S. prices are extraordinarily high, and that the gap between U.S. prices and those in other wealthy nations is actually widening.[1] The top line in each pair of bars shows the 2002 U.S. price excess over those in other nations; the bottom line shows the smaller excess for the year 2000.

It appears likely that the gap between U.S. drug prices and those in other wealthy nations is going to grow substantially greater in the years ahead. The European Court of Justice has issued a ruling that, if upheld, will result in lower drug prices in many of the 15 European Union nations.[2] The ruling would regularize the practice of moving drugs from one nation to another within the EU. The probable result will be that many Europeans will pay substantially lower prices for medications. Responses available to drug makers include accepting the resulting revenue loss, raising U.S. prices still higher, and fighting for higher prices in EU nations.

Exhibit 1

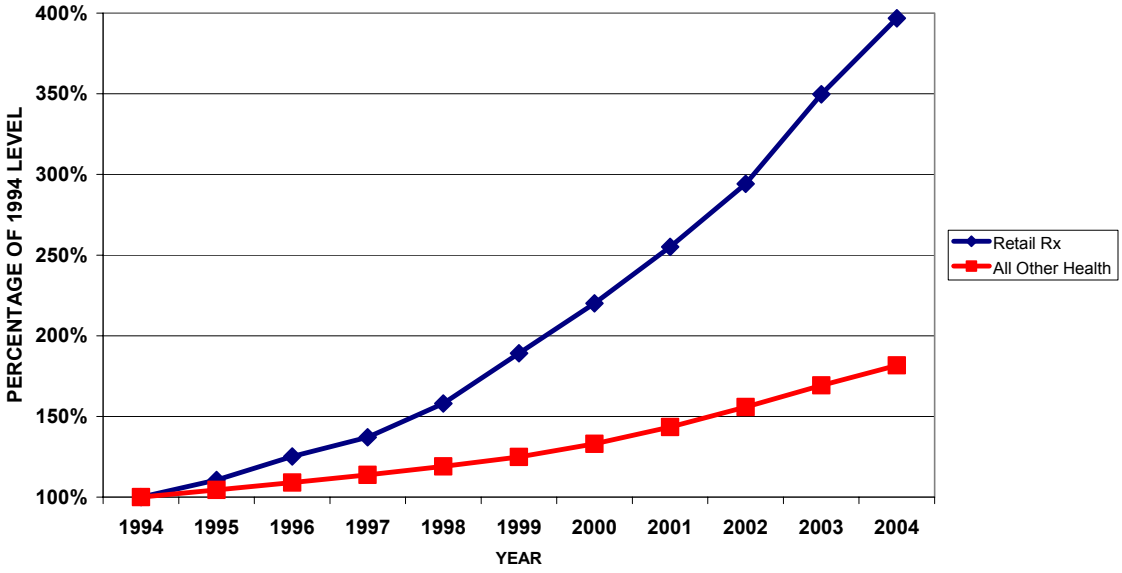
Rise in U.S. Brand Name Drug Price Excess over Prices in 7 Nations, 2000 to 2002



2. ***Spending on retail prescription drugs here has doubled every five years since 1994***, rising more than twice as fast as the rest of health spending, as indicated in Exhibit 2. Further, spending on retail prescription drugs has grown more than 4.5 times as fast as the U.S. economy as a whole.[3]

Exhibit 2

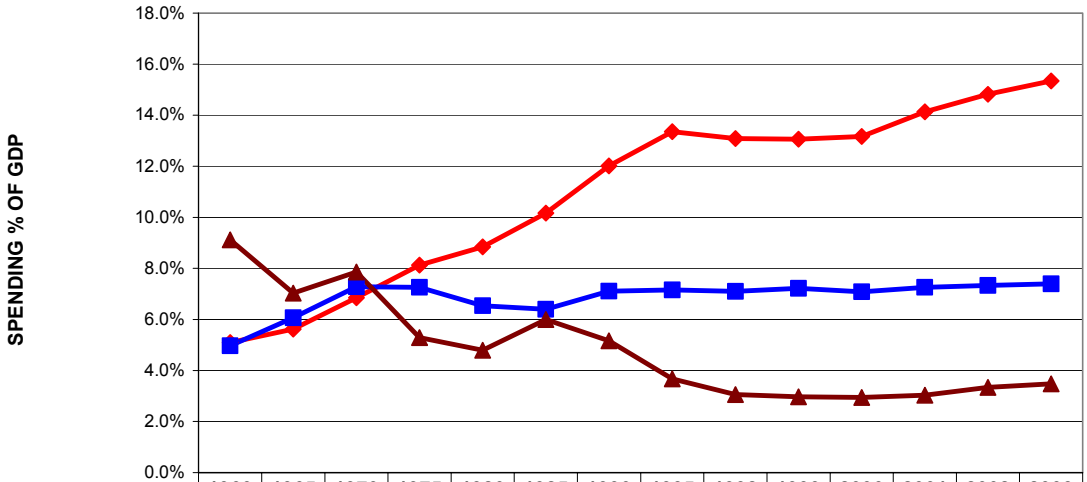
RETAIL PRESCRIPTION DRUG AND ALL OTHER HEALTH SPENDING, 1994 - 2004, AS PERCENTAGE OF 1994 SPENDING



3. The continuing rise in prescription drug prices is particularly worrisome, given that health care spending itself represented more than fifteen percent (15%) of the gross domestic product in 2003, four times reported defense spending and double education spending. (Please refer to Exhibit 3.) In 1970, by contrast, health, education, and defense spending were all about the same share of the economy—about seven percent of GDP.

Exhibit 3

HEALTH, EDUCATION, AND DEFENSE SPENDING, U.S., 1960 - 2003, AS PERCENT OF GDP



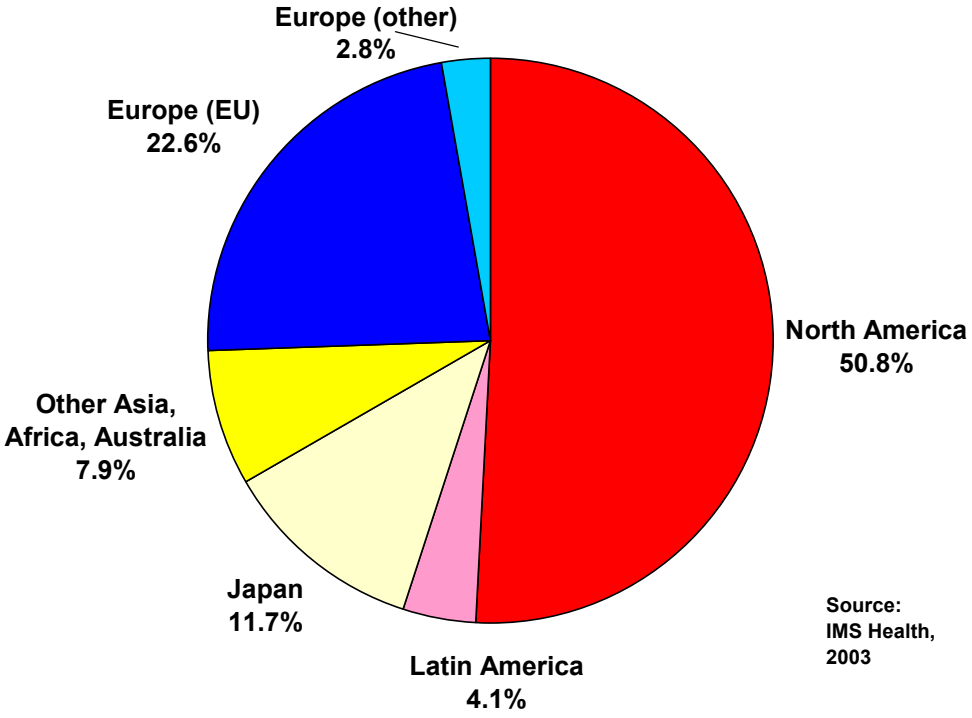
	1960	1965	1970	1975	1980	1985	1990	1995	1998	1999	2000	2001	2002	2003
HEALTH	5.1%	5.6%	6.8%	8.1%	8.8%	10.2%	12.0%	13.4%	13.1%	13.1%	13.2%	14.1%	14.8%	15.3%
EDUCATION	5.0%	6.1%	7.3%	7.3%	6.5%	6.4%	7.1%	7.2%	7.1%	7.2%	7.1%	7.3%	7.3%	7.4%
DEFENSE	9.1%	7.0%	7.9%	5.3%	4.8%	6.0%	5.2%	3.7%	3.1%	3.0%	2.9%	3.0%	3.3%	3.5%

YEAR

4. As shown in Exhibit 4, the world's drug makers drew more than one-half their revenue from North America in 2002, up from one-third in 1996.[4] The great majority of that revenue comes from the United States.

Exhibit 4

SHARES OF WORLD'S Rx SPENDING, 2002



Source:
IMS Health,
2003

II. IMPORTING IS HEALTHY AND SAFE

Prescription drugs, medical supplies, food, and other goods subject to adulteration routinely and safely move across the U.S. – Canadian border. The net additional benefits of importing prescription drugs from Canada into the United States are substantial, whereas the net additional risks, if any, are minimal. That conclusion follows from an analysis of the number of patients who will be helped medically by lower-cost prescriptions, and how much they will be helped, versus the number of patients who will be harmed by importation, and how much they will be harmed. For the reasons that follow, the evidence is clear that the net benefits will be enormous, whereas the net risks are negligible.

1. Net Additional Benefits of Importing

Many Americans suffer avoidable death, disability, illness, and pain owing to their inability to afford needed medications. Multiple studies confirm that patients do not fill their doctors' prescriptions. It seems likely that many other patients do not even go to the doctor to ask for prescriptions, knowing that they cannot afford to fill them. The benefits associated with importing lower-priced drugs will therefore be enjoyed by patients who today do not obtain prescriptions or do not fill them.

The unmet need for medications is very substantial. In a 1999 report prepared for the U.S. House of Representatives Prescription Drug Task Force, my colleague and I estimated that roughly one-quarter of all Americans lacked insurance for prescription drugs.[5] That share has surely increased over the past five years, owing to a rise in the number of Americans without any health insurance, to a loss of retiree health insurance coverage, and even to an apparent rise in the share of persons covered by job-based health insurance that excludes prescription drug coverage.[6]

Numerous recent surveys have found evidence of substantial unmet need for medications in the United States, especially among seniors, whose health problems are greater and whose rates of drug coverage are lower than in the under-65 population. A study in eight states, for example, found that nearly one-fourth of seniors surveyed reported that, because of high costs, they skipped doses of medication or failed to obtain prescribed drugs.[7] In the same survey, chronically ill seniors who were uninsured for drugs skipped medications at rates 2-3 times higher than those who had drug coverage.

A November 2002 Harris poll found that surveyed adults reported these striking problems within the previous year:

- 18 percent—and 33 percent of those in fair or poor health—had failed to ask for prescriptions because of their cost
- 22 percent—and 41 percent of sicker adults—failed to fill a prescription because of the cost
- 15 percent—and 29 percent of sicker adults—took a lower dose to make it last longer
- 18 percent—and 37 percent of sicker adults—took a drug less often than prescribed to make it last longer.[8]

More recently, an Associated Press/Ipsos poll found that one-third of Americans report that paying for medications is a problem.[9]

The inability to afford medications is more acute among African Americans and Latinos than among non-Latino Caucasians.[10]

Caregivers also see these problems. Inability to afford medications is a "substantial barrier" to patient compliance with physician directives.[11]

Caregivers in safety-net hospitals and clinics also report substantial difficulty in helping patients who lack drug coverage obtain the medications they need, with health center pharmacies, in some cases, having to turn away patients when funding runs short.[12]

Often, sadly, it is easiest to measure the harm associated with lack of medications when new price barriers to using drugs are introduced. Tamblyn and colleagues found that introducing prescription drug cost-sharing for older patients in Quebec led to a drop in use of essential drugs by 9 percent. Adverse clinical events increased from 5.8 per 10,000 person months to 12.6.[13] The clinical harm suffered by the large numbers of Americans uninsured or underinsured for prescription drugs must be substantial.

Similarly, Soumerai and colleagues found that limits on prescription drug use in the New Hampshire Medicaid program led to substantial increases in use of emergency mental health services and inpatient care by elders.[14]

Rising drug prices have also for several years been associated with the erosion of prescription drug coverage under employers' retiree health programs—and even with the truncation of coverage under such programs. This is not surprising, since more than one-half of retiree health costs are from prescription drugs.[15]

In a recent four-day period, two instances of cuts in private or public prescription drug programs were announced. Both cuts were said to be caused partly by high drug costs.

- Rising drug prices were implicated in placing some 800 AIDS in the U.S. on waiting lists for vital medications.[16]

- Two New Hampshire hospitals ended their program of subsidized drug purchases. They blamed a combination of low reimbursement rates and the rising cost of prescription drugs.[17]

When drug prices are lowered, through importation or other means, more patients will be able to fill more prescriptions. While there is some disagreement about the size of the increase in use in response to lower prices, I believe it will be substantial.[18] Much of the unmet need just described will be met, easing human suffering.

2. Net Additional Risks of Importing

The prohibition on drug importation, and high drug prices, have together created an unregulated black market for prescription drugs, one that can be eliminated by allowing regulated imports. Drug makers' artificially high U.S. prices spur importing without accompanying oversight or controls. While almost all Canadian drugs are safe, some corrupt or careless suppliers may sell risky medications. Some desperate patients may buy them. High prices here drive both actions. If the United States achieved lower drug prices through legal importation, patients would have no need to buy from unsafe or illegal operators, domestic or foreign. Today's rare unsafe imports are therefore a reason to legalize importation—not a pretext for intransigence.

The dangers associated with importing drugs from Canada to the United States have been highly exaggerated. Negative analyses of the safety issues involved in importing prescription drugs from Canada focus on purportedly unsafe drugs seized in connection with the prescription drug black market, without giving adequate consideration to the regulatory controls that would be involved in a legal importation framework.

For example, on September 29, 2003, the FDA issued a press release stating that it found "Hundreds of Potentially Dangerous Imported Drug Shipments."[19] The FDA declared that 1,019 of 1,153 packages (88 percent) "were violative because they contained unapproved drugs." Packages were selected if they originated in nations "from which drugs are known to be exported via the mail." It is worth noting that only 16 percent of the packages were from Canada, which in itself suggests that a legal program of importation from Canada would reduce the risks associated with black market drugs from non-Canadian sources.

The FDA cited several specific problems: unapproved drugs, drugs requiring careful dosing, drugs with inadequate labeling, improperly packaged drugs, drugs withdrawn from the market, animal drugs not approved for human use, drugs with dangerous interactions, drugs requiring subsequent patient monitoring, and controlled substances.

The FDA reported no tallies of the ways in which the 1,019 "violative" drugs failed legal tests, but it appears from the FDA's public statements that the largest problem was the FDA's own inadequate testing. According to the Associated Press, FDA Associate Commissioner William Hubbard reportedly "conceded the drugs hadn't been tested for safety [at the border by the FDA or Customs] and that in most instances drugs imported by consumers are illegal regardless of their safety."[20]

By allowing the legal importation of prescription drugs from Canada, the FDA could adopt regulations requiring testing of imported drugs. Indeed, the proposal offered by the State of Illinois includes rigorous testing requirements for imported drugs.

There are several additional indications that importing drugs from Canada is not dangerous.

- When pressed, the FDA has apparently not been able to identify a single American patient who has been harmed by importing drugs from Canada.[21] The FDA's Director of Pharmacy Affairs said "'I can't think of one thing off the top of my head where somebody died or somebody got put in the hospital because of these

medications. I just don't know if there's anything like that.'" Similarly, a spokesperson for Health Canada said that organization "'does not have any information that would indicate that any Americans have become ill or have died as a result of taking prescription medications purchased from Canada.'"

- United Health, a large insurer, announced in October of 2002 that it would reimburse patients who bought drugs in Canada or other nations. That new policy applied to some 97,000 persons who bought insurance though AARP.[22]

- The Associated Press has reviewed the 473 complaints to state regulators about pharmacies and pharmacists in Minnesota from 1999 to 2004. None "alleged an error by a foreign pharmacy."[23]

- The State of Minnesota has inspected mail order pharmacies in Canada and found some of them safe enough to list on a state web site, along with comparative prices.[24]

- The governor of New Hampshire has found that importing drugs from Canadian pharmacies would be safe. The state's crime laboratory performed a blind analysis of drugs bought in Canada and drugs bought in New Hampshire. No differences were found.[25]

Drug importing should not be declared illegal because it is dangerous. Rather, it should be recognized that drug importing can sometimes be dangerous because it is illegal.

High U.S. drug prices and the prohibition on importation have together resulted in a domestic U.S. black market for prescription drugs and other unsafe practices that endanger patient safety. For example:

- BNA reported in 2000 that high drug costs were responsible for an internet black market in fertility drugs.[26]

- The *New York Post* described illegal marketing of outdated drugs and cited the head of the state attorney-general's Medicaid Fraud Control Unit who attributed this to the high price of drugs in the U.S.[27]

- The *Boston Globe* reports an increase in the theft and diversion of prescription drugs in the New York region.[28]

- The *Wall Street Journal* noted that the Caremark PBM has been sued by pharmacists for reselling medications that other patients had returned. Most states prohibit this practice because it is believed to be unsafe.[29]

These are avoidable consequences that could be reduced or eliminated outright through the legal importation of prescription drugs.

III. IMPORTING WILL RESULT IN SIGNIFICANT COST REDUCTIONS

If adequate supplies of drugs can be imported from Canada, the dollar savings to U.S. patients and other payers would be enormous. These dollar savings would be in addition to the direct, indirect, and intangible benefits of better health associated with greater ability to afford needed medications.

In 2001 U.S. Senate testimony, I estimated that Americans would save some $38.4 billion in one year on brand name prescription drugs if manufacturers sold in the U.S. at Canadian prices.[30] I estimate that U.S. retail drug spending will have risen by 55.5 percent from 2001 to 2004. Applying this 55.5 percent increase to the figures included in that 2001 testimony, I project that Americans would save some $59.7 billion at manufacturers' prices in 2004 were U.S. brand name prescription drugs sold at Canadian prices. [31] State-by-state projected spending and savings are set forth in Exhibit 5.

These are the gross savings. They assume that Americans cease buying current prescriptions at U.S. prices and start buying those prescriptions at Canadian prices. There is no allowance for demanding greater numbers of prescriptions in response to the lower prices.

These savings would also be reduced, to some extent, by the cost of inspecting drugs imported from Canada. The inspection regime required by federal statute for importation of prescription drugs is not trivial. [32] But the inspection costs are unlikely to equal even one percent of the dollar savings and the direct, indirect, and intangible benefits accruing from lower prices.

Exhibit 5

State-by-State Projected Spending on Brand Name Drugs in 2004, and Savings if the U.S. Paid Canadian Prices

($ millions)

	Brand Name Drug Spending in 2004 at Factory Prices	Savings if Paid Canadian Prices			Brand Name Drug Spending in 2004 at Factory Prices	Savings if Paid Canadian Prices
Alabama	$2,723	$1,022		Montana	$411	$154
Alaska	$233	$87		Nebraska	$1,098	$412
Arizona	$2,453	$921		Nevada	$838	$314
Arkansas	$1,585	$596		New Hampshire	$686	$258
California	$13,229	$4,966		New Jersey	$6,223	$2,336
Colorado	$1,703	$639		New Mexico	$706	$264
Connecticut	$2,376	$893		New York	$12,500	$4,692
Delaware	$527	$198		North Carolina	$4,504	$1,691
D. C.	$316	$118		North Dakota	$338	$126
Florida	$10,889	$4,087		Ohio	$6,842	$2,568
Georgia	$4,318	$1,621		Oklahoma	$1,854	$695
Hawaii	$546	$205		Oregon	$1,611	$605
Idaho	$586	$219		Pennsylvania	$8,837	$3,317
Illinois	$6,958	$2,611		Rhode Island	$701	$263
Indiana	$3,613	$1,356		South Carolina	$2,308	$866
Iowa	$1,658	$622		South Dakota	$353	$132
Kansas	$1,499	$563		Tennessee	$3,737	$1,403
Kentucky	$2,745	$1,031		Texas	$10,571	$3,968
Louisiana	$2,646	$992		Utah	$989	$372
Maine	$801	$300		Vermont	$322	$121
Maryland	$2,946	$1,106		Virginia	$3,739	$1,403
Massachusetts	$3,812	$1,431		Washington	$2,814	$1,056
Michigan	$6,818	$2,560		West Virginia	$1,362	$512
Minnesota	$2,618	$983		Wisconsin	$3,062	$1,149
Mississippi	$1,689	$635		Wyoming	$233	$87
Missouri	$3,184	$1,194		***USA***	$159,107	$59,724

FURTHER AFFIANT SAYETH NOT.

_____
Professor Alan Sager, Ph.D.

SUBSCRIBED AND SWORN TO BEFORE ME
this ____ day of April, 2004.

_____
Notary Public

NOTES

[1] Calculated from data in Patented Medicine Prices Review Board, 2002 Annual Report , Ottawa: The Board, 30 May 2003, and earlier years. For the 2002 report, please see, http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf, access confirmed 24 March 2004.

[2] Jeanne Whalen and James Kanter, "EU Court Backs Resale of Drugs," *Wall Street Journal Online,* 2 April 2004, www.online.wsj.com.

[3] We calculate and project a rise of 296.7 percent in retail prescription drug spending between 1994 and 2004. Adding a six percent rise in nominal gross domestic product to the U.S. Bureau of Economic Analysis's 2003 GDP estimate yields a 65 percent rise in nominal GDP between 1994 and 2004. 2.967/0.65 = 4.56. For BEA GDP data, please refer to http://www.bea.gov/bea/dn/gdplev.xls, access confirmed 16 February 2004. Assuming continued low inflation, the six percent nominal rise is roughly in line with the Mortgage Bankers' Association of America projection of a real rise in GDP in 2004 of 4.7 percent. See "Mortgage Bankers: US GDP To Grow Over 4% Next 3 Years," Dow Jones Business News, 22 January 2004, http://biz.yahoo.com/djus/040122/1305001257_2.html, access confirmed 16 February 2004.

[4] 1997: IMS Health, "World Review, 15 Largest Pharmaceutical Markets in the World, 1997," www.ims-global.com/insight/world_in_brief/new_yearly/largest.htm, accessed 5 May 1999.

2002: IMS Health, "IMS Reports 8 Percent Constant Dollar Growth in 2002 Audited Global Pharmaceutical Sales to $400.6 Billion," www.imshealth.com, accessed 26 February 2003.

[5] Alan Sager and Deborah Socolar, *Affordable Medications for Americans*, Report for the Prescription Drug Task Force, United States House of Representatives, 27 July 1999, www.house.gov/berry/taskforce/taskforcestudies.shtml or www.healthreformprogram.org (see U.S. Health Reform, prescription drugs, reports).

[6] See, for example, Bruce Stuart and others, "Employer-sponsored Health Insurance and Prescription Drug Coverage for New Retirees: Dramatic Declines in Five Years," *Health Affairs,* Web exclusive, 23 July 2003, www.healthaffairs.org.

[7] Dana Gelb Safran and others, "Prescription Drug Coverage and Seniors: How Well Are States Closing the Gap?" *Health Affairs*, 31 July 2002, posted at www.healthaffairs.org

[8] Harris Interactive, "Higher Out-of-Pocket Costs Cause Massive Non-Compliance in the Use of Prescription Drugs," 9 December 2002, www.harrisinteractive.com

[9] Will Lester, "Almost a Third of Americans Say Paying for Drugs Is a Problem in Their Families," Ipsos News Center, www.ipsos-na.com/news/pressrelease.cfm?id=2064, 25 February 2004.

[10] Marie Reed and J. Lee Hargraves, "Prescription Drug Access Disparities among Working-age Americans," Center for Studying Health System Change *Issue Brief*, No. 73, December 2003.

[11] "Out-of-pocket Costs Are a Substantial Barrier to Prescription Drug Compliance," Harris Interactive *Health Care News*, Vol. 1, Issue 32 (20 November 2001).

[12] Suzanne Felt-Lisk et al., "Monitoring Local Safety-Net Providers: Do They Have Adequate Capacity?" *Health Affairs*, September/October 2002, p. 277, 280.

[13] Robyn Tamblyn, Rejean Laprise, James A. Hanley, and others, "Adverse Events Associated with Prescription Drug Cost-sharing among Poor and Elderly Persons, *Journal of the American Medical Association*, Vol. 285, No. 4 (24/31 January 2001), pp. 421-429.

[14] Stephen B. Soumerai and others, "Effects of Limiting Medicaid Drug-reimbursement benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients with Schizophrenia," *New England Journal of Medicine,* Vol. 331, No. 10 (8 September 1994), pp. 650-655.

[15] See, for example, "Study Finds Continuing Cuts in Retirees' Health Benefits," Associated Press, *Wall Street Journal Online,* 14 January 2004.

[16] Lisa Richwine, "AIDS Patients Face Drug Barriers, Activists Say," Reuters, 6 April 2004.

[17] Holly Ramer, "Reimbursement Rates Halt Drug Program," *Union-Leader,* 2 April 2004.

[18] Alan Sager and Deborah Socolar, How Much Would Drug Makers' Profits Rise under a Medicare Prescription Drug Benefit? A Response to PRI/PwC's Undocumented and Disjointed Critique of Our 31 October 2003 Report, Boston: Health Reform Program, Boston University School of Public Health, 2 April 2004, 2nd edition, www.healthreformprogram.org.

[19] "FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments," *FDA News*, P03-73, 29 September 2003.

[20] Theresa Agovino, "States Exploring Drug Import Options," Associated Press, 14 October 2003, www.montanaforum.com/rednews/2003/10/14/build/health/rx-canada.php?nnn=3.

[21] Tony Pugh, "FDA Lacks Examples of Canadian Drugs Harming Americans," Knight-Ridder Newspapers, 26 November 2003.

[22] David Espo, "United Health to Cover Foreign Drugs, AP, 11 October 2002.

[23] "Pharmacy Complaints Show None on Canadian Imports," *Fargo (N.D.) Forum,* 22 March 2004 (Associated Press).

[24] See, for example, "Minnesota Officials Send Letter to FDA about Plan," Kaiser Family Foundation Health Policy Report, 11 March 2004, www.haisernetowrk.org.

[25] Mark Hayward, "Benson Report Finds Canadian Drugs Safe," *Union-Leader*, 25 March 2004.

[26] Dana Elfin, "High Cost Said to Spur Internet Black Market in Fertility Drugs," BNA Special Report, *Pharmaceuticals,* Vol. 8, No. 29 (17 July 2000), pp. 1228 ff.

[27] Christopher Francescani, "Drug-selling Scams Put Patients at Risk," *New York Post,* 20 November 2000.

[28] Christopher Rowland, "Trafficking on Rise in Prescription Drugs," *Boston Globe,* 2 April 2004.

[29] Barbara Martinez, "Lawsuit Claims a PBM Resold Returned Drugs," *Wall Street Journal Online,,* 5 April 2004.

[30] Alan Sager, *Americans Would Save $38 Billion in 2001 If We Paid Canadian Prices for Brand Name Prescription Drugs: How to Win Those Savings and Use Them to Protect All Americans against High Drug Costs without Hurting Drug Makers or Drug Research,* Invited testimony before the U.S. Senate Commerce Committee, Subcommittee on Consumer Affairs, 5 September 2001, www.healthreformprogram.org, published in United Sates Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, *Comparative Pricing of Prescription Drugs Sold in the United States and Canada, and the Effects on U.S. Consumers,* Washington: U.S. Government Printing Office, 2003, pp. 71-86. Also at http://commerce.senate.gov/hearings/090501Sager.pdf.

[31] Actual savings in a given state would vary slightly from those calculated here. That is because these calculations make three simplifying assumptions:

a) That prescription drug spending in 2001 is distributed among the states in the same proportions as reported by the Health Care Financing Administration's Office of the Actuary for 1998. (See United States Health Care Financing Administration, 1980-1998 State Health Care Expenditures Estimates, 29 September 2000, posted on-line at http://www.hcfa.gov/stats/nhe-oact/stateestimates/.)

b) That private insurance, Medicaid, and self-pay shares of the market are similar from state to state. These actually vary somewhat from state to state.

c) That discounts and rebates are shared evenly among the states; in reality, these also vary somewhat from state to state.

Further, these calculations, while updated from the 2001 estimates in proportion to the rise in retail drug spending between 2001 and 2004, do not reflect changes in the U.S. – Canadian differential in prices for brand name drugs. And, as shown earlier in Exhibit 1, that differential has been widening somewhat in recent years. In 2000, U.S. prices were 60 percent above Canadian levels but this excess had risen to 67 percent in 2002.

[32] Rod R. Blagojevich, "Citizen Petition to Provide Certification to Congress under Section 804 (*l*) of the Federal Food, Drug, and Cosmetics Act, and to Authorize a Pilot Program for Importation of Prescription Drugs in the State of Illinois," Part C, Amendment of 21 *CFR* § 203.10.